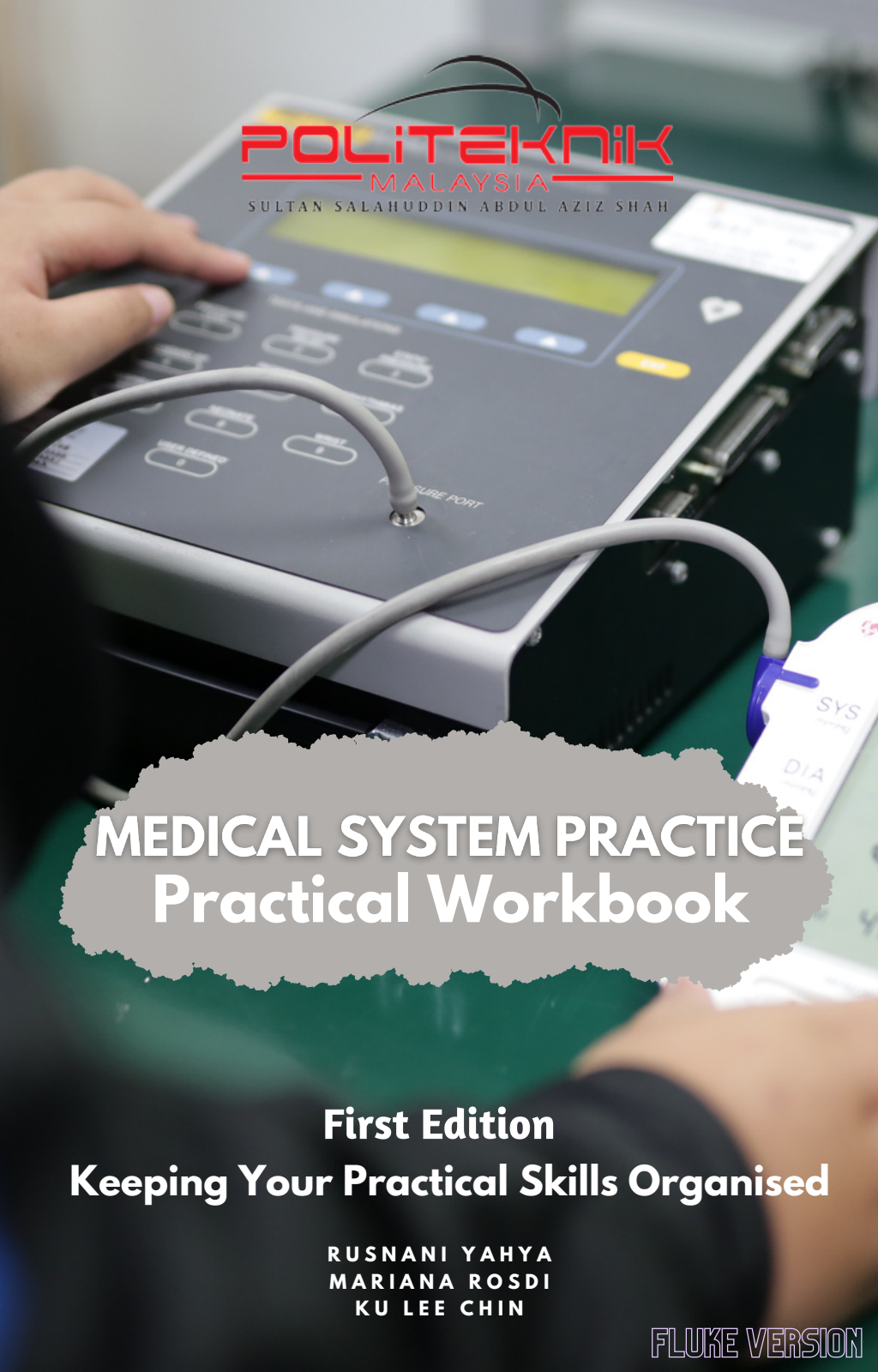

MEDICAL SYSTEM PRACTICE
Practical Workbook

First Edition

Keeping Your Practical Skills Organised

RUSNANI YAHYA
MARIANA ROSDI
KU LEE CHIN

FLUKE VERSION

POLITEKNIK MALAYSIA
SULTAN SALAHUDDIN ABDUL AZIZ SHAH

MEDICAL SYSTEM PRACTICE
Practical Workbook

FIRST EDITION 2022

ELECTRICAL ENGINEERING DEPARTMENT

@JABATAN PENGAJIAN POLITEKNIK DAN KOLEJ KOMUNITI
KEMENTERIAN PENGAJIAN TINGGI

MEDICAL SYSTEM PRACTICE
Practical Workbook

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PREFACE

This practical workbook is filled with information and procedure to give students a ready reference and instructional material for medical equipment maintenance activities.

It is designed to enable the students to learn by themselves and/or by the guidance of their instructor, to discover new basic maintenance procedures, and terminologies, and to acquire new knowledge and skills in the maintenance of biomedical equipment.

The practical workbook consists of six different chapters; Electrical Safety Test for medical equipment according to IEC 60601 standard, Electrical Safety Test for medical equipment according to IEC 61010 standard, Electrical Safety Test for medical equipment according to IEC 62353 standard, Plan Preventive Maintenance for medical equipment according to IEC 62353 standard, Operating and Maintaining Anesthesia Machine and Performance Test for Infusion Pump Machine, which are broke down into simple lessons, with accompanying activities and exercises. Written in simple language, each lesson features the fundamentals of medical equipment maintenance standards, basic steps, safety precautions, and a diagram of connections from different types of equipment, brand, and model in this practical workbook.

The students may now share this knowledge with others who need the motivation to learn. Selected medical equipment is made for a simple and easy understanding of medical equipment activities. But being a person who possesses knowledge, skills, and attitude in maintenance technical activities is a different thing.

