

# TECHNICAL ASESSMENT REPORTS

Medical Device, Equipment & Machine

*Work-Based Learning (WBL) Experiences in Malaysian Polytechnic*

## CHIEF EDITOR

**Dr. Sabariah Binti Bohanudin**

### Editors

Muhammad Syamil Arif Bin Amri

Siti Hajar Binti Ismail

Tengku Anis Zuhayrah Binti Tengku Amran







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## **TECHNICAL ASSESSMENT REPORTS** **Medical Device, Equipment and Machine**

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## **Disclaimer**

The information stated in this book is designed to provide information based on the technical assessment report on medical device, equipment and machine done by final year students of Bachelor of Electronic Engineering Technology (Medical Electronic) With Honours during their work-based learning activities in concessionaries. The writings include examples, images, and references are provided for informational purposes only. Any opinions expressed in this presentation constitute our judgement at the time of issue are subject to change. We believe that the information contained in this presentation is correct and that any estimates, opinions, conclusions or recommendation are reasonably held or made as to their accuracy or reliability (which may change without notice) or other information contained in this presentation. To the maximum extent permitted by law, we disclaim all liability and responsibility for any or indirect loss or damage which may be suffered by any recipient through relying on anything contained in or omitted from this presentation.





## PREFACE

Welcome to this eBook, a compilation of Technical Assessment Reports authored by our final-year students pursuing a Bachelor of Electronic Engineering Technology (Medical Electronic) with Honours at the Electrical Department of Politeknik Sultan Salahuddin Abdul Aziz Shah. These dedicated individuals have successfully completed their work-based learning attachments with the support of Advance Pact Sdn Bhd, a generous concessionary. Within the pages of this eBook, you'll find valuable insights and research contributions from these talented students. Their diverse perspectives and diligent efforts have culminated in a collection of reports that span a wide range of topics and applications in the field of electronic engineering. As you delve into the following pages, you'll have the opportunity to explore the depth and breadth of their work. We hope that this compilation will serve as both an informative resource for those interested in electronic engineering and a testament to the dedication and passion of our students.

Listed below are the authors of these reports, along with a brief overview of the scope of their contributions:

Writers	Scope
Mohamad Saiful Bin Mohd Yusoff	Defibrillator
Siti Noor Farrahien Binti Manan	Holter Monitor
Iman Najihah Binti Yusoff	Ventilator
Muhammad Syamil Arif Bin Amri	Anaesthesia Machine
Nor Sazlin Binti Samsudin	Slit Lamp
Siti Hajar Binti Ismail	Cardiotocography (CTG)
Venu Ramasamy	Dialyzer Reprocessing Unit
Ahmad Ribie Bin Mohd Sazali	Blood Warmer
Dinie Qusyairy Bin Zulkipli Amin	Slide Stainer
Nor Hafizah Binti Abdul Halim	Centrifuge
Mirza Asyraaf Bin Abd Rashid	NIBP (Vital Sign)
Tharshini A/P Prakas	Blood Gas Analyzer (ABG)
Ellia Rosnie Binti Budi Kartono	Ultrasound Machine
Tengku Anis Zuhayrah Binti Tengku Amran	Haemodialysis Machine

We extend our heartfelt gratitude to the students for their hard work, to the Electrical Department for their unwavering support, and to Advance Pact Sdn Bhd for their invaluable partnership in fostering experiential learning.

We invite you to enjoy and learn from the wealth of knowledge presented in these reports. Thank you for joining us on this educational journey.

Dr. Sabariah binti Bohanudin  
Principal Lecturer,  
Electrical Department,  
Politeknik Sultan Salahuddin Abdul Aziz Shah  
15 September 2023



## TERMINOLOGIES

AHR	Abnormal Heart Rate
ARDS	Acute Respiratory Distress Syndrome
AECG	Ambulatory Electrocardiography
ASA	American Society of Anaesthesiologists
ABG	Arterial Blood Gas Analyzer
AV	Arteriovenous
ASIS	Asset and Services Information System
BPS	Backup Power Supply
BER	Beyond Economic Repair
BEMS	Biomedical Engineering Maintenance Services
BP	Blood Pressure
B	Body floating
BF	Body Floating
BDU	Breath Delivery Unit
CO <sub>2</sub>	Carbon dioxide
CA	Cardiac Arrest
CF	Cardiac Floating
CTG	Cardiotocograph
CVC	Central Venous Catheter
Cl	Chloride
COPD	Chronic Obstructive Pulmonary Disease
CM	Corrective Maintenance
CCU	Critical Care Unit
DVT	Deep Vein Thrombosis
DNA	Deoxyribonucleic Acid
DICOM	Digital Imaging and Communications in Medicine
ECG	Electrocardiography
EC	Erythrocyte Concentrates
EST	Extended Self -Test
FHR	Fetal Heart Rate
FAST	Focused Assessment with Sonography in Trauma
FFP	Fresh Frozen Plasma
GUI	Graphic User Interface
HPC	Haematopoietic Progenitor Cells
HDU	Haemodialysis Unit
HR	Heart Rate
HEBHK	Hospital Enche' Besar Hajjah Khalsom
HSI	Hospital Sultan Ismail
HSA	Hospital Sultanah Aminah
HTSMTI	Hospital Temenggung Seri Maharaja Tun Ibrahim
IVC	Inferior Vena Cava
ICU	Intensive Care Unit

# TERMINOLOGIES

IMV	Intermittent Mandatory Ventilation
IEC	International Electronic Commison
IV	Intravenous fluid
LED	Light-Emitting Diode
LCD	Liquid-Crystal Display
MD	Maxim Diagram
ME	Medical Equipment
MOH	Minister of Health
MSK	Musculoskeletal
NICU	Neonate Intensive Care Unit
N <sub>2</sub> O	Nitrous oxide
NIBP	Non-Invasive Blood Pressure
NHR	Normal Heart Rate
O <sub>2</sub>	Oxygen
SPO <sub>2</sub>	Oxygen saturation
PC	Personal Computer
PPM	Planned Preventive Maintenance
PSSUQ	Post-Study System Usability Questionnaire
PDM	Predictive Maintenance
PCV	Pressure Control ventilation
PSV	Pressure Support Ventilation
ROI	Rate of Investment
RM	Ringgit Malaysia
RI	Routine Inspection
SN	Serial Number
SST	Short Self -Test
AgCl	Silver Chloride
SIMV	Synchronous Intermittent Mandatory Ventilation
TOCO	Taco Tonometer
T&C	Technical and Commissioning
TAR	Technical Assessment Report
TEMP	Temperature
ANSI	The American National Standards Institute
TTE	Transoesophageal Echocardiography
VILI	Ventilator-Induced Lung Injury
WBL	Work-Based Learning



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# DEFIBRILLATOR

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March 2021

**Abstract**— A defibrillator is a machine that used to shock the victim's heart and restore the heart's normal rhythmic patterns. When a defibrillator is used, it in effect kicks the heart into action again, causing it to resume sending blood throughout the bloodstream. At the same time, the monitoring function is used by using 3-leads defibrillator to monitor the patient's heart rhythm until it became normal again. The aimed of this study is to carry out a research work on the types of different model of defibrillator that has been used in Hospital Sultanah Aminah Southern Johor. Besides, the collection of data between these two models of defibrillator in this hospital has been conducted in order to gather the information of the machine. Furthermore, comparisons of data between two models are been develop from the data analysis and it can be concluded that one of defibrillator recorded least of rate of failure during its lifespan.

**Keyword**- Defibrillator, signal processing, heart, heart rhythm, Hospital Sultanah Aminah

## 1.0 Introduction

Defibrillation is a common treatment method for life-threatening cardiac arrhythmias, ventricular fibrillation and pulse-less ventricular tachycardia. Defibrillation consists of delivering a therapeutic dose of electrical energy to the affected heart area [1]. This depolarizes a critical mass of the heart muscle, terminates the arrhythmia and allow normal sinus rhythm to be re-established by the body's natural pacemaker, the sino-atrial node of the heart. Defibrillator machine can be external, trans-venous, or implanted, depending on the type of device used situation needed [1]. Some external units, known as automated external defibrillator (AED), automate the diagnose process of treatable rhythms, meaning that lay responder or bystander are able to use them successfully with minimum, or in some cases no training at all [1][2]. The purpose of this Technical Assestments Reports (TAR) is to compare Biphasic Defibrillator Machine with a several brands that have at Hospital Sultanah Aminah, Southern Johor. Comparison between different all brand with same function, parameter and specification. In this report, comparison that will elaborate are about maintenance, breakdown of the machine, physical characteristic, and usage of user with different brand. Besides that, at the end of this TAR, we can suggest and make decision on which one is the best model that will be choose. The defibrillator that will be compared are Zoll M Series and Nihon Kohden TEC-5500 Series

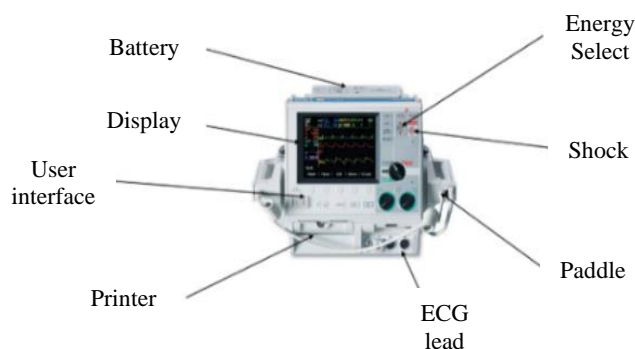


## 1.1 Defibrillator

Generally, de- is a reverse action of any action that have done. Fibrillation is a very fast, irregular heart rhythm in the heart chambers. Then, defibrillation is an action to undo or reverse the abnormal or irregular heart rhythm by using defibrillator machine. A defibrillator machine works by using a high-voltage to deliver an electric current through the heart so it's shocked back into normal condition. The patient's heart receives roughly 300 joules of electricity energy. The type of defibrillator is consisting of an electric supply unit and a pair of metal electrode called paddle that are pressed firmly on the patient's chest using insulating plastic handle (to protect the user from get shock also). The paddle is put above and left-side of the chest and the other one slightly beneath and to the right. Another way is by placing one paddle on the front of the body and the other one at the back. In order for the electric current to flow properly and to reduce the risk of skin burn, the electrode have to be applied close enough together to get the good electrical contact with the skin. A solid or liquid conducting gel is usually applied to the paddle placement area before place the paddle. This section review on general function of defibrillator based on its physical layout. There are various studies and research that has been revised and were compiled together during the development of this assessment report. The studies are divided into three subsections consists of physical layout of the defibrillator, specifications of the defibrillator and the types of models of defibrillator. Along to the objective of this research is to design a research work on defibrillator, the related studies on the existing defibrillator has been revised.

## 1.2 Physical layout of Defibrillator

Figure 1.1 shows the physical layout of a defibrillator.



**Figure 1.1:** Physical layout of defibrillator

Based on Figure 1.1, the device is a versatile automated external defibrillator with or without manual capabilities and may be configured to operate in manual, advisory or semi-automated modes. Semi-automated versions of the device have a distinctive front panel with a single "ON" position. Conventional hospital style devices, which can be configured for manual, advisory or semi-automated operation. When operating in the manual configuration the device operates as a conventional defibrillator where the device's charging and discharging is fully controlled by the operator. In advisory and semi-automatic modes, some features of the device are automated and a sophisticated detection algorithm is used to identify ventricular fibrillation and determine the appropriateness of defibrillator shock delivery. Units may be configured to automatically charge, analyse, recharge, and prompt the operator to "PRESS SHOCK," depending on local protocols. The unit is switched from the semi-automated mode to manual mode for ACLS use by pressing the appropriate soft key on the front panel.

### 1. Defibrillator Paddles

A defibrillator paddles is a graphical representation that deliver the shock through paddles placed directly on the heart.

### 2. Defibrillator Recorder

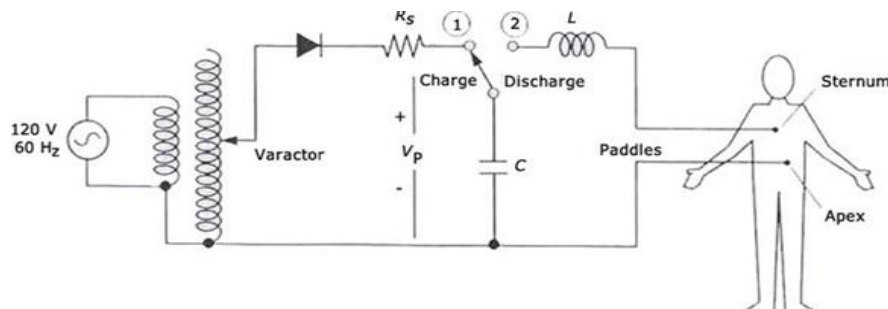
A strip recorder is provided to document events. The strip recorder normally operates in the delay mode (6 seconds) to insure capture of critical ECG information. The recorder may be activated manually by pressing the RECORDER button. It will be activated automatically whenever a defibrillation SHOCK is delivered, a heart rate alarm occurs, or the rhythm analysis function is activated. The strip recorder may also be configured not to print during these events.

### 3. Gel Pads

Gel pads are used to reduce transthoracic impedance when paddles are applied directly to the chest wall to deliver a shock. Besides The

### 1.3 Principle of Defibrillator

Because of the electrical energy shock must be delivered all of sudden, then the main component that is used to store such a huge energy is capacitor. An energy storage capacitor is charge at the relatively slow rate from the AC line by means of a step-up transformer and rectifier arrangement for a battery and DC to DC converter arrangement. During defibrillation, the energy stored in the capacitor is then delivered (discharged) at a relatively rapid rate (in order of milliseconds) to the chest of subject through the patient's own resistance. The discharge resistance which the patient represents as purely ohmic resistance of 50 to  $100\Omega$  approximately for a typical electrode size of  $80\text{cm}^2$ . Energy level of defibrillator is from 2 to 400 joules (J) depends on the size of the patient and skin resistance. It required voltage in the range of 1000 to 6000 volts depend on the duration of the DC pulse. The current range is from 1 to 20 ampere (A). Figure 1.2 shows the basic circuit diagram of defibrillator.



**Figure 1.2:** Basic circuit of defibrillator

The first principle in defibrillator is closed-chest method. Defibrillation of the heart was possible only when the chest cavity was open during surgery [2]. The technique used an alternating current from a 300 or greater volt source delivered to the sides of the exposed heart by 'paddle' electrodes where each electrode was a flat or slightly concave metal plate of about 40 mm diameter [2]. The closed-chest defibrillator device which applied an alternating current of greater than 1000 volts, conducted by means of externally applied electrodes through the chest cage to the heart, was pioneered by Dr V [2]. Eskin with assistance by A. Klimov in Frunze, USSR (today known as Bishkek, Kyrgyzstan) in the mid-1950s. Then, move to direct current. In 1959 Bernard Lown commenced research into an alternative technique which involved charging of a bank of capacitors to approximately 1000 volts with an energy content of 100-200 joules then delivering the charge through an inductance such as to produce a heavily damped sinusoidal wave of finite duration (~5 milliseconds) to the heart by way of paddle electrodes [3]. The work of Lown was taken to clinical application by engineer Barouh Berkovits with his "cardioverter". Afterward, Portable units become available. Today portable defibrillators are among the many very important tools carried by ambulances [3]. They are the only proven way to

resuscitate a person who has had a cardiac arrest unwitnessed by EMS who is still in persistent ventricular fibrillation or ventricular tachycardia at the arrival of pre-hospital providers. Gradual improvements in the design of defibrillators, partly based on the work developing implanted versions, have led to the availability of Automated External Defibrillators [4]. These devices can analyse the heart rhythm by themselves, diagnose the shockable rhythms, and charge to treat.

This means that no clinical skill is required in their use, allowing lay people to respond to emergencies effectively. Ultimately, change to a biphasic waveform [4]. The defibrillator machine operates in two principles, monophasic and biphasic. Monophasic defibrillation is the earlier technology used in defibrillator. Monophasic means the current delivered by the machine travel in only one direction between the paddles. It required higher escalating energy levels (200-300J) to convert VF/ pulse-less VT. This method is less effective and being replaced with a latest method called 'biphasic defibrillation'. The biphasic defibrillation means the paddle delivers the current in one direction during the first phase and in opposite direction during the second phase [4]. Biphasic waveform shocks of 200 J are safe, equivalent or higher efficiency than damped



sinusoidal waveform shocks of 360 J. It is more effective than monophasic defibrillation and at

the same time reduce the risk of burn skin because of the lower power level.

1.4 Related type and model of defibrillator

This subsection will explain types and model of defibrillator that are available and have been sold for hospital use in Malaysia. There are various design and model of defibrillator that can be used to monitor the condition of patient’s cardiac and identify some types of structural heart disease, and evaluate cardiac efficiency. Table 1.1 shows the type and model of defibrillator.


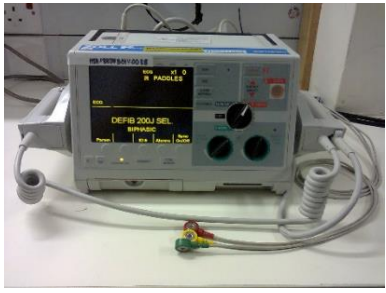
Table 1.1: The type and model of defibrillator

Model	Physical Layout of defibrillators
Zoll M Series	
Nihon Kohden Cardioline TEC-5500 Series	
Philips HeartStart XL Defibrillator	
Physio-Control LifePak 12	

## 1.5 Specification of defibrillator

Table 1.2 show the specification of both defibrillator which is between Nihon Kohden and Zoll M Series. The specification that compared is between the type of the protection, LCD display, dimension of the defibrillator, the weight, type of battery, the power input, frequency and power consumption.

**Table 1.2:** Specification of defibrillator

Nihon Kohden	Brand	Zoll M Series
Cardiolife TEC-5500 Series	Model	Biphasic 12 Leads
	Picture	
<ul style="list-style-type: none"> <li>AC power: Class I</li> <li>Type CF</li> <li>Battery Power. Internally powered equipment</li> <li>Maximum energy: 270J</li> </ul>	Type of protection	<ul style="list-style-type: none"> <li>AC power: Class I</li> <li>Type CF</li> <li>Battery power. Internally powered equipment</li> <li>AC Power: 100-120 ~ 50/60 Hz, 220-240 ~ 50 Hz, 220 VA</li> <li>Maximum energy: 200J</li> </ul>
All parameter with various colour display	LCD display	All parameter with one colour display
2901x- x 172 H x 335 D mm	Dimension	62 W X 173H x 208 D mm
<ul style="list-style-type: none"> <li>Approx. 6.3 kg (with battery)</li> <li>Approx. 5.5 kg (without battery)</li> </ul>	Weight	Weight: 5.23 kg
<ul style="list-style-type: none"> <li>With fully charged new battery at 20°C ambient temperature</li> <li>Minimum 70 discharges at 270J</li> <li>Minimum 150 minutes continuous monitoring</li> <li>Minimum 90 minutes fixed mode</li> <li>pacing (ISO pulse/min,200mA)</li> </ul>	Battery	<ul style="list-style-type: none"> <li>Type: Sealed lead acid</li> <li>Cells: 5</li> <li>Operating Time: About 2.5 hours</li> <li>Charging Time: About 7.2 hours</li> </ul>
45 VA	Power input	DC Input: 10-29 V. 130 W
50 or 60 Hz	Frequency	50 Hz 60 Hz ( $\pm 3$ Hz)
45 W or less	Power consumption	60 W or less

Based on Table 1.2, first comparison of the specification is by type of the protection. For Nihon Kohden and Zoll M Series, both machines share the same type of protection which is ac power are Class I, type CF and internally powered equipment. But for maximum energy that can be delivered is different which Nihon Kohden is 270J and for Zoll M Series is 200J. For LCD display, Nihon Kohden have all parameter with the various colour display but for Zoll M Series have all parameter with one colour display. Nihon Kohden have bigger dimension with 290W X 172H X 335D but for Zoll M Series is little small than Nihon Kohden with dimension 262W x 173H x 208D mm. Next comparison is between the weight of the machine. Weight for Nihon Kohden is 6.3kg with battery and 5.5 kg without battery but for Zoll M series is 5.23 kg. Power input for Nihon Kohden is difference with Zoll M Series which is 45VA but for Zoll M Series is 10-29VA. Nihon Kohden and Zoll M Series also share the same frequency which is 50@60 Hz. Lastly, the comparisons between Nihon Kohden and Zoll M Series are power consumption. Power consumption for Nihon Kohden is 45W or less a for Zoll M Series is 60W.

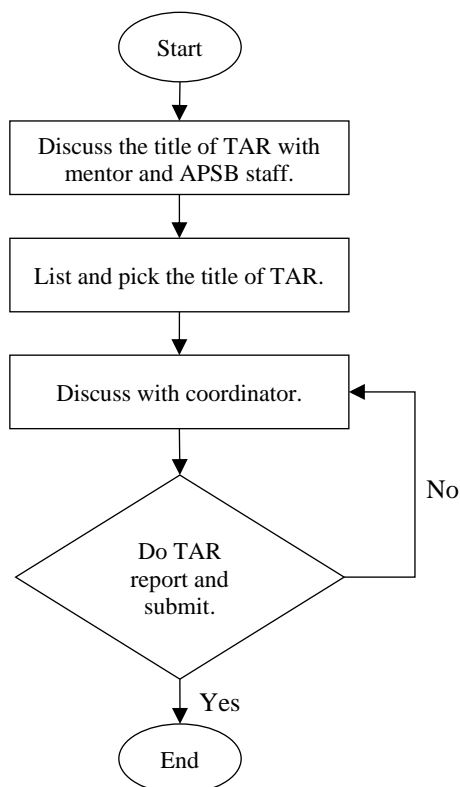


## 2.0 Methodology of the assessment

In this study of technical assessment report, there are two flow progress to complete the result data and analysis. The first flow chart is to discuss with mentor what medical device to choose as a main title of these assessment. For more specified we should choose the one type of ward or patient to get a specified and better comparison. Second flow is to choose a model and makes an analysis the comparison between several type of model device based on specification, maintenance, breakdown of the machine, physical characteristic, and install based.

### 2.1 Flowchart process preparing TAR

Figure 1.3 demonstrates the flowchart of the overall progress that are carried out during this studies. There are three phases that are involved in this research along to the objectives that has been stated earlier.

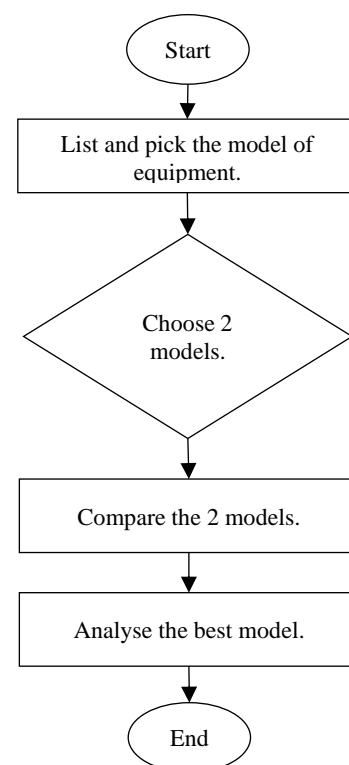


**Figure 1.3:** Flow chart process of preparing Technical Assessment Report (TAR)

### 2.2 Flowchart of Report

Figure 1.4 shows flowchart process of data analysis in technical assessment report (TAR). The process is to choose the best model from five models by technical specification based on user requirement. The next step is choosing the model that based on the same parameter which is biphasic type and external manual defibrillator.

For the first process is start with identify user requirement specification for device. After that, compare two models of defibrillator by technical specification based on user requirement and according to physical characteristic, breakdown maintenance and user friendly. If the defibrillator that being choose is not manual external biphasic, the machine will list out. Stage 2 process start with collecting data for the two models based on After Sale service, Maintenance, Product review, and Spare part. Figure 3.2 show the flowchart flow of the report.



**Figure 1.4:** Flow work of the TAR

Based on the Figure 1.4, the flowchart shows the flow of making the report of technical assessment report. First, we are need to list and the model of defibrillator. Next, need to choose the model based on the same parameter which is biphasic mode and external manual defibrillator. Then, compare two model of the machine according to the physical characteristic, breakdown, maintenance and user. friendly. Lastly, analysis the best model of the defibrillator.

### 2.2.1 Data Collection

Since every hospital in Malaysia using ASIS system to record the data for all medical equipment, the process of collecting data can be easier for technical team and engineer to review the condition of the equipment during their usage. **Figure 1.5** shows the website log in page on the website of ASIS.

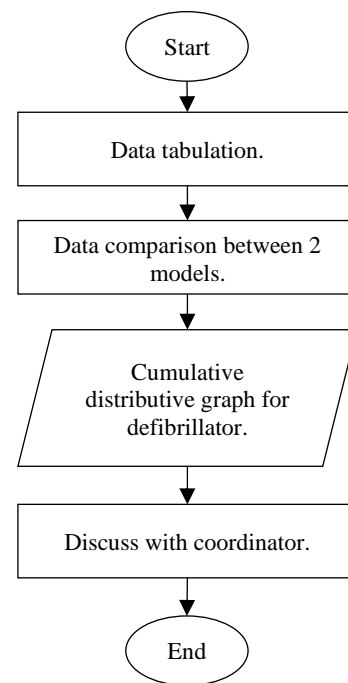


**Figure 1.5:** ASIS log in system

Figure 1.5 represents Asset and Services Information System (ASIS) webpage that has been used in Government Hospital in Malaysia. This system is monitored under Ministry of Health and this system is a formal site for medical officer and technical team in hospital. However, this system only can be access by certified person only as this system stores all the medical equipment data for the hospital and the data is confidential and security. Hence, the data of defibrillator can be accessed by the technical team for this research.

### 2.2.2 How to analyse data

Data analysis is conducted after collecting the information from the system Figure 1.6 demonstrates on the flowchart on how to analyse all the data that have been obtained.



**Figure 1.6:** Flowchart on method on analysis

Based on the Figure 1.6, the methodology on how to analyse data consists of a few steps and procedures that need to follow. Starting with the data tabulation between two types of defibrillator model, which is Nihon Kohden TEC-5500 Series and Zoll M series. Table 1.3 exemplifies on the data tabulation sample method for this research work.

**Table 1.3:** Data tabulation of defibrillator

Model	Nihon Kohden	Zoll M Series
Lifespan		
Purchase cost (RM)		
Type of failure		
Rate of failure		
Maintenance cost (RM)		

Besides, research work then continued with the comparison between two model of defibrillator to analyse the performance of each model during their lifespan. Along to the table that has been constructed, equipment performance can be analysed by using comparison method of two model that consists a few aspects in terms of parameters that will be measured and specifications of each model of defibrillator.

**Table 1.4:** Performance analysis on defibrillator

Parameter	Nihon Kohden	Zoll M Series
Type of failure		
Rate of failure		
Rate of usage		
Downtime cost		

Table 1.4 shows on how performance of each model is conducted by using comparison method. For this method parameters based on technical requirement is measured. This method is to perform an analysis on each equipment and to discover pros and cons between the two models in the hospitals. The significance of constructing all the methodology is to recommend the best defibrillator for hospital based on technical research on this assessment.

### 3.0 Result and analysis

This section shows the result from our collected data such as from difference hospital database and user requirement specification form. The data are analysed and generated graph by using Microsoft Excel. The result that analysed is discussed in this chapter and aim of this research is to develop a comparison between several models of defibrillator that use at Hospital Sultanah Aminah. The user can get the clearer view which type of model is more suitable for the hospital usage. Table 1.5 shows the total of defibrillator registered in HAS between 2017 to 2020.

**Table 1.5:** Total machine register from 2017-2020

Model	Number of registered machines
Nihon Kohden	22
Zoll M Series	16
Total	38

From the Table 1.5, we see that the total of machine that registered at Hospital Sultanah Aminah. The total of Zoll M Series that registered is more than Nihon Kohden TEC-5500 Series. This is because Zoll M Series is cheaper than

Nihon Kohden. Besides, Zoll M Series is friendly user and much easy to handle by the user.

**Table 1.6:** Comparison of failure

Model	Type of failure	Number of failures	Rate of failure
Nihon Kohden	ECG lead	2	4.17%
	Battery	1	2.08%
	Motherboard	3	6.25%
	Casing	1	2.08%
	Discharge module	2	4.17%
Zoll M Series	ECG lead	4	8.33%
	Battery	2	4.17%
	Motherboard	2	4.17%
	Casing	2	4.17%
	Discharge module	1	4.17%

The most failure defibrillator among this brand is Nihon Kohden which the rate of failure is 25%. This is because a bit of Nihon Kohden machine that installed in hospital is the old machine. The comparison that can made is battery. Battery is quite familiar to be a most failure in medical device. In this case, battery from Zoll M series is more quality than Nihon Kohden. As we can see, the rate of failure for Zoll M Series is 30% which is lower than Nihon Kohden which is 45%.

As we know, motherboard is an important part of medical device. Motherboard is the main part which is to make the operated. Based on the data, Nihon Kohden is the most device that having problem with motherboard. The rate of failure for Nihon Kohden is 25% which is higher than Zoll M Series. This is because, the version of this Nihon Kohden is already obsolete. The motherboard is old and there is no part that can be replaced.

For Zoll M Series, the higher rate of failure is casing. Casing of this device is easy to break due to less rugged. Based on the data, the rate of failure is 33%. The casing is easily broken because the machine cannot be placed directly to sunlight. For the Nihon Kohden, discharge module is the one of type of failure that always happen. This is because, the discharge module cannot be discharge after pressing the shock button either at paddles or at the control pad. The paddle also being the one of most type of failure for the Nihon Kohden device. Such as, the button



of shock and discharge does not function. Hence, the machine also cannot detect the paddles even the paddles already plug in.

Lastly, the most common type of failure for both device is ECG lead. Sometime the ECG lead cannot detect at the machine even already plug in. Next is the reading of the ECG is high even use the tester.

### 3.1 Comparison based on User Requirement Specification

The process starts with identify user requirement specification for defibrillator on specific ward and department. After that, list out the all different from two devices that have been selected. Then, compare between two models by technical specification based on user requirement.

**Table 1.7:** Comparison of specification between two model

Model Item	Zoll M Series	Nihon Kohden
External paddle	Adult and pediatric	Adult and pediatric
Maximum energy	200J	270J
Mode of operation	Biphasic	Biphasic
Size/Weight	Smaller/lighter	Bigger/heavier
Display	All parameter with one colour display	All parameter with various colour display
AED function	Yes	Yes
Paddle placement	Side of body	Top of body
Display type	LCD	LCD
Weight (KG)	5	6.1
Battery charging time	4 hours	<3 hours
Department	ANE and ICU	All department
Selection button	Control panel	Control panel
Charging time	<7s	5s
Basic check	No (only defib tester)	Yes

Based on the Table 1.7 shows the comparison between two model. The first is external paddle. This both device is using the same type of paddles which is external paddles which is placed beside the device. Second is maximum energy that can be charged. For the Zoll M Series, the maximum energy is 200J but the maximum energy for Nihon

Kohden is 270J which is higher than Zoll M Series. Next is mode of operation. This both device is using the same mode of operation which is biphasic mode. After that is size and weight. For Zoll M Series, the size is small and lighter with 5 kg weight compared to Nihon Kohden which is bigger and heavier with 6.1 kg without battery. For the display, Zoll M Series have all parameter with one colour display but for the Nihon Kohden, this device have all parameter with varies colour display. The display type for Zoll M Series and Nihon Kohden is same which is LCD display. Both of this device have AED function.

Besides, the paddles placement for this both device is little difference which is for Zoll M Series is at the side of body but for Nihon Kohden is on the top of the body. For the battery charging, Zoll M Series need four hours to battery charged full but for the Nihon Kohden just need 3 hours and below to battery charged full. This both device are installed at difference place which is for Zoll M Series placed at Accident and Emergency(ANE) and Intensive Care Unit( ICU) department but for Nihon Kohden placed at all department expect Accident and Emergency (ANE) department. Zoll M Series and Nihon Kohden share the same selection button for shock and discharge which is all the button selection at the control panel but the charging time for this both device is difference which is for Zoll M Series need 7 second and below to charge but the Nihon Kohden just need 5 second to charge. Zoll M Series do not have basic check but only can check with defibrillator tester but Nihon Kohden come with internal basic check which is can run basic check without using defibrillator tester.

### 3.2 Analysis between two models

In this section, Table 1.8 show the analysis that produce between two model of defibrillator which is Nihon Kohden and Zoll M Series. The analysis that made is between display, physical characteristic, paddle placement, switch, and button, deliver energy, duration in industry, energy select and maintenance.

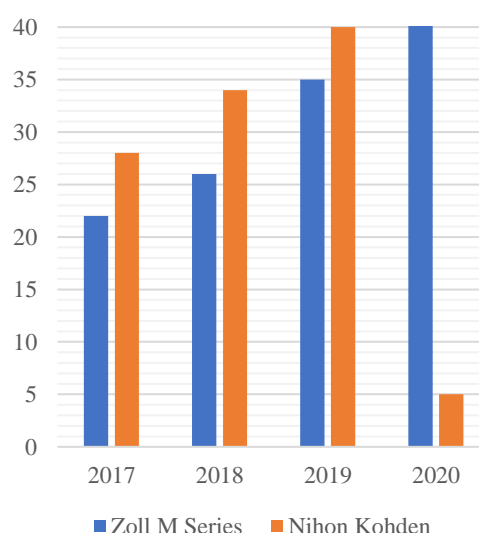
**Table 1.8:** Analysis between two model

Description	Zoll M Series	Nihon Kohden	The Best Model
Display	All parameter with one colour display	All parameter with various colour display	Nihon Kohden
Physical characteristic	Smaller and lighter (5KG)	Bigger and heavier (6.1KG)	Zoll M Series
Paddle placement	Side of body	Top of body	Nihon Kohden
Switch and button	Specific select switch and button to operate between monitor, pacer, defib and energy select.	Monitor, defib and energy select share the same knob	Nihon Kohden
Energy delivery	can be selected at machine and paddle	at machine only	Zoll M Series
Duration in industry	used for long time	new in industry	Nihon Kohden
Energy selects	Push button	Knob selection	Nihon Kohden
Maintenance	Complicated	Easier	Nihon Kohden

Based on Table 1.8 shows the analysis between two model of defibrillator. The best model for the display is Nihon Kohden which is all parameter with various colour. This is because easy to differentiate between the parameter. Next is physical characteristic. The best model is Zoll M Series because this device is smaller and less weight. Easy for the user to use and to take the defibrillator to another place. Then, the best model for paddles placement is Nihon Kohden which is on the top of the machine. This is because the user can reach easily when performing the action. For Zoll M Series is quite hard to release paddle because this device has the paddle lock.

Besides that, the best model for switch and button is Nihon Kohden, which is monitor, defib and energy select share the same knob button.

This is easy to refer for energy select but Zoll M Series is the best model for deliver energy because the energy can be selected at the machine and paddles while Nihon Kohden just can be selected at machine only. Last but not least, Nihon Kohden be the best model for energy select because is just turn the knob that already have indicator beside Zoll M series that need to push button to refer for selected energy. Finally, is the maintenance. The best model of defibrillator for maintenance is Nihon Kohden which is the maintenance is friendly and easy to troubleshoot compared to Zoll M Series which is the component inside the machine is more complicated and need more time to troubleshoot. Bar graph in Figure 1.7 show the comparison breakdown in four years between Zoll M Series and Nihon Kohden TEC-5500 Series.

**Figure 1.7:** Average of percentage breakdown

Based on Figure 1.7, total machine registered of Zoll M Series and TEC-5500 Series were analyze by refer to system in APBeSYS and information by the technical staff. In system and information by technical staff usually breakdown because of the paddle conductivity, ECG lead intermittence, and printer problem. From the graph, the breakdown is increased from 2017 to 2020 because this machine has always been used.

This is because this machine can be operated easily, so it became user first choice. It can be seen like at the ICU ward, although there are three Zoll M Series defib and TEC-5500 have only one, the user will still use TEC-5500. Zoll M Series seems like rarely been used because it seems like the machine is always in good condition without any dirt like gel on the paddle.

## **4.0 Conclusion**

Based on assessment of the equipment, it can be concluded that Nihon Kohden TEC-5500 Series as a better and most reliable defibrillator than Zoll M Series. This is because the model even its technology back dated compare to Zoll M Series, but it still can perform at very best condition. Surely the breakdown much more compares to Zoll M Series but this is because this machine is always been used by user compare to Zoll M Series. Besides that, because of user seldom use Zoll M Series, the breakdown only such as problem to setting the date and time. The TEC-5500 Series seems easier to be operated especially in an emergency situation because the paddle can be reached easily and the energy setting can be selected quicker compare to Zoll M Series.

## **5.0 Recommendation**

Based on analysis of the equipment, it can be concluded that Nihon Kohden TEC-5500 Series is the best model for defibrillator. This is because Nihon Kohden is the one of the model Defibrillator that easy to handling and operate. However, the user must know the proper procedure to handling the machine. The user also must follow the standard operation procedures and always perform proper cleaning, maintenance such as always clean the chassis and put the machine at proper place. Troubleshooting for Nihon Kohden TEC-5500 Series is easy when we can be verifying where the faulty either it inside the machine or outside the machine. Then troubleshooting also must follow the guided line which is in HEPPM checklist and always use genuine part only. All the troubleshooting must be followed by proper cleaning and must do the electrical safety test to avoid a leakage current.



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# AMBULATORY ECG: HOLTER MONITOR

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**Abstract**— Holter monitor is widely used to record and analyse the electrical activity of the heart data outside of the clinical setting. It is one of the types of ambulatory ECG device which allow the clinical to monitor the heart rhythms of the patients. ECG leads attached to the patient's chest and collected continuously over 24 to 48 hours. The patient as well is encouraged to perform their daily activities, but they must avoid any bathing or showering. Holter monitor is a suitable device in identifying the cardiac arrhythmias. The problems of Holter monitor often occur whenever the patient has finished using the device and the corrective maintenance need an action to be taken. In this research has found that several models of Holter monitor produce several types of error. The aims in this report are to select the best model of Holter monitor which based on the model's specification, rate of failure and user-friendly. Thus, the best model is chosen to minimize the corrective maintenance and be more user-friendly. The comparison between two different models has been made to determine which model is suitable and to be recommended to the hospital's user for the future used.

**Keywords**- Ambulatory electrocardiographic ECG, Medical monitor, Holter recorder, Microvit MT-101, Medilog AR12 Plus

## 1.0 Introduction

Ambulatory ECG monitoring is the continuous recording of ECG signals from patients while they are at home and engaged in routine daily activities [1]. These are non-invasive or minimally invasive diagnostic exams that have been shown to be very efficacious and cost-effective in the right clinical scenario [2]. From the pioneering work of Dr. Norman Holter, who published his landmark article in Science1 (1961) discussing a new technique for continuous portable electrocardiography, ambulatory ECG monitoring has evolved to include myriad device designs that provide a wide array of recording options [3].

Ambulatory electrocardiographic monitoring, or "Holter monitoring," is commonly used to assess cardiac rhythm over a period of 24–48 hours, typically in the outpatient setting [4]. Holter monitoring has been particularly useful in patients to diagnose intermittent arrhythmias, including supra-

ventricular tachycardia (SVT) and atrial fibrillation [5] [6].

There are two categories of AECG devices can be distinguished which continuous recorders are known as Holter recorders that can typically record for 24 or 48 Hours and intermittent recorders that can be used for weeks or even months [7]. Novel intermittent recorders can extend the monitoring time for several years [8]. Moreover, they can communicate to a remote clinical centre for real-time reporting of events. The use of one or another device will depend on how frequently the symptoms to be diagnosed occur [9].

The purpose of this Technical Assessment Report (TAR) is to compare the Holter Monitor by various specifications and recommendations to the company which brand of the Holter Monitor are the best to be used by the hospital. The three objectives of this study indicate a guideline process in developing this research. The research is to study the Holter Monitor, to analyze the different models of Holter Monitor, and to discover the best model of Holter Monitor. This research had found that Holter Monitor Medilog AR12 Plus is the best model for hospital diagnostic in order to reduce the total breakdown. Moreover, it has more advantages compared to the Holter Monitor Microvit MT-101 in terms of specification, breakdown, and user-friendly.

### 1.1 Problem Statement

Ambulatory electrocardiographic (ECG) monitoring is used to help doctors to diagnose intermittent cardiac arrhythmias which occur only infrequently and unpredictably [10]. For example, arrhythmias frequently produce sudden symptoms but typically are no longer present by the time a person gets to a doctor [11]. This is because of minor or major breakdown are occurred before and after the operating of the equipment. Therefore, it is significant to make a comparison between two models which is the best to be used to minimize the number of breakdowns and user friendly.

### 1.2 Objectives

In this research consists three objectives which act as a direction in process to develop this study. The objectives are as following:

- To investigate part of the Holter monitor.
- To analyse the different models of Holter monitor
- To determine the best model of Holter monitor.

### 1.3 Scope of Study

The scope in this semester of Work-Based Learning (WBL) is to make a full comparison between these two models of Holter Monitor. Additionally, discuss the concept, specifications, and breakdowns by the user in Hospital Sultanah Aminah (HSA), Johor Bahru. By doing the comparison, the best model will be chosen and recommended based on the reliability for the user and provide the simplest maintenance.

### 1.4 Significant of Study

This Technical Assessment Report (TAR) is carried out to discover the best Holter monitor which is user-friendly and easy to use, easy to get spare part for repair. Thus, the best model of the device will be recommended to the user to purchase for the next time [1].

## 2.0 Holter Monitor

An automated and battery-powered device designed to continuously record electrocardiographic signals in ambulatory patients which is also known as a Holter recorder for periods normally from 24 to 72 hours to detect temporary ventricular arrhythmias, after myocardial infarction, or for detecting other cardiac disorders [2]. It typically includes a small cassette tape recorder or a digital medium that has no moving parts with appropriate signal amplifiers worn by the patient, and a set of surface electrodes normally five which are placed on the chest of the patient [10]. The recording is analysed at a medical facility using an electrocardiographic Holter analyser or a computer, with dedicated software [11].

### 2.1 Ambulatory ECG system architecture

The concepts of AECG monitoring that could be used for both continuous ECG recording or automatic arrhythmia detection [12]. These systems have an architecture consisting mainly of 5 building blocks which are electrodes, analog front-end, digital back-end, input/output ports, and power supply [13].



### 2.1.1 Electrodes

The electrode interfaces the skin with the ECG sensor. It consists of silver metal coated with an AgCl surface layer and is bathed in an electrolyte solution containing Cl<sup>-</sup> [14]. This electrolyte solution helps to reduce the resistance of the last layers of the epidermis, maximizing electrical voltage transfer between the skin and the input amplifier [15]. Wet electrodes have an adhesive that secures the electrode on the skin, preventing mechanical displacement. However, in long-time recordings, they can cause skin irritation and patient discomfort.

### 2.1.2 Input/output Ports

The data that get in and out of the ECG system also need to be managed by input/output ports. ECG signals can be stored in a solid-state memory and accessed later via a communications port [16]. Alternatively, data can be transferred via a radio transmitter to a receptor located in a different location. Interaction with the system can be performed in both ways allowing the user to introduce data into the device, such as personal information, or triggering an action when the patient feels symptoms. In addition, the device can display information to the user, such as battery status, detection of significant events, or high level of noise [17].

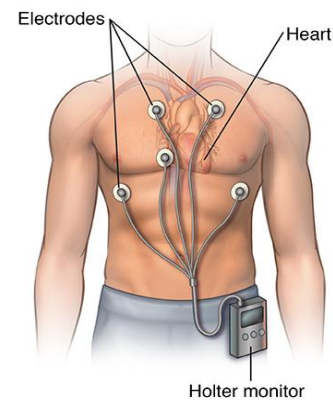
### 2.1.3 Power Supply

Ambulatory devices are typically powered by batteries that can be single-use or rechargeable. Common single-use batteries are made of alkaline electrolyte, which combines good performance with a low price. Rechargeable batteries have a lower energy storage capability than those for single use. Currently, lithium-ion batteries are the preferred rechargeable power supply because of high-energy density (up to 500 Wh/L) and light weight [18].

## 2.2 Application of Holter Monitor in clinical

Holter monitor has several tiny electrode patches which attach to the skin, and as well stick by small wires to a recording device shows in Figure 2.1. With careful application of the electrodes is important for good recording, patient's comfort, and electrode security. Better grip and a minimal resistance between skin and electrode is required to make sure the highest quality ECG recording. The device can be worn around the neck or tie to a belt. The electrodes, wires and recording device are hidden under clothes [28].

Figure 2.1 shows the application of the Holter Monitor on human body.



**Figure 2.1:** The application of Holter Monitor

Throughout the test based on Figure 2.1, the patient needs to keep the Holter dry and avoid bathing of the chest area [7]. They as well must record all the activities that they had perform and any symptom while wearing the Holter such as palpitation, chest pain or shortness of breath. After the test is completed, they can remove the device by themselves and return it to the Holter labs to explain the results after 2 weeks [29].

## 2.3 Types of Ambulatory Electrocardiogram

Various types of ambulatory ECG monitoring have been evolved over the years, to match different clinical situation. These types include continuous recorder/ Holter, intermittent recorder and implantable recorder.

### 2.3.1 Continuous Recorder

Continuous recorders (Holter recorders) can continuously store several ECG leads for a few days. Typically, continuous recorders are used for 24 or 48 hours [17]. However, new devices can offer autonomy for up to 7 days and can record several channels that permit the reconstruction of the standard 12-lead system [7]. Holter recorders allow detection of both symptomatic and asymptomatic events. However, because of the limitation in monitoring time, they cannot be used for the diagnosis of infrequent events [19].

The interpretation of the data is typically done by computer after the monitoring period and supervised by a technician [20]. Because several electrodes are applied to the skin, they are not well-tolerated by patients for long periods of time. Recently, novel leadless devices with a patch form have been developed with the aim of improving patient comfort [21].

### 2.3.2 Intermittent Recorders

Intermittent recorders store ECG signals only when there is an event of interest. They can be patient-triggered on the presence of symptoms or they can use real-time algorithms to automatically detect disturbances in the rhythm [17]. These devices record usually 1 or 2 ECG channels and because the battery can be replaced or recharged, they can be used for several weeks or months. Typically, these devices have a fixed period of recording that can go from some seconds to minutes per event [22].

There are 2 types of intermittent recorders which are patient-activated and loop recorders [17]. Patient-activated recorders are carried by the patient and they start recording an ECG signal when the patient activates the device, usually because of the presence of symptoms [23]. These devices are not typically worn continuously. They are single lead, often cable less and easy to use, thus better tolerated by patients [24]. However, they cannot detect asymptomatic episodes and often they do not capture the initiation of the arrhythmia.

Alternatively, loop recorders can be worn continuously by the patient. These devices continuously record and discard the data (loop recording) until there is an event which triggers permanent storage of the ECG signal [25]. The event is triggered by the patient in the presence of symptoms (patient-activated loop recorder) or automatically by an algorithm that can detect arrhythmic events (auto triggered loop recorder or arrhythmia monitor) [17].

### 2.3.3 Implantable Devices

Implantable devices, such as pacemakers or implantable cardio vertebra defibrillators, can typically monitor rhythm abnormalities and can store several episodes of interest in permanent memory [26]. They found that an optimal electrode position under the skin can lead to ECG signals, with signal quality that is sufficient for detecting arrhythmias. A subcutaneous implantable loop recorder dedicated to monitoring ECG rhythm has been developed in the last decade. These devices have several years of autonomy and have been suggested to be a good tool for very long-term monitoring [27].

## 2.4 Types of Ambulatory ECG in HSA

The ambulatory monitor can record cardiac rhythm continuously or intermittently and as well can be worn externally or implanted [27]. In Hospital Sultanah Aminah (HSA) consists of only two types of an ambulatory monitor which are continuous recorder known as Holter monitor and intermittent recorder which is also known as Event monitor.

There are several models of Holter monitor models in HSA such as Microvit MT-101 (Schiller AG) as shown in Figure 2.2 and Medilog AR12 Plus (Schiller AG) as shown in Figure 2.3. For event monitor model, consists of GemsTrak AF (GTSM-AF-6) from Universal Medical Inc shown in Figure 2.4 and Micro ER from Life Watch AG. In this Technical Assessment Report (TAR) will be focusing only on models of Holter monitor.

Figure 2.2 presented the physical layout of the

Holter Monitor brand of Microvit MT-10.



**Figure 2.2:** Holter Monitor Microvit MT-101

The MT-101 in Figure 2.2 is a compact two/three channel (4 or 6 lead cable) Holter recorder. It uses standard alkaline non-rechargeable batteries or high-capacity rechargeable batteries, and can record up to 72 hours of data (batteries need to be changed every 24 hours). Patient isolation when connected to the PC is provided by opto isolation. The MT-101 comes with a 4 or 6 lead cable (2 / 3 channels) [9]. Figure 2.3 shows physical layout of Holter Monitor Medilog AR12 Plus.

Figure 2.3 demonstrate the model of holter monitor, Holter Monitor Medilog AR12 Plus.



**Figure 2.3:** Holter Monitor Medilog AR12 Plus

Based on Figure 2.3, Medilog AR12 Plus offers to recording the ECG amplitude due to heart's mechanical connection to the rib cage, breathing causes the electrical heart vector to turn and therefore changes the ECG amplitude. Furthermore, the AR12 plus can be equipped with an optional Bluetooth module [8].

Figure 2.4 shows the is the image of the Event Monitor GEMSTrak AF.



**Figure 2.4:** Event Monitor GEMSTrak AF

Based on Figure 2.4, in order for symptomatic events being recorded by the patient, GEMSTrak AF automatically records asymptomatic ECG data without patient involvement. GEMSTrak AF uses accurate, embedded algorithms to detect and record episodes of Atrial Fibrillation, Bradycardia, and Tachycardia. The ECG data that GEMSTrak AF provides can help physicians with early diagnosis and treatment of illusive arrhythmias. In addition, this device is a comfortable and convenient monitor for patients to wear and use during day-to-day activities. The recorder's extended memory and programming options offer the physician flexible set-up and configuration.

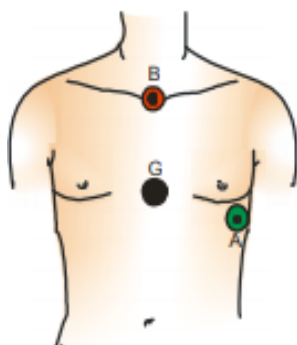
## 2.4.1 Electrode Specification and Placement of Microvit MT-101 and Medilog AR12 Plus

In Table 2.1 shows the specifications in terms of patient cables and channel types used for both models. Microvit MT-101 appears with patient cable for 4 or 6 leads and the channels are 2 or 3 channels. While the Medilog AR12 Plus comes in various patient cables which are 3, 5 and 7 leads as well used 1 or 3 channels. Table 2.1: Specifications on Electrodes for Microvit MT-101 and Medilog AR12 Plus

**Table 2.1:** Specifications on Electrodes for Microvit MT-101 and Medilog AR12 Plus

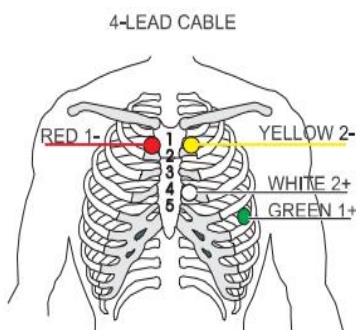
ITEM	MICROVIT MT-101	MEDILOG AR12 PLUS
Patient cable	4 or 6 leads	3, 5, or 7 leads
Channels	2 or 3 channels	1 or 3 channels

Many ECG grip electrodes are suitable for use. As ECG electrodes from different manufacturers have different electrical properties, the choice of ECG electrodes can affect the measurement results and quality. Make sure that only high-quality electrodes are used. The main channel which channels I is used for different real-time evaluations [8]. The positioning of these electrodes is therefore of special importance. Also, must ensure that there is no strain on the electrodes. The 3-lead variant of the Medilog AR12 plus records only one ECG channel as shown in **Figure 2.5**.



**Figure 2.5:** Placement Electrode for 3-Leads

**Figure 2.6** shows the typical electrode position for a 4-lead for 2-channel recording [9].

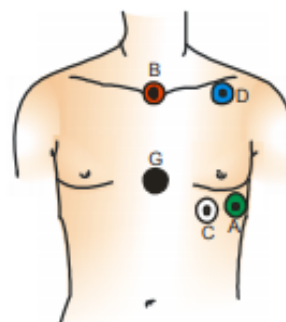


**Figure 2.6:** Placement Electrode for 4-leads.

Holter ECGs use a bipolar lead system which is one positive and the other one is negative lead for each channel. Channel 1 estimate to modified lead  $V_5$ . To restore the

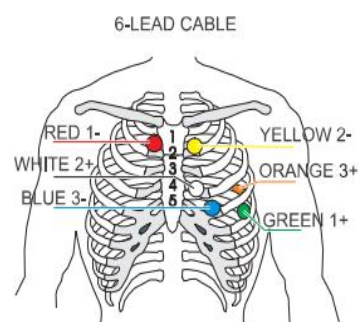
channel 1, place the RED negative electrode under the clavicle on the right Sterna margin. Then, place the GREEN positive electrode in the fifth left intercostals space on the anterior auxiliary line [10].

With 5 leads, the user gets a choice of seven views which including an anterior view. The leads can be built as shown in **Figure 2.7**. The ECG impulses sent to Holter monitor [11].



**Figure 2.7:** Placement Electrodes for 5-Leads.

Figure 2.8 shows the typical electrode placement for a 6-lead cable of 3-channel recording [9].

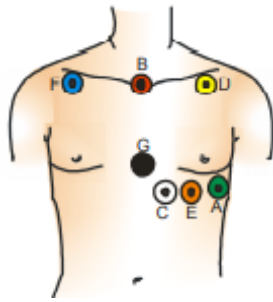


**Figure 2.8:** Placement Electrodes for 6-Leads.

To restore the channel 2, place the YELLOW negative electrode under the clavicle on the right Sterna margin. Then, place the WHITE positive electrode in the forth left intercostals space on the anterior auxiliary line [10].

Figure 2.9 indicates the typical electrode position for a 7-lead for 3-channel recording.





**Figure 2.9:** Placement Electrodes for 7-Leads.

To restore the channel 3, place the BLUE negative electrode in the fourth left intercostals space near the sternum. Then, place the ORANGE positive electrode on the back in the fifth left intercostals space between the spine and the scapula [10].

#### 2.4.2 Accessories Used for Microvit MT-101 and Medilog AR12 Plus

Every model of the Holter monitor device which is Microvit MT-101 and Medilog AR12 Plus packs with their accessories. Table 2.2 shows the Accessories Used for Microvit MT-101 and Medilog AR12 Plus

**Table 2.2:** Accessories Used for Microvit MT-101 and Medilog AR12 Plus

COMPONENT	MICROVIT MT-101	MEDILOG AR12 PLUS
<b>Patient cable</b>	i) 4-leads, 2 channels ii) 6-lead, 3 channels	3, 5, or 7 leads
<b>Power cable</b>	YES	YES
<b>Recorder pouch</b>	Pouch with belt	Pouch with shoulder strap
<b>Miscellaneous</b>	i) Blue sensor 25sets ii) SD Memory Card 512 MB with schiller logo	i) O-Ring Seal ii) Housing Kit Lock iii) Cover

These accessories in Table 2.2 are important to keep in a safe place as it is hard to get the spare parts. Each of the accessories has a specific function for a user when using the device. Both

models provide same items which are power cable and recorder pouch.

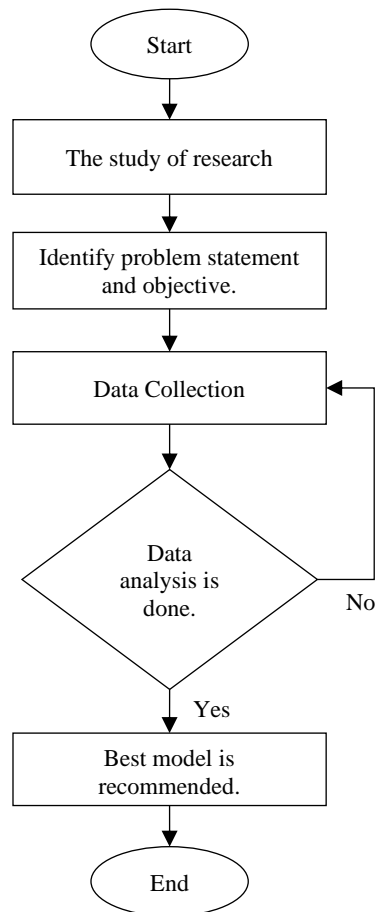
However, there is a difference in terms of the design for the pouch where Microvit MT-101 uses a belt to tighten while Medilog AR12 Plus applies shoulder strap. The function of this pouch is to prevent the Holter device from damage and avoid any liquid contact. Thus, it can minimize the total breakdown and cost. Most of the Holter device as well gives patient cable to the user usage that is based on the models.

### 3.0 Methodology

There are several methodologies has been used to collect the data for the data analysis such as ASIS and MyAPBESYS. It is significant platform where it used to update the information of the medical equipment in HSA. In addition, collect the data from the person in charges of the medical department assets. The manual of the Holter is applied as a referring tool to study the placement of electrodes, the accessories, specification, maintenance, and others.

#### 3.1 Flow of Progress

The Figure 2.10 shows the flow chart of the research in completing Technical Assessment Report (TAR) for the semester.



**Figure 2.10:** The flowchart progress of TAR

Based on Figure 2.10 the flowchart of completing the Technical Assessment Report (TAR) starts with a discussion with the mentor and in charge of staff for the medical equipment that would be chosen. The discussion is based on most often breakdowns for the equipment and common problems which always occur when the equipment is used. Then, decide the objectives for the TAR project, and data are collected via ASIS, MyAPBESYS, and manuals of the device. Lastly, all the data are tabulated and compared, and the best model is chosen.

### 3.2 Data Collection

The data collection in this research are from three type of references. First is from the Asset and Services Information System (ASIS), from MyAPBESYS and as well manuals as a reference.

#### 3.2.1 ASIS Data Collection

Figure 2.11 presented the page from website ASIS.



**Figure 2.11:** Main menu of ASIS

Asset and Services Information System (ASIS) is a central platform system which is created by the Ministry of Health (MOH) in Figure 2.11. It is a complete and combined with management system for assets and services. It provides data assets of Hospital Sultanah Aminah (HSA) and BEMS department. By using this platform, the data of the equipment chosen is extracted such as the total downtime, rate of breakdown and as well maintenance cost. Then, the data of maintenance for both models to tabulated and compared is extracted in Microsoft Excel.

#### 3.2.2 MyAPBESYS Data Collection

MyAPBESYS is a database and management system which commonly used in Advance Pact Sdn Bhd in Figure 2.12.



**Figure 2.12:** Main menu of MyAPBESYS

The system in Figure 2.12 is utilized for purchase intended such as spare part acquire, stock purchase and submitting the report. Furthermore, the information of the equipment can be obtained with the system like asset tag number, device location, status, purchase cost and others.

### 3.2.3 User Manual and Service Manual

A manual is an important medium used as a reference to understand technical information for each model of the equipment. It is consisting of main parts of the device, accessories used, and specifications. In addition, from the manuals gives knowledge regarding error occur on the device and solution to troubleshoot the error.

## 4.0 Result and Data Analysis

In this chapter, the two models of Holter monitor are compared. By comparing both models with various factors could help the Biomedical Engineering department and hospital to have a better device when purchasing. The factors which are been compared is based on corrective maintenance, total cost, and rate of downtime. The data is extracted in excel format which received from the online platform such as ASIS and MyAPBESYS.

### 4.1 Comparison of specifications for Microvit MT-101 and Medilog AR12 Plus

Table 2.3 shows the comparison of the specifications for Holter monitor Microvit MT-101 and Medilog AR2 Plus.

**Table 2.3:** Comparison of the specifications

ITEM	MICROVIT MT-101	MEDILOG AR12 PLUS
Dimensions	94 x 61 x 20 mm	60 x 76 x 23 mm
Weight	110g (with battery)	115g (without battery)
Battery type	1 x AA 1.5V battery	1 x AAA 1.5V battery
Resolution	12 bits	12 bits

ITEM	MICROVIT MT-101	MEDILOG AR12 PLUS
Sampling rate	500 Hz or 1000 Hz	4000 - 8000 Hz
Data transmission	Built-in USB 2.0 interface	Bluetooth module
Memory medium	SD memory card 64-512 MB	SD (Secure Digital) or SDHC (Secure Digital High Capacity) 128MB - 32GB
Protection against water	NONE	IPX4

Table 2.3 categorized the specification for the Microvit MT-101 weighs only 110g which has included with battery and used battery type of AA 1.5V alkaline compared to the Medilog AR12 Plus weighs is 115g without battery included. This device utilizes the battery type of AAA 1.5V alkaline where the size is small [1]. In addition, use SD Memory Card to stores the information needed about the cardiac arrest of the patient [2] and as well the Meanwhile, the Microvit MT-101 use USB 2.0 interface to transmit the ECG data from the Holter monitor device to the PC.

USB 2.0 device can operate at a low bandwidth at 1.5 Mbps or full bandwidth at 12 Mbps [3]. However, the Medilog AR12 Plus has operates with more advanced technology to transmit the data which is Bluetooth. The Bluetooth technology manages the communication channel of the wireless part. The Bluetooth modules can send and receives the data wirelessly by using two devices. It is not expensive and connects automatically with another Bluetooth device at a range of 30 feet [4].

Medilog AR12 Plus comes with two memory medium such as SD or SDHC memory card. SDHC (Secure Digital High Capacity) was created to fulfil the demand for HD (High Definition) video and high-resolution recording [5]. Compared to Microvit MT-101 only implement one type of memory medium such as SD memory card. Besides that, the additional benefit for Medilog AR12 Plus is implanted with advanced feature of IPX4. It is considered splash

proof and can be used in several situations. This feature can be used for outdoor activities. The reason is because that it can endure outdoor condition such as rains. It is not only splash proof but as well sweat proof, which means it will survive whenever contact with human sweat and still be able to work properly [6].

The rate of failure in 4 years for Medilog AR12 Plus and Microvit MT-101

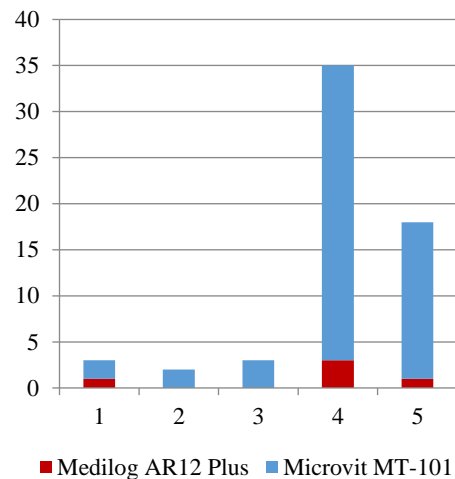
## 4.2 Rate of Maintenance

Table 2.4 shows the Rate of Maintenance for 4 years. From years 2016 to 2020 the data of both models are accumulated to be examined and measured.

**Table 2.4:** The rate of failure in 4 years for Medilog AR12 Plus and Microvit MT-101

Rate of Maintenance in 4 Years	Medilog AR12 Plus	Microvit MT-101
2016	4	9
2017	8	17
2018	2	5
2019	2	5
2020	2	5

Based on Figure 2.13 the rate of maintenance in from year 2016 until 2020 the result is shown in Figure 2.13



**Figure 2.13:** Rate of Maintenance in 2016-2020 for both models.

From Figure 2.13, the result shows that Microvit MT-101 has the high-level in rate of maintenance in 2016 and 2017 at 9 and 17. Meanwhile, the Medilog AR12 Plus has only 8 for maintenance in 2017. This device requires maintenance of RI. During Routine Inspection (RI), the technician or engineer will check performance of the device physically. Ensure that the device does not have any damage or broken on external body and as well the device is functioning well when use.

## 4.3 Rate of Failure

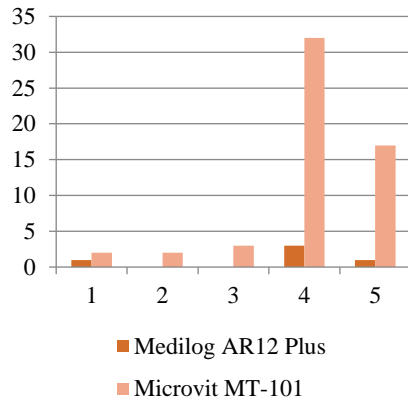
Table 2.5 shows the Rate of Failure for 4 years. From years 2016 to 2020 the data of both models are collected to be analyzed and compared.

**Table 2.5:** Rate of Failure in 2016-2020 for both models

Rate of Failure in 4 Years	Medilog AR12 Plus	Microvit MT-101
2016	1	2
2017	0	2
2018	0	3
2019	3	32
2020	1	17

**Table 2.5**, the rate of failure from year 2016 until 2020 resulted that the Medilog AR12 Plus has five failure and Microvit MT-101 has 56 failure.

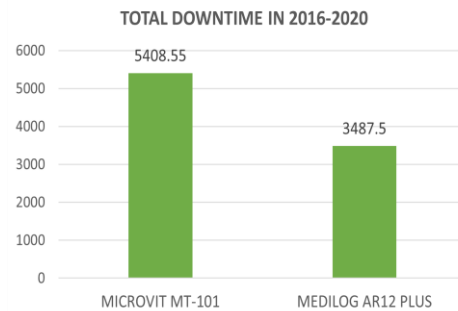
Figure 2.14 illustrates the rate of failure in 2016-2020 between two models.



**Figure 2.14:** Rate of Failure in 2016-2020 for both models

From Figure 2.14, the result shows that Microvit MT-101 has recorded the highest rate of failure compared to Medilog AR12 Plus in 2019. Moreover, in 2020, Microvit MT-101 has remains leading the top value which is collected at 17. Meanwhile, the Medilog AR12 Plus has 1 for rate of failure in the same year. The reason this happen is because of Microvit MT-101 usually occur the major problem such as motherboard damage, battery holder broken and ECG cannot be read. While, the Medilog AR12 Plus only appear minor problems like change the ECG cable and SD memory card.

Rate of Failure in 4 Years	Medilog AR12 Plus	Microvit MT-101
2016	1	2
2017	0	2
2018	0	3
2019	3	32
2020	1	17



**Figure 2.15:** Total downtime in 4 years for both models

The result shown in the Figure 2.15 that Microvit MT-101 have higher downtime for 5408.55 hours than Medilog AR12 Plus which has only 3487.5 hours. The reason is this happen is because of the corrective maintenance for Medilog AR12 Plus only consists of a minor problem such as replace the SD memory card and new ECG cables. However, in order to replace the items, have to wait for spare parts to arrive. Meanwhile, the Microvit MT-101 need more time to calibrate the ECG cables to get an accurate reading and require advice from the vendor to repair the device.

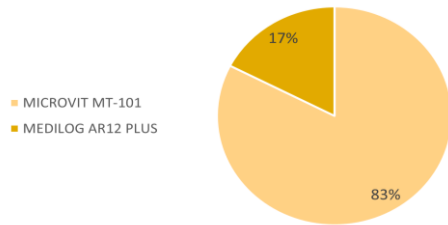
#### 4.4 Total of Downtime

The Figure 2.15 indicates the total hour of downtime for 4 years from 2016 to 2020 for Microvit MT-101 and Medilog AR12 Plus.



#### 4.5 Total Cost of Breakdown

Figure 2.16 illustrates the pie chart of the total cost of breakdown for both models Microvit MT-101 and Medilog AR12 Plus.



**Figure 2.16:** Total Cost of Breakdown for both models

From the result found that in Figure 2.16 Microvit MT-101 has highest cost to repair compared to Medilog AR12 Plus. This is because that the causes of damage on battery holder. Due to this problem, the holter casing necessary to fully replaced which leads to more expensive in cost services. With the vendor's support as well could make the service cost become pricey. For Medilog AR12 Plus, only need to change the basic component such as ECG cables and SD memory card which has cost less price.

#### 4.6 Rate of Investment

Table 2.6 shows the Rate of Investment for both models in past 4 years. The data is collected to determined which model is the best to be used for hospital usage.

**Table 2.6:** Rate of Investment for both models

Model	Medilog AR12 Plus	Microvit MT-101
Description		
Rate of Maintenance in past 4 years	18	41
Rate of Failure in past 4 years	5	56
Total of Downtime	3487.5	5408.55

The data in Table 2.6 of corrective maintenance that has been carried out for past 4 years is shown in Figure 2.15. The frequency of data indicates that the rate of failure for Holter Monitor model Microvit MT-101 is higher than Medilog AR12 Plus which has 32 of rate of failure while Medilog AR12 Plus only recorded 3 of failure.

*% Relative error for frequency failure*

$$= \frac{(F_{total} - F_{measured})}{F_{total}} \times 100\%$$

*% Relative error for frequency failure*

$$= \frac{(61 - 56)}{61} \times 100\%$$

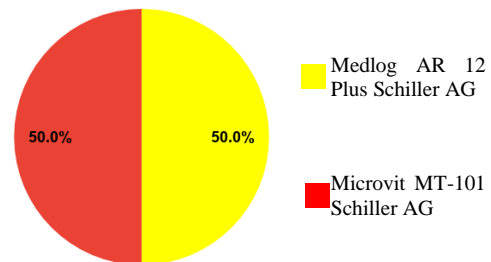
$$= 8.2\%$$

Based on the frequency above shows the percentage of failure for Microvit MT-101 is 8.2% more than Medilog AR12 Plus. The percentage can be calculated by using relative error percentage formula that has been stated above.

#### 4.7 Questionnaire Analysis

The questionnaires was distributed among user, a number of 12 respondents have been recorded. The respondents have selected which model they preferred either Microvit MT-101 or Medilog AR12 Plus. In Figure 2.17 to Figure 2.20 show the analysis of each questions.

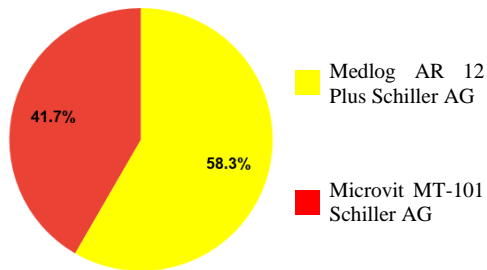
Figure 2.17 shoes the piechart on Question 1 regarding which model has the least problem



**Figure 2.17:** Respond on model with the least problem.

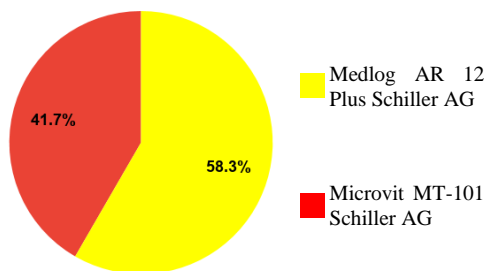
Figure 2.17 shows the user have to choose which model has the least record for problem Figure 2.18 shows that both has the same vote which at 50%.

In question 2, user have to choose which model is easier to be used when trasmit the data to the computer. In Figure 2.18 shows that 58% prefer Medilog AR12 Plus over Microvit MT-101 that recorded 41.7% who recommend it.



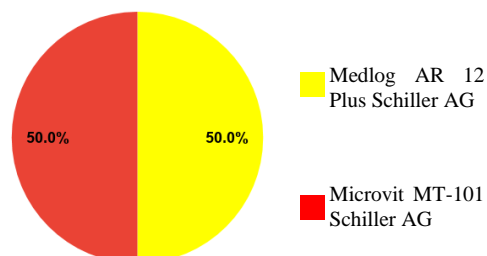
**Figure 2.18:** Respond on ease of use.

In Figure 2.19 shows the user need to select which model that they consider have a better features in terms of specifications, the usage method and user-friendly. Medilog has more voted which at 58% while Microvit MT-101 only gets 42%.



**Figure 2.19:** Respond on model with better features.

Question 7 in Figure 2.20 is a question where the user have to determine which model is the best model to be used for HSA usage. Both models receive the same vote at 50%.



**Figure 2.20:** Respond on preferred model.

## **4.8 Summary of Result and Data Analysis**

To be summarize, from the results has finalize that Holter monitor model Medilog AR12 Plus from Schiller AG compared to Microvit MT-101 is better in terms of cost repair and frequent breakdown. The reason for this is that the Medilog AR12 Plus provides more advantages in servicing. For example, most of the corrective maintenance only occur the minor problem such as replacing the ECG cables and SD memory card. In addition, the repairing process is not complicated as Microvit MT-101 due to minor problems. This device as well does not need assists from the vendor. Hence, it could save the cost of the breakdown and minimize the downtime of the device.

## **5.0 Conclusion**

From this study, it can be concluded that Ambulatory Electrocardiogram (ECG) can be divided into several types such as continuous recorder (Holter), intermittent recorder (event) and implantable. Holter monitoring have an ability to continuously record ECG data over 24 and 48 hours. Meanwhile, the event monitor can provide nearly real-time data analysis when the patient transmits a recording in proximity to the symptomatic event over seconds or minute and implantable recorder can trigger automatically or by patient activation via placement of an activator over the device. In this Technical Assessment Report (TAR) will focusing only in Holter monitor models that has been used in Hospital Sultanah Aminah (HSA) such as Microvit MT-101 and Medilog AR12 Plus. The data is collected from the interface platform like ASIS and MyAPBESYS. Furthermore, the aims for this TAR are to compare which models are better for biomedical department and hospital usage. From the data analysis, found that Medilog AR12 Plus is better than Microvit MT-101. The reason is because that repairing process is not complicated due to minor problems. As well does not need assists from the vendor. Hence, Medilog AR12 Plus is definitely the best model for hospital medical department in order to reduce the total of downtime and cost service. Besides that, this device has more advantages because of it is user-friendly, more advanced features and can minimize the total of breakdown.

## **6.0 Recommendation**

Based on analysis assessment done, Medilog AR12 Plus recommend as the best model to be used in Hospital Sultanah Aminah (HSA). From technical reviews, the model is reliable, has cheaper spare part cost, and the repairing is not complicated. For the user review, the model is more user-friendly, low cost, and easy to use for patient and lab technician.

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# VENTILATOR

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**Abstract**— Ventilator is a machine that support breathing. Ventilator also called a breathing machine or respirator. These machines are mainly used in hospitals. Ventilators get oxygen into the lungs, remove carbon dioxide from the body, help patient breathe easier, and breathe for people who have lost all ability to breathe on their own. Ventilator is very important at hospital as it is a life support machine for patient in need. The purpose of this study is to collect the data and make research about the different model of ventilator that use in Sultan Ismail Hospital, Johor Bahru. Other than that, to learned and know about the function and specification of the ventilator. The data for device were collected based on hospital data. Besides, the collection data for two different model of ventilator were collected to investigate the total of breakdowns in first purchase years to six years, type of breakdown, total downtime (hours) and total cost repaired. Based on the assessment and analysis done it can be recommended that Puritan Bennett 840 is better than Puritan Bennett 980 since the Puritan Bennett 840 is user friendly and easy to handle the problem than Puritan Bennett 980.

**Keywords**- ventilator, breathing, breakdown, analysis, Puritan Bennett

## 1.0 Introduction

Mechanical ventilation is a life-sustaining therapy for the treatment of patients with acute respiratory failure [1]. The history of ventilation started with an emphasis on ventilator-induced lung injury (VILI) [1]. Then, the noted Greek physician and scientist who lived in the second century, introduced about the importance structure of anatomy to understand the disease related to the lung. He studied respiration and taught that breathing was required to maintain the circulation (i.e., the physical act of breathing caused the heart to beat) [1]. One of the professors of anatomy also were make research about the anatomy that reference to positive pressure ventilation as we know it today and we currently do at intensive care Unit (ICU).