The Authors

STUDENT INFORMATION

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Synopsis

MEDICAL SYSTEM PRACTICE covers the knowledge of necessary standards for safety in medical device according to International and Malaysian Standard requirements. This course emphasizes on electrical safety of medical equipment and safe use of anesthesia machine. This course also provides the knowledge and skills of maintenance for medical equipment including safety test and performance test and also the safety system of infusion devices.

Learning Outcome

PLO5: Apply appropriate techniques, resources, and modern engineering and IT tools to well-defined engineering problems, with an awareness of the limitations (DK6).

CLO2: Perform the skills in maintenance and testing process for medical equipment by using appropriate standards (P4, PLO 5)

PRACTICAL WORK 1

Electrical Safety Test for medical equipment according to IEC 60601 standard

At the end of the experiment, students will be able to

(i) Perform Electrical Safety Test using IEC 60601 Standard for specified medical devices.

(ii) Measure the main voltage, insulation resistance and different type of leakage current.

Apparatus

NIBP machine (Device Under Test)

Electrical Safety Analyzer (Fluke ESA620)

Before perform electrical safety test, please complete the details below:

Equipment Under Test (EUT): _____

Brand/Manufacturer: _____

Model: _____

Origin: _____

Serial Number: _____

Class: _____

Types: _____

Accessories: _____

_____

_____

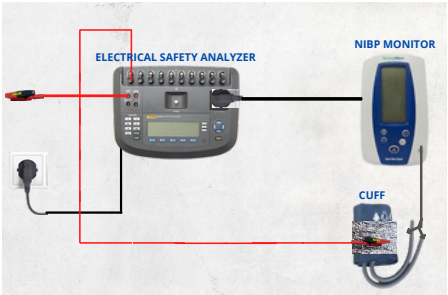


Figure 1: Connection Between Medical Equipment and Analyzer

PROCEDURE:

1. Connect the DUT to ESA 620 as indicated in the Figure 1
2. Select function STANDARDS, then use ◄► up and down to select a test standard : *IEC60601&ANSI/AAMI ES60601-1*, the press F1.

PART A: Mains Voltage

1. Ensure the DUT power is OFF
2. Select the function V.
3. Measure and record the value of Live to Neutral (F1), Neutral to Earth (F2) and Live to Earth (F3).
4. Select Exit (F5).

Table 1.1 : Mains Voltage

	Measured Value (V)
Live to Neutral	
Neutral to Earth	
Live to Earth	

PART B: Insulation Resistance

1. Ensure the DUT power is OFF
2. Select the function MΩ.
3. Select Mains-PE (F1), then press TEST, record the measured value.
4. Select A.P-PE (F2), then press TEST, record the measured value.
5. Select Exit (F5

Table 1.2 : Insulation Resistance

	Measured Value (MΩ)
Mains to Protective Earth	
Applied Parts to Protective Earth	

PART C: Earth Leakage Current

1. Ensure the DUT power is ON
2. Select the function μA and Earth (F1).
3. Measure the **Normal Condition**. Press POLARITY to **NORMAL** and press NEUTRAL to **CLOSED**, then record the measured value.
4. Measure the **Open Neutral**. Maintain the POLARITY to **NORMAL** and press NEUTRAL to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE** and press NEUTRAL to **CLOSED**, then record the measured value.
6. Measure the **Open Neutral, Reversed Mains**. Press POLARITY to **REVERSE** and press NEUTRAL to **Open**, then record the measured value.
7. Select Exit (F5).

Table 1.3 : Earth Leakage Current

	High Limit (uA)	Measured Value (uA)	PASS/FAIL
Normal Condition	5000		
Open Neutral	10000		
Normal Condition, Reversed Mains	5000		
Open Neutral, Reversed Mains	10000		

PART D: Enclosure Leakage Current

1. Ensure the DUT power is ON
2. Select the function μA and Enclosure (F2).
3. Measure the **Normal Condition**. Press POLARITY to **NORMAL**, NEUTRAL to **CLOSED**, and EARTH to **CLOSED,** then record the measured value.
4. Measure the **Open Neutral**. Maintain the POLARITY to **NORMAL**, NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
5. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, NEUTRAL to **OPEN** and EARTH to **OPEN**, then record the measured value.
6. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, NEUTRAL to **CLOSED**, and EARTH to **CLOSED,** then record the measured value.
7. Measure the **Open Neutral, Reversed Mains**. Maintain the POLARITY to **REVERSE**, NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
8. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, NEUTRAL to **OPEN** and EARTH to **OPEN**, then record the measured value.
9. Select Exit (F5).

Table 1.4 : Enclosure Leakage Current

	High Limit (uA)	Measured Value (uA)	PASS/FAIL
Normal Condition	100		
Open Neutral	500		
Open Earth	500		
Normal Condition, Reversed Mains	100		
Open Neutral, Reversed Mains	500		
Open Earth, Reversed Mains	500		

PART E: Patient Leakage Current

1. Ensure the DUT power is ON
2. Select the function μA and More (F4).
3. Use  up and down to select the lead like this  , press F1. Use  up and down to set the leakage:AC+DC.
4. Measure the **Normal Condition**. Press POLARITY to **NORMAL**, NEUTRAL to **CLOSED**, and EARTH to **CLOSED,** then record the measured value.
5. Measure the **Open Neutral**. Maintain the POLARITY to **NORMAL**, NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
6. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, NEUTRAL to **OPEN** and EARTH to **OPEN**, then record the measured value.
7. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, NEUTRAL to **CLOSED**, and EARTH to **CLOSED,** then record the measured value.
8. Measure the **Open Neutral, Reversed Mains**. Maintain the POLARITY to **REVERSE**, NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
9. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, NEUTRAL to **OPEN** and EARTH to **OPEN**, then record the measured value.
10. Select Exit (F5).

Table 1.5 : Patient Leakage Current

	High Limit (uA)	Measured Value (uA)	PASS/FAIL
Normal Condition	100		
Open Neutral	500		
Open Earth	500		
Normal Condition, Reversed Mains	100		
Open Neutral, Reversed Mains	500		
Open Earth, Reversed Mains	500		

PART F: Patient Auxiliary Leakage Current

1. Ensure the DUT power is ON
2. Select the function μA and Patient Auxiliary (F3).
3. Use  up and down to set the leakage:AC+DC.
4. Measure the **Normal Condition**. Press POLARITY to **NORMAL**, NEUTRAL to **CLOSED**, and EARTH to **CLOSED,** then record the measured value.
5. Measure the **Open Neutral**. Maintain the POLARITY to **NORMAL**, NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
6. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, NEUTRAL to **OPEN** and EARTH to **OPEN**, then record the measured value.
7. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, NEUTRAL to **CLOSED**, and EARTH to **CLOSED,** then record the measured value.
8. Measure the **Open Neutral, Reversed Mains**. Maintain the POLARITY to **REVERSE**, NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
9. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, NEUTRAL to **OPEN** and EARTH to **OPEN**, then record the measured value.
10. Select Exit (F5).

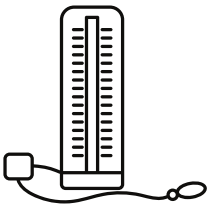
Table 1.6 : Patient Auxiliary leakage Current

	High Limit (uA)	Measured Value (uA)	PASS/FAIL
Normal Condition	100		
Open Neutral	500		
Open Earth	500		
Normal Condition, Reversed Mains	100		
Open Neutral, Reversed Mains	500		
Open Earth, Reversed Mains	500		

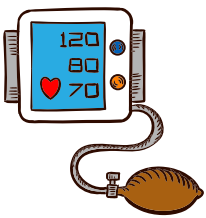
DISCUSSION:
Discuss your observations from theoretical, simulation result and practical result.

CONCLUSION:
Give your conclusion pertaining to the experiment.

Exercise 1

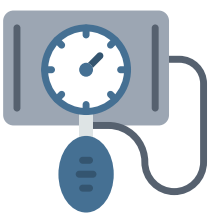


1. What is the function of Non Invasive Blood Pressure Monitor?



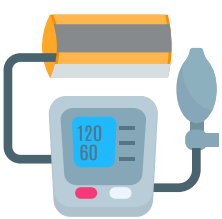
2. What is unit measurement of blood pressure?

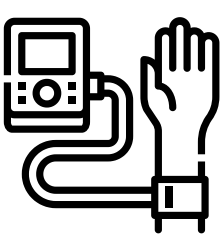
3. What are the normal reading of human blood pressure ?



4. List FIVE (5) blood pressure monitor in the market.

Manufacturer	Model





5. What is the definition of IEC 60601?

PRACTICAL WORK 2

Electrical safety test for medical equipment according to IEC 61010 standard

At the end of the experiment, students will be able to

(i) Perform Electrical Safety Test using IEC61010 Standard for specified medical laboratory equipment.

(ii) Measure the main voltage, insulation resistance and different type of leakage current.

Apparatus

Microscope RaxVision (Device Under Test)

Electrical Safety Analyzer (Fluke ESA620)

Before perform electrical safety test, please complete the details below:

Equipment Under Test (EUT): _____

Brand/Manufacturer: _____

Model: _____

Origin: _____

Serial Number: _____

Accessories: _____

_____

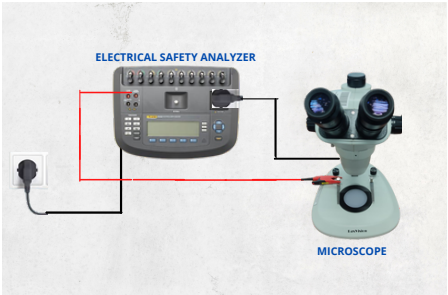


Figure 2: Connection Between Medical Equipment and Analyzer

PROCEDURE:

1. Connect the DUT to ESA 620 as indicated in the Figure 1
2. Select function STANDARDS, then use ◄► up and down to select a test standard : ***IEC 61010***, then press F1.

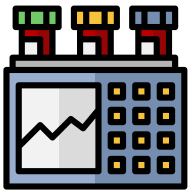
PART A: Accessible Voltage Test

1. Ensure the DUT power is OFF
2. Select the function V.
3. Press POLARITY to **NORMAL**, press NEUTRAL to **CLOSED** and EARTH to **CLOSED**, then record the measured value
4. Press POLARITY to **NORMAL**, press NEUTRAL to **CLOSED** and EARTH to **OPEN**, then record the measured value
5. Press POLARITY to **NORMAL**, press NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value
6. Press POLARITY to **REVERSE**, press NEUTRAL to **CLOSED** and EARTH to **CLOSED**, then record the measured value.
7. Press POLARITY to **REVERSE**, press NEUTRAL to **CLOSED** and EARTH to **OPEN**, then record the measured value.
8. Press POLARITY to **REVERSE**, press NEUTRAL to **OPEN** and EARTH to **CLOSED**, then record the measured value.
9. Select Exit (F5).

Table 2.1 Accessible Voltage Test

Conditions	Measured Value (V)
Normal polarity	
Normal polarity, earth open	
Normal polarity, neutral open	
Reversed polarity	
Reversed polarity, earth open	
Reversed polarity, neutral open	

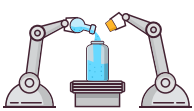
Exercise 2



1. Explain the definition of IEC61010

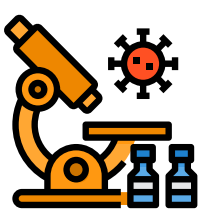
2. List FIVE (5) of medical laboratory equipment

3. Which department related to the medical laboratory equipment?



4. List all the safety test related to medical laboratory equipment

5. Explain the importance of safety test for medical laboratory equipment.



PRACTICAL WORK 3

Electrical Safety Test for medical equipment according to IEC 62353 standard

At the end of the experiment, students will be able to

(i) Perform Electrical Safety Test using IEC62353 Standard for specified medical laboratory equipment.