Figure 3.1 demonstrates The iron lung that use to treat patient polio [1]



**Figure 3.1:** The iron lung that use to treat patient polio [1]

In 1876, the iron lung is made as shows in Figure 3.1. It upgrades from researched about ventilator used to treat patient with Polio. It is Negative Pressure Ventilation. Then the technology of ventilator is upgraded with Lung-Protective Ventilator Strategies that used for now [1]. It is positive pressure ventilation. Nowadays, ventilator is controlled by microprocessor [2]

Ventilators are machines that blow air, or air with extra oxygen, into the airways and lungs. The airways are pipes that carry oxygen-rich air to the lungs when you breathe in. They also carry carbon dioxide (a waste gas) out of the lungs when breathe

out. Ventilator is divided into many ranges for patient such from neonate to adult. The operation mode for adult patient and neonate is different. Ventilator also have range that used for different condition such as transport and portable.

Ventilators were categorized as a life support machine. Hence the ventilator machine is use at intensive care unit (ICU) and Neonate Intensive Care Unit (NICU), Red zone accident and emergency and Critical Care Unit (CCU). This machine used for critical patient that related to

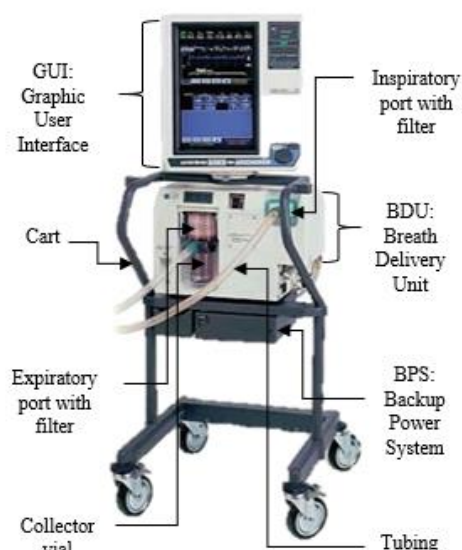
affect lung function and cause difficulty in breathing. Example disease that needs to use ventilator machine to stabilize the condition are lung diseases like asthma, Chronic Obstructive Pulmonary disease (COPD), lung cancer, acute respiratory distress syndrome (ARDS), stroke, brain injury and drug overdose [3]. The person that knows and the person in charges to setup the ventilator is respiratory therapist [4] medical Assistant and the nurse who have trained with how to use ventilator.

## 2.0 Ventilator

Ventilator is very critical equipment in hospital since it is a life support machine for patient in need. Ventilator takes over the body's breathing process when disease has caused the lungs to fail. Hence it gives the patient time to fight off the infection and recover. The data consist of physical layout of the ventilator, the operation, application and principle of the ventilator, type of model that were choose, specifications of the ventilator tools that use for ventilator and plan preventive maintenance of ventilator.

### 2.1 Physical specification of ventilator

Ventilator is an automatic machine designed to provide all or part of the work the body must do to move gas into and out of the lungs. The ventilator uses pressure to blow air into the lungs. This pressure is known as a positive pressure. A patient will exhale the air at their own, but sometimes the ventilator done for patient. The amount of oxygen the patient receives can be controlled through a monitor connected to the ventilator. The Figure 3.2 shows and explained about the physical specification of ventilator.



**Figure 3.2:** Physical Specification of ventilator

1. **GUI (Graphic User Interface)** – Graphic User Interface provides the operator interface to and from the ventilator. Ventilation mode, parameters, and alarm settings are entered by the operator via the GUI.

2. **BDU (Breath Delivery Unit)** – Breath Delivery Unit is a pneumatic system, under control of the breath delivery (BD) central processing unit (CPU), mixes oxygen and air and controls gas flow to the patient.

3. **BPS (Backup Power System)** – Backup Power System will automatically charge while the ventilator is connected to ac power and will operate the system up to 30 minutes with new, fully charged batteries. The BPS does not supply the compressor unit or the humidifier with electrical power. The ventilator automatically switches back to ac power when facility power returns within the required limits.

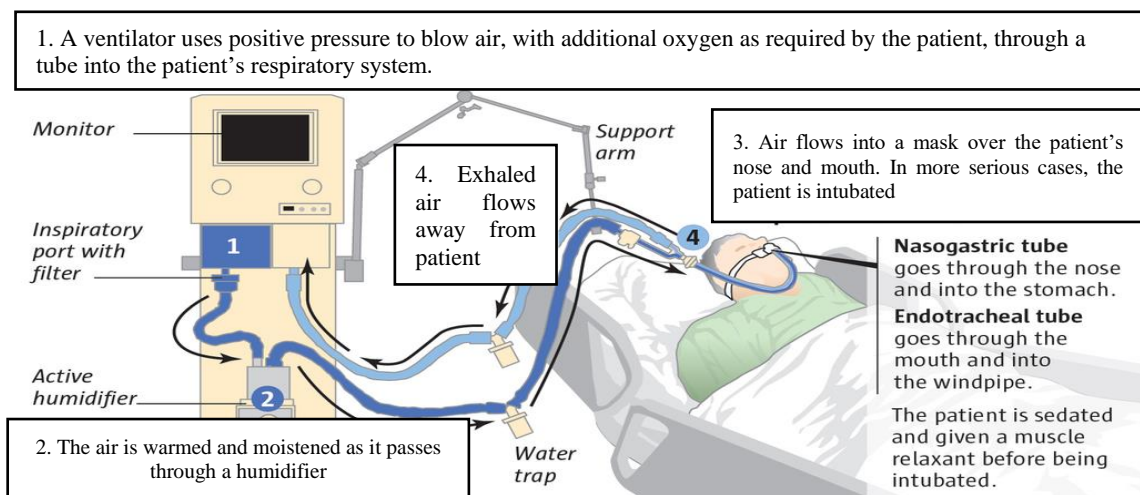
4. **Cart** - It also provides mobility for the ventilator. Brakes on the front casters prevent the cart from rolling and turning.

5. **Inspiratory port with Filter** – This filter will flow air to the patient.
6. **Expiratory port with Filter** – Exhaled air flowing from the patient.
7. **Tubing** – To flow the air between expiratory filter and inspiratory filter.
8. **Collector vial** – to protect the expiratory system from bulk moisture in the exhaled gas. Use to attach drainage bag.

Figure 3.2 shows the physical specification of ventilator that mostly the general ventilators have the same parts and accessories. The ventilator consists of GUI (Graphic User Interface) or monitor to show the result of the patient. Then the BDU (Breath Delivery Unit) is related to system for related breath for patient. It is included the connection from Patient (Expiratory filter) and to patient (Inspiratory Filter). Then the ventilator also has the BPS (Backup Power System) as another power to switch on. Other than that, it also has cart and casters that easy to move the ventilator around. Then the ventilator consists of tubing that flow air and collector vial to protect the expiratory system from bulk moisture in the exhaled gas.

## 2.2 Operation, Application and Principle of ventilator

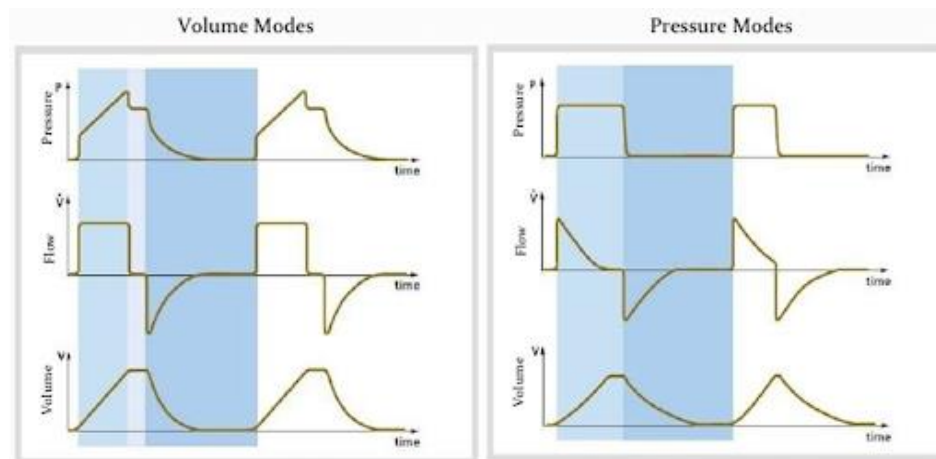
For the Operation it required three basic components which are a source of input energy to drive the device, while oxygen and air is needed to use the ventilator. Then, converting input energy into output energy in the form of pressure and flow to regulate the timing and size of breaths. Lastly, monitoring the output performance of the device and the condition of the patient. The application of ventilator involves the patient and machine of ventilator. Figure 3.3 shows the application of ventilator that use at patient. Connection for patient were set up.



**Figure 3.3: Application of Ventilator**

The connection for patient were set up before the machine is use at the patient as shown in Figure 3.3. The accessories that connect for patient are support arm, inspiratory port with filter, active humidifier, Inspiratory line with water trap, Y-piece, Expiratory line with water trap, Expiratory Port, flexible connector, proximal flow pressure sensor, nebulizer, Nasogastric tube and Endotracheal tube. After done the setup, the short self –test (SST) of the machine needs to be done before attached the machine to the patient. The SST is to check the tubing for patient and all flow for patient no leakage and in a good condition. If the short self-test is passing then the ventilator machine saves to use for patient.

Principle of ventilator which is ventilation. The goal of ventilation is to facilitate  $\text{CO}_2$  release and maintain normal  $\text{PaCO}_2$ . Ventilation related to Minute ventilation ( $V_E$ ) [5].  $V_E$  regulated by brain stem, responding to  $\text{PH}$  and  $\text{PaCO}_2$ . Ventilation in context of ICU, first increased  $\text{CO}_2$  production. Use for fever, Sepsis injury, overfeeding. Second is Increase the  $V_D$ . It uses for lung injury, ARDS and Pulmonary embolism. Second principle is Oxygenation. The primary goal of oxygenation is to maximize  $\text{O}_2$  delivery to blood ( $\text{PaO}_2$ ). Alveolar –arterial  $\text{O}_2$  gradient. Equilibrium between oxygen in blood and oxygen in alveoli, A-a gradient measures efficiency of oxygenation,  $\text{PaO}_2$  partially depends on ventilation but more on  $V/Q$  matching. Oxygen in context of ICU is  $V/Q$  mismatching which is Patient position (supine) and Airway pressure, pulmonary parenchymal disease, small airway disease [5]. Figure 3.4 show the graph of Volume modes and pressure mode.



**Figure 3.4:** The graph of volume mode and Pressure mode [6]

Figure 3.4 show the volume modes and pressure mode. Pressure-cycled modes deliver a fixed pressure at variable volume (neonates) and volume-cycled modes deliver a fixed volume at variable pressure (adults). The adult patient can use mode volume and pressure. For the neonate only suitable use the pressure mode. For pressure cycle modes it consists of Pressure Support Ventilation (PSV), Pressure Control Ventilation (PCV), CPAP and BiPAP. For volume cycle mode consist of Control, Assist, Assist/Control, Intermittent Mandatory Ventilation (IMV) and Synchronous Intermittent Mandatory Ventilation (SIMV) [5].

## 2.3 Related brand and Model of Ventilator

In this section is explained about the brand and model of ventilator that use in Malaysia and Sultan Ismail Hospital. Table 3.1 shows the listing of brand and model that use at Sultan Ismail Hospital for adult and use at Intensive Care Unit and other area. All of this have the same function which is used to support patient's breathing.



**Table 3.1:** The list of ventilators that use in Sultan Ismail Hospital

	Brand	M odel	List
1.	Aeonmad	VG 70	1
2.	Coviden	Puriten Bennett 980	3
		Puriten Bennett 840	30
3.	Respironics	Bipap Vision	1
		Philips V60	1
4.	Carefusion	Oscillatory Ventilator 3100a	1
5.	Hamilton	Hamilton C2	3



Based on the Table 3.1 shows that the total list of ventilators for adult that use at Sultan Ismail Hospital is 40. The most use by the user is Puritan Bennett 840 with 30 machines active at the hospital. All the brand and model have their own specification with different cost. All of this also have their own lifespan as determined by the manufacturer. Based on the objective, this research is only focus on two models that to be compared for this technical assessment as shown in Table 3.2.

**Table 3.2:** Comparison between two models of ventilator

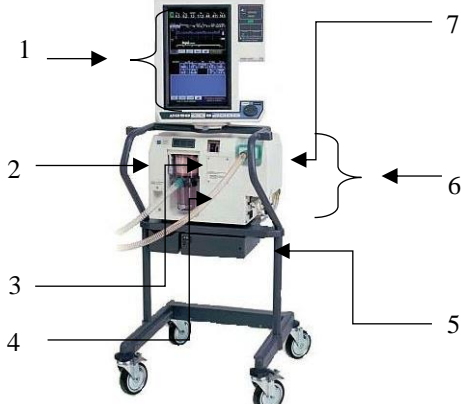
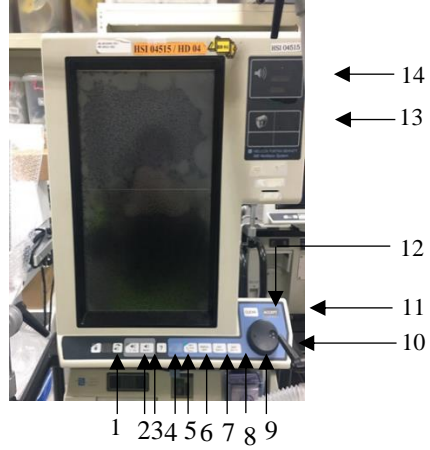
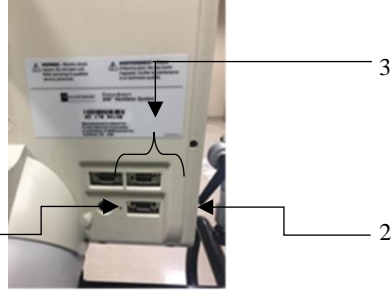
	PURITAN BENNETT 840 (PB840)	PURITAN BENNETT 980 (PB980)
<b>Picture</b>		
<b>Price</b>	<b>RM119,500.00</b>	<b>RM135,900.00</b>
<b>Physical layout (Screen mobility)</b>	The screen on the Puritan Bennett 840 ventilator does not swivel as far, and it has no dome light. It provides visual alarms on the front side, which are not visible when standing behind the Puritan Bennett 840 ventilator.	The Puritan Bennett 980 ventilators offer numerous improvements on physical design, The Puritan Bennett 980 ventilator's 15-inch screen rotates 170 degrees about a vertical axis in either direction (creating 350 degrees of visibility) and can be tilted up to 45 degrees from vertical to allow for better viewing of both content and alarms.
<b>Mode Standby</b>	Mode standby for Puritan Bennet 840, need to turn off, then turn on back.	Mode standby for Puritan Bennett 980, does not need to turn the device off and on.
<b>Alarm</b>	The Puritan Bennett 840 alarm has a set volume that doesn't change automatically to alarms that have not been responded to.	The Puritan Bennett 980 ventilator elevates its decibel level at 30 seconds and again at 60 seconds automatically with an alarm that has not been responded to if the set volume is lower than the maximum setting.
<b>Graphics</b>	The Puritan Bennett 840 offers fewer options for selecting views, it's not configurable, and it doesn't provide data monitoring or graphics	The Puritan Bennett 980 ventilator touch screen works like a smartphone.

Based on Table 3.2, the comparison of physical layout between two models of ventilators has been displayed. The price is different. The PB 980 have higher price than PB840. This is because the PB 980 have advanced software. For the physical layout sections the screen for PB 980 is easier to view as it can rotates 170 degrees which is creating 350 degrees of visibility. It also can be tilted up to 45 degrees. For the standby mode the PB 980 does not need to turn on and off, while PB 840 need to turn off and turn on back. It can say that PB 980 is faster to done the mode standby than PB840. For the alarm the PB 980 can automatically lower the volume but PB 840 only can setting the volume. Therefore, the PB 840 volume is user friendly than PB 980. Lastly, the graphics is more advanced for PB 980 than PB 840. These two models of ventilator have the same manufactures which is Coviden and their lifespan also same, which are 10 years.

## 2.4 Specification of ventilator

The specifications of two models were choose in this section. First is Puritan Bennett 840 and Puritan Bennett 980. Table 3.3 shows the specification of Puritan Bennett 840.

**Table 3.3:** Specification of Puritan Bennett [7]

Puritan Bennett 840	
<p>Physical Layout</p> 	<ol style="list-style-type: none"> <li>1. GUI: Graphic User Interface</li> <li>2. Cart</li> <li>3. Expiratory Filter</li> <li>4. Collector vial</li> <li>5. BPS: Backup Power System</li> <li>6. BDU: Breath Delivery Unit</li> <li>7. Inspiratory filter</li> </ol>
<p>Front of GUI</p> 	<ol style="list-style-type: none"> <li>1. Screen Lock Key</li> <li>2. Volume Key</li> <li>3. Silence Key</li> <li>4. Alarm Reset Key</li> <li>5. Info key</li> <li>6. 100% O2/CAL 2 MIN key</li> <li>7. Manual INSP key</li> <li>8. EXP Pause key</li> <li>9. INSP Pause key</li> <li>10. Knob</li> <li>11. Accept</li> <li>12. Clear</li> <li>13. System operation indicator</li> <li>14. Alarm indicator</li> </ol>
<p>Rear View of GUI</p> 	<ol style="list-style-type: none"> <li>1. Remote Alarm</li> <li>2. Null Modem Port</li> <li>3. Two Serial Port</li> </ol>

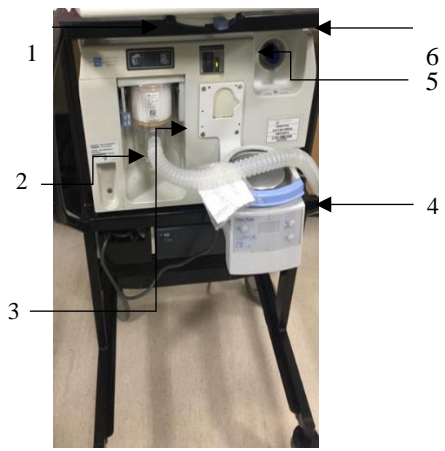
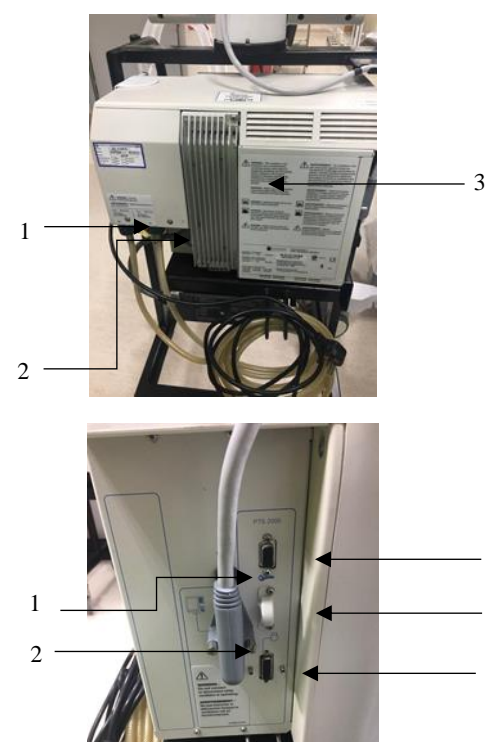
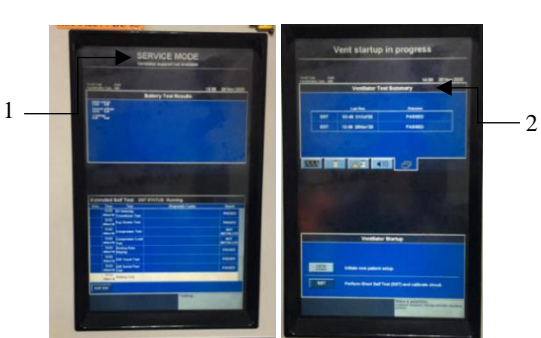

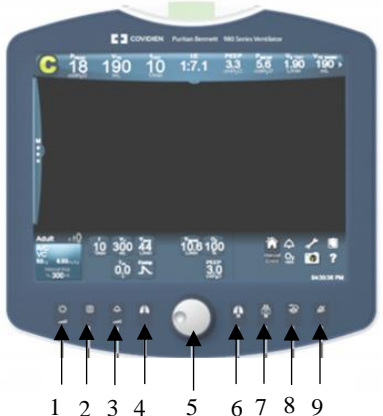
Puritan Bennett 840	
<p>Front of BDU</p>  <p>1. Ventilator Operation Indicator 2. Exhaust Port 3. From Patient Port 4. Humidifier Outlet 5. Power Switch and Indicator 6. To Patient Port</p>	
<p>Rear View of BDU and I/O Panel of BDU</p>  <p>Rear View of BDU 1. High Pressure Air Fitting 2. High Pressure Oxygen Fitting 3. Power Supply</p> <p>I/O Panel of BDU 1. Reset Button 2. GUI Cable Connection 3. Compressor data cable 4. Data Key 5. Performance Test System</p>	
<p>Display</p>  <p>1. Display for service mode 2. display for Vent start up in progress</p>	

Table 3.3 show the specification of Puritan Bennett 840. 30 of these models were use at Hospital Sultan Ismail. The ventilators have seven important part which are GUI, cart, expiratory filter, BPS, BDU and inspiratory filter. It also has 11 key functions with one knob. The key is a soft key. For the screen at GUI provides a communication path between the ventilator and the operator. The screen is a touch screen. When use the touch screen, soft keys and knob on the GUI, the practitioner gives initial instructions and data to ventilator. It also consists high pressure air and oxygen fitting and power supply at the rear of BDU. The BPS provides dc power to the BDU in the event that ac power is lost. Therefore, the BPS can power the ventilator for transport purposes within the respiratory care facility. The BPS should always be connected to the ventilator during operation. It also backup for an alarm only. When use the ventilator need to connect the machine at AC power. The PB 840 is suitable use for neonate, child and adult, but at Hospital Sultan Ismail use it for adult. Table 3.4 shows the physical Specification of Puritan Bennett 980.

**Table 3.4:** Specification of Puritan Bennett 980 [8]

Puritan Bennett 980	
<p>Physical layout</p> 	<ol style="list-style-type: none"> <li>1. GUI: Graphic User Interface</li> <li>2. Expiratory filter part</li> <li>3. Casters</li> <li>4. BDU: Breath Delivery Unit</li> <li>5. Inspiratory Filter</li> </ol>
<p>Front of GUI</p> 	<ol style="list-style-type: none"> <li>1. Display brightness key</li> <li>2. Display lock key</li> <li>3. Alarm volume Key</li> <li>4. Manual Inspiration key</li> <li>5. Rotary encoder (knob)</li> <li>6. Inspiratory pause key</li> <li>7. Expiratory pause key</li> <li>8. Alarm reset key</li> <li>9. Alarm silence key</li> </ol>

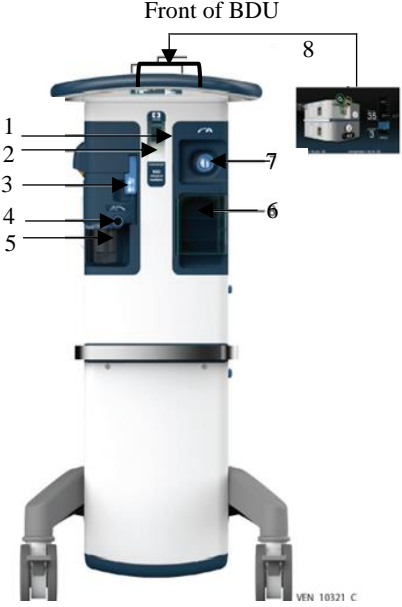
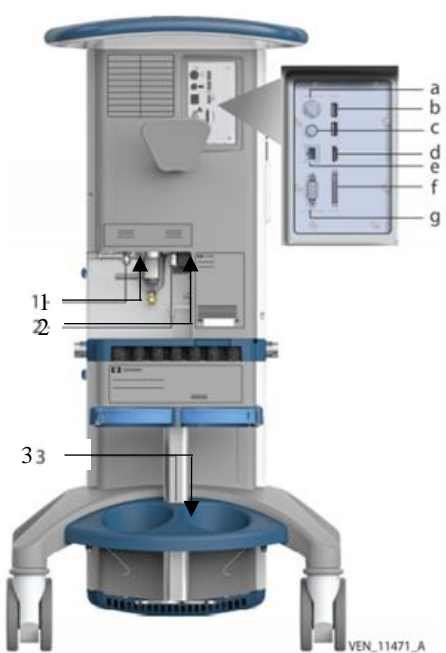
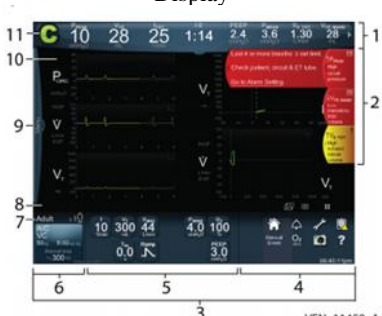
Puritan Bennett 980	
<p>Front of BDU</p>  <p>VEN 10321 C</p>	<ol style="list-style-type: none"> <li>1. Power Switch</li> <li>2. AC Power indicator</li> <li>3. Expiratory Filter latch</li> <li>4. Expiratory filter</li> <li>5. Condensate Vial</li> <li>6. Option connector panel door</li> <li>7. Internal inspiratory filter</li> <li>8. Status display</li> </ol>
<p>Rear view of BDU and I/O panel of BDU</p>  <p>VEN_11471_A</p>	<p>Rear view of BDU</p> <ol style="list-style-type: none"> <li>1. Oxygen inlet</li> <li>2. Air Inlet</li> <li>3. Cylinder mount</li> </ol> <p>I/O panel of BDU</p> <ol style="list-style-type: none"> <li>a. Service mode switch</li> <li>b. USB port (2x)</li> <li>c. Remote alarm port</li> <li>d. HDMI port</li> <li>e. Ethernet connector</li> <li>f. Service port</li> <li>g. RS-232 serial port</li> </ol>
<p>Display</p>  <p>VEN_11459_A</p>	<ol style="list-style-type: none"> <li>1. Patient data area</li> <li>2. Alarm banners</li> <li>3. Constant access area</li> <li>4. Constant access icons</li> <li>5. Current settings area</li> <li>6. Vent Setup button</li> <li>7. patient type indicator</li> <li>8. Prompt area</li> <li>9. Menu tab</li> <li>10. Waveform area</li> <li>11. Breath phase indicator</li> </ol>



Table 3.4 shows the specifications for ventilator Puritan Bennett 980. The ventilators have an advanced software. The important part for Puritan Bennett 980 is GUI, Expiratory filter, casters, BDU, Inspiratory filter and status display. The Puritan Bennett 980 display at GUI is a touch screen. The GUI also have a small size and can rotate 170 degrees. The ventilators have 8 keys with function and one knob. The key is a touch pad. When use the touch screen, touch pad, knob on the GUI it will give data to ventilator for functioning. Other than that, the PB 980 consists of oxygen inlet and also air inlet to connect the oxygen and air wall. For this ventilator it has the battery powered compressor. It increases opportunities to transport and mobilize patients. The PB 980 also design for use on patient population sizes from neonatal (NICU) through adult who weight minimum 0.3kg. Therefore, at hospital Sultan Ismail use this ventilator for adult.

## 2.5 Tools used for ventilator.

Every device or machine have their own tools to check or test the performance of the machine. For the ventilator it uses the ventilator tester as a tool for ventilator. There are a lot of type ventilator tester that use in Malaysia which are different brand and model. Ventilator test consists of an evaluation of the accuracy of controls and instruments including the alarm signals and the evaluation of the trigger signals for the assisted ventilation. In addition, the conformity of the patient connection with the corresponding standard and the usability are tested. Figure 3.5 shows the ventilator tester that have and use in Malaysia.



(a) Fluke VT900A Gas Flow Analyzer Ventilator



(b) Rigel VenTest 800 gas flow Analyzer



(c) Certifier Flow Analyzer Plus Ventilator Test system 4080

**Figure 3.5:** Ventilator Tester

The Figure 3.5 shows the ventilator tester that use for ventilator in Malaysia. For the Hospital Sultan Ismail, Certifier Flow Analyzer plus Ventilator Test system 4080 were used as a tester for all type ventilator.

## 2.6 Plan Preventive Maintenance of Ventilator

The plan preventive maintenance done for all ventilator or other machine are based on the plan preventive maintenance checklist (PPM checklist) from Kementerian Kesihatan Malaysia. The ventilators have their own self-test which are which are Extended Self-Test (EST) that done by technical, Short Self-Test (SST) that can done by technical and need to done by user before attached or use machine for patient. The PPM checklist can get in ASIS system. In the checklist consist of eight parts that need to complete. First is asset detail. The biomedical engineer needs to complete the asset detail of the machine that done for PPM. Then, the special precaution part. Before do the PPM the biomedical engineer needs to use Personnel Protection Equipment (PPE), need to follow the procedure and make sure the tester use done calibrated. Third is test apparatus parts. The list of test apparatus needs to use the correct tester for the ventilator which are Electrical Safety Analyser, Ventilator Tester, oxygen analyser and pressure meter. After that, the part four in checklist is qualitative task. The qualitative task is done with check all the outer of the machine. The physical integrity of all the accessories, board, and casing of the ventilator were check. The sound of the ventilator for alarm were check. All the sensor calibration were check. The Extended Self-Test (EST) also were done in this part. For part five is the preventive maintenance task. The preventive maintenance task is related to inspect and clean the outer and inner of the ventilator. The battery checked also done in this part. For part six is

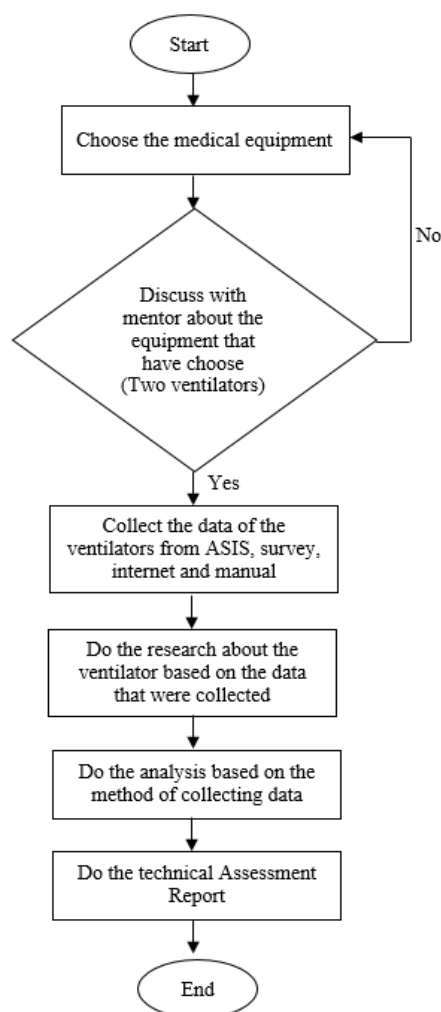
quantitative task. This part will use the ventilator tester, oxygen analyser and pressure meter. The test needs to be done for ventilator are regular setting verification, volume check, breath rate check oxygen concentrate check and lastly PEEP check. All the measured value were recorded in this part and all the test have own limit or tolerance. For part seven is related to Electrical safety test. Electrical safety analyser is used to done the electrical safety test for ventilator. Lastly, the notes. The notes related to ventilator were done at this part. The Plan Preventive Maintenance must be done accordingly to the given and set date. For the ventilator the PPM need to be done two times in one year with six monthlies.

### 3.0 Methodology

Methodology of this study involve the analysis that have done for this assessment. First is explained about the overall process of this researched. Then it explained about how to collect data using the method which are, ASIS, survey, internet and service and user manual of every equipment.

#### 3.1 Flowchart of the assessment

Figure 3.6 shows the flow of works on assessment of two models of ventilators that were choose. The overall flow from the first until the end of the assessment were show in this flowchart.



Based on Figure 3.6, the flowchart of the overall process assessment that have done for this researched. Start with choose the equipment that have in Hospital Sultan Ismail. Every student needs to choose equipment at hospital where their WBL hospital. After choose the equipment, made the discussion with mentor at the hospital. If the mentor agreed, then the research was process. If not, need to search another equipment. Then the ventilators were chosen. Two ventilators with different model were choose to do the comparison for this researched. The ventilators are brand Coviden, model Puritan Bennett 840 and Puritan Bennett 980. Then the data were start collected from ASIS, survey internet and the journal and manual. After collect the data, the researched is made with every data that get. After that, the analysis has been done based on the method of collecting data and researched that have made. In the analysis the data and graph were reviewed. Lastly, the all the data analysis is written in technical assessment report.

#### 3.2 Method of collecting data for the analysis

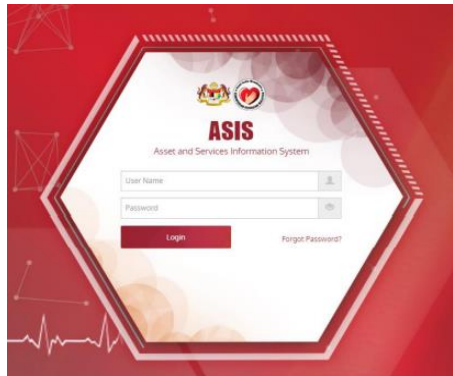
This section is about on how to collect data that use for the analysis. All the data is related with the two equipment that were choose which are Puritan Bennett 840 and Puritan Bennett 980.

**Figure 3.6:** Flowchart of the Assessment

### 3.2.1 How to collect data

ASIS – Asset and Service Information system

ASIS is stand for Asset and Services Information system. It is used at the government Hospital in Malaysia. ASIS is monitored by Ministry of Health Malaysia. Figure 3.7 shows the ASIS system website.



**Figure 3.7:** The ASIS System

The function of ASIS based on Figure 3.7 is to save all the data related the services at the hospital. The services that have in the ASIS is Bio-Medical Engineering maintenance and Services (BEMS), Facility Engineering Maintenance Services (FEMS), Cleaning Services (CLS), and Linen and Laundry Services (LLS). All the services were used at the Hospital. ASIS can use by the services team in hospitals. Therefore, this system can access by the certain person as the data is confidential. The data were taken with the permission for the researched. This researched is related for BEMS. All the data of every asset in the hospital are in the ASIS. The medical equipment in the hospital is asset of the hospital, therefore the data related the medical equipment is in the ASIS. The example data in the ASIS are the purchase date, number of assets, location of the asset and the maintenance history, of every medical equipment in the hospital.

#### **Survey with questionnaire about the ventilator**

The survey was done for this researched to collect data of the two ventilators. The survey method used in the researched is for collecting data from a respondent to gain information and insights into about the topic that were discussed. In this research, the respondents are from user in Hospital Sultan Ismail who are use the ventilator Puritan Bennett 840 and Puritan Bennett 980 at Intensive care unit (ICU) and Neonate Intensive Care Unit (NICU) The user are medical assistant, and the nurses.

#### **Internet**

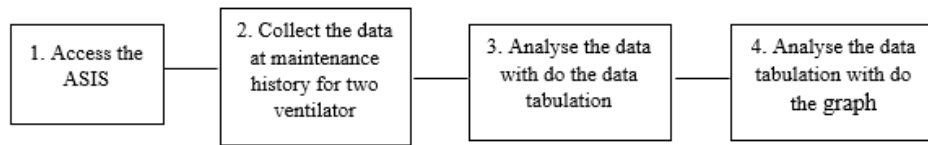
Other way of collecting data is from internet. All the general information of the ventilator were searched in the internet. Other than that, the online journal also was searched in the internet. In the internet the image of the ventilator, the article about the ventilator were used.

#### **Service and user Manual of the ventilators**

Service and the user manual of the ventilators were used to collect data of the Puritan Bennet 840 ventilator and Puritan Bennett 980 ventilator. In the manual the information such as specification of the ventilator, function every part at the ventilator, common problem and solution for the common problem of the ventilator can use as a data in this researched

### 3.2.2 Data Analysis

After collecting the data, the data were analysed. The data were analysed with do the data tabulation. Then data from two ventilators were compared. The data from table were analyse in the graph and lastly one of the ventilators were choose. The data that need to tabulate is from the ASIS. Figure 3.8 shows the process of collected the data and analyse data from the ASIS.



**Figure 3.8:** The process of the data taken from the ASIS

Based on Figure 3.8, the first process was accessing the ASIS, then the data at maintenance history were collected for each ventilator. After that, the data of maintenance history were tabulate using the Excel to take the information. Figure 3.9 shows the data tabulation of maintenance history of the ventilator using the Excel.

Figure 3.9 demonstrates the data tabulation produced for the models of the ventilator are listed in the Excel.

Service Work Date / Target Date	Work Category	Type	Total Downtime	Total Cost (RM)	Action Taken

**Figure 3.9:** Data tabulation at the Excel

After data were tabulate at the Excel as shows in Figure 3.9, two ventilator data were compared in the table the data that were compared are performance of the ventilator. The performance is rate of breakdown, type of breakdown, downtime (hours) and total cost of repaired (RM). Table 3.5 shows the comparison of Puritan Bennett 840 and Puritan Bennet 980 with the performance.

**Table 3.5:** Data table comparison of the ventilator with their performance

Parameter	Puritan Bennett 840	Puritan Bennet 980
Rate of breakdown		
Type of breakdown		
Downtime (Hours)		
Total cost of repaired (RM)		

Based on Table 3.5, the data were analysed with compared method of two ventilator with parameter which are rate of breakdown to know how many times the machine have breakdown, type of breakdown such as problem with board, sensor, general maintenance and loose part, Downtime (hours) to know how long the machine have breakdown and total cost of repaired (RM) for each machine when have breakdown. The data that analyse by graph will explain at the analysis.

The second data that need to analyse are from survey that made for user. The data from survey is made at the google form. The questionnaire is made at google then the data were tabulate. After the data were tabulate the data were analyse using the pie chart. Table 3.6 shows the data that tabulate from google form.

**Table 3.6:** Data table of two ventilator with question and value of percentage.

Question	Percentage (%)	
	Puritan Bennett 840	Puritan Bennet 980
1.The model that user friendly and easy to use		
2.The model that has least problem and breakdown		
3.The model that able to complete the task quickly and setup easily		
4.The model that display the error clearly		
5.The model which easy to move in and move out		
6.The model that provide clear information for the system		
7.The model that have advanced software		
8. I prefer this model		

The data in Table 3.6 were analysed with take the value of percentage for every question in google form. What one is the model that user prefers based on the questions survey on the lists. Lastly, the pie chart was done at the analysis chapter.

## 4.0 Analysis of the data assessment

In this section will explain all the analysis of this research work. It consists of the graph and chart of the data for each equipment that were compared.

### 4.1 Data table analysis of comparison for the ventilator with their performance

Table 3.7 shows the data that analyse from the maintenance history in the ASIS. All the performance were takes in the first purchase until six years life of the machine. The purchase date for Puritan Bennett 840 is 26 April 2004 and Puritan Bennett 980 is 24 November 2014.

**Table 3.7:** Comparison performance of the ventilator in 6 years

Parameter	Puritan Bennett 840	Puritan Bennet 980
Rate of breakdown in past 6 years	22	16
Type of breakdown	Sensor, battery, loose part, GUI and general maintenance	
Downtime in breakdown (Hours)	499.5 hours	3777.7 hours
Total cost of repaired (RM)	RM 5457	RM 12599.69

Based on Table 3.7, the puritan Bennett 840 has the highest rate of breakdown in the first six years than the Puritan 980. For the downtime the Puritan Bennett 840 is the highest downtime than Puritan Bennett 980. This is because the rate of breakdown Puritan Bennett 840 is higher than Puritan Bennett 980. For the Total cost of the repaired the Puritan Bennett 980 is the expensive than the Puritan Bennett 840.

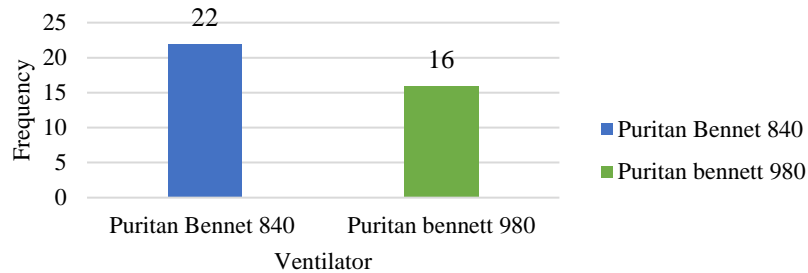


## 4.2 Graphical Analysis from data table

All the parameter data for two ventilators were analyse and elaborate in the graphical analysis.

### 4.2.1 Rate of breakdown

The rate of breakdown of the ventilators in 6 years for two ventilators were analyse in this graph. Figure 3.10 shows the rate of breakdown graph for the ventilators.

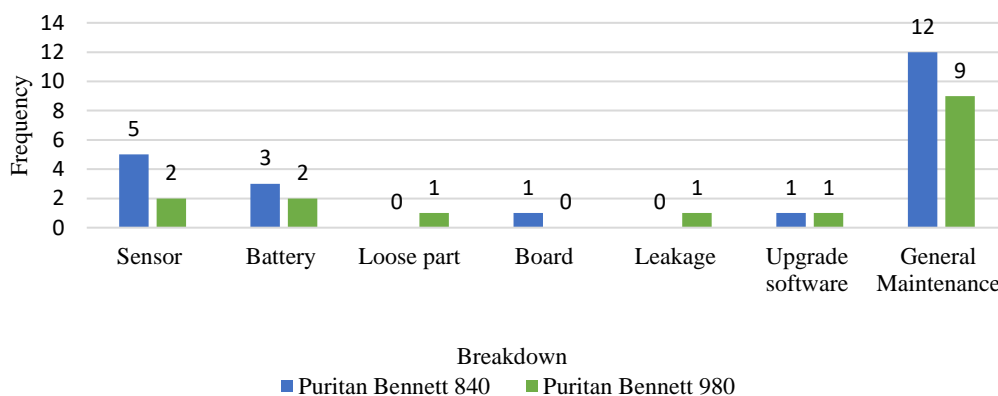


**Figure 3.10: Rate of Breakdown**

Based on Figure 3.10, the rate of breakdown in 6 last years for Puritan Bennett 840 and 980. The frequency of rate of breakdown for the Puritan Bennett 840 is 22 while the Puritan Bennett 980 is only 16. This show that the Puritan Bennett 840 is frequently have breakdown than Puritan Bennett 980.

### 4.2.2 Type of breakdown

The type of breakdown for two ventilators were identify in the maintenance history in ASIS for each ventilator. The types of breakdowns are Sensor, battery, loose part, board, leakage, upgrade software and general maintenance. Figure 3.11 shows the type of breakdown that happen at two ventilators.



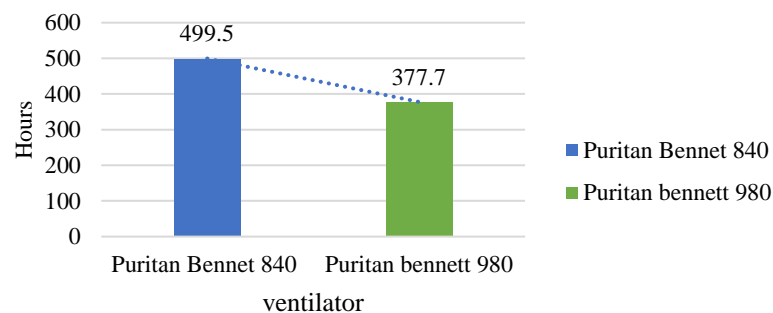
**Figure 3.11: Graph Type of Breakdown**

Based on Figure 3.11, the comparison of the ventilator for type of breakdown with the frequency. For the sensor of ventilator, the highest frequency is Puritan Bennett 840. The Puritan Bennet 840 is frequently changing the sensor rather than the Puritan Bennett 980. Then for the battery the frequency of the Puritan Bennett 840 is higher than Puritan Bennett 980. The breakdown of loose part the Puritan Bennett 980 had loose part while Puritan Bennett 840 does not loose part in the time between first years to six years past. Then the Puritan Bennett 840 had change board while Puritan Bennett 980 does not change board for

six years past. For the leakage problem the Puritan Bennett 980 had happened while Puritan Bennett does not happen. Two of these ventilators had upgrade the software to use the ventilator. Lastly the general maintenance or servicing that had done were the Puritan Bennett 840 have higher frequency which are 12 than Puritan Bennett 980 which are nine.

#### 4.2.3 Downtime in breakdown

The total downtime is count only for breakdown. Downtime of the machine is the how long the time of the machine breakdown or in unscheduled maintenance. Figure 3.12 shows the total of downtime in breakdown for two ventilators.

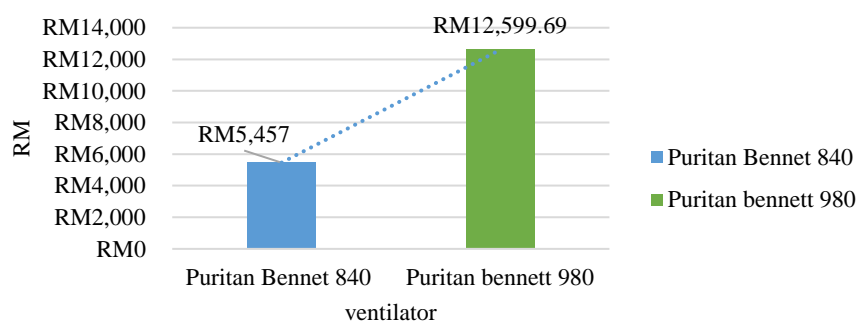


**Figure 3.12:** Graph of Total Downtime

Referring to Figure 3.12, the total downtime for the ventilator. The graph show that Puritan Bennett 840 have the higher Total downtime which is 499.5 in hours and Puritan Bennett 980 with only 377.7 hours. This is because Puritan Bennett 840 have higher rate of breakdown than Puritan Bennett 980.

#### 4.2.4 Total cost of repaired

The total cost of repaired the equipment were analyse in the graph that shown in Figure 3.13.



**Figure 3.13:** Graph of Total cost repaired (RM)

Based on Figure 3.13, the Puritan Bennett 980 total cost of repaired is higher than Puritan Bennett 840. The total cost repaired of Puritan Bennett 980 is RM12,599.69 and for Puritan Bennett 840 is RM5,457.00.

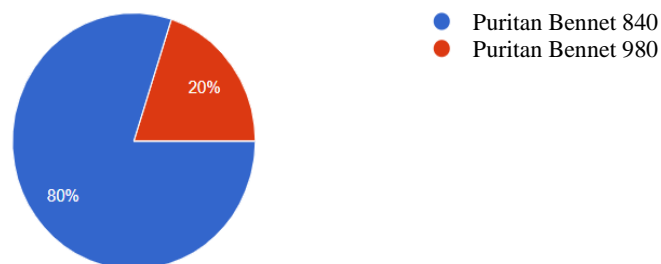
### 4.3 Chart analysis from the survey

In this survey, the user from Hospital Sultan Ismail were participated. The user is from unit Intensive care and Neonate intensive care. They were answer based on their experience that use and manage the ventilator. Table 3.8 shows the data table of question with the percentage of result that get from the questionnaire.

**Table 3.8:** Data table question with percentage from the survey

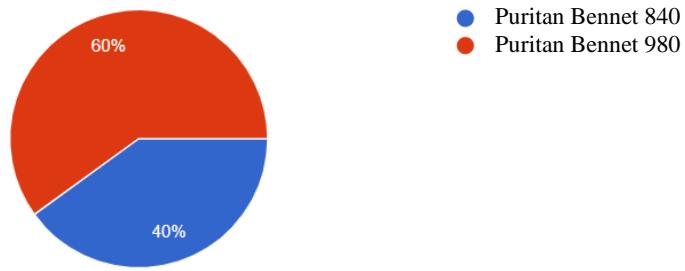
Question	Percentage (%)	
	Puritan Bennett 840	Puritan Bennett 980
1.The model that user friendly and easy to use	80%	40%
2.The model that has least problem and breakdown	40%	60%
3.The model that able to complete the task quickly and setup easily	60%	40%
4.The model that display the error clearly	60%	40%
5.The model that easy to move in and move out	40%	60%
6.The model that provide clear information for the system	40%	60%
7.The model that have advanced software	20%	80%
8. I prefer this model	80%	20%

Table 3.3 are the list for eight question, all the questions have the different choice from the user. From the data tabulation above, for all the question, the data were analyse using the pie chart. Figure 3.14 shows the chart of the respondent's survey for question one.



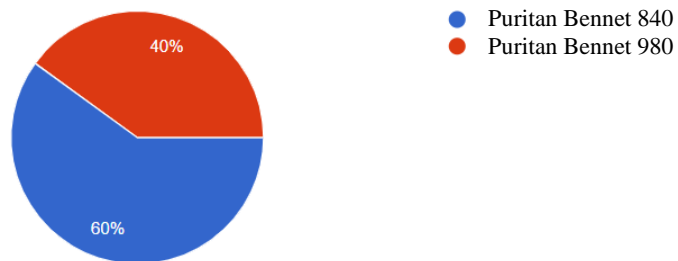
**Figure 3.14:** Respondent's survey

The result from pie chart shows in, Figure 3.14 80% respondents agree that Puritan Bennett 840 is the model that user friendly and easy to use while 20% respondents only agree that Puritan Bennett 980 with the statement. Figure 3.15 shows the chart of the respondent's survey for question two.



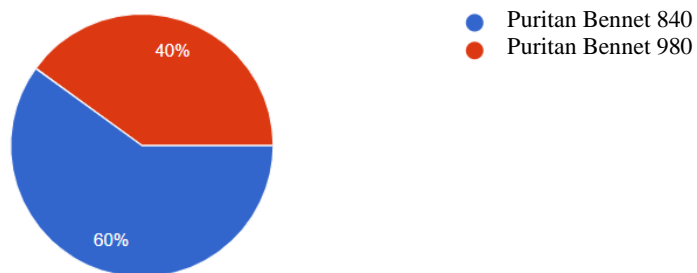
**Figure 3.15:** Respond on model with least breakdown.

The result from pie chart shows in Figure 3.15, 60% of respondents agree that Puritan Bennett 980 is the model that has least problem and breakdown. 40% respondents agree that Puritan Bennett 840 with that statement. Figure 3.16 shows the chart of the respondent's survey for question three.



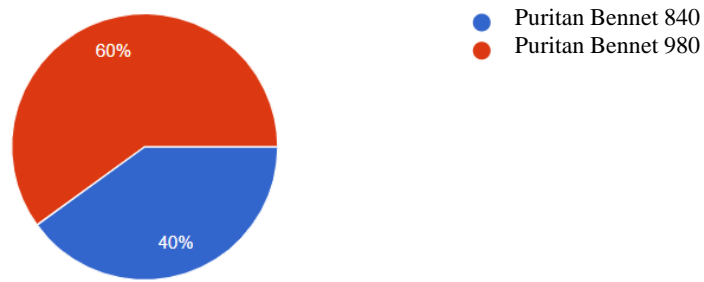
**Figure 3.16:** Respond on task completion rate.

The result from pie chart shows in Figure 3.16 that 60% respondents agree that Puritan Bennett 840 is the model that able to complete the task quickly and set up easily. While 40% respondents agree for Puritan Bennett 980. Figure 3.17 shows the chart of the respondent's survey for question four.



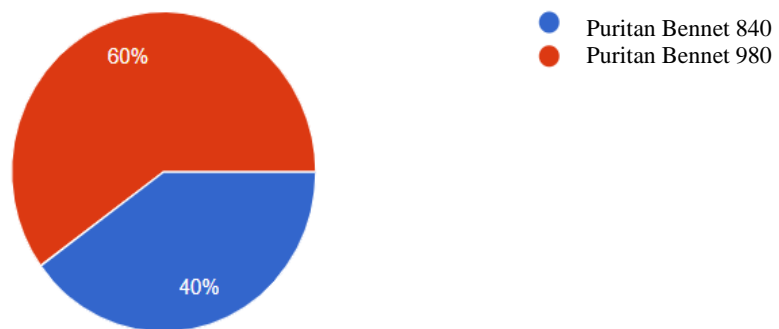
**Figure 3.17:** Respond on error display clearly.

The result from pie chart shows in Figure 3.17, 60% respondents are agreed that Puritan Bennett 840 is the model that display the error clearly. While 40% respondents agree for Puritan Bennett 980. Figure 3.18 shows the chart of the respondent's survey for question five.



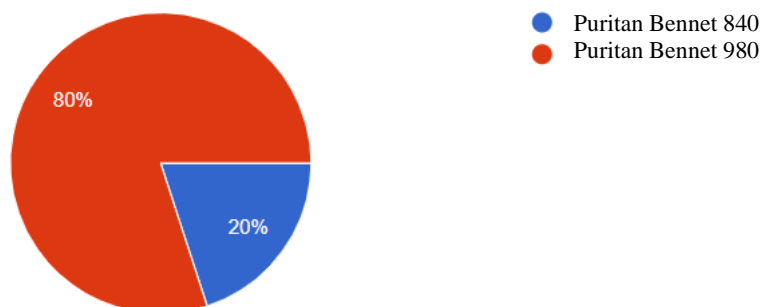
**Figure 3.18:** Respond on model mobility.

The result from pie chart shows in Figure 3.18, 60% of respondents agree that Puritan Bennett 980 is the model that easy to move in and move out. Another 40% respondents agree that Puritan Bennett 840 with that statement. Figure 3.19 shows the chart of the respondent’s survey for question six.



**Figure 3.19:** Respond on model information displayed.

The result from pie chart shows in Figure 3.19, 60% of respondents agree that Puritan Bennett 980 is the model that provide the clear information for the system. Another 40% respondents agree that Puritan Bennett 840 with that statement. Figure 3.20 shows the chart of the respondent’s survey for question seven.

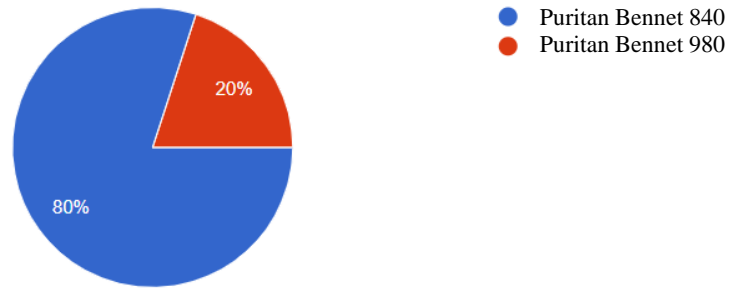


**Figure 3.20:** Respond on better software.

The result from pie chart shows in Figure 3.20, 80% of respondents agree that Puritan Bennett 980 is the model that have advanced software. Another 20% respondents agree that Puritan Bennett 840 with that statement.

Figure 3.21 shows the of the respondent’s survey for question eight.





**Figure 3.21:** Respond on model preference.

Figure 3.21, 80% respondents are answer that Puritan Bennett 840 is the model that they prefer to use. While 20% respondents answer for Puritan Bennett 980 as the model that they choose.

For the conclusion of the analysis, Puritan Bennet 840 and Puritan Bennett 980 have the own advantage and disadvantage. From the analysis that get from the ASIS system and show in the graphical analysis for rate of breakdown, the Puritan Bennett 840 have higher breakdown than Puritan Bennett 980. This is because the Puritan Bennett 840 is the old version, while Puritan Bennett 980 is the new upgrade version. The manufacturer upgraded to least the breakdown of the machine. Hence the Puritan Bennet 840 were high change to get highest breakdown. For the second analysis is type of breakdown. One of the types of breakdowns is about the battery. The PB 840 have frequently change the battery, it is because the battery is battery lead acid battery while the PB 980 use the lithium ions battery. Other type of breakdown the sensor of the PB 840 is frequently change than PB 980. The third analysis is about total of downtime. The PB 840 have higher total downtime than PB 980, this is because PB 840 had frequently breakdown. Lastly the PB 980 have the higher total cost of repaired because PB 980 have and advance software than PB 840. For the survey from user, the conclusion is mostly the user more prefer to use the Puritan Bennett 840 as it is user friendly, easy to use, easy to set up and complete the task quickly. From the user survey, they complaint about the graphic user interface of Puritan Bennett 980 have more problem than Puritan Bennett 840. This is because graphic user interface the Puritan Bennett 980 is fully electronic and Puritan Bennett 840 is semi electronic. Therefore, the graphic user interface that fully electronic frequently have problem and difficult to repair as it will problem the whole graphic user interface.

## 5.0 Conclusion and Recommendation

For the conclusion, in this assessment that have done, we able to collect data about the ventilator that use in Hospital Sultan Ismail, Johor Bahru. Then we also learn and know about the function and specification of the ventilator. After that, we are able to compare the ventilator machine with two different model that use in Hospital Sultan Ismail, Johor Bharu. Based on the analysis done, it can be recommended that Puritan Bennett 840 has better characteristic than Puritan Bennett 980. Although the puritan Bennett 840 have high rate of breakdown, high total downtime in breakdown, it easy to handle the breakdown problem than Puritan Bennett 980 that have complicated to solve the breakdown problem in technically. Other than that, the components part of the Puritan Bennett 840 is cheaper than components or parts for Puritan Bennett 980. It can relate that the total cost repaired of the Puritan Bennett 980 is higher than Puritan Bennett 840. Moreover, the Puritan Bennett 840 is the most prefer model than Puritan Bennett 980 that choose by user as it is easy to use, can complete the task quickly, and display the error clearly. For the recommendation, the puritan Bennett 840 need to upgrade the version and the graphic user interface for Puritan Bennett 980 to be easy to use.

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# ANAESTHESIA MACHINE

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**Abstract**— Anaesthesia machine is used to deliver general anaesthesia to the patients as they undergo a medical procedure. The machine receives medical gases from a gas supply, controls the flow and reduces the pressure of desired gases to a safe level, vaporizes volatile anaesthetics into the final gas mixture, and delivers the gases to a breathing circuit that is connected to the patient's airway. This machine is operated by nurse anaesthetists or medical assistants and is operated in operational theatres. The faulty of anaesthesia machine occur frequently before and after operating hours. Thus, corrective maintenance needs to be done. This research finds that different model of anaesthesia machine poses different kind of frequent faults. The best unit need to be decided to reduce the corrective maintenance and be more user-friendly. Choosing the right, reliable, convenient, and affordable machine has been the focus that can satisfy both user and technician work aspect. The purpose of this technical assessment report is to choose the best model of anaesthesia machine based on comparison between the models by specification, user friendly, and reliability which later be recommended to the industry for future use.

**Keywords**- anaesthesia machine, operational theatre, medical gases, Avance CS2, Leon Plus Neo.

## 1.0 Introduction

Anaesthesiology is the medical specialty concerned with the total perioperative care of patients before, during, and after surgery [1]. It encompasses anaesthesia, intensive care medicine, critical emergency medicine, and pain medicine [2]. The most important piece of equipment that the anaesthesiology uses is the anaesthesia machine. Anaesthesia machine is a type of life support machine that is used in surgical centres or operational theatre and is operated by trained personnel such as anaesthesiologist, nurse anaesthetists and medical assistants.

The basic function of anaesthesia machines is to deliver oxygen (O<sub>2</sub>) and anaesthetic gases, remove carbon dioxide (CO<sub>2</sub>) from the breathing system and provide controlled ventilation to patients as they undergo a medical procedure [3]. The anaesthesia machine receives medical gases from a gas supply, controls the flow and reduces

the pressure of desired gases to a safe level, vaporizes volatile anaesthetics into the final gas mixture. The anaesthesia machine is then delivers the gases to a breathing circuit that is connected to the patient's airway [3].

There are two types of anaesthesia machine which are intermittent flow and continuous flow. In intermittent devices, the gas flow only on demand when triggered by the patient's own inspiration [3]. Continuous flow which mostly found in modern anaesthesia machine or Boyle's machine, is designed to provide an accurate supply of medical gases mixed with an accurate concentration of anaesthetic vapour and deliver the gas continuously to the patient at a safe pressure and flow [3]. The most commonly used device is the continuous flow, which provides a steady flow of air containing a regulated supply of gas [3].

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The purpose of this Technical Assessment Report (TAR) is to compare the anaesthesia machine model by several specification and recommend to company of which model of the anaesthesia machine are the best to be used in Hospital Sultan Ismail (HSI). Three objectives which be a guideline in process to develop this research are to study on the anaesthesia machine, to analyse the different model of anaesthesia machine and to determine the best model of anaesthesia machine. Research found that anaesthesia machine model of Avance CS2 is absolutely the best model for hospital operational theatre. It has more advantages compare to the Leon Plus Neo in term of specification, maintenance, and user friendliness.

## 1.1 Problem Statement

Anaesthesia machine is an important machine used in operational theatre. Numerous numbers of request of corrective maintenance received in one for different type of machine. Minor or major breakdown are occurred before and after the operation of the machine. It is important to maintain the status of the unit in functioning so that treatment of the patient can be done smoothly. Frequent rate of breakdown will contribute to high downtime. Thus, it is important to make a comparison between two anaesthesia machine models and choose the best one to reduce the number of breakdowns, for user friendliness and reliability.

## 1.2 Objective

The study has three objectives which be a guideline in the development of this research. The objectives are:

- To study the anaesthesia machine.
- To analyse the different models of anaesthesia machine.
- To recommend the best model of anaesthesia machine.

## 1.3 Scope of Project

The scope in this semester of Work Based Learning (WBL) is to make a full comparison between these two models of anaesthesia machine: GE Avance CS2 and Leon Plus Neo. Moreover, this study also discusses on the physical layout, specifications, parameters, and maintenance of the machine. By carrying out an analysis and comparison we can choose the better anaesthesia machine for user to handle easily and technicians to fix the problems quickly.

## 1.4 Project Significant

The technical assessment report is conducted to find the best anaesthesia machine that are user and technical friendly, lower maintenance cost, low fixing difficulty and reliable. So, the best model of machine will be recommending to the user to purchase for in the future.

## 2.0 Literature Review

The literature review is very useful for the future development of the research. In this section, previous work by different researchers is analysed and compared. There is also the need to study on the actual product for developing and modifying the research. All the information that has been studied is well written in this section such as study on anaesthesia machine and a review of the other research that related to the project.

## 2.1 Anaesthesia Machine

The basic design of an anaesthesia machine consists of pressurised gases supplied by cylinders or pipelines to the anaesthetic machine, which controls the flow of gases before passing them through a vaporiser and delivering the resulting mixture to the patient through the breathing circuit [4]. The early Boyle's machine had five elements, which are still present in modern machines:

- A high-pressure supply of gases
- pressure gauges
- flow meters
- vaporizer
- breathing system

**Figure 4.1** shows the example of the modern anaesthesia machine design.



**Figure 4.1:** Design of modern anaesthesia machine.

Modern anaesthesia machine has evolved from a simple pneumatic device to a complex array of mechanical, electrical, and computer-controlled components. Much of the driving force for these changes have been to improve patient safety and user convenience [5]. Though many modifications have been brought out still the basic design has not much changed.

## 2.2 Functions of Anaesthesia Machine

The machine performs four essential functions:

- Provides  $O_2$ .
- Accurately mixes anaesthetic gases and vapours.
- Enables patient ventilation.
- Minimises anaesthesia related risks.

## 2.3 Principle of Anaesthesia Machine

The anaesthetic machine dispenses the gases that are necessary to induce sleep and prevent pain to patients during surgical procedures or other potentially painful manipulations [6]. The basic anaesthetic delivery system consists of a source of oxygen ( $O_2$ ), an  $O_2$  flowmeter, a precision vaporizer, which produces a vapor from a volatile liquid anaesthetic, a patient breathing circuit which include the tubing, connectors, and valves, and a scavenging device that removes any excess anaesthetic gases. This is critical since room pollution with anaesthetic gases may lead to health problems to the patients and the users [6].

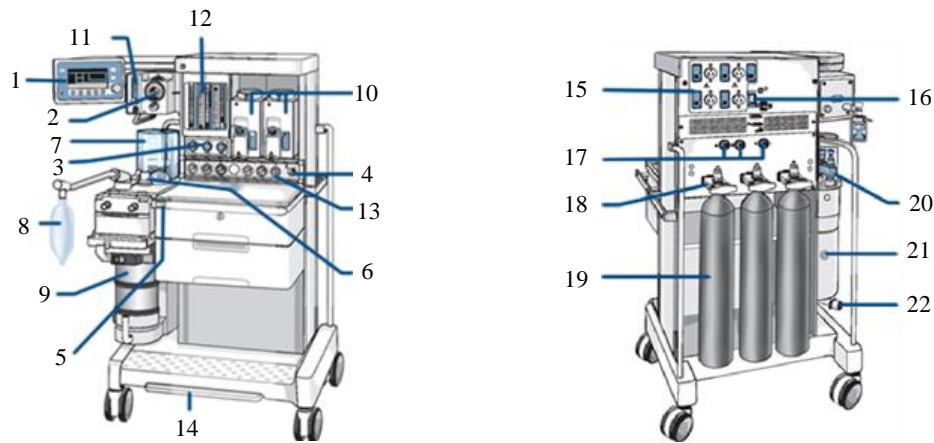
During delivery of gas anaesthesia to the patient,  $O_2$  flows through the vaporizer and picks up the anaesthetic vapours. The  $O_2$ -anaesthetic mix then flows through the breathing circuit and into the patient's lungs, usually by spontaneous ventilation which is the respiration. Occasionally, it is necessary to use assisted ventilation, especially when opening the thoracic cavity [7].

## 2.4 General Anaesthesia Machine Components

The anaesthesia machine consists of two main system components which are electrical system and pneumatic system. These two systems work simultaneously in providing treatment to patient. Modern anaesthesia machines have become very sophisticated, incorporating many built-in safety features and devices, monitors, and multiple microprocessors that can integrate and monitor all components [3]. Moreover, modular machine designs allow a wide variety of configurations and features. Anaesthesia machines include numerous safety features that alert the anaesthesia provider to malfunctions and avert user errors [8]. Figure shows the components of a general anaesthesia machine of their front panel and back panel.

Figure 4.2 shows the components of a general anaesthesia machine on its front panel and back panel.





**Figure 4.2:** Front panel and back panel of a general anaesthesia machine

Based on Figure 4.2, an anaesthesia machine consists of display, controls, gas inlet and gas outlet. Table 4.1 shows the description of each item on the front panel of the machine.

### 2.4.1 Front Panel

**Table 4.1:** Front panel description [3][4].

Item	Name	Description
1	System display	All anaesthesia delivery systems have integrated electronic safety monitors intended to avert patient injuries.
2	Pressure regulator	Reduce the pressure from each cylinder and provide a relatively constant outlet pressure in the presence of a variable inlet pressure.
3	Flow controls	Allow the user to select the balance gas and set a desired oxygen concentration and total flow, leaving the calculation of individual gas flow rates to the machine
4	System switch	Used to turn the system on and off. When the system is turned on, the display will show the power-up screen and the system does a series of automated self-tests.
5	O <sub>2</sub> flush button	Each anaesthesia machine has an oxygen flush system that can rapidly deliver oxygen to the common gas outlet to flush anaesthetic agents out of the breathing circuit
6	APL valve	A spring-loaded device that controls the flow of gas from the breathing circuit to the scavenger system.
7	Bellows	Consists of a distensible bellows that is housed in a clear rigid chamber. The bellows is functionally equivalent to the reservoir bag; it is attached to, and filled with gas from, the breathing circuit.
8	Reservoir bag	An elastic bag that serves three functions breathing circuit. First, it that allows changes in breathing circuit gas volume. Second, it provides a means for manually pressurizing the circuit to control or assist ventilation. Third, it provides a safety limit on the peak pressure.
9	Absorber canister	Absorb carbon dioxide from the patient.
10	Vaporizers	Vaporizers are designed to add an accurate amount of volatilized aesthetic to the compressed gas mixture. Anaesthetic vapours are pharmacologically potent.
11	Auxiliary O <sub>2</sub> flowmeter	Auxiliary O <sub>2</sub> flowmeter is a self-contained flowmeter with its own flow control valve, flow indicator, and outlet. They are useful for attaching a nasal cannula or other supplemental oxygen delivery devices.
12	Flowmeters	A flowmeter assembly shows the resulting flow rate.
13	Pressure gauge	Measures the pressure in the cylinder or pipeline. The pressure gauges for oxygen, nitrous oxide and medical air are mounted in a front-facing panel on the anaesthetic machine
14	Brake	Lock the machines' wheels while in use to prevent it from moving around.

User interaction between the machine is mostly happened on the front panel of the machine. The front panel holds the function in controlling the parameter and displaying the parameter.

## 2.4.2 Back Panel

Table 4.2 Shows the description of back panel of a general anaesthesia machine.

**Table 4.2:** Back panel description [3][4].

Item	Name	Description
15	Electrical outlets	These are intended to power monitors and other devices. As a rule, these outlets should only be used for anaesthesia monitors.
16	Main circuit breaker	There are circuit breakers for both the anaesthesia machine and the outlets. When a circuit breaker is activated, the electrical load should be reduced, and the circuit breaker reset
17	Pipeline inlet	Compressed gases from the hospital pipeline system enter the machine through flexible hoses. The inlet connector for each gas is unique in shape to prevent the connection of the wrong supply hose to a given inlet
18	Cylinder yokes	Hold small, compressed gas cylinders. Each yoke is designed to prevent incorrect placement of a cylinder containing another gas.
19	Supply cylinders	Supply cylinders provide compressed gas for emergency backup and for use in locations without piped gases
20	Waste gas receiver	Gas collection assembly that receives waste gases to prevent potentially adverse effects on health care workers.
21	Back cover	Cover the back panel from being exposed.
22	Scavenging connector	Connect the machine to the hospital vacuum inlet via flexible hose to dispose the waste gas from the collection assembly.

Based on Table 4.2, the back panel of the machine is where the gases enter, and excess gases exit the machine. The machine is supplied with gases through pipeline inlet and excess gases exit through scavenging system.

## 2.5 Anaesthesia Machine Safety Features

Misuse of anaesthesia gas delivery systems is three times more likely than failure of the device to cause equipment-related adverse outcomes [9]. Equipment misuse is characterized as errors in preparation, maintenance, or deployment of a device. Preventable anaesthetic mishaps are frequently traced to an operator's lack of familiarity with the equipment or a failure to check machine function, or both. These mishaps account for only about 2% of cases in the American Society of Anaesthesiologists' (ASA) Closed Claims Project database [10]. The breathing circuit was the most common single source of injury (39%) which nearly all damaging events were related to misconnects or disconnects [10]. In decreasing frequency, other causes involved vaporizers (21%), ventilators (17%), and oxygen supply (11%). Other more basic components of the anaesthesia machine were responsible in only 7% of cases [10]. The American National Standards Institute (ANSI) and subsequently the ASTM International published standard specifications for anaesthesia machines and their components [8]. Table 4.3 lists essential features of a modern anaesthesia machine.

**Table 4.3:** Essential safety features on a modern anaesthesia machine [8].

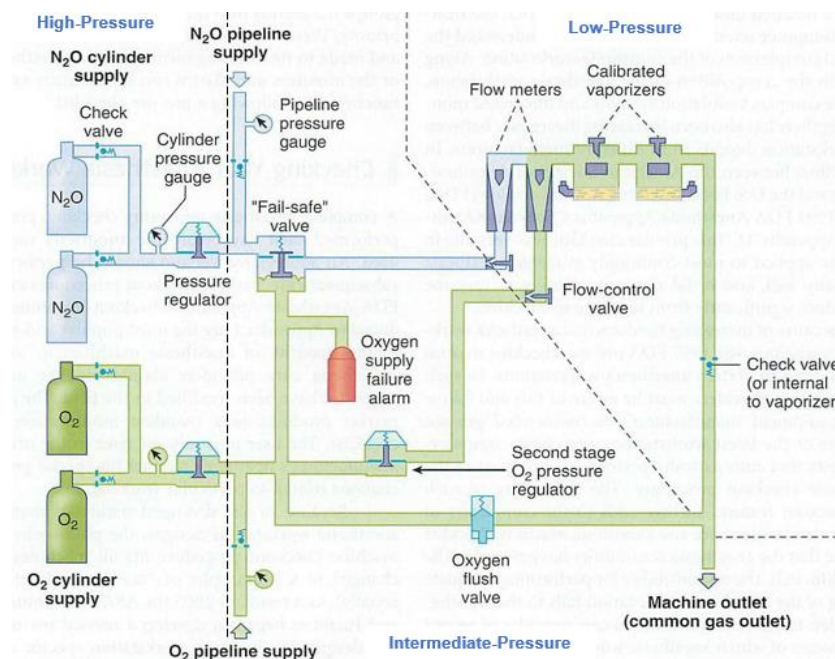
No	Essential Features	Purpose
1	Noninterchangeable gas-specific connections to pipeline inlets (DISS)1 with pressure gauges, filter, and check valve	Prevent incorrect pipeline attachments; detect failure, depletion, or fluctuation
2	Pin index safety system for cylinders with pressure gauges, and at least one oxygen cylinder	Prevent incorrect cylinder attachments; provide backup gas supply; detect depletion
3	Low oxygen pressure alarm	Detect oxygen supply failure at the common gas inlet

No	Essential Features	Purpose
4	Oxygen failure safety device (shut-off or proportioning device)	Prevent administration of nitrous oxide or other gases when the oxygen supply fails
5	Oxygen must enter the common manifold downstream to other gases	Prevent hypoxia in event of proximal gas leak
6	Oxygen concentrations monitor and alarm	Prevent administration of hypoxic gas mixtures in event of a low-pressure system leak; precisely regulate oxygen concentration
7	Automatically enabled essential alarms and monitors	Prevent use of the machine without essential monitors
8	Vaporizer interlock device	Prevent simultaneous administration of more than one volatile agent
9	Capnography and anaesthetic gas measurement	Guide ventilation; prevent anaesthetic overdose; help reduce awareness
10	Oxygen flush mechanism that does not pass-through vaporizers	Rapidly refill or flush the breathing circuit
11	Breathing circuit pressure monitor and alarm	Prevent pulmonary barotrauma and detect sustained positive, high peak, and negative airway pressures
12	Exhaled volume monitor	Assess ventilation and prevent hypo- or hyperventilation
13	Mechanical ventilator	Control alveolar ventilation more accurately and during muscle paralysis for prolonged periods
14	Scavenger system	Prevent contamination of the operating room with waste anaesthetic gases

Based on Table 4.3, the anaesthesia machine has evolved and made the machine safer to be used by the user and to the patient. New safety features are added to the machine as new technology is developed. The safety features listed above have their own purpose to ensure safety in the effort to reduce or to eliminate accident related to anaesthesia during surgical procedure.

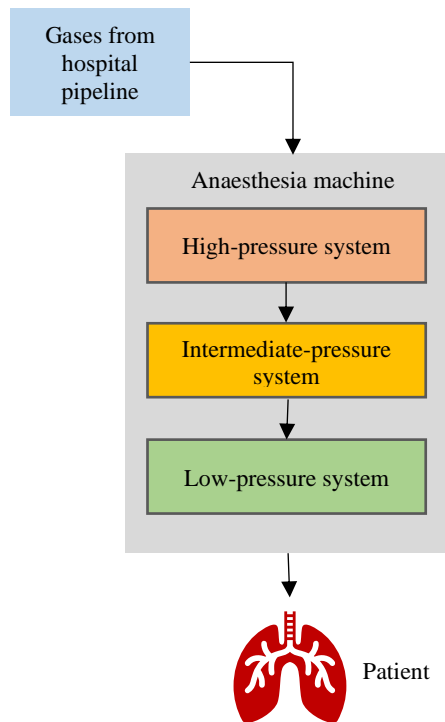
## 2.6 Anaesthesia Machine Pneumatic System

Pneumatics is the technology of compressed air [11]. In the application of anaesthesia machine, pressure of gases from the hospital pipeline is reduced to ensure the gas is constant and safe to be delivered to the patient. Figure 4.3 shows the division of pneumatic system in anaesthesia machine.



**Figure 4.3:** Division of pneumatic system in anaesthesia machine.

Based on Figure 4.3, the pneumatic system of an anaesthesia machine is subdivided into three smaller systems based on the amount of pressure seen in each one [4]. Those are high-pressure system, intermediate-pressure system, and low-pressure system. The high-pressure system receives gases at cylinder pressure, reduces the pressure and makes it more constant, the intermediate pressure system receives gases from the hospital pipeline and delivers them to the flow meters or O<sub>2</sub> flush valve and the low-pressure system, which takes gases from the flow meters to the machine outlet and also contains the vaporizers [4]. The flow of the gases is illustrated in Figure 4.4.