(ii) Measure the main voltage, protective earth, insulation resistance, current consumption test, direct equipment leakage current, direct applied part leakage current, differential equipment leakage current, alternative equipment leakage current and alternative applied part leakage current

Apparatus

Defibrillator (Device Under Test)

Electrical Safety Analyzer (Fluke ESA620)

Before perform electrical safety test, please complete the details below:

Equipment Under Test (EUT): _____

Brand/Manufacturer: _____

Model: _____

Origin: _____

Serial Number: _____

Class: _____

Types: _____

Accessories: _____

_____

_____

Figure 3 : Connection Between Medical Equipment and Analyzer

PROCEDURE:

1. Connect the DUT to ESA 620 as indicated in the Figure 3
2. Select function STANDARDS, then use up and down to select a test standard : ***EN62353 & VDE751***, then press F1.

PART A: Mains Voltage

1. Ensure the DUT power is OFF
2. Select the function V.
3. Measure and record the value of **Live to Neutral**, **Neutral to Earth** and **Live to Earth**.
4. Select Exit (F5).

PART B: Protective Earth (PE)

1. Ensure the DUT power is OFF
2. Select the function Ω.
3. Connect test lead from 2 wire jack to the null jack. Press Zero Leads (F4)
4. Connect test lead from 2 wire jack to the protective earth pin at the DUT.
5. Press LOW (F1), Measure and record the value of PE.
6. Select Exit (F5).

PART C: Insulation Resistance

1. Ensure the DUT power is OFF
2. Select the function 

.
3. Select Mains-PE, then press 

, record the measured value.
4. Select A.P-PE, then press 

, record the measured value.
5. Select Mains-A.P, then press 

, record the measured value.
6. Select Exit (F5).

PART D: Current Consumption Test

1. Ensure the **DUT** power is **ON**
2. Select the function 

.
3. Record the value.

PART E: Direct Equipment Leakage Current

1. Ensure the **DUT** power is **ON**
2. Select the function 

. Then select **Direct Equipment (F1).**
3. Measure the **Normal Condition,** press 

to **NORMAL**, and 

to **CLOSED,** then record the measured value
4. Measure the **Open Earth**. Maintain the 

to **NORMAL**, and 

to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press 

to **REVERSE**, and 

to **CLOSED,** then record the measured value.
6. Measure the **Open Earth, Reversed Mains**. Maintain the 

to **REVERSE**, and 

to **OPEN**, then record the measured value.
7. Select Exit (F5).

PART E: Direct Applied Part Leakage Current

1. Ensure the **DUT** power is **ON**.
2. Select the function μA, then select **Direct Applied Part.**
3. Measure the **Normal Condition**. Press POLARITY to **NORMAL,** then record the measured value.
4. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE,** then record the measured value.
5. Select Exit (F5).

PART F: Differential Equipment Leakage Current

1. Ensure the **DUT** power is **ON**
2. Select the function μA, then select **Differential (AC)**
3. Measure the **Normal Condition,** press POLARITY to **NORMAL**, and EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, and EARTH to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, and EARTH to **CLOSED,** then record the measured value.
6. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, and EARTH to **OPEN**, then record the measured value.
7. Select Exit (F5).

PART G: Alternative Equipment Leakage Current

1. Ensure the **DUT** power is **OFF**
2. Select the function μA, then select **Alternative Equipment (AC)**
3. Measure the **Normal Condition,** press EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**, press EARTH to **OPEN**, then record the measured value.
5. Select Exit (F5).

PART H: Alternative Applied Part Leakage Current

1. Ensure the **DUT** power is **OFF**
2. Select the function μA, then select **Alternative Applied Part (AC),** then record the measured value
3. Select Exit (F5).

Table 3.1 : Table of Test Result

			TEST RESULT			
			Measured Value	Pass	Fail	Not Applicable
ELECTRICAL SAFETY						
Mains Voltage (V) - ***(UUT Power OFF)***		Live-Neutral (L1-L2)				
		Live-Earth (L1-GND)				
		Neutral-Earth (L2-GND)				
Protective Earth (PE) Resistance (Ω)	< 0.3 Ω	***(UUT Power OFF)***				
Insulation Resistance (MΩ) - ***(UUT Power OFF)***		Mains-PE				
		AP-PE				
		Mains-AP				
Equipment Current (A)		***(UUT Power ON)***				
Leakage Current (µA)						
1) a) Direct Equipment (AC) - ***(UUT Power ON)***						
< 500 µA (Class I, B,BF,CF) **OR** < 100 µA (Class II, B,BF,CF)		Normal Polarity, Closed Earth				
		Normal Polarity, Open Earth				
		Reverse Polarity, Closed Earth				
		Reverse Polarity, Open Earth				
b) Direct Applied Part (AC) - ***(UUT Power ON)***						
< 5000 µA (Class I & II, BF) **OR** < 50 µA (Class I & II, CF) **OR** < 100 µA (Defib Paddles CF)		Normal Polarity				
		Reverse Polarity				
2) Differential (AC) - ***(UUT Power ON)***						
< 500 µA (Class I, B,BF,CF) **OR** < 100 µA (Class II, B,BF,CF)		Normal Polarity, Closed Earth				
		Normal Polarity, Open Earth				
		Reverse Polarity, Closed Earth				
		Reverse Polarity, Open Earth				
3) a) Alternative Equipment (AC) - ***(UUT Power OFF)***						
< 1000 µA (Class I, B,BF,CF) **OR** < 500 µA (Class II, B,BF,CF)		Closed Earth				
		Open Earth				
b) Alternative Applied Part (AC) - ***(UUT Power OFF)***						
< 5000 µA (Class I & II, BF) **OR** < 50 µA (Class I & II, CF) **OR** < 100 µA (Defib Paddles		***(UUT Power OFF)***				

DISCUSSION:
Discuss your observations from theoretical, simulation result and practical result.