**Figure 4.4:** Flow of gases from hospital pipeline to the patient.

Based on Figure 4.4, the gases from the hospital pipeline enters the anaesthesia machine at high-pressure. The high-pressure system will reduce the gas pressure around 37 to 55 PSIG. The reduced gases pressure is then received by the intermediate-pressure system. Next, the gases flow to the low-pressure system which the pressure is reduced to about 15 PSIG, slightly above the atmospheric pressure. Constant and suitable gases pressure is delivered to the patient.

### 2.6.1 High-Pressure System

The high-pressure system consists of all parts of the machine, which receive gas at cylinder pressure [3]. These include the following:

- Hanger yoke which connects a cylinder to the machine,
- Yoke block, used to connect cylinders larger than size E or pipeline
- Hoses to the machine through the yoke
- Cylinder pressure gauge, which indicates the gas pressure in the cylinder
- Pressure regulator, which converts a high variable gas pressure into a lower, more constant pressure, suitable for use in the machine.

### 2.6.2 Intermediate-Pressure System

Intermediate-pressure system is the components of the machine which receive gases at reduced pressures usually 37 to 55 PSIG [4]. These include the following:

- pipeline inlets and pressure gauges
- Oxygen pressure-failure device (fail-safe) and alarm
- Flowmeter valves
- Oxygen and nitrous oxide second-stage regulators
- Oxygen flush valve

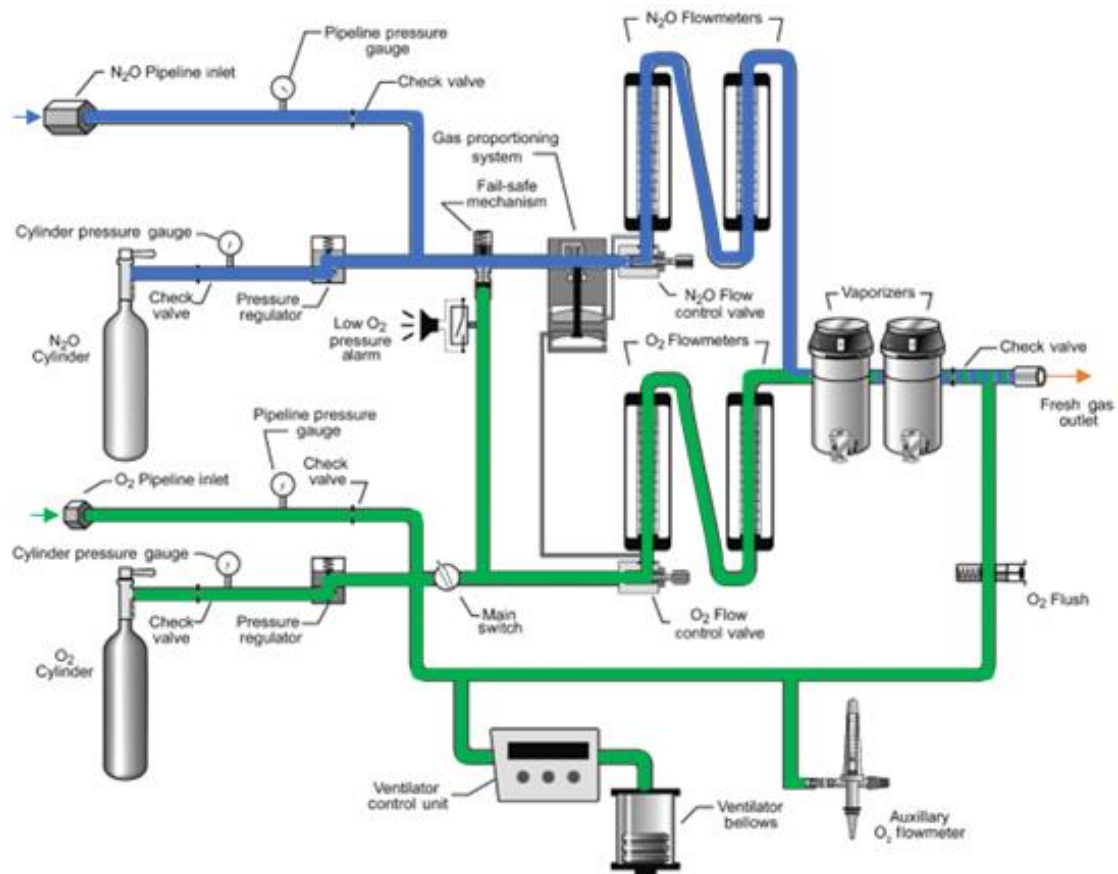
### 2.6.3 Low-Pressure System

The low-pressure system is the part of the machine downstream of the flow meters in which the pressure is slightly above the atmosphere [4]. The components in this system are:

- Valves
- Flowmeter tubes
- Vaporizers mounted on the back bar
- Check valves
- Common gas outlet.

## 2.7 Flow of Compressed Gas in Anaesthesia Machine

The anaesthesia machine is a precision gas mixer. Compressed gases enter the machine from the hospital's centralized pipeline supply or from compressed gas cylinders [12]. The flow of gas in anaesthesia machine is made possible with the application of pneumatic system. Figure 4.5 shows the internal piping of anaesthesia machine and the placement of its component within the machine.



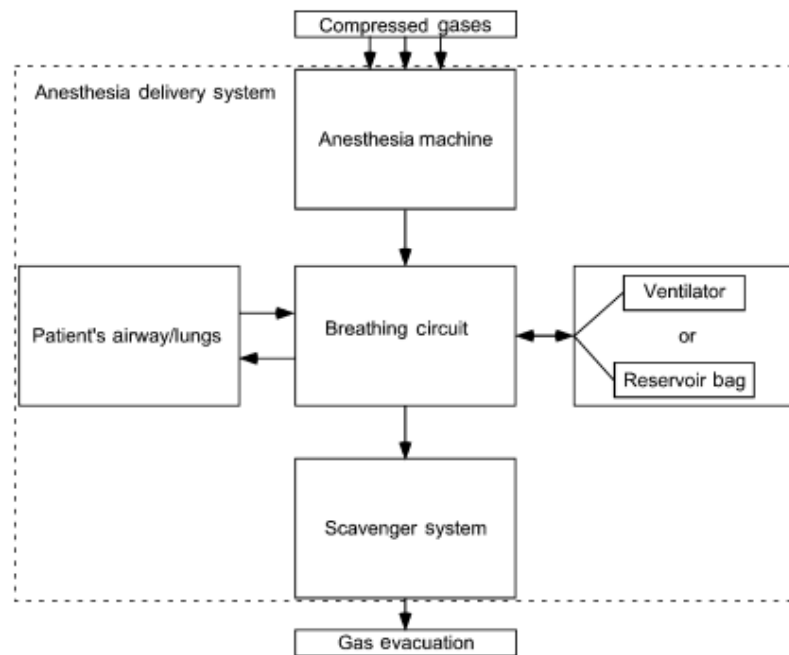
**Figure 4.5:** Internal piping and placement of components within the anaesthesia machine.

Based on Figure 4.5, the green indicates oxygen (O<sub>2</sub>), and blue indicates nitrous oxide (N<sub>2</sub>O). The compressed gases are regulated to specified pressures, and each pass through its own flow controller and flow meter assembly. A mechanical ventilator attaches to the breathing circuit but can be excluded with a switch during spontaneous or manual ventilation. The compressed gases then are mixed together and may flow through vaporizers where anaesthetic vapor is added. The final gas mixture then exits the common gas outlet which also called the fresh gas outlet to enter the breathing circuit [12].

## 2.8 Anaesthesia Delivery System Components

The anaesthesia delivery system consists of four components which are a breathing circuit, an anaesthesia machine, a waste gas scavenger system, and an anaesthesia ventilator [13]. The arrangement of anaesthesia machine delivery system is illustrated in Figure 4.6.





**Figure 4.6:** Block diagram of anaesthesia delivery system components.

Based on Figure 4.6, the breathing circuit is the functional centre of the system [12]. It is physically and functionally connected to each of the other components and to the patient's airway. There is a one-way flow of gas from the anaesthesia machine into the breathing circuit, and from the breathing circuit into the scavenger system. There is a bidirectional flow of gas between the breathing circuit and the patient's lungs, and between the breathing circuit and the anaesthesia ventilator or reservoir bag.

The ventilator and the reservoir bag are functionally interchangeable units, which are used during different modes of ventilation [14]. During spontaneous and manually assisted modes of ventilation, the elastic reservoir bag is used as a source of inspired gas and a low impedance reservoir for exhaled gas [14]. The anaesthesia ventilator is used during mechanically controlled ventilation to automatically inflate the lungs using prescribed parameters.

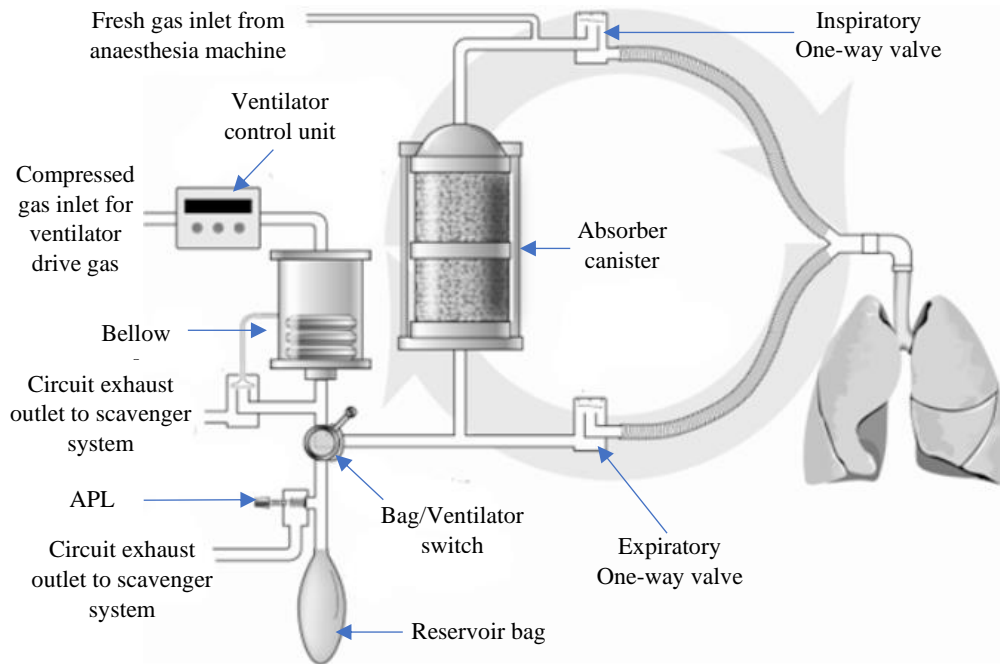
During inhalation, gas flows from the anaesthesia ventilator or reservoir bag through the breathing circuit to the patient's lungs. The patient's bloodstream takes up a small portion of gas from the lungs and releases carbon dioxide (CO<sub>2</sub>) into the lungs [14].

During exhalation, gas flows from the patient's lungs through the breathing circuit back to the anaesthesia ventilator or reservoir bag. This bulk flow of gas, between the patient and the ventilator or reservoir bag, constitutes the patient's pulmonary ventilation [12]. The volume of each breath is referred to as tidal volume, and the total volume exchanged for one minute is referred to as minute volume [14].

Over time, the patient absorbs oxygen and anaesthetic agents from, and releases CO<sub>2</sub> to, the gas in the breathing circuit [14]. Without intervention, the gas within the breathing circuit would progressively decrease in total volume, oxygen concentration, and aesthetic concentration [1]. The anaesthesia provider, therefore, dispenses fresh gas into the breathing circuit, replacing the gas absorbed by the patient. Using the anaesthesia machine, the anaesthesia provider precisely controls both the flow rate and the concentration of various gases in the fresh gas [3]. The anaesthesia machine is capable of delivering a total fresh gas flow that far exceeds the volume of gas absorbed by the patient [3]. When higher fresh gas flows are used, the excess gas is vented into the scavenger system to be evacuated from the operating room [12].

## 2.9 Breathing Circuit

There are different kind of breathing circuits in anaesthesia machine such as open, semi-open, semi-closed and closed [14]. The function of any breathing circuit is to deliver oxygen and anaesthetic gases and eliminate carbon dioxide [12]. The most common type is the semi closed circle system. It is so named because expired gases can be returned to the patient in a circular fashion [12]. Figure 4.7 shows the schematic of semi-closed breathing circuit and the gas circulation.



**Figure 4.7:** Schematic of the circle semi-closed breathing circuit [9].

Based on Figure 4.7, the one-way valves permit flow in only one direction. The components of the circle system include a carbon dioxide absorber canister, two one-way valves, a reservoir bag, an adjustable pressure-limiting valve, and tubes that connect to the patient, ventilator, anaesthesia machine, and scavenger system [15].

During inspiration, the peak flow of gas exceeds  $25 \text{ L min}^{-1}$ . As a result, the patient will inspire both fresh gas and gas stored in the reservoir bag or the ventilator bellows [12]. Inspired gas travels through carbon dioxide absorber canister, past the one-way inspiratory valve, to the patient.

During exhalation, gas travels from the patient, past the one-way expiratory valve, to the reservoir bag or ventilator bellows, depending upon the position of the bag-ventilator selector





switch. The one-way valves establish the direction of gas flow in the breathing circuit. Carbon dioxide is not rebreathed because exhaled gas is directed through the carbon dioxide absorber canister prior to being reinhaled [9].

Fresh gas from the anaesthesia machine flows continuously into the breathing circuit. During inhalation, this gas joins with the inspiratory flow and is directed toward the patient [12]. During exhalation, the fresh gas enters the breathing circuit and travels retrograde through the carbon dioxide absorber canister toward the reservoir bag [3]. The gas does not travel toward the patient because the inspiratory one-way valve is closed during exhalation [12]. Thus, during exhalation, gas enters the reservoir bag from the expiratory limb and from the carbon dioxide absorber canister.

## 2.10 List of Anaesthesia Machine in Hospital Sultan Ismail

Hospital Sultan Ismail (HSI) possess a few numbers of anaesthesia machines and are in the department of operational theatre (DOT). Table 4.4 shows the list of anaesthesia model available in HSI.

**Table 4.4:** List of anaesthesia machine in HSI.

Model	Description
<b>Aestiva/5 7900</b> 	<b>Manufacturer:</b> Datex Ohmeda Inc <b>Make:</b> America <b>Total unit:</b> 1 <b>Purchase cost:</b> RM189,000.00 <b>Commissioning date:</b> 23 November 2015 <b>Location:</b> Operational theatre
<b>Avance CS2</b> 	<b>Manufacturer:</b> Datex Ohmeda Inc <b>Make:</b> America <b>Total unit:</b> 6 <b>Purchase cost:</b> RM127,000.00 <b>Commissioning date</b> <ul style="list-style-type: none"> <li>• Batch 1(3 units): 30 December 2014</li> <li>• Batch 2 (1 unit): 22 October 2017</li> <li>• Batch 3 (2 units): 8 November 2018</li> </ul> <b>Location:</b> Operational theatre
<b>Carestation 650 A1</b> 	<b>Manufacturer:</b> Datex Ohmeda Inc <b>Make:</b> America <b>Total unit:</b> 1 <b>Purchase cost:</b> RM182,000.00 <b>Commissioning date:</b> 30 October 2019 <b>Location:</b> Operational theatre
<b>Leon Plus</b> 	<b>Manufacturer:</b> Heinen + Loweinstein Gmbh <b>Make:</b> Germany <b>Total unit:</b> 4 <b>Purchase cost:</b> RM153,000.00 <b>Commissioning date:</b> <ul style="list-style-type: none"> <li>• Batch 1(2 units): 19 December 2013</li> <li>• Batch 2 (2 units): 15 October 2014</li> </ul> <b>Location:</b> Operational theatre

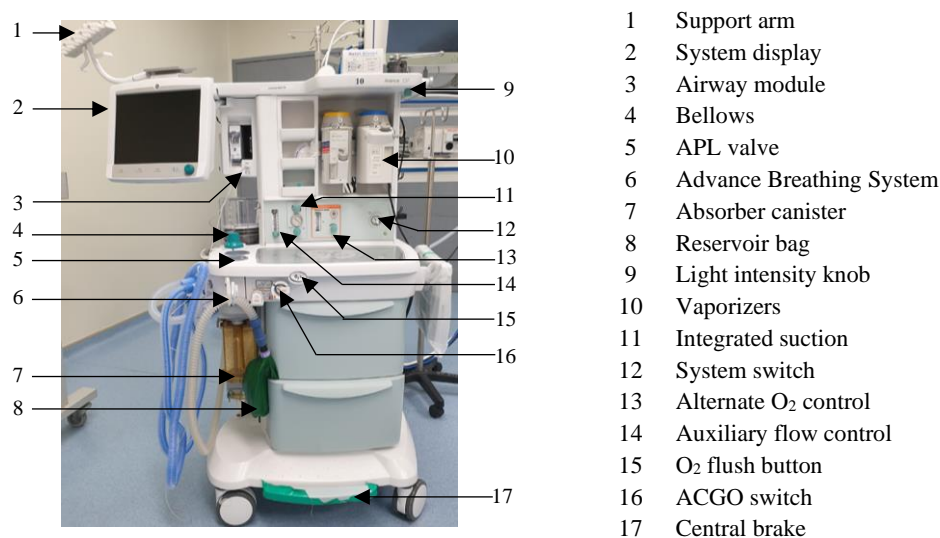
Based on Table 4.4, HSI has a total of 12 anaesthesia machines. The anaesthesia machine has an expected lifespan of ten years. Anaesthesia machine that aged beyond ten years will be process for beyond economic repair (BER) and replaced with new asset. Among those listed models, the most frequently used during surgery cases are Avance CS2 and Leon Plus Neo.

## 2.11 Avance CS2

The Avance CS2 is a fully integrated Carestation that combines anaesthesia delivery, patient monitoring, and data management into one innovative system. The Avance CS2 streamlines patient monitoring, anaesthesia, and ventilation information for clinicians at the point of care to help ensure accurate agent delivery and help enable faster clinical decision making. The ecoFLOW feature a display option that provides a graphical representation of oxygen flow and anaesthetic agent use. With this technology, clinicians can adjust oxygen levels to help avoid unnecessarily high gas flow rates while providing visual guidance [16].

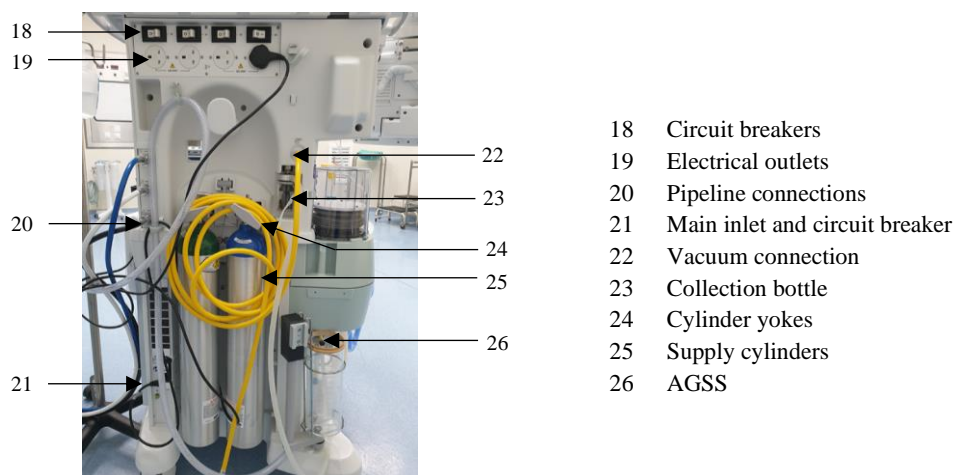
### 2.11.1 Avance CS2 Components

Main components are placed on the front panel, back panel, and the breathing unit of the machine. Figure 4.8. illustrates the front panel of the machine.



**Figure 4.8:** Front panel of Avance CS2

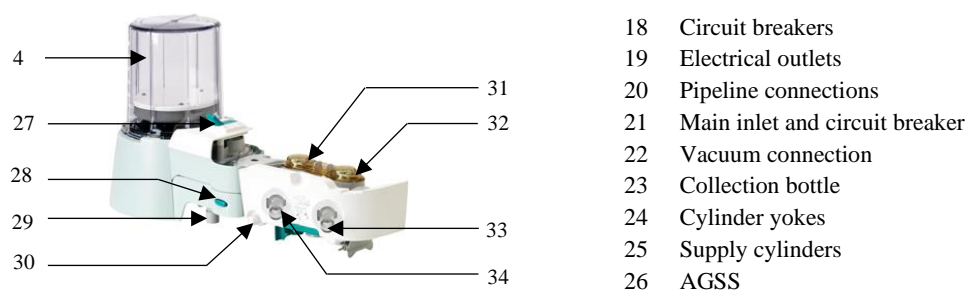
The front panel of Avance CS2 includes the display, parameters monitor, parameter controls, and the breathing system unit where the user interaction happened. Figure 4.9 shows the back panel of it.



**Figure 4.9:** Back panel of Avance CS2.

Based on Figure 4.9. the gases enter the machine through pipeline inlets or supply cylinders on the back panel. There are area also electrical outlets to power up other monitoring devices.

**Figure 4.10** shows the breathing system unit of Avance CS2



**Figure 4.10:** Breathing system unit of Avance CS2

Based on Figure 4.10, the breathing system unit in Avance CS2 is called the Advance Breathing System (ABS). The ABS is where the circulation of gas mixtures happened between the machine and the patient.

## 2.11.2 Avance CS2 Technical Specification

Each anaesthesia machine has their own specification and record of performance. Table 4.5 shows the key specification for Avance CS2.

**Table 4.5:** Avance CS2 technical specification [17].

Physical Specifications			
Dimensions	139 x 77 x 76 cm	Connection type	DISS-male, DISS-female, AS4059, BSPP 3/8, S90-116, or NIST
Weight	147 kg	Pipeline input range	280 kPa to 600 kPa
Brakes	Central brake	Gas Control	
Electrical Specifications		Fresh gas generator	Electronic mixer
Power input	220-240Vac, 50/60Hz	Flow range	0 and 150 mL/min to 15 L/min
Circuit breakers	8A	Accuracy	±10% of setting
Outlets	4 outlets on back, 2A	O <sub>2</sub> concentration range	21% to 100% when Air is available
Battery	battery time is up to 90 minutes when fully charged.	O <sub>2</sub> concentration accuracy:	<ul style="list-style-type: none"> <li>• 2.5% (Total Flow ≤ 15 L/min)</li> <li>• 5% (Total Flow &lt; 1 L/min)</li> <li>• 6.5% (Total Flow &lt; 0.4 L/min)</li> </ul>
Battery type	Internal rechargeable sealed lead acid	O <sub>2</sub> flush	25 L/min
Environmental Specifications		Breathing circuit parameters	
System operation		Volume	<ul style="list-style-type: none"> <li>• 2.7 L Vent Mode</li> <li>• 1.2 L Bag Mode</li> </ul>
Temperature	10° to 40°C	Compliance	
Humidity	15 to 95% relative humidity	Bag mode	1.82 mL/cmH <sub>2</sub> O
System storage		Mechanical mode	Automatically compensates for compression losses within the absorber and bellows assembly
Temperature	-25° to 60°C	Expiratory resistance	
Humidity	15 to 95% relative humidity	<ul style="list-style-type: none"> <li>• with 60 l/min</li> <li>• with 30 l/min</li> <li>• with 5 l/min</li> </ul>	3.80 cmH <sub>2</sub> O 1.47 cmH <sub>2</sub> O 0.46 cmH <sub>2</sub> O
Oxygen cell storage	-15° to 50°C		
APL-valve			
Range	0.5 to 70 cmH <sub>2</sub> O		
Adjustment range of rotation	<ul style="list-style-type: none"> <li>• 0.5 to 30 cmH<sub>2</sub>O (0 to 230°)</li> <li>• 30 to 70 cmH<sub>2</sub>O (230 to 330°)</li> </ul>		
Pneumatic Specifications			
Central gas supply	Connections for O <sub>2</sub> , N <sub>2</sub> O and AIR		

Anaesthetic Agent Delivery	
Vaporizers	Tec 6 Plus, Tec 7
Mounting	Tool-free installation Selectatec manifold interlocks and isolates vaporizers
Anaesthesia ventilator	
Accuracy (volume)	<ul style="list-style-type: none"> <li>• &gt; 210 mL = better than 7%</li> <li>• ≤ 210 mL = better than 15 mL</li> <li>• &lt; 60 mL = better than 10 mL</li> </ul>
Display	15 inches
Tidal volume	<ul style="list-style-type: none"> <li>• 5 to 1500ml (Volume Control, PCV-VG and PCV modes)</li> <li>• 20 to 1500ml (SIMV volume)</li> </ul>

Respiratory monitoring	
Airway pressure	
Range	-20 to +100 cmH <sub>2</sub> O
Accuracy	±1 cmH <sub>2</sub> O
Tidal volume	
Range	150ml to 2000ml
Accuracy	±6% or 30 mL
Minute volume	
Range	2 to 20 L/min
Accuracy	±6%
Flow	
Range	1.5ml to 100 L/min
Accuracy	±6%
Gas monitor	
O <sub>2</sub>	galvanic fuel cell or paramagnetic
C O <sub>2</sub>	Measurement with infrared spectrometry inspiratory/end tidal
N <sub>2</sub> O	Measurement with infrared spectrometry inspiratory/end tidal

**Table 4.5** describe the specification of Avance CS2 in term of physical, electrical, environmental, pneumatic and its performance.

### 2.11.3 Avance CS2 Features

The Avance CS2 include nearly all the basic modern anaesthesia machine feature that have to offer. Moreover, this model included with the following specific features:

- Movable 15" touch screen with CARESCAPE user interface for the unified CARESTATIO\* user experience
- ecoFLOW provides information that may help clinicians mitigate the risk of hypoxic mixtures during low and minimum flow
- ecoFLOW for visualizing agent consumption and help in mitigating wasteful over delivery of fresh gas flow
- User configurable 'Quick Picks' for rapid selection of FiO<sub>2</sub> and total flow combinations

### 2.11.4 Avance CS2 Ventilation Mode

Modes of ventilation have classically been divided up into pressure or volume-controlled modes, a more modern approach describes ventilatory modes based on three characteristics. The characteristic is the trigger that determine flow versus pressure, the limit which determines the size of the breath, and the cycle that ends the breath. Different modes of ventilation allow more efficient and safe ventilation of certain types of patients. Avance CS2 offer the following mode of ventilation:

- VCV (Volume Control) Mode with tidal volume compensation
- Pressure Control
- Pressure Controlled Ventilation-Volume Guaranteed (PCV-VG)
- SIMV (Synchronized Intermittent Mandatory Ventilation)
- (Volume and pressure)
- PSVPro\* (Pressure Support with Apnea backup)
- CPAP+PSV (Pressure support mode)
- SIMV PCV-VG

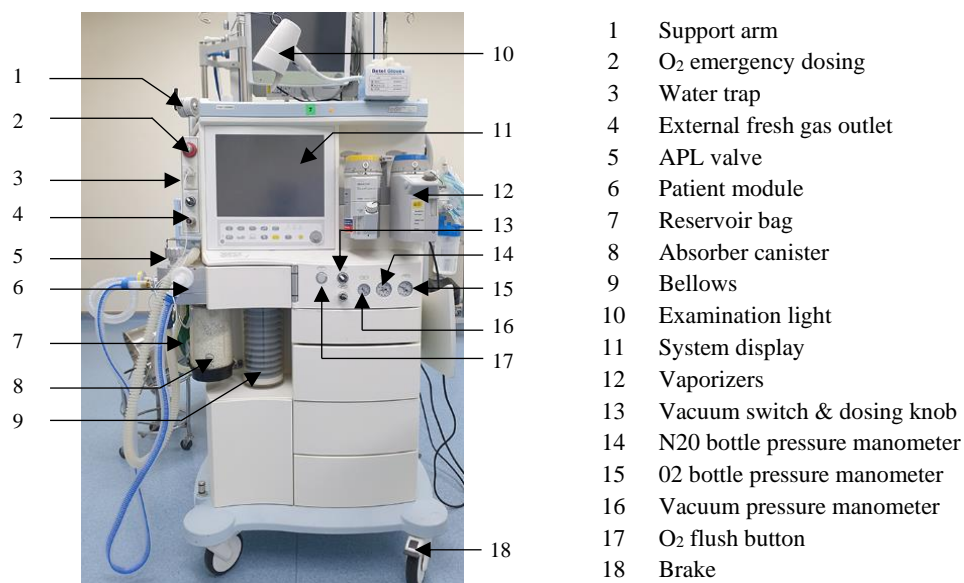


## 2.12 Leon Plus Neo

Leon plus is developed modularly as a genuine platform concept. This modern anaesthesia assistant can be integrated completely in users' specific work environment and trimmed exactly to their personal operations. Its individual configurability guarantees maximum comfort and the optimum support during its introduction, in the operating room, during therapy and in every hospital system.

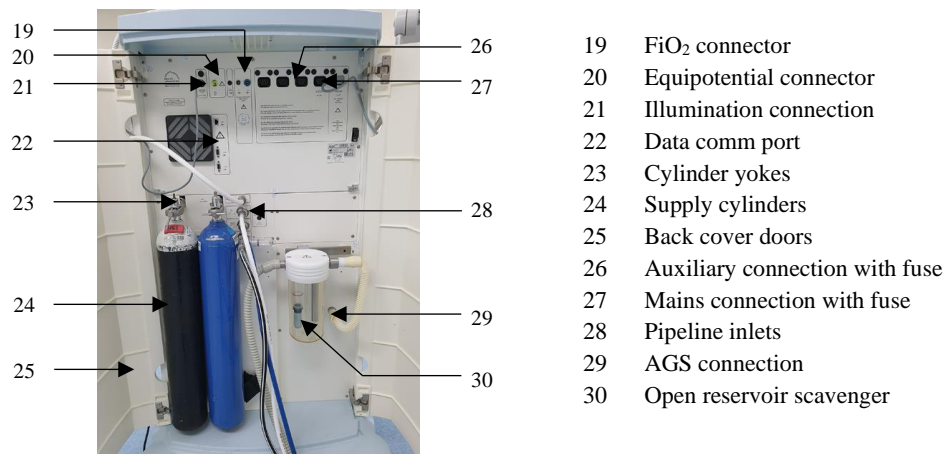
### 2.12.1 Leon Plus Neo Components

Leon Plus Neo has a number of main components that are placed on the front panel, back panel, and the breathing unit of the machine. Figure 4.11: Front panel of Leon Plus Neo. Figure 4.11 shows the front panel of Leon Plus Neo.



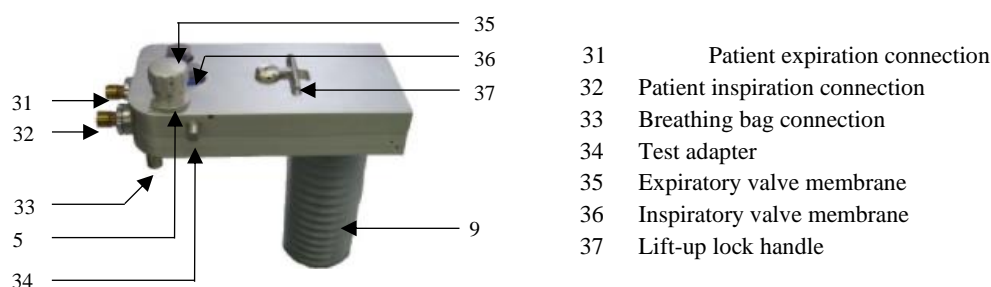
**Figure 4.11:** Front panel of Leon Plus Neo.

Based on Figure 4.11, the front panel of Leon Plus Neo is where the user interaction happened. The front panel include the display, parameters monitor, parameter controls, and the breathing system unit. Figure 4.12 shows the back panel of the machine.



**Figure 4.12:** Back panel of Leon Plus Neo.

Based on Figure 4.12, the back panel of the machine is where the gases are being supplied. The gases enter the machine through pipeline inlets or supply cylinders. There are area also electrical outlets to power up other monitoring devices.



**Figure 4.13:** Breathing system unit.

Based on Figure 4.13, the breathing system unit in Leon Plus Neo is called the patient module. The patient module is where the circulation of gas mixtures happened between the machine and the patient.

### 2.12.2 Leon Plus Neo Technical Specification

Each anaesthesia machine has their own specification and record of performance. Table 4.6 shows the key specification for Avance CS2.

**Table 4.6:** Leon Plus Neo technical specification [18].

Physical Specifications	
Dimensions	140 x 92 x 67 cm
Weight	128 kg
Brakes	Brakes on rollers
Electrical Specifications	
Power input	220-240Vac, 50/60Hz
Power consumption	95 VA
Outlets	4 outlets on back, 2A
Battery	> 100 minutes (fully charged)
Battery power	2 x 12 VDC with 7.2 Ah
Environmental Specifications	
System operation	
Temperature	-15° to 35°C
Humidity	20 to 80% relative humidity
System storage	
Temperature	-15° to 60°C
Humidity	20 to 80% relative humidity
Oxygen cell storage	1° to 50°C
APL–valve	
Range	up to a minimum of 90 Pa*100
Accuracy	±5 %

Pneumatic Specifications	
Central gas supply	Connections for O <sub>2</sub> , N <sub>2</sub> O and AIR
Connection type	Standard NIST
Pipeline input range	280 kPa to 600 kPa
Gas Control	
Fresh gas generator	Electronic fresh gas blender for 3 gases
Flow range	0.2 – 18 l/min
Accuracy	< 0.5 l/min ± 0.05 l/min and > 0.5 l/min 10%
O <sub>2</sub> concentration range	21 – 100 Vol.%
O <sub>2</sub> concentration accuracy:	± 5%
O <sub>2</sub> flush	35 L/min
O <sub>2</sub> –emergency dosing	OFF, 4, 5, 6, 7, 8, 9, 10, 12, 15 l/min
Breathing circuit parameters	
Volume	<ul style="list-style-type: none"> <li>• 2.6 L MAN/ SPONT</li> <li>• 5.3 L in mechanical</li> </ul>

Compliance	
MAN/SPONT	2.6 ml/Pa*100
Mechanical	5.3 ml/Pa*100
Expiratory resistance	
• with 60 l/min	5.4 Pa*100
• with 30 l/min	3.7 Pa*100
• with 5 l/min	2.5 Pa*100
Anaesthetic Agent Delivery	
Vaporizers	Tec 6, Tec 7
Mounting	Selectatec or Dräger-compatible anaesthetic vaporizer connections
Anaesthesia ventilator	
Accuracy (volume)	up to 150 ml $\pm$ 10% at a minimum of $\pm$ 10 ml from 150 ml $\pm$ 5% at a minimum of $\pm$ 15 ml
Display	15 inches
Tidal volume	<ul style="list-style-type: none"> <li>20 – 600 ml (paediatric)</li> <li>300 – 1600 ml (adult)</li> <li>20 – 1600 ml (IBW)</li> </ul>

Respiratory monitoring	
Airway pressure	
Range	-4 – 100 Pa*100
Accuracy	$\pm$ 4% at minimum of 2 Pa*100
Tidal volume	
Range	0 – 5000 ml
Accuracy	$\pm$ 10% or 5 ml
Minute volume	
Range	0 – 50 l
Accuracy	$\pm$ 10% or 50 ml
Flow	
Range	-200 – 200 l/min
Accuracy	$\pm$ 10 %
Gas monitor	
O <sub>2</sub>	galvanic fuel cell or paramagnetic
CO <sub>2</sub>	Measurement with infrared spectrometry inspiratory/end tidal
N <sub>2</sub> O	Measurement with infrared spectrometry inspiratory/end tidal

Table 4.6 describe the specification of Avance CS2 in term of physical, electrical, environmental, pneumatic and its performance.

### 2.12.3 Leon Plus Neo Features

The Leon Plus Neo is compromising the modern anaesthesia machine feature. In addition, this model offers the following specific features:

- 15" TFT colour display.
- Electronic fresh gas blender.
- Gas monitor with automatic detection of anaesthetic gas and anaesthetic gas mixture.
- One-hour rechargeable battery buffering.
- Neonate mode of treatment.
- Two Interface connections RS 232Com 1 VueLink /Intellibridge (Philips).
- Com 2 HulBus (PDMS, et cetera)
- Mount option: cart, wall, and ceiling suspension. Illustration of wall and ceiling suspension are illustrated in Figure 4.14 and Figure 4.15



**Figure 4.14:** Leon Plus Neo mounted on ceiling suspension.



**Figure 4.15:** Wall mounted Leon Plus Neo.

Based on Figure 4.14 and Figure 4.15, the Leon Plus Neo can be mounted on the ceiling suspension or wall. These are the extra option the user can choose to suit the configuration of the operational theatre.

#### 2.12.4 Leon Plus Neo Ventilation Mode

Modes of ventilation have classically been divided up into pressure or volume-controlled modes, a more modern approach describes ventilatory modes based on three characteristics. The characteristic is the trigger that determine flow versus pressure, the limit which determines the size of the breath, and the cycle that ends the breath. Different modes of ventilation allow more efficient and safe ventilation of certain types of patients. Leon Plus Neo offer the following mode of ventilation:

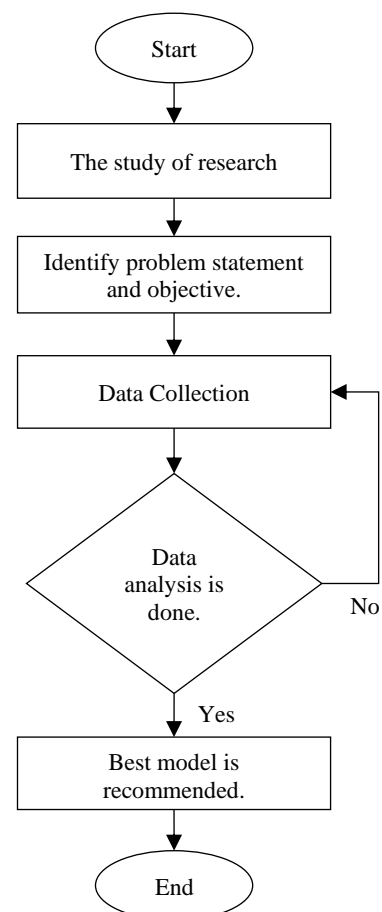
- Intermittent Mandatory Ventilation (IMV) Pressure Control
- Pressure Controlled Ventilation (PCV) SIMV (Synchronized Intermittent Mandatory Ventilation)
- Synchronized Intermittent Mandatory Ventilation (S-IMV)
- Synchronized Pressure Controlled Ventilation (S-PCV)
- Pressure Supported Ventilation (PSV)
- Ventilation mode Heart-Lung Machine (HLM)
- Manual Ventilation (MAN)
- Spontaneous Respiration (SPONT)
- Monitoring (MON)

### 3.0 Methodology

In this part, different methodology has been applied to collect the data for data analysis. The methodology applied such collect the data through ASIS and MyAPBESYS where it uses as one the important platform to update the information of equipment. Next, manual considered as an important tool to study the block diagram, principal operation, parts of unit, steps to operate and others. In addition, the internet and questionnaire are extra methodology applied to gain information. Surfing internet able to give clear vision of specific unit with pictures and videos while questionnaire is prepared to collect the feedback from user.

#### 3.1 Progress Flow

Figure 4.16 shows the flow chart of the research that has been carried out through the semester. The steps need to arrange accordingly to complete the research within the time frame allocated.



**Figure 4.16:** Flow chart in completing the research.

Based on the Figure 4.16, the flowchart is the Figure 4.16 shows the description of the progression of technical report assessment. The progress was start with choosing the equipment by consulting with senior engineer on most frequent receive request for corrective maintenance. Followed by finding for problem statement by discussing with in charges of the equipment. Next, identify the objectives and the further data are collected via ASIS, MyAPBESYS and referring manual. Lastly, the data are tabulated and compared. The suitable equipment was chosen.

### 3.2 Data Collection via ASIS

The data are collected via Asset and Service Information System (ASIS) such as purchase date, purchase cost, total downtime, maintenance history, and maintenance cost. Maintenance history for both models is attached in Appendix B and Appendix C. The main menu interface of ASIS is shown in Figure 4.17. The information collected were tabulated and compared.



**Figure 4.17:** Main menu interface of ASIS.

Based on Figure 4.17, ASIS is created by Ministry of Health, Malaysia comprehensive and integrated management system for assets and services. Biomedical Engineering department are mainly using this system to update the information regarding asset. It also functions as medium providing data regarding asset in between hospital and the BEMS department. The management team as well the technical team need to up to date the asset information in this system.

Different type of information is able to collect in this platform such as number of unit available in the hospital, types of breakdowns, types of part replacement, purchasing date and others. This data may use to analyse and differentiate the equipment chosen.

### 3.3 Additional Data Collection via MyAPBESYS

MyAPBESYS is an information and management system that is used within Advance Pact Sdn Bhd. The system is heavily used for procurement and other purposes such as spare parts purchase, stock purchase, and report submitting. Figure 4.18 shows the main menu interface of MyAPBESYS.



**Figure 4.18:** Interface of MyAPBESYS.

Based on Figure 4.18, MyAPBESYS, assets can be searched and information regarding the machine can be obtained. Information such as tag number, device location, condition, status, purchase cost and more are accessible. Nonetheless, MyAPBESYS data are heavily imported from ASIS.

### 3.4 User Manual and Service Manual

One of the main references for the studies is user manual and service manual. The parts of the anaesthesia machine and patient circuit flow was studied. The manuals provide adequate information regarding anaesthesia machine. Information regarding each faulty was provided in the manuals. Moreover, technician and specialist referred the manual to identify parts of faulty.

### 3.5 Questionnaire to Users

Questionnaire set was prepared to distribute to the users of anaesthesia machine at operational theatre department. The questionnaire was created by using Google Forms, a simple platform to done questionnaire which later be analysed. The sample of the questionnaire is attached in the appendix A. By collecting data via user, it can help to choose the best model of anaesthesia machine which can be suggested to the Biomedical Engineering department as well to the hospitals. To reduce the faulty faced by the user during treatment, this questionnaire set may be able to help the technician to propose the better model of anaesthesia machine to the user. The example of questionnaire is attached in appendices.

### 3.6 Internet

Surfing the internet by collecting information regarding the anaesthesia machine function, specification of the unit, machine theory and principle of operation. It is important to understand the basic principle of anaesthesia machine to analyse the root cause of each faulty of the unit.

## 4.0 Analysis and Discussion

Data was collected from different source and analysed to make a reasonable outcome for this assessment report. By comparing both unit with several factor to give a best suggestion to the Biomedical Engineering department and hospital for the better asset purchasing. This analysis able to help the users to identify the frequent unit of anaesthesia machine faced highest number of faulty. Moreover, the biomedical engineers able to choose the better specification unit that can provide the good service to patients without less faulty.

### 4.1 Comparison Between Avance CS2 and Leon Plus Neo

The comparison of the anaesthesia machine is made by analysing the data taken from ASIS and MyAPBESYS regarding the asset information, maintenance, purchase, and register. The data is tabulated in Table 4.7 and compared in Figure 4.19 to Figure 4.22. All data taken are year to date (YTD) as of 1<sup>st</sup> February 2021.

**Table 4.7:** Data retrieved from ASIS and MyAPBESYS.

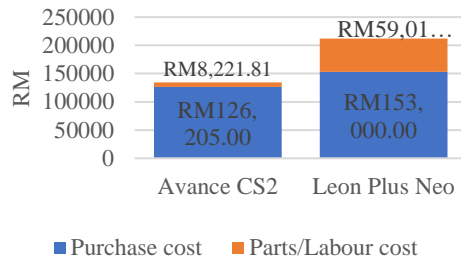
Model Item	Avance CS2	Leon Plus
Made in	America	Germany
Manufacturer	Datex- Ohmeda Inc	Heinen + Lowenstein Gmbh
Commissioning date	10 DEC 2014	15 OCT 2014
Asset age	6 years 3 months	6 years 5 months
Purchase cost	RM 126,204.00	RM 153,000.00
Labour cost	RM 2321.81	RM 3030.53
Parts cost	RM 5,900.00	RM 55,984.00
Cumulative parts/labour cost	RM 8,221.81	RM 59,014.53
Total downtime	3157.61	1714.04

Table 4.7 is the tabulation of data retrieved from ASIS. The information of the assets such as manufacturer, commissioning date, asset age, cost of machine and downtime are placed side by side in the table to differentiate between Avance CS2 and Leon Plus Neo



#### 4.1.1 Total Cost

Total cost is the sum of purchase cost and cumulative of parts and labour cost. Avance CS2 has the total cost at RM134,426.81 while Leon Plus Neo has the total cost at RM212,014.53. Comparison of cost for each model is illustrated in Figure 4.19.

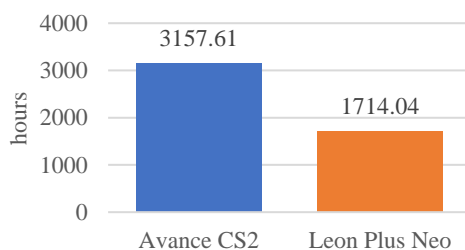


**Figure 4.19:** Cost comparison.

Based on Figure 4.19, cost for Leon Plus Neo is significantly higher compared to Avance CS2 in every aspect. For instance, Avance CS2 is purchased at only RM126,204 while Leon Plus Neo is purchased at RM153,000. For maintenance cost, Leon Plus Neo recorded an amount of RM59,014.53 for the last 5 years. Avance CS2 maintenance cost is cheaper which cost at RM8,221.81 for the same period of time. Thus, Leon Plus Neo cost 45% more compared to Avance CS2.

#### 4.1.2 Downtime

Downtime is the period of time in which the machine is out of order. In this case, the model with the lowest downtime is better. Figure 4.20 shows the comparison of total downtime between the two models.



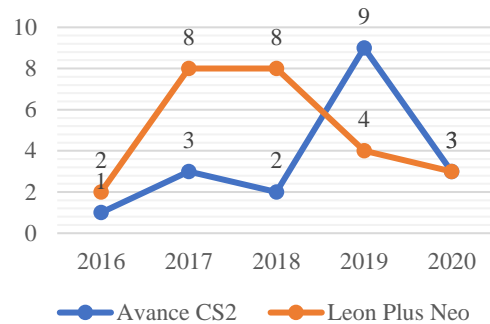
**Figure 4.20:** Downtime comparison.

Based on Figure 4.20, Avance CS2 recorded significantly higher downtime compared to Leon Plus Neo. Avance CS2 downtime is 59% higher compared to Leon Plus Neo. This is due to some

parts for Avance CS2 are not available locally. Thus, it needed to be shipped from overseas which consume times.

#### 4.1.3 Rate of Breakdown

Rate of breakdown is the number of breakdowns that occurred in a year within 5 years span. Figure 4.21 shows the rate of breakdown between the two models.



**Figure 4.21:** Rate of breakdown comparison.

Based on Figure 4.21, Leon Plus Neo have the highest rate of breakdown at an average of 5 breakdown per year while Avance CS2 have an average rate of 3.6 breakdown per year.

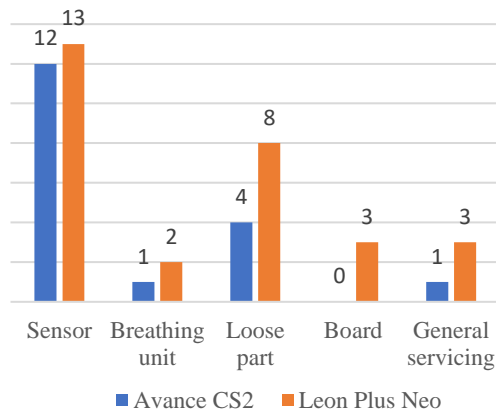
#### 4.1.4 Type of Breakdown

This is the analysis for the frequent type of breakdown for each model. Some breakdowns occur simultaneously. For example, technician have to replace both O<sub>2</sub> sensor and flow sensor in the same workorder. Data is tabulated in Table 4.8

**Table 4.8:** Type of breakdown taken from maintenance history.

Model		Avance CS2	Leon Plus Neo
Type of Breakdown			
Sensor	O <sub>2</sub> sensor	7	7
	CO <sub>2</sub> module	1	3
	Flow sensor	4	3
Breathing unit	Canister	1	1
	O-ring	0	1
Loose part		4	8
Board		0	3
General servicing		1	3

Based on Table 4.8, both models recorded almost the same type of breakdown. Both models have high count of breakdown on sensor and loose part. Comparison of type of breakdown is illustrated in Figure 4.22.

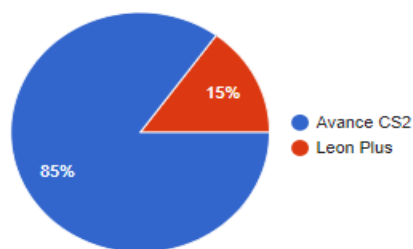


**Figure 4.22:** Type of breakdown comparison.

Based on Figure 4.22, both models showed the trend of the same breakdown. The only different is Leon Plus Neo had higher rate of breakdown.

## 4.2 Questionnaire Analysis

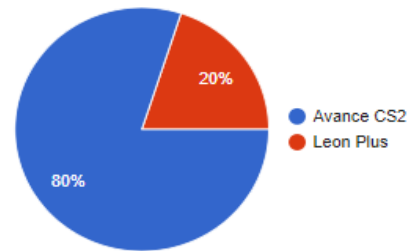
From the questionnaire that was distributed among user, a number of 20 respondents have been recorded. The respondents have selected which features they preferred either Avance CS2 or Leon Plus Neo. Figure 4.23 shows the piechart for question 1 which is based on the ease of used between the two models.



**Figure 4.23:** Respond on the ease of used.

Based on Figure 4.23, user have to choose which model is easier to be used. The piechart shows that 85% prefer Avance CS2 over Leon Plus Neo that recorded only at 15%.

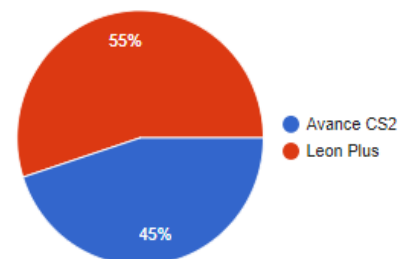
Figure 4.24 shows the piechart for question 2 which is based on the model with the least problem.



**Figure 4.24:** Respond on the model that have the least problem.

Based on Figure 4.24, Avance CS2 have the least problem. Avance CS2 is preferred by most user that chosen by 80% of the user compared to 20% of model Leon Plus Neo.

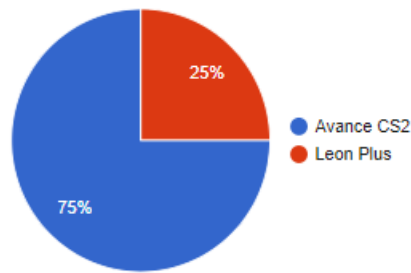
Figure 4.25 shows the piechart for question 3. In question 3, user must choose which model can complete a task quickly such as routine system check-up.



**Figure 4.25:** Respond on the model that able to complete a task quickly.

Based on Figure 4.25, Leon Plus Neo is preferred by 55% of users in term of task completion rate. Avance CS2 is only chosen by 45% of the user.

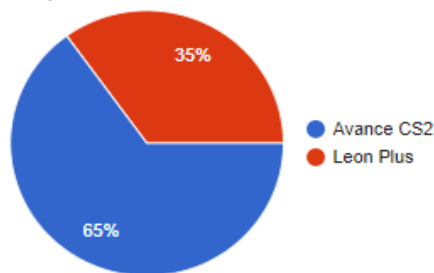
Figure 4.26 shows the piechart for question 4. Question 4 is about the clarity of error message when an error occurs.



**Figure 4.26:** User preference on the clarity of error message.

Figure 4.26 shows that Avance CS2 display the error message much clearer. Avance CS2 is preferred by 75% of users regarding the matter.

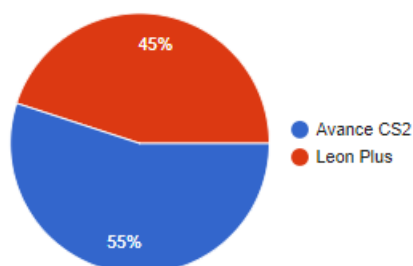
Figure 4.27 shows the piechart for question 5 which is based on the interface of the model. In question 5, the user has to choose which interface of anaesthesia machine they preferred.



**Figure 4.27:** Respond on better display interface.

Based on Figure 4.27, 65% of user prefer the interface of Avance CS2 while the remaining 35% prefer the interface of Leon Plus Neo.

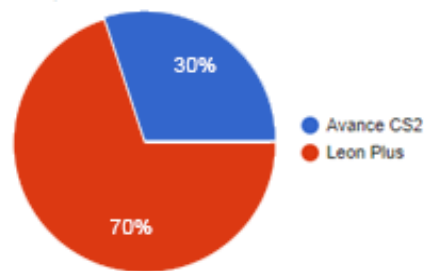
Figure 4.28 shows the piechart for question 6 which is based on the clarity of information displayed on the machine. For instance, the step-by-step info that has to be done to do calibration or daily check-up routine on the machine.



**Figure 4.28:** Respond on the clarity of information displayed on the machine.

Figure 4.28 shows a nearly close tie between the two models. 55% of user preferred Avance CS2 while the remaining 45% of user preferred Leon Plus Neo.

Figure 4.29 shows the piechart for question 7 which is based on the feature of the model. In question 7, users are required to choose which model have the better features that can help patient to receive better treatment procedure.



**Figure 4.29:** Respond on the better features of the models.

Figure 4.29 shows that 70% of the user believe Leon Plus Neo provide better feature in comparison to Avance CS2.

According to the result, Avance CS2 is preferred by the user of operational theatre in HSI. Avance CS2 is chosen for its user friendliness, low rate of failure, clarity of error displayed, user interface, information provided by the machine, and features. It only lack at a point which is the time take to complete a task.

## 5.0 Conclusion

In conclusion, anaesthesia machine is one of the high-end life support equipment which need to be maintain accordingly to save life of patients. The study of anaesthesia machine was done in the completion of this research. The common breakdown of each anaesthesia machine models was identified, and cause of each breakdown are analysed altogether. Moreover, the steps to troubleshoot for these different models were learnt. Next, the best model is suggested to the users at the end of analysis. It has been proven with data analysis that Avance CS2 had given the better service and less difficulty to the user during treatment. Both models were bought in 2014 and the age between them is only 2 months apart. Expensive asset does not mean it is the better. Leon Plus Neo was bought at a higher price tag and recorded the highest rate of breakdown with different types of breakdowns. Moreover, the maintenance cost Avance CS2 is significantly cheaper compared to Leon Plus Neo. Next, Avance CS2 have the higher downtime due to spare part is not available locally and needed to be shipped from oversea at the time. Avance CS2 downtime could be lower if the spare part is available locally at the time. Nonetheless, Leon Plus Neo does offer more features in treating patients but the machine is quite complex to be used. The user in HSI prefer simpler and reliable machine. Technical assessment report has given us the chance to explore more on one specific equipment with complete data. The work-based learning internship help student to identify their place of interest and capability to become specialist on a specific equipment.

## 6.0 Recommendation

Based on the assessment and analysis done, Avance CS2 is the best model to be used in HSI. From technical perspective, the model is reliable, significantly cheaper spare part cost, and the difficulty in repairing the machine is low. As for user perspective, the model is much more user friendly, cheaper, and simpler to be used while treating patients.

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# SLIT LAMP

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**Abstract**— The purpose of this paper is to write a Technical Assessment Report (TAR) about one medical equipment that known as slit lamp that have been used at Hospital Enche' Besar Hajjah Khalsom, Kluang. Based on this study comparison between two models of slit lamp which are Inami L-0187 and Righton MW50D has been discussed. Basically, slit lamp is a device that have been used by the doctor to diagnose the eye diseased of the patients. The ophthalmologist can look the different of abnormal and normal eyes in closer look. The ophthalmologist also can see structure at the front of the eye and structure inside the eye. In addition, the comparison of data between two models are carried out to investigate the rate of maintenance and rate of usage among these two models. Based on analysis done it can be recommended that RT Righton MW50D model shows the best performance of slit lamp.

**Keywords** – Slit lamp, eye disease, medical equipment, diagnosed medical equipment

## 1.0 Introduction

A slit lamp combines a microscope with a very bright light. The slit lamp exam is a standard diagnostic procedure that also known as biomicroscopy. Each of the advance technology must have their own history. A slit lamp machines also have their own history. Back then, in 1900s the slit lamps have evolved significantly. Purkinje who are studied the iris with an adjustable microscope by illuminating the field of view. One year later, Louis de Wecker combin an eyepiece, objective and adjustable condensing lens within a tube that known as uniocular slit lamp. The Wecker's invention was continued by Siegfried Czapski by added binocularity to the microscope. However, none of this development by these individuals had sufficient and adjustable illumination to be of much clinical benefit. The development of the first true slit lamp to illuminate the eye was built by Allvar Gullstrand who is an ophthalmologist and 1911 Nobel Laureate. Then, Henker and Vogt improved from Gullstrand's device in the 1910s by creating an adjustable slit lamp and combined Czapski's microscope with Gullstrand's slit lamp illumination. From this development then finally produce the modern slit lamp biomicroscope.

A slit lamp is a microscope that used a bright light during an eye exam. The bright light will help the ophthalmologist to look a closer look at the different structures at the front and structures inside the eye. Before entering the exam, the ophthalmologist will advices if the eye was dilated with dilating drops the patient should not drive after examination because of the dilating drops will blurry the sight. The procedures while doing the examination: -



- The ophthalmologist may apply dye that called as fluorescein. This dye was administered as an eye drop or on a small thin paper strip that touches the white of the eye.
- The ophthalmologist administers a series of eye drops that will dilate the pupils. Its take 20 minutes for the drop works.
- Once the pupils were dilated, the doctor will repeat the eye exam. At this time the lens will be closed to the eye.
- The dilated pupils become very large that will make the eyes sensitive toward light.
- After the exam, wearing the sunglasses will help until the pupil becomes normal again.

There were many types of disease will be detected by using slit lamp such as cataracts, corneal injury, damage sclera, detachment of retina, macular degeneration, disease or swelling of the middle layer of the eye, optic nerve like glaucoma, eye bleeding and the presence of a foreign body in the eye.

## 1.1 Objective

In this study, there are four objectives in ensuring the works can be done successfully.

- To produce a research work on the types of different model of slit lamp that has been used in Hospital Enchee' Besar Hajjah Khalsom, Kluang (HEBHK).
- To investigate the specifications of two different model of slit lamp that have been choose in HEBHK.
- To study the common problem on the slit lamp and equipment performance during its lifetime.
- To recommend the best slit lamp model used in the hospital.

## 1.2 Significant of Studies

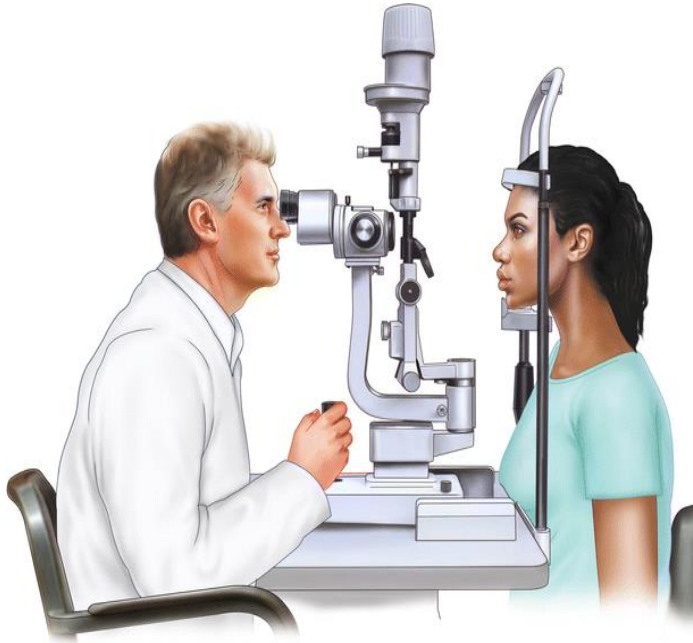
The significant of this study is to focus on the two types of slit lamp that are commonly used in ward and ophthalmology clinic (Klinik Pakar 5). Next, to study between old equipment and new equipment of slit lamp in HEBHK. Lastly, the scope of studies is slit lamp model in ward and ophthalmology clinic in HEBHK

## 2.0 Slit Lamp

This section review on general function of slit lamp based on physical layout. There are various studies and research that has been revised and were compiled together during the progressing of this assessment report. The studied are divided into three subsections consists of physical layout of the slit lamp, specifications of the slit lamp and type of slit lamp model. Along to the objective of this research is to design research work on slit lamp and related studies about the existing slit lamp has been revised.

### 2.1 Physical layout of slit lamp

The illustrations of physical layout of slit lamp are explained very well in Figure 5.1. In term of diagnostic electronic equipment, slit lamp was very useful to help ophthalmologist to look clearly the structure in front of the eye and structure inside the eye. The descriptions were explained very well at the below.



**Figure 5.1:** Position of ophthalmologist and patients while examination

### 1. Position of Patients and Ophthalmologist

The Figure 5.1 shows that the position of patients and ophthalmologist while using the slit lamp. The patients must put their chin on the chin rest to keep their head steady while exam.

### 2. Biomicroscope

The biomicroscope is literally a microscope that help ophthalmologist to see the tiny things clearly.

### 3. Bulb

Bulb will supply a very bright light to help the ophthalmologist to look clearly the different structure of external and internal of the patient's eye.

Based on Figure 5.1, the examination of slit lamp was very helpful to discover the patient's disease without making any surgery because the slit lamp itself can focused on closer look of the structure in front and in the eye including optic nerve. Slit lamp used a special bulb known as halogen bulb to produce the light. It is because halogen bulb produce no shadow and it can avoid any parallax error while examination. The prices of halogen bulb quite expensive rather than other bulb in the market.

## 2.2 User Level Care

Each medical equipment has their own manual maintenance and both user and engineer must be followed to increase the equipment lifespan, reduce cost of maintenance and avoid error while doing the examination towards patients. First, remove the dust and clean the slit lamp daily. Basically, the microscope was sealed and if the sealed not broken cannot enter in the microscope. The dust should be removed gently by using a cloth or suitable brush. Second, always keep the equipment covered by dust cover when the equipment was not in used. The dust cover can be anything like cloth or proper plastic. Then, an optical part of the microscope may get the growth of fungi if the instrument is not properly cared. The humidity helps the growth of fungi. So, to avoid the growing of the fungi, it is important to keep bag of desiccating agents like silica gel in a bag within the dust cover of the instrument when not in used. Also, it is important to remove the instrument away from the room if the room is to be washed and is likely to remain damp for some time.

## 2.3 Preventive Maintenance

### a. Care of the slit

A knob or a knurled wheel is available for varying the width and height of the slit lamp and also for opening the slit completely. Also, with the slit completely open, one can get circular spots of light of different sizes. The knob or wheel is spring loaded and the adjustment of the load is such that the motion of the knob or wheel is not too tight or loose. too tight a motion will lead to greater wear and tear while too easy a motion will be frustrating for the user.

### b. Care of the filters

In fact, the slit lamp has a disc that carries some filters that can be brought under the slit. The filters are to be treated like the other optical elements of the instrument. Clean moist cloth can be used for the cleaning.

### c. Care of lenses

The condensing lenses between the bulb and the slit as well as the focusing lens between the slit and the exit, and the front silvered mirror or total reflecting prism used for directing the beam towards the subject of the illumination systems, need clean when brightness of the is low. Both prism and mirror should be replaced in their proper setting as they were before removal. Condensing lenses may not have the same curvature on either side. It is important that the lenses are positioned correctly so that the slit image is free from aberrations produced by lenses.





## 2.4 Check List for Preventive Maintenance

- Does the table top move up and down freely?
- Does the chin rest and head rest move freely in the stand?
- Does the joy stick function properly?
- Is the bulb turned on when the switch is on?
- Does the brightness of the slit vary when the brightness control knob is operated?
- Does the slit width function smoothly?
- Does the slit height function smoothly?
- Does the inclination of the slit to the vertical function smoothly?
- Does the mechanism for opening the slit completely and bringing in the various circular apertures function smoothly?
- Does the mechanism for rotating the illumination system function smoothly?
- Does the mechanism for tilting the illumination system function in instruments where this facility exists?
- Is the image of the slit projected on a piece of paper held at the chin rest stand seen clearly in the microscope?
- Is the slit image bright?

## 2.5 Related Types and Model of Slit Lamp

This subsection shows the brand and types of slit lamp model that available in the market. Some of them was available at the government hospital and some of them was used at the private hospitals. There is the various design of slit lamp but with the same function which is to diagnosed eye disease. Table 5.1 shows several models of slit lamp and its specification.

**Table 5.1: Models of slit lamp and its specification**

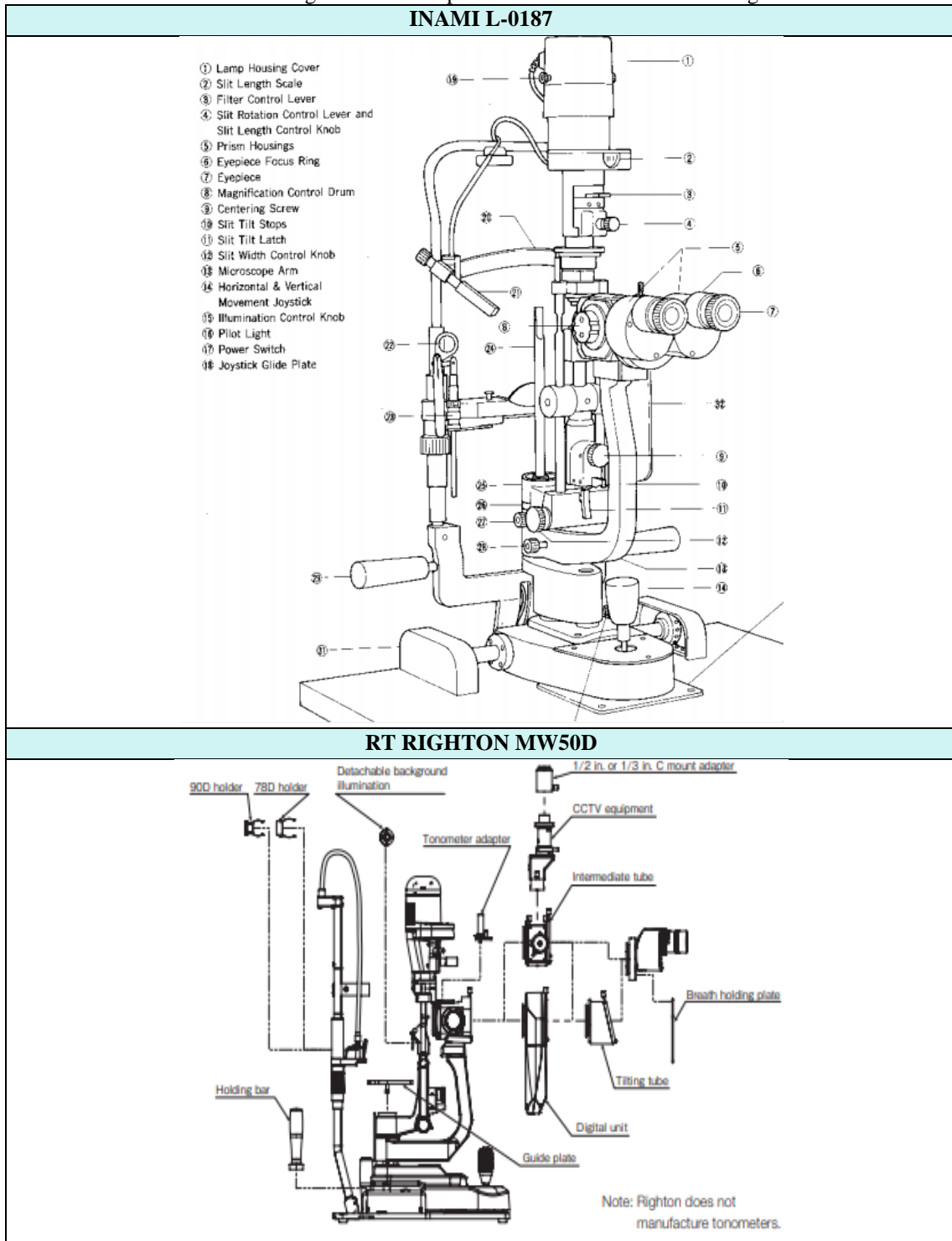
Models of slit lamp and its specification	
 <p><b>a) HAWK-IT3 SLIT LAMP</b></p> <p>Top illumination with halogen bulb. This slit lamp consists of three steps of magnification like slit imager, HD camera and HD software. Made from India</p>	 <p><b>d) ZEISS SL 800</b></p> <p>Reveal details for diagnosis and optimizes your work flow, uncover details, enhance focus and expanded capabilities.</p>
 <p><b>b) KEELER PSL ONE HAND HELD</b></p> <p>Keeler designed with strength to withstand the daily trauma of demanding. PSL is light weight, durable and robust. Made from British.</p>	 <p><b>e) INAMI L-0187</b></p> <p>Bulb used halogen 12V 50W. It's come with dust cover, spare bulb, breath shield and chin rest tissue. Have adjustable slit width and heat absorption.</p>
 <p><b>c) TAKAGI 700 GL LPH</b></p> <p>New OM-6 operating microscope. Larger breath shield and better protection. Made from Japan</p>	 <p><b>f) RT RIGHTON MW50D</b></p> <p>Low power consumption and longer life. Input in AC and output in DC. Made from Japan.</p>

Based on Table 5.1, we can conclude that there are many types of brands and manufacturer of the slit lamp. The slit lamp has their own function based on the physical structure. The modern slit lamp has more features rather than the old one.

## 2.6 Specification of Slit Lamp.

The specifications and accessories of slit lamp model Inami L-0187 can be compared with model RT Righton MW50D as shown in Table 5.2 and Table 5.3. Table 5.2 shows that the schematic diagram with labelling of different model that were used at Hospital Enchee' Besar Hajjah Khalsom, Kluang are Inami L-0187 and RT Righton MW50D.

**Table 5.2:** Schematic diagram of slit lamp model Inami L-0187 and RT Righton MW50D



Based on Table 5.2, both slit lamps look very similar even though it was different model and manufacturer. Both of these models were made from Japan. Hospital Kluang was a new hospital and their equipment not too much. So only two model of slit lamp was available and used at the hospital. The slit lamp was available at ward and ophthalmology clinic. Inami L-0187 was used for 9 years at the hospital meanwhile RT Righton MW50D was used for 5 months only. This is because before this just one model only that available at the hospital. For addition, RT Righton MW50D was used by the expert ophthalmologist only.

Table 5.3 shows the differentiation between specification and accessories within two different model Inami L-0187 and Righton MW50D.

**Table 5.3:** The comparison of specifications and accessories between Inami and Righton slit lamp

SLIT LAMP	INAMI L-0187	RT RIGHTON MW50D
Specification	<p><b>Parallel Tube Stereomicroscope</b></p> <ul style="list-style-type: none"> <li>- Eyepiece 15x</li> <li>- Variable magnification 10x</li> <li>- Working distance 98mm</li> <li>- Eyepiece adjustment +6D to -6D</li> <li>- P.D adjustment 48-78mm</li> </ul> <p><b>Illumination system</b></p> <ul style="list-style-type: none"> <li>- Slit length 0.2,1,3,4,6,10mm step</li> <li>- Slit width from 0-10mm</li> <li>- Slit image rotation 0-180 degree</li> <li>- Slit tilt 5,10,15 and 20 degrees</li> <li>- Filter disc open, cobalt blue,50% neutral density, beat absorbing, red free green</li> <li>- Lamp 12V, 50W halogen</li> </ul>	<p><b>Microscope</b></p> <ul style="list-style-type: none"> <li>- 5 step magnifications microscope</li> <li>- Objective angle 13.2 degree</li> <li>- Total magnification 5x, 10x, 16x, 25x, 50x</li> <li>- Actual field of view 44.5,22.3,9</li> <li>- Eyepiece lens magnification 12.5x</li> <li>- Eyepiece dioptr range -8D to +8D</li> <li>- PD adjustment 55mm to 80mm</li> <li>- Working distance 100.5mm</li> <li>- Reaching distance 314.0mm</li> </ul> <p><b>Illumination system</b></p> <ul style="list-style-type: none"> <li>- Light source white LED 5W</li> <li>- Slit width 0 to 16mm</li> <li>- Slit rotation angle 90 degree to left and right</li> <li>- Slit aperture 1 to 12mm</li> <li>- Slit tilting angle 0,5,10,15,20</li> <li>- Slit swing 8mm to left or right</li> <li>- Filters transparent, ND (12.5%), green and cobalt blue filters</li> </ul>
Accessories	<ul style="list-style-type: none"> <li>- Applanation tonometer</li> <li>- Beam splitter module</li> <li>- Teaching tube with image rotation</li> <li>- 35mm camera adaptor</li> <li>- 35mm SLR camera body with automatic film advance</li> <li>- CCD TV camera and adaptor</li> </ul>	<ul style="list-style-type: none"> <li>- 90D holder, 78D holder</li> <li>- Chin rest paper</li> <li>- Holding bar</li> <li>- Breath guard</li> <li>- Grease plate</li> <li>- Tonometer adapter</li> <li>- Imaging unit</li> <li>- Inclination tube</li> <li>- Beam splitter</li> <li>- Security key</li> </ul>

From the Table 5.3, the Righton MW50D have many features than the Inami one. Then the additional accessories of Righton slit lamp is much than the Inami slit lamp.

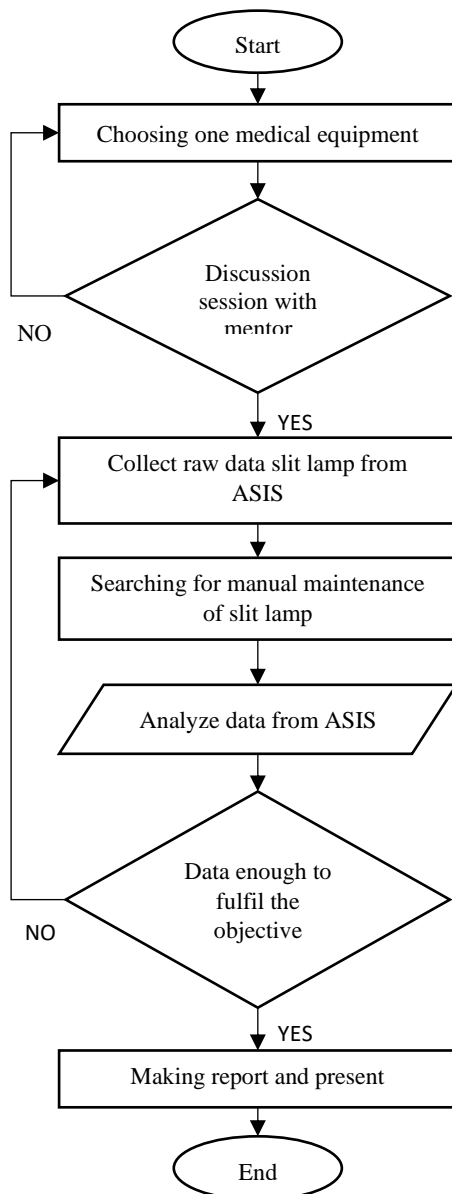


### 3.0 Methodology

This section will discuss on research methodology that has been carried out through the assessment. The layout of the section will be divided into several parts of subsections. The major sections are including the progress work on this assessment that consists of flowchart on overall research work. Then, it contains a simple explanation on the applied method and a mini conclusion.

#### 3.1 Flowchart

Figure 5.2 shows the flowchart while doing the research on technical assessment report.



**Figure 5.2:** Flowchart while doing the research.

By referring to the objective and significant of studies, there were three phases or part that involved in this research like discussion with the mentor, collect data from the ASIS and analysing the data that taken from the ASIS and manual.

From the flowchart in Figure 5.2, the progress of works in doing the research starting with selecting one of medical equipment that important for the user. After selecting the slit lamp as the title for the research, make the discussion with mentor either it was brilliant idea with the proper way to start the research. Then collect raw data from the ASIS to find the rate of maintenance and rate of failure. In fact, ASIS is a platform that have been used for any biomedical engineering to update new activity with medical equipment. ASIS is a term stand for Asset and Services Information System. ASIS very important for the engineer and doctor to update any breakdown and technical skill need to solve the problem.

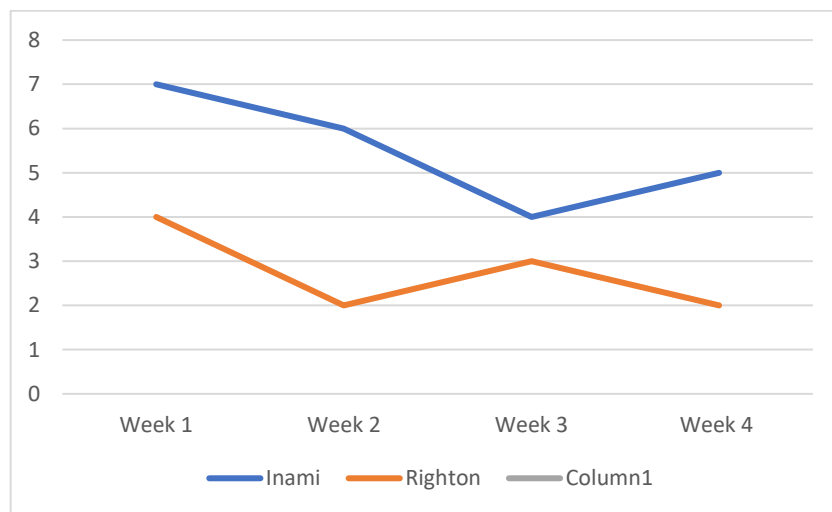
Next, searching for manual maintenance for both Inami slit lamp and Righton slit lamp to study about what kind of the breakdown and the proper way to solve the breakdown. Usually, the manual maintenance will give from the vendor while buying the medical equipment. If the data was enough to do the research, started making report and do the presentation

## 4.0 Analysis the data

This section shows how the raw data taken from the ASIS and manual maintenance was analysed and show the final result. The data that will be analysed are the common problem on the slit lamp during life time, rate of usage of slit lamp and rate of maintenance of slit lamp.

### 4.1 Rate of usage

Figure 5.3 shows the data about rate of usage between slit lamp model Inami and Righton.



**Figure 5.3:** Rate of usage slit lamp per week on December 2020

Figure 5.3 stated the rate of usage between slit lamp models Inami L-0187 and RT Righton MW50D on December 2020. The data was taken by week because of the slit lamp itself rarely use. The slit lamp was focused on diagnose patients' eye only. Rate of usage here means how many times the equipment was used on the patients. The data was taken from making the survey from medical assistance in charge.

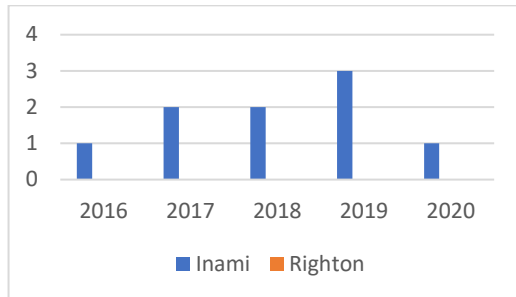
In December contains 31 days which mean four weeks complete. On first week, the Inami slit lamp state seven times usage meanwhile Righton slit lamp state four times usage. On second week, the Inami slit lamp state six times

usage meanwhile Righton slit lamp state two times of usage. On third week, the Inami slit lamp state four times usage meanwhile Righton slit lamp state three times of usage. On fourth week, the Inami slit lamp state five times of usage meanwhile Righton state two times of usage.

From the line chart, we can conclude that the rate of usage for Inami slit lamp was higher than Righton slit lamp. The data was taken from the same slit lamp with tagging KLN000473. Righton slit lamp model does not have tagging number yet because of the equipment was under warranty.

## 4.2 Rate of maintenance

Figure 5.4 shows the data about rate of maintenance of slit lamp model Righton and Inami by year.



**Figure 5.4:** The rate of maintenance slit lamp by year

Based on Figure 5.4 shows the rate of maintenance by year of the slit lamp. Basically, Inami slit lamp was used at the Hospital Enche' Besar Hajjah Khalsom for nine years. It was a very long-life time for the medical equipment. The data was taken from the ASIS platform. The bar chart shows the rate of maintenance for Inami slit lamp with tagging number KLN000473. The data taken on five years latest where are 2016,2017,2018,2019 and 2020.

On 2016, the Inami slit lamp have one time of breakdown. The maintenance type is corrective maintenance. Request detail stated that the slit lamp was not functioning. Response finding by an engineer found that the bulb was burn out. An engineer solves the problem by changing bulb with the new one.

On 2017, Inami slit lamp have two times of breakdown. The type of corrective maintenance. Request detail from user stated that slit lamp not functioning. The respond finding by an engineer found that the filament of slit lamp was burn. The problem was solving by changing the old bulb with the new one. The same breakdown happens twice.

On 2018, Inami slit lamp have two times of breakdown. The maintenance type is corrective maintenance. For first breakdown, request details from user stated that slit lamp problem. Respond finding by an engineer is machine light off and filament of the slit lamp burn. The breakdown

was solved by replaced the old bulb with the new one. For second breakdown, request details by user stated that slit lamp problem. The response finding by an engineer found that controller x and y axis hard to move meanwhile the other function was in good condition. The problem was solved by cleaning and remove dust along x and y axis space and controller ball. Then putting back the silicon grease and adjust the controller setting.

On 2019, Inami slit lamp has three times of breakdown. The type of maintenance is corrective maintenance. First breakdown, request detailed by user stated that bulb burn out. The response finding by an engineer is bulb burn out. The action taken by engineer is replace the old bulb with the new one. Second breakdown, request detail by user stated that bulb blow. Respond finding by an engineer state that light reflection is not bright and clear. The action taken was changing halogen bulb with the new one and cleaning the lens. Third breakdown, request details by user state that bulb problem. Respond finding by an engineer stated that bulb burn out. The action taken to solve the problem changing the old one with the new one. After do the performance test, the machine was ready to use.

On 2010, the Inami slit lamp faced one time of breakdown. The type of maintenance is corrective maintenance. Request detailed from the user state that the bulb problem. Response finding by an engineer is bulb burn out. The action taken to solve the problem is replace the old bulb with the new one. After do the performance test the equipment was ready and available to use.

There were no data taken from RT Righton MW50D slit lamp because it was new equipment that have been used only for five months. In other words, the Righton slit lamp still under warranty. When there are any breakdown or failure of the equipment, vendor will be invited to the hospital to solve it. Vendor is a company that supply medical equipment to the hospital.

From the data we can conclude that maximum rate of maintenance that faced by Inami slit lamp is three time and the maximum rate is one time in a year. The most of breakdown faced by the slit lamp is the bulb burn out.

### 4.3 Common problem

The third analysis is commonly problem that the equipment faced. The data was taken from the ASIS platform. Commonly problem that faced by Inami slit lamp is bulb burn out. It is usually happened because the filament in the bulb was burn. To solve this problem an engineer must change the new bulb to make sure it can work properly again. The prices of one bulb are RM350.00, the bulb itself quite expensive because of it was halogen bulb produce no shadow. So, it helps very much while ophthalmologist examine the patient's eye.

In addition, the slit lamp of Inami bulb in AC circuit. An AC bulb was not good as a LED bulb. The advanced technology of slit lamp usually used the LED bulb to increase the lifetime of the bulb. For Righton slit lamp that nor has any common problem yet. In the nutshell, the common problem for Inami slit lamp is bulb burn out. To increase a lifetime of the bulb slit lamp need to change with LED bulb. This is very important to avoid the equipment become BER. BER means Beyond Economic Repair. For BER equipment cannot be used anymore.

## 5.0 Conclusion and recommendation

From this research, the two types of slit lamp are commonly used in ward and ophthalmology clinic are Inami L-0187 and RT Righton MW50D. To develop this Technical Assessment Report (TAR) I need to study between the old equipment and new equipment of slit lamp at the Hospital Kluang. I success produce research on the types of different model of slit lamp that has been used in HEBHK. Next, I done investigated the specifications of two different model of slit lamp that has been choose in HEBHK. Then, I done study the common problem on the slit lamp and equipment performance during the life time. Between these two models of slit lamp, I would choose Righton MW50D because of it have much features than the Inami L-0187. Last but not least the Inami L-0187 was already used for nine years and it was old for the ages of the equipment.

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# CARDIOTOCOGRAPH(CTG)

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**Abstract**— Cardiotocography technique is used routinely during pregnancy and labour to assess fetal well-being. Hence, cardiotocograph (CTG) is used to record the fetal heart rate (FHR) and contractions of uterus during labour. In particular, CTG is one of important equipment that used in obstetrics department in a hospital. The aimed of this study is to design a research work on the types of different model of CTG that has being used in Segamat Hospital. Hence, collection of data between two models of CTG in Segamat Hospital is conducted in order to gather the information of the equipment. In the addition, analysis of the equipment is based on the comparison between two models based on the assessment among two models of CTG. Based on this study, it can be recommended that CTG model Sonicaid has very big potential to use in the hospitals since this model has high return of investment to the hospital and management.

**Keywords**- Cardiotocograph, foetal heart rate, assessment, Sonicaid

## 1.0 Introduction

Fetal heart rate monitoring is a process that is carried out during pregnancy and labour to keep track of the fetal heart rate and uterine contractions. Electronic fetal monitoring was introduced in early of 1970s with the advent of CTG. In obstetrics, monitoring and evaluating of foetal heart rate is important during pregnancy and labour. In order detect the changes in fetal heart rate, cardiotocography is a technical method that is used routinely during pregnancy and labour to asses fetal well-being [2].

Cardiotocograph (CTG) is an equipment which is used to perform the monitoring and recording the fetal heart rate and uterine activity. In particular, there is no specific research work conducted a comparison between two different models of CTG in Segamat Hospital. Generally, CTG machine has ultrasound transducer and tocodynamometer transducer or known as TOCO transducer. Both sensors are placed against the mother's abdomen. In the addition, ultrasound records the fetal heart rate and TOCO transducer monitor the contractions of the uterus.

## 2.0 Cardiotocograph

This section review on general function of the cardiotocograph based on its physical layout. There are various studies and research that have been revised and were compiled together during the development of this assessment report. The studies are divided into three subsections consist of the physical layout of the CTG, specifications of the CTG, and the types of models of CTG. The objective of this research is to design a research work on CTG, the related studies on the existing CTG have been revised

## 2.1 Physical Layout of Cardiotocograph

The illustrations of the principle of operation of the cardiotocograph are explained in. In terms of electronic fetal monitoring, it is either external or internal. Electronic fetal monitoring is a valuable tool for measuring fetal well-being and assessing labour progress. According to [3] in their research, there are two methods that have been used in measuring and recording fetal heart rate. For external recording, the general specifications and method is reviewed in Figure 6.1.

External monitoring is one of the common methods that has been used in recording fetal heart rate. Sensors are placed against the mother's abdomen and connected all the sensors to the monitors which will produce a baby's heart rate as shown in Figure 6.1. This equipment usually used during antenatal which is before birth and during labour to monitor the baby's condition[2].

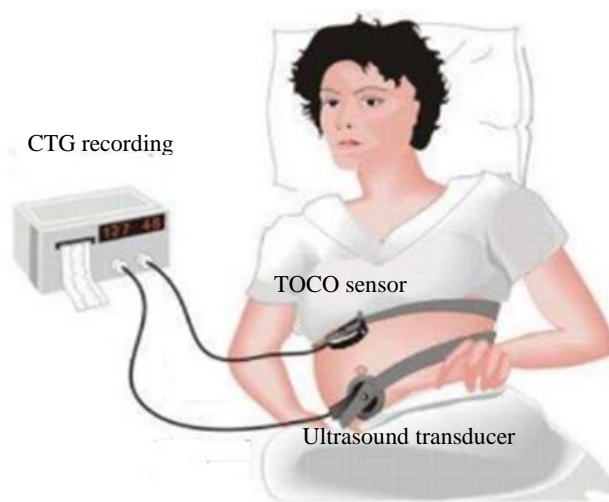
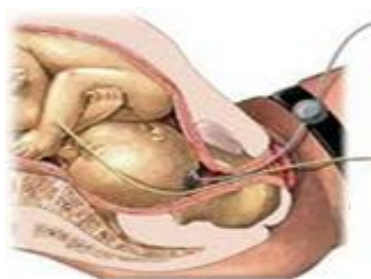


Figure 6.1: Application of CTG Machine [1]

- 1. TOCO transducer**
  - a tocotonometer which operates on the strain gauge principle to measure displacement.
- 2. Ultrasound transducer**
  - A small round ultrasound (high-speed sound waves) disc with ultrasound gel on mother's abdomen and held in place by a lightweight stretchable band or belt.
- 3. Fetal monitor**
  - Monitor that displays the foetal heart rate and contractions activities during pregnancy.
  - Build in alpha-numeric display and graph display mode to record both activities [2]
- 4. Graph Paper**
  - The result of the fetal heart rate and percentage of contractions are printed out on graph paper since contractions activities need to monitor continuously before upcoming delivery process.

Another method of recording fetal heart rate is displayed as in Figure 6.2, which is called the internal measurement using CTG. This method is different from external monitoring whereas

requires a cervical involves pressure the the fetal fetal



Fetal scalp electrode (FSE), an internal fetal heart rate monitor

Intra-urine pressure catheter (IUPC), an internal contraction monitor

uterine cavity, as well as attaching a scalp electrode to head to adequately measure the electric activity of the heart[3].



## 2.2 Related Types and Model of CTG

This subsection will explain types and models of CTG that are available and have been sold for hospital use in Malaysia. There are various designs and models of CTG that can be used to monitor the condition of fetal and uterine activity before giving birth process as shown in Table 6.1

**Table 6.1:** Related types and model of CTG






List of models of CTG		
		
SONICAID TEAM IP	SONICAID TEAM	PHILIPS AVALON FM20
		
EDAN F9	SONICAID TEAM 3A	

Table 6.2 illustrates a list of the model that has been used in most of the hospital in Malaysia. Various types and models enable users to select the CTG based on their preferences and its specifications. These five models are common models that available in Malaysia. Based on the listing, it can be observed that the CTG model Sonicaid is a major model CTG that has been used in Malaysia. These models have their own lifespan where the maximum years of lifespan that is recommended by manufacturers are 10 years. However, this research work only focuses on two models in Segamat Hospital as displays in Table 6.2.

**Figure 6.2:** Internal recording of FHR [3]

**Table 6.2:** Focus Model on CTG in Segamat Hospital

MODEL	
Sonicaid Team IP	Phillips Avalon FM20



- Manufacturer: Huntleigh Healthcare Ltd
- Origin: United Kingdom
- Lifespan: 11 years 1 months



- Manufacturer: Philips Medical Systems
- Origin: Germany
- Lifespan: 8 years 2 months

By referring to Table 6.2, these studies emphasize two different models of CTG that include Sonicaid Team IP and Philips Avalon FM20. General information and specifications are stated in Table 6.2, where these two models are distributed from different manufacturers. For an instance, Sonicaid Team IP is made in the United Kingdom manufactured in Germany. Also, by considering their lifespan in Team IP has been used in years aback while Philips Avalon

Transducer port

different models of CTG, the equipment considered an illustrious in this study. Also, the model also considered a vital



a) Front panel

while Philips Avalon FM20 these two models selected the hospital where Sonicaid Segamat Hospital for 11 FM20 age is 8 years. Along with the objectives of this assessment to analyse the performance between two lifespan of each piece of important element that needs to be part of the purchase cost of each element in this research.

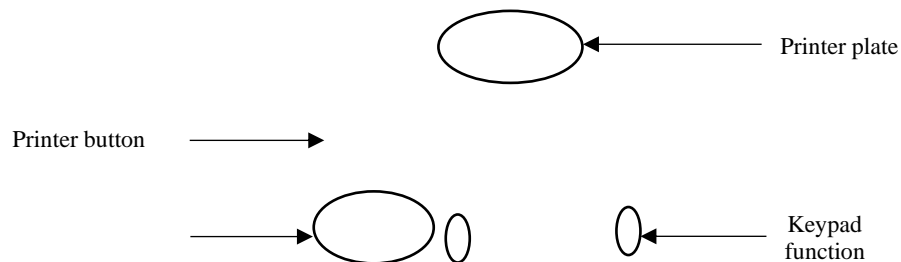
## 2.3 Physical Specifications

This subsection will demonstrate selected CTG model such as Philips Avalon FM20.



## of CTG

the specifications of two Sonicaid Team IP and





**Figure 6.3:** Sonicaid Team IP

Figure 6.3 exemplifies the technical specifications for the CTG model Sonicaid IP. This model was consisting of several parts that are functions to monitor the fetal heart rate and uterine activities during the labour process. This model consists of the main unit where includes the connector for the transducer, main display, and keypad with 8 functional buttons. This model using a manual keypad and does not have a touchscreen system. All the button functions according to the mode that has been set up. In the addition, this model also includes the printer unit so the result from the monitoring process can be recorded since during the third trimester of pregnancy, the doctor keeps the track of the condition fetal heart rate and uterine activity to ensure that the baby and the mothers are in good condition before giving birth process. Also, this model includes the transducers such as an ultrasound transducer to monitor fetal heart rate and a sensitive pressure transducer, called TOCO transducer that functions to track the contractions activity of the uterus before the labour process.

Figure 6.4 demonstrates the physical specifications for CTG model Philips FM20. The layout referred to the operators and service manual that distributed by manufacturer.

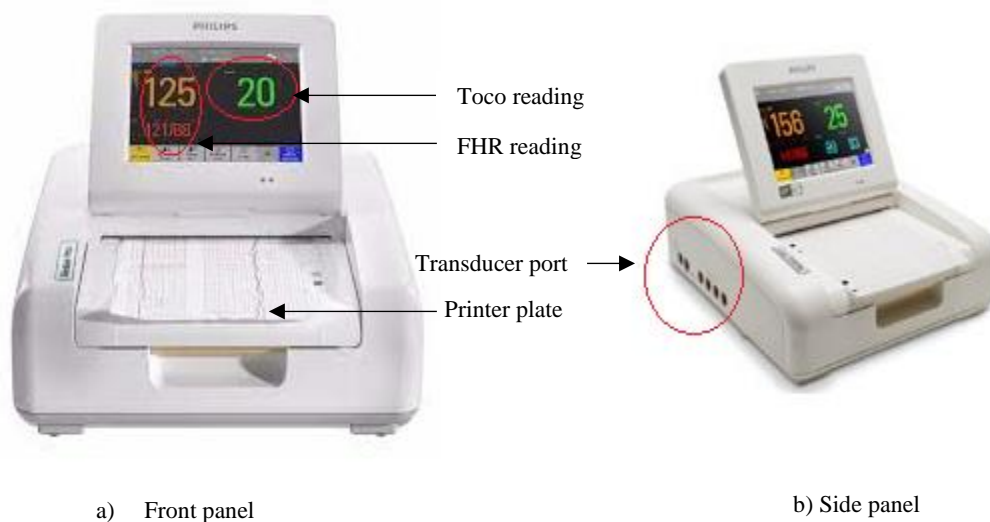
Printer unit

Monitor unit

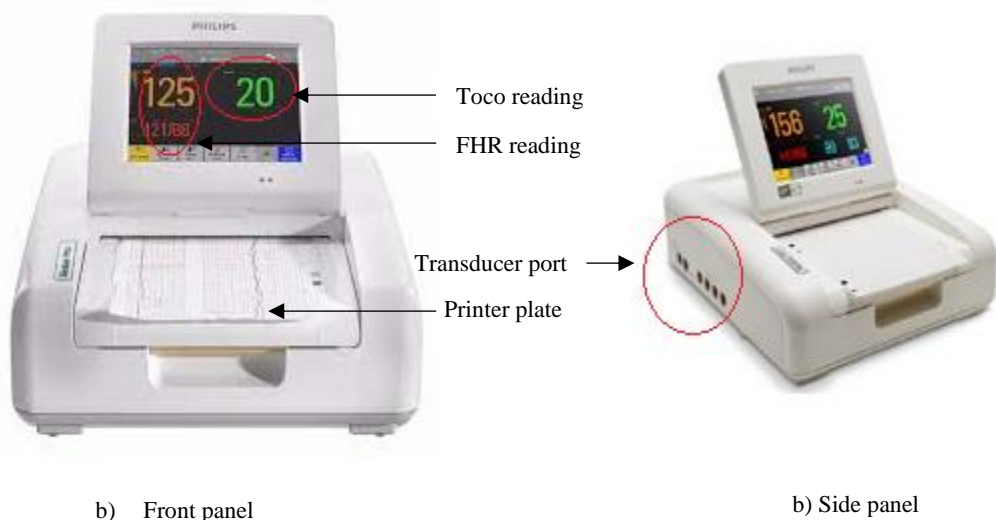
Power cord

Connector  
between printer to  
CTG monitor

b) Back panel



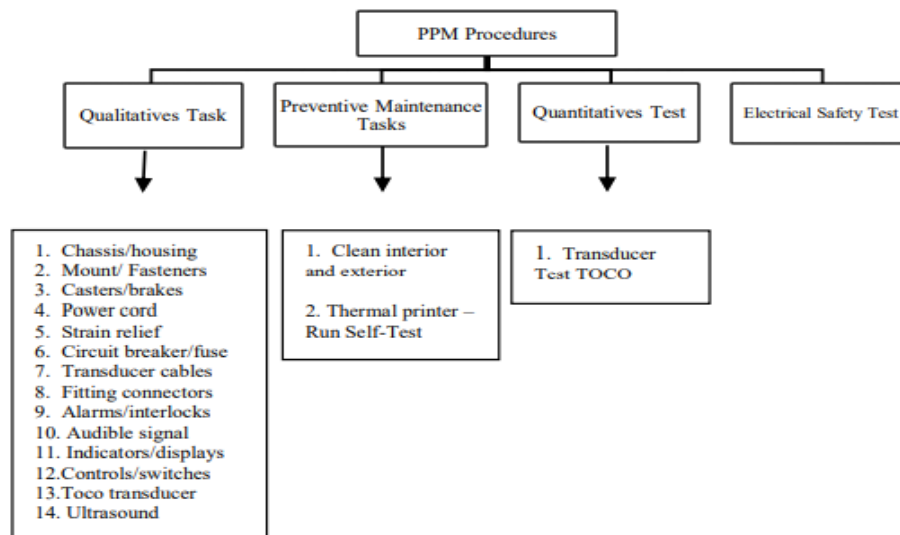
**Figure 6.4:** Philips Avalon FM20 Parts and specifications



**Figure 6.4** illustrates the specifications for the CTG model Philips Avalon FM20. This model has general specifications same as Sonicaid Team IP. However, this model built-in touchscreen technology by replacing the usual display. The lifespan of this model in Segamat Hospital is 8 years 2 months while the Sonicaid Team IP has been used for 11 years 1 month in this hospital. The significance of choosing these two models is to compare the performance of the CTG between two different manufacturers and the specifications of the equipment.

## 2.4 Standard of Procedures for Planned Preventive Maintenance for CTG

This subsection will explain on standard of procedure planned preventive maintenance (PPM) for cardiotocograph. According to [8], SOP is set of steps of step-by-step instructions compiled by an organization to help workers carry out routine operations where this method aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunications and failure to comply with industry regulations. According to [9], this procedure provides more detailed instructions for some tasks that are commonly encountered in the other procedures. Steps of conducting PPM for CTG involved qualitative and quantitative tasks that are required for PPM procedures and can be shown in Figure 6.5



**Figure 6.5:** PPM Procedures and requirement

Hierarchy chart in Figure 6.5 demonstrates on lists of procedures that are compulsory during planned preventive maintenance (PPM) on cardiotocograph. Generally, list of PPM on medical equipment are followed requirement from Ministry of Health (MoH) Malaysia. For each equipment which PPM need to be conducted, there will be a checklist that need to be printed from Central Management Information System (CMIS) by the biomedical staff. All BEMS in all hospital will use this standard checklist to conduct PPM on each equipment. PPM checklists are provided to ensure that scheduled maintenance on the medical equipment is conducted follows all the objectives and prerequisite of the equipment itself. PPM checklist can guide the biomedical staffs on how to check the equipment with the right parameter and make sure that the equipment is well maintained.

From the chart in Figure 6.5, PPM for CTG consists of three main tasks that involves qualitative task, preventive maintenance and quantitative task. Qualitative task consists of visual inspection on the equipment. Meanwhile, quantitative task includes measurement and calibration of the performance test. For an instance, quantitative task for CTG includes the measurement of US and TOCO transducer by using Fetal Simulator Analyzer. Another procedure during PPM on CTG is perform Electrical Safety Test or known as EST which is very important during perform PPM on medical equipment. Furthermore, equipment which failed during EST test will not be used until the problems or breakdown are fixed. User will be notified of the anticipated time of repair. Besides, the equipment which undergone PPM and pass all the test, PPM sticker will be attached on the equipment to display the next PPM date. Then, the checklist of PPM will be verified by user to notify that PPM is perfectly carried out by the technical.

## 2.5 PPM Tools and Analyzer for CTG

This subcategory will discuss on the tools and analyser that is used to perform the PPM. There are two main tools that are used during perform PPM for CTG in analysing the performance of CTG.

### 2.5.1 Fetal Heart Rate Simulator/ CTG Analyzer

displays Fetal Simulator Analyzer that is used to analyse the performance test on CTG. The aimed of using analyser on the CTG is to ensure that CTG that has been used in the hospital are fit in terms of performance based on its technical specifications.



**Figure 6.6:** Fetal Simulator

Analyzer [9]

According to [9], this analyzer simulates fetal and maternal ECG as well as uterine activity to test and troubleshoot fetal electronic or CTG unit. The simulator provides signals to simulate fetal heartbeat by ultrasound as well as by a direct ECG signal and provides signals to simulate uterine activity externally and internally by a strain gauge signal [9]. This simulator can conduct fetal heart rate by external ultrasound sensor, fetal heart rate by direct electrocardiogram (DECG) and maternal heart rate by maternal electrocardiogram.

### 2.5.2 Electrical Safety Analyzer (ESA)

Figure 6.7 shows Electrical Safety Analyzer that is used to analyse the performance electrical safety test on CTG and other medical equipment. Electrical safety test is one of compulsory test that need to carried out during PPM where safety testing ensures the safety of the clinicians, patients or even visitors who may come in contact with any electrical devices.

Electrical safety testing ensures medical equipment (ME) is electrically safety for use in a healthcare environment by testing for breakdown or damage. Medical device safety testing is more stringent when compared with generic electrical devices. Patients are significantly exposed to electrical hazards as they are connected directly to electrical devices.



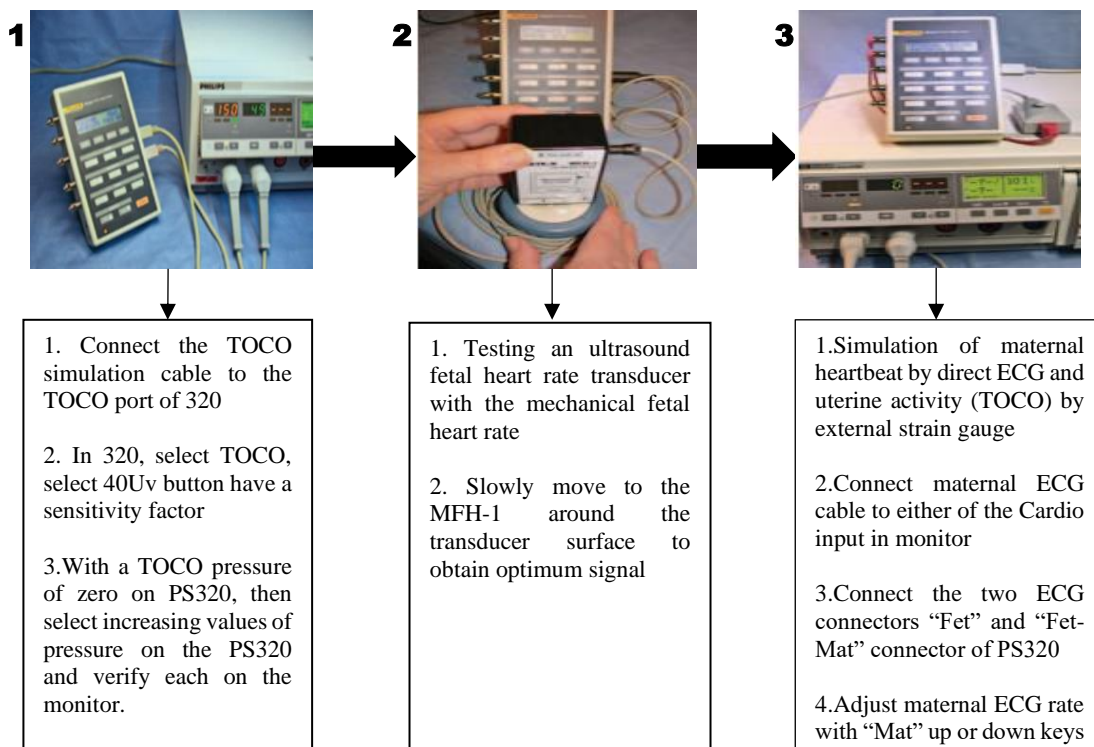


**Figure 6.7:** Electrical Safety Analyzer [10]

Based on the Figure 6.7, EST has also applied part that is classified into different classifications such as type B(body), BF (body floating) and CF (cardiac floating). For CTG, this medical equipment is classified into CF since this equipment connected with the ECG module where ECG is one of cardiac part in the body.

## 2.6 Procedures of Planned Preventive Maintenance on Cardiotocograph

Steps of planned preventive maintenance on cardiotocograph are discuss in this section. There are a few performance tests that are need to carried out to analyse the device performance.



**Figure 6.8:** PPM Procedures for CTG using CTG Analyzer

Block diagram in

**Figure 6.8** demonstrates the procedures and steps during conducted performance tests on CTG by using Fetal Simulator Analyzer or known as CTG analyzer. To start off, the CTG is connected to the analyzer by connect the transducers, US1 and TOCO transducer to the US1 and TOCO port on the side of the analyzer. To perform TOCO test, set up TOCO pressure of zero on the analyzer then select increasing value of pressure and verify the values between the monitor and reading on the analyzer. Second steps in performing performance tests on the CTG is testing ultrasound transducer, US by testing the US with the mechanical fetal heart rate. Slowly move the mechanical fetal heart rate (MFH) around transducer face to obtain the optimum signal of the transducer. These two tests are very important to ensure all the transducer are in good condition to use on the patient.

## 2.7 Common Problems and Solutions

This subsection will explain the common problems and solutions on two models of CTG, Sonicaid Team IP and Philips Avalon FM20. By referring service manual for both models, the general problems that usually occurred are documented in Table 6.3.

**Table 6.3:** Common problems and solutions for CTG

Model	Common Failure	Solutions
<b>Sonicaid Team IP</b>	Team Menu does not appear when switch on	1.Switch the Team unit off 2.Switch ON again, holding [MENU] key 3.Wait for Team unit to beep, then release the [MENU] key
	Team Menu does appear when switch on, but in different language	1.Switch Team unit off. 2.Switch ON again, hold the [/] key. 3.Wait for the Team unit to beep, then release the [/] key.
	During print the result, CTG trace is blank	On Team IP, select which transducer that wish to store. If using yellow transducer, the user needs to selected yellow transducer for storage.
	TOCO channel of the CTG graph is 'scratchy and distorted.	Enabled Actogram and be unaware of the effect it has in trace. Try turning Actogram off the MENU
<b>Philips Avalon FM20</b>	Touchscreen functionality has been temporarily disabled	Check if touchscreen functionality has been disabled (padlock symbol on Main screen key). If yes, press and hold the main screen key to re-enable touchscreen operation.
	The INOP "Check paper" is issued	1.Ensure paper is loaded correctly and close the drawer 2.Clean paper sensor 3.If paper sensor is defective, exchange paper sensor
	Poor print quality	1.Adjust Thermal Printhead setting. Then, run the recorder Self-test to verify correct printing. 2.If Thermal Printhead defective, exchange the Thermal Printhead.

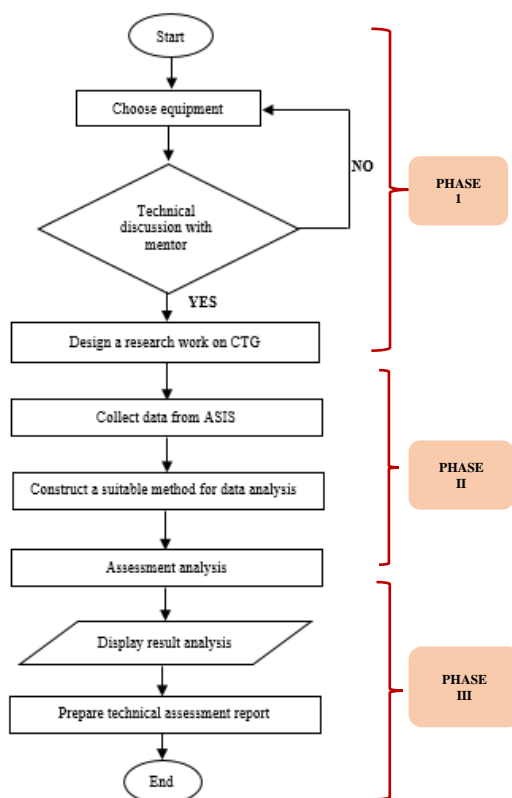
Table 6.3 displays the common problems and solutions that usually occurs on Sonicaid Team IP and Philips Avalon FM20. Common failure and solutions are based on the technical manual that has been documented by the manufacturer.

### 3.0 Methodology

This section will discuss on research methodology that has been carried out through the assessment. The layout of the sections will be divided into several parts of subsections. The major sections are including the progress work on this assessment that consists of flowchart on overall research work. Then, it will be continued with the explanation on the methods that has been used in order to accomplished this technical assessment

#### 3.1 Flowchart of assessment

Figure 6.9 demonstrates the flowchart of the overall progress that are carried out during these studies. There are three phases that are involved in this research along to the objectives that has been stated earlier.



**Figure 6.9:** Flowchart of technical assessment on CTG

Phase I of the flowchart shows the initial procedure that has been carried out where the process of choosing suitable equipment for the assessment. In the addition, technical discussion has been made between the student and mentor to recognize suitable equipment for this research.

For Phase II, the progression carried out on gathering data and information of Sonicaid Team IP and Philips Avalon FM20 from ASIS. Generally, ASIS system stores all the data and equipment information for hospital. Recording data into ASIS is very important to ensure the data of an equipment are being stored for future references. After collecting the data, a suitable method is constructed to analyse all the information for two different types of CTG in Segamat Hospital.

The last phase of the assessment is conducting a technical analysis between both CTG by approaching techniques that consists of comparison between two model in order to evaluate one of best CTG that recommended for hospital use. The research then continued by performing analysis into graphic view and prepared full technical assessment report on these studies.

#### 3.2 Method of Analysis

This section will illustrate on the methodology on how to collect data and analyse the data that obtained from the system for Sonicaid Team IP and Philips Avalon FM20 in Segamat Hospital.

##### 3.2.1 Data collection

Since in Segamat Hospital using ASIS system to record the data for all medical equipment, the process of collecting data can be easier for technical team and engineer to review the condition of the equipment during their lifespan.

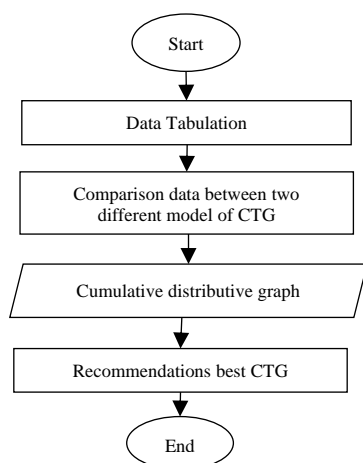


**Figure 6.10:** ASIS system

Figure 6.10 represents Asset and Services Information System that has been used in Government Hospital in Malaysia. This system is monitored under Ministry of Health and this system is a formal site for medical officer and technical team in hospital.

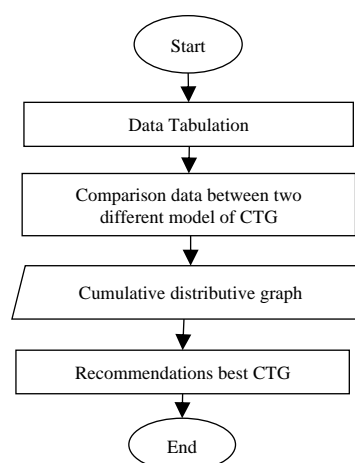
### 3.2.2 Data Analysis

Data analysis is conducted after collecting the information from the system. Figure 6.11 demonstrates on the flowchart on how to analyse all the data that have been obtained.



**Figure 6.11:** Flowchart on how to analyse all the data that have been obtained.

Based on Data analysis is conducted after collecting the information from the system. Figure 6.11 demonstrates on the flowchart on how to analyse all the data that have been obtained.



**Figure 6.11:** Flowchart on how to analyse all the data that have been obtained.

Based on Figure 6.11, the methodology on how to analyse data consists of a few steps and procedures that need to follow. Starting with the data tabulation between two types of CTG model, which is Sonicaid Team IP and Philips Avalon FM20. Table 6.4 exemplifies on the data tabulation sample method for this research work.

**Table 6.4:** Data tabulation of CTG model

No Tag	
Maintenance Work No.	
Work Category	
Type	
Total Downtime	
Total Cost (RM)	
Action Taken	

Table 6.4 shows the tabulation of data based on two different types of model CTG that has been chosen for this research work. Tabulation of data in Excel consists of work category, total maintenance and common problems and solutions for the breakdown for each equipment. This method is compulsory in order to organize and sort out information that obtained from raw data in the system.

Besides, research work then continued with the comparison between two model of CTG to analyse the performance of each model during their lifespan. Along to the table that has been constructed, equipment performance can be analysed by using comparison method of two model that consists a few aspects in terms of parameters that will be measured and specifications of each model of CTG.

**Table 6.5:** Performance analysis on CTG

No	Parameter	Sonicaid	Phillips
1	Type of failure		
2	Rate of failure		
3	Rate of usage		
4	Downtime cost		

Table 6.5 illustrates on how performance of each model is conducted by using comparison method. For this method, parameters based on technical requirement is measured. This method is to perform an analysis on each equipment and to discover pros and cons between the two models in the hospitals. The significance of constructing all the methodology is to recommend the best CTG for hospital based on technical research on this assessment.

#### 4.0 Assessment Analysis

This section will discuss on the assessment analysis that has been carried out for this research work. Therefore, this study includes 4 units of CTG which consists of 2 units from each model that has been used in Segamat Hospital. The layout of this section is divided into several subsections that illustrates on the method of analysis for this project.

##### 4.1 Collection data and table of comparison

This subsection will display the data analysis for two model of CTG in Segamat Hospital. Table of comparison consists several parameters that has been chosen for this research work as shown in Table 6.6.

**Table 6.6:** Data collection table.

Model		Sonicaid	Phillips
Item			
1	Total breakdown in 5 years	44	57
2	Downtime (hours/min)	5027.44	12680.20
3	Repair cost	5996.08	52502.90

Table 6.6 represents the collection of data from 2 units of each model in Segamat Hospital. The table consists of technical analysis to evaluate the performance of each model in 5 years past starting from 2015 to 2020. Generally, the maximum lifespan of CTG that is

recommended from manufacturer is within 10 years of usage. The parameters that are measured consists of unscheduled maintenance which is total breakdown of the equipment in 5 years past, total downtime hours during the maintenance and total downtime repairs for each model.

**Table 6.7:** Type of failure comparison

Model		Sonicaid	Phillips
Breakdown			
1	US faulty	2	5
2	TOCO faulty	4	4
3	Printer	1	4
4	LCD display	3	12

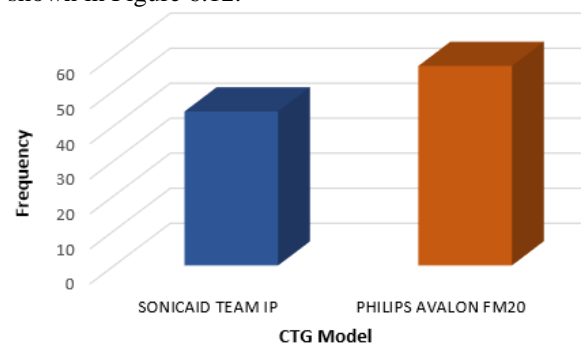
In the addition, Table 6.7 shows the comparison for types of failure that has been documented in the system. These types of failure are common problems that occur during unscheduled maintenance for these two models of CTG in Segamat Hospital. The types of failure consist of ultrasound transducer or known as US transducer faulty, TOCO transducer faulty, thermal printer faulty and LCD display for monitoring.

#### 4.2 Graphical Analysis

Graphical analysis for parameters that are tabulated in Table 6.6 are explained in this section where the data of the total breakdown, types of failure, total downtime repair cost and total downtime hours for two CTG will be analysed.

##### 4.2.1 Total breakdown between two model of CTG

Analysis for total breakdown for past 5 years is shown in Figure 6.12.

**Figure 6.12:** Total breakdown for past 5 years

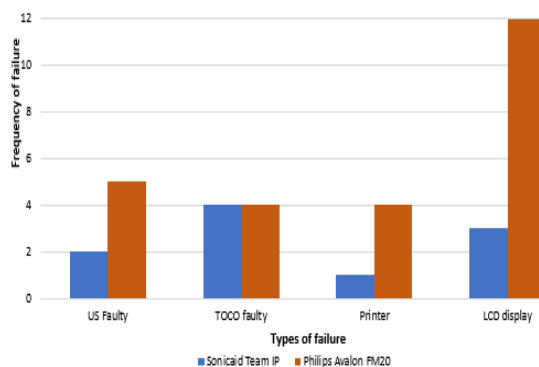
The data of unscheduled maintenance that has been carried out for last 5 years is illustrated in Figure 6.12 The frequency of data showed that the total breakdown for CTG model Philips Avalon FM20 is higher than Sonicaid model which CTG Philips recorded 57 of total breakdown while Sonicaid only recorded 44 of breakdown.

$$\% \text{ Relative error} = \frac{(F_{\text{total}} - F_{\text{measured}})}{F_{\text{total}}} \times 100\%$$

$$\begin{aligned} \% \text{ Relative error for frequency breakdown} \\ &= \frac{(101 - 57)}{101} \times 100\% \\ &= 43.56\% \end{aligned}$$

The frequency showed the percentage of breakdown for Philips CTG is 43.56% more than Sonicaid Team IP. The percentage can be calculated by using relative error percentage formula that has been stated above. Types of failure between two model of CTG

Figure 6.13 demonstrated the data analysis on types of failure between two Sonicaid Team IP and Philips Avalon FM20 in past 5 years.



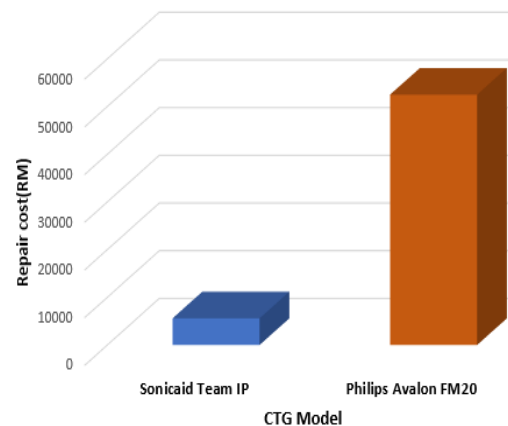
**Figure 6.13:** Types of failures

Based on the observation that has been carried out, there are 4 common problems that always occur during the breakdown for these two models of CTG. Ultrasound transducer or known as US transducer and TOCO transducer is two main common problems that has been recorded where for US faulty, frequency of failure for CTG Philips is higher than Sonicaid. This can be observed from the graph in Figure 6.13, where Philips CTG recorded 5 amounts of frequency of

US failure while Sonicaid CTG only recorded 2 failures in past 5 years. The summarization from the data displayed that Philips printer faulty calculated greater than Sonicaid Team IP printer. Also, for LCD display faulty, Philips CTG documented the amount of frequency higher than Sonicaid CTG. Since Philips Avalon FM20 built in touchscreen design, the amount of failure also affected where touchscreen display is more sensitive and need a proper usage and maintenance by the user.

## 4.2.2 Total downtime repair analysis

Figure 6.14: Total downtime repair demonstrated data analysis on total downtime repair cost that has been laboured on these two models of CTG in past 5 years.



**Figure 6.14:** Total downtime repair

Based on the Figure 6.14, the total of repair cost also calculated in order to investigate the performance of each model as shown in Figure 6.14. The result from the graph proven that Philips Avalon FM20 cost for its maintenance is RM52502.90 while downtime repair cost for Sonicaid Team IP only RM5596.06. The differences of the repair cost might be included the price for spare part for each model.

$$\begin{aligned} \% \text{ Relative error for frequency breakdown} \\ &= \frac{(58600 - 53000)}{58600} \times 100\% \end{aligned}$$

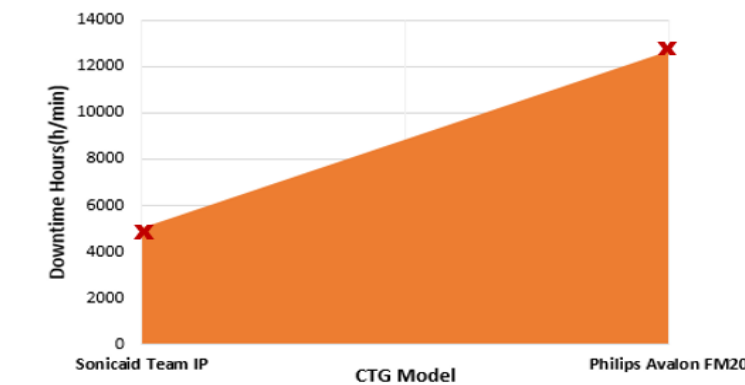


$$= 9.5\%$$

In the addition, the differences of the maintenance costs can be calculated by using percentage of relative error where the calculation shows that Philips Avalon FM20 has 9.5% higher than Sonicaid Team IP. The increasing of the maintenance cost for CTG model Philips Avalon FM20 influenced by the price of the spare part that has been replaced especially the LCD display for the monitor. The sensitivity of the touchscreen and improper usage by user affected the maintenance cost for this model.

### 4.2.3 Total downtime hour analysis

Figure 6.15 stated the downtime hours during maintenance for both models, Sonicaid Team IP and Philips Avalon FM20.



**Figure 6.15:** Total downtime hours during breakdown

Based on the result has been measured, it can be concluded that the total downtime hours for CTG Philips is greater than Sonicaid Team IP. The total time for Sonicaid is 5027.44 h/min while the total downtime hours for Philips Avalon FM20 is 12 680.95 h/min. All the results for downtime hours are calculated starting from the work order is published for unscheduled maintenance in ASIS until the work done and were closed into the ASIS system.

### 4.3 Discussions

From the research work that has been carried out, there are several findings that can be analysed. From the data analysis given, there are many factors that can influence the result and the value of the maintenance cost. Firstly, the price of the spare part of each model. According to [4], the price for 1 unit US transducer is around RM5K to RM6K. Costly spare parts affect the maintenance cost of CTG models especially the Philips Avalon FM20 as this model recorded 5 times of replacement US transducer rather than Sonicaid Team IP.

Furthermore, the findings of this assessment showed that CTG model Philips Avalon FM20 repetitively replaced their LCD display and also affect their performance. Since this model used touchscreen technology, it can be concluded that this model is high sensitivity different to Sonicaid Team IP. For an instance, in 5 years a back, CTG model Philips documented 12 breakdowns on LCD display instead of Sonicaid that only recorded only 3 times of breakdown in 5 years a back. The percentage of relative error based on the total rate of failure and total maintenance cost on Philips Avalon FM20 proved that this model has high rate of maintenance and can give a disadvantage to the technical team and management in order to balance the financial cost during their breakdown.

### 5.0 Conclusion

To be concluded, this technical assessment enable student to design a research work on the types of CTG that has been used in Segamat Hospital. In particular, CTG is one of important equipment in the hospital that used in labour room during giving birth process. Furthermore, comparison between two models in terms of its types and specifications helps biomedical technical team to analyse the most reliable model that can be used and recommend to the hospital. Last but not least, the common problems and failure for both CTG model has been analysed and the result from the analysis is satisfied according to the objectives of this assessment.

## 6.0 Recommendations

For recommendations, this assessment proved that CTG model Sonicaid Team IP is more reliable model to use in the hospital rather than CTG model Philips Avalon FM20 based on the result from the technical analysis given. This can be observed from the data that shows Sonicaid history maintenance least than Philips Avalon FM20. The recommendations of this model consider a few aspects where Sonicaid purchase cost much cheaper than Philips Avalon FM20. This reason can give more benefits towards hospital management to cut their financial and it will be good for them since return of investment for Sonicaid is high. Last but not least, based on the analysis that has been conducted through the research, it can be recommended that Sonicaid performance shows a smaller number of breakdown although the lifespan of this model is longer than CTG model Philips Avalon FM20. The fewer number of breakdown maintenance will give a lot of benefit to the management since its indirectly saving cost of maintenance that need to be spent to troubleshoot the equipment.

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# DIALYZER REPROCESSING UNIT

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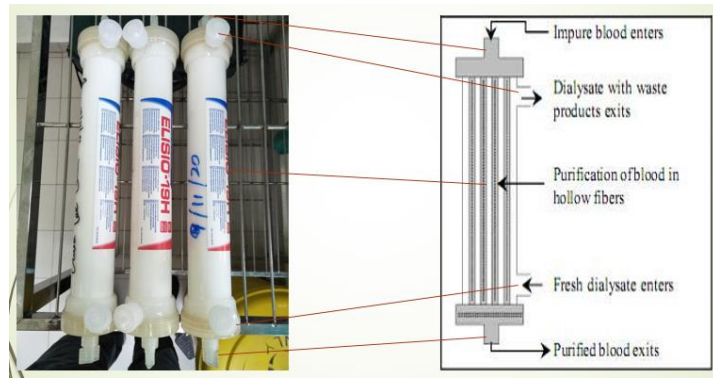
**Abstract**— The practice of reprocessing and reusing hemodialyzers can be traced to the very origins of chronic haemodialysis. The basic process associated with the reuse of hemodialyzers remains the same after over 50 years of practice: upon completion of a dialysis treatment the used dialyzer is cleaned, tested for efficacy and integrity, high-level disinfected or sterilized, and stored in a controlled environment for subsequent use. Reprocessing can be performed manually or by automated reprocessing systems. Automated systems provide control and consistency to the process. Commonly used chemical disinfectants and sterilants include formaldehyde, and peracetic acid. A dialyzer is often referred to as an “artificial kidney.” Its function is to remove the excess wastes and fluid from the blood, when the patient’s kidneys can no longer perform that task. Reprocessing dialyzer machines have been used worldwide for economic advantage improvement in blood-dialyzer membrane biocompatibility, and benefits of preventing the first-use syndrome which is an anaphylactoid reaction to the dialysis membrane causing wide-range of symptoms including cardiac arrest. The machines have helped shorten the period of cleaning, leak testing, and sterilant filling. Performance indices can be measured by total cell volume (TCV) measurement. It is suggested that a dialyzer is suitable for reuse only when a TCV value is at least at 80% of the baseline. Advantages associated with dialyzer reuse include economic, efficacy and environmental returns while disadvantages include possible increased infections, exposure to chemical agents, development of antibodies and changes in dialyzer performance. The aim of this technical report is to study and analyse the different models of dialyzer reprocessing unit. Moreover, it is also to identify the problems in both models of dialyzer reprocessing unit and explaining the methods to carry out investigation and analysing the different models in use. Based on assessment and analysis done on two models, it can be recommended Alcavis Maky 21.1 is the best dialyzer unit used in hospital since 2017.

**Keywords**- dialyzer, reprocessing, sterilant, total cell volume (TCV), economics

## 1.0 Introduction

Patient on haemodialysis are often surprised to learn that the complex dialysis machine next to them isn’t the device that’s cleaning their blood of excess wastes and fluid. Instead, a filter, called a dialyzer that is encased in plastic and inserted into a holder on the front or side of the dialysis machine, is actually doing the work of cleaning the blood. The dialysis machine supports the work of the dialyzer with pumps, heaters, safety monitors and alarms.

Dialyzer reuse has been practiced in the United States since the early 1960s. Patients who choose to reuse their dialyzers are given an individual dialyzer that they will continue to use for the number of times specified by their doctor or until it is no longer efficient. Patients do not “share” dialyzers; each patient has his or her own.



**Figure 7.1:** Types of dialyzer and the functions of each parts

Dialyzer reuse has been practiced in the United States since the early 1960s. Patients who choose to reuse their dialyzers are given an individual dialyzer that they will continue to use for the number of times specified by their doctor or until it is no longer efficient. Patients do not “share” dialyzers; each patient has his or her own.

A dialyzer is often referred to as an “artificial kidney.” Its function is to remove the excess wastes and fluid from the blood, when the patient’s kidneys can no longer perform that task. Dialyzers are made of a thin, fibrous material. The fibres form a semipermeable membrane, which allows smaller particles and liquids to pass through. The dialyzer is encased in a sealed plastic cylinder about a foot long and approximately two to three inches in diameter with openings at the top and bottom. During treatment dialysate (dialysis solution) and your blood flow through the dialyzer (but they never touch). Fresh dialysate from the machine enters your dialyzer through one opening and blood enters through the other. Wastes are filtered out of your blood into the dialysate. Dialysate containing waste products leaves the dialyzer and is washed down the drain, while the cleaned blood goes back into your body [1].

There are different sizes of dialyzers. These sizes are related to the blood volume that will go through them, which depends on the patient’s size and weight. Your kidney doctor will prescribe the right-sized dialyzer for you.

Dialyzers can remain functional after more than one use, which is why many facilities reuse them. Dialyzers are reused for a certain number

of times or until it no longer works efficiently, whichever comes first. Each doctor sets his or her own policy for the maximum number of reuses. Some dialysis facilities do not reuse dialyzers, and patients at those facilities are given new dialyzers for each haemodialysis session [2].

Patients are given the choice of whether or not to reuse their dialyzers. Facilities that reuse must follow strict guidelines to ensure the reused dialyzers are labelled with the patient’s name, cleaned properly, sterilized and working so the patient can have an optimal dialysis treatment

## 2.0 Principle of Operation

Patients only reuse their own dialyzer, meaning that no other patient has or will ever use it. Dialyzers are never shared between patients. After your dialysis session is complete, a facility member (either your renal nurse or a patient care technician) will take you off the dialysis machine and seal your dialyzer, which is labelled with your name, in a plastic bag. The dialyzer is then sent to a reuse technician who will follow strict procedures to make sure your dialyzer is clean, sterile and in good working condition before you use it again [3].

### 2.1 How is reused performed?

The reuse technician will first do a visual inspection of the dialyzer for blood or fibre clots. The technician will also note the number of times the dialyzer has been used. If the dialyzer is due to be replaced, the technician will replace it with



a new one in the size prescribed by the physician. If the dialyzer can be reused, the technician will place it into the reuse machine to start the cleaning process. The reuse machine cleans the dialyzer using water treated with reverse osmosis. This water is highly purified and cleans the dialyzer without leaving traces of particles and chemicals [4].

**1. Reprocessing** – After treatment is finished, dialyzer is cleaned, tested and then filled with a sterilant (Renalin). The machine performs a pressure test and blood volume test

a. During the cleaning phase, any blood that remains in your dialyzer at the end of treatment is flushed out of the fibres.

b. A volume test is performed on the dialyzer to ensure that the fibres that carry the blood are open and not clotted off. If your dialyzer fails the volume test, it will be thrown away, and a new dialyzer will be pre-processed for your next treatment. The blood volume test ensures that the dialyzer's capacity is above 80% of the dialyzer's stated size. If there are any holes in the dialyzer, or if the blood volume is less than 80% of the dialyzer's size, it is replaced with a new one. If any problems are detected during the reuse test, the reuse machine indicators let the reuse technician know, and the dialyzer is disposed of in the proper manner.

c. A pressure test is performed on the dialyzer to ensure that the fibres that carry the blood are not broken. If your dialyzer fails the pressure test, it will be thrown away, and a new dialyzer will be pre-processed for your next treatment.

After the reuse machine has cleaned and tested the dialyzer, it will then be filled with disinfectant and stored for at least 11 hours. Just before the patient's next dialysis treatment, the dialyzer is rinsed with saline solution until all disinfectant is removed. A test is performed to make sure no disinfectant is left in the dialyzer. Once it is tested, the dialyzer is ready to use for the dialysis treatment [3] [4].

**2. Inspection** – After dialyzer is reprocessed, the reuse technician will visually inspect dialyzer

and check for the following: a. Confirm that the level (volume) of sterilant (Renalin) in the dialyzer is sufficient b. Confirm that the blood and dialysate ports on dialyzer are capped and not leaking. c. Check that the dialyzer is not damaged or leaking. d. Confirm that both the inside and outside of dialyzer look clean.

**3. Labelling** – After passing the inspection, the technician will place a new information label on dialyzer. The label will show: a. Patient name. b. Number of times patient have used dialyzer. c. Date and time dialyzer was last reprocessed. d. Initials of the person who reprocessed the dialyzer.

**4. Storage** – After dialyzer is reprocessed, inspected and labelled, the technician will store your dialyzer in a clean and safe area until it is time for you to use it again.

**5. Inspection and presence testing** – Before dialyzer is prepared for use, the dialysis staff must inspect dialyzer AGAIN and test the dialyzer for the following:

a. Verify that the sterilant (Renalin) was in dialyzer for the correct amount of time.

b. Confirm that the level (volume) of sterilant (Renalin) in the dialyzer is sufficient.

c. Confirm that the dialyzer is properly labelled and that it passed all the tests when it was reprocessed. Patient name must also be printed clearly and correctly on the dialyzer.

d. Make sure that the blood and dialysate ports are capped and that no fluid is leaking from the dialyzer.

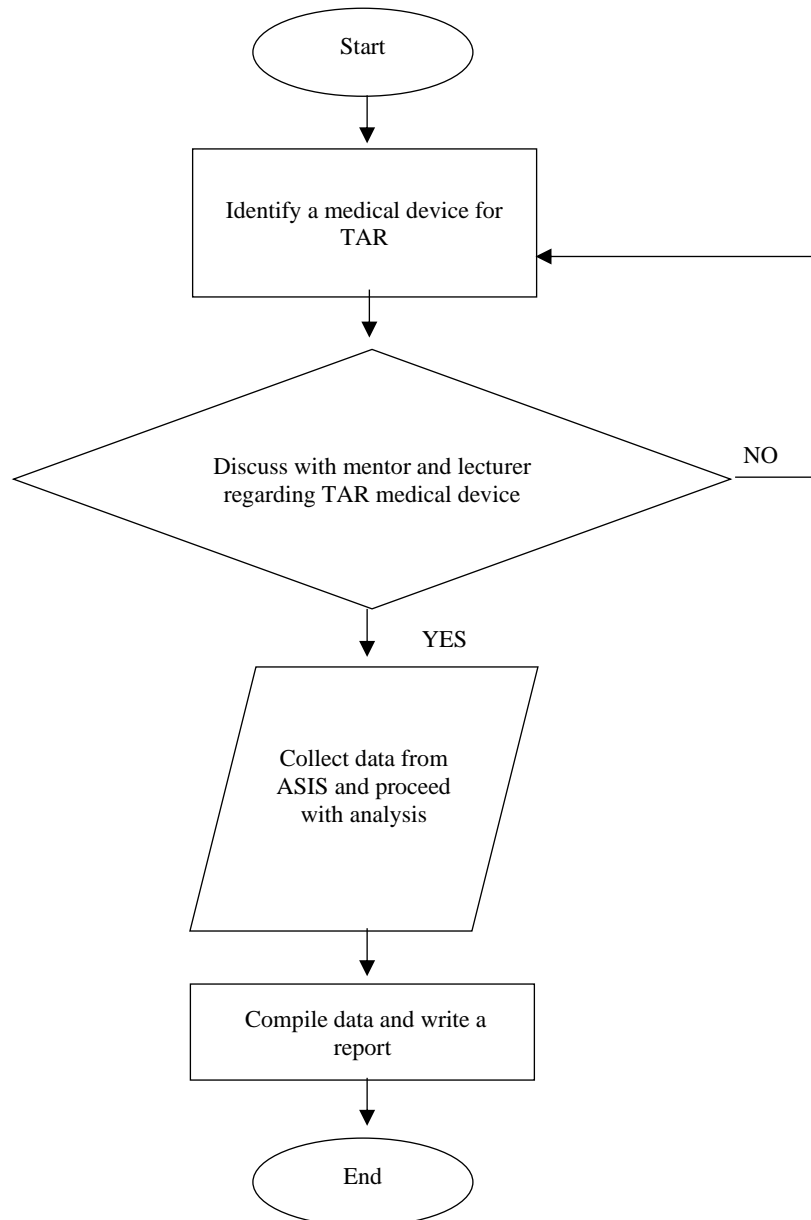
**6. Rinsing and residual testing** – Before treatment begins, the staff must rinse the sterilant (Renalin) from the dialyzer and then perform a residual test to confirm that the sterilant (Renalin) has been rinsed out.

**7. Post treatment** – When the treatment is completed, dialyzer will be capped and sent to the dialyzer reprocessing room. The dialyzer will be reprocessed, and the cycle will be repeated [5]

### 3.0 Methodology

This chapter outlines the methodology of the research of two different model of dialyzer reprocessing unit. There are two different model which are Renatron 100 series and Alcavis Maky 211. The study of this assessment includes the specifications and design of the machines and the common problem happen during corrective maintenance in both different model of dialyzer reprocessing unit.

The progress of this research is shown in Error! Reference source not found.. Need analysis is conducted in order to determine the common problems in two different model of dialyzer reprocessing unit. Moreover, more data are collected in ASIS platform in order to carry out this analysis. Furthermore, I also seek some advices from my mentor and also did some reviewing before I presented here in this report.



**Figure 7.2:** Flowchart process of preparing TAR

### 3.1 Methodology of Assessment

There are 2 types of dialyzer reprocessing unit that being used in Hospital Muar. The first model is Renatron PA 100 /100 series, manufactured by Minntech Corporation, US. Moreover, the second model is Alcavis HDC Maky 21.1, manufactured by Angelini Pharma Inc, US. There are few other brands of dialyzer reprocessing unit in the market with better specifications at variant price. Figure 7.3 shows Renatron PA 100 series. This machine used at haemodialysis unit and there are total of 3 units in used.



**Figure 7.3:** Renatron PA 100 series

Based on Error! Reference source not found., there are three units used in haemodialysis unit in Hospital Muar. The machines started operate since 2006 and until now. Whereas for Maky 21.1 have 2 units and the machines are latest which been using since 2017

Figure 7.4 shows Alcavis HDC Maky 21.1. This machine used at haemodialysis unit and there are total of 2 units in used.

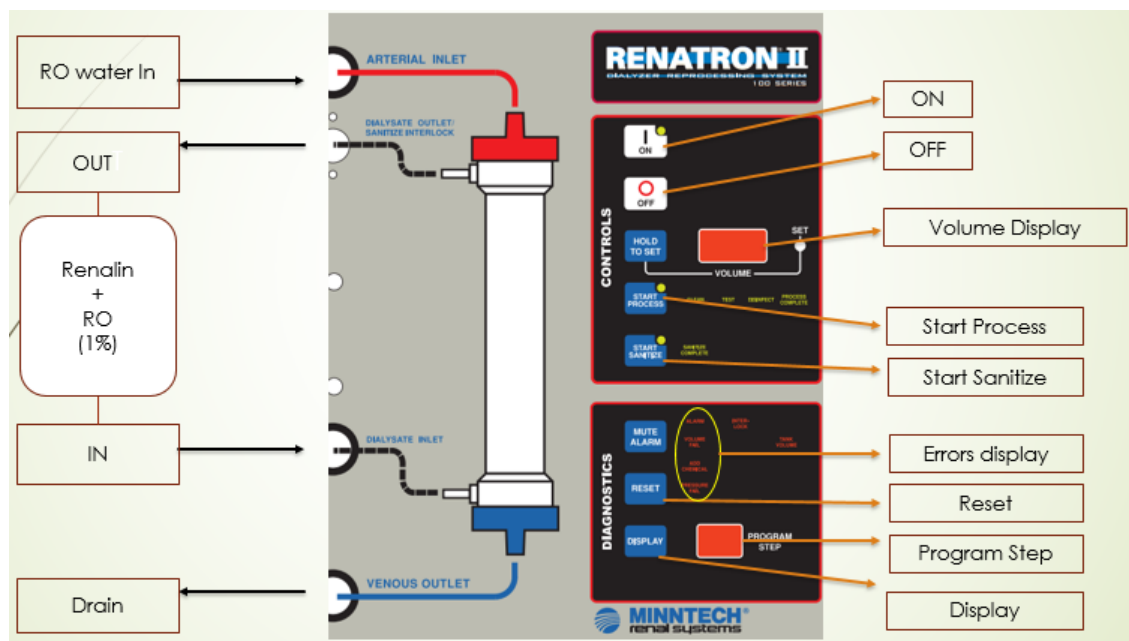


**Figure 7.4:** Alcavis HDC Maky 21.1

Based on **Figure 7.4** , there are two units used in haemodialysis unit in Hospital Muar. Both machines started operate since 2017 and until now. Whereas for Renatron PA 100 series have 3 units and some of the machines are old from year 2006, latest which is on 2014.

### 3.2 Physical Layout and Specifications

Renatron PA 100 Series Dialyzer Reprocessing Station with Selectable Programs (for Standard, High Efficiency and High Flux Dialyzers). Station includes drip tray and inlet pressure gauge. Key component of the Renatron PA 100 Series System, an automated dialyzer reprocessing system designed for the international market. Error! Reference source not found. shows the physical layout of Renatron PA 100 s eries labelled with features of each button.



**Figure 7.5:** Physical layout of Renatron PA 100 series

Based on Figure 7.5 there are some specifications in Renatron PA 100 series as below: -

Automated Reprocessing Cycle

Venous Line Clamp - Secure venous outlet line

Colour coding - Provides visual cues to dialyzer orientation

Header Integrity Test (select units) - Diagnostic test to verify that the header is on securely with O-ring in place

Failed Volume Test - Limits the number of volume retests to two

Culture Sample Cycle - Separate cycle for ease of taking water samples

Dedicated Clean/Rinse Cycle - Aggressive Formula 409® cycle for heavily deposited lines and machines

**Table 7.1:** Specifications of Renatron PA 100 series model dialyzer reprocessing unit

Specifications	
Weight	22.7kg
Size	W 14.5 inches x D 12.3 inches x H 16 inches
Fuses	100-120 VAC, one 4A 3AG (1.25 inches x 0.25 inches) 220-240 VAC, two T2A (5mm x 20mm)
Power Supply Voltage	460 VA maximum
Type	B
Class	1
Price per unit	RM 26 500.00

Based on table 7.1 Error! Reference source not found. this is manufacturing given specifications for Renatron PA 100 series. The weight slightly heavier than Maky 21.1 which is 22.7kg. However, the size of Renatron is smaller than Alcavis 21.1. Both have same power supply voltage which is 460 VA maximum. Both Renatron and Maky 21.1 are classified as class 1 and type B. Then, the price per unit for Renatron is RM26 500 which is consider cheaper than Maky 21.1. Figure 7.6 shows the physical layout of Maky 21.1.

**Figure 7.6:** Physical layout of Maky 21.1

Based on Figure 7.6, The MAKY 21.1 Dialyzer Reprocessing System holds the 510K since September 26, 2003. It has nine (9) operating programs that can be employed as a semiautomatic or completely automated system, linking as many MAKY's together (maximum 9) as required to function in large facilities or centralized reprocessing centres. The programs are "standard, high efficiency and high flux." Each of those offers an extended cleaning cycle, if it is determined that a dialyzer requires extra effort to clean. The other three (3) programs are available for the medical director to employ as he chooses, but specifically in anticipation of the availability of hemodiafilters, which have a port for fluid replacement, that may require significant alterations in the approach to reprocessing.

**Table 7.2:** Specifications of Maky 21.1 model dialyzer reprocessing unit

Specifications	
Weight	18 kg
Size	17" (43.18cm) W x 23" (58.42cm) H x 17" (43.18cm)
Fuses	100-120 VAC, one 4A 3AG (1.25 inches x 0.25 inches) 220-240 VAC, two T2A
Power Supply Voltage	460 VA maximum
Type	B
Class	1
Price per unit	RM 33 000.00

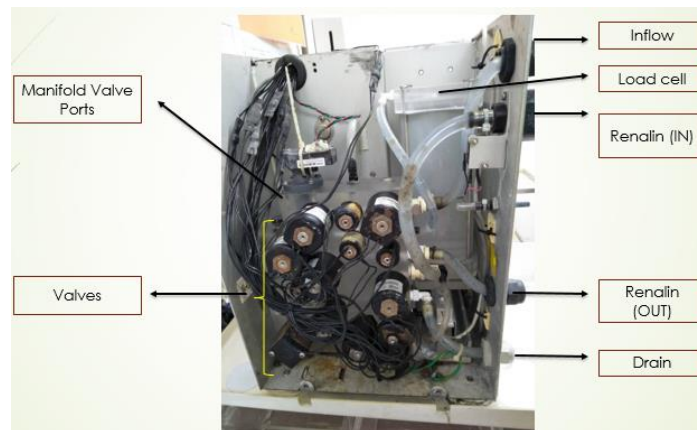
Based on Table 7.2, this is manufacturing given specifications for Alcavis Maky 21.1. The weight slightly lighter than Renatron 100 series which is 18kg. However, the size of Maky 21.1 is bigger than Renatron 100 series Both have same power supply voltage which is 460 VA maximum. Both Maky 21.1 and Renatron 100 series are classified as class 1 and type B. Then, the price per unit for Maky 21.1 is RM33000 which is consider expensive than Renatron 100 series.

### 3.3 Hardware Components

Both Renatron PA 100 series and Maky 21.1 have manifold valves that control the movement of RO water and chemical disinfect in and out of the machine. They also use the aggressive reprocessing system. It uses dynamic procedures to clean the dialyzers. The agitation used will be noted during the HPAP process. HPAP stands for Hydro-Pneumatic Agitation Process.

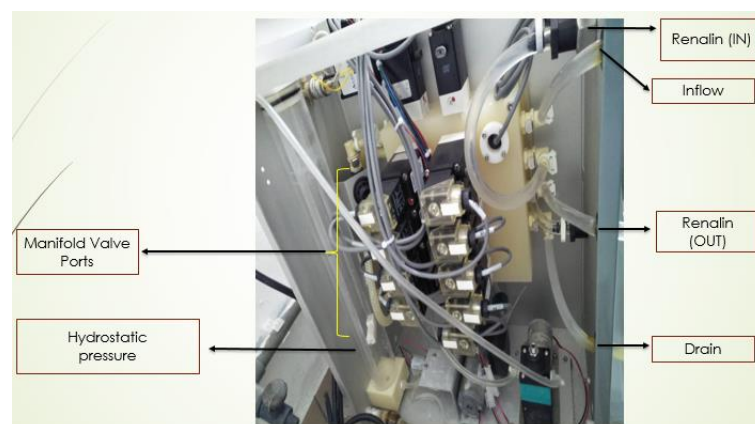
In Renatron PA 100 series, it uses the load cell calibration in order to measure the total cell volume of the dialyzer. Whereas, in Maky 21.1 it uses Hydrostatic Pressure, thus no-load cell is needed. If the test fails the MAKY will repeat it one more time automatically. If it still fails, it will give the option to Preclean, Reprocess the Dialyzer again, Repeat the Test or Discard the Dialyzer. Both load cell and hydrostatic pressure used in Renatron PA 100 series and Maky 21.1 are to measure the total volume cell (TCV) where TCV must be above 80% of the stated size dialyzer.

Figure 7.7 shows the internal components of Renatron PA 100 series. The components consist of manifold valve ports and solenoid valves, one load cell and dc pump.



**Figure 7.7:** Internal components of Renatron PA 100 series

Based on Figure 7.7, this machine consists of 12 solenoid valves which used to close, open, dose, distribute liquid in a pipe. The specific purpose of a solenoid valve is expressed by its circuit function. Moreover, it also consists of load cell to measure the TCV of dialyzer during process.



**Figure 7.8:** Internal components of Maky 21.1

Based on Figure 7.8, this machine consists of 10 solenoid valves which used to close, open, dose, distribute liquid in a pipe. The specific purpose of a solenoid valve is expressed by its circuit function.



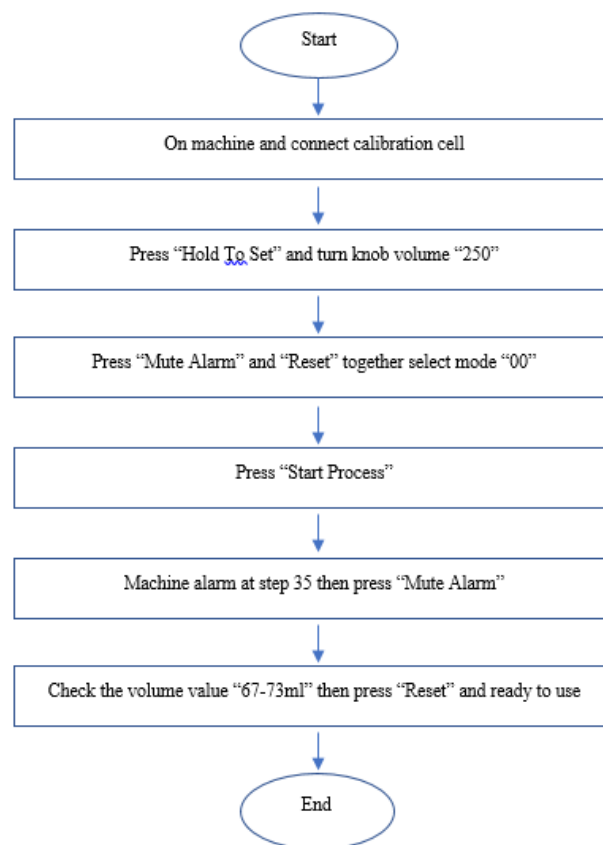
Moreover, this machine has no load cell but it used hydrostatic pressure to measure the TCV of dialyzer during process.

### 3.4 Calibration procedure

The calibration procedure for these two models is different from each other. These calibrations need to be conducted every day in order to maintain good condition for the machines.

#### Renatron PA 100 series

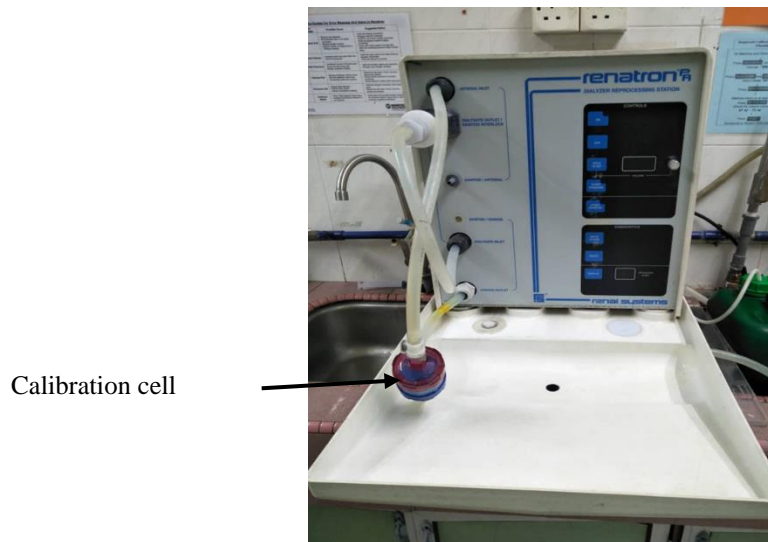
For Renatron PA 100 series, the calibration procedure carries out once a day every morning before start doing reprocessing procedure. In order to do the calibration procedure, must use calibration cell. Calibration cell act as the dialyzer where it can measure the total cell volume (TCV). Error! Reference s ource not found. shows the flow chart of calibration procedure.