CONCLUSION:
Give your conclusion pertaining to the experiment.

Exercise 3

1. Explain the function of Defibrillator.

_____

_____

_____

2. Are there different defibrillators for children?

_____

_____

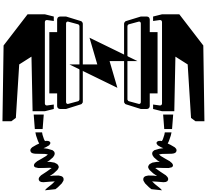
_____

_____

3. What is energy range for defibrillator Lifepak 20e

_____

_____



4. Discuss the difference between defibrillator, AED dan Pacemaker?

_____

_____

_____

_____

_____

5. Find in the service/user manual, the accuracy of the defibrillator Lifepak 20e.

_____

_____

PRACTICAL WORK 4

Plan Preventive Maintenance for medical equipment according to IEC 62353 standard.

At the end of the experiment, students will be able to

(i) Perform Plan Preventive Maintenance using appropriate safety Standard for specified medical equipment.

Apparatus

SPO2 Analyzer

SPO2 machine (Device Under Test)

Electrical Safety Analyzer (Fluke ESA620)

Before perform plan preventive maintenance, please complete the details below:

Equipment Under Test (EUT): _____

Brand/Manufacturer: _____

Model: _____

Origin: _____

Serial Number: _____

Class: _____

Types: _____

Accessories: _____

_____

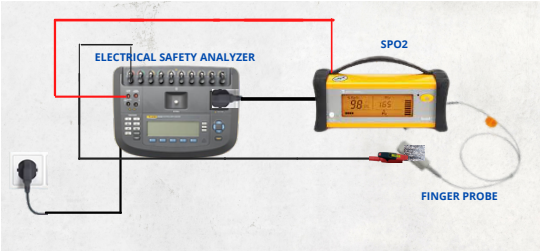


Figure 4.1: Connection Between Medical Equipment and Safety Analyzer

A : ELECTRICAL SAFETY TEST

PROCEDURE:

1. Connect the DUT to ESA 620 as indicated in the Figure **4.1**
2. Select function STANDARDS, then use up and down to select a test standard : ***EN62353 & VDE751***, then press F1.

PART A: Mains Voltage

1. Ensure the DUT power is OFF
2. Select the function V.
3. Measure and record the value of **Live to Neutral**, **Neutral to Earth** and **Live to Earth**.
4. Select Exit (F5).

PART B: Protective Earth (PE)

1. Ensure the DUT power is OFF
2. Select the function Ω.
3. Connect test lead from 2 wire jack to the null jack. Press Zero Leads (F4)
4. Connect test lead from 2 wire jack to the protective earth pin at the DUT.
5. Press LOW (F1), Measure and record the value of PE.
6. Select Exit (F5).

PART C: Insulation Resistance

1. Ensure the DUT power is OFF
2. Select the function MΩ.
3. Select Mains-PE, then press TEST, record the measured value.
4. Select A.P-PE, then press TEST, record the measured value.
5. Select Mains-A. P, then press TEST, record the measured value.
6. Select Exit (F5).

PART D: Current Consumption Test

1. Ensure the **DUT** power is **ON**
2. Select the function A.
3. Record the value.

PART E: Direct Equipment Leakage Current

1. Ensure the **DUT** power is **ON**
2. Select the function μA. Then select **Direct Equipment (F1).**
3. Measure the **Normal Condition,** press POLARITY to **NORMAL**, and EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, and EARTH to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, and EARTH to **CLOSED,** then record the measured value.
6. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, and EARTH to **OPEN**, then record the measured value.
7. Select Exit (F5).

PART F: Differential Equipment Leakage Current

1. Ensure the **DUT** power is **ON**
2. Select the function μA, then select **Differential (AC)**
3. Measure the **Normal Condition,** press POLARITY to **NORMAL**, and EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, and EARTH to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, and EARTH to **CLOSED,** then record the measured value.
6. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, and EARTH to **OPEN**, then record the measured value.
7. Select Exit (F5).

PART G: Alternative Equipment Leakage Current

1. Ensure the **DUT** power is **OFF**
2. Select the function μA, then select **Alternative Equipment (AC)**
3. Measure the **Normal Condition,** press EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**, press EARTH to **OPEN**, then record the measured value.
5. Select Exit (F5).

PART H: Alternative Applied Part Leakage Current

1. Ensure the **DUT** power is **OFF**
2. Select the function μA, then select **Alternative Applied Part (AC),** then record the measured value
3. Select Exit (F5).

Table 4.1 : Table of Test Result

			TEST RESULT			
			Measured Value	Pass	Fail	Not Applicable
ELECTRICAL SAFETY						
Mains Voltage (V) - *(UUT Power OFF)*		Live-Neutral (L1-L2)				
		Live-Earth (L1-GND)				
		Neutral-Earth (L2-GND)				
Protective Earth (PE) Resistance (Ω)	< 0.3 Ω	***(UUT Power OFF)***				
Insulation Resistance (MΩ) - *(UUT Power OFF)*		Mains-PE				
		AP-PE				
		Mains-AP				
Equipment Current (A)		***(UUT Power ON)***				
Leakage Current (µA)						
1) a) Direct Equipment (AC) - *(UUT Power ON)*						
< 500 µA (Class I, B,BF,CF) **OR** < 100 µA (Class II, B,BF,CF)		Normal Polarity, Closed Earth				
		Normal Polarity, Open Earth				
		Reverse Polarity, Closed Earth				
		Reverse Polarity, Open Earth				
b) Direct Applied Part (AC) - *(UUT Power ON)*						
< 5000 µA (Class I & II, BF) **OR** < 50 µA (Class I & II, CF) **OR** < 100 µA (Defib Paddles CF)		Normal Polarity				
		Reverse Polarity				
2) Differential (AC) - *(UUT Power ON)*						
< 500 µA (Class I, B,BF,CF) **OR** < 100 µA (Class II, B,BF,CF)		Normal Polarity, Closed Earth				
		Normal Polarity, Open Earth				
		Reverse Polarity, Closed Earth				
		Reverse Polarity, Open Earth				
3) a) Alternative Equipment (AC) - *(UUT Power OFF)*						
< 1000 µA (Class I, B,BF,CF) **OR** < 500 µA (Class II, B,BF,CF)		Closed Earth				
		Open Earth				
b) Alternative Applied Part (AC) - *(UUT Power OFF)*						
< 5000 µA (Class I & II, BF) **OR** < 50 µA (Class I & II, CF) **OR** < 100 µA (Defib Paddles		***(UUT Power OFF)***				