**Figure 7.9:** Flow chart of calibration procedure

Based on the Figure 7.9, the calibration procedure of Renatron PA 100 series starting with ON the machine and connect the calibration cell. The calibration cell act as dialyzer. Then follow the steps according to the flow chart and lastly the result must be in 67-73ml. If didn't get the result, must redo the calibration until get the result that needed.

Figure 7.10 shows the calibration procedure of Renatron PA 100 series.



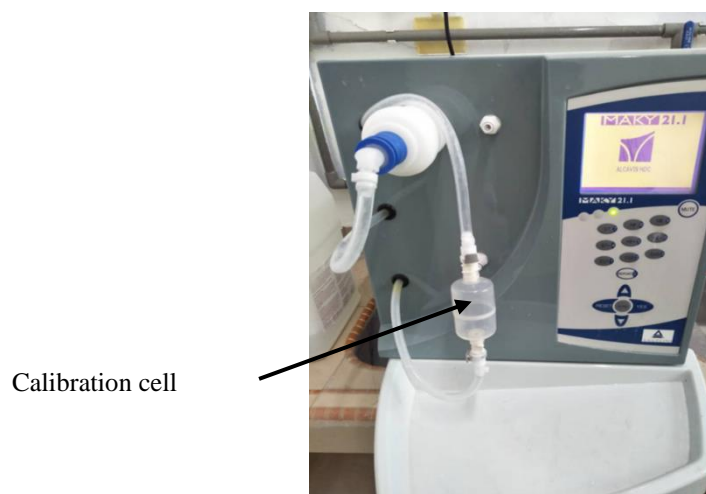
**Figure 7.10:** Calibration procedure (Renatron PA 100 series)

Based on Figure 7.10, before do the calibration procedure must connect the calibration cell. The calibration cell act as dialyzer where it used to measure the total cell volume (TCV) of dialyzer during the process. This calibration must conduct every morning before starts reprocessing procedure.

#### **Maky 21.1**

This option will determine the original (first) TCV. This value will be used as the 100% value for future comparison. Dialyzer pre-processing also serves to wash out any manufacturing residue in the dialyzer, the presence of which may contribute to “first use syndrome” which ranges from reactions to discomfort. The pre-processed dialyzer may be linked to a specific patient during this same procedure. The pre-process option is only available when the database is being used. When the database is not used, selecting this option will have no effect.

Below here Error! Reference source not found., shows the calibration procedure of Maky 21.1.



**Figure 7.11:** Calibration procedure (Maky 21.1)

Based on Figure 7.11, before do the calibration procedure must connect the calibration cell. The calibration cell act as dialyzer where it used to measure the total cell volume (TCV) of dialyzer during the process. This calibration must conduct every day before starts reprocessing procedure.

Figure 7.12 shows the total cell volume (TCV) of processed dialyzer. TCV must be above 80% of stated size dialyzer.



**Figure 7.12:** Total Cell Volume (TCV) of processed dialyzer

## 4.0 Analysis

Based on the problem statement, I conducted the analysis by collecting data of breakdown for past 4 years for two different model of dialyzer reprocessing unit. All the data collected from ASIS platform with the guidance from mentor and supervisor.

Furthermore, data collected of breakdown for Renatron PA 100 series and Maky 21.1 from the year 2017 to 2020 are manipulated in a table. Table 7.3 shows the data of breakdown for Renatron PA 100 series from year 2017 to 2020.

**Table 7.3:** Total breakdown of Renatron PA 100 series from year 2017 to 2020

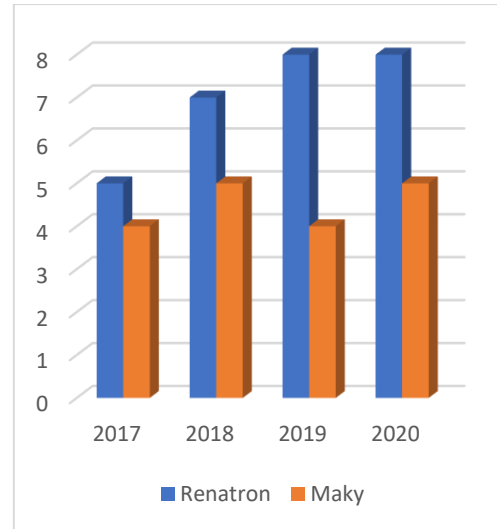
Years	Total Breakdown
2017	5
2018	7
2019	8
2020	8

However, I also managed to manipulate the data of breakdown for Maky 21.1. Table 7.4 shows the data of breakdown for Maky 21.1 from year 2017 to 2020. Below here shows the total breakdown of Maky 21.1 from year 2017 to 2020.

**Table 7.4** the total breakdown of Maky 21.1 from year 2017 to 2020

Years	Total Breakdown
2017	4
2018	5
2019	4
2020	5

Data collected from the Table 7.3 & Table 7.4 for Renatron PA 100 series and Maky 21.1 manipulated into a histogram graph as shown in Figure 7.13. Figure 7.13 shows the comparison of common problems in Renatron PA 100 series and Maky 21.1 from year 2017 to 2020.

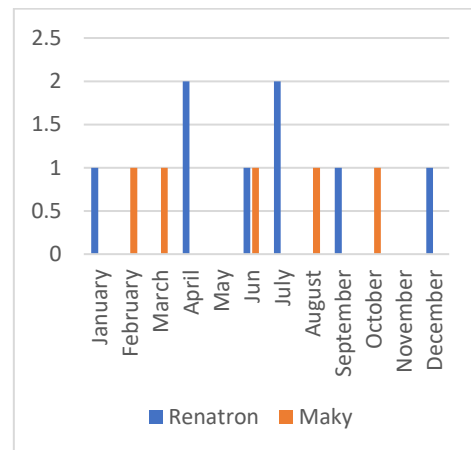


**Figure 7.1.13:** Comparison of common problem in Renatron and Maky 21.1 from year 2017 to2020

From the histogram graph, clearly shown that Renatron PA 100 series has the highest total breakdown every year from 2017 to 2020. Whereas, Maky 21.1 has the lowest total breakdown every year from 2017 to 2020.

Then, further analysis conducted to analyse the common problems occurred in both Renatron PA 100 series and Maky 21.1 in year 2020. Since year 2020 is the highest recorded breakdown compared to previous years.

Figure 7.14 shows the breakdown from January to December in year 2020 for Renatron PA 100 series and Maky 21.1.



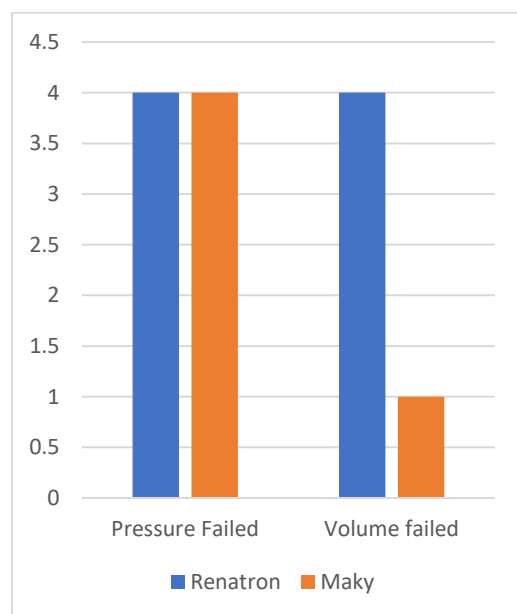
**Figure 7.14:** breakdown from january to december in year 2020

According to Figure 7.14, there are total of 12 breakdowns in year 2020 which Renatron recorded breakdown for 6 months which are in January, April, Jun, July, September and December. However, Maky 21.1 recorded breakdown for 5 months which are in February, March, Jun, August, and October.

Moreover, in Renatron PA 100 series there are few problems recorded during the corrective maintenance. The problems recorded such as pressure failed due to leaking at manifold valve, volume failed due to load cell, piping leaking and tank volume failed due to improper action occurred within the mixing tank.

Furthermore, in Maky 21.1 there are also few problems recorded during the corrective maintenance. The problems recorded such as pressure leaking at connector and calibration failed during the process of cleaning.

Figure 7.15 shows the number of pressures failed and volume failed in both Renatron and Maky in year 2020. From the graph, then I analysed the problem and cause of the problem to occur during the process.



**Figure 7.14:** Number of pressure failure and volume failure in Renatron and Maky

Based on the graph, clearly shown that Renatron PA 100 series machine has 4 problems for pressure failed and 4 problems for volume failed. Whereas, Maky 21.1 has 4 problems for pressure failed and 1 problem for volume failed

Further analysed, found that common problem that cause the volume failed in Renatron due to inaccurate reading from load cell. This problem sometimes repeats the same problem few times that cause volume failed during the process.

However, in Maky only one work order recorded in the system in year 2020. So, I did analysis on what causes the volume failed in Renatron PA 100 series and Maky 21.1.

In my analysis, the main cause of volume failed in Renatron PA 100 series due to problem in load cell. Sometimes load cell shows inaccurate reading when there is impact or movement to the machine. Other than that, the load cell calibration sometimes will be changed after few processes of treatment.

However, in Maky 21.1 it used the hydrostatic pressure instead of using the load cell. Thus, no load cell is needed. If the test fails the MAKY will repeat it one more time automatically. If it still fails, it will give the option to Preclean, Reprocess the Dialyzer again, Repeat the Test or Discard the Dialyzer.

Hydrostatic pressure is the pressure exerted by a fluid at equilibrium at a given point within the fluid, due to the force of gravity. Hydrostatic pressure increases in proportion to depth measured from the surface because of the increasing weight of fluid exerting downward force from above.

## 5.0 Conclusion

In a conclusion, the objectives for this assessment achieved where I able to understand and enhanced my knowledge on the two different model of dialyzer reprocessing unit (Renatron 100 series & Maky 21.1). Moreover, I also able to analyze the common problem occurred in Renatron and Maky during the process.

From this report, I able to understand the specifications and functions of two different model of dialyzer reprocessing units which are Renatron PA 100 series and Maky 21.1. Moreover, I also able to recognize each part contains in both different models and their functions for the reprocessing. From the analysis carry out in this report, I can able to analysed the common breakdown occurred during the corrective maintenance from year 2017 to 2020. Besides that, I also managed to find out the causes for the breakdown which are pressure failure due to leaking at manifold valves or connectors, volume failure due to load cell or inaccurate calibration, tank volume failure due to improper action occurred within the mixing tank and piping leaking.

Besides that, I able to find out the reason for no recorded volume failure in Maky 21.1 in year 2020. This is because Maky 21.1 uses hydrostatic pressure instead of using load cell where it can reduce the volume failure problem.

## 6.0 Recommendations

Based on the assessment and analyse done on Renatron PA 100 series and Maky 21.1 models, it can be recommended that Maky 21.1 model is the best to be used in hospital as dialyzer reprocessing unit since it has high reliability and consistency in measuring the total cell volume (TCV) in processed dialyzer.

The future recommendation will be for upcoming dialyzer reprocessing unit must have hydrostatic pressure so that it reduces the problem to happen during the process. Future dialyzer must reduce the number of solenoid valves used in the machine and made them a compact manifold valves so that can minimize the space in the dialyzer reprocessing unit.



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# BLOOD WARMER

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**Abstract**— A blood warmer is a medical device used in hospitals for pre-warming blood being administered intravenously or by other parenteral routes to body temperature levels to prevent hypothermia in the physically traumatized or surgical patients This technical report will explain about the part of description, principle of operation, specification, features and common breakdown of the two blood warmer devices. The data analysis will compare the rate of failure, type of failure and cost of breakdown on each of the blood warmer devices. One of the two devices will be selected for the best model based on the data analysis.

**Keywords**- Blood Warmer, Barkey Plasmatherm, Animec AM 2S.

## 1.0 Introduction

Hypothermia is a condition in which core temperature drops below the required temperature for normal metabolism and body functions which is defined as 35.0°C (95.0°F). Body temperature is usually maintained near a constant level of 36.5–37.5°C (98–100°F) through biologic homeostasis or thermoregulation. If exposed to cold and the internal mechanisms are unable to replenish the heat that is being lost, a drop in core temperature occurs. As body temperature decreases, characteristic symptoms occur such as shivering and mental confusion.

Hypothermia is the opposite of hyperthermia which is present in heat exhaustion and heat stroke. The lowest documented body temperature from which anyone has recovered was 13.0°C (55.4°F), in a drowning incident involving a 7-year-old girl in Sweden in December 2010.[6]

Normal human body temperature in adults is 34.4–37.8°C (94–100°F).[9] Sometimes a narrower range is stated, such as 36.5–37.5°C (98–100°F).[10] Hypothermia is defined as any body temperature below 35.0°C (95.0°F). It is subdivided into four different degrees, mild 32–35°C (90–95°F); moderate, 28–32°C (82–90°F); severe, 20–28°C (68–82°F); and profound at less than 20°C (68°F).[11] This is in contrast to hyperthermia and fever which are defined as a temperature of greater than 37.5°C (99.5°F)-38.3°C (100.9°F).

A blood warmer is a medical device used in hospitals for pre-warming blood being administered intravenously or by other parenteral routes to body temperature levels to prevent hypothermia in the physically traumatized or surgical patients. The salient features of such equipment are: (a)Warmer for blood; (b)Achieve a temperature of 38°C.

## 2.0 Blood Warmer

Blood is stored at 2°C and needs to be warmed up during blood transfusion to between 37°C and 41°C. During surgery or after an accident blood loss can be considerable. Due to this blood loss, the patient can suffer from anaemia (reduce number of blood cells) and low blood pressure (loss of blood volume) which can be life threatening. Blood transfusion are also often used for treatments of blood related disease like leukaemia the blood is warmed up to body temperature before infusing it into the patient. The blood must not be heated above 43°C or the blood cells will die (haemolysis).

There are different types of blood warmer, some blood warmer has a water bath where the water is heated up to a set temperature. A blood bag is put in to the bath to warm up. The other types have a coiled blood line around its body. While the blood is flowing through the coiled blood line it heats the blood to the set temperature

### 2.1 Description of the Device

This section will be reviewing the part of description with its function for two devices of blood warmer. Table 8.1 shows the description of blood warmer parts.

**Table 8.1:** Part of description with its function for two blood warmer devices that is Barkey Plasmatherm and Animec AM 2S

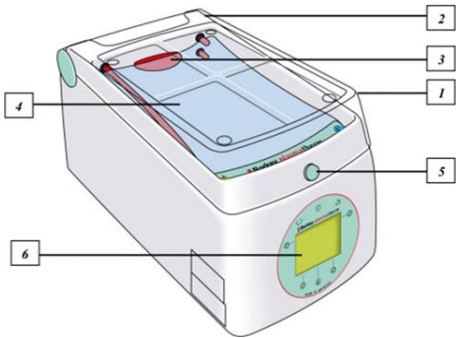
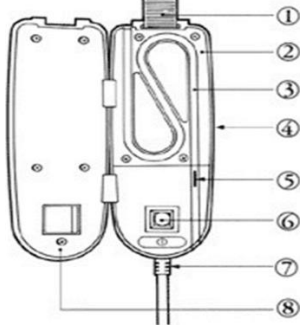
Barkey Plasmatherm	Animec AM-2S
	
1. <b>Heating chamber cover</b> – Covers the heating chamber while heating or thawing is in progress.	1. <b>Adjustable suspension belt</b> – To hang the device on an IV stand or other support and adjust height from the floor.
2. <b>Filler opening</b> – The filler opening is used to fill the device with heat transfer fluid.	2. <b>Heating plate</b> – For heating infusion fluid in the tubing.
3. <b>Paddle</b> – Gently agitates FFP's during the heating process.	3. <b>Tube channel</b> – Place the tubing inside the 'S' shaped channel.
4. <b>Heating cushion</b> – Heat transfer fluid flows through the heating cushions. The cushions heat the materials placed in the device and keep them warm.	4. <b>Main body</b>
5. <b>Cover locking/release button</b> – The locking/release button is used to open and close the heating chamber cover.	5. <b>Temperature sensor</b> – Sensing temperature of the effluent at the exit point of the device. When the power is turned on, the green LED will illuminate. The switch cover protects against the accidental introduction of fluids into device from splashing.
6. <b>Operating panel</b> – The Barkey plasmatherm has an operating panel on the front of the device with a multi-line display, 6 button and 2 lamps (LEDs).	6. <b>Power switch</b> – Press this button to turn on/off the main power.
-	7. <b>Electrical cord</b>
-	8. <b>Cover</b>

Table 8.1 shows the part of description with its function for two blood warmer devices that is Barkey Plasmatherm and Animec AM 2S.

## 2.2 Principle of Operation

The principle of operation of two devices of blood warmer can be compare as shown in the Table 8.2.

**Table 8.2:**Table of the principle of operation of the devices

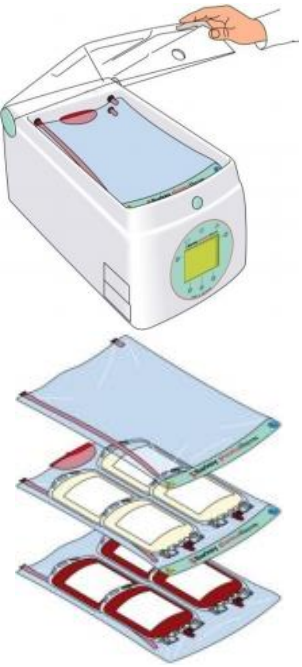

Barkey Plasmatherm		<p>The Barkey plasmatherm is configured as an electronically regulated dry heating device with an enclosed heating chamber. Bags of fresh frozen plasma (FFP), blood and erythrocyte concentrates (EC), cryoconserved preparations, cryoconserved stem cells (HPC = haematopoietic progenitor cells) or infusion solutions are placed between soft heating cushions made from a flexible synthetic material. A heat transfer fluid (distilled or demineralised water) flows through the heating cushions which heat up the materials placed in the device and keep them warm.</p>
Animec AM-2S		<p>The ANIMEC Infusion/Blood Warmer is an electrically powered dry warmer that supplies heat to the infusion/blood set tubing. The tubing is placed in as “S” shaped channel through the heating plate. Temperature sensors in contact with the tubing control the heating and regulate effluent temperature. The temperature of fluids attained by use of ANIMEC depends on many factors – including initial fluid temperature, room temperature, flow rate and tubing size.</p>

Table 8.2 shows the comparison of principle of operation of two devices of blood warmer which is Barkey Plasmatherm and Animec AM 2S

## 2.3 Specifications

The physical and electrical specification of two devices of blood warmer can be compared as shown in the Table 8.3.

**Table 8.3:**Table of specifications of the devices

Barkey Plasmatherm	Manufacturer	Barkey GmbH & Co. KG Gewerbestrasse 8 33818 Leopoldshoehe	
	Type	Barkey plasmatherm	
	Order No.	212.10043	230 VAC / 50 - 60 Hz
		212.10044	115 VAC / 60 Hz
	Typical capacity	4 bags / 500 ml or 2 bags / 800 ml	
		Emergency: 8 bags / 250 ml	
	Power supply	230 VAC / 50 - 60 Hz or 115 VAC / 60 Hz	
	Typical power consumption	< 0.25 W	Standby
		< 35 Watt	Program pause
		< 75 W	Program "PLASMA" 45°C
		1600 Watt	max.
	Sound pressure level	< 45 dB(A)	
	Current consumption	7 A at 230 VAC	max.
		14 A at 115 VAC	max.
	Fusing	8 A slow at 230 VAC	
		15 A slow at 115 VAC	
	Battery type	Lithium CR 1225, 3 V	
	Interfaces/devices	optional:	
		Barcode scanner Log printer	
	Overtemperature protection	software controlled:	setpoint + 1.0 °C
		electronic:	48 ± 1.0 °C
	Temperature setting	Variable from	+37 to +45 °C
		Default setting	+37 °C
	Display accuracy	0.1 °C	
	Ambient temperature	Operating	Storage/transport
		+10 to +40 °C	-20 to +70 °C
	Humidity (non-condensing)	30 to 75 %	30 to 90 %
	Air pressure	700 to 1060 hPa 700 to 1060 hPa	
	Operating mode	Continuous	
	Dimensions	(w x d x h mm)	
		Cover closed	340 x 600 x 320 mm
		Cover open	340 x 600 x 720 mm
	Weight empty	18 kg	
	Fill quantity	approx. 9 litres	
	Refill quantity	approx. 1 litre (device warning)	
	Protection rating	I	
	MDD classification	II a	
	Enclosure class	IP21	
	Identification	CE 0123	

Animec AM-2S	Model	AM-2S-4A [AM-2S-4B]	
	Tube size	3.0 – 4.0mmØ	
	Flow rate	1 – 12ml/min	
	Power requirement	230V±% ~ (AC) 50/60Hz 60VA [115V±10% ~ (AC) 50/60Hz 100VA]	
	Classification	Class 1 equipment	
	Operating mode	Continuous operation equipment	
	AP/AGP	Ordinary equipment (Not AP/AGP equipment)	
	Applied part type	Type BF	
	Heater	Number of heaters	: 1
		Type	: silicone rubber heater
		Wattage	: 55W (at 230V ~) [66W (at 115V ~)]
	Heat exchange	Dry heat exchange	
	Operating temperature range	1 – 12ml/min	
		37 - 27°C (At input fluid temperature 20°C)	
	Operating condition	0 - 40°C	
		30 – 95% relative humidity Non condensing	
	Transportation and storage condition	-15 - 45°C	
		10 – 95% relative humidity Non condensing	
	Heating plate temperature	Max. 42°C	
	Body dimension	176(L) X 65(W) X 36(H) [mm]	
	Weight	560g	
	Standard durable years	5 years	

Table 8.3 shows the comparison of specification of two devices of blood warmer which is Barkey Plasmatherm and Animec AM 2S.

## 2.4 Features

Table 8.4 show the features of two devices of blood warmer.

**Table 8.4:** Table of features of the devices.

Barkey Plasmatherm	Animec AM-2S
<ul style="list-style-type: none"> <li>Designed for simple and intuitive handling – Menu navigation in local language, short-cut programs and optional documentation software.</li> <li>The short-cut programs for blood, plasma, HPC, Octaplas and user can be customized in terms of time and temperature – Can be used in a temperature range between +37°C and +45°C.</li> <li>The cleaning effort for the user is also minimal.</li> <li>Offers the possibility of electronic documentation of the warming or thawing process – Barkey TCP Logging Tool can be used to document barcodes, device users, time and temperature of the executed program.</li> </ul>	<ul style="list-style-type: none"> <li>Automatic regulation of fluid temperature – The temperature of the warning plate adjusts according to the desired temperature of the effluent.</li> <li>Less heat loss after warming – ANIMEC's small size required minimal tubing between the patient and the unit.</li> <li>No disposable bags or coil are required. The compact design saves valuable time and expense.</li> <li>Quick set up – the IV tube is inserted directly into the warmer.</li> <li>Rapid warm up – ready to use in 4 minutes.</li> <li>Safe performance is guaranteed utilizing silicon coated heating plates and multiple sensors for accurate temperature control.</li> </ul>


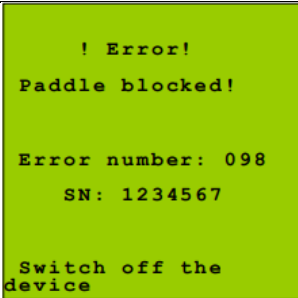
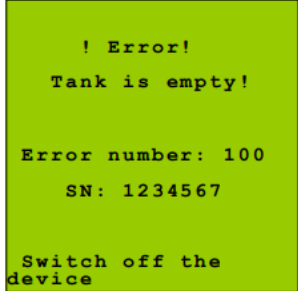
Table 8.4 above shows the features of two devices of blood warmer which is Barkey Plasmatherm and Animec AM 2S



## 2.5 Common Breakdown

This section will be reviewing the common breakdown of two devices of blood warmer in Table 8.5.

**Table 8.5:** Table of common breakdown of the devices

Barkey Plasmath erm	Error	Display	Solution
	<b>1. Moisture sensors</b> If any liquid has leaked inside the device heating chamber, the moisture sensors in the base of the chamber triggers an intermittent acoustic signal and a warning message flashes in the display.		<ul style="list-style-type: none"> <li>► Press the confirm button ("OK").</li> <li>► Switch off the device.</li> <li>► Clean, disinfect and dry the heating cushion and the heating chamber.</li> <li>► Replace the filter paper (dry-paper).</li> </ul>
	<b>2. Paddle blocked</b> If the paddle for the special "Undulation" function is blocked, the following error message is displayed:		<ul style="list-style-type: none"> <li>► Note the error message.</li> <li>► Make a note of the error number (098) and serial number (SN).</li> <li>► Switch off the device.</li> </ul>
	<b>3. Tank is empty</b> If the tank is empty or if the level in the tank has fallen below a critical level for the heating, the following error message is displayed:		<ul style="list-style-type: none"> <li>► Note the error message.</li> <li>► Switch off the device.</li> <li>► Top up with water as described in the Chapter Filling with water.</li> </ul>

Animec AM-2S	<p><b>1. Damage of the main body</b></p>	<div data-bbox="667 190 976 414"> </div> <p>A. Cut the adjustable suspension belt, and remove it from the main body</p> <div data-bbox="1050 190 1353 414"> </div> <p>B. Attach the new adjustable suspension belt to the main body.</p> <div data-bbox="667 474 967 698"> </div> <p>C. Put the belt through the plastic buckle.</p> <div data-bbox="1050 474 1350 698"> </div> <p>D. Put the steel ring into the loop of the belt.</p> <div data-bbox="667 743 960 967"> </div> <p>E. Turn the steel ring.</p> <div data-bbox="667 1025 957 1249"> </div> <p>F. Confirm the steel ring is attached.</p> <div data-bbox="1042 1025 1343 1249"> </div> <p>G. Confirm that the plastic part is attached firmly.</p>
	<p><b>2. Damage of the cover</b></p>	<div data-bbox="667 1317 976 1541"> </div> <p>A. Screw down inside of the cover and take off the stainless board.</p> <div data-bbox="1050 1317 1350 1541"> </div> <p>B. Take off the hinges from the cover.</p> <div data-bbox="667 1608 983 1832"> </div> <p>C. Screw down inside of the new cover and take off the stainless board.</p> <div data-bbox="1062 1608 1369 1832"> </div> <p>D. Attach the hinges into the new cover</p>

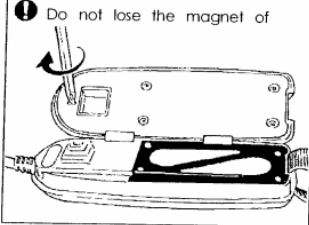
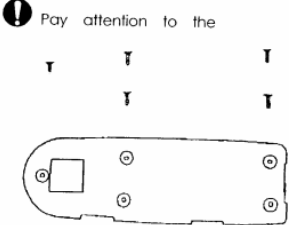
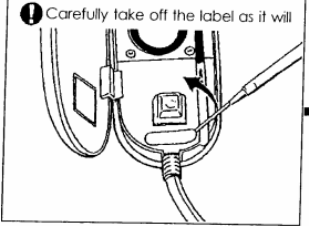
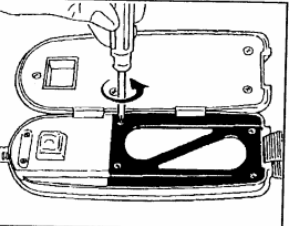
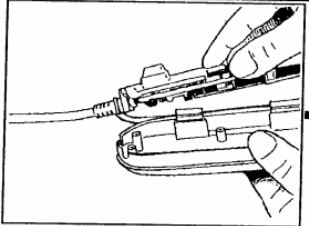
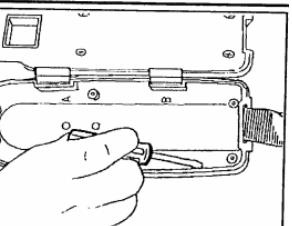
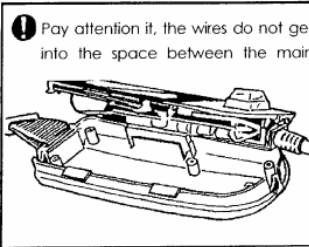
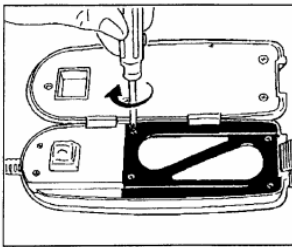
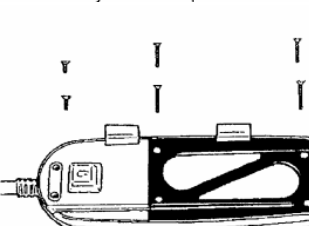
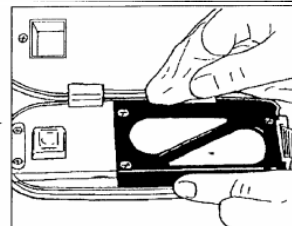
		<div data-bbox="667 197 976 421">  <p>❗ Do not lose the magnet of</p> </div> <div data-bbox="1050 197 1343 421">  <p>❗ Pay attention to the</p> </div> <div data-bbox="667 430 976 470"> <p>E. Attach the stainless board into the new cover and screw up.</p> </div>
<p>Animec AM-2S</p>	<p><b>3. Damage of the heating unit</b></p>	<div data-bbox="667 486 976 710">  <p>A. Open the cover and take off the "I / O" label.</p> </div> <div data-bbox="1050 486 1343 710">  <p>B. Take off the fixed screws from the control/heating unit.</p> </div> <div data-bbox="667 768 976 992">  <p>C. Take off the control/heating unit from the main body.</p> </div> <div data-bbox="1050 768 1343 992">  <p>D. Wipe off the remaining waterproof sealing material on the main body.</p> </div> <div data-bbox="667 1050 976 1296">  <p>❗ Pay attention it, the wires do not get into the space between the main</p> <p>F. Attach the new control/heating unit to the main body and screw up.</p> </div> <div data-bbox="1050 1050 1343 1296">  </div> <div data-bbox="667 1355 976 1579">  <p>❗ Pay attention not to screw up with wrong screw.</p> </div> <div data-bbox="1050 1355 1343 1579">  <p>❗ Wipe of the stick out of the waterproof sealing material.</p> </div>

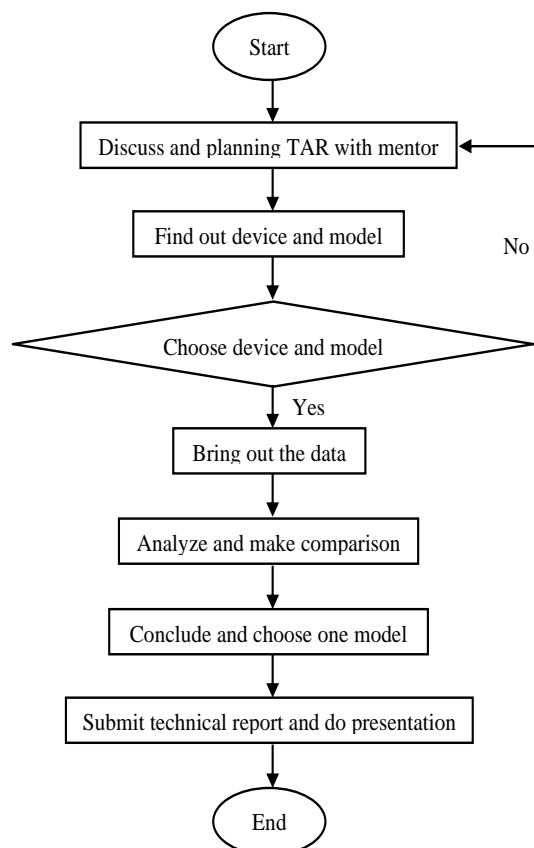
Table 8.5 above shows the common breakdown and solution on how to repair the two devices of blood warmer which is Barkey Plasmatherm and Animec AM 2S.

### 3.0 Methodology

In this study of technical assessment report (TAR), there are two flowchart progress to complete the result data and analysis. The first flowchart is about process preparing TAR. Planning and discuss with mentor what medical device to choose as a main title of these assessment is very important. For more specified we should choose the one type of ward or patient to get a specified and better comparison based on user requirement specification. Second flowchart is about process of find out data and analyse data. For this process has two stages. First stage to choose the best two over five by technical specification based on user requirement. Second stage is to choose the best one of two model based on product review, maintenance, spare part, company record and frequent install based.

#### 3.1 Flowchart Process Preparing TAR

Figure 8.1 shows flowchart process of preparing technical assessment report (TAR). This process starts with discuss and planning about TAR with mentor. After that, find out device and model that have in company or do maintenance. Then, choose device and choose five model of device. Bring out the data for all models and do analysing and make comparison for two stages. After passed of the stage, conclude and choose the best model. Lastly, submit technical assessment report and do presentation.

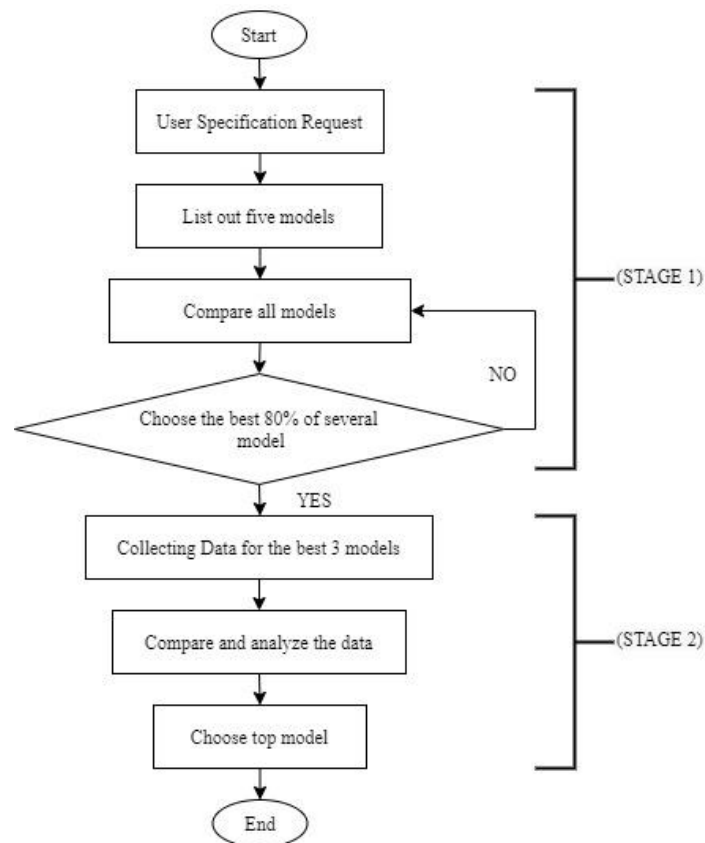


**Figure 8.1:** Flowchart process preparing TAR

Flowchart in Figure 8.1 shows the process preparing Technical Assessment Report from start planning and end with submit the report and presentation.

### 3.2 Flowchart Process of Data Analysis

Figure 8.2 shows flowchart process of data analysis in technical assessment report (TAR).



**Figure 8.2:** Flowchart process of data analysis

Flowchart in Figure 8.2 shows the process of data analysis, that has two stage which is Stage 1 is choose two models by part of description, principle of operation, specifications, features and common breakdown and Stage 2 choose the top from two models based on comparison rate of failure, type of failure and cost of breakdown part using table diagram and Bar chart

## 4.0 Data Analysis

This chapter shown the result from our collected from two difference models. The data are analysed and generated graph by using Microsoft Excel. The result that analysed is discussed in this chapter and aim of this research is to develop a comparison between two models of blood warmer.

### 4.1 Comparison Rate of Failure

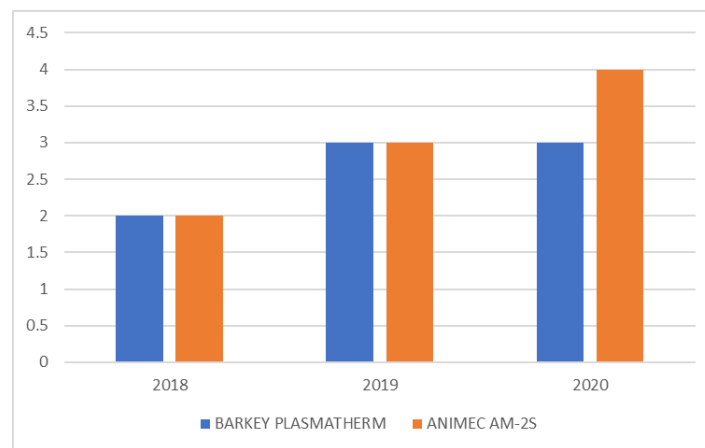
This section will be reviewing the comparison rate of failure of two devices of blood warmer in

**Table 8.6** and Figure 8.3.

**Table 8.6:**Table of comparison rate of failure

Model \ Years	2018	2019	2020
Barkey Plasmatherm	2	3	3
Animec AM-2S	2	3	4

**Table 8.6** above shows the comparison rate of failure for the two different model of blood warmer which is Barkey Plasmatherm and Animec AM 2S. The data was collected from the past three years.



**Figure 8.3:**Bar Chart for Rate of Failure

Bar chart in Figure 8.3 shows the comparison rate of failure of the two blood warmer model from the past three years based on the data in

**Table 8.6.**

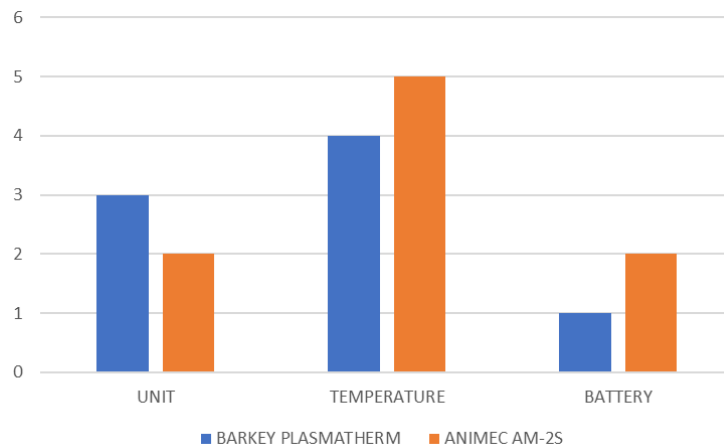
## 4.2 Comparison type of failure

This section will be reviewing the comparison type of failure of two devices of blood warmer in Table 8.7

**Table 8.7:**Table of comparison type of failure between models

Model \ Failure	Unit	Temperature	Battery
Barkey Plasmatherm	3	4	1
Animec AM-2S	2	5	2

Table 8.7 above shows the comparison common type of failure for the two different model of blood warmer which is Barkey Plasmatherm and Animec AM 2S. The data was collected from the past three years.



**Figure 8.4:** Bar Chart for Type of Failure.

Bar chart in Figure 8.4 shows the comparison type of failure of the two blood warmer model from the past three years based on the data in Table 8.7.

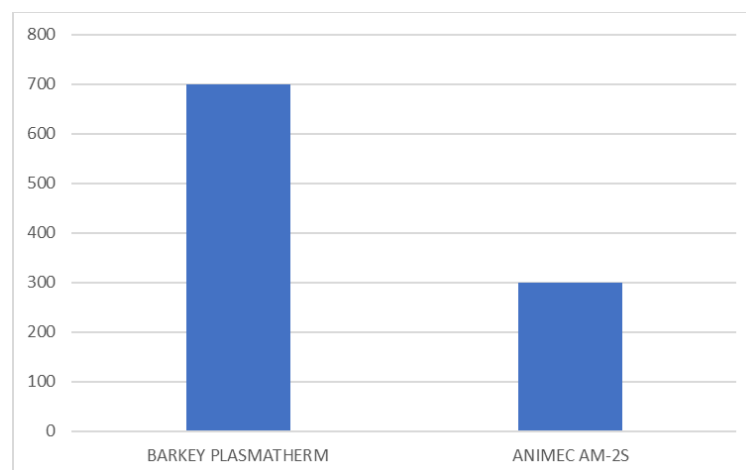
### 4.3 Comparison cost of breakdown

This section will be reviewing the comparison cost of breakdown of two devices of blood warmer in Table 8.8 and Figure 8.5.

**Table 8.8:** Table of comparison cost of breakdown

Model	Cost (RM)
Barkey Plasmatherm	700
Animec AM-2S	300

Table 8.8 above shows the comparison estimated cost of breakdown for the two different model of blood warmer which is Barkey Plasmatherm and Animec AM 2S. The data was collected from the past three years.



**Figure 8.5:** Bar Chart for Cost of Breakdown



Bar chart in Figure 8.5 shows the comparison cost of breakdown of the two blood warmer model from the past three years based on the data in Table 8.8.

## 5.0 Conclusion

For the conclusion, blood warmer is a very important in context to improve the design of the devices incidents occasionally occur during infusion administration, that may compromise patient safety, in hospital. Every blood warmer model has its own manufacturer-based features and advantages.

In my opinion blood warmer for model Animec AM 2S is the best model among two selected devices. It would be best to suggest Animec AM 2S to users for potential purchases, as analysed in this TAR. In terms of maintenance, spare part, install based, company record (after sale service) and product review, it has the most advantages compared to others. It can be concluded that the Animec AM 2S is the best alternative for introducing more blood warmer properties.

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# AUTOMATIC SLIDE STAINER

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**Abstract**— Automated Slide stainers are devices that automate the staining of peripheral blood and other hematologic smears to facilitate laboratory microscope differential counts using Wright's stain, a Romanowsky stain. The operator inserts slides into a carrier and selects a time or programmed procedure. This study is to choose the best model of automatic slide stainer for use based on comparison between the models by specification, user friendly, breakdown and frequently use by user. This research finds that different model of automatic slide stainer poses different kind of frequent faults. The best unit need to be decided in order to reduce the corrective maintenance and be more user-friendly. Choosing the right, convenient and affordable machine is been a high priority to choose for reliable machine and less work by the user. The comparison between two different model can be good research to analyse which model is suitable and lastly be suggested to the hospital's user for the future used. Based on assessment and analysis made slide stainer model Shandon Varistain 24-4 is the best model to recommended.

**Keywords**- Slide Stainer, Laboratories, Shandon Varistain 24-4, Lecia ST5010.

## 1.0 Introduction

Clinical and pathology laboratories are implementing automated staining methods with increasing frequency. Automated stainers have a wide range of applications. The ways in which manual staining is replaced by instruments can be simple and basically mechanical, or sophisticated and controlled by microprocessors. Varying applications of automated staining technology allow users to choose a system that best meets their laboratory's needs. Automated slide-staining systems designed for histochemistry or special stains (SS) as they are commonly known immunohistochemistry (IHC), and in situ hybridization (ISH).

First, it is important to note that automated slide-staining systems used for SS, IHC, and ISH procedures are fundamentally different from instruments designed for routine H&E (hematoxylin and eosin) staining, in that reagents are applied to individual slides in small, controlled volumes rather than fully immersing slides in a large volume of reagent. This is necessary because the chemical reactions involved in non-routine staining protocols are far more sensitive, and of-ten require that a series of reagents be applied in a specified order to create bound molecular complexes.

Although there is many designs and technique that being used in Automatic slide stainer, all this technique can be divided into two type, stainer that dip the slide and stainer that applied the stain.

The purpose of this Technical Assessment Report (TAR) is to compare the Automatic Slide Stainer machine model by several specification and recommend to company which brand of the Slide Stainer are the best to be used by hospital. Three objectives which it's be a guideline in process to develop this research are to study on the Automatic slide stainer, to analyse the different model of Automatic slide stainer and to determine the best model of Automatic slide stainer. Research found that Automatic slide stainer model of Shandon Varistain 24-4 is absolutely the best model for hospital operational theatre to decrease the total of downtime. It has more advantages compare to the Lecia ST5010 in term of specification and price

## **1.1 Problem Statement**

Slide Stainer is important machine to used in laboratory. There is so many slide stainer to be choose based on function or program that need to be done and also the reagent that being provided by certain vendor. It is important to choose the right machine for the right test and right reagent that being used. Minor or major breakdown of this machine can cause delay in laboratories result cause the stain needs to be done manually which the result is inconsistence.

## **1.2 Objective**

The study has three objectives which it's be a guideline in process to develop this research. The objectives are:

- To study the automatic slide stainer machine.
- To analyse the different method of slide staining.
- To determine the best model of automatic slide stainer machine.

## **1.3 Scope of Project**

The scope of this technical assessment report is to make a full comparison between these two models of Automatic slide stainer machine Lecia ST5010 and Shandon Varistain 24-4. This study discusses type of slide staining process and specification of the machine

## **1.4 Project Significant**

The technical assessment report is conducted to find the best Slide Stainer that suitable for Hospital laboratories usage and the testing that being conducted. The machine also needs to be user and technical friendly, affordable and reliable, easy to get spare part and reagent options. This machine will be recommended to user for next purchase.

## **2.0 Literature Review**

The literature review is very useful for the future development of the research. In this chapter, previous work by different researchers is analysed and compared. There is also the need to study on the actual product for developing and modifying the research. All the information that has been studied is well written in this chapter such as study on slide stainer and a review of the other research that related to the project. Figure 9.1 shows the schematic of a manual H&E staining procedure.

## 2.1 Machine Description

The basic function of slide stainer is to enhance visualization of the cell or certain cellular components under a microscope. Cells may also be stained to highlight metabolic processes or to differentiate between live and dead cells in a sample. Sometimes the liquid used is simply water, but often stains are added to enhance contrast. Once the liquid has been added to the slide, a coverslip is placed on top and the specimen is ready for examination under the microscope.

## 2.2 Principle of Automatic Slide Stainer

Consider the 25 steps of a manual H&E stain procedure outlined. The stain takes about 25 minutes to complete. Six minutes of this are hands-on time for the technologist. These 6 minutes are distributed over the entire 25 minutes. Compare this with the throughput of various automated stainers.

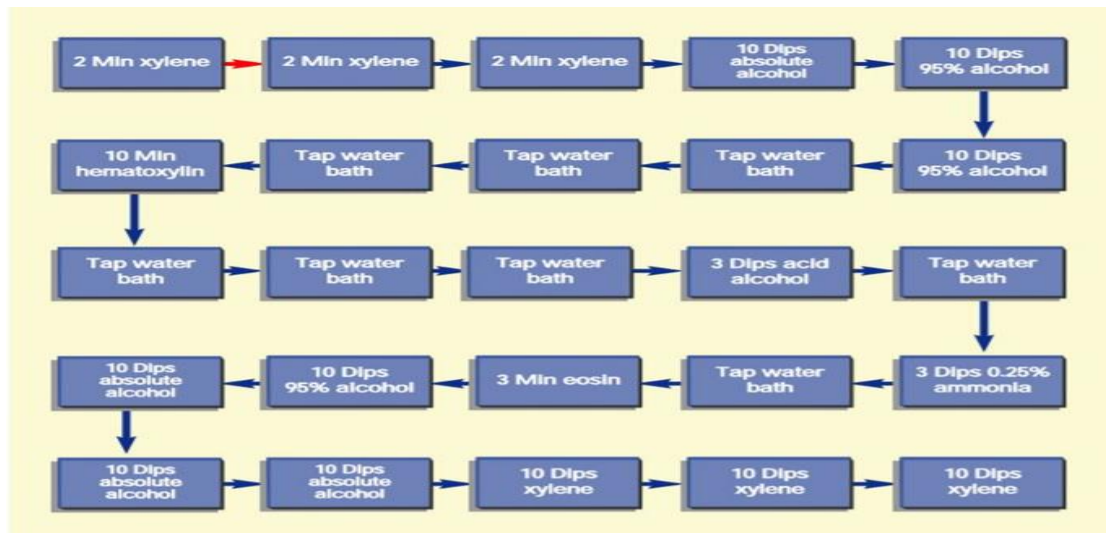
The benefits of using autostainers can be more than time savings. Repetitive motion, bending, and twisting are reduced, as are the injuries attributable to these movements. Some stainers have built-in fume hoods or can be operated under a hood, which eliminates some chemical exposure. Stainers offer an advantage in consistency of technique by eliminating personal variation. They also maintain a consistent temperature for temperature-sensitive procedures.

They can save space and money. The footprint, or space requirement, of some stainers is smaller than the manual stain apparatus required for some procedures. A manual Papanicolaou (Pap) stain line, for example, occupies an area of 30 x 23in, vs the 20 x 20in needed by a centrifugal stainer that can process the same number of slides. Other stainers may require more room than a manual procedure. In many cases the workspace can be rearranged so the area is used more efficiently. The built-in fume hoods available with many stainers eliminate the need for larger overhead hoods. Equipment that applies stain does so more conservatively, reducing reagent use and contamination.

## 2.3 Stainer that Dip the Slide

Stainers that dip the slide into the stain (bath stainers) can be of either linear or batch design. Linear stainers have a carrier mechanism. Slides are loaded onto this mechanism 1 at a time, then sequentially dipped into staining solutions. The slides are clipped into slide holders, which attach to the carrier mechanism. The carrier mechanism moves at a constant rate, and the slides exit the machine singly. Slides are raised and lowered into the baths by the contact between the slide holder and a small ridge in the bath containers.

Batch stainers move racks containing several slides through baths of staining solution. An early approach with this method used a rotary tissue processor as a batch stainer. The timing of the processing cycle was changed from 24 hours (overnight) to 1 hour, and staining racks were hooked into the tissue basket carriers on the processor. Slides progressed through processing beakers filled with stain solution. Stainers that use this principle are still manufactured. Sophisticated, programmable batch stainers are now available that use robotic arms to move the racks of slides from one position to the next. Agitation of the slides in the bath can be programmed, if desired. The arms usually move on X,Y coordinates. Some equipment using this principle can perform multiple stain procedures in parallel, mimicking the actions of a person doing 2 different things at once.



**Figure 9.1:** Schematic of a manual H & E staining procedure.

A hybrid of the linear and batch type bath stainers is a linear batch stainer it moves racks of slides through a series of stain containers. The racks may hold a small or large number of slides, depending on the system used and the laboratory's workload requirements. Continuous staining of racks is possible; a technologist can load 1 rack while another is processing.

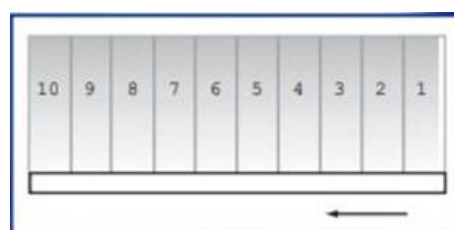
## 2.4 Stainer that Apply Stain

Stainers that apply stain to the specimen on the slide operate in 1 of 3 different ways.

### Capillary Gap Stainers

Capillary gap stainers force or draw the stain between the specimen slide and another surface. A familiar example of this technology is the platen-type stainer in use for many years in hematology departments for Wright's staining. Rotating worm gears move slides, face down, along a platen (plane surface) which has holes through which stain can be pumped at appropriate intervals. The advancing slides press a switch as they pass each staining station, activating a pump. This principle has been applied more recently to Pap and H&E staining. Because each advancing slide triggers stain application individually, the platen-type stainer is a linear stainer. The stain is discarded after the slide moves to the next station, so the bulk containers of stain are not contaminated. The instrument pumps stain from the closed bulk containers to the platen via small tubing. This minimizes reagent evaporation.

Capillary gap technology is also employed in stainers that use 2 slides face-to-face to provide the capillary gap. Stain solution is drawn between the slides by capillary action. Robotic arms move holders of paired slides to staining, draining, and rinsing stations. This application of capillary gap technology uses very little stain solution and has been used for immunohistochemical staining of large numbers of slides.

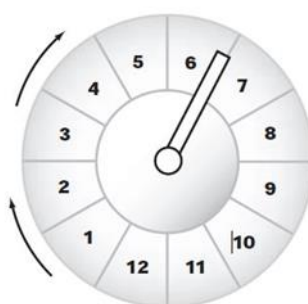


**Figure 9.2:** Capillary Gap Stainer schematic representation.

A variation of capillary gap staining uses a plastic device, or slide cover, that fits against the slide. Stain reagents are then dispensed through this device a robotic arm picks up reagent and drops it into the space between the cover and the slide according to a programmed stain protocol. The reagent is drawn down over the specimen on the slide by gravity. This instrument uses very small quantities of reagent, and is used for immunohistochemistry. Figure 9.2 shows the capillary stainer schematic representation.

### **Centrifugal Stainers**

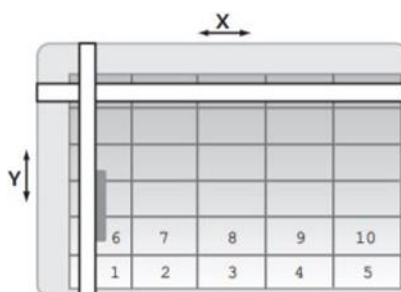
Centrifugal stainers spray stain onto the specimen as the slides rotate past spray nozzles in a spinning chamber. Common applications of this technology are Pap, Gram, acid-fast, and hematology staining. The prepackaged reagents are in closed containers with pump tubing. This eliminates evaporation and contamination of reagents. Figure 9.3 shows the centrifugal slide stainer schematic representation.



**Figure 9.3:** Centrifugal Slide Stainer schematic representation

### **Flat-Method Stainers**

“Flat-method” stainers drop staining solutions onto the specimen as the slide lies flat within the stainer. Many immunohistochemistry stainers use this principle; some employ robotic arms to apply solutions to the slides. Some flat-method stainers use a robotic arm programmed with X, Y coordinates to pick up and apply solutions to slides located in a rectangular grid. Other instruments employ a rotating carousel and swinging arm; the arm picks up reagents and dispenses them as the slides move **Figure 9.4** shows the flat-method slide stainer schematic representation.



**Figure 9.4:** Flat-method slide stainer schematic representation.

Type	Size	Throughput/ Time to Stain	Accessories	Requirements	Applications
<b>Bath</b>					
Batch	Average length 40-48 in	24-66 Slides/rack; time depends on program.	May be compatible with coverslipper; some have built-in hood.	May require running water and drain; may have waste collection	H&E, special stains, Pap, hematology
Linear	43-60 In long	360-720 Slides/h; 12-14 min/slide	Some have built-in hood and slide dryer.	Usually require water and drain	H&E, Pap, Gram's, other determined by user
<b>Capillary gap</b>					
Platen	19-36 In long	Varies according to system and application	Some may be compatible with coverslipper; some have built-in hood.	Usually require prepackaged reagents; may require a drain	Hematology, H&E, Pap
Slide cover	26 In long time; time	20 Slides at a time; depends on program.	—	Pretreatment of slides may be necessary.	IHC
Slide-to-slide	Up to 90 in long	60 Slides/rack; usually 2.5 h	—	Pretreatment of slides may be necessary.	IHC
<b>Centrifugal</b>					
	Average 20 × 20 in	12 Slides at a time; time depends on program, averages 6-8 min	—	Prepackaged reagents; may require a drain; usually doesn't require a hood	Pap, Gram's, AFB, hematology
<b>Flat</b>					
Carousel	Greater than 27-41 in long	20-40 Slides depending on system; time varies according to program; often 1.5 h	May perform some pretreatment.	Slides require deparaffinization; may require prepackaged or manufacturer's reagents; require waste container	IHC
XY Grid	Averages greater than 40 in long	Usually 36-48 slides at a time; time depends on program; often 2 h for IHC	May perform some pretreatment; some models offer deparaffinization.	May require prepackaged reagents; require waste container	IHC, possibly H&E and special stains
IHC indicates immunohistochemistry; AFB, acid-fast bacilli stain; Pap, Papanicolaou stain.					

**Figure 9.5:** Comparison of different type of slide stainer.

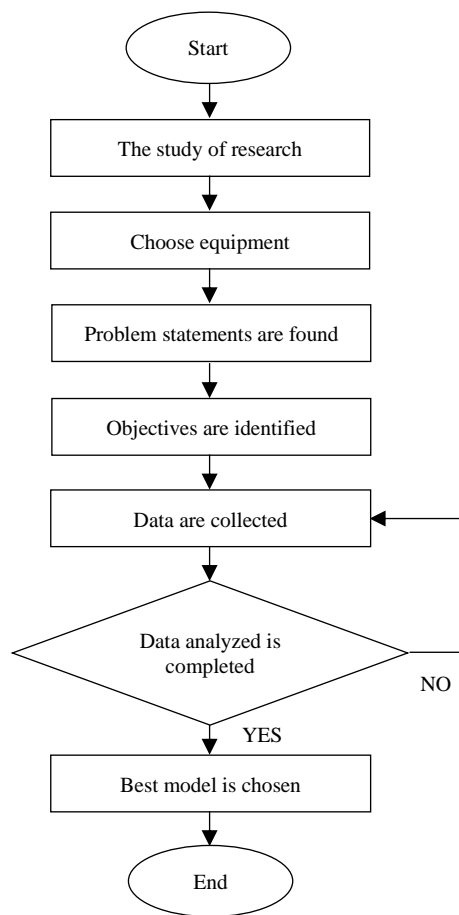
### 3.0 Methodology

In this part, different methodology has been applied to collect the data for data analysis. The methodology applied such collect the data through ASIS and MyAPBESYS where it uses as one the important platform to update the information of equipment. Next, collect data from the person in charges of the operational theatre department assets. Manual considered as one the important tool that referred to study the block diagram, principal operation, parts of unit, steps to operate and others. In addition, the internet is extra methodology applied to gain information. Surfing internet and activities during assessment of equipment able to give clear vision of specific unit with pictures and videos.

#### 3.1 Progress Flow

Figure 9.6 shown on the flow chart of the research has been carried out through the semester. The steps need to arrange accordingly to complete the research within the time frame allocated.



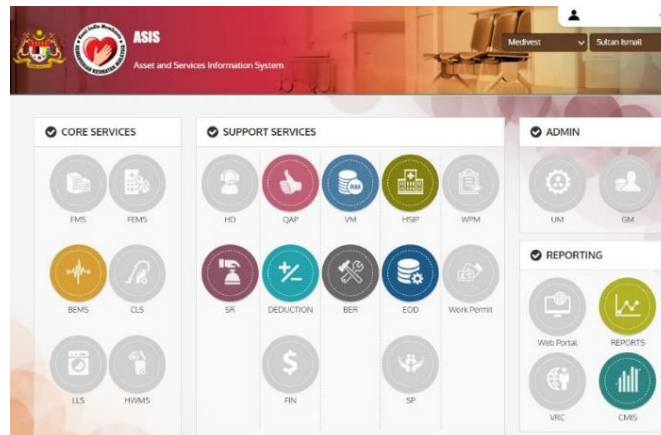


**Figure 9.6:** Flow chart in completing the Technical Assessment Report.

The flowchart above described on the progression of technical report assessment was start. The progression was start with choosing the equipment by consulting with senior engineer on most frequent receive request for corrective maintenance. Followed by finding for problem statement by discussing with in charges of the equipment. Next, identify the objectives and the further data are collected via ASIS, MyAPBESYS and referring manual. Lastly, the data are tabulated and compared. The suitable equipment was chosen.

### 3.2 Data Collection via ASIS

The data are collected via Asset and Service Information System (ASIS) such as purchase date, purchase cost, total downtime, total breakdown, and maintenance cost. The information collected were tabulated and compared. ASIS is created by Ministry of Health, Malaysia comprehensive and integrated management system for assets and services. Biomedical Engineering department are mainly use this system to update the information regarding asset. It also functions as medium providing data regarding asset in between hospital and the BEMS department. The management team as well the technical team need to up to date the asset information in this system. Figure 9.7 shows the interface of ASIS.



**Figure 9.7:** Main menu interface of ASIS

Different type of information is able to collect in this platform such as number of unit available in the hospital, types of breakdowns, types of part replacement, purchasing date and others. This data may use to analyse and differentiate the equipment chosen

### 3.3 Additional Data Collection via MyAPBESYS

MyAPBESYS is an information and management system that is used within Advance Pact Sdn Bhd. The system is heavily used for procurement and other purposes such as spare parts purchase, stock purchase, and report submitting. Figure 9.8 shows the main menu interface of MyAPBESYS. Through MyAPBESYS, assets can be searched and information regarding the machine can obtained. Information such as tag number, device location, condition, status, purchase cost and more are accessible. Nonetheless, MyAPBESYS data are heavily imported from ASIS. Figure 9.8 shows the interface of MyAPBESYS.



**Figure 9.8:** Interface of MyAPBESYS

### 3.4 User Manual and Service Manual

One of the main references for the studies is user manual and service manual. The parts of the anaesthesia machine and patient circuit flow was studied. The manuals provide adequate information regarding anaesthesia machine. Information regarding each faulty was provided in the manuals. Moreover, technician and specialist referred the manual to identify parts of faulty.

## 4.0 Analysis and Discussion

Data was collected from different source and analysed to make a reasonable outcome for this assessment report. By comparing both unit with several factor to give a best suggestion to the Biomedical Engineering department and hospital for the better asset purchasing. This analysis able to help the users to identify the frequent unit of anaesthesia machine faced highest number of faulty. Moreover, the biomedical engineers able to choose the better specification unit that can provide the good service to patients without less faulty.

### 4.1 Comparison between Leica ST5010 and Shandon Varistain 24-4

The comparison of the Automatic Slide Stainer is made by analysing the data taken from ASIS and MyAPBESYS regarding the asset information, maintenance, purchase, and register. The data is tabulated in Table 9.1

**Table 9.1:** Lecia ST5010 vs Shandon Varistain 24-4

	Lecia ST5010	Shandon Varistain 24-4
Tag no	MKA150095	MKA10166
Made	German	USA
Commissioning date	27 Dec 2012	31 Dec 1998
Purchase cost	RM 96,900	RM 49,999
Size (cm)	109 x 67x 51	51 x 74 x 74
No of slide	11	Up to 64
Program possible	15	3
Staining station	18	24
Total downtime	1806.8	22186.5

#### 4.1.1 Purchase Cost

Purchase cost is the cost that being bought during commissioning time. These two machines have 14 years gap during commissioning time. Although Lecia ST5010 price is RM96 900 while Shandon Varistain 24-4 RM 49 999 it fair to say that it almost the same price if there is no significant gap of commissioning time.

#### 4.1.2 Number of slides

For number of slides that can be place in one time, Shandon Varistain 24-4 can perform up to 64 slides depending on procedure and rack that being use. It can do 64 slides with standard rack, 40 with Consul rack, 20 with Sakura rack, and 40 with Hacker rack. While Lecia ST5010 can only do 11 slides per procedure.

#### 4.1.3 Staining Station

For staining station which is the number of reagents that can be store in the machine Shandon Varistain 24-4 can hold 24 reagents in total which is 6 reagents more than Lecia ST5010. The type of reagent is depending on user and procedure that want to be held.

## 5.0 Conclusion

In conclusion Automatic slide stainer is important lab equipment that every hospital needs to have because it helps to speed up the testing result by reducing work load and also ensure that the result is consistence during the procedures. The study of Automatic slide stainer machine has be done by researching the type of slide staining process and also type of procedure. Two Automatic slide stainer has being choose during this research where the result is Shandon Varistain 24-4 far more superior that Lecia ST5010 because not only it more chippers, it also can contain more slide which up to 64 slide per procedure than Lecia ST5010 that can only do 11 per procedure. The only down side is it was an old model and can only perform 3 programs where Lecia ST5010 can do 15 different programs. Technical assessment report has given us the chance to explore more on one specific equipment with complete data. The work-based learning internship help student to identify their place of interest and capability to become specialist on a specific equipment.

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# CENTRIFUGE

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**Abstract**— A centrifuge is a device used to separate mixed components based on size, density, average viscosity, and rotor speed. A centrifuge is commonly used in laboratories for the separation of biological molecules from coarse extracts example like sample of blood. Besides that, the centrifuge is also one of the important pieces of laboratory equipment that is used in a certain department in the hospital like hematology department. The aim of this study is to design a research work on the types of different models but with the same brand of centrifuge that has been used in the Hospital Melaka. Therefore, the data collection between two models of the centrifuge in Hospital Melaka has been conducted to gather information about the equipment. Other than that, the comparison data between two models of centrifuge is carried out to investigate the rate of failure and the rate of application of the two different models of the centrifuge. Eventually, the recommendation has been made based on data analysis and it can be concluded that one of the centrifuges recorded the least rate of failure for its lifespan during these several years.

**Keywords**- Centrifuge, mixed components, rotor, separation of biological molecules, assessment

## 1.0 Introduction

The centrifuge is one of the critical pieces of laboratory equipment that separates the particles from a solution or sample according to the size, shape, density, viscosity of the medium through the use of the rotor [1]. In a centrifuge, the sample is stored in a rotating rotor around a fixed point (axis), producing a force perpendicular to the axis. The separation is achieved by spinning the vessel containing the material at high speed where the centrifugal force pushes the heavier material outside of the vessel. These devices are available in most laboratories, from academic to clinical to research, and are used to clean cells, subcellular organelles, viruses, proteins, and nuclear acids [2].

For information, the centrifuge machine was introduced in early of 1400's in dairy industry and begin to be commercialized in

1800's. As time goes on, the centrifuge technology is increasingly developed and in 1869, the centrifuge machine was able to be use in laboratory which served as one of the important developments in the discovery of DNA inheritance [3]. In addition, there are several types of centrifuges used for the separation of different molecules, but all work on the principle of sedimentation [4].

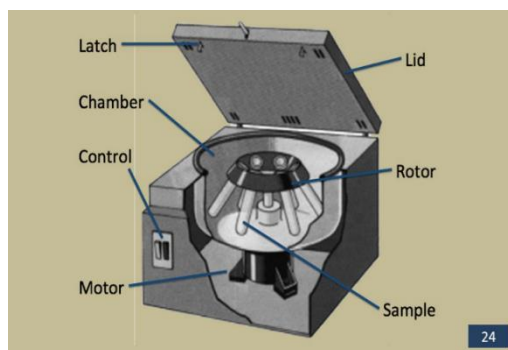
The principle of sedimentation or also known as centrifugation technique is where the rotor acceleration causes the centripetal force to act on the rotor and the centrifugal tube. This causes the densest material in the tube to be pushed in a radial direction. This also causes the lighter particles to shift and move towards the centre. Many particles can be stuck at the bottom of the centrifugal tube, especially when using a centrifugal machine. These particles are commonly known as the particles and the solution described has created a supernatant [5].

## 2.0 Centrifuge

This section review on the general function of a centrifuge based on its physical layout and all the accessories involved. There are several studies and research that has been carried out and revised and were accumulated together during the development of this assessment report. The studies are divided into three subsections consists the physical layout of the centrifuge, the specifications of the centrifuge, and the types of model of the centrifuge. Equivalent with the objective of this research that is to design a research work on the centrifuge, the related studies on the existing centrifuge have been revised.

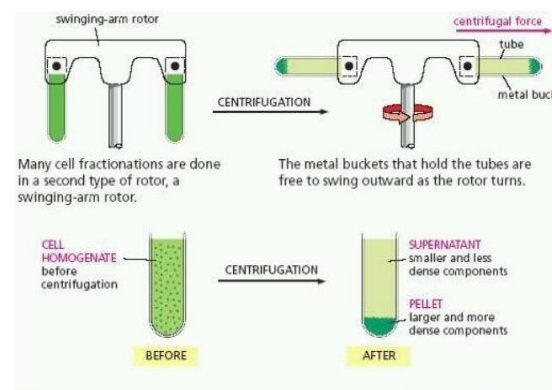
### 2.1 Physical Layout of Centrifuge

The illustrations of the physical layout of the centrifuge are explained in Figure 10.1. In terms of the operation of the centrifuge, this machine uses a rotor to separate two materials with different densities in the sample by accelerating the sample by utilising the sedimentation principle according to [5]. It has arisen as one of laboratory equipment that is important in separation process of the solutions and concerning on protein and nucleic matter research. Figure 10.1 below shows the view of the centrifuge equipment with the accessories.



**Figure 10.1:** Physical Layout of Centrifuge

Based on Figure 10.1, the rotor is placed inside the chamber of the centrifuge and the sample will be put in the rotor. Next, the motor that is placed inside the centrifuge functions as the mechanisms that rotate the rotor and also as one of the important contributing factors in the centrifugation process. The lid of the centrifuge must always be closed properly during the process to avoid the sample slipping out the centrifuge and at the same time prevent the machine from damaged. Figure 10.2 shows the centrifugation process which is the technique of separating components in the sample that involves the centrifugal force that acts on it.



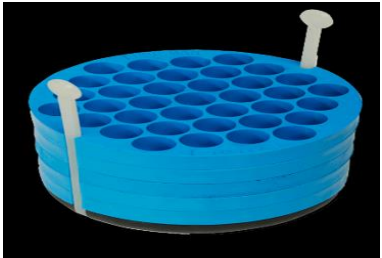


**Figure 10.2:** Centrifugation Process [7]

Based on Figure 10.2, the separation of cell constituents in the blood is done by the process of differential centrifugation which is a process in which centrifugal acceleration is adapted to precipitate certain cellular constituents and leave the others in a suspended state. During different blood centrifugation processes, the samples are divided into two phases that are pellets formed by cell pellets and supernatant that can be cell or cell-free [8]. The term centrifugal force is used to refer to one of two different concepts in which the inertial force is observed in the non-inertial reference frame and the corresponding reaction force of the centripetal force. The two different forces are equal in magnitude, but the centrifugal force is opposite to the direction of the centripetal force [7].

Figure 10. shows the accessories of the centrifuge. Each of the accessories give a huge contribution in the sedimentation process especially on the motor and the rotor.

**Table 10.1:** Accessories of Centrifuge

Parts and Accessories of Centrifuge	Function
<p>Motor</p> 	<ul style="list-style-type: none"> <li>- Centrifuge motor are high torque, series-wound DC motors, the rotation of which increases as the voltage is increased.</li> <li>- Modern centrifuges have induction drive motors that have no brushes to change.</li> </ul>
<p>Swing Out Rotor</p> 	<ul style="list-style-type: none"> <li>- Also called as horizontal rotor because the bucket or shelf that supports the centrifugal tube is suspended in such a way that it allows it to swing to a horizontal plane while under the influence of the centrifugal field.</li> </ul>
<p>Fixed Angle Rotor</p> 	<ul style="list-style-type: none"> <li>- This rotor holds the tubes at an angle to the axis of rotation.</li> <li>- The angle varies with different rotor between 25° to 40°.</li> <li>- The result to be achieved is faster than in horizontal rotor.</li> </ul>
<p>Adapters</p> 	<ul style="list-style-type: none"> <li>- Inserts for centrifuge buckets.</li> <li>- Designed to provide support for tubes, bags, bottles, and more during centrifuging.</li> </ul>

By referring to the table above, these two rotor, swing angle or horizontal angle rotor and fixed angle rotor could have different diameters but the same rotational speed. Since acceleration is a product of angular and radial angles, rotor measurement is a contributing factor. Consequently, the relative centrifugal force (RCF) is used as a standard unit and is measured in g [5].



## 2.2 Related Types and Model of Centrifuge


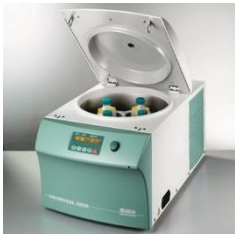
In this subsection will be explained about the types and models of the centrifuge that are available and that have been use in hospital in Malaysia. There are various types, design, model, and brand of centrifuge that had been manufactured and been used in the laboratory and research field as shown in Table 10.2. The centrifuge is designed to facilitate the process in separating the different materials contained in the solutions or sample such as blood.

**Table 10.2:** Different Model of Centrifuges

List of Model of Centrifuge			
			
Hettich Universal 320 R	Hettich EBA 280	Medifuge	Hettich EBA 20
			
Hermle Z366	LC-8 Benchmark Scientific	Allegra X-30	

According to the Table 10.2, it shows several of the different model of centrifuges that has been used in most of the hospital and laboratory in Malaysia. With the various types and model of the centrifuges enabled the user or person involves in research and laboratory field to select the device based on their preferences and its specifications. These type and model of the centrifuge are commonly used and available in Malaysia market especially for centrifuge from model Hettich-Zentrifugen. Each of these models have their own lifespan that is recommended by a manufacturer. However, for this research work, only two different model of centrifuges will be focused on as displayed on **Table 10.3**

**Table 10.3: Focus Models of Centrifuges**

Hettich EBA 20	Hettich Universal 320 R
 <ul style="list-style-type: none"> <li>• Manufacturer: Hettich-Zentrifugen GmbH.</li> <li>• Origin: Germany</li> <li>• Lifespan: 8 years</li> <li>• Cost: RM7500.00</li> <li>• Asset Age: 10 years</li> </ul>	 <ul style="list-style-type: none"> <li>• Manufacturer: Hettich-Zentrifugen GmbH.</li> <li>• Origin: Germany.</li> <li>• Lifespan: 8 years.</li> <li>• Cost: RM26500.00</li> <li>• Asset Age: 7 years.</li> </ul>

By referring Table 10.3, this research emphasizing two different models of centrifuge that are Hettich EBA 20 and Hettich Universal 320 R that is used in Hospital Melaka. The general information and specifications of the centrifuges is shown in Table 10.3 where these two centrifuges are different models but is distributed from the same manufacturers which is Hettich-Zentrifugen GmbH from Germany. According to the information given, these two centrifuges are selected by evaluate their lifespan in the Hospital Melaka where the Hettich EBA 20 has been used for 10 years while Hettich Universal 320 R has been used for 7 years. Following the objective of this assessment to investigate and analyse the performance between two different model of centrifuges, the lifespan of the equipment gives an important element that need to be notable in this research. Other than that, the cost for purchasing these two centrifuges also considered as one of the important factors in this study. For Hettich EBA 20, the purchasing cost is cheaper than Hettich Universal 320 R. where the price for Hettich EBA 20 is RM7500.00 while the price for Hettich Universal 320 R is RM26500.00. Although the centrifuge Hettich EBA 20 is cheaper, but the centrifuge has good quality, and can be used for a longer time. Meanwhile, for Hettich Universal 320 R, the price is expensive than EBA 20 but this centrifuge also has good quality and the usage on this centrifuge is more frequently than EBA 20.

## 2.3 Specification of the Centrifuges

In this subsection will illustrates the specifications of two different models of centrifuges that had been selected which consists of Hettich EBA 20 and Hettich Universal 320 R. The comparison of the specifications for these two models of centrifuge is shown in **Table 10.4**.

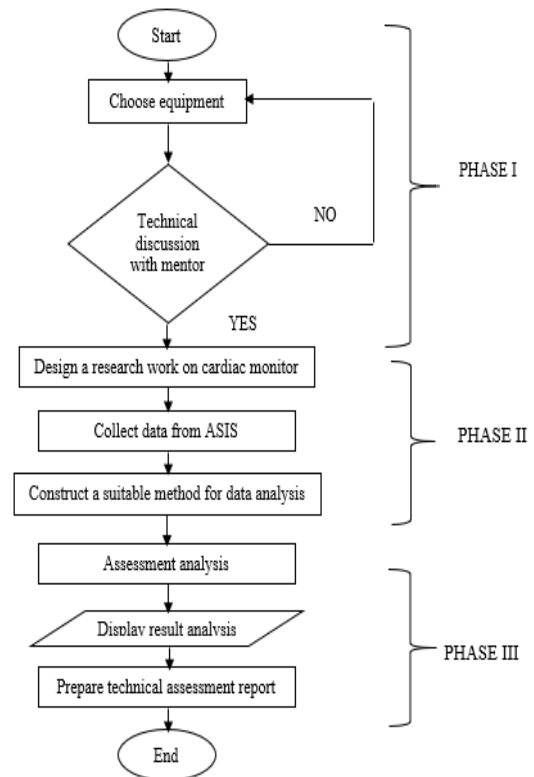
**Table 10.4** Table 10.4: The Specifications of the Two Different Models of Centrifuges

## 3.0 Methodology of Assessment

These sections will bandy on inquisition methodology that has been carried out through the assessment. The layout of the sections will be divided into several parts of subsections. The major sections are including the progress work on this assessment that consists of a flowchart on overall inquisition work. besides, it'll be continued with the explanation of the method that has be used in order to make this specialized assessment.

### 3.1 Flowchart of the Assessment

Figure 10.3 demonstrates the flowchart of the overall progress that's carried out during this study. There are three phases that are involved in this inquisition along with the objectives that have been stated previously.



**Figure 10.3:** Flowchart of Assessment on Centrifuges

From the Figure 10.3 above, Phase I of the flowchart shows the initial procedure that has been carried out where the process of selecting the suitable equipment for the assessment. In addition, the technical discussion has been made between the student and mentor to recognize suitable equipment for this research.

Next, for Phase II, the progression carried out on gathering data and information of two different model of centrifuges, Hettich EBA 20 and Hettich Universal 320 R from ASIS system. Generally, the ASIS system stores all the data and equipment information for hospitals recording data into ASIS which is genuinely important to ensure the data of the equipment are being stored for future references. After collecting the data, a suitable method is

constructed to analyse all the information obtained for the two different models of the centrifuges.

The last phase of the assessment is by conducting a technical analysis between both centrifuges by approaching techniques that consist of a comparison between two models in order to evaluate one of the best centrifuges recommended for hospital use. The research then continued by performing analysis into graphic view and prepared a full technical assessment report on these studies.

## 3.2 Method of Analysis

This section will demonstrate the methodology on how to collect the data and analyse the data that obtained from the ASIS system for Hettich EBA 20 centrifuge and Hettich Universal 320 R centrifuges.

### 3.2.1 Data Collection

Basically, since the hospital using ASIS system to record the data for all medical equipment, the process of collecting data can be easier for the technical team and engineer to review the condition of the equipment during their lifespan.

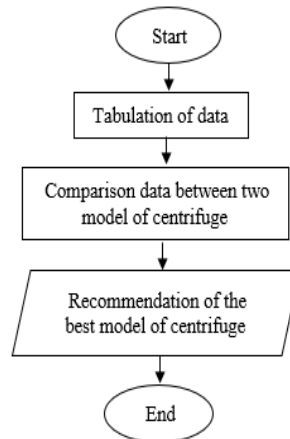


**Figure 10.4:** ASIS system

Figure 10.4: ASIS system represents Asset and Services Information System that has been used in Government Hospital in Malaysia. The ASIS system is monitored under Ministry of Health and the system is a formal site for medical officer and technical team in hospital. However, this thing can be access by certified person only as this system stores all the medical equipment data for the hospital and the data is private and confidential. Hence, the data of centrifuge in the hospital can be accessed by the technical team for this research.

### 3.2.2 Data Analysis

Data analysis is conducted after obtaining the information from the system. Figure 10.5 demonstrates on the flowchart on how to analyse all the data that have been obtained.



**Figure 10.5:** Flowchart of method of analysis

Based on Figure 10.5, the methodology on how to analyse data consists of a few steps and procedures that need to follow. Starting with the data tabulation between two types of centrifuges model, which is Hettich EBA 20 and Hettich Universal 320 R.

**Table 10.5:** Data Tabulation of Centrifuges

Model	Lifespan	Purchase cost (RM)	Type of failure	Rate of failure	Maintenance cost
Hettich EBA 20					
Hettich Universal 320R					

To illustrates, Table 10.5 shows the tabulation of data based on two different model of the centrifuges that has been chosen for this research work. Besides, in this tabulation of data consists of equipment lifespan, the purchase cost for each of the model, types of failures, rate of failures and also maintenance cost that has been spent on breakdown for each model. This method is compulsory in order to organize and sort out information that obtained from raw data in the ASIS system.

Next, research work then continued with the comparison between two model of the centrifuges to analyse the performance of each model during their lifespan. Along to the table that has been constructed, equipment performance can be analysed by using comparison method of two model that consists a few aspects in terms of parameters that will be measured and the specifications of each model of the centrifuges. Table 10.6 shows on how performance of each model is conducted by using comparison method.

**Table 10.6:** Performance Analysis on Centrifuges

Parameters	Hettich EBA 20	Hettich Universal 320R
Type of failure		
Rate of failure		
Rate of usage		
Downtime hours		

According to the Table 10.6, the parameters based on technical requirement is measured. This method is to perform an analyse on each equipment and to discover pros and cons between the two centrifuge models in Hospital Melaka. The significance of constructing all the methodology is to recommend the best centrifuge for hospital based on technical research on this assessment.

## 4.0 Assessment Analysis

This section will be discussed on the assessment analysis that has been carried out for this research work. Hereby, this study includes several units of centrifuges which consists of 2 units of centrifuges with

different models that has been used in Hospital Melaka. The structure of this section is divided into several subsections that demonstrates on the method of analysis for this research work.

#### 4.1 Collection Data and Table of Comparison

In this subsection will display the data analysis for two model of the centrifuges used in Hospital Melaka. The table of comparison will consist of several parameters that has been selected for this research work as shown in Table 10.7. Table 10.7 shows the collection of data from two different model of the centrifuges in Hospital Melaka.

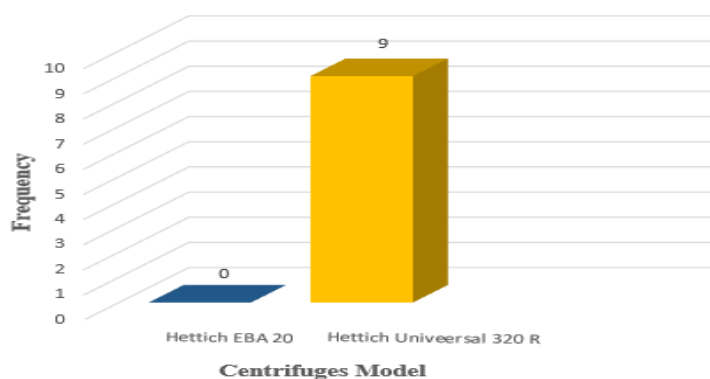
**Table 10.7:**Performance Analysis on Centrifuges

Model	Hettich EBA 20	Hettich Universal 320R
Parameters		
Total breakdown		
Downtime hours		
Total downtime repair		

The table consists of technical analysis to evaluate the performance of each model of centrifuges in 5 years starting from 2015 to 2020. For information, the expected lifespan for each of the model recommended by the manufacturer is 8 years in usage. The parameters that are measured consists of unscheduled maintenance such as total breakdown of the equipment in the past 5 years, the total downtime hours for the maintenance, and total downtime repairs cost for the breakdown of each model.

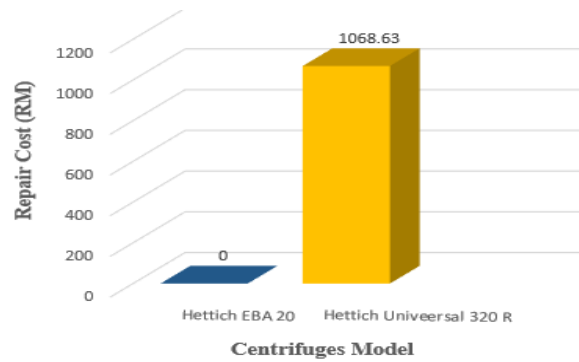
#### 4.2 Graphical Analysis

The graphical analysis for parameters from the tabulation data in Table 10.7 are illustrated in this section. The analysis for total breakdown for past 5 years is shown in Figure 10



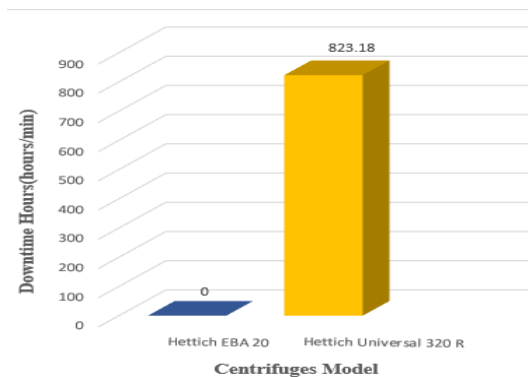
**Figure 10.6:** Total Breakdown for Past 5 Years

The data of unscheduled maintenance that has been carried out for past 5 years since 2015 to 2020 is illustrated in Figure 10.6. Based on the data, the frequency of total breakdown for the centrifuge Hettich Universal 320 R is higher than Hettich EBA 20 in which Hettich Universal 320 R has 9 total breakdowns while for Hettich EBA 20 there is no breakdown occur for the past 5 years.



**Figure 10.7:** Total Downtime Hours(hours/min)

Figure 10.7 stated the downtime hours during maintenance for each model of the centrifuges. According to the result that has been measured, it can be concluded that the total downtime hours for Hettich Universal 320 R is greater than Hettich EBA 20. The Hettich Universal 320 R have 823.18 h/min for total downtime while for Hettich EBA 20 there is no total downtime as the centrifuges never has breakdown along the time it being used in Hospital Melaka. All the results for downtime hours are calculated starting from the work order is requested and updated for unscheduled maintenance in ASIS until the work order is done and were closed in the ASIS system.



**Figure 10.8:** Total Cost Downtime Repair (RM)

Based on Figure 10.8, it shows the total costs downtime repair for both of the model. In addition, the total downtime repair is also calculated in this research in order to investigate the performance of each model of the centrifuge. The result from the graph illustrates the Hettich Universal 320 R has the higher cost than Hettich EBA 20 where the cost of downtime repair for Hettich Universal 320 R is RM1068.63 while for Hettich EBA 20 there is no payment or costing for the downtime repair as the centrifuge don't have any breakdown for the past 5 years.



## 5.0 Conclusions

### 5.1 Introduction

In this section, we will conclude about the two different models of centrifuge that had been analysed. A decision should be made if user asked as to suggest which device should be bought between two devices. As a technical staff, we will play a role as a biomedical engineer in recommending which device that suit the best for the laboratory department or other certain department so that the workflow of the department can function smoothly without any further problem.

### 5.2 Conclusions

By referring to all the data obtained and the results after being analysed, there are so many things that can be concluded. First thing first, according to the result and data obtained from the ASIS system, the journal, article, website, discussions and other references, we can see that centrifuge from the Hettich-Zentrifugen manufacturer have a good quality and reliable equipment especially for laboratory equipment. We can see that centrifuge for Hettich EBA 20 model since the first year of it being used at the hospital which is in 2010 until 2020, there is no breakdown occur on it although it already ages for 10 years and already overlimit their lifespan which is 8 years.

Other than that, for the Hettich Universal 320 R also from the same manufacturer that is Hettich-Zentrifugen, we can see there are several breakdowns occur to the equipment since their first year of it being used in Hospital Melaka since 2013 to 2020. However, based on the breakdown that have occurred, we can say that the failure is not giving major or critical effect to the centrifuge as the common failure that always occur to the Hettich Universal 320 R centrifuge is only a system error, imbalance error and also lid lock error. For the two error which is system error and imbalance error, the thing that need to be done is only setting back the system and do the calibration on the centrifuge and the centrifuge will be functioning good. Only for the lid lock error that we need to replace the new spring as the spring keep attend to be broke and lose due to the excessive usage of the centrifuge.

Last but not least, it is also important to consider the situation between the usage and the maintenance services of the equipment in the hospital and the usage and maintenance services of the equipment in other laboratory or research field in addition to evaluating the specifications and the quality of the equipment from other aspects. Overall, we can say that the centrifuge from Hettich EBA 20 models is good and more reliable to be use than Hettich Universal 320 R.

## 6.0 Recommendations

As for the recommendations, we believe that both of the centrifuge is good and reliable for the used in laboratory and other department in Hospital Melaka. However, regardless of the model of the equipment, the user also must play important roles in keeping the equipment in good condition. So for that, the user must use the equipment properly and efficiently by following the standard operation of the equipment to avoid any damage or breakdown from occur frequently on that equipment. Furthermore, the maintenance of the equipment especially for the laboratory equipment must also be done by following the standard and correct procedure and importantly must followed the scheduled maintenance that had been set up so that it will keeps the repairs call for the equipment in minimum way.

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# NON-INVASIVE BLOOD PRESSURE (VITAL SIGN MONITOR)

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**Abstract**— In developing countries, measurement of vital sign data is generally performed in hospitals or laboratories where patients are kept under observation with many electrodes attached to the body. The combination of biomedical data acquisition systems and information technology (IT) enables continuous real time monitoring of physiological data, increasing the likelihood of medical treatment and medical research for patients. To achieve this goal, research and development of various wearable smart sensors, sensor miniaturization, signal processing, wireless transmission, and database development have been conducted for this important data. Our goal is to implement a usable system that can be used in locations outside the coverage areas of hospitals and medical institutions. In this paper we present the current stage of the project where some smart modules to recommend the best non-invasive vital sign monitor at the hospital. Preliminary results on non-invasive blood pressure (NIBP), electrocardiogram, and wireless are also presented.

**Keywords** – Vital Sign, NIBP, technical specification, model

## 1.0 Introduction

Vital sign monitor applications span areas from long term monitoring of patient's health in hospitals. These monitors are invaluable aids that give health care providers immediate readings regarding a patient's status. This almost instantaneous information helps define the treatment a patient might need at any given time. There are many types of NIBP vital sign that use from many hospitals in other foreign country include Malaysia.

Body temperature may be abnormal due to fever (high temperature) or hypothermia (low temperature). A fever is indicated when body temperature rises about one degree or more over the normal temperature of 98.6 degrees Fahrenheit, according to the American Academy of Family Physicians. Hypothermia is defined as a drop in body temperature below 95 degrees Fahrenheit. According to the Environmental Protection Agency, mercury is a toxic substance

that poses a threat to the health of humans, as well as to the environment. Because of the risk of breaking, glass thermometers containing mercury should be removed from use and disposed of properly in accordance with local, state, and federal laws. Contact your local health department, waste disposal authority, or fire department for information on how to properly dispose of mercury thermometers.

The pulse rate is a measurement of the heart rate, or the number of times the heart beats per

## 2.0 Literature Review

This chapter is about technical assessment and discussion of technical specification for four models of NIBP vital sign monitor that used at Hospital Tuanku Jaafar Seremban, Negeri Sembilan.

The literature review also knows the academy study or observation is carried out to find the information or data necessary to carry out a technical assessment and explain the functions and specifications of the model device or components that used.

Furthermore, this chapter will also describe the existing device of infusion pump that using in ICU ward and find out the different types of model to makes a comparison based on technical part of infusion pump.

### 2.1 NIBP (Vital Sign Monitor)

There are four main vital signs that routinely monitored by medical professional. Body temperature, heart rate, respiration rate, blood pressure, pulse oxygenation (oxygenation of fresh arterial blood) and also blood glucose. Temperature, heart rate can be obtained from the wrist.

#### 2.1.1 Body temperature

Body temperature can provide an insight into the physiological state of person [2] [3]. Figure 11.1 shows the body temperature chart.

minute. As the heart pushes blood through the arteries, the arteries expand and contract with the flow of the blood. Taking a pulse not only measures the heart rate the normal pulse for healthy adult's ranges from 60 to 100 beats per minute. The pulse rate may fluctuate and increase with exercise, illness, injury, and emotions. Females ages 12 and older, in general, tend to have faster heart rates than do males. Athletes, such as runners, who do a lot of cardiovascular conditioning, may have heart rates near 40 beats per minute and experience no problems.

#### BODY TEMPERATURE CHART

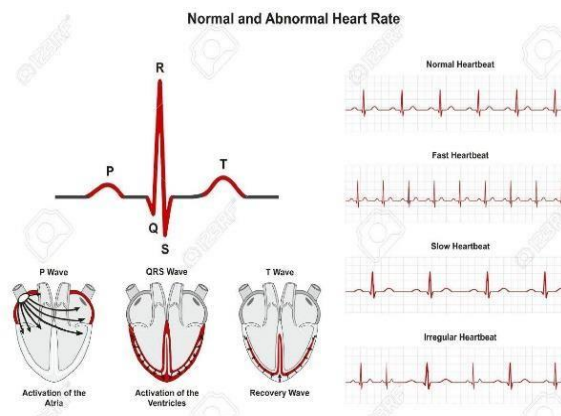
Age	Normal	°C to °F Temperature Conversion Chart
Body Temperature for a Baby	A normal temperature in babies and children is about <b>36.4°C (97.5°F)</b> , but this can vary slightly. A <b>fever</b> is usually considered to be a temperature of <b>38°C (100.4°F) or above</b> .	36.4 °C = 97.6 °F 36.5 °C = 97.7 °F 37.0 °C = 98.6 °F 37.4 °C = 99.4 °F
Body Temperature for Children	The average normal body temperature for children is about 37°C (98.6°F).	37.6 °C = 99.6 °F 38.1 °C = 100.6 °F 39.0 °C = 102.2 °F
Body Temperature for Adults	Normal body Temperature under the arm (axillary) is about 36.5°C (97.7°F)	40.0 °C = 104.0 °F 41.0 °C = 105.8 °F

**Figure 11.1:** Temperature of Human Body

Based on Figure 11.2, elderly, fever may help to verify an ongoing infection when there are no other specific sign and symptoms [3] [1]. The body temperature depends on the measurement site. If it at room temperature (25°C), the normal wrist temperature is around 32°C while the body core temperature is around 37°C and fever as 38°C [3] [2]

### 2.1.2 Heart Rate

The function of the human heart is to pump oxygenated blood and nutrients to the body and remove carbon dioxide and other waste [2]. The heart rate or pulse is the frequency of cardiac cycle, expressed as beats per minute (b.pm.) and the change of heart rate is the indicator of any change to the physical or mental state of a person [2]. Heart rate can be measured manually by listening directly to the heartbeat by using a stethoscope or at the wrist from the radial artery and it also can be measured from the carotid artery at the neck.



**Figure 11.2:** Normal Vs Abnormal Heartrate

The graph of Normal and Abnormal Heartrate is shown in Figure 11.2 base don the by the physical state of the heart.

### 2.1.3 Spo2

Brand	Welch Allyn
Model	Welch Allyn Spot Vital Sign
Weight / Dimension	<ul style="list-style-type: none"> <li>2kg</li> <li>14.5cm (W) x 24.6cm (H) x 12.0cm (D)</li> </ul>
Power source	<ul style="list-style-type: none"> <li>7.2 V DC at 1.0 A rechargeable sealed lead acid internal battery</li> <li>AC Power Supply</li> </ul>
Battery life	<input type="checkbox"/> 90% to 100% after 12 hours
Mounting	<input type="checkbox"/> Self-supporting on rubber

of haemoglobin in the blood (oxygenated and nonoxygenated haemoglobin). In the wristband Spo2 will be measured at the fingers of the patients.

### 2.2 Product Review

Welch Allyn Spot Vital Sign

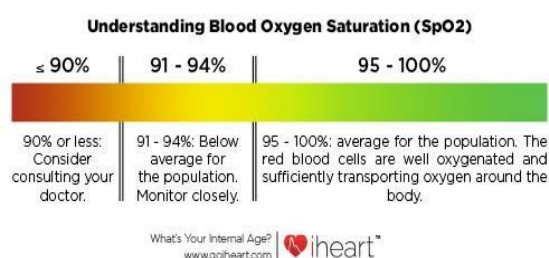
- Mindray vs-600
- Edan M3 Vital Sign Monitor

### 2.3 Model 1: WELCH ALLYN SPOT VITAL SIGN

#### 2.3.1 Specification

**Table 11.1:** Specification

Spo2 stands for peripheral capillary oxygen saturation, an estimate of the amount of oxygen in the blood. Figure 11.3 shows the blood oxygen saturation level.



**Figure: 11.3:** Blood oxygen saturation (Spo2)

Based on Figure 11.3, it is the percentage of oxygenated haemoglobin (haemoglobin containing oxygen) compared to the total amount

### 2.3.2 The physical layout of Welch Allyn spot vital sign

Figure 11.3 shows a physical layout of Welch Allyn spot vital sign.



**Figure 11.3:** Physical diagram of Welch Allyn spot vital sign.

### 2.3.3 Welch Allyn spot vital sign feature

There are several features of models and can be summarize as belows;

- Lightweight and portable with a variety of mounting options
- All configurations include NIBP, pulse rate and MAP
- Optional SureTemp® Plus thermometry
- Optional Masimo® or Nellcor® pulse oximetry (SpO2)
- One of the most cost-effective multi-parameter devices on the market
- Measures NIBP, pulse rate, temperature and SpO2 in about 30 seconds

Portability	<input type="checkbox"/> May be hand-carried when held by the rear handle.
Blood Pressure	<input type="checkbox"/> mmHg to 300 mmHg <input type="checkbox"/> <b>Systolic range</b> 60 mmHg to 250 mmHg <input type="checkbox"/> <b>Diastolic range</b> 30 mmHg to 160 mmHg <input type="checkbox"/> <b>Accuracy</b> Blood pressure accuracy meets or exceeds SP10-1992 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: $\pm 5$ mmHg mean error, 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.  <input type="checkbox"/> <b>Overpressure cutoff</b> 305 mmHg -0/+15 mmHg
Temperature	<input type="checkbox"/> <b>Accuracy Calibration</b> accuracy: $+0.2^{\circ}\text{F}$ ( $+0.1^{\circ}\text{C}$ ). <input type="checkbox"/> <b>Range</b> Maximum: $109.4^{\circ}\text{F}/43.0^{\circ}\text{C}$ Minimum: $86.0^{\circ}\text{F}/30.0^{\circ}\text{C}$ <input type="checkbox"/> <b>Determination time:</b> Oral: approximately 4 seconds Axillary: approximately 10 seconds Rectal: approximately 15 seconds
Pulse Oximetry	<input type="checkbox"/> <b>Performance measurement ranged</b> SpO2: 70 to 100% Pulse Rate: 25 - 240 beats per minute (BPM) <input type="checkbox"/> <b>SpO2 accuracy</b> Saturation: 70% to 100% No Motion: Adults, Pediatrics $\pm 2$ digits Motion: Adults, Pediatrics $\pm 3$ digits Low Perfusion: Adults, Pediatrics $\pm 2$ digits

## 2.4 Model 2: Mindray vs-600

### 2.4.1 Specification

**Table 11.2:** Specification for Mindray vs-600

Brand	Mindray
Model	Vs-600
Weight / Dimension	<ul style="list-style-type: none"> <li>1.7kg</li> <li>175mm (W) x 135mm (H) x 145mm (D)</li> </ul>
Power source	<ul style="list-style-type: none"> <li>100-240 VAC <math>\pm 10\%</math> 50/60 Hz</li> <li>Internal battery 6VDC</li> </ul>
Battery life	<ul style="list-style-type: none"> <li>3000mAh 6 V</li> <li>6 hours with full battery (&lt;125 ml/h)</li> </ul>
Power consumption current	<ul style="list-style-type: none"> <li>50 VA maximum</li> </ul>
Power management and interface board	<ul style="list-style-type: none"> <li>Charge and discharge of battery and charge detection; v DC/DC conversion: outputs 12V and 5V DC power;</li> <li>Control over power On/Off key and AC, BAT indicator;</li> <li>Communication transmission among parameter modules;</li> <li>Providing isolation power for the SpO2 module; and, Providing external connectors, filter and protection for these connectors.</li> </ul>
Blood Pressure	<ul style="list-style-type: none"> <li>0 mmHg to 300 mmHg</li> <li><b>Systolic range</b> 60 mmHg to 280 mmHg</li> <li><b>Diastolic range</b> 30 mmHg to 200 mmHg</li> <li><b>Accuracy</b> Blood pressure accuracy meets or exceeds SP10-1992 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: <math>\pm 5</math> mmHg mean error, 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.</li> <li><b>Overpressure cut off</b> 305 mmHg -0/+15 mmHg</li> </ul>



**Figure 11.4:** Shows physical diagram of Mindray vs-600

### 2.4.3 Features for Mindray vs-600

There are several features of Mindray vs-600 model;

- Super high-definition display provides bright and clear view.
- Weighing less than 1.7 kg, its lightweight design provides a highly mobile vital signs solution
- Super Li-ion battery provides more than 22 hours of continuous monitoring
- Trusted temperature measurement provides fast temperature reading
- PI (Perfusion Index) provides caregivers
- with an indication of the reliability of SpO2

### 2.4.2 The physical layout of Mindray vs-600 vital sign monitor

Figure 11.4 shows physical layout diagram of Mindray vs-600 model.

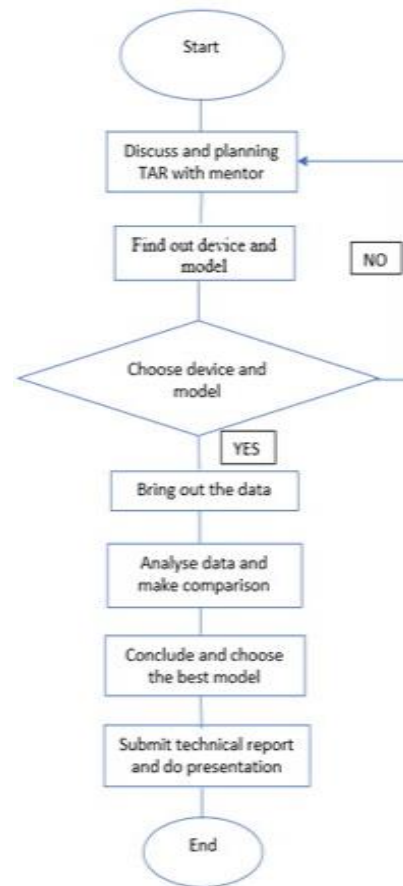


### 3.0 Methodology

Technical Assessment Report (TAR) study has two progress flow charts to complete the outcome data and analysis. The first flow chart is about the TAR preparation process. It is very important to plan and discuss with your mentor the medical equipment to be selected as the main subject of this assessment. To be clearer, we need to choose one type of ward or patient to be determined by the specifications of the user needs and to get a better comparison. The second flow chart is about the process of finding and analysing data. There are two steps to this process. The first step is to choose 1 of the best 3 according to your technical specifications based on your needs. The second level is to choose the best of the two models based on product reviews, maintenance, spare parts, company records and frequent installations.

#### 3.1 Flowchart process preparing TAR

Figure 11.5 shows the flow chart process for preparing a technical assessment report (TAR). The process begins with a discussion and planning of the TAR with a mentor. Then look for devices and models that are in your company or perform maintenance. Then select your device and select two device models. Extract data for two models that be choose, perform analysis and make a comparison. After passing the comparison, draw conclusions and choose the best model. Finally, submit a technical assessment report and make a presentation.



**Figure 11.5:** Flowchart process preparing TAR.

Flowchart in Figure 11.5 shows the process preparing Technical Assessment Report from start planning and end with submit the report and presentation.

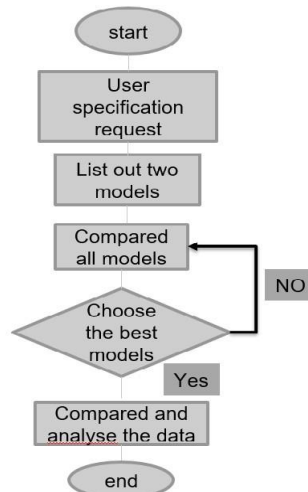
#### 3.2 Flowchart process of data analysis

In Figure 11.6 shows flowchart process of data analysis in technical assessment report (TAR). This process has two stage which is Stage 1 is choose the best 80% from 2 models by technical specification based on user requirement using matrix diagram and Stage 2 choose the top from 2 models based on Maintenance, after sale service, Product review and Spare part using matrix diagram

Stage 1 process start with identify user requirement specification for device. List out the frequent Install Based of device from six hospital and list two models of device with higher population. After that, compare between two models by technical specification based on user requirement using Matrix chart. Choose the best from two vital sign. Stage 2 process start with collecting data for the best 2 models based on, Maintenance, Product review, and Spare part. Choose top of the best model.

**Figure 11.6:** Flowchart process of data analysis

Flowchart in Figure 11.6 shows the process of data analysis. These processes have two stage which stage 1 is comparing two model based on user requirement specification and stage 2 is comparing best 2 model based on maintenance, spare part, after sale service, install based and product review.



## 4.0 Result and analysis

### 4.1 Introduction

This chapter will discuss the data analysis that has been carried out to produce this project. The layout of this chapter is divided into several subtopics that describe the analysis method for this project.

### 4.2 Comparison based on User Requirement Specification.

Stage 1 process start with identify user requirement specification for NIBP vital sign monitor on general ward. After that, list out the breakdown and instalment based of device from the hospital and list three models of device with higher population. Then, compare all models by technical specification based on user requirement using Matrix diagram.

#### 4.2.1 List quantity of non-invasive blood pressure vital sign monitor from two model at the hospital

**Table 11.3:** Table of quantity model of NIBP vital sign monitor that used at the hospital.

No	Model	Total	Used
----	-------	-------	------

1	Welch Allyn Spot Vital Sign	140	80
2	Mindray vs-600	112	70

Table 11.3 shows the install-based data for two model of non-invasive blood pressure vital sign monitor located at the hospital and the quantity that been used.

#### 4.2.2 Matrix diagram for Stage 1

**Table 11.4:** The comparison between two models NIBP vital sign monitor

Model Type		Welch Allyn Spot vital sign	Mindray vs-600
		SCORED	
P R I O R I T Y	1. Time taken to start and respon	3 Seconds	2 Seconds
	Score	5	4
	2. Specific button & user friendly	Ready to use	Ready to use
	Score	5	4
	3. Applicable Set	Can use other brand set	Can use other brand set
	Score	5	5
	4. General Ward	Use in ward	Use in ward
	Score	5	5
	5. Battery life (mA/h)	2200mAh	3000mAh
	Score	3	4
ADDITIONAL	6. Weight	2kg	1.7kg
	Score	5	3
	7. Size (mm)	145mm (W) x 246mm (H) x 120mm (D)	175mm (W) x 135mm (H) x 145mm (D)
	Score	2	3
TOTAL		30	28

5 = Very good      4 = Good      3 = moderately effective      2 = Kindly effective  
1 = Not effective

Table 11.4 shows the matrix diagram for stage 1. These table is to compare three models of NIBP vital sign monitor based on user requirement specification. For user requirement specification divided by two sections are priority and additional. The priority section user requirement time taken to start and respond, specific button and user friendly, applicable set, general ward, and battery life. For additional section user requirement are weight, size. All specification will be mark based on user requirement from level 1 not effective until level 5 very good.

### 4.3 Stage 2 – Comparison based on, Maintenance, Product Review, Spare Parts and Install based.

Stage 2 process start with collecting data for the best 3 models based on Maintenance, Spare part, After Sale service, Install based and Product review. Then compare and analyse data by using Matrix diagram. After that used Pareto Chart to choose the best 80% from 3 models. Lastly, Choose top of the best model.

#### 4.3.1 Matrix Diagram for stage 2

**Table 11.5:** Comparison between models of NIBP matrix diagram for 2 models

Model Type	Welch Allyn Spot Vital Sign	Mindray VS-600
	SCORED	
1.Maintenance	- Average breakdown twice a week - Rarely breakdown request from applied part	- Average breakdown once a week - Rarely breakdown request from applied part and battery
Score	<b>5</b>	<b>5</b>
2.Spare part	- Bp cuff leaked problem - spo2 probe malfunction - Easy to get spare part items at the short time	- Spo2 probe malfunction -Bp cuff leaked -Battery problem -Only retail seller can provide spare part items and need to wait for several days
Score	<b>4</b>	<b>3</b>
3.Install based	All departments hospital Total = 80	General ward only Total = 40
Score	<b>5</b>	<b>4</b>
4.Product review	High rating and good respond review from user	Medium rating on product review from user
Score	<b>5</b>	<b>4</b>
<b>Total score</b>	<b>19</b>	<b>16</b>

5 = Very good  
effective  
1 = Not effective

4 = Good

3 = Moderate effective

2 = Kindly

Table 11.5 shows the matrix diagram for stage 2. These table is to compare best two models of nibp vital sign monitor based on maintenance, spare part, install based and product review. The markers will be given through the information that has been taken from the biomed staff viewpoint that has used the two models

## 5.0 Conclusion

In conclusion, NIBP vital sign monitor are very important in the context of improving the design of devices that sometimes occur during the administration of the vital sign monitor. Each NIBP vital sign monitor model has its own characteristics and advantages based on its own manufacturer. But as evaluated, the two NIBP vital sign model found that, in many ways, the optimal Welch Allyn Spot vital sign model performs better than the others. Spare parts and lower overall replacement costs are more readily available in the Mindray vs-600.

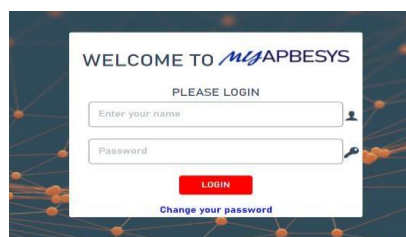
From the results has been identified of the NIBP vital sign monitor that has been done, we have understood the function of the vital sign monitor machine. We also study and make an observation how vital sign monitor can provide a good system in good care patient health status. Technical assessment report also brings advantages and positive results to students who should be concerned because it can also build teamwork capabilities among students, mentors, and teachers.

## 6.0 Recommendation

Based on the assessment and analysis has done. Welch Allyn Spot Vital Sign can be recommended a better and most reliable vital sign monitor than Mindray vs-600. Welch Allyn Spot Vital Sign have best featured from its technology more comfortable and friendly user compare to Mindray vs-600, in addition it the lowest breakdown than the other model and can perform at very best condition. Of course, the breakdown much more compares to Mindray vs-600 but this is because this machine is always been used by user compare to that.

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# BLOOD GAS ANALYZER (ABG)

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**Abstract**— One of the most important points of treatment research in the management of critically ill patients is the Arterial Blood Gas analyzer (ABG). This equipment used for directly measuring pH, partial pressure of carbon dioxide ( $p\text{CO}_2$ ) and oxygen ( $\text{O}_2$ ), usually in arterial whole blood specimens. Measurements are made using three different sets of electrodes. Arterial blood gas (ABG) is an integral aspect of the diagnosis and treatment of high-risk patient's oxygenation status and acid-base balance, as well as the care of critically ill patients in the Intensive Care Unit (ICU). There are several models of ABG that is available in market and each of it have their own pros and cons. In this situation, a lot of requests regarding corrective maintenance and high repair costs are received by hospitals. Thus, the study is conducted through a comparison between Radiometer ABL800 Basic and Stat Profile Phox Plus L. At Hospital Tuanku Jafaar, these models are commonly used. The purpose of this research is to make comparison between two different models of ABG machine, to investigate the breakdown history and features in order to come out with better units and to recommend the best ABG machine model at hospital. The data and information are collected through Asset and Service Information System (ASIS), Central Management Information System (CMIS) and also survey questionnaire to related person. Data analysis are focused on its commission details, equipment costing, maintenance cost, breakdown history, breakdown cost, problem of causes and user-friendly among users. Based on assessment, from the data collection, the best model would be strongly recommended to user for future purchasing process.

**Keywords** – Arterial blood gas (ABG), Intensive care unit (ICU), Asset and Services Information System (ASIS), Central Management Information System (CMIS), corrective maintenance

## 1.0 Introduction

Arterial blood gas analysis is a common investigation in emergency departments and intensive care units for monitoring patients with acute respiratory failure. It also has some applications in general practice, such as assessing the need for domiciliary oxygen therapy in patients with chronic obstructive pulmonary disease. An arterial blood gas result can help in the assessment of a patient's gas exchange, ventilatory control and acid-base balance.

An ABG test measures the blood gas tension values of the arterial partial pressure of oxygen ( $\text{PaO}_2$ ), and the arterial partial pressure of carbon dioxide ( $\text{PaCO}_2$ ), and the blood pH and arterial oxygen saturation ( $\text{SaO}_2$ ). The bicarbonate level in the blood can also be calculated by ABG test. Many blood-gas analyzers will also report concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin. ABG testing is mainly used in pulmonology and critical-care medicine to determine gas exchange across the alveolar-capillary membrane. ABG testing also has a variety of applications in other areas of medicine.



The three electrodes were introduced in about 1960 following inventions by R Stow ( $\text{CO}_2$ ) and L Clark ( $\text{pO}_2$ ) both dating from 1954. Internal computers calculate  $\text{O}_2$  saturation, base excess, bicarbonate, and other derived variables from these outputs such as the compensation by the body for acid–base abnormalities. Arterial  $\text{pO}_2$  and  $\text{pCO}_2$  can be approximated using heated skin surface ‘transcutaneous’ electrodes, which are commonly used in premature infants and nurseries [1].

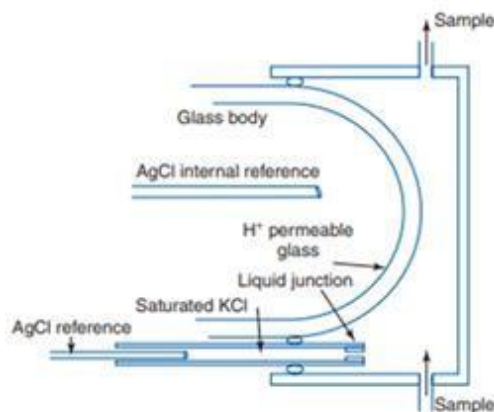
## 2.0 Electrodes

Electrochemical devices usually referred to as electrodes have been used to analyse blood gas values. The function of these specific electrode is explained below. All electrodes used in blood gas analysis measure changes in either electrical current or voltage and equate these changes with chemical measurements.

### 2.1 The pH electrodes

The pH is a measurement of the acidity of the blood, indicating the number of hydrogen Ions  $[\text{H}^+]$  present. Most of the hydrogen ions in the body are the result of carbohydrate and protein metabolism. The concentration of hydrogen ion is maintained within a tight range of 7.35–7.45 by 3 mechanisms working in concert at different time frames and at different levels. The blood and tissue buffering system is activated within seconds, followed by the respiratory system where  $\text{CO}_2$  is moderated within minutes, and the renal system where  $\text{H}^+$  is excreted and  $\text{HCO}_3^-$  recovered over several hours or days to reach equilibrium [2].

A pH and reference electrode is schematically shown in Figure 12.1.[3]



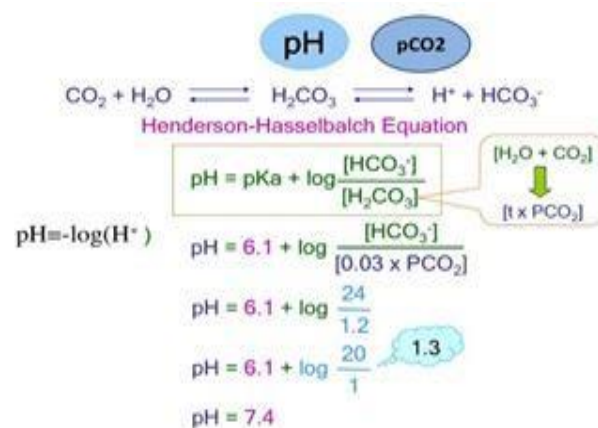
**Figure 12.1:** Blood pH electrode with a junction to a reference electrode in a thermostatted cuvette

Based on Figure 12.1 in 1905, according to Max Cremer hydrogen ions permeated some kinds of very thin glass, producing electrical potential gradients across the glass. In 1909, Fritz Haber and Z Klemensiewicz invented the first glass pH electrode [1]. Its potential was a linear function of pH, not  $\text{H}^+$  ion concentration. In 1925, the first glass cup-shaped blood pH electrode was produced by Phyllis T Courage. By 1933, capillary blood pH electrodes were being made commercially. Blood pH was corrected to  $37^\circ\text{C}$  by Rosenthal factor ( $0.0147\text{ }^\circ\text{C}^{-1}$ ) until thermostatted blood pH electrodes became available in the 1950s

### 2.2 Partial Pressure of Carbon Dioxide ( $\text{pCO}_2$ ) measurement

The normal pCO<sub>2</sub> range reflects the amount of CO<sub>2</sub> dissolved in the blood. Carbon dioxide is produced by the internal respiration of tissue cells and excreted from the body by external respiration via the lungs.

To assess hypothermic pulmonary gas, exchange a laboratory for highly accurate pCO<sub>2</sub> analysis using the Henderson-Hasselbalch (HH) equation which is shown in Figure 12.2[4]. This required measuring plasma CO<sub>2</sub> content by acidification and extraction in a manometric Van Slyke apparatus and measuring pH and correcting it to 37°C. In Copenhagen's communicable disease hospital in 1950, sometimes up to 100 patients at a time were manually ventilated by volunteers using a bag and mask with O<sub>2</sub>. The laboratory director Poul Astrup, needing a faster analytic method than the HH equation, devised a new simple method. He measured pH before and after equilibrating the sample with known pCO<sub>2</sub>. He then computed patient pCO<sub>2</sub> by extrapolation. His method became the standard for the rest of the decade shown in **Figure 12.2**



**Figure 12.2:** Henderson-Hasselbalch Equation

From Figure 12.2 the Henderson-Hasselbalch equation is for estimating the pH of a buffer solution and finding the equilibrium pH in an acid-base reaction. The formula for the Henderson-Hasselbalch, where pH is the concentration of [H<sup>+</sup>], pKa is the acid dissociation constant, and HCO<sub>3</sub><sup>-</sup> and H<sub>2</sub>CO<sub>3</sub> are concentrations of the conjugate base and starting acid. The equation can be used to determine the amount of acid and conjugate base needed to make a buffer solution of a certain pH.

### 2.3 Partial Pressure of Carbon Dioxide (pCO<sub>2</sub>) electrode

In August 1954, Richard W. Stow, Ph.D. (Associate Professor of Physical Medicine) a physical chemist, reported the design of a CO<sub>2</sub> electrode at the fall meeting of the American Physiologic Society in Madison, Wisconsin [5][6]. He covered a glass bulb-shaped pH electrode with a rubber glove through which CO<sub>2</sub> can diffuse but H<sup>+</sup> cannot, over a film of distilled water. However, Stow's electrode drifted because various cations in pH glass altered the distilled water pH. This electrode was stabilized by John Severinghaus at the National Institute of Health (NIH) by adding bicarbonate and salt, and was manufactured by many firms from 1959 onwards. A blood pCO<sub>2</sub> electrode is illustrated in Figure 2.3.

### 2.4 Oxygen electrode

In 1950, Leland Clark at Antioch College, Ohio used perfused isolated liver to study steroid metabolism. He needed oxygenated blood so he built a bubble oxygenator and discovered how to

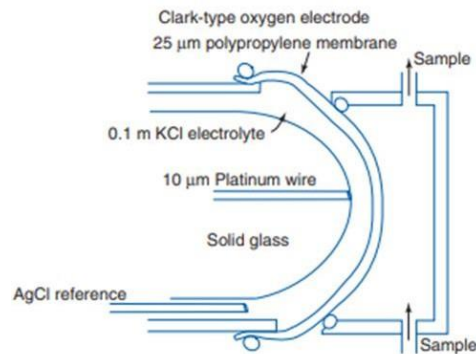
defoam the blood using silicone oil on glass wool. Figure 12.3 shows the invention of a method of defoaming in a bubble oxygenator introduced by Leland Clark.



**Figure 12.3:** Leland Clark with his invention of a method of defoaming in a bubble oxygenator (1952).

To prevent blood protein in Figure 12.3 from poisoning a platinum disc cathode sealed in glass, he covered it in cellophane. It served his purpose but it was inaccurate, requiring very high flow past the sensor due to the oxygen depletion at the membrane surface due to cathode consumption. In October 1954, by mounting a reference electrode and cathode in electrolyte in a sealed probe, Clark was able to replace cellophane with a less O<sub>2</sub> permeable and electrically insulating polyethylene membrane shows in figure 12.4 [4].

Figure 12.4 shows a polarographic oxygen electrode, a negatively biased platinum cathode donates electrons. There are two electrodes within a single unit, both of which are found behind a single semi-permeable membrane. This is a polypropylene membrane (O<sub>2</sub> - permeable), preventing bacteria, proteins, sediment traversing it. There are two electrodes which is platinum cathode and Ag/AgCl anode shows in Figure 12.4 the platinum cathode is the wire cathode act as a catalyst and Ag/AgCl anode is increases stability of the circuit and it guards against drift due to concentration of the pO<sub>2</sub> electrolyte which is KCL, 0.1mmol.



**Figure 12.4:** Schema of Clark's polarographic PO<sub>2</sub> electrode, after cathode size was greatly reduced to avoid 'stirring' effect

#### Dissolved oxygen:

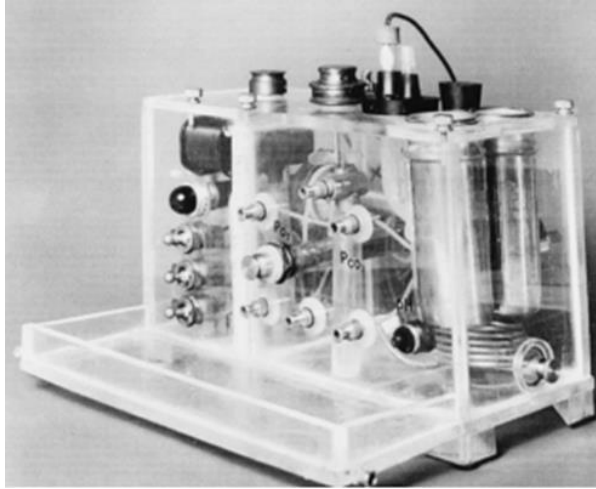


In the Figure 12.4 the only major functional change since Clark's original invention has been to reduce the cathode diameter from 2 mm to about 10 mm, requiring far more sensitive current analysis, which was not available 50 years ago. This almost eliminated the need for the sample to be rapidly stirred. The electrolyte usually contains KCl, and may have added agents for viscosity. No separator is needed between cathode and membrane. The cathode is biased to about - 0.65 V at which all oxygen molecules reaching the cathode are reduced. Cathode current is a linear function of the membrane surface pO<sub>2</sub>.

In 1958, Severinghaus and Bradley created the first three-function blood gas analyzer by mounting a Clark pO<sub>2</sub> electrode with a tiny stirring paddle, a Stow-Severinghaus pCO<sub>2</sub> electrode, and a commercial pH electrode in a water bath at 37°C which is showed in Figure 12.4. A small tonometer was included in which blood could be equilibrated with air or a known gas to calibrate the Clark electrode. Modern blood gas analyzers compute many variables from the three measured values.

## 2.5 Transcutaneous PO<sub>2</sub>

PaO<sub>2</sub> can be estimated transcutaneously using a flat Clark type PO<sub>2</sub> electrode, typically internally heated to about 43°C. Heating causes sufficient dermal vasodilation to raise skin capillary PO<sub>2</sub> to nearly equal arterial PO<sub>2</sub>. Heating also raises blood PO<sub>2</sub> by about 7% per degree, while skin oxygen consumption reduces surface PO<sub>2</sub>, these two factors approximately cancelling each other out [1].



**Figure 12.5:** First three-function blood gas apparatus (pH, partial pressure of carbon dioxide [pCO<sub>2</sub>], and partial pressure of oxygen [pO<sub>2</sub>] electrodes) built by Severinghaus and Bradley (1959).

The Figure 12.5 shows the first blood gas analyzer containing three electrodes in a water bath at 37°C with tonometer for preparing blood for calibration of pO<sub>2</sub> electrode. Reproduced from Severinghaus JW in 2002. The invention and development of blood gas apparatus.

## 2.6 Transcutaneous pCO<sub>2</sub>

Arterial pCO<sub>2</sub> can also be estimated transcutaneously using flat CO<sub>2</sub> electrodes heated to 43°C to increase skin capillary blood flow. The signal must be corrected -4.7% per degree to 37°C, and reduced about 4 Torr to compensate for skin metabolism and electrode surface cooling.

## 2.7 O<sub>2</sub> Saturation

Oxygen saturation measures the percentage of hemoglobin that is fully combined with oxygen as represented by the oxygen-hemoglobin dissociation saturation curve. The plateau of the hemoglobin dissociation curve shows that there is a substantial reserve for oxygen, and hemoglobin saturation remains high at about 75–80% at pO<sub>2</sub> greater than 40mmHg.

## 2.8 PRINCIPAL OPERATION OF BLOOD GAS ANALYZER

### Measurement of pH (Acidity)

The pH electrode is a “glass” electrode consisting of a 3-dimensional latticework of a central Silicon atom surrounded by 4 Oxygen atoms. There is incorporation of various metal oxides ( $\text{Ca}^{2+}$ ,  $\text{Na}^{+}$ ) into the glass membrane, allowing for variant sensitivity of the electrode. The metal oxides lose electrons and therefore become cations to the incorporated oxygen molecules. Charge is displaced across the membrane resulting in the “flow” of current across the glass. The one side of the glass is exposed to a buffer of pH which is reference electrode, the other side is exposed to blood which is test solution. Figure 12.6 shows the pH electrode. The glass membrane is then a partition with differing  $[\text{H}^{+}]$  on either side, establishing a potential difference via the concentration gradient. The pH remains constant despite the change in  $[\text{H}^{+}]$  due to the action of the inner buffer solution. The reference electrode will maintain a constant electrical potential despite changes in pH. The potential difference is measured, and changed to a direct reading of  $[\text{H}^{+}]$  which is then converted into a determinable pH value. Figure 12.6 shows the measurement of pH electrodes.

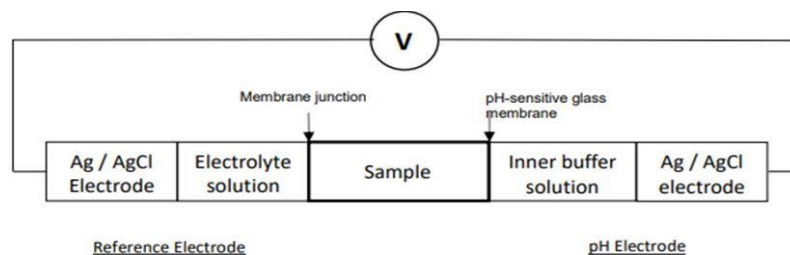


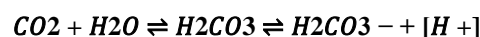
Figure 12.6: pH electrode

Based on Figure 12.6, the pH electrode has a standard life-span of about one year. This is secondary to the consumption of metal oxides ( $\text{AgCl}$ ) in the glass membrane. Calibration is by solutions of known pH is one of  $\text{pH} = 6.841$ , and the other  $\text{pH} = 7.383$  then the latter is the “reference” solution for example point  $0\text{mV}$ . There is an air bubble in the solution which allows for expansion and contraction of the buffer solution.

The problem with the pH electrode is the pH electrode measurement requires a constant temperature. Thus, in a hypothermic patient there is an increase in the solubility of carbon dioxide in the blood resulting in a reduction of  $\text{pCO}_2$  and thus an increase in the pH falsely. The entire electrode is surrounded by a thermal couple control system to maintain the temperature at  $37^\circ\text{C}$ . In addition, the electrodes are maintained to be active to ensure that there are no holes in the membranes this is obviously performed by the machine. Electrodes are also cleaned regularly to remove any debris accumulation.

### Measurement $\text{PaCO}_2$ (Carbon dioxide tension)

The Severinghaus Electrode is the mainstay of carbon dioxide measurement from the arterial blood gas. It is essentially a pH electrode, but contains the pH and reference electrodes within one device. Because of the prolonged equilibration and calibration, the result takes a long time to determine ( $\text{PaCO}_2 \propto [\text{H}^{+}]$  \*).

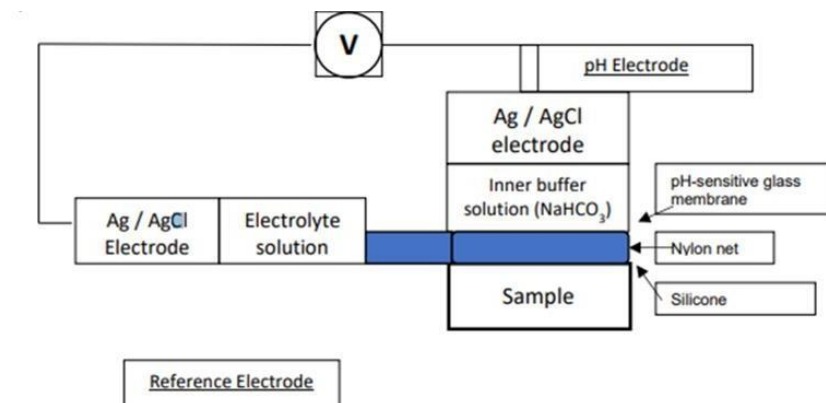


The pH electrode presented to a thin film of sodium bicarbonate ( $\text{NaHCO}_3$ ) via a silicon membrane which is permeable to  $\text{CO}_2$ , but impermeable to blood cells. This equilibrates with the blood and becomes the “test” solution. Based on Figure 12.7 there is a buffer solution held in contact with the silicon membrane by nylon or glass wool. The bicarbonate buffer has a concentration of  $0.001\text{mol/l}$ . Then the reference electrode houses  $\text{Ag} / \text{AgCl}$ , which is direct contact with the buffer solution. Silicon membrane is permeable to  $\text{CO}_2$  but there are no other ions that can affect the change of Ph.

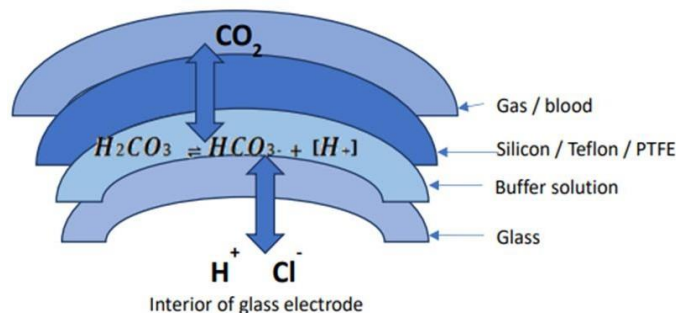


**Figure 12.7:**  $\text{PaCO}_2$  measurement

Based on Figure 12.7, the change in  $[\text{H}^+]$  is read by the voltmeter which gives a reading via calibration in units of  $\text{paCO}_2$ . The Severinghaus electrode advantageously is accurate and stable. It is however, slow due to the diffusion across the plastic membrane, and the time to react with water and easily prone to electrode damage. It is incredibly temperature sensitive and the reaction is catalysed with the addition of carbonic anhydrase.



**Figure 12.8:** Carbon Dioxide electrode



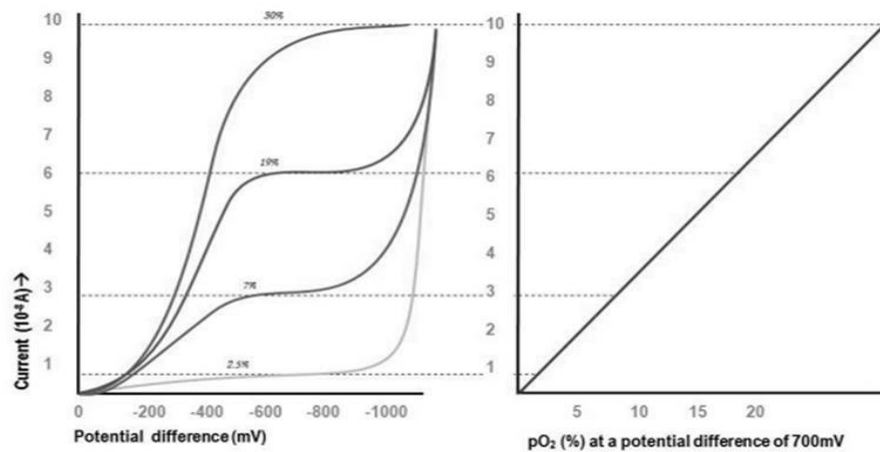
**Figure 12.9:** Indicating layers of Carbon Dioxide

### Measurement of PaO<sub>2</sub> (Oxygen tension)

The Clarke electrode measures the tension of oxygen in solution, which is directly proportional or equated to oxygen content of the blood. The principle is that a certain number of O<sub>2</sub> molecules within a salt solution will produce a current.

**Ohm's Law is the governing principle:**

$$V=IR$$

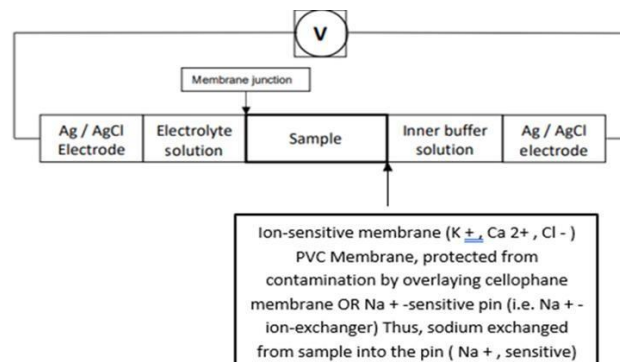


**Figure 12.10:** Current against potential voltage (anion) in solution used to determine concentration and nature of ions in solution.

Based on Figure 12.10, thus increasing [O<sub>2</sub>] results in a higher current produced. By increasing the voltage applied from 0 – 0.45 V the resultant current increases for any PaO<sub>2</sub>. The current reaches a plateau at a potential difference (V) of 0.45 – 0.85 V. We can then observe that there is a failure of the ever-increasing V to drive any further O<sub>2</sub> reduction at the cathode. Different plateau pressures will be generated or elucidated dependent on the partial pressure of O<sub>2</sub>.

### Measurements of electrolytes (Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup>, Cl<sup>-</sup>)

Essentially this is made up of a measuring and a reference electrode. K<sup>+</sup>, Ca<sup>2+</sup>, Cl<sup>-</sup> measuring electrode of Ag/AgCl electrode covered with an ion-specific, selective PVC membrane. Cellophane covers this PVC membrane, protecting it from contamination. Na<sup>+</sup> measuring electrode is Na<sup>+</sup>-ion exchanger and it is Na<sup>+</sup>-sensitive pin replaces the PVC. Calibration of all systems are performed with standard solutions of known ionic content. Figure 12.11 below shows the explanation of measurement of electrolyte K<sup>+</sup>, Ca<sup>2+</sup>,



**Figure 12.11:** Electrodes measuring electrolyte



### Measurement of metabolites (glucose, lactate)

The measurement of glucose and lactate are vital by a rapid, reliable and reproducible means. These values are determined by the oxidation of  $\text{H}_2\text{O}_2$  (hydrogen peroxide). There are two electrodes in the electrolyte solution. It is important to note that there is a silver/ silver chloride (Ag / AgCl) CATHODE and a Platinum (Pt) ANODE this contrasts with the Clark electrode. Each electrode is then covered by a 3- layered membrane the Figure 12.12 below shows the explanation of the layers.

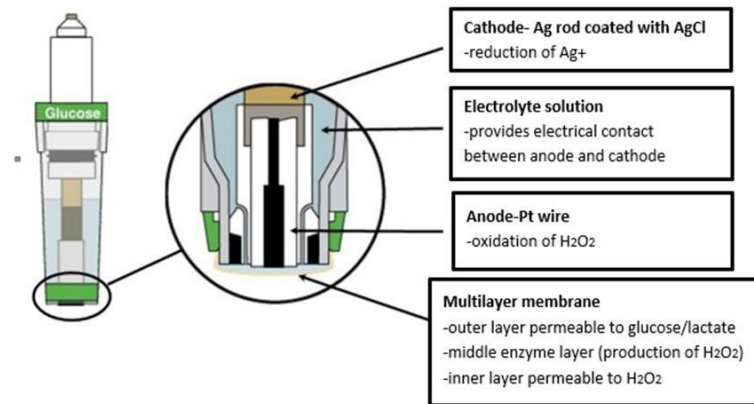


Figure 12.12: Explanation of the layer

### Measurement of bilirubin and co-oximetry (Spectrophotometry)

Figure 12.13 shows the mechanism and component of spectrometer.

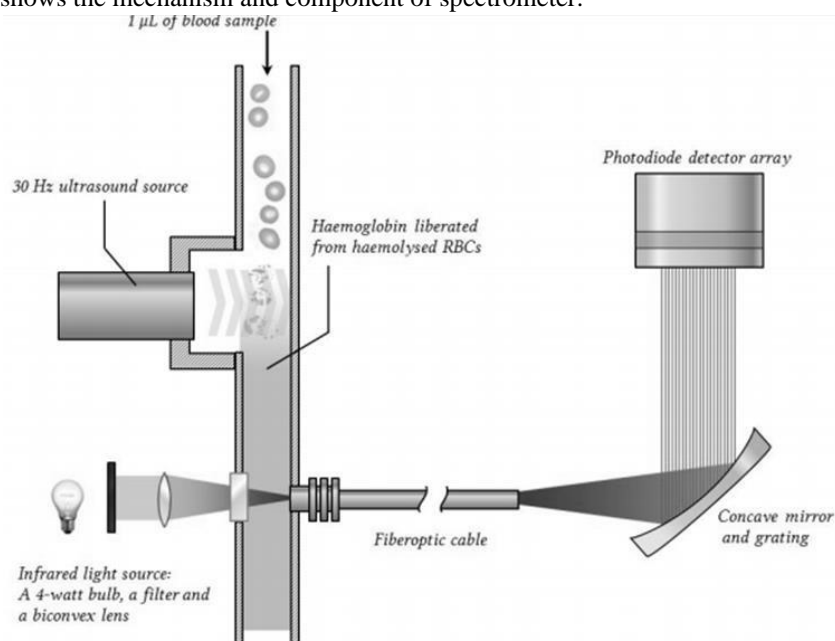


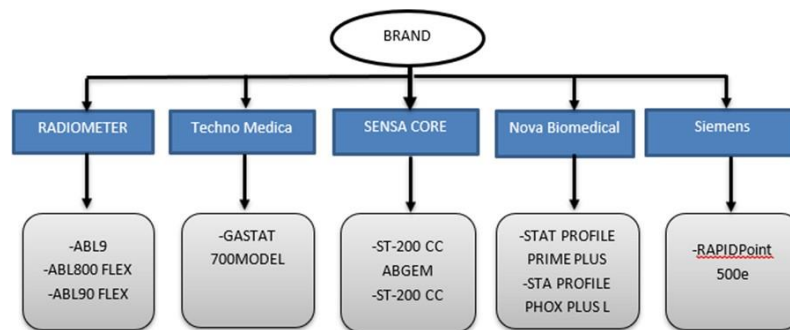
Figure 12.13: The mechanism and components of the spectrometer

The mechanism and components of the spectrometer in Figure 12.13 Spectrophotometry passing radiation through a sample and determining the quantity absorbed. This is further defined as the quantitative measurement of reflection or transmission of material as a function of the wavelength ( $\lambda$ ). Hemoglobin (Hb) derivatives include Oxy-Hb, de-oxy-Hb, Met-Hb, Carboxy-Hb, Fetal Hb. Haematocrit is determined

as a derived measure through the conductivity of the blood sample would be applied in ABG analyzers without spectrophotometry installed.

## 2.9 Type of Arterial Blood Gas Analyzer

The common brand and model of ABG which is shown in Figure 12.14. Each ABG have its own specification and features shows in Figure 12.14



**Figure 12.14:** Common brand and model of ABG

From Figure 12.14 there are 5 brands of ABG there are RADIOMETER, Techno Medika, SENSE CORE, Nova Biomedical and Siemens.

## 2.10 Model Description

There were two models have been compared to ensure the best model for user, which is Radiometer ABL800 Basic and Stat Profile Phox Plus L. This is because for improve the quality and quantity of purchasing the machine.

## 2.11 Radiometer ABL800 Basic (Radiometer)

The ABL800 basic analyzers are intended for in Vitro testing of samples of whole blood for the parameters pH, pO<sub>2</sub>, pCO<sub>2</sub>, cK<sup>+</sup>, cNa<sup>+</sup>, cCa<sup>2+</sup>, cCl<sup>-</sup>, cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO<sub>2</sub>, and the hemoglobin fractions FO<sub>2</sub>Hb, FCOHb, FMetHb, FHHb and FHbF). In vitro testing of samples of expired air for the parameters pO<sub>2</sub> and pCO<sub>2</sub> and in vitro testing of pleura samples for the pH parameter. The feature of Radiometer ABL800 Basic ABG model is mentioned in Figure 12.15, Figure 12.16, Figure 12.17 and Figure 12.15.



**Figure 12.15:** Front view of Radiometer ABL800 Basic

Based on Figure 12.15, the function of colour touch screen is 10.4" LCD for operation and management of the analyzer. Waste container for waste collection. A sensor detects when container is full, and a message is displayed on the screen. Then the rinse solution for rinsing the liquid transport system after various analyzer activities. Cal 1 solution performing for 1-and 2-point calibrations. Cal 2 solution performing for 2-point calibrations. Cleaning solution for cleaning the liquid transport system of lipid deposits. Right cover to access solutions and pumps. Syringe inlet flap Lift to introduce syringe samples and quality control solutions. Capillary inlet flap Lift to introduce capillary samples.



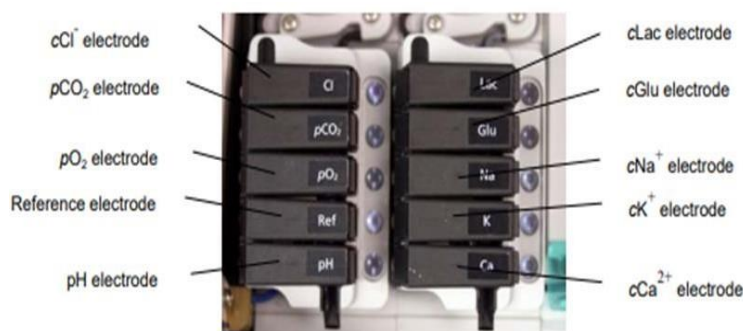
**Figure 12.16:** Features of Radiometer ABL800 Basic

Figure 12.16, shows the feature of radiometer. For the inlet module accepts samples from a syringe or test tube or a capillary. For the pH/Blood Gas (BG) module is to measures pH,  $pO_2$ ,  $pCO_2$  and  $cCl^-$ . For the Electrolyte/Metabolite (EI/Met) module is to measures  $cCa^{2+}$ ,  $cK^+$ ,  $cNa^+$ ,  $cGlu$  and  $cLac$ . Met II module is to measures creatinine. Oximetry (Oxi) module is to measures  $ctHb$ ,  $sO_2$ ,  $FHHb$ ,  $FO_2Hb$ ,  $FCOHb$ ,  $FMetHb$ ,  $FHbF$  and  $ctBil$ . Solution pump is to transports solutions through the liquid transport system. Waste pump is to transports liquid to the waste container.



**Figure 12.17:** Back view of Radiometer ABL 800 Basic

Figure 12.17 shows the sensor module of Radiometer ABL800 Basic. Gas 1 cylinder is containing a gas mixture of 5.61 % is CO<sub>2</sub>, 19.76 % is O<sub>2</sub>, balance 74.64 % is N<sub>2</sub>. Gas 2 cylinder contains a gas mixture of 11.22 % is CO<sub>2</sub>, < 0.04 % is O<sub>2</sub>; balance > 88.74 % is N<sub>2</sub>. Fan for cooling internal components. Other than that, gas cylinder socket for mounting the gas cylinders. Power switch for turning the analyzer on (position I) and off (position O). Figure 12.18 shows the sensor module.



**Figure 12.18:** Sensor module

The sensor module in Figure 12.18 has 10 electrodes.

## 2.12 Stat Profile Phox Plus L

The Stat Profile pHox Analyzer is intended for in vitro diagnostic use by health care professionals in the quantitative determination of pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, oxygen saturation (SO<sub>2</sub> %), hematocrit (Hct), hemoglobin (Hb) in heparinized whole blood [7].

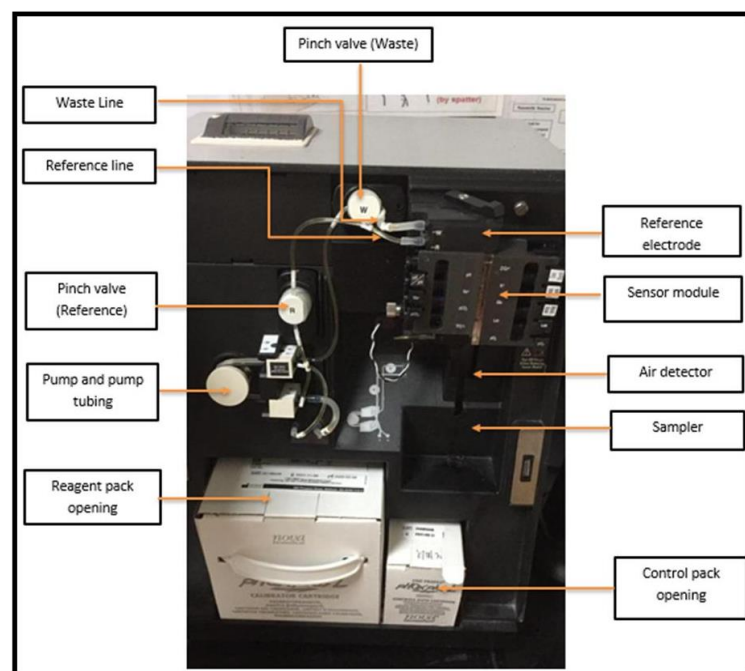
The analytes measured on the Stat Profile pHox Plus L Analyzer which is blood gases, oxygen saturation, hematocrit and hemoglobin oxygen. Whole blood measurement of blood gases which is (pCO<sub>2</sub>, pO<sub>2</sub> and pH) is used in the diagnosis, and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases. Oxygen saturation is used to assess the oxygenation of hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Also used in the diagnosis and treatment of cyanosis.

Sodium or lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes can be used on the Stat Profile pHox Analyzer. The sample size is 70  $\mu\text{L}$  for normal mode and 45  $\mu\text{L}$  for micro mode (blood gases only). The feature of Stat Profile Phox Plus L ABG model is mentioned in Figure 12.18 and Figure 12.19.



**Figure 12.19:** Front view of Stat Profile Phox Plus L

Then the whole blood measurement of hematocrit in Figure 12.19 is used to estimate that red blood cells are present in sufficient quantity to carry oxygen and carbon dioxide. Oxygen is carried from the lungs throughout the body by hemoglobin present in red blood cells. Measurement of hemoglobin provides the clinician with information regarding the evaluation of chronic and acute anemias and also with information pertaining to the potential oxygen transport capability of the hemoglobin.



**Figure 12.20:** Features of Stat Profile Phox Plus L

The sampler allows for the aspiration of the sample. The sampler has 2 sampling positions which is horizontal for the aspiration of a sample from a capillary tube and inclined for the aspiration of the sample

from a syringe. There are no special adapters are required to aspirate a sample from a capillary tube. The capillary or syringe positions are selected by pressing the Black Capillary key or the White Syringe key.

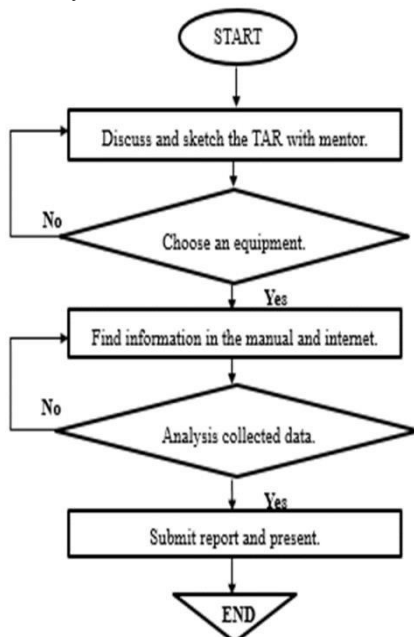
The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains the hematocrit impedance electrode and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference electrode at the top of the sensor module, 3 sensors on the left side, 2 sensors on the right side. In addition to the Hct sensor located in the preheater, there are 6 sensors which is reference electrode, Na<sup>+</sup>, pCO<sub>2</sub>, SO<sub>2</sub> (optic), pH, and pO<sub>2</sub>. A window in the door allows flow path visibility and is augmented by a backlight. The sensors clip into the sensor module, and electrical contact is automatically made.

### 3.0 Methodology

This section will cover the details explanation of methodology that was being used to develop the Technical Assessment Report (TAR). The method is proposed to achieve the objective of the project that will accomplish a perfect result. This methodology chapter discussed about the process of research which is carried out to GAIN accurate data.

#### 3.1 The Process of Research

The Figure 12.21 shows the flowchart of the process for research, which is carried out according to assessment. The assessment is mentioned based on the schedule, which is prepared by the institute.

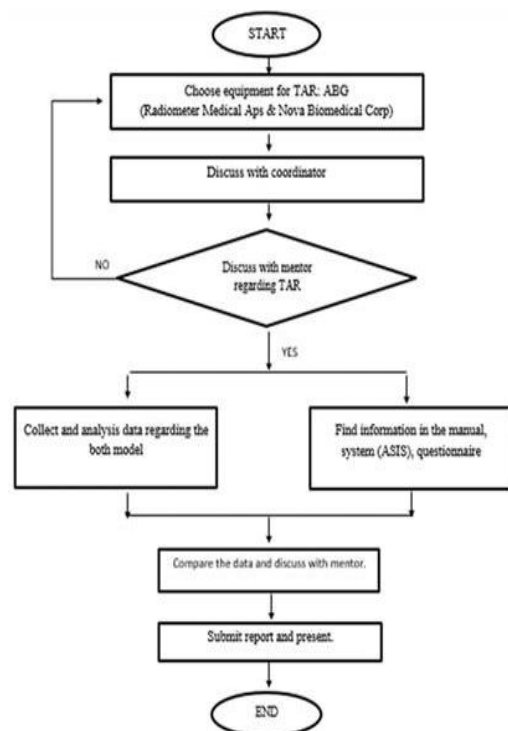


**Figure 12.21:** The process of research

Based on Figure 12.21, the TAR is started from discussion and sketch with mentor. Then, it is chosen through mentor guideline. Then, TAR will ensure by the information collected. Latterly, the data is analyzed by the information. While concluding the report the process will end up.

#### 3.2 The Flowchart of technical assessment report

The flowchart of TAR is conducted according to follow, which is identified through the schedule as shown in Figure 12.22.



**Figure 12.22:** Flowchart of the Technical Assessment Report



The Figure 12.22 is started from choosing ABG unit, which is Radiometer Abl800 Basic & Stat Profile Phox Plus L. Next, the report is discussed with the mentor to confirm the machine. Then, based on the model specification the data is collected and analysed. Latterly, the

information is also collected in the system such ASIS, CMIS, internet and manual book. Besides that, the compare data is discussed with the mentor to ensure it. Lastly, the process is end up with submitting the report and presentation.

### 3.3 Asset and Services Information System (ASIS)

The Figure 12.23 and Figure 12.24 shows the webpage of ASIS and homepage of ASIS which is the details of all the asset and the explanation of the ASIS.



Figure 12.23: Webpage of ASIS



Figure 12.24: Homepage of ASIS

Asset and Services Information System is a website to obtain the systematic process of developing, operating, maintaining, upgrading, and disposing of assets in the most cost-effective manner. ASIS is can be used by many workers from different departments such as BEMS, FEMS, FMS, CLS, LLS, and HWMS. The data of each department can be viewed by applicable according to the responsibility. For the BEMS, it is divided into 3 parts such as Master,

transaction, and report. This is to obtain the maintenance, history of asset and services.

### 3.4 CENTRAL MANAGEMENT INFORMATION SYSTEM (CMIS)

The Central Management Information Systems (CMIS) is now called e-urus hospital to better establish the CMIS as a key tool in managing and monitoring the five privatized services. This system is created before ASIS. This is because to operate the data systematically. Once the ASIS took place, then CMIS is used to trace the history of asset or equipment.



Figure 12.25: Homepage of ASIS – CIMS option

Based on Figure 12.25, development of the e- urus hospital required an enormous step forward that is the implementation of the data warehouse. While accessing information was formerly a very slow and sequential process (days to weeks) in which information users were obliged to follow the hierarchical route via the IT department, the data warehouse environment provides a connection delivering parallel access and fast delivery (instantly online).