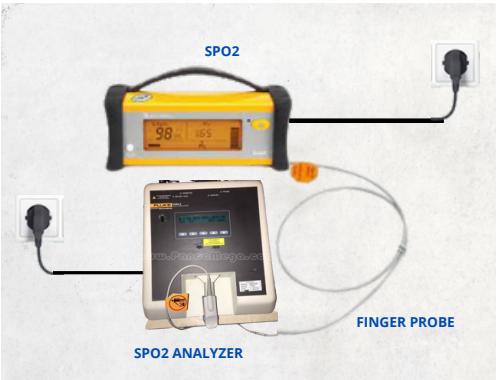


Figure 4.2: Connection Between Medical Equipment and SPO2 Analyzer

B : PERFORMANCE TEST

PULSE RATE ACCURACY

1. Connect the DUT to SPO2 Analyzer as indicated in Figure 4.2.

2. Switch ON the SPO2 Analyzer

3. From the main menu of the SPO2 Analyzer, press the soft key labeled 'MORE' for the second menu and press the soft key labeled 'MAKE'. Use the plus and minus keys to scroll through the available makes.

4. Select the make of the pulse oximeter to be tested. When the correct make appears on the screen, press the 'ESC' key to return to the main menu.

5. From the main menu, press the soft key labeled 'SIM' to enter the simulation mode.

6. Begin the manual simulation by pressing the soft key labeled 'MAN'. Use the plus and minus keys to adjust the O2 level and pulse rate.

7. Set the pulse rate as per the checklist

8. Turn on the SPO2 machine and initiate the measurement.

DISCUSSION:

Discuss your observations from theoretical, simulation result and practical result.

CONCLUSION:

Give your conclusion pertaining to the experiment.

Exercise 4

1. Explain the function of Pulse Oximeter

_____

_____

_____

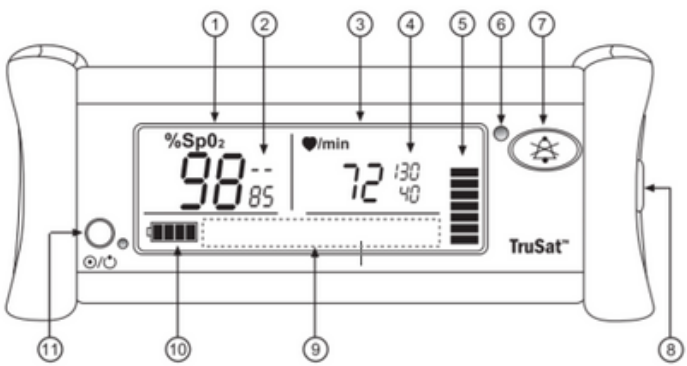
2. A pulse oximeter consists of

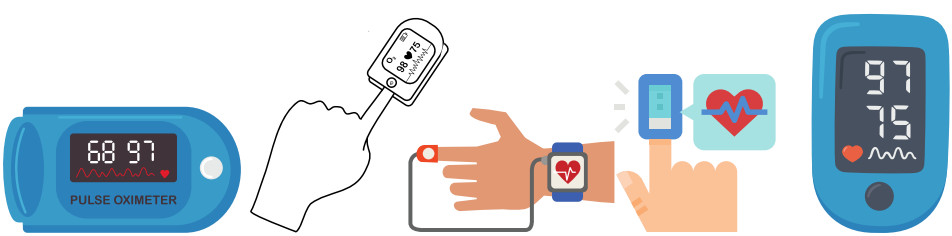
_____

_____

_____

3. Refer to GE_Trusat_User Manual, name the monitor features label below.





PRACTICAL WORK 5

Operating and Maintaining Anesthesia Machine

At the end of the experiment, students will be able to

(i) Perform Electrical Safety Test using IEC62353 Standard for specified medical laboratory equipment.

(ii) Measure the main voltage, insulation resistance and different type of leakage current.

Apparatus

Anesthesia Machine (Device Under Test)

Electrical Safety Analyzer (Fluke ESA620)

Before perform safety test, please complete the details below:

Equipment Under Test (EUT): _____

Brand/Manufacturer: _____

Model: _____

Origin: _____

Serial Number: _____

Class: _____

Types: _____

Accessories: _____

_____

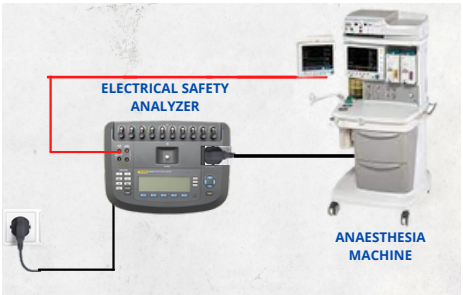


Figure 5: Connection Between Medical Equipment and Safety Analyzer

1. Connect the DUT to Safety Analyzer as indicated in the Figure **5**
2. Select function STANDARDS, then use up and down to select a test standard : ***EN62353 & VDE751***, then press F1.

PART A: Mains Voltage

1. Ensure the DUT power is OFF
2. Select the function V.
3. Measure and record the value of **Live to Neutral**, **Neutral to Earth** and **Live to Earth**.
4. Select Exit (F5).

PART B: Protective Earth (PE)

1. Ensure the DUT power is OFF
2. Select the function Ω.
3. Connect test lead from 2 wire jack to the null jack. Press Zero Leads (F4)
4. Connect test lead from 2 wire jack to the protective earth pin at the DUT.
5. Press LOW (F1), Measure and record the value of PE.
6. Select Exit (F5).

PART C: Insulation Resistance

1. Ensure the DUT power is OFF
2. Select the function MΩ.
3. Select Mains-PE, then press TEST, record the measured value.
4. Select A.P-PE, then press TEST, record the measured value.
5. Select Mains-A. P, then press TEST, record the measured value.
6. Select Exit (F5).

PART D: Current Consumption Test

1. Ensure the **DUT** power is **ON**
2. Select the function A.
3. Record the value.

PART E: Direct Equipment Leakage Current

1. Ensure the **DUT** power is **ON**
2. Select the function μA. Then select **Direct Equipment (F1).**
3. Measure the **Normal Condition,** press POLARITY to **NORMAL**, and EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, and EARTH to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, and EARTH to **CLOSED,** then record the measured value.
6. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, and EARTH to **OPEN**, then record the measured value.
7. Select Exit (F5).

PART F: Direct Applied Part Leakage Current

1. Ensure the **DUT** power is **ON**.
2. Select the function μA, then select **Direct Applied Part.**
3. Measure the **Normal Condition**. Press POLARITY to **NORMAL,** then record the measured value.
4. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE,** then record the measured value.
5. Select Exit (F5).

PART G: Differential Equipment Leakage Current

1. Ensure the **DUT** power is **ON**
2. Select the function μA, then select **Differential (AC)**
3. Measure the **Normal Condition,** press POLARITY to **NORMAL**, and EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**. Maintain the POLARITY to **NORMAL**, and EARTH to **OPEN**, then record the measured value.
5. Measure the **Normal Condition, Reversed Mains**. Press POLARITY to **REVERSE**, and EARTH to **CLOSED,** then record the measured value.
6. Measure the **Open Earth, Reversed Mains**. Maintain the POLARITY to **REVERSE**, and EARTH to **OPEN**, then record the measured value.
7. Select Exit (F5).

PART H: Alternative Equipment Leakage Current

1. Ensure the **DUT** power is **OFF**
2. Select the function μA, then select **Alternative Equipment (AC)**
3. Measure the **Normal Condition,** press EARTH to **CLOSED,** then record the measured value
4. Measure the **Open Earth**, press EARTH to **OPEN**, then record the measured value.
5. Select Exit (F5).

PART I: Alternative Applied Part Leakage Current

1. Ensure the **DUT** power is **OFF**
2. Select the function μA, then select **Alternative Applied Part (AC),** then record the measured value
3. Select Exit (F5).

Table 5.1 : Table of Test Result

			TEST RESULT			
			Measured Value	Pass	Fail	Not Applicable
ELECTRICAL SAFETY						
Mains Voltage (V) - *(UUT Power OFF)*		Live-Neutral (L1-L2)				
		Live-Earth (L1-GND)				
		Neutral-Earth (L2-GND)				
Protective Earth (PE) Resistance (Ω)	< 0.3 Ω	***(UUT Power OFF)***				
Insulation Resistance (MΩ) - *(UUT Power OFF)*		Mains-PE				
		AP-PE				
		Mains-AP				
Equipment Current (A)		***(UUT Power ON)***				
Leakage Current (µA)						
1) a) Direct Equipment (AC) - *(UUT Power ON)*						
< 500 µA (Class I, B,BF,CF) **OR** < 100 µA (Class II, B,BF,CF)		Normal Polarity, Closed Earth				
		Normal Polarity, Open Earth				
		Reverse Polarity, Closed Earth				
		Reverse Polarity, Open Earth				
b) Direct Applied Part (AC) - *(UUT Power ON)*						
< 5000 µA (Class I & II, BF) **OR** < 50 µA (Class I & II, CF) **OR** < 100 µA (Defib Paddles CF)		Normal Polarity				
		Reverse Polarity				
2) Differential (AC) - *(UUT Power ON)*						
< 500 µA (Class I, B,BF,CF) **OR** < 100 µA (Class II, B,BF,CF)		Normal Polarity, Closed Earth				
		Normal Polarity, Open Earth				
		Reverse Polarity, Closed Earth				
		Reverse Polarity, Open Earth				
3) a) Alternative Equipment (AC) - *(UUT Power OFF)*						
< 1000 µA (Class I, B,BF,CF) **OR** < 500 µA (Class II, B,BF,CF)		Closed Earth				
		Open Earth				
b) Alternative Applied Part (AC) - *(UUT Power OFF)*						
< 5000 µA (Class I & II, BF) **OR** < 50 µA (Class I & II, CF) **OR** < 100 µA (Defib Paddles		***(UUT Power OFF)***				

DISCUSSION:
Discuss your observations from theoretical, simulation result and practical result.

CONCLUSION:
Give your conclusion pertaining to the experiment.

Exercise 5

1. Explain the function of Anaesthesia Machine

_____

_____

_____

2. List THREE (3) brand/model of Anaesthesia Machine in the market

_____

_____

_____

3. Name the features label below.

PRACTICAL WORK 6

Performance Test for Infusion Pump Machine

At the end of the experiment, students will be able to

(i) Perform Electrical Safety Test using IEC62353 Standard for specified medical laboratory equipment.

(ii) Measure the main voltage, insulation resistance and different type of leakage current.

Apparatus

Infusion Pump machine (Device Under Test)

Infusion Pump Analyzer

Before perform safety test, please complete the details below:

Equipment Under Test (EUT): _____

Brand/Manufacturer: _____

Model: _____

Origin: _____

Serial Number: _____

Class: _____

Types: _____

Accessories: _____

_____

VERIFY UNIT OPERATES ON BATTERY

1. Check that AC power indicator is lit when the power cord is plugged into outlet.
2. Unplug the AC power cord and perform the remainder of the functional test on battery power. Write your **OBSERVATION** on Table 6.1

Table 6.1 : Verify Unit Operates on Battery

AC power cord	Battery indicator

POLE CLAMP FUNCTION

1. Check the physical condition of the pole clamp. The pole clamp should be securely fastened to the infusion pump. The clamp mechanism should move freely.