### 3.5 QUESTIONNAIRE

The method applied during the progression of this report is observation from the questionnaire.



The survey is conducted with 20 participants according to the machine to obtain better equipment for usage. The main purpose of the survey is to identify the problem, which is faced by the user and technician. From the survey, the need

analysis is clarified to carry further steps to reduce the burden. The finding helps improve the effectiveness of device functioning. Besides that, the survey is carried out at Hospital Tuanku Jafaar, Seremban.

## 4.0 Result and Analysis

This section is described about the result of the TAR project as evidence from the data collection via questionnaires, CMIS and ASIS. Based on the data collection, the comparison of machine is presented clearly in the form of tabulation. Then, the analysis of data collected is clearly obtained with a conclusion on which model of ABG machine in Hospital Tuanku Jaafar, Seremban is the best model.

The basic information regarding the ventilator is collected and analysed via CMIS and ASIS. This is because to confirm the detail of ABG that valid for comparison. The comparison of ABG is recognized the best model as shown in Table 12.3.

**Table 12.3:** Comparison between Radiometer and Nova Biomedical Corp

<b>Radiometer ABL800 Basic (Radiometer)</b>	<b>COMPARISON (MODEL)</b>	<b>Stat Profile Phox Plus L (Nova Biomedical Corp)</b>
Denmark	<b>ORIGIN COUNTRY</b>	USA
25-Sep-2013	<b>COMMISSIONING DATE</b>	06-Nov-2013
17-Jun-2013	<b>PURCHASE DATE</b>	17-Jun-2013
5	<b>EXPECTED LIFESPAN (YEARS)</b>	5
7.7	<b>AGE</b>	7.7
WCPCU (Ward pediatric)	<b>USER AREA NAME</b>	WCLHD (High Dependency Ward)
Radiometer Medical Aps	<b>MANUFACTURER</b>	Nova Biomedical Corp
RM 263,500	<b>PURCHASE COST (RM)</b>	RM 53,334
12	<b>WARRANTY PERIOD</b>	12
24-Sep-2014	<b>WARRANTY EXPIRY DATE</b>	05-Nov-2014
RM 12,768.83	<b>MAINTENANCE COST(RM)</b>	RM 68,093.12

As stated in Table 12., the information is collected according to the similar option for compare the data. The ABG is chosen from HDW department that purchased in same year with different manufacture and price. The basic data information is very helpful to compare the uptime and downtime of machine.

### 4.1 Common Breakdown In 2020

The problem of breakdown cannot be estimated easily because of the model, brand and design of the machine. Each machine contains different type of breakdown according to features. For example, common error of Stat Profile Phox Plus L is blood clot or blood stain on the tubing of the electrode. So, it has to be

clean the head of electrode and perform flushing to waste tubing. Rather than that, the Table 12.3 below show the common problem of breakdown for ABG in 2020 had been recorded.

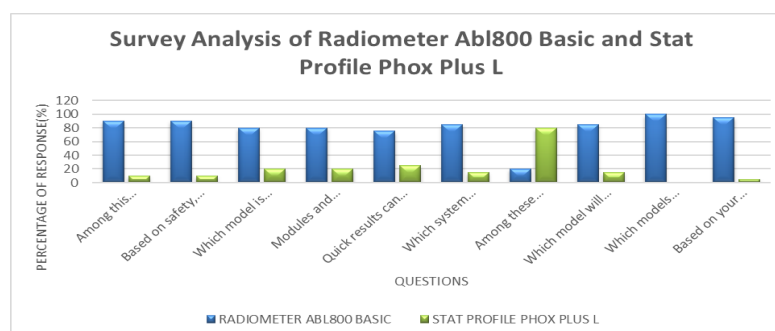


**Figure 12.26:** Common Breakdown of Radiometer ABL800 Basic and Stat Profile Phox Plus L

From figure 12.26 the common Common Breakdown of Radiometer ABL800 Basic is lower than the Stat Profile Phox Plus L.

## 4.2 Analysis of Data for Questionnaire

The survey analysis is clearly stated by comparing with graph based on ABG model. From the Figure 12.26 the colour of bar graph will be shown the respondent choice regarding the ABG model. graphs



**Figure 12.26:** The Survey of Radiometer and Nova Biomedical Corp

Therefore, from Figure 12.26 most of respondent is choose the option of Radiometer ABL800 Basic. In this case, the Radiometer is identified user friendly compared to Stat Profile Phox Plus L by calculating the opinion of respondent. Most of respondent is selected for Stat profile Phox Plus L because the ABG can be used but frequently have technical error and breakdown compared to Radiometer.

## 5.0 Conclusion and Recommendation

The summarization of ABG is mentioned due to the data analysis. The best model of ABG is identified according to data. Based on the previous chapter, there is a lot of knowledge and the information, which is known also data collection. From the data, the recommendation is proceeding to user and technician for their future purchasing.

As conclusion, above analysis is the evidence that research had been achieve the objective. The analysis on each model is done by comparing the purchasing cost, warranty period, frequency of breakdown, the types of breakdowns and the maintenance cost. the Radiometer Abl800 Basic ABG is best model compare to Stat Profile Phox Plus L. The survey analysis is clearly identified the best model is Radiometer by most of choose the option of Radiometer in the questionnaire. This is because Radiometer is user friendly in order of safety and testing before it is used while is compared to Stat Profile Phox L. Besides that, Stat Profile Phox L also encountered high breakdown and high cost of maintenance breakdown compared to Radiometer Abl800 Basic. The data analysis is clearly stated the comparison of both ABG model in the way of strong down the best and better choice for future purchasing based on survey at HTJS. Although, the machine is having advantages and disadvantages make sure the user prefer to which machine is better in the way quality and specification.

As recommendation, user should use the device properly and follow standard operating procedure each model and do a cleaning and maintenance such as cleaning the chassis. When cleaning the chassis should use suitable liquid and detergent. User also should follow all the manual book and attend for user training. For technical staff should be maintain the machine in good condition by run plan preventive maintenance follow the guided line (HEPPM check list) and replace genuine part only. All the maintenance should be following as plan.

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# ULTRASOUND MACHINE

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**Abstract**— Ultrasound imaging uses sound waves to produce pictures of the inside of the body. It is used to help diagnose the causes of pain, swelling and infection in the body's internal organs and to examine a baby in pregnant women and the brain and hips in infants. In particular, ultrasound machine usually used in hospital radiology department and are performed either by radiologist or a sonographer. The purpose of this research is to compare Ultrasound Machine by several brand, model and recommend to company which brand of the unit are the best to be used by hospital. Therefore, the data information between two model of ultrasound are collected to identify the suitable model of Ultrasound Machine for hospital based on comparison between the models by specification, user friendly, breakdown and frequently use by user. Furthermore, collection of data can be conducted with concession staff and system ASIS. Lastly, based on analysis done, it can be recommended that the ultrasound machine can be more users friendly and easy to use by user in terms of system program and installation. So, the breakdown that related with mishandling by user can be reduced in total breakdown and Cumulative parts cost.

**Keywords**- sound wave, radiology, radiologist, ASIS and breakdown

## 1.0 Introduction

Ultrasound machine is a medical imaging device that used high- frequency sound waves to produce pictures of the inside of the body. It is used to help diagnoses the causes of pain, swelling and infection in the body's internal organs and to examine a baby in pregnant women and also the brain and hips in infants [1]. The image of ultrasound is captured in real-time; it also can show movement of the body's internal organs as well as blood flowing through the blood vessels. The ultrasound imaging is no ionizing radiation exposure unlike X-ray imaging. During an ultrasound examination, a transducer (probe) is placed directly on the skin or inside a body opening. A thin layer is applied to the skin so that the ultrasound waves are transmitted from the transducer through the gel into the body. Ultrasound imaging (sonography) uses high-frequency sound waves to view inside the body. Because ultrasound images are captured in real-time, they can also show movement of the body's internal organs as well as blood flowing through the blood vessels.

Unlike X-ray imaging, there is no ionizing radiation exposure associated with ultrasound imaging.

Ultrasound is the most widely used medical imaging method for viewing the fetus during pregnancy. Routine examinations are performed to assess and monitor the health status of the fetus and mother. Ultrasound examinations provide parents with a valuable opportunity to view and hear the heartbeat of the fetus, bond with the unborn baby, and capture images to share with family and friends. There are several types of ultrasound imaging scanning for different application which is external, internal and endoscopic scan. These three types of ultrasounds produce difference sound wave depends on frequency at each transduce to view internal organ of patients [1]. The purpose of this Technical Assessment Report (TAR) is to compare the ultrasound machine by several specification and recommend to company which brand of the ultrasound machine are the best to be use by hospital. Three objectives which it's be

a guideline in process to develop this research are to study about the ultrasound machine to analyse the different model and brand of ultrasound machine and to determine the best model for hospital imaging in order to decrease the total of breakdown.

## 2.0 Ultrasound Description

The ultrasound machine uses to produce an image so that organs inside the patient body can be examined. The machine needs a high-frequency to send out sound waves, which reflect off body structures. A computer receives the waves from transducer and uses the waves to create a picture. Unlike with an x-ray or CT scan, the ultrasound is safe and painless because the machine does not use ionizing radiation. Ultrasound imaging is a non-invasive medical test that helps physicians diagnose and treat medical conditions [2]. Conventional ultrasound displays the images in thin, flat sections of the body [2]. The technology ultrasound

Advancements in ultrasound technology include three-dimensional (3-D) ultrasound that formats the sound wave data into 3-D images and also in 4-D images. A Doppler ultrasound study may be part of an ultrasound examination. Basically, there had three type of Doppler ultrasound which is colour Doppler uses a computer to convert Doppler measurements into an array of colours to show the speed and direction of blood flow through a blood vessel. Second, Power Doppler is a newer technique that is more sensitive than colour Doppler and capable of providing greater detail of blood flow, especially when blood flow is little or minimal. Power Doppler, however, does not help the radiologist determine the direction of blood flow, which may be important in some situations. Lastly, Spectral Doppler displays blood flow measurements graphically, in terms of the distance travelled per unit of time, rather than as a colour picture. It can also convert blood flow information into a distinctive sound that can be heard with every heartbeat [2].

Figure 13.1 shows the Scanning Systems, Ultrasonic, General-Purpose machine brand Toshiba model Xario Xg Ssa-680 that has been compared with ultrasound machine brand GE model Venue 40



**Figure 13.1:** Toshiba Xario Xg Ssa-680

Ultrasound Toshiba Xario Xg Ssa-680 offer uncompromised imaging performance, backed by an abundance of unique, clinically proven technologies. Its full range of advanced imaging functions that the image can be visualize a several minute with tissue detail, precision and more accurate diagnosis.

Figure 13.2 shows the scanning systems, ultrasonic, general-purpose machine GE Venue 40 which is much smallest and compact compare to ultrasound Toshiba model Xario Xg Ssa-680.



**Figure 13.2:** The Scanning Systems, Ultrasonic, General-Purpose machine GE Venue 40

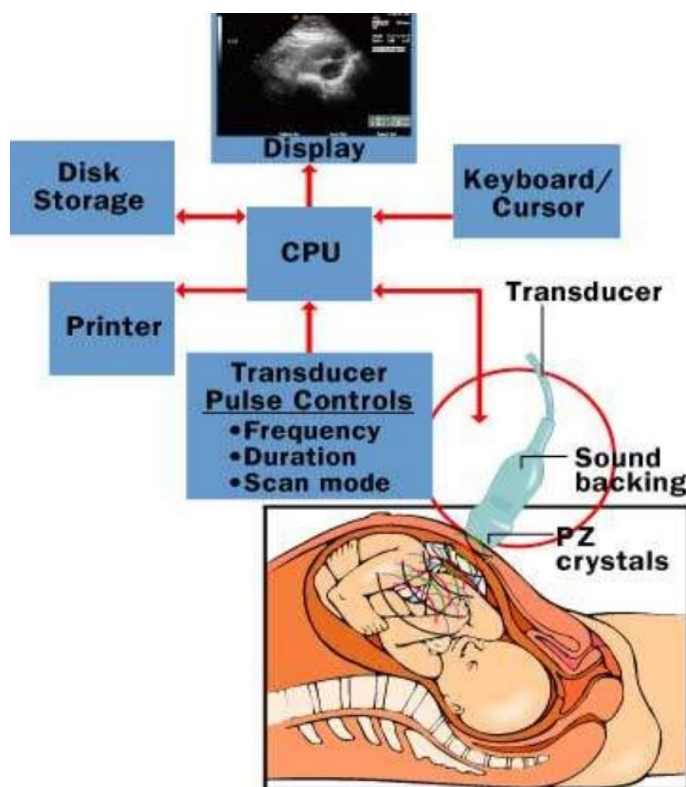
Figure 13.2 shows the ultrasound GE Venue 40 which is general –purpose category ultrasound that provide precision and exceptional image quality in an affordable, proven-reliable ultrasound system. The pattern recognition technology accurately reveals the structure of the needle within anatomy and also have a flexible data management and connectivity option with optional Digital Imaging and Communications in Medicine (DICOM) that can be explain this is a standard of communication and management of medical imaging information and related data.

DICOM can make medical imaging information interoperable. Another advantage of GE Venue 40 is can help speed the image that can be storage and archiving at the point of care and at the patient's bedside.

## 2.1 Standard Operation

Ultrasound imaging used same method involved in the application of sonar that used by bats, ships and fishermen. The sound wave will bounce back when it strikes an object. To measuring this sound wave, it is possible to determine how far away the object is as well as the object's size, shape and consistency. This includes whether the object is solid or filled with fluid. In medical, ultrasound is used to detect changes in the condition of organs, tissues, and vessels and to detect abnormal masses, such as tumours.

The ultrasound examination, a transducer will transmit the sound wave and records the echoing waves. When the transducer is placed at the patient's skin, it sends small pulse of inaudible, high-frequency sound waves into the patient's body. As the sound waves bounce off internal organs, fluids and tissues, the sensitive receiver in the transducer records tiny changes in the sound's pitch and direction. These signature waves are instantly measured and displayed by a computer, which in turn creates a real-time picture on the monitor. One or more frames of the moving pictures are typically captured as still images. Short video loops of the images may also be saved. Doppler ultrasound, a special ultrasound technique, measures the direction and speed of blood cells as they move through vessels. The movement of blood cells causes a change in pitch of the reflected sound waves (called the Doppler effect). A computer collects and processes the sounds and creates graphs or colour pictures that represent the flow of blood through the blood vessels.



**Figure 13.3:** shows the standard procedure for ultrasound machine which is explain how the ultrasound work or process the results

### 1. Transducer

The transducer produced sound wave to determine the condition of patient's organ. The data will transmit and receive at the same time to deliver the sound wave directly to CPU that can convert to data processing.

### 2. Display

The displays will produce an image that transducer receive the data from examination of patient. The image can be monitor and record the activities.

### 3. Disk Storage

The purpose of disk storage is to store the data of examination.

### 4. Keyboard/Cursor

Keyboard or cursor that can be used to moving objects on the monitor and scrolling back in freeze mode. Also, it can control the adjustment of brightness of depth image.

### 5. Printer

The result from examination is printed out on graph paper since the image need to monitor continuously before upcoming examination.

### 6. CPU

CPU is a hardware where it carries out the instructions of a program. The data from transducer, keyboard and disk storage will link to CPU to generate input or output operation of system



## 2.2 Category of Ultrasound

There have a several categories of ultrasound to monitor each part of patient's body. The first category is a scanning system, ultrasonic, cardiac where this type used to view the condition of heart in a real-time capture. Secondly, scanning ultrasound, obstetric/gynaecologic category which mean this scanning often used to monitor the condition of baby, fetus or placanta. However, this type will to leads a little discomfort for patients because the transducer needs to inserted in vagina. Thirdly, the category where to diagnose the eyes of patients which is scanning system, ultrasonic, ophthalmic. This ultrasound very special because the method of transducer that they are used is Scan A and Scan B. Usually transducer used piezoelectric crystal method to produce sound wave but ultrasound ophthalmic used method brightness and time-amplitude to view the condition of eye. Lastly, the ultrasound general purpose, this type very usefully in several condition to monitor because it provides a various of transducer that can be used to diagnose the condition inside body's patient

### 2.2.1 Scanning system, ultrasonic, cardiac

Ultrasound cardiac was specifically designed for real-time, non-invasive imaging were to capture structures of heart which mean it used to detect the condition mitral and aortic stenosis and determine the extent of damage from suspected myocardial infarction and also it can diagnose a congenital cardiac defect such as patent ductus arteriosus and transposition of the great arteries. However, this ultrasound also can be used instead of cardiac catheterization to monitor Ventricular function [1]. The method that commonly used in surgery for detecting myocardial ischemia and monitor cardiac output is transesophageal echocardiography (TTE).

This method allows to analysis of regional cardiac wall motion, in which abnormalities have been shown to develop within 15 seconds of coronary occlusion. Cardiac ultrasound used Doppler scanners to determine the direction, speed of blood flow and also give the physical physician profiles of arteries and veins throughout the body. This method that applies to diagnose atherosclerotic obstructions, occlusions, disease and incompetence by means of a 2D, real-time image of the organ or vessel, as well as a profile of blood-flow velocity through the area being examined. Vascular ultrasound imaging is the primary screening method for deep vein thrombosis (DVT) [1]. In several cases, the contrast arteriography can be preventing by using vascular ultrasonic scanning system, which is it requires vessel cannulation, contrast media injection and ionizing radiation exposure



**Figure 13.4:** Heart Condition Examination

Figure 13.4 show that the method that has been used in monitoring the condition structures of heart. transducer is placed against on the patient's chest and also the ultrasound gel which is Aquasonic 100 should be apply before the transducer place on patient because it can prevent any air space between the probe and patient's skin in order to create a better image during examination. during labour to monitor the baby's condition

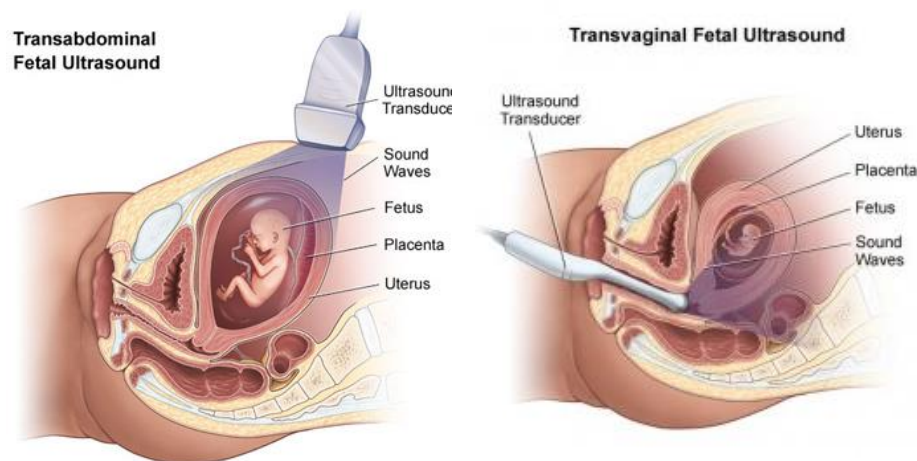


### 2.2.2 Scanning Ultrasound, Obstetric/ Gynecologic

Obstetric ultrasound used to produce an image of baby (embryo or fetus) within a pregnant woman, as well as the mother's uterus and ovaries. This ultrasound also had Doppler system to monitor the blood flow in the umbilical cord, fetus or placenta. In this type of ultrasound, the procedure transvaginal ultrasound can be performed. It involves the transducer are inserted into the vagina after the bladder are empty. The transducer can help to monitor further in patient's uterus before insert the transducer in patient' vagina the protective cover is placed over the transducer and lubricated with small amount of gel. However, at times during an examination, the transducer needs to press more firmly to get closer to the embryo or fetus to better visualize the structures. Normally, discomfort may occur but it minimal temporary only. The transvaginal scanning also fell a little discomfort because of the transducer are inserted in vagina.

This ultrasound examination normally completed within 30 minutes. Furthermore, Obstetric ultrasound cannot identify all fetal abnormalities. Consequently, when there are clinical or laboratory suspicions for a possible abnormality, a pregnant woman may have to undergo nonradiologic testing such as a blood test or amniocentesis (the evaluation of fluid taken from the sac surrounding the fetus) or chorionic villus sampling (evaluation of placental tissue) to determine the health of the fetus, or she may be referred by her primary care provider to a perinatologist (an obstetrician specializing in high-risk pregnancies) [2]

Figure 13.5 shows the technique the scanning Ultrasound of Obstetric/and Gynecologic that used to monitor the condition of patient pelvic.



**Figure 13.5:** Technique in Scanning Ultrasound, Obstetric/ Gynecologic [3]

#### 1. Ultrasound transducer

The transducer that placed at abnormal and vagina patient during examination.

#### 2. Sound waves

The sound waves that to produces a picture inside patient's body.

#### 3. Fetus

an unborn or unhatched vertebrate especially after attaining the basic structural plan of its kind

#### 4. Placenta

The placenta is formed from some of these rapidly dividing cells. The placenta functions as a life-support system during pregnancy. Oxygen, nutrients, and hormones are transferred across the placenta to the fetus. Waste products from the fetus are transferred back across the placenta for removal [5].

## 5. Uterus

Uterus, also called womb, an inverted pear-shaped muscular organ of the female reproductive system, located between the bladder and the rectum. It functions to nourish and house a fertilized egg until the fetus, or offspring, is ready to be delivered [6].

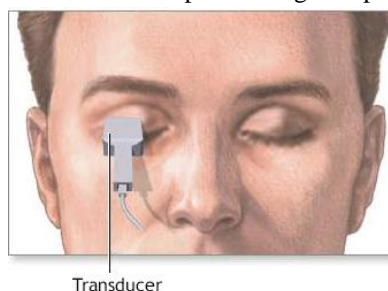
Based on Figure 13.5 The transabdominal fetal ultrasound used on women's pregnancy where the ultrasound is conducted to determine the baby's age, track the baby's growth and also find anything of problem that can be occur during pregnancy. Usually, this method is used to determine the sex of the baby. However, the possibilities to view gender of babies because of the baby's genitals are not visible due to current position it is in. Second technique is transvaginal fetal ultrasound. This method is used to obtain images of organs and structures that are located in the lower abdomen or pelvis. These types of ultrasounds are conducted on both men and women to identify disorders like kidney stones, bladder tumors, and problems with the urinary bladder. Pelvic ultrasounds are most often performed on women to examine the bladder, uterus, cervix, ovaries, and fallopian tubes. These examinations can help to diagnose problems that women may experience, such as abnormal bleeding, pelvic pain, and other menstrual problems. By examining female reproductive organs, this type of ultrasound can find and identify ovarian growths, cysts, fibroid tumors, fallopian tube problems, and ovarian or uterine cancers. Pelvic ultrasounds are used in men to examine the bladder, prostate, and seminal vesicles [3].

### 2.2.3 Scanning system, ultrasonic, ophthalmic

The function of ultrasound ophthalmic is to monitor or diagnose the eye where the eye is a superficial fluid filled structure and in this ultrasound is an easy-to-use modality for visualization of ocular pathology and anatomy. The principle of this ultrasound is same as other application ultrasound. Sound wave are required to generated a frequency greater than 20,000 Hz (20kHz) and the echoes bound back to the transducer by tissue in its path. The piezo-electric crystal in the transducer will vibrate when the sound wave return. This means the electrical impulses that had converted an image or other data.

The transducer that are used in ophthalmologic is A-Scan and B-Scan. Where in A-Scan or time-amplitude scan, the frequency is generated at 8 MHz and the sound wave are converted into spikes that correspond with tissue interface zones where it works by emitting a sonic pulse and measuring the time and amplitude of the echo. Furthermore, it also can help determine intraocular lens power. Meanwhile, the role of B-Scan or brightness amplitude are collected the data by using transducer at frequency 10MHz to produces a corresponding image. That can be explain it produce two-dimensional reconstructed image of internal body structure based on reflected sound waves.

Figure 13.6 shows as the example of an ultrasound probe designed specifically for ophthalmic use.



**Figure 13.6:** Example of an ultrasound probe designed specifically for ophthalmic use

According to Figure 13.6, it can be show that the procedure which uses ultrasound to test for abnormalities in the eye. The ultrasound helps evaluate the farthest part of the eyeball when there are

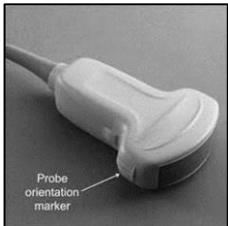



cataracts. The test may help diagnose retinal detachment of other disorders in the eye, as well as disorders and lesions behind the eye

## 2.2.4 Scanning system, ultrasonic, general-purpose

The ultrasound general purpose is ultrasound machine where it can use several applications such as diagnose unborn baby, cardiac structure and other part of patient's body because in this ultrasound provide multiple probe option available according to several applications of diagnose various of transducer or probe that can be used in examination to patient's body. Commonly the transduce that always used in ultrasound general purpose are linear, curvilinear, phased array/sector and intracavitary.

Table 13.1 shows the transducer type and clinical use in ultrasound system. The curvilinear that provide frequency between 2-5 MHz. It grants a wide, fan-shaped scanning area on the screen.

**Table 13.1:** Type of transducer and clinical used for each of transducer

Probe	Frequency (MHz)	Applications
1. Curvilinear 	2–5	FAST, renal, aorta, IVC, pelvic, bladder, bowel, appendicitis
2. Linear 	6–15	15 Ocular, trachea, thyroid, thoracic, vascular access, DVT, MSK, soft tissue, appendicitis
3. Intracavitary 	8–13	Peritonsillar abscess, pelvic
4. Phased array/sector 	1–5	Cardiac, abdominal, renal, pediatric abdomen, bladder, bowel, IVC

This type of probe is mostly used for evaluating deep structure in the abdomen and pelvis. Usually, clinical situation for this type of transducer are patients with abdominal pain to evaluate for abdominal aortic aneurysm or gallbladder pathology, abdominal pain in pregnancy or the focused assessment with sonography in trauma (FAST examination). After that, the footprint shape for linear transducer with frequency range between 6-15 MHz. It can provide a detailed anatomic resolution and is ideal for evaluating superficial structures. A wide variety of pathology can be seen at bedside with this type of probe, such as deep various thrombosis, musculoskeletal trauma, subcutaneous foreign bodies and abscesses, testicular torsion, pneumothorax and ocular pathology. Furthermore, another function of linear probe is it can be used to guide

such procedures as venous access (central and peripheral). Next, the intracavitary probe that had a curvilinear crystal with a wide view. Nevertheless, the frequency that can be emitted around 8MHz until 13 MHz. It can assume that the frequency is much higher than other curved probe. So, that mean the resolution of the image is better because of the higher frequency. The application for this probe is to view the oral pathology and transvaginal pelvic evaluations.

Abbreviations: DVT, deep venous thrombosis; FAST, focused assessment with sonography in trauma; IVC, inferior vena cava; MSK, musculoskeletal

### **1. Curvilinear**

This probe design generally used to view the abdomen and pelvis application. The probe also can be called as convex probe. The crystal is aligned along a curved surface which results in a wide field of view image

### **2. Linear**

This probe usually used for superficial imaging. The crystals that aligned in a linear fashion within a flat head and the sound waves was produced in a straight line. It also providing better resolution and less penetration.

### **3. Intracavitary**

The design of intracavitary probe quite difference with other probe because the probe's elongated shape that allows it to be inserted close to the anatomy being evaluated. Also it has a curved face that can creates a better wide field of view of almost 180°. The purpose of this probe is to used in gynaecological application.

### **4. Phased array/Sector**

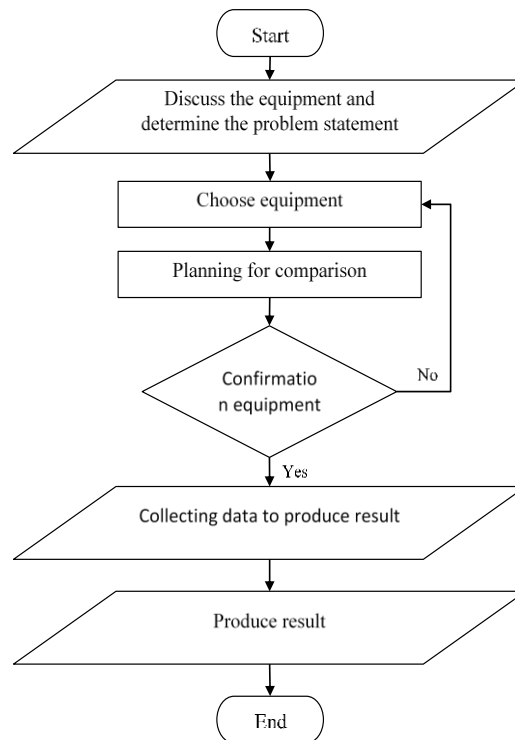
The phased array or sector commonly used for cardiac imaging, imaging between ribs and small spaces. The crystals in probe are grouped closely together. This probe has smaller and flatter footprint than curvilinear probe.

## **3.0 METHODOLOGY**

In this section contain methodology of this research of technical assessment report, there are the flow process to complete the result data and analysis which is process where to choose an equipment and analysis the comparison between several type of brand and model of equipment.

### **3.1 Progress Flow**

Figure 13.7 shows, flow chart operation to finish the technical assessment report which is discussion that need to be conducted with student and concession staff. Next step is choosing the equipment that need to analysed and also planning the process of comparison between two different ultrasound model. Finally, the data can be collected and also the outcome result can be producing.



**Figure 13.7:** Flow chart of assessment to the equipment

Figure 13.7 explains that the whole process to complete the Technical Assessment Report (TAR). It means this process will start with discussion of the title of Technical Assessment Report (TAR) project with mentor and concession staff. Then, choose the best title of research study based on list at hospital equipment. Then exchange view about the title of project and at the same time get the confirmation from coordinator about the title of project. After that, if the title that agree from coordinator. It can start do the TAR project and submit proposal to coordinator. Next, get the information the proposal is submit to coordinator and finish the TAR project.

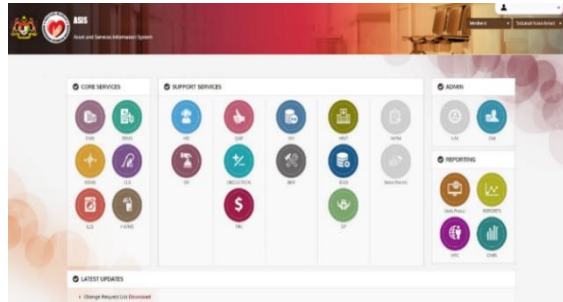
## 3.2 Data Collection

Data collection in this study research can be from two type of sources. From central system Asset and Services Information System (ASIS) build up by Minister of Health (MOH) and from distributed questionnaires among technical staff and hospital laboratories user by using standardized questionnaires sample from Post-Study System Usability Questionnaire (PSSUQ).

### 3.2.1 Asset and Services Information System

Asset and Services Information System (ASIS) is a platform central system built up by the Ministry of Health (MOH), Malaysia is a comprehensive and integrated management system for assets and services. By using this platform, we be able to extract the details about our focused equipment. The maintenance data for both devices was extracted in Microsoft Excel form which is then used for our studies in research.

Figure 13.8 shows the interface of home menu from ASIS central website. There are several categories to be choose depend on which one we preferred to access.



**Figure 13.8:** Interface of main menu from ASIS

Figure 13.8 can be explaining the system that concession company used to key in the data that are related with each scope. For example, core services BEMS is for BEMS data information and same goes to other core services. The data need to compile with they each core

## 4.0 DATA ANALYSIS

This section shown the result from our collected data such as from ASIS database also from questionnaire online and offline on paper. The data are analyzed and generated graph by using Microsoft Excel. The result that analyzed is discussed in this chapter. Since the aim of this research is to develop a comparison between ultrasound machine. The user can get the clearer view which type of model is more suitable to the hospital usage.

### 4.1 RESULT

Table 13.2 below shows the list of breakdowns for ultrasound machine GE VENOUS 40 for year 2011 until 2020.

**Table 13.2:** Maintenance history for GE Venous 40

Maintenance Work No.	Service Work Date / Target Date.	Total Downtime	Total Cost (RM)	Action Taken
WO/BEMS/JHR002/18 02/000079	12-Feb-2018 00:00	0.00	49.34	Checked & found password error. Check system & log in password ok. Handed over the machine in proper working condition.
WO/BEMS/JHR002/17 10/000114	14-Oct-2017 00:00	0.00	110.32	Check and found option key missing. Put option key, test OK. Handed over the machine in proper working condition.
WO/BEMS/JHR002/17 10/000122	15-Oct-2017 00:00	286.08	124.11	Check and found probe not detect. Reconfigure the setting and option key. Test all, ok. Handed over the machine in proper working condition.
HSI/A4/B00701/16	12-Apr-2016 00:00	144.00	100.00	Check the system. Found Option Key was deleting by user. Request new Option Key from vendor. Key in the key and tested all, OK. Handed over the machine in proper working condition.
HSI/A4/B02645/16	14-Dec-2016 00:00	3.00	300.00	Call vendor to get the license key. Try insert the license, test OK. Option key: BS9SP-L4HNZ-ZYMWS-N2X55-BFKGW
HSI/A4/B02656/16	15-Dec-2016 00:00	622.00	100.00	Check port pin. Found pin not align and bend. Perform alignment pin and fine tune at service mode. Tested all probe, OK. Handed over the machine in proper working condition.
HSI/A4/B00006/15	01-Apr-2015 00:00	217.00	75.00	Replace with new probe (12L-SC probe). Machine tested and handed over in normal working condition.
HSI/RQ/A4/B96288/15	22-Mar-2015 00:00	1.50	39.34	Found password error. Log in password ok. Handed over the machine in proper working condition.

Based on the table above, the GE Venous had 8 time of breakdown after 6 years of purchase. Mostly the problem that occur are program system error, and mishandling by user such as connection the transducer with connector that can lead to port pin align and bend. Lastly, transducer probe is damage which is the image dropout that can cause black lines on the ultrasound reading. The full detail of information maintenance for ultrasound machine GE VENOUS 40 can refer to appendix where it explains the schedule and unscheduled work order for year 2011 until 2020. Table 13.3 shows the maintenance history for Toshiba Xario Xg Ssa-680.

**Table 13.3:** Maintenance history for Toshiba Xario Xg Ssa-680

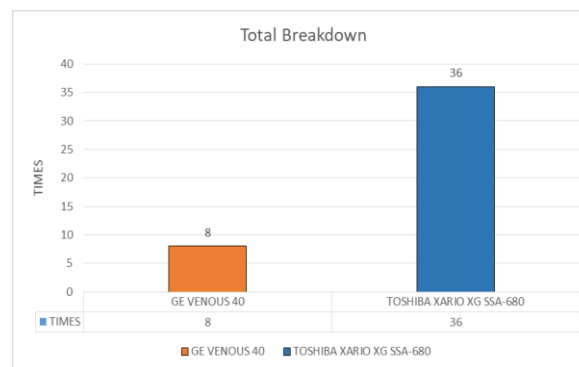
Maintenance Work No.	Service Work Date / Target Date.	Total Downtime	Total Cost (RM)	Action Taken
WO/BEMS/JHR002/1904/000177	25-Apr-2019 00:00	0.00	75.50	Under RW. Refer to ADS/BEMS/JHR002/2019/05/000005.
WO/BEMS/JHR002/1805/000045	08-May-2018 00:00	0.00	62.50	Check & found image not clear. Adjust brightness & frequency setting. Test machine ok. User verified, ok. Handed over the machine in proper working condition.
HSI/A4/B00752/16	19-Apr-2016 00:00	3.00	100.00	Check the image. Found the STC not set properly. Set STC and verify the image with user. Handed over the machine in proper working condition.
HSI/A4/B01035/16	25-May-2016 00:00	1.00	25.00	Check with user. Explain how to use setting for clear image. Machine in good working condition. Handed over the machine in proper working condition.
HSI/A4/B02486/16	22-Nov-2016 00:00	1.00	40050.00	Check convex probe image. Have artifact. Replace the probe. Handed over the machine in proper working condition.
HSI/A4/B02651/16	15-Dec-2016 00:00	1.00	50.00	Checked and found machine cannot register new patient. Resetting and tested unit functioning. Unit returns to service.
HSI/A4/B00634/15	14-Jun-2015 00:00	2.00	100.00	Visited and deleted all the old image and reboot the system. Machine tested and handed over in proper working condition.
HSI/RQ/A4/B80809/12	28-Mar-2012 00:00	0.00	4.00	Replaced the Cartridge by New One
HSI/RQ/A4/B82552/12	27-Jul-2012 00:00	0.00	100.00	Repair the Button And Tested Ok. Hand Over the Machine In Proper Working Condition.
HSI/RQ/A4/B87096/13	02-May-2013 00:00	0.00	50.00	Touch Screen Keypad Not Function Normally
HSI/RQ/A4/B88137/13	20-Aug-2013 00:00	0.00	125.00	Open the Touch Screen Panel Slide By Slide. Check the Connection. Spray The Connection With Contact Cleaner And Clean The Pin. Put Back The Connection. Tested All, Ok. Observe, Ok. Machine In Good Working Condition.
HSI/RQ/A4/B88363/13	06-Sep-2013 00:00	0.00	100.00	Found The Touch Panel Display Intermittent Problem - Miss Alignment. Perform Tcs Calibration, All Pass But Still Occur. Suspect Tcs Panel Faulty
HSI/RQ/A4/B88364/13	06-Sep-2013 00:00	0.00	100.00	Check The Patient Data. Many Que. Clear All Data. Keep Observe.
HSI/RQ/A4/B88411/13	12-Sep-2013 00:00	0.00	100.00	Send The Printer To Hp Center. Printer Obsolete And No More Support To Repair. Recommend To Buy New Version System.
HSI/RQ/A4/B88714/13	08-Oct-2013 00:00	0.00	62.00	Check The System. No Patient List In Work List And No Image. Reboot The System. Check The Patient List, View Patient Image, Ok. Handed Over The Machine In Proper Working Condition.



Maintenance Work No.	Service Work Date / Target Date.	Total Downtime	Total Cost (RM)	Action Taken
HSI/RQ/A4/B8878 5/13	16-Oct-2013 00:00	0.00	50.00	Check the job status. Many data in job status. Deleted all data. Restart the system. Try to send all patient images to pacs, successfully. User test, ok. Handed over the machine in proper working condition.
HSI/RQ/A4/B8910 7/13	19-Nov-2013 00:00	0.00	50.00	Problem found in that. Dust inside the track ball and clean the same. Machine tested and handed over in proper working condition.
HSI/RQ/A4/B8922 7/13	28-Nov-2013 00:00	0.00	50.00	Check the system. All ok. Ask it department to check the network. Tested all, ok. Machine in good working condition.
HSI/RQ/A4/B9262 0/14	14-Jul-2014 00:00	0.00	50.00	Abex engineer check, all ok. Ask user (doctor) to check and test, ok. Machine in good working condition.
HSI/RQ/A5/B9451 9/14	18-Dec-2014 00:00	0.00	7.00	Do performance test for ultrasound transducer, passed. Check physical condition, no defected. Check all keypad, passed. Unit is in good condition.
HSI/RQ/A4/B7461 7/11	07-Jan-2011 00:00	66.00	50.00	System Tested Ok Machine Handed Over In Proper Working G Condition
HSI/RQ/A4/B7526 3/11	10-Mar-2011 00:00	1466.00	50.00	Problem Found In That Ink Cartridges Not In Original Supplier Recommend To Buy From Manufacturer
HSI/RQ/A4/B8258 3/12	01-Aug-2012 00:00	26.00	100.00	Repair the key pad and tested ok. Machine handed over in proper working condition.
HSI/RQ/A4/B8829 7/13	29-Aug-2013 00:00	29.00	50.00	Problem found in that, dicom error to many que in network. Clear all que and tested ok. Machine handed over in proper working condition.
HSI/RQ/A4/B8848 4/13	22-Sep-2013 00:00	29.00	50.00	Check the query of status job. Found many data que on status job. Delete all data. Test send new image to pacs, done and complete. Handed over the machine in properly working condition.
HSI/RQ/A4/B8876 8/13	14-Oct-2013 00:00	38.00	50.00	Check the system. Open worklist and try to sent image to pact, ok successful. Machine in good working condition.
HSI/RQ/A4/B8879 8/13	18-Oct-2013 00:00	120.00	50.00	Perform Touch Screen Calibration. Select Auto Calibration. Calibration Successfully. Test Machine and Observe, Ok. Handed Over The Machine In Proper Working Condition.
HSI/RQ/A4/B8888 3/13	29-Oct-2013 00:00	120.00	50.00	Check the que list. Clear all list done transfer. Test sent to pacs, successfully. Handed over the machine in proper working condition
HSI/RQ/A4/B8889 4/13	29-Oct-2013 00:00	2017.00	100.00	Problem Found In That Touch Panel Calibration Fail Need To Replace New One
HSI/RQ/A4/B8892 9/13	31-Oct-2013 00:00	285.00	50.00	Same Request With W.Order Rq/A4/B88894/13 - 29/10/13
HSI/RQ/A4/B8906 0/13	14-Nov-2013 00:00	168.00	100.00	Delete all job status completed, fail and stoppable. Restart the system. Send the image to pacs, successfully. Machine in good working condition.
HSI/RQ/A4/B9104 8/14	16-Feb-2014 00:00	2645.00	100.00	Problem found in that tcs panel hang intermittently reset the pcb and cables tested ok machine kept under observation.
HSI/RQ/A4/B9106 7/14	12-Feb-2014 00:00	1.00	50.00	Printer obsolete and no more support to repair. Recommend to buy new version system.

HSI/RQ/A4/B9114 1/14	25-Feb-2014 00:00	5.00	250.00	Check The System. Cannot Send Image. Check the Network, Fail. It Problem. Machine Ok. After Network It Stable And Ok, Image Can Send Successfully.
HSI/RQ/A4/B9164 5/14	10-Apr-2014 00:00	1.00	50.00	Found probe rubber sleeve cut put tape properly and tested ok. Machine handed over in proper working condition

Based on the Table 13.3, it shows the list of breakdowns for Toshiba Xario Xg Ssa-680 that occur after purchase. Mostly breakdown that always occur during year 2013 which is touch Screen Panel not function normally and also the data storage always full that can lead to ultrasound machine unable to save a new data and need to clean or delete the data Queue on Status job. Furthermore, the probe damage also is included in unscheduled work order and need to replace with new probe to ultrasound machine working properly in diagnose patients. The full detail of information maintenance for ultrasound machine Toshiba Xario Xg Ssa-680 can refer to appendix where it explains the schedule and unscheduled work order for year 2009 until 2020.



**Figure 13.9:** Total breakdown GE Venous 40 and Toshiba Xario Xg Ssa-680 for 2009 – 2020.

The common breakdown for GE Venous 40 is system program error and also mishandling by user such as connection the transducer with connector that can lead to port pin are not align and bend and option key was deleted by user. So, it needs to request new option key from vendor. Meanwhile, the total breakdown for Toshiba Xario Xg Ssa-680 is bigger than GE Venous 40 which is 36 times. Usually, the breakdown is occurring because of probe damage, system format error and the query of status job always fully in the system and need to delete all data once the memory are fully.

## 4.2 Analysis

### 4.2.1 Downtown comparison

Table 13.4 below shows the comparison between two types of ultrasounds which is GE Venous 40 and Toshiba Xario Xg Ssa-680.

**Table 13.4:** Data comparison between the two models

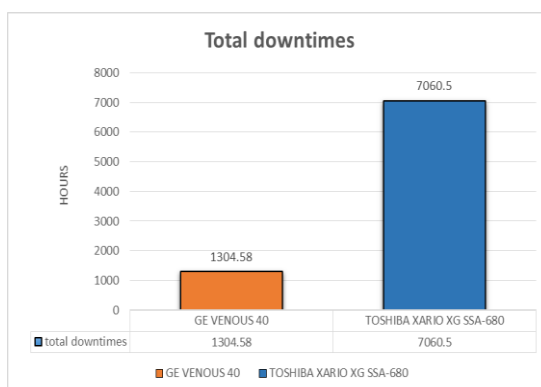
GE VENOUS 40	Manufacturer	TOSHIBA XARIO XG SSA-680
GE Healthcare	Brand	Toshiba
VENOUS 40	Model	XARIO XG SSA-680
27-Apr-2012	Purchase date	30-Jun-2009
198900.00	Purchase cost (rm)	195000.00
1844.95	Total cumulative parts/labour cost (rm)	43315.23

This type of ultrasound has a different purchase price. The table shows that GE VENOUS 40 more expensive compared to TOSHIBA XARIO XG SSA-680. However, the total cumulative or labour cost for GE VENOUS 40 show that are less than TOSHIBA XARIO XG SSA-680.

#### 4.2.2 Breakdown Comparison

Figure 13.10 show the total breakdown for GE VENOUS 40 compared to TOSHIBA XARIO XG SSA-680 from 2009 to 2020. For twelve years in use, the GE VENOUS 40 only got breakdown 8 times, meanwhile the TOSHIBA XARIO XG SSA-680 got 36 times breakdown for the whole twelve years in used. This statistic data proved that GE VENOUS 40 only breakdown about quarter of TOSHIBA XARIO XG SSA-680 number of breakdowns. It means that GE VENOUS 40 has less breakdown compare to TOSHIBA XARIO XG SSA-680.

Figure 13.11 show the total hours of downtime for twelve years (2009 – 2020) for ultrasound GE VENOUS 40 and TOSHIBA XARIO XG SSA-680.



**Figure 13.10:** Total downtime GE Venous 40 and Toshiba Xario Xg Ssa-680 for 2009 – 2020.

Based on Figure 13.10 the TOSHIBA XARIO XG SSA-680 have higher downtime compared to GE VENOUS 40 through its have lower breakdown count. The observation found why this happen because, the corrective maintenance for GE Venous 40 only included a minor problem such as touch screen keypad not function, adjust setting the brightness of image in system or probe need to replacement with new one. Toshiba Xario Xg Ssa-680 can burst the downtime once the Problem Found In that Ink Cartridges not in original supplier and need to buy from manufacturer.

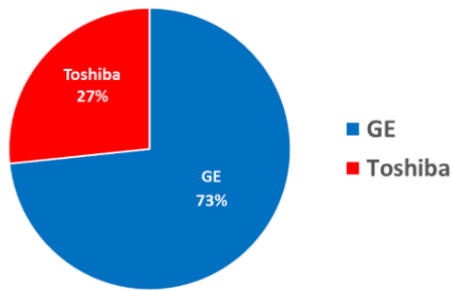
#### 4.2.3 User Feedback

Figure 13.11 shows the pie chart feedback from user and technical according to the selected equipment that has been asked. Percentages shown the respondent are prefer GE more than Toshiba.

16 questions was distributed to user including 3 categories:

- Questions 1 – 6: System Usefulness (SYSUSE)
- Questions 7 – 12: Information Quality (INFOQUAL)
- Questions 13 – 16: Interface Quality (INTERQUAL)

The Question given are refer to the Post-Study System Usability Questionnaire (PSSUQ) sample standardized questionnaire.



**Figure 13.11:** Respondent feedback according to usability of GE Venous 40 and Toshiba Xario Xg Ssa

Figure 13.11 explains that the questionnaire was conducted to analysed the usefulness and user friendly for two different model of ultrasound. Based on the graph pie chart percent for GE Vanous is 73% and Toshiba Xario Xg Ssa-680 is 27%. So, The GE Venous 40 are preferable compare Toshiba Xario Xg Ssa-680.

## 5.0 Conclusion

Ultrasound machine GE VENOUS 40 have better specification and the less downtime during years of operation to compare with Ultrasound machine Toshiba Xario Xg Ssa-680. Although the costing price are quiet expensive compare to the Toshiba Xario Xg Ssa-680, GE VENOUS 40 is fit to use for hospital imaging requirement and it have low total breakdown compare to Toshiba Xario Xg Ssa-680. It has more advantages compare to the Toshiba Xario Xg Ssa-680 in term of specification, downtime and user friendly.

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# HAEMODIALYSIS

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**Abstract**— Haemodialysis is a machine with a medical procedure to remove fluid and waste products from the blood and the function is to correct electrolyte imbalances. This is accomplished using a machine and a dialyzer also referred to as an "artificial kidney." Haemodialysis is used to treat both acute (temporary) and chronic (permanent) kidney failure. A gap has been found where haemodialysis machine breakdown can bring a problem in the operation of the hospital. This is because due to the lack of a haemodialysis machine for every patient. The objective of this report is to compare the differences between the two brands of haemodialysis machine based on category related. Hence, the collection of the data will be used as a method to complete the report. The output from the data analysis will determine which of the haemodialysis machine has the highest return of investment. Based on the assessment and analysis done it can be recommended that Surdial 55 Plus is the best brand of haemodialysis machine than Dialog.

**Keywords**- haemodialysis, compare, technical, corrective maintenance, plan preventive maintenance.

## 1.0 Introduction

Kidneys usually filter and remove waste products and excess fluid from the blood. Haemodialysis is a way of replacing some of the functions of the kidney, if the kidneys have failed, using a machine will filter and clean the blood. Blood is pumped out of the body to the machine where it is passed through a series of tiny tubes, in an 'artificial kidney' or 'dialyser'. The tubes are the construction of a special membrane that allows waste products and fluid to pass across it. A clear fluid called 'dialysate' is passed outside the tubes in the opposite direction. As the blood passes in one direction and the dialysate in the other, waste products and excess water pass into the dialysate. Which is then pumped out of the machine and the waste discarded down a drain, as the cleaned blood is pumped back into the body [1].

Haemodialysis has been selected as the medical equipment machine that will be compared based on some categories to search for a good brand for the haemodialysis itself. First and foremost, the main objective is to compare the different brand of haemodialysis. Next, to analyse the data and information that has been gathered. Lastly, to recommend the best choice of a brand based on the analysis result.

The selected medical equipment, haemodialysis has been chosen to resolve the gap that has been observed in the hospital. If a breakdown occurs on the haemodialysis machine, the operation of the hospital will be delayed due to the lack of medical equipment equipped for every patient. Every patient has their own schedule to [1] come for dialysis treatment haemodialysis is usually done three times a week, for 3 to 4 hours a day, depending on how well the kidneys work, and how much fluid weight they have gained between treatments. Moreover, the haemodialysis machine generally placed under the department of the haemodialysis unit.

In this technical assessment report, Section 2 discusses detail about haemodialysis physical layout, brand, model, manufacturer and principal operation. Section 3 discusses methods applied to obtain data for comparison and analysis. Section 4 covers results and data analysis, graph. Section 5 discusses the conclusion, and recommendation which is obtained after the analysis has been made and present in the report. Section 6 shows the references based on research paper articles and journal related.

## 2.0 Haemodialysis

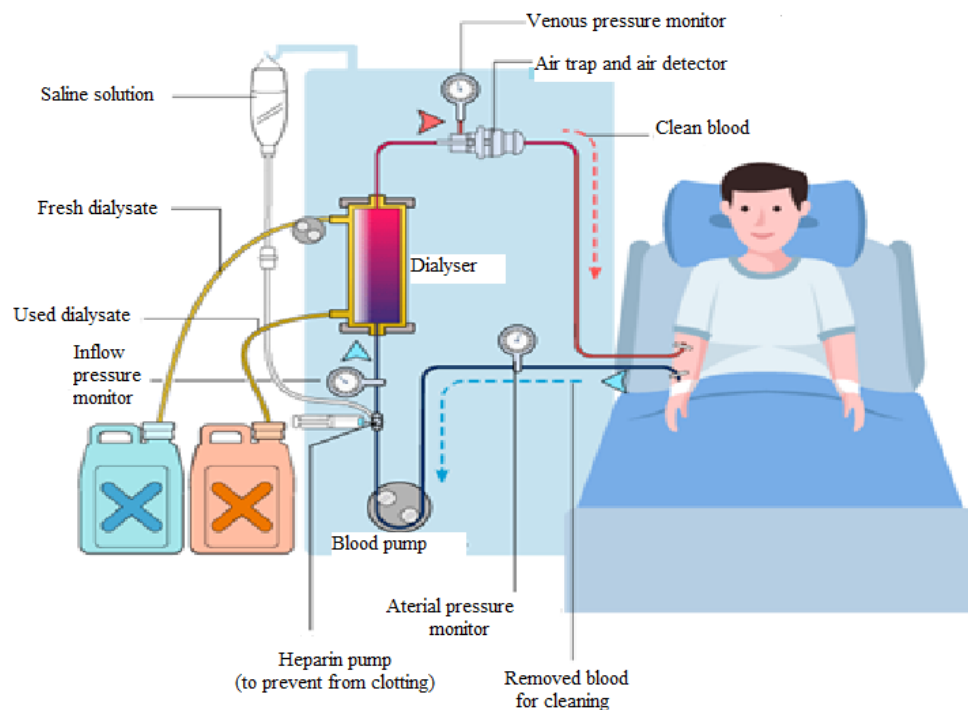
Haemodialysis is a machine used in dialysis that filters a patient's blood to remove excess water and waste products when the kidneys are damaged, dysfunctional, or missing. The dialysis machine itself can be thought of as an artificial kidney.

Inside, it consists of more plastic tubing that carries the removed blood to the dialyser, a bundle of hollow fibres that forms a semipermeable membrane for filtering out impurities. In the dialyser, blood is diffused with a saline solution called dialysate, and the dialysate is in turn diffused with blood. When the filtration process is complete, the cleansed blood is returned to the patient [1].

This section will explain details on the physical layout of the haemodialysis. Next, types and model used in the hospital. The electrical safety test characteristic and haemodialysis meter. Moreover, part and its function along with principal operation will be discussed.

### 2.1 Physical layout of Haemodialysis

Figure 14.1 illustrates the haemodialysis machine connection with the patient.



**Figure 14.1:** Connection of haemodialysis to the patient



Figure 14.1 explains the physical layout structure of the haemodialysis machine to connect with the patient. The clean blood is removed for cleaning, the tube followed through the arterial pressure monitor and blood pump to the dialyzer. The clean blood comes out from the dialyzer and going through a venous pressure monitor and air trap detector to the patient's body

## 2.2 Types and Model

Before starting any experiment, it is important to identify the type, model and brand of the machine that is related. For example, plan preventative maintenance activity start with confirmation and addressing the asset model, brand, manufacturer and location.

Table 14.1 shows the list of active haemodialysis machine with model and types which is sold and selected to operate in the hospital.

**Table 14.1:** List of haemodialysis machine active in hospital

No.	Model	Model/Brand/Manufacturer
1.		Dialog + , B Braun Type: single patient
2.		Model: Surdial 55 Plus Brand: Nipro manufacturer: Nipro Corp Type: single patient





No.	Model	Model/Brand/Manufacturer
3		<p>Model: 4008S Manufacturer: Fresenius</p>
4		<p>Model: Prismaflex Manufacturer: Gambro</p>

Table 14.1 shows some of the model for the haemodialysis machine that is has been selected in the hospital. First and foremost, the first model is Dialog 55+. Secondly, the model is from Surdial 55 Plus. Third, the model is Fresenius 4008S and lastly is model Prismaflex. This technical report will compare the haemodialysis machine which is active in Hospital Temenggung Seri Maharaja Tun Ibrahim (HTSMTI). There are three active brands in HTSMTI Fresenius 4008S, (Nipro) Surdial 55 Plus and Dialog +, (B Braun), within these three models two brand is chosen, Dialog + B Braun and Nipro Surdial. The haemodialysis machine is selected by the range of the year which is not more than 10 years from the technical and commissioning process (T&C).

## 2.3 Electrical Safety Test

Haemodialysis machine is a Class I equipment has a protective earth. The basic means of protection is the insulation between live parts and exposed conductive parts such as the metal enclosure. Class I medical electrical equipment should have fuses at the equipment end of the mains supply lead in both the live and neutral conductors, so that the supplementary protection is operative when the equipment is connected to an incorrectly wired socket outlet. Figure 14.2 show the symbol that can be seen on the haemodialysis machine.





**Figure 14.2:** Symbol on earth equipment

The electrical safety test for haemodialysis machine use IEC 62353 Medical Electrical Equipment - recurrent test and test after repair of ME equipment, defines the requirements for electrical safety testing of medical electrical (ME) equipment and systems during routine intervals.

## 2.4 Applied Part

Applied part is part of the medical equipment, which is designed to come into physical contact with the patient, or parts that are likely to be brought into contact with the patient. Table 14.2 show the applied part for haemodialysis machine and its specification.

**Table 14.2:** Applied part for haemodialysis machine

SYMBOL	TYPE
	Degree of protection against electric shock: Type CF- Blood Pressure Cuff only
	Degree of protection against electric shock: Type B

The applied part belongs to haemodialysis machine is the degree of protection against electric shock is Type CF the symbol is illustrates in the table. The second type of degree of protection against electric shock is Type B. it is important to identify the type for any medical equipment (ME) for the safety of the patient and electrical safety test activity.

## 2.5 Haemodialysis Meter

The haemodialysis meter application is for the Haemodialysis machines and RO-Water Systems. It can measure Conductivity, Temperature, Pressure and Flow.

Figure 14.3 shows the haemodialysis meter HDM97BQ.

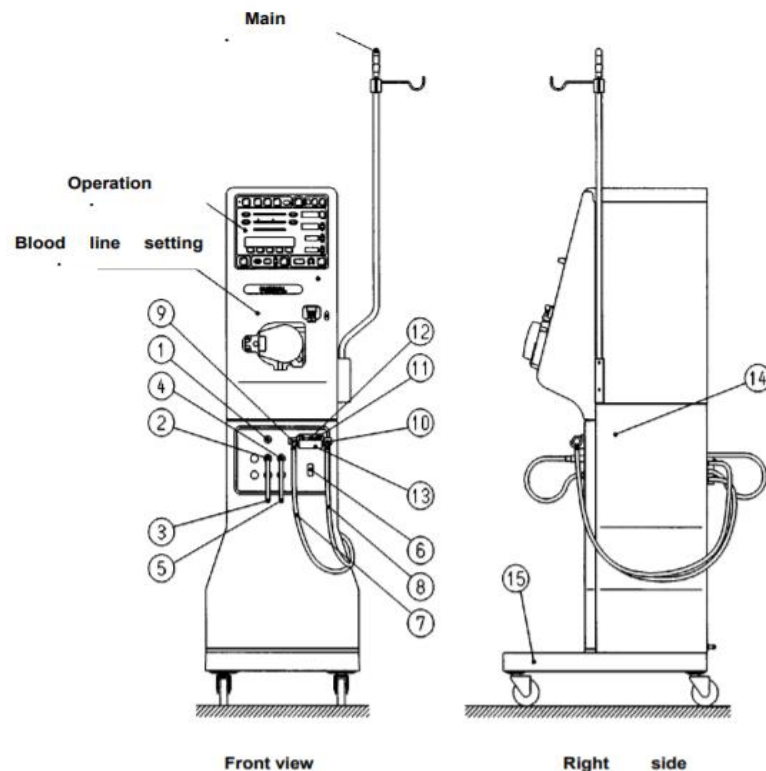


**Figure 14.3:** Haemodialysis meter

Based on Figure 14.3, haemodialysis meter HDM97BQ is used to check if the measurement of the haemodialysis machine is correct to its range. For example, the temperature needs to be exact value with the haemodialysis meter. The value of each measurement can be referring from the manual book from manufacturer.

## 2.6 Part and module

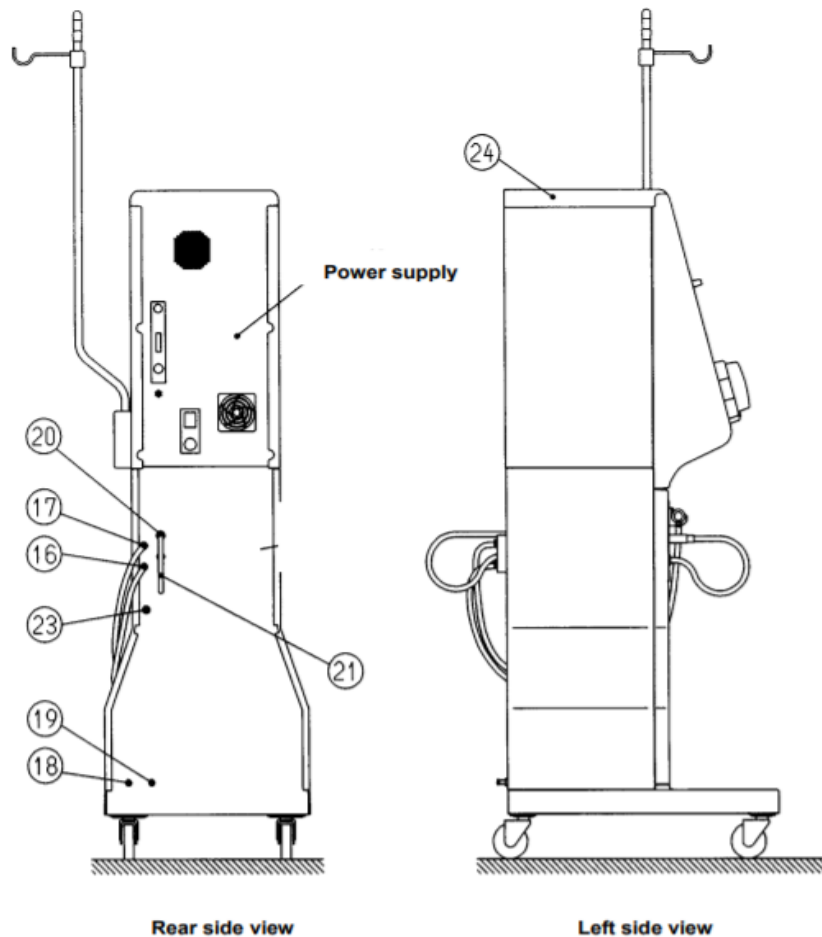
1. This section describes on the module and part of the Surdial 55 Plus [3]  
The Figure 14.4 illustrates the diagram of Surdial 55 Plus.



**Figure 14.4:** Front and right side of brand Surdila55 Plus

From Figure 14.4, the image of part for the Surdial 55 Plus and its function will be explained in details by number in sequence from the table below.

Figure 14.5 below shows the position of the Surdial 55 Plus.



**Figure 14.5:** The rear and left side of the Surdial 55 Plus

From the diagram the part is labelled by number. The labelling part of number in the figure explain in the table below.

Table 14.3 explains the part and its function from the number in Figure 14.4 and Figure 14.5.

**Table 14.3:** The part with the and purpose and function

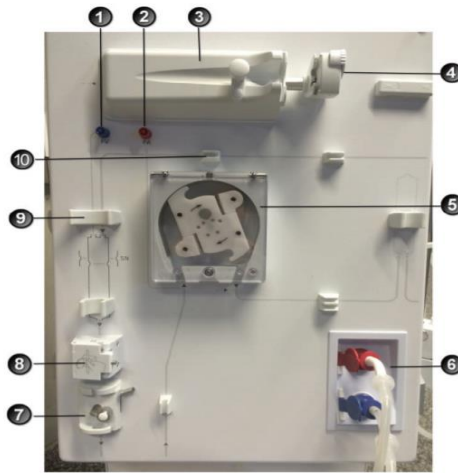
No.	Component	Purpose and function
1	Sampling port	Port used to take dialysis sample
2	Rinse port for A concentrate	Port used to connect to connector of bicarbonate A concentrate connector
3	Connector for a concentrate	Connector used to connect connector of B concentrate container
4	Rinse port for B concentrate	Port used to connect connector of B concentrate container during rinsing operation
5	Connector for B concentrate	Connector used to connect connector of bicarbonate B concentrate connector

6	Flow meter	Meter use to indicate flow rate of dialysis supplied to dialyzer
7	Dialysate return tube	Tube used to return used dialysate to port” from dialyzer ”
No.	Component	Purpose and function
8	Dialysate supply tube	Tube used to supply fresh dialysate to port “to dialyzer”
9	Dialysate return coupler	Coupler used to connect used dialysate return tube to dialyzer
10	Dialysate supply coupler	Coupler used to connect fresh dialysate supply tube to the dialyzer
11	Bypass connector	Connector used to bypass ports” from dialyzer” when coupler Nos 9 and 10 are set to the machine during rinsing operation
12	Limit SW for bypass connector	SW used to detect whether coupler is received in coupler holder
13	Coupler holder	Holder used to receive coupler during rinsing operation
14	Dialysate flow rate regulating needle valve	Valve used to regulate dialysate flow rate in closed circuit
15	Container support	Support used to load dialysate concentrate container
16	Port “from dialyzer”	Port used to return used dialysate from dialyzer
17	Port “to dialyzer”	port used to supply fresh dialysate to dialyzer
18	Water supply port	Port used to connect hose for supplying purified water to the machine
19	Drain port	Port used to connect hose for draining used dialysate
20	Port for connector of disinfectant concentrate connector	Port used to Connector used to connect connector of disinfectant concentrate container when disinfectant or acid rinsing is not executed
21	Connector for disinfectant concentrate container	Connector used to connect disinfectant concentrate container during disinfection/rinsing; or that used to connect acetic acid concentrate container during acid rinsing
22	Blood leak sensor	Sensor used to detect blood leak
23	Priming flow rate regulating needle valve	Valve used to regulate flow rate of priming solution
24	Tray	Tray used to hold tools during dialysis by placing it on the machine top

From the table above the part and function of Surdial 55 Plus is cleared to show the details on the haemodialysis machine brand of Surdial 55 Plus.

2. This section describes on the module and part of the Dialog+ B Braun

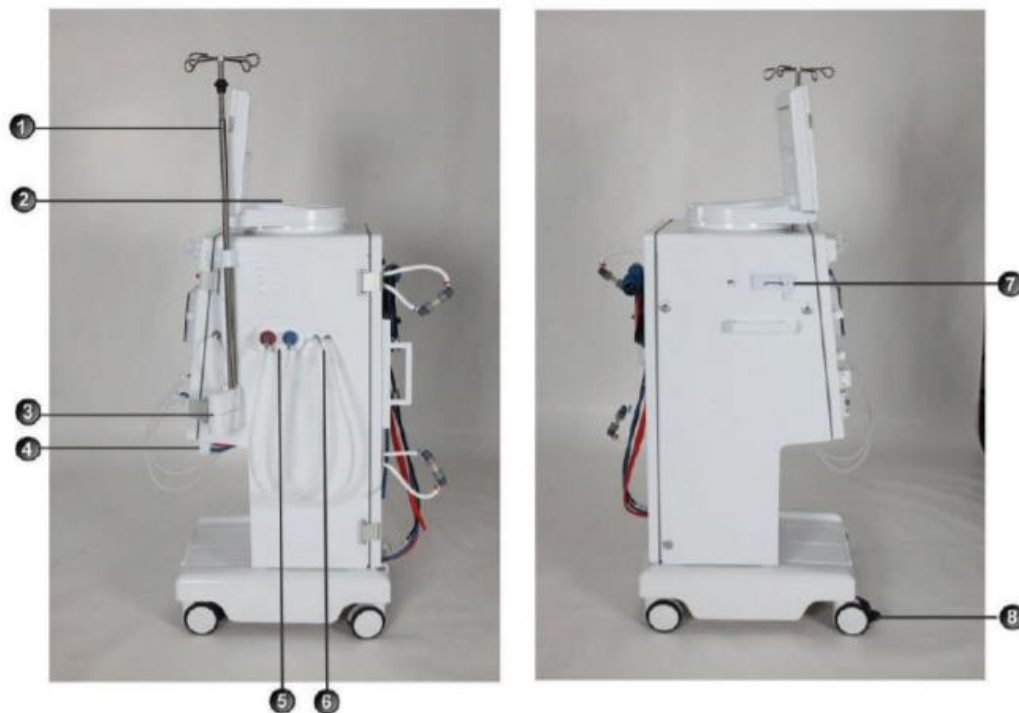
The Figure 14.6 show the part and function for the Dialog +



**Figure 14.6:** The front view of single pump for haemodialysis machine brand Dialog+.

- 1) Venous pressure sensor connection(blue)
- 2) Arterial pressure sensor connection(red)
- 3) Heparin pump
- 4) Syringe stops
- 5) Blood pump (one or two blood pumps depending on basic model)
- 6) Rinsing chambers for concentrate rods
- 7) Venous tube clamp
- 8) Safety air detector (SAD) and red sensor
- 9) Fixture for the chamber of the blood tubing system
- 10) Fixture for blood tubing system

The Figure 14.7 shows the diagram of side views for the Dialog +



**Figure 14.7:** Basic model side views

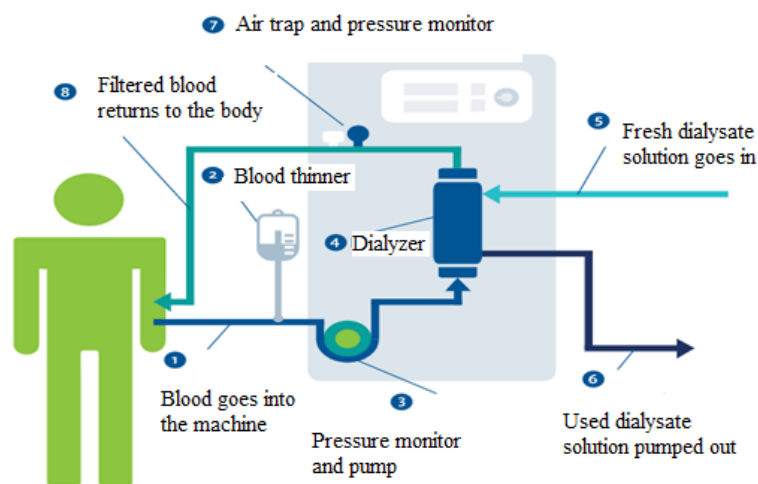
The part in Figure 14.7 is listed below:

- 1) Infusion pole (in some model's pole may not be adjustable)
- 2) Multifunctional tray
- 3) Bicarbonate cartridge holder (optional)
- 4) Connection for central concentrate supply
- 5) Connection for disinfectant
- 6) Connection for dialyzer tubing and rinsing bridge
- 7) Card reader
- 8) Wheel lock

## 2.7 Principal operation

The principal operation of the haemodialysis machine will be explained in this section.

Figure 14.8 is the physical layout of the haemodialysis machine tube connection.



**Figure 14.8:** Diagram for basic haemodialysis machine tube direction.

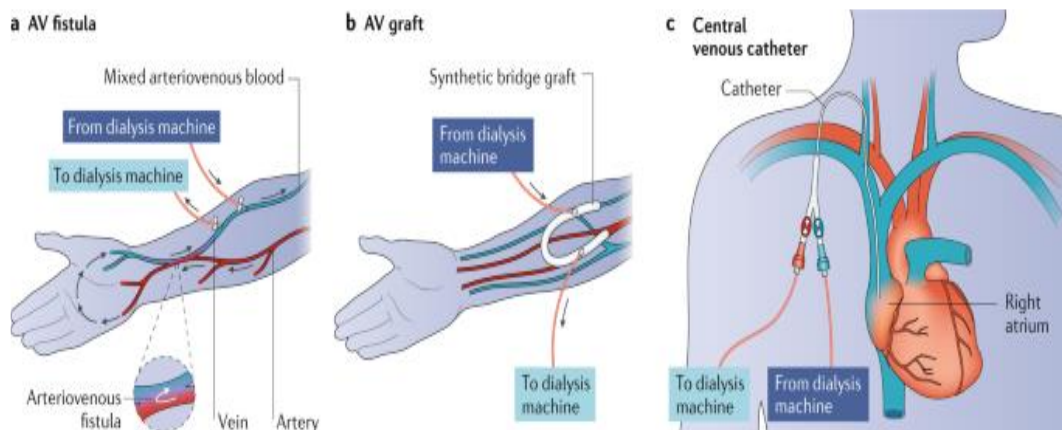
Figure 14.8, two tubes are connected via the patient haemodialysis access. Blood flows from the body into the machine through one of the tubes. The doctor prescribes blood thinner as part of the treatment, it will be added to keep the blood from clotting while it's in the machine. A pressure monitor and pump work together to keep the flow at the right rate. The blood enters the dialyzer where it's filtered. Dialysate solution enters the dialyzer, and it draws the way out of the blood. Used dialysate solution is pumped out of the machine and discarded. The blood goes through another pressure monitor and an air trap to make sure it's safe to go back into the body. The cleaned blood returned to the body through the second tube attached to your access site.



## 2.8 Application

The application for haemodialysis machine is located generally in the haemodialysis Unit (HDU). Person in charge in the usage of the haemodialysis is Medical Assistant (MA), nurses, and biomedical technician and engineer. The direct user for haemodialysis is patient with kidneys problem. There are three different types of dialysis access used for haemodialysis, a process in which blood is transported from the body for cleaning. Central venous catheter (CVC), Arteriovenous fistula (AV Fistula), Arteriovenous graft (AV Graft) [5].

Figure 14.9 show the types of dialysis access available in dialysis treatment.



**Figure 14.9:** Three different type of dialysis access used for haemodialysis.

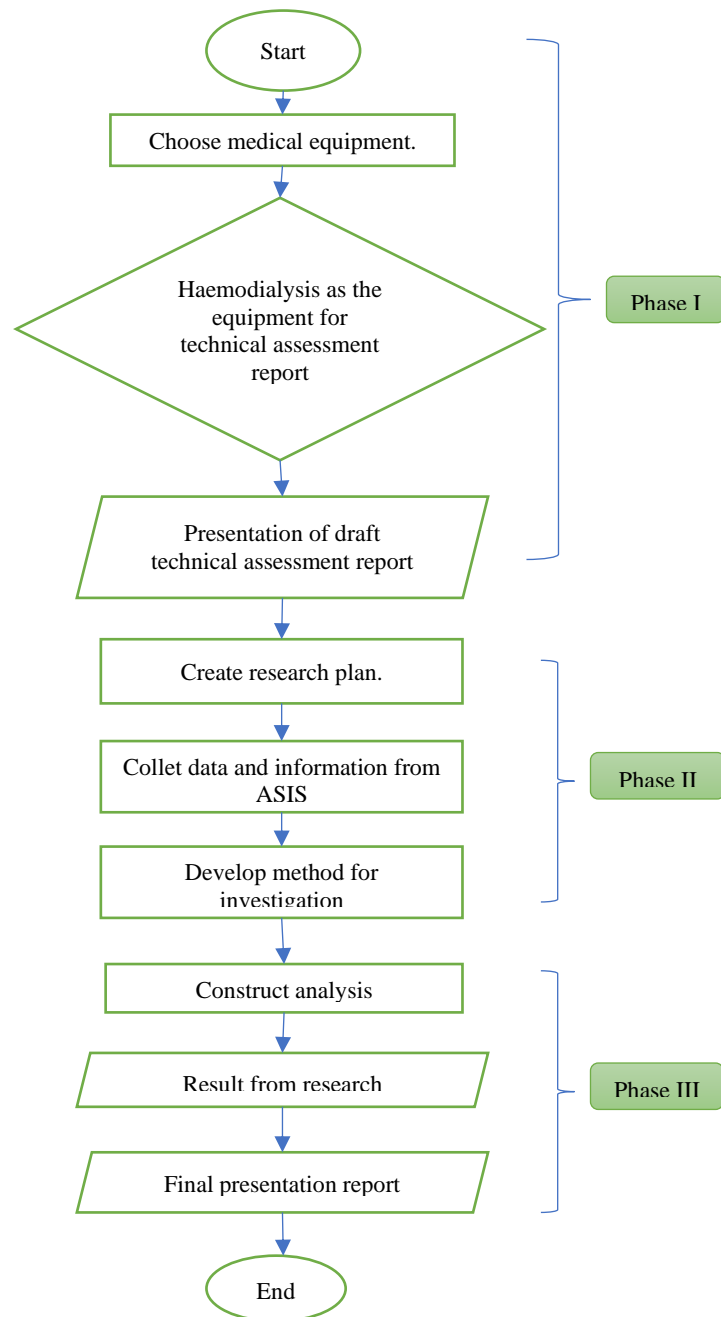
Figure 14.9 shows three places that can be apply for the patient to perform the dialysis treatment. Different types of dialysis access used for haemodialysis, a process in which blood is transported from your body for cleaning. Central venous catheter (CVC), Arteriovenous fistula (AV Fistula), Arteriovenous graft (AV Graft). The first type of access will look at is a central venous catheter (CVC), which is a flexible, long, plastic, y-shaped tube that is threaded through the skin into a central vein in your neck, chest, or groin. A CVC is not usually intended to be a permanent type of access. If the immediate or emergency dialysis is needed or cannot receive and do not have an AV fistula or graft, it will require a CVC. The second type of dialysis access is an AV fistula, which is an actual surgical connection made between an artery and a vein. An AV fistula is most often created in the non-dominant arm, but sometimes it can be created in the leg. This access results in an increased blood flow rate through the vein, which helps enlarge and strengthen the vein. An AV fistula allows a higher rate of blood to flow back and forth from the vein to a dialysis machine. An AV fistula is the preferred access of all the types of haemodialysis access and is often referred to as the “gold standard.” In 2013, 65% of all patients in the United States Renal Data system were exclusively using an AV fistula at the end of one year of dialysis. The third type of access, called an AV graft, functions similarly to an AV fistula. If the blocked or damaged veins, or veins that are too small for a fistula, it is a candidate for an AV graft. AV graft placement is also a surgical procedure, but instead of connecting the artery directly to the vein, one end of a small hollow, synthetic tube will be connected to the vein, and the other end will be connected to your artery.