Figure 6: Connection Between Medical Equipment and Safety Analyzer

FLOW RATE ACCURACY

1. Connect the DUT to Infusion pump analyzer as indicated in the Figure **6**(Step 3 – 11)
2. Prime the set so that there is no air in the tubing.
3. With the tubing draining into a container, open the flow control mechanism on the tubing set.
4. Hold the reservoir high enough above the tubing so that fluid flows through the tubing under the force of gravity.
5. Allow fluid to flow through the tubing until no air bubbles can see in the tubing.
6. Insert the set into the infusion pump.
7. Connect the three-way stopcock to the channel 1 port on the Infusion pump analyzer.
8. Connect the patient infusion tubing to one port of the stopcock.
9. Fill the syringe with the solution and connect this to the other port of stopcock.
10. Connect a piece of tubing to the drain port of channel 1 and run the tubing into a container to catch the used solution.
11. From the main menu of the Infusion pump analyzer, use the arrow keys to highlight 'SETUP' under channel 1 and the press 'ENT'. Select 'PRIME'
12. Close the stopcock port connected to the infusion tubing, leaving the ports to the syringe and infusion pump analyzer open.
13. Inject the solution in the syringe into infusion pump analyzer until 'START' appears on the screen. Select 'Auto Start. The infusion pump analyzer will start the flow test when it detects flow from the pump.
14. Close the port to the syringe, leaving the ports to the tubing and the infusion pump analyzer open.
15. Set the flow rate on the infusion pump device to 60mL/hr. and set the dose to 10mL. Start the infusion pump device.
16. When the pump alarms complete, select 'END' on the infusion pump analyzer to end the test. Clear the alarm on the pump. The measured flow rate should be within 10% of the set rate.

Table 6.2: Flow Rate Accuracy

Flow Rate (mL/hr)	Dose (mL)	Accuracy 10% (mL/hr)	Measured Flow Rate (mL/hr)
60	10	54 - 66	
120	10	108-132	

VOLUME ACCURACY

1. Set up the infusion pump and the infusion pump analyzer as described previously in Flow Rate Accuracy.
2. The infusion pump analyzer will measure flow rate and volume simultaneously.
3. The delivered volume should be within 10% of the set volume.

Table 6.3: Volume Accuracy

Volume (mL)	Accuracy 10% (mL)	Measured Volume (mL)
10	9-11	

INFUSION COMPLETE/KVO (Keep Vein Open)

1. At the conclusion of an infusion, the infusion pump should alarm 'infusion complete' or 'KVO'.
2. If the pump alarms 'KVO' it is supplying a very low flow rate to keep the vein open if another infusion needs to be given.
3. Measure the KVO rate using the 'FLOW' function of the infusion pump analyzer.
4. Set up the infusion pump with a high flow rate and low volume, 300mL/hr and 2mL.
5. Start the pump and allow the infusion to complete.
6. When the infusion is complete, do not stop the pump, instead silence the alarm and let the pump run.
7. Enter the 'FLOW' screen on the infusion pump analyzer to measure the KVO rate. Several minutes may be required for the analyzer to be able to measure the low rate.
8. The measured rate should be within 10% of the infusion pump's KVO rate.

Table 6.4: KVO Rate

KVO rate (mL/hr)	Accuracy 10% (mL/hr)	Measured KVO rate (mL/hr)
1	0.9-1.1	

OCCLUSION DETECTION PRESSURE

1. From the channel set up menu on the infusion pump analyzer, select 'OCCULUSION'.
2. Prime the infusion pump analyzer with the syringe if necessary.
3. Set the flow rate on the infusion pump to 100mL/hr.
4. Set the volume to 10mL or more so that the volume will not deliver before the test complete.
5. Start the pump, select 'START' on the infusion pump analyzer.
6. Select 'END' on infusion pump analyzer when the pump alarms occlusion.
7. Note the pressure at which the pump alarms.
8. Compare the measured pressure to the occlusion pressure of the pump. The occlusion pressure will be specific to the model.
9. Check the service manual for the specific pressure. The measured occlusion pressure should be within 1 psi of the pump's occlusion pressure.

Table 6.5: Occlusion Pressure

Occlusion pressure (psi)	Accuracy ± 1psi	Measured occlusion pressure (psi)
20 psi	19 - 21	

DISCUSSION:
Discuss your observations from theoretical, simulation result and practical result.

CONCLUSION:
Give your conclusion pertaining to the experiment.

Exercise 6

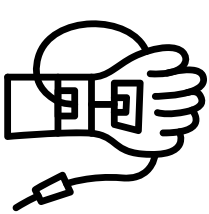
1. What are the three major problems of infusion pumps?

2. What are the risks of using an infusion pump to the patient?

3. What is the purpose of an infusion pump?

4. What is occlusion in infusion pump?

5. What is the difference between syringe pump and infusion pump?





BIBLIOGRAPHY

Booklet : A Guide to Electrical Safety, Standards of 60601 and 62353, Fluke Biomedical, 2010

O.N. Pandey, Rakesh Kumar, Bio-Medical Electronic : Katson Books ,2006

User Manual : ESA 620 Electrical Safety Analyzer, Fluke Corporation, 2008

Anthony Y.K. Chan, Biomedical Device Technology: Principles and Design. 2nd Edition. Charles C Thomas Publisher,2016

Paul H.King, Richard C. Fries, Arthur T. Johnson, Design Of Biomedical Devices and System. 3th Edition.CRC Press, 2015

Joseph D. Bronzino, Donald R. Peterson, Biomedical Engineering Fundamental. CRC Press, 2015

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