## 3.0 Methodology

This section will discuss on research methodology that has been carried out through the entire assessment. The structure of the section will be divided into several parts of subsection. To achieve the objective of the technical report there are some methods use to investigate and identify the data needed to get the result.

### 3.1 Flowchart of assessment

Figure 14.10 illustrate the flowchart for the development of technical assessment. There are three phases involve following the objective for the project.



**Figure 14.10:** Flowchart of assessment of equipment

From the Figure 14.10 there are three phases involve in the assessment, phase I, phase II and phase III.

Phase I are the beginning of the project where observation has been made to observe any gap that can be seen in medical equipment maintenance activity. Next, haemodialysis machine has been selected as the title and draft report was presented to the lecturers.

Phase II is creating a research plan, planning the structure of the technical report, things that need to observe from the haemodialysis machine, the data is then collected from ASIS and the method for analysing data is created.

Phase III is processing the data to make analysis. The result from analysis then will be conclude and recommend for a good brand of haemodialysis machine. This progress end with a final presentation.

## 3.2 Tools

The data analysis that has been collected are coming from some tool such as ASIS and manual book.

### 1. ASIS (Asset and Services Information System)

Ministry of Health, Malaysia comprehensive and integrated management system for assets and services. In this system all the information about the medical equipment such as purchase date ppm breakdown and cost can be access. The government hospital use ASIS to track the progression of work from biomedical engineering unit.

Figure 14.11 shows the image of ASIS portal.



**Figure 14.11:** ASIS portal

The picture show that to log in into the ASIS system the ID and password user must be insert. Only workers with ID ca access the system. It is confidential and only hospital under the biomedical unit can manage the information inside.

### 2 Manual book

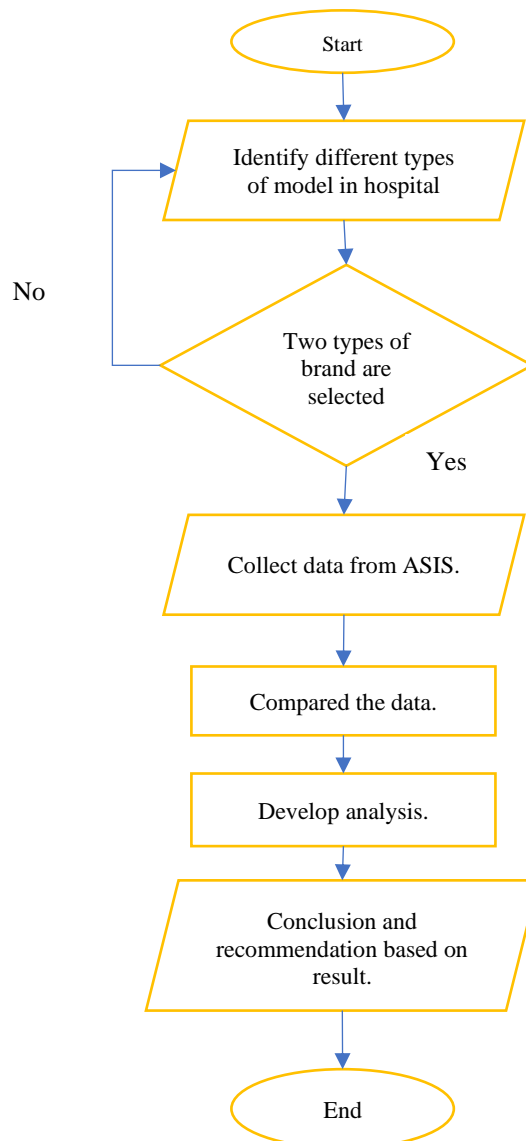
A manual provides instructions or guidelines on how to perform an activity and serves as a reference book on the activity. In order to understand about the haemodialysis machine, refer to the manual book is the best choice, the manual book provide purpose, principal also technical information such as trouble shooting and cause of the technical problem. From manual user and engineer will be guided to the proper use of machine

### 3 Google scholar, Research Gate

Google scholar and Research Gate are one of the websites that contains a lot of research paper and journals that can be used as additional information and reference to get the better understanding of the machine.

### 3.3 Flowchart of the investigation methodology

The Figure 14.12 demonstrates the flowchart of the methodology involve in the investigation.



**Figure 14.12:** Flowchart of method in the investigation

Based on Figure 14.12 the methodology of investigation started with identifying the different types of haemodialysis model. Then select only two model that has been active for not more than 10 years. This is because ageing machine are not comparable with new machine. Next collecting the data from ASIS and compared. With the data analysis is developed. Lastly, conclusions are made following the objective and recommendation are based on the result from analysis.

## 4.0 Result and analysis

Table 14.4 below shows the difference between brand (A) Nipro Sordial 55 Plus and brand (B) Dialog+ based on category.

**Table 14.4 :**Matrix synthesis by categories between Sordial 55 Plus and Dialog+



Category	A	B
<b>Figure</b>		
<b>Brand /model</b>	Nipro sordial 55	Dialog +
<b>Manufacturer</b>	Nipro corp	B Braun
<b>Size Dimensions (W x D x H)</b>	280 x 420 x 1365 mm	510 x 637 x 1678 mm
<b>Weight</b>	72 kg	85 kg
<b>Power supply</b>	AC 230 V/AC 110 V $\pm 10\%$	230 V (option: 120/240 V)
<b>Purchase Price</b>	31,980	30,722
<b>Years start</b>	2019	2016
<b>Total years used</b>	3 years	6 years
<b>Warranty</b>	Under warranty	Not under warranty
<b>Hours used</b>	02018	21574
<b>Breakdown per month average</b>	1	4
<b>Total breakdown</b>	1	24
<b>Cost for breakdown</b>	56.81	8,384.78
<b>Total cost for all</b>	436.58	16045.38
<b>Total downtime</b>	13.81	243.82
<b>Total ppm</b>	3 per year (2019-2020)	1 per year
<b>Total cost ppm</b>	297.51	1,168.25
<b>Total ppm per year</b>	3	5
<b>Common problem</b>	Blood detector / blood sensor	Leaking and need services in cleaning interior, resolder board, Cleaning power supply board. Change fuse. Service blood pump. Service heater block Service UF pump Cleaning interior. Service membrane chamber. Cleaning all filter Flushing all valve.

Table 14.4 listed the difference between Sordial 55 Plus and Dialog + by categories. The categories are figure of the haemodialysis machine , brand and model of the haemodialysis machine, manufacturer, size, and dimension of the equipment, weight of the machine in kilogram, the power supply in voltage, purchase price in Ringgit Malaysia, the years when the machine started to operate and active, the machine is still under warranty or not, hours has been operated, average of breakdown or corrective maintenance for each month, total number of breakdown, the cost of breakdown or corrective maintenance, total cost for breakdown and plan preventive maintenance activity, total of downtime, total number of plan preventive maintenance, total plan preventive maintenance by year, total plan preventive maintenance per years and common problems occur in corrective maintenance.

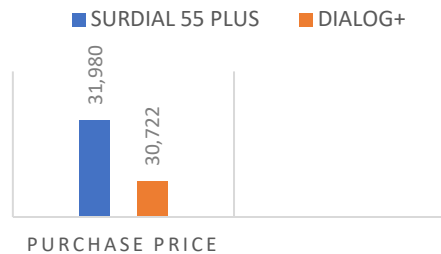
Table 14.5 shows the purchase price of Dialog + and Surdial 55 Plus.

**Table 14.5:** Purchase price between Dialog +and Surdial 55 Plus.

MODEL	PURCHASE PRICE
SURDIAL 55 PLUS	31,980
DIALOG+	30,722

Table 14.5 shows the purchase price of Dialog + RM 30,722 and Surdial 55 Plus 31,980.

Figure 14.13 is the purchase price for Surdial 55 Plus and Dialog +.



**Figure 14.13:** Graph of Purchase price between Surdial 55 Plus and Dialog +

The graph show that the price of Surdial 55 Plus is higher than Dialog +.

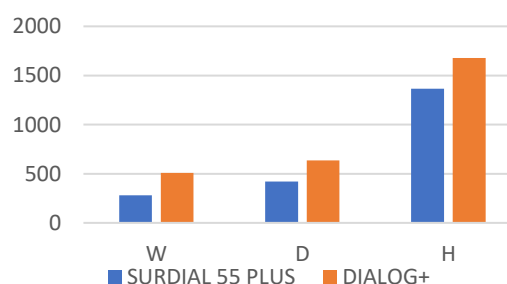
Table 14.6 illustrates the difference in size of the brand A and B in quantity of Width x Depth x High in unit (mm)

**Table 14.6:** The dimension between Surdial 55 Plus and Dialog+

MODEL	WIDTH	DEPTH	HIGH
SURDIAL 55 PLUS	280	420	1365
DIALOG+	510	637	1678

Table 14.6 shows the dimension of Surdial 55 plus width is 280 (mm) the depth 420mm and the high is 1365 mm. while Dialog + the width is 510, the depth is 637 and the high is 1678.

Figure 14.14 is the dimension between Surdial 55 Plus and Dialog +



**Figure 14.14:** Dimension between Surdial 55 Plus and Dialog +

Figure 14.14 shows that the dimension of Dialog is bigger than Surdial 55 Plus.

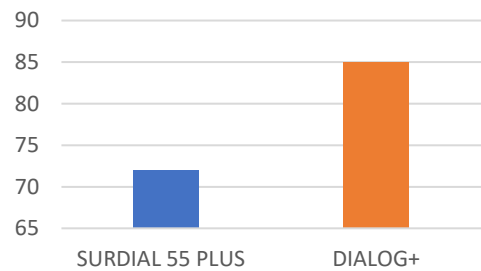
Table 14.7 the difference between weight of thee brand A and brand B

**Table 14.7:** Difference between weight of Surdial 55 Plus and Dialog +

MODEL	WEIGHT (KG)
SURDIAL 55 PLUS	72
DIALOG+	85

Table 14.7 shows the data of Surdial 55 Plus is 72 kg and Dialog + is 85 kg.

Figure 14.15 is the weight of Surdial 55 Plus and Dialog.



**Figure 14.15:** Graph 3 of weight between Surdial 55 Plus and Dialog +

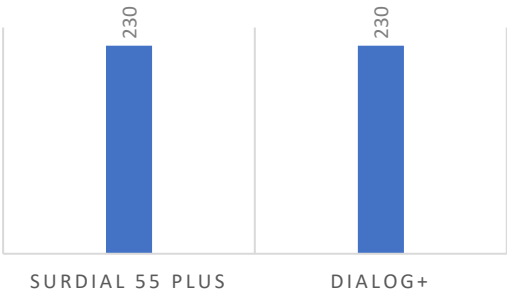
Figure 14.15 demonstrates that Surdial 55 Plus is lighter than Dialog +. The Table 14.8 show difference between power supply for brand A and B

**Table 14.8:** The value of power supply

MODEL	POWER SUPPLY (V)
SURDIAL 55 PLUS	230
DIALOG+	230

Table 14.8 shows the value of power supply for Surdial 55 Plus and Dialog + is 230V.

Figure 14.16 is power supply of Surdial 55 Plus and Dialog



**Figure 14.16:** The value of power supply

Figure 14.16 proves that Surdial 55 Plus and Dialog + have the same power supply.



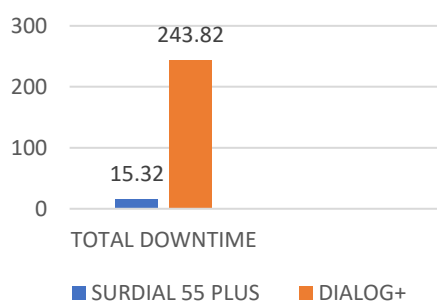
Table 14.9 shows the total downtime between two brands.

**Table 14.9:** Value of total downtime

MODEL	TOTAL DOWNTIME
SURDIAL 55 PLUS	15.32
DIALOG+	243.82

Table 14.9 shows the total downtime for Surdial55 Plus is 15.32 and Dialog + is 243.82.

Figure 14.17 is the total downtime of Surdial 55 Plus and Dialog



**Figure 14.17:** The total downtime

From the Figure 14.17 total downtime for Surdial 55 Plus is lower than Dialog +.

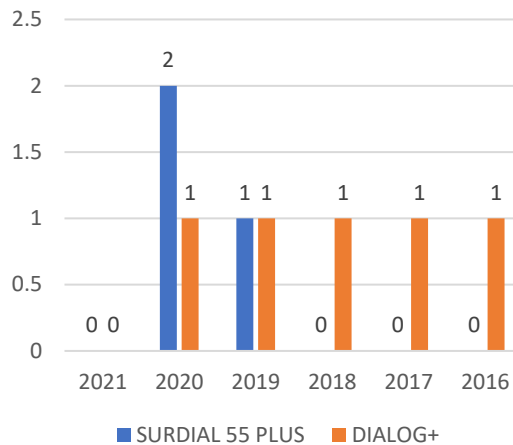
1. Table 14.10 shows rate of plan preventive maintenance

**Table 14.10:** The rate of plan preventive maintenance for Surdial 55 Plus and Dialog+

Year	SURDIAL 55 PLUS	DIALOG+
2021	0	0
2020	2	1
2019	1	1
2018	0	1
2017	0	1
2016	0	1

Table 14.10 show the rate of plan preventive maintenance for Surdial 55 Plus in 2019 until 2021 is 3 and Dialog+ in 2016 until 2021 is 5.

Figure 14.18 is the plan preventive maintenance activity for Surdial 55 Plus and Dialog



**Figure 14.18:** The rate of plan preventive maintenance activity within the two brands

Figure 14.18 show the rate of plan preventive maintenance between Surdial 55 Plus and Dialog +. The average of the rate between Surdial55 Plus and Dialog + is one every year from 2016 until 2021.

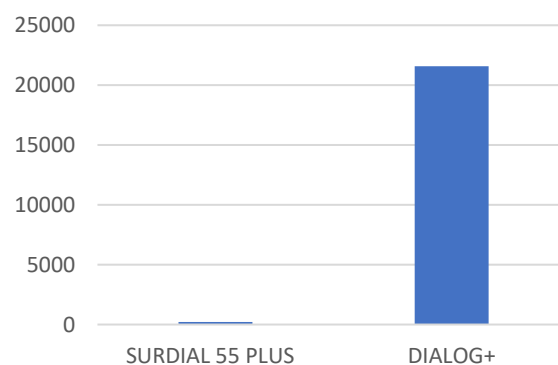
Table 14.111 show total hours used for haemodialysis machine of Surdial 55 Plus and Dialog

**Table 14.11:** Total hours of haemodialysis machine of Surdial 55 Plus and Dialog +.

MODEL	HOURS
NIPRO	218
DIALOG+	21574

Table 14.11 shows the Surdial 55 plus has 218 hours while Dialog has 21574.

Figure 14.9 is the total hours of Surdial 55 Plus and Dialog +.



**Figure 14.19:** The hours between Surdial 55 Plus and Dialog +

Figure 14.9 the total hours between Surdial 55 Plus are 218 which is lower than the Dialog Plus with 21574.

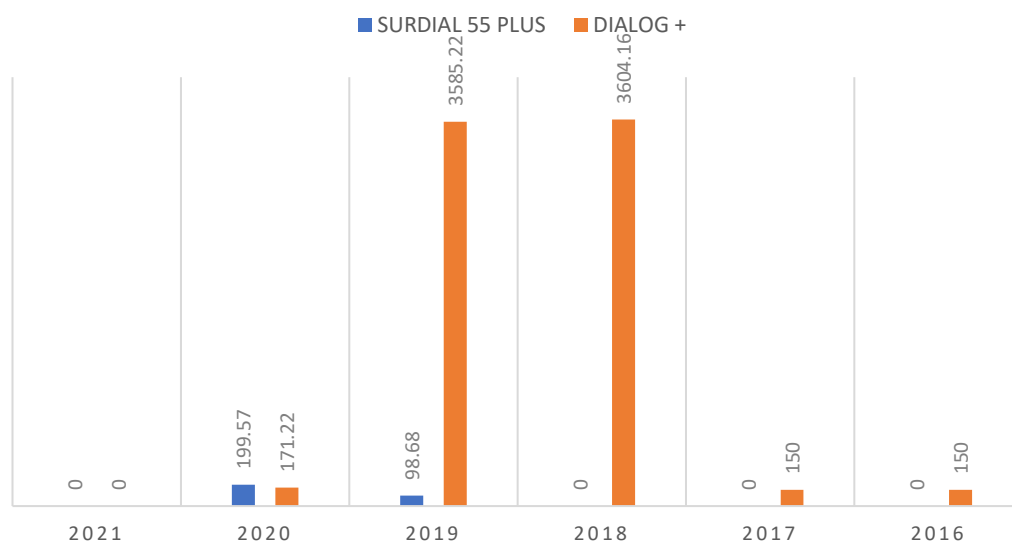
Table 14.12 show the cost of plan preventive maintenance by year.

**Table 14.12:** The cost of plan preventive maintenance by year for both Surdial 55 Plus and Dialog+

YEAR	SURDIAL 55 PLUS	DIALOG +
2021	0	0
2020	199.57	171.22
2019	98.68	3585.22
2018	0	3604.16
2017	0	150
2016	0	150

Table 14.12 shows the cost of plan preventive maintenance by year for both Surdial 55 Plus and Dialog+. Surdial 55 plus has 0 in 2021, 199.57 in 2020 and 98.68 in 2019. Dialog + has 150 in 2016 and 2017, it also has 3604.16 in 2018, 3585.22 in 2019, 171.22 in 2020 and 0 in 2021.

The Figure 14.20 is the total cost of plan preventive maintenance for Surdial 55 Plus and Dialog +



**Figure 14.20:** The total cost for plan preventive maintenance activity for both brand Surdial 55 Plus and Dialog+

From the Figure 14.20 by the year 2021 both of the brand has no plan preventive maintenance activity while in 2020 the plan preventive maintenance cost for Dialog+ is lower than Surdial 55 plus.

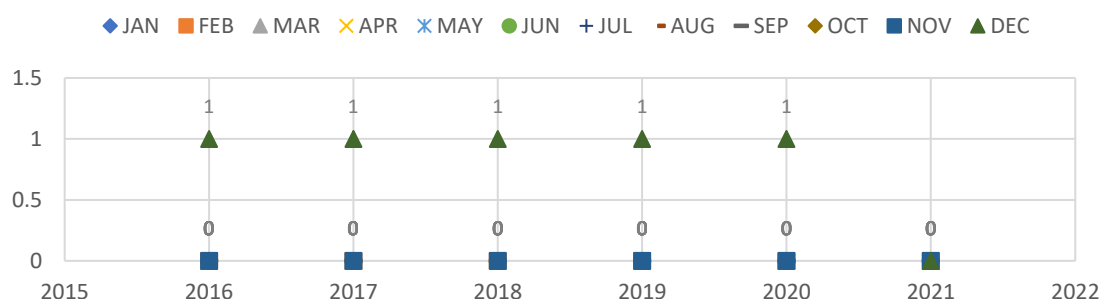
The Table 14.13below present the number of plan preventive maintenance activity per month for Dialog +

**Table 14.13:** The number of plan preventive maintenance activity per month of Dialog+

Year	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
2021	0	0	0	0	0	0	0	0	0	0	0	0
2020	0	0	0	0	0	0	0	0	0	0	0	1
2019	0	0	0	0	0	0	0	0	0	0	0	1
2018	0	0	0	0	0	0	0	0	0	0	0	1
2017	0	0	0	0	0	0	0	0	0	0	0	1
2016	0	0	0	0	0	0	0	0	0	0	0	1

Table 14.13 shows the number of plan preventive maintenance for Dialog + per month from January until November there is no plan preventive maintenance activity. Plan preventive maintenance activity has been done 1 month of December.

Figure 14.21 shows the plan preventive maintenance graph for Dialog + by month.



**Figure 14.21:** Plan preventive maintenance per month Dialog+ in a year

The plotted graph shows that plan preventive maintenance activity for Dialog+ has been done once a year and in the month of December.

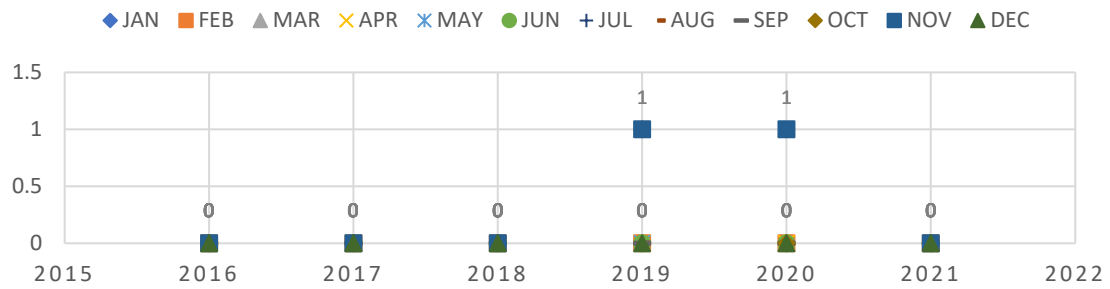
Table 14.14 presents the plan preventive maintenance per month for Surdial 55 Plus.

**Table 14.14:** Plan preventive maintenance by month from January to December in year 2016 until 2021

YEAR	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
2021	0	0	0	0	0	0	0	0	0	0	0	0
2020	0	0	0	0	1	0	0	0	0	0	1	0
2019	0	0	0	0	0	0	0	0	0	0	1	0
2018	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0
2016	0	0	0	0	0	0	0	0	0	0	0	0

Table 14.14 of plan preventive maintenance per month for Surdial 55 Plus. In May there is one plan preventive maintenance activity and in month of November there is one for both year 2019 and 2020.

Figure 14.22 shows the plan preventive maintenance for the Surdial 55 Plus.



**Figure 14.22:** Plotted the month of plan preventive maintenance activity for Surdial 55 Plus

From the above graph the plan preventive maintenance activity for Surdial 55 plus is one in 2019 and two times in year 2020.

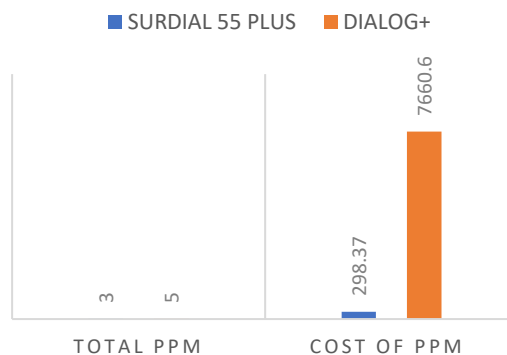
Table 14.15 shows the data of comparison of plan preventive maintenance between Surdial 55 Plus and Dialog +.

**Table 14.15:** Total PPM and cost for both brand

MODEL	SURDIAL 55 PLUS	DIALOG+
TOTAL PPM	3	5
COST OF PPM	298.37	7660.6

In the table the total number for plan preventive maintenance activity for Surdial 55 Plus is 3 and Dialog + is 5, while in the cost of plan preventive maintenance Surdial 55 Plus is 298.37 and Dialog + is 7660.60.

Figure 14.23 shows the comparison between total and cos of maintenance activity of Surdial 55 Plus and Dialog +.



**Figure 14.23:** The comparison of total PPM and cost of the two brands

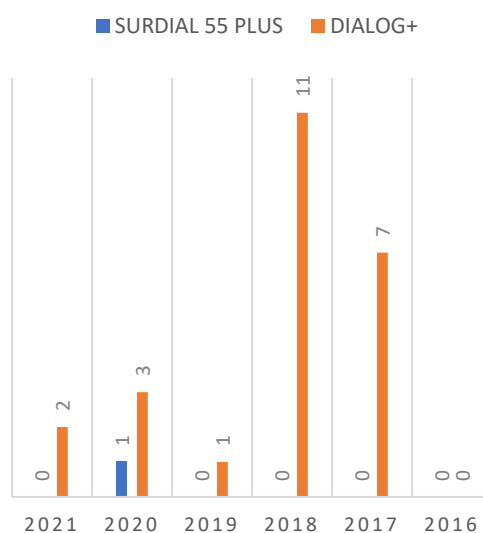
The graph shows that the dialog+ have the highest rate and cost of PPM

**Table 14.16** shows rate of corrective maintenance between Surdial 55 Plus and Dialog+

**Table 14.16:** Comparison between rate of corrective maintenance Surdial 55 Plus and Dialog+

MODEL	SURDIAL 55 PLUS	DIALOG+
TOTAL CORRECTIVE MAINTENANCE	1	24
COST OF CORRECTIVE MAINTENANCE	56.81	8,384.78

Figure 14.24 shows the graph of the comparison between rate of corrective maintenance Surdial 55 Plus and Dialog+



**Figure 14.24:** The comparison between the rates of corrective maintenance between both brands  
The graph shows the rate of corrective maintenance of Dialog + is higher than Surdial 55 Plus.

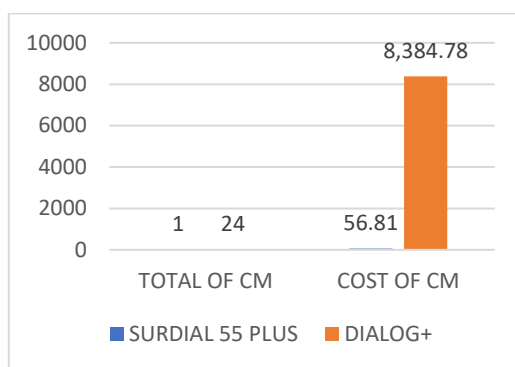
Table shows the cost of corrective maintenance between surdial 55 plus and dialog +

**Table 14.17:** The comparison by year for corrective maintenance on Dialog + and Surdial 55 plus

MODEL	SURDIAL 55 PLUS	DIALOG+
2021	0	2
2020	1	3
2019	0	1
2018	0	11
2017	0	7
2016	0	0

Table 14.17 shows the data of Surdial 55 Plus and Dialog +. Total of corrective maintenance for Surdial 55 Plus is 1 and Dialog + is 24. The total cost of corrective maintenance for Surdial 55 Plus is 56.81 and Dialog + is 8,384.78.

Figure 14.25 shows the total cost and rate of Surdial 55Plus and Dialog +.



**Figure 14.25:** The total cost and rate of Surdial 55Plus and Dialog

The figure shows that Dialog + has the highest in cost and rate of the corrective maintenance than Surdial 55 Plus.

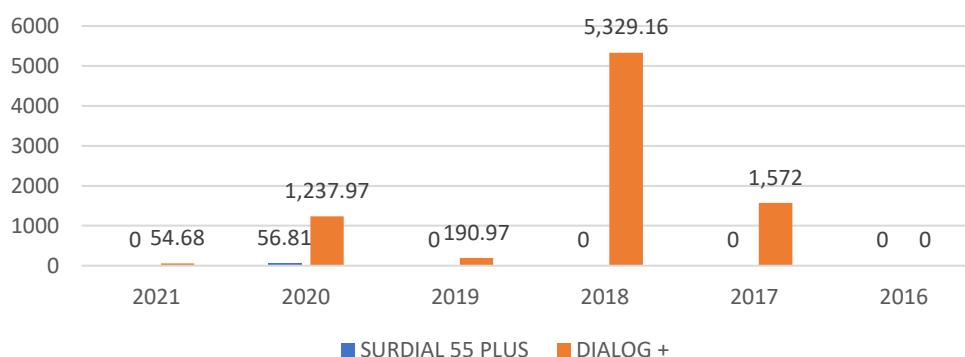
Table 14.18 shows the total cost of corrective maintenance for surdial 55 plus and dialog + per year

**Table 14.18:** The cost of corrective maintenance for Surdial 55 Plus and Dialog +

MODEL	SURDIAL 55 PLUS	DIALOG +
2021	0	54.68
2020	56.81	1,237.97
2019	0	190.97
2018	0	5,329.16
2017	0	1,572
2016	0	0

From the Table 14.18 it shows the data of cost for corrective maintenance for Surdial 55 plus and Dialog + by year from 2016 until 2021

Figure14.26 shows cost for Surdial 55 Plus and Dialog + from year 2016 and 2021.



**Figure 14.26:** Cost for Surdial 55 Plus and Dialog + from year 2016 and 2021

Based on the graph we can see that Dialog + has the highest cost of corrective maintenance than Surdial 55 plus



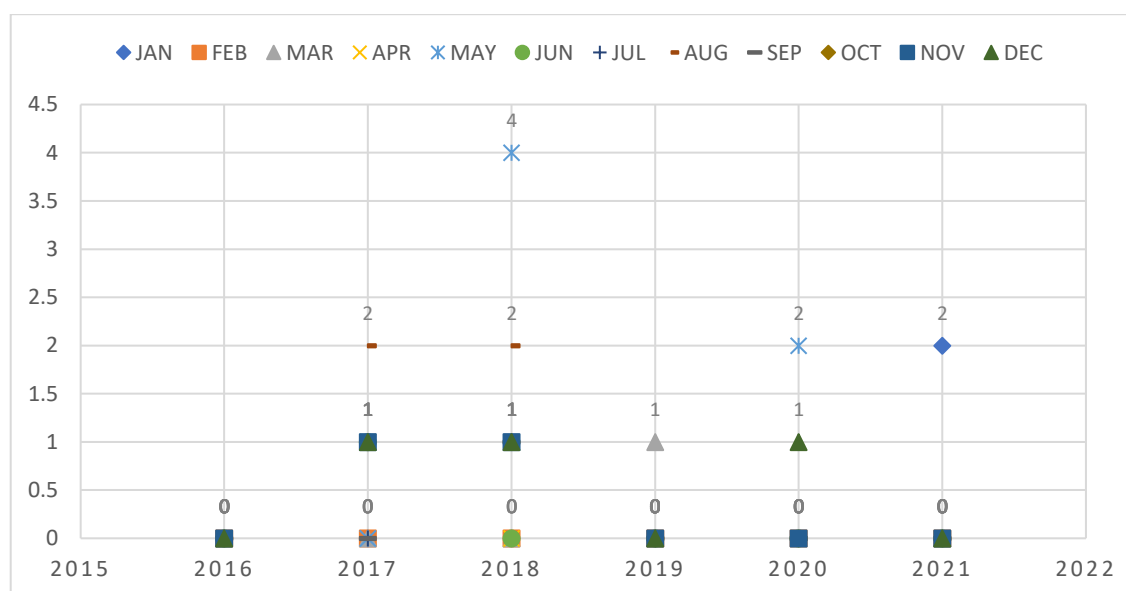
Table 14.19 below illustrates the corrective maintenance in every month for Dialog+.

**Table 14.19:** The value of corrective maintenance for dialog + in month

YEAR	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
2021	2	0	0	0	0	0	0	0	0	0	0	0
2020	0	0	0	0	2	0	0	0	0	0	0	1
2019	0	0	1	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	4	0	1	2	1	1	1	1
2017	0	0	0	1	0	1	0	2	0	1	1	1
2016	0	0	0	0	0	0	0	0	0	0	0	0

The Table 14.19 present the data of corrective maintenance in every month for the years of 2016 until 2021.

The figure 14.27 shows the plotted month of having corrective maintenance activity.



**Figure 14.27:** Corrective maintenance per month for Dialog+

From the Figure 28, the most plotted month is in December and the most plotted month in a year is 2018, this graph shows that Dialog+ has high corrective maintenance.

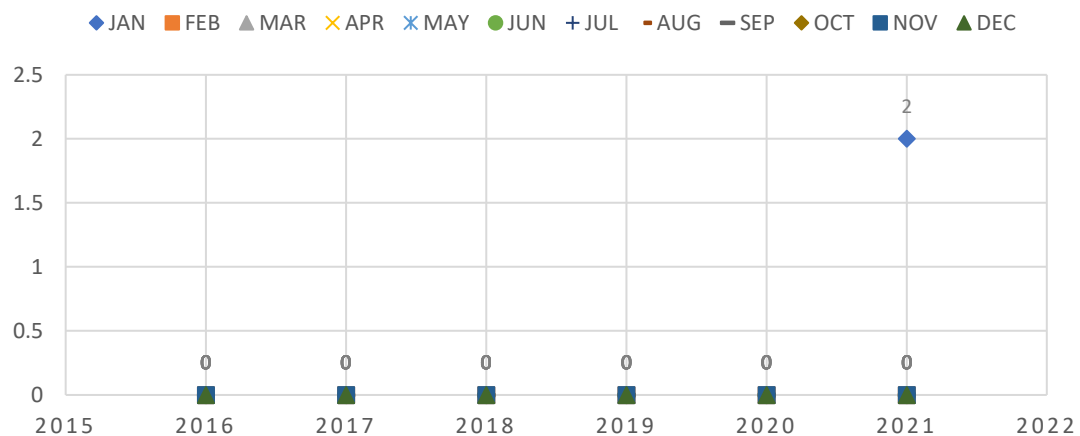
Table 14.20 show the corrective maintenance per month for Surdial 55 Plus.

**Table 14.20:** The rate of corrective maintenance for Surdial 55 Plus by month in a year.

YEAR	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
2021	2	0	0	0	0	0	0	0	0	0	0	0
2020	0	0	0	0	0	0	0	0	0	0	0	0
2019	0	0	0	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0
2016	0	0	0	0	0	0	0	0	0	0	0	0

The Table 14.20 shows the data of corrective maintenance for Surdial 55 Plus from January to December per year.

Figure 14.28 shows the plotted month for every year that has corrective maintenance for Surdial 55 Plus.



**Figure 14.28:** Corrective maintenance for every month in a year for Surdial 55 Plus

From the Figure 14.28 Nipro Surdial 55 plus has a minimum amount of corrective maintenance with only 2 times between the three years after purchasing.

From the data collected we can summarize the rate of plan preventive maintenance the rate of corrective maintenance and the rate of cost.

$$\text{Rate of investment} = \frac{(\text{purchase price} - \text{cost of PPM and CM})}{\text{Purchase price}} \times 100\%$$

**Table 14.21:** Rate of investment

Model	Purchase prize	Cost of PPM	Cost of CM	Rate of investment(ROI)
SURDIAL 55 PLUS	31,980	298.37	56.81	98.88%
DIALOG+	30,722	7660.6	8384.78	47.77%

From the data analysis that's been made the haemodialysis brand Surdial 55 Plus has the high rate of investment with 98.88 percent. It also has the low rate and of cost of the plan preventive maintenance and the low cost of corrective maintenance while Dialog + have higher rate of plan preventive maintenance and higher cost of the plan preventive maintenance. Furthermore, it also has the higher rate and cost of the corrective maintenance than Surdial. The lower the cost of plan preventive maintenance activity and corrective maintenance the higher the rate of investment.

## 5.0 Conclusion and Recommendation

In short, the different between Surdial 55 plus and Dialog + has been compared. The data of both brand of haemodialysis machine also has been analyse. It can be seen from the output graph and table that Surdial 55 plus has lower rate of maintenance activity which cause a lower output in the cost of corrective maintenance and plan preventive maintenance. Lastly the best brand to use in haemodialysis is recommended which is Surdial 55 Plus.

## References

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- [2] Dialog + Dialysis Machine, "Instruction for use SW 9.1x", B Braun Avitum AG , Melsungen, Germany, May 2016.
- [3] Service Manual Single Patient Dialysis Machine, Surdial, Nipro Corporation Version No.0R2135-1105 Honjo-Nishi, Kita-Ku, OSAKA, JAPAN.
- [4] EBME.co.uk Ltd. "An introduction to electrical safety testing in accordance with IEC 62353" Ludgate Hill, London 24, October, 2019[Online serial]. Available: <https://www.ebme.co.uk/articles/electrical-safety/classes-and-types-of-medical-electrical-equipment>
- [5] Azura Vascular Care, "The 4 Types of Dialysis Access", "Info Dialysis Access", "Dialysis Access", 27, June 2017[Online serial]. Available: <https://www.azuravascularcare.com/infodialysisaccess/types-of-dialysis-access/>

# APPENDICES

## Appendix A

Questionnaire that is distributed to the users of OT, HSI.

2/10/2021

Anaesthesia Machine (GA)


### Anaesthesia Machine (GA)

Assalamualaikum and hello to everyone. This survey form is created in the requirement of my technical assessment report and study to produce a result in comparing two different models of the anaesthesia machine (GA). Do answer the following questionnaire in the favor of your choice. Your time in participating in this survey is highly appreciated. Thank you very much.

Regards,  
Muhammad Syamli Arif Bin Amri  
WBL Student, Politeknik Sultan Salahuddin Abdul Aziz Shah

\* Required

Avance CS2 & Leon Plus



AVANCE CS2

LEON PLUS

1. This model is easy to use. \*

☐ Avance CS2

☐ Leon Plus

2. This model has the least problem. \*


☐ Avance CS2

☐ Leon Plus


3. Able to complete the task quickly by using this model. \*

☐ Avance CS2

☐ Leon Plus



[https://docs.google.com/forms/d/e/1FAIpQLScpitMMwkXedyKL\\_Gc1RSBgRouWJiRn62ynJV0tcXv3esNPw/viewform](https://docs.google.com/forms/d/e/1FAIpQLScpitMMwkXedyKL_Gc1RSBgRouWJiRn62ynJV0tcXv3esNPw/viewform)



1/2

4. This model displays the error message clearly. \*

- ☐ Avance CS2
- ☐ Leon Plus

5. The interface on this model is better. \*

- ☐ Avance CS2
- ☐ Leon Plus

6. The information (such as instructions, on-screen messages, and other documentation) provided with this system is clear. \*

- ☐ Avance CS2
- ☐ Leon Plus

7. The features of this model can help the patient to have a better procedure. \*

- ☐ Avance CS2
- ☐ Leon Plus

8. Overall, I prefer this model. \*

- ☐ Avance CS2
- ☐ Leon Plus

9. Share your opinion on the GA model of Avance CS2 and Leon Plus. You may write your answer in English or Bahasa.

Your answer

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Google Forms



## Appendix B

Asset maintenance history for Avance CS2.

Date	Type	Total Downtime	Total Cost (RM)	Action Taken
30-Nov-20	PPM	2.50	71.02	PPM done.
22-Jun-20	Corrective Maintenance	3.60	1042.61	Checked unit, found O <sub>2</sub> calibrate not passed. Test by tester, out of range. Change new O <sub>2</sub> sensor. Test unit ok. Ready to use.
1-Jun-20	PPM	2.50	71.02	PPM done.
27-Apr-20	Corrective Maintenance	0.80	1014.88	Checked unit, O <sub>2</sub> not accurate. Calibrate, not pass. Change new O <sub>2</sub> sensor. Test unit ok.
20-Apr-20	Corrective Maintenance	1.33	1029.76	Change new O <sub>2</sub> sensor. Do full test, ok. Functioning test ok. Ready to use.
23-Apr-20	Corrective Maintenance	0.62	4.76	Double request. Refer WO/BEMS/JHR002/2004/000123.
16-Dec-19	Corrective Maintenance	1.12	14.20	Calibrate CO <sub>2</sub> module, functioning test ok.
16-Nov-19	Corrective Maintenance	1.67	1032.89	Change new O <sub>2</sub> sensor. Do full calibration. Functioning test ok. Ready to use.
2-Dec-19	Corrective Maintenance	2.27	1028.40	Change new O <sub>2</sub> sensor. Performance leaking test, ok. Functioning test ok. Ready to use.
1-Dec-19	PPM	2.50	71.02	PPM done.
7-Jul-19	Corrective Maintenance	2526.30	486.48	Change new flow sensor. Self-test perform pass. Ready to use.
12-Oct-19	Corrective Maintenance	1.40	28.40	Check external. Check internal. Check tubing. Reconnect all loose part. Troubleshoot. Performance leak test, OK. Ready to use.
19-Sep-19	Corrective Maintenance	0.00	32.89	Check external. Performance self-test. Reconnect loose part. Performance self-test, pass. Ready to use.
2-Jun-19	PPM	3.00	100.16	PPM work done
3-Apr-19	Corrective Maintenance	0.00	144.17	Check and clean interior part. Verify interior part functioning. Reconnect all loose part. Perform leak test pass. Performance test done pass. Unit ready to use.
11-Mar-19	Corrective Maintenance	0.00	156.25	Check and clean, interior part. Verify interior part, functioning. Reconnect all loose part. Performance test done, pass. Unit ready to use.

23-Feb-19	Corrective Maintenance	0.00	175.17	Check and clean interior part. Verify interior part functioning. Reconnect all loose part. Perform leak test pass. Performance test done pass. Unit ready to use.
9-Dec-18	PPM	3.00	90.62	PPM work done.
27-Nov-18	Corrective Maintenance	0.00	626.20	Change new O <sub>2</sub> sensor. Calibrate O <sub>2</sub> 21% and 100%, pass. Unit ready to use.
10-Jun-18	PPM	3.00	100.16	PPM work done.
13-May-18	Corrective Maintenance	0.00	187.50	Perform oxygen calibration fail. Check & clean interior part. Verify interior part functioning. Perform full calibration. Calibration pass. Performance test done pass. Unit ready to use.
12-Dec-17	PPM	2.00	125.00	PPM work done.
4-Oct-17	Corrective Maintenance	0.00	85.25	Change new flow sensor. Calibrate flow sensor pass. Performance test done pass. Unit ready to use.
14-Jun-17	Corrective Maintenance	530.00	50.00	Change new flow sensor and O <sub>2</sub> sensor. Calibrate O <sub>2</sub> sensor, pass. Performance test done, pass. Unit ready to use.
12-Jun-17	PPM	3.00	150.00	PPM work done.
12-Mar-17	Corrective Maintenance	46.00	25.00	Change new flow sensor and oxygen sensor. Perform pre use test after air wall, inlet return to normal. Performance test done, pass. Unit ready to use.
15-Dec-16	PPM	3.00	150.00	PPM done as per checklist.
7-Oct-16	Corrective Maintenance	10.00	33.00	Canister leakage. Check and clean canister. Perform leak test, ok.
11-Jun-16	PPM	3.00	46.00	PPM done as per checklist.
3-Dec-15	PPM	3.00	46.00	PPM done for external only.
1-Jun-15	PPM	2.00	3.00	Machine under warranty.



## Appendix C

Asset maintenance history for Leon Plus Neo.

Date	Type	Total Downtime	Total Cost (RM)	Action Taken
27-Jul-20	Corrective Maintenance	1029.67	8850.00	Replace new O <sub>2</sub> and flow sensor. System test, pass. Ready to use.
16-Jun-20	Corrective Maintenance	0.50	4.54	Double request. Refer WO/BEMS/JHR002/2006/000082.
14-Jun-20	Corrective Maintenance	66.97	7042.61	Found system test intermittent pass. Change new flow sensor. Test unit ok.
18-Mar-20	PPM	3.00	85.22	PPM done.
7-Feb-20	Corrective Maintenance	1.38	32.89	Check exterior part. Check all connection tubing. Retighten all connection tubing. Perform system test pass. Test unit ok. Ready to use.
15-Sep-19	Corrective Maintenance	0.00	32.89	Change CO <sub>2</sub> sampling line. Perform self-test. Self-test, pass. Ready to use.
7-Jul-19	Corrective Maintenance	0.00	1944.17	Check and clean interior part. Verify interior part. Found oxygen sensor error. Change new oxygen sensor. Perform leak test pass. Performance test done pass. Unit ready to use.
26-Apr-19	Corrective Maintenance	0.00	6157.83	Clean interior part and found require PPM kit. Change new PPM kit. Perform pre-test pass. Perform performance test done pass. Unit ready to use.
16-Apr-19	Corrective Maintenance	0.00	168.17	Check and clean interior part. Verify interior part functioning. Found O-ring problem. Change new O-ring. Perform leak test pass. Performance test done pass. Unit ready to use.
20-Mar-19	PPM	3.00	95.15	PPM work done
28-Oct-18	Corrective Maintenance	24.77	114.48	Check and clean interior part. Verify interior part functioning. Reconnect all loose part. Retest done pass. Performance test done pass. Unit ready to use.
20-Aug-18	Corrective Maintenance	0.00	120.83	Check and clean interior port. Verify interior part functioning. Reconnect all loose part. Calibrate flow sensor pass. Performance test done pass. Unit ready to use.
1-Apr-18	Corrective Maintenance	0.00	86.50	Check and clean interior part. Verify interior part functioning. Reconnect loose part. Calibrate touch screen pass. Performance test done pass. Unit ready to use.
24-Mar-18	PPM	3.00	90.62	PPM work done.

27-Feb-18	Corrective Maintenance	0.00	82.23	Checked & clean interior part. Verified interior part functioning. Reconnect loose part. Perform leak test passed. Test performance passed. Unit ready to use.
22-Feb-18	Corrective Maintenance	0.00	26619.89	Check interior touch screen and found connection problem. Require changing new front panel. Change new front panel. Verify functioning. Calibrate touch screen. Verify functioning. Calibrate touch screen pass. Performance test done pass. Unit ready to use.
12-Feb-18	Corrective Maintenance	168.75	100.16	Check and clean interior part. Reconnect all loose part. Verify interior part. Perform touch screen calibration pass. Unit ready to use.
23-Jan-18	Corrective Maintenance	0.00	95.61	Check and clean interior part. Found need to change oxygen sensor. Change new oxygen sensor. Performance test done pass. Calibrate oxygen sensor pass. Unit ready to use.
11-Jan-18	Corrective Maintenance	0.00	2086.50	Change new oxygen sensor. Perform oxygen sensor calibration pass. Perform leak test fail. Performance test done, fail. Clean and verify part exterior. Perform leak test pass. Performance test done. Unit ready to use.
20-Dec-17	Corrective Maintenance	0.00	0.00	check & clean interior screen panel. verify functioning cable. verify functioning board. reconnect all lose cable. perform touch screen calibration, pass. performance test passed. unit ready to use.
21-Nov-17	Corrective Maintenance	0.00	86.50	Change new canister soda lime. Perform leak test pass. Performance test done pass. Verify setting pass. Unit ready to use.
20-Nov-17	Corrective Maintenance	0.00	86.50	Check and clean interior part. Verify interior part functioning. Perform leak test pass. Calibrate flow sensor and oxygen sensor pass. Performance test done, pass. Unit ready to use.
4-Nov-17	Corrective Maintenance	0.00	86.50	Check and clean interior part (patient & module screen). Verify interior part (patient module & screen). Retighten interior part (patient module & screen). Perform leak test and calibrate touch screen pass. Performance test done, pass. Unit ready to use.
25-Oct-17	Corrective Maintenance	0.00	82.74	Check and clean breathing unit. Verify breathing unit. Perform leak test pass. Performance test done, pass. Unit ready to use.
5-Sep-17	PPM	3.00	150.00	PPM work done.

18-May-17	Corrective Maintenance	73.00	150.00	On unit and perform pre use test, fail. Clean screen and perform screen calibration, fail. Clean interior and check connection. Perform screen calibration several times, pass. Performance test done, pass. Unit ready to use.
22-Mar-17	PPM	1.00	50.00	Unit in use.
13-Mar-17	Corrective Maintenance	25.00	4010.00	On unit and run self-test, fail. Error high pressure appear due to high air wall inlet. Found breathing area error. Change new PPM kits. Run self-test, pass. Performance test done, pass. Unit ready to use.
9-Mar-17	Corrective Maintenance	98.00	150.00	Clean exterior and interior part. Change new assembly controller board. Perform pre use test, pass. Performance test done, pass. Unit ready to use.
6-Sep-16	PPM	3.00	150.00	PPM done as per checklist.
8-Aug-16	Corrective Maintenance	37.00	50.00	Check breathing plate. Open machine. Repair 110 assy PCB connection. Check DC converter module. Check all wiring connection. Run calibration, passed. Run machine. Unit functioning.
11-Aug-16	Corrective Maintenance	75.00	75.00	Check unit, oxygen error. Try to calibrate, error. Change oxygen sensor. Unit tested, ok. Unit ready to use.
21-Mar-16	PPM	3.00	46.00	PPM done as per checklist.
7-Sep-15	PPM	2.00	31.00	PPM done for external only.

## Appendix D



	Strongly Agree				Strongly Disagree			
	1	2	3	4	5	6	7	N.A.
10. It was easy to find the information I needed.								
11. The information was effective in helping me complete the tasks and scenarios.								
12. The organization of information on the system screens was clear.								
13. The interface of this system was pleasant.								
14. I liked using the interface of this system.								
15. This system has all the functions and capabilities I expect it to have.								
16. Overall, I am satisfied with this system.								

Questions 1 to 16: Overall

Questions 1 to 6: System Usefulness (SYSUSE)

Questions 7 to 12: Information Quality (INFOQUAL)

Questions 13 to 16: Interface Quality (INTERQUAL)

Source: uiuxtrend.com

## Appendix E

Table below show the list of maintenance for ultrasound machine GE VENOUS 40 for year 2011 until 2020.

Maintenance Work No.	Service Work Date / Target Date.	Work Category	Type	Total Downtime	Total Cost (RM)	Action Taken
SWO/BEMS/JHR002/2102/000105	17-Feb-2021 00:00	Scheduled	PPM	2.00	161.18	PPM done as per checklist.
SWO/BEMS/JHR002/2008/000096	19-Aug-2020 00:00	Scheduled	PPM	2.00	65.78	PPM done as per checklist.
SWO/BEMS/JHR002/2002/000108	19-Feb-2020 00:00	Scheduled	PPM	2.00	153.12	PPM done as per checklist.
SWO/BEMS/JHR002/1908/000116	21-Aug-2019 00:00	Scheduled	PPM	2.00	90.62	Performed PPM as per checklist.
WO/BEMS/JHR002/1802/000079	12-Feb-2018 00:00	Unscheduled	Corrective Maintenance	0.00	49.34	Checked & found password error. Check system & log in password ok. Handed over the machine in proper working condition.
SWO/BEMS/JHR002/1902/000115	20-Feb-2019 00:00	Scheduled	PPM	2.00	69.44	PPM done as per checklist.
SWO/BEMS/JHR002/1808/000141	28-Aug-2018 00:00	Scheduled	PPM	2.00	145.83	PPM done as per checklist.
SWO/BEMS/JHR002/1802/000271	27-Feb-2018 00:00	Scheduled	PPM	2.00	95.39	PPM done as per checklist.
WO/BEMS/JHR002/1710/000114	14-Oct-2017 00:00	Unscheduled	Corrective Maintenance	0.00	110.32	Check and found option key missing. Put option key, test OK. Handed over the machine in proper working condition.
WO/BEMS/JHR002/1710/000122	15-Oct-2017 00:00	Unscheduled	Corrective Maintenance	286.08	124.11	Check and found probe not detect. Reconfigure the setting and option key. Test all, ok. Handed over the machine in proper working condition.
SM/HSI/02253/2017	28-Aug-2017 00:00	Scheduled	PPM	1.00	75.00	PPM done as per checklist
SM/HSI/00299/2017	02-Mar-2017 00:00	Scheduled	PPM	2.00	41.00	ppm done as per checklist
SM/HSI/04702/2016	04-Sep-2016 00:00	Scheduled	PPM	1.00	50.00	PPM done as per check list
SM/HSI/02791/2016	03-Mar-2016 00:00	Scheduled	PPM	2.00	100.00	PPM done. Machine OK.
SM/HSI/01247/2015	26-Aug-2015 00:00	Scheduled	PPM	2.00	100.00	PPM done as per check list

HSI/A4/B00701/16	12-Apr-2016 00:00	Unscheduled	Corrective Maintenance	144.00	100.00	Check the system. Found Option Key was delete by user. Request new Option Key from vendor. Key in the key and tested all, OK. Handed over the machine in proper working condition.
HSI/A4/B02645/16	14-Dec-2016 00:00	Unscheduled	Corrective Maintenance	3.00	300.00	Call vendor to get the licence key. Try insert the licence, test OK. Option key: BS9SP-L4HNZ-ZYMWS-N2X55-BFKGW
HSI/A4/B02656/16	15-Dec-2016 00:00	Unscheduled	Corrective Maintenance	622.00	100.00	Check port pin. Found pin not align and bend. Perform alignment pin and fine tune at service mode. Tested all probe, OK. Handed over the machine in proper working condition.
HSI/A4/B00006/15	01-Apr-2015 00:00	Unscheduled	Corrective Maintenance	217.00	75.00	Replace with new probe (12L-SC probe). Machine tested and handed over in normal working condition.
HSI/RQ/A4/B96288/15	22-Mar-2015 00:00	Unscheduled	Corrective Maintenance	1.50		
HSI/PPB/HSI/76420/2012	01-Oct-2012 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/78356/2013	25-Feb-2013 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/81242/2013	26-Aug-2013 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/83447/2014	24-Feb-2014 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/86212/2014	25-Aug-2014 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/88946/2015	23-Feb-2015 00:00	Scheduled	PPM	1.50		PPM done as per checklist

## Appendix F

Table below show the list of maintenance for ultrasound TOSHIBA XARIO XG SSA-680 for year 2009 until 2020

Maintenance Work No.	Service Work Date / Target Date.	Work Category	Type	Total Downtime	Total Cost (RM)	Action Taken
SWO/BEMS/JHR002/2012/000170	30-Dec-2020 00:00	Scheduled	PPM	2.00	139.20	PPM done as per checklist.
SWO/BEMS/JHR002/2001/000006	01-Jan-2020 00:00	Scheduled	PPM	2.00	145.83	PPM done as per checklist. Asset under RW. Refer to ADS/BEMS/JHR002/2019/10/000006.
WO/BEMS/JHR002/1904/000177	25-Apr-2019 00:00	Unscheduled	Corrective Maintenance	0.00	75.50	Under RW. Refer to ADS/BEMS/JHR002/2019/05/000005.
SWO/BEMS/JHR002/1901/000007	02-Jan-2019 00:00	Scheduled	PPM	2.00	139.20	PPM done as per checklist.
WO/BEMS/JHR002/1805/000045	08-May-2018 00:00	Unscheduled	Corrective Maintenance	0.00	62.50	Check & found image not clear. Adjust brightness & frequency setting. Test machine ok. User verified, ok. Handed over the machine in proper working condition.
SWO/BEMS/JHR002/1801/000008	06-Jan-2018 00:00	Scheduled	PPM	2.00	0.00	PPM done as per checklist.
SM/HSI/02017/2017	06-Jul-2017 00:00	Scheduled	PPM	2.00	100.00	PPM done as per checklists
SM/HSI/00011/2017	08-Jan-2017 00:00	Scheduled	PPM	1.00	75.00	PPM done as per checklist
SM/HSI/04464/2016	10-Jul-2016 00:00	Scheduled	PPM	4.00	100.00	Department closed due to replacement public holiday.
SM/HSI/02428/2016	06-Jan-2016 00:00	Scheduled	PPM	2.00	100.00	PPM done as per checklist
SM/HSI/00963/2015	02-Jul-2015 00:00	Scheduled	PPM	2.00	39.00	PPM done as per checklist. Ultrasound is in good condition.
HSI/A4/B00752/16	19-Apr-2016 00:00	Unscheduled	Corrective Maintenance	3.00	100.00	Check the image. Found the STC not set properly. Set STC and verify the image with user. Handed over the machine in proper working condition.



HSI/A4/B01035/16	25-May-2016 00:00	Unscheduled	Corrective Maintenance	1.00	25.00	Check with user. Explain how to use setting for clear image. Machine in good working condition. Handed over the machine in proper working condition.
HSI/A4/B02486/16	22-Nov-2016 00:00	Unscheduled	Corrective Maintenance	1.00	40050.00	Check convex probe image. Have artifact. Replace the probe. Handed over the machine in proper working condition.
HSI/A4/B02651/16	15-Dec-2016 00:00	Unscheduled	Corrective Maintenance	1.00	50.00	checked and found machine cannot register new patient. Resetting and tested unit functioning. Unit returns to service.
HSI/A4/B00634/15	14-Jun-2015 00:00	Unscheduled	Corrective Maintenance	2.00	100.00	Visited and deleted all the old image and reboot the system. Machine tested and handed over in proper working condition.
HSI/RQ/A4/B8080 9/12	28-Mar-2012 00:00	Unscheduled	Corrective Maintenance	0.00	4.00	Replaced The Cartridge by New One
HSI/RQ/A4/B8255 2/12	27-Jul-2012 00:00	Unscheduled	Corrective Maintenance	0.00	100.00	Repair The Button and Tested Ok. Hand Over the Machine in Proper Working Condition.
HSI/RQ/A4/B8709 6/13	02-May-2013 00:00	Unscheduled	Corrective Maintenance	0.00	50.00	Touch Screen Keypad Not Function Normally
HSI/RQ/A4/B8813 7/13	20-Aug-2013 00:00	Unscheduled	Corrective Maintenance	0.00	125.00	Open The Touch Screen Panel Slide By Slide. Check The Connection. Spray The Connection With Contact Cleaner And Clean The Pin. Put Back The Connection. Tested All, Ok. Observe, Ok. Machine In Good Working Condition.

HSI/RQ/A4/B883 63/13	06-Sep-2013 00:00	Unscheduled	Corrective Maintenance	0.00	100.00	Found The Touch Panel Display Intermittent Problem - Miss Alignment.Perform Tcs Calibration,All Pass But Still Occur.Suspect Tcs Panel Faulty
HSI/RQ/A4/B883 64/13	06-Sep-2013 00:00	Unscheduled	Corrective Maintenance	0.00	100.00	Check The Patient Data. Many Que. Clear All Data. Keep Observe.
HSI/RQ/A4/B884 11/13	12-Sep-2013 00:00	Unscheduled	Corrective Maintenance	0.00	100.00	Send The Printer To Hp Center. Printer Obsolete And No More Support To Repair. Recommend To Buy New Version System.
HSI/RQ/A4/B887 14/13	08-Oct-2013 00:00	Unscheduled	Corrective Maintenance	0.00	62.00	Check The System.No Patient List In Work List And No Image.Reboot The System. Check The Patient List, View Patient Image, Ok. Handed Over the Machine In Proper Working Condition.
HSI/RQ/A4/B887 85/13	16-Oct-2013 00:00	Unscheduled	Corrective Maintenance	0.00	50.00	Check The Job Status. Many Data In Job Status.Deleted All Data.Restart The System.Try To Send All Patient Images To Pacs, Successfully.User Test, Ok. Handed Over the Machine in Proper Working Condition.
HSI/RQ/A4/B891 07/13	19-Nov-2013 00:00	Unscheduled	Corrective Maintenance	0.00	50.00	Problem Found in That.Dust Inside the Track Ball And Clean The Same. Machine Tested and Handed Over in Proper Working Condition.

HSI/RQ/A4/B892 27/13	28-Nov-2013 00:00	Unscheduled	Corrective Maintenance	0.00	50.00	Check The System.All Ok.Ask It Department To Check The Network.Tested All,Ok.Machine In Good Working Condition.
HSI/RQ/A4/B926 20/14	14-Jul-2014 00:00	Unscheduled	Corrective Maintenance	0.00	50.00	Abex Engineer Check, All Ok. Ask User (Doctor) To Check And Test, Ok. Machine In Good Working Condition.
HSI/RQ/A5/B945 19/14	18-Dec-2014 00:00	Unscheduled	Corrective Maintenance	0.00	7.00	Do Performance Test for Ultrasound Transducer, Passed. Check Physical Condition, No Defected. Check All Keypad, Passed. Unit Is In Good Condition.
HSI/PPB/HSI/634 76/2010	04-Jan-2010 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/655 81/2010	05-Jul-2010 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/680 20/2011	03-Jan-2011 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/709 29/2011	04-Jul-2011 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/729 55/2012	02-Jan-2012 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/757 82/2012	02-Jul-2012 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/778 17/2013	31-Dec-2012 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/808 02/2013	01-Jul-2013 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/829 36/2014	30-Dec-2013 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/857 72/2014	30-Jun-2014 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/PPB/HSI/884 40/2015	29-Dec-2014 00:00	Scheduled	PPM	1.50		PPM done as per checklist
HSI/RQ/A4/B668 16/09	01-Dec-2009 00:00	Unscheduled	Corrective Maintenance	1.00	7.00	System Tested And Handed Over In Proper Working Condition

HSI/RQ/A4/B746 17/11	07-Jan-2011 00:00	Unscheduled	Corrective Maintenance	66.00	50.00	System Tested Ok Machine Handed Over In Proper Working G Condition
HSI/RQ/A4/B752 63/11	10-Mar-2011 00:00	Unscheduled	Corrective Maintenance	1466.00	50.00	Problem Found In That Ink Cartridges Not In Original Supplier Recommend To Buy From Manufacturer
HSI/RQ/A4/B825 83/12	01-Aug-2012 00:00	Unscheduled	Corrective Maintenance	26.00	100.00	Repair The Key Pad And Tested Ok. Machine Handed Over In Proper Working Condition.
HSI/RQ/A4/B882 97/13	29-Aug-2013 00:00	Unscheduled	Corrective Maintenance	29.00	50.00	Problem Found In That, Dicom Error To Many Que In Network. Clear All Que And Tested Ok. Machine Handed Over In Proper Working Condition.
HSI/RQ/A4/B884 84/13	22-Sep-2013 00:00	Unscheduled	Corrective Maintenance	29.00	50.00	Check The Query Of Status Job. Found Many Data Que On Status Job. Delete All Data. Test Send New Image To Pacs, Done And Complete. Handed Over the Machine In Properly Working Condition.
HSI/RQ/A4/B887 68/13	14-Oct-2013 00:00	Unscheduled	Corrective Maintenance	38.00	50.00	Check the System.Open Worklist and Try to Send Image 7to Pact, Ok Successful. Machine in Good Working Condition.
HSI/RQ/A4/B887 98/13	18-Oct-2013 00:00	Unscheduled	Corrective Maintenance	120.00	50.00	Perform Touch Screen Calibration. Select Auto Calibration. Calibration Successfully. Test Machine and Observe, Ok. Handed Over the Machine In Proper Working Condition.

HSI/RQ/A4/B888 83/13	29-Oct-2013 00:00	Unscheduled	Corrective Maintenance	120.00	50.00	Check The Que List. Clear All List Done Transfer. Test Sent To Pacs, Successfully. Handed Over The Machine In Proper Working Condition.
HSI/RQ/A4/B888 94/13	29-Oct-2013 00:00	Unscheduled	Corrective Maintenance	2017.00	100.00	Problem Found In That Touch Panel Calibration Fail Need To Replace New One
HSI/RQ/A4/B889 29/13	31-Oct-2013 00:00	Unscheduled	Corrective Maintenance	285.00	50.00	Same Request With W.Order Rq/A4/B88894/13 - 29/10/13
HSI/RQ/A4/B890 60/13	14-Nov-2013 00:00	Unscheduled	Corrective Maintenance	168.00	100.00	Delete All Job Status Completed, Fail And Stoppable.Restart The System. Send The Image To Pacs, Successfully.Mach ine In Good Working Condition.
HSI/RQ/A4/B910 48/14	16-Feb-2014 00:00	Unscheduled	Corrective Maintenance	2645.00	100.00	Problem Found In That Tcs Panel Hang Intermittently Reset The Pcb And Cables Tested Ok Machine Kept Under Observation.
HSI/RQ/A4/B910 67/14	12-Feb-2014 00:00	Unscheduled	Corrective Maintenance	1.00	50.00	Printer Obsolete And No More Support To Repair.Recommen d To Buy New Version System.
HSI/RQ/A4/B911 41/14	25-Feb-2014 00:00	Unscheduled	Corrective Maintenance	5.00	250.00	Check The System.Cannot Send Image.Check The Network,Fail.It Problem.Machine Ok.After Network It Stable And Ok,Image Can Send Successfully.
HSI/RQ/A4/B916 45/14	10-Apr-2014 00:00	Unscheduled	Corrective Maintenance	1.00	50.00	Found Probe Rubber Sleeve Cut Put Tape Properly And Tested Ok .Machine Handed Over In Proper Working Condition

## GLOSSARY

Terminology	Justification of Application	Page
Anaemia	A condition in which you lack enough healthy red blood cells to carry adequate oxygen to your body's tissues	8-2
Anaesthesia Machine	It is a medical device used to generate and mix a fresh gas flow of medical gases and inhalational anaesthetic agents for the purpose of inducing and maintaining anaesthesia.	4-1 4-3 4-11
Anaesthesia Pneumatic System	A system in anaesthesia machine that responsible in managing the pressure of gases before be delivered to the patient	4-3 4-6 4-8
Arterial Blood Gas (ABG)	ABG is to measures the amount of oxygen(O <sub>2</sub> ), carbon dioxide (CO <sub>2</sub> ), acidity (pH) in the blood	12-2 12-4 12-5
Blood Warmer	A medical device used to preheat blood intravenously or by other injection methods to body temperature levels to prevent hypothermia in traumatized or surgically injured patients.	8-1 8-2
Boyle's Machine	Early model of anaesthesia delivering device which is designed to provide an accurate supply of medical gases mixed with an accurate concentration of anaesthetic vapour, and to deliver this continuously to the patient at a safe pressure and flow.	6-2 6-4 6-5
Breathing Circuit	Is a connection in circuit between the patient and anaesthesia machine to deliver a mixture of gases?	4-10
Cardiotocography (CTG)	It is an equipment used both before birth (antenatally) and during labour to monitor the baby for any signs of distress.	6-2 6-4 6-5
Centrifuge	A centrifuge is a laboratory device that is used for the separation of fluids, gas or liquid, based on density.	10-1 10-2
Defibrillator	A defibrillator is a machine that used to shock the victim's heart and restore the heart's normal rhythmic patterns	1-1 1-2
Extended Self-Test (EST)	EST is a user-initiated self-test, intended to be run by the service technician, that verify the integrity of the ventilator's subsystems using operator participation. EST will check the pneumatics, power supply, safety system, memory, front panels controls, indicator and digital and analog electronics.	3-9
Fetal Heart Rate	Fetal heart rate monitoring measures the heart rate and rhythm of your baby (fetus)	5-1 5-2
Haemolysis	The rupturing of red blood cells and the release of their contents into surrounding fluid.	8-2
Holter Monitor	Holter monitoring is a continuous test to record your heart's rate and rhythm for 24 hours and also sometimes called ambulatory electrocardiography	2-1 2-4 2-5

## GLOSSARY

Terminology	Justification of Application	Page
Extended Self-Test (EST)	EST is a user-initiated self-test, intended to be run by the service technician, that verify the integrity of the ventilator's subsystems using operator participation. EST will check the pneumatics, power supply, safety system, memory, front panels controls, indicator and digital and analog electronics.	3-9
Fetal Heart Rate	Fetal heart rate monitoring measures the heart rate and rhythm of your baby (fetus)	5-1 5-2
Haemolysis	The rupturing of red blood cells and the release of their contents into surrounding fluid.	8-2
Holter Monitor	Holter monitoring is a continuous test to record your heart's rate and rhythm for 24 hours and also sometimes called ambulatory electrocardiography	2-1 2-4 2-5
Hyperthermia	An abnormally high body temperature caused by a failure of the heat-regulating mechanisms of the body to deal with the heat coming from the environment.	8-1
Hypothermia	A condition in which the core temperature falls below the temperature required for normal metabolism and body functions.	8-1
Intravenous	A medical technique that delivers fluids, medications and nutrition directly into a person's vein	8-1
Leukaemia	A group of blood cancers that usually begin in the bone marrow and result in high numbers of abnormal blood cells.	8-2
NIBP vital sign monitor	Vital sign monitor applications span areas from long term monitoring of health in hospitals. These monitors are invaluable aids that give health care providers immediate reading regarding a patient status.	11-1
Ophthalmologist	A specialist in the branch of medicine concerned with the study and treatment of disorders and disease of the eye.	5-3
Rotor	A centrifuge rotor is the rotating unit of the centrifuge, which has fixed holes drilled at an angle.	10-1 10-2 10-3
Short-Self Test (SST)	The SST is a short and simple sequence of test for ventilator that verifies proper operation breath delivery hardware, check the patient circuit for leaks and measures the circuit compliance and resistance. Done by the user.	3-3 3-9
Slit lamp	An equipment that diagnoses the disease of eye without doing any surgery. It can show the structure in front of the eye and in the eye clearly.	5-3 5-6 5-7
Transducer	A transducer is a device that converts energy from one form to another. Usually, a transducer converts a signal in one form of energy to a signal in another.	6-1 6-2 6-7
Ultrasound Machine	A medical imaging device that used high- frequency sound waves to produce pictures of the inside of the body.	13-1
Ventilator	Ventilator is the machine that supports breathing which gets oxygen into the lungs and removes carbon dioxide from the body.	3-1 3-2



# Special Appreciation

We extend our special appreciation to all individuals who have played a pivotal role in the Work-Based Learning (WBL) activities for our students. Their dedication and support have been invaluable throughout this journey.

## JOHOR

### **Hospital Sultanah Aminah, Johore**

Mohd Akmal Bin Abu Yasmin  
Zulpakaruddin Bin Othman

### **Hospital Sultan Ismail**

Siti Hafidzah Binti Selamat  
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### **Hospital Pakar Sultanah Fatimah**

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### **Hospital Hajjah Besar Enche Kalsom**

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### **Hospital Segamat**

Abdul Hadi Bin Muhamad Nasri

### **Hospital Mersing**

Nor Zakila Bin Yusoff

### **Hospital Temenggong Seri Maharaja Tun Ibrahim**

Ramlah Binti Mazlan

## MELAKA

### **Hospital Melaka**

Nurhamizah Binti Hamdan  
Mohammad Rafiq Bin Omar

## NEGERI SEMBILAN

### **Hospital Tunku Jaafar**

Mohd Arif Bin Abu Bakar  
Nurfarhana Binti Burhanuddin

List of lecturers on behalf of the BEU programme in the institution;

### **Head of Electrical Engineering Department:**

Ts. Norazlina Binti Jaafar  
Hanizah binti Anaitullah (former)

### **Head of Programme:**

Nurul Maisarah binti Kamaruddin  
Nurul Huda binti Mohamd Saleh (former)

### **WBL Coordinator:**

Suryani binti Ilias

### **Course Coordinator:**

Dr. Sabariah binti Bohanudin

### **Lecturers (WBL observation):**

Ku Lee Chin  
Yaakub bin Omar  
Dr. Wan Rosemehah binti Wan Omar  
Zarina binti Che Amin

# TECHNICAL ASESMENT REPORTS

## Medical Device, Equipment & Machine

### *Work-Based Learning (WBL) Experiences in Malaysian Polytechnic*



**Dr. Sabariah binti Bohanudin** is a distinguished Principal Lecturer in the Department of Electrical Engineering at Politeknik Sultan Salahuddin Abdul Aziz Shah, where she has been serving since 2007. Her extensive academic journey and contributions to the institution are remarkable. Her dedication to education led her to become involved with the Advance Diploma in Electronic Engineering (Medical Electronic), known as AEU, in 2009. Later, in 2014, she took on a significant role in the Bachelor of Electronic Engineering Technology (Medical Electronic) with Honours, the BEU program. Her educational background is impressive. She earned her first degree in Electrical, Electronic, and System Engineering from Universiti Kebangsaan Malaysia in 1989. Subsequently, she furthered her academic pursuits and achieved a master's degree in Computer and Communication Engineering from the same institution in 2007. Her commitment to research and knowledge development culminated in the completion of her Ph.D. in Wireless Communication Engineering, specializing in Localization, in 2020. She brings a wealth of knowledge and expertise to the classroom, where she imparts her wisdom to BEU students. She has had a pivotal role in teaching various

electronic engineering courses, contributing significantly to the students' academic growth. Furthermore, her dedication extends to her role as the course coordinator for Electromagnetic Field Theory, Power Electronics, and Technical Assessment Report (TAR), a crucial component of the Work-Based Learning (WBL) program. Through her leadership, these courses have flourished, providing students with essential skills and knowledge. Her commitment to education and her extensive experience makes her a valuable asset to the Department of Electrical Engineering and the BEU program. Her contributions have undoubtedly enriched the educational experience of countless students.



**Muhammad Syamil Arif Bin Amri** is a dedicated and ambitious electrical engineering student who embarked on his academic journey at Politeknik Sultan Salahuddin Abdul Aziz Shah in 2014. His passion for electronic engineering led him to pursue the Diploma in Electronic Engineering (Medical), known as DEU, and later the Bachelor of Electronic Engineering Technology (Medical Electronics) with Honours, the BEU program, in 2018. During his time as a student, he demonstrated exceptional analytical and research skills. His particular focus was on wireless hand gesture devices designed to assist aphasic patients, a project that showcased his dedication and ingenuity. His efforts were duly recognized when he received the prestigious "Best Final Year Project" award during his bachelor's degree program. In 2020, He began his professional journey as a Biomedical Engineer at Advance Pact Sdn Bhd. In this role, he assumed significant responsibilities, including the management and maintenance of diagnostic, therapeutic, laboratory, and other medical devices at Hospital Mersing. His commitment to ensuring the proper functioning of critical medical equipment

contributed to the well-being of patients and healthcare professionals. Currently, Muhammad Syamil holds the position of a diligent Service Engineer at Best Contact (M) Sdn Bhd, a role he has undertaken since 2022. In this capacity, he specializes in diagnostic imaging systems, including general X-ray machines, MRI, CT scans, and C-arms. His expertise and dedication play a crucial role in ensuring the reliability and performance of these essential medical technologies. His journey from a driven student to a skilled and responsible Biomedical Engineer and now a Service Engineer showcases his commitment to the field of electrical engineering and his dedication to contributing to the healthcare industry. His achievements and professional growth are commendable and reflect his passion for making a difference in the world of medical electronics.



**Siti Hajar Ismail** is a passionate Head of Biomedical Engineer in Hospital Rompin, Pahang since 2022. She is responsible for managing and facilitates the operations for Biomedical Engineering Services (BEMS) department in Hospital Rompin, Pahang. Early of her studies, she is a former student in Electrical Engineering Department in Politeknik Sultan Salahuddin Abdul Aziz Shah and earned a Diploma in Electronic Engineering (Medical Electronic) in 2018. Later, she further her studies in Bachelor of Technology in Electronic Engineering (Medical Electronic) with Honours and obtained her first degree on 2021 by successfully delivered her final project on The Development of Multi-Operable Medical Checker for Outpatient in 2020. She starts her career journey as a biomedical engineer and served as Junior Engineer – Supervisor in Hospital Segamat, Johor for Advance Pact Sdn Bhd since 2021 until 2022 in assisting Head of BEMS to manage the service of Biomedical Engineering Department Services. Currently, she has been attached to the MNE Solutions (M) Sdn Bhd to serve one of the branches of the company in Hospital Rompin, Pahang in Biomedical Engineering Services Department aka BEMS.



**Tengku Anis Zuhayrah Binti Tengku Amran** is a dedicated biomedical technician from Siti Group of Healthcare Sdn Bhd and a former student from Politeknik Sultan Salahuddin Abdul Aziz Shah. She begins her journey in medical electronic devices from 2015 until 2020 as a diploma student in Electronic Engineering (Medical) and pursues her studies in the same field with a Bachelor of Electronic Engineering Technology (Medical Electronics) with Honours. She successfully delivered her final year project, Smart First Aid Kit in diploma and Microsleep Detection Using Eye Blink Sensor, in degree.

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