POLITEKNIK MALAYSIA

KEMENTERIAN PENGAJIAN TINGGI

KOLEJ KOMUNITI MALAYSIA

MEDICAL EQUIPMENT PARAMOUNT SAFETY

KU LEE CHIN
MARIANA ROSDI
RUSNANI YAHYA

ELECTRICAL ENGINEERING DEPARTMENT

MEDICAL EQUIPMENT PARAMOUNT SAFETY

Writers
Ku Lee Chin
Mariana Rosdi
Ts Rusnani Yahya

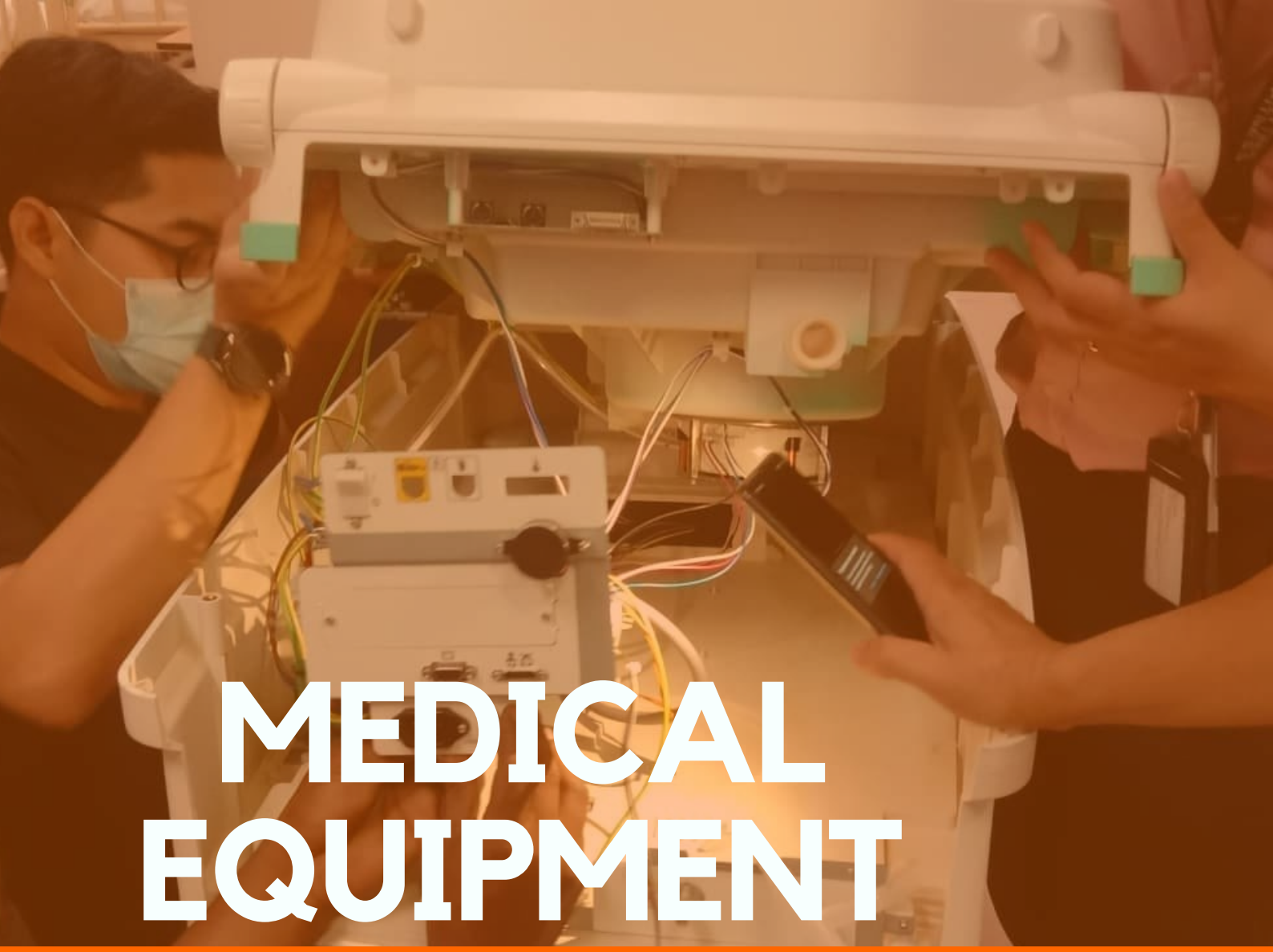
Editor
Mariana Binti Rosdi

e-ISBN : 978-967-2044-69-7

First Publication 2021

Published by:

UNIT PENERBITAN
Politeknik Sultan Salahuddin Abdul Aziz Shah
Persiaran Usahawan,
Seksyen U1,
40150 Shah Alam
Selangor
Telephone No.: +603 5163 4000
Fax No. : +603 5569 1903



MEDICAL EQUIPMENT PARAMOUNT SAFETY

ALWAYS TAKE PREVANTIVE MEASURES

THE BIOMEDICAL ENGINEERING EBOOK

MEDICAL SYSTEM PRACTICE

Meet YOUR Expert

Mrs Ku Lee Chin
Lecturer of Bachelor Medical Electronics Engineering Technology
lohleechin1@gmail.com

BE KIND TO YOUR MIND

Master of Technic And Vocational Education
University Technology Malaysia (UTM)
Bachelor of Electrical Engineering Medical Electronics)
University Technology Malaysia (UTM)

Mrs Mariana Rosdi
Lecturer of Diploma Medical Electronics Engineering
annemariarose77@gmail.com

BE SMART TO YOUR DEVICES

Master of Technic And Vocational Education
Kolej Universiti Tun Hussein Onn (KUiTTHO)
Bachelor of Electrical Engineering Medical Electronics)
Kolej Universiti Teknologi Tun Hussein Onn (KUiTTHO)

Ts Rusnani Yahya
Lecturer of Diploma Medical Electronics Engineering
rusnani@psa.edu.my

BE A RESPONSIBLE USER

Master of Science (Mechanical Engineering)
University Technology Malaysia (UiTM)
Bachelor of Electrical Engineering Medical Electronics
University Tun Huseein Onn Malaysia (UTHM)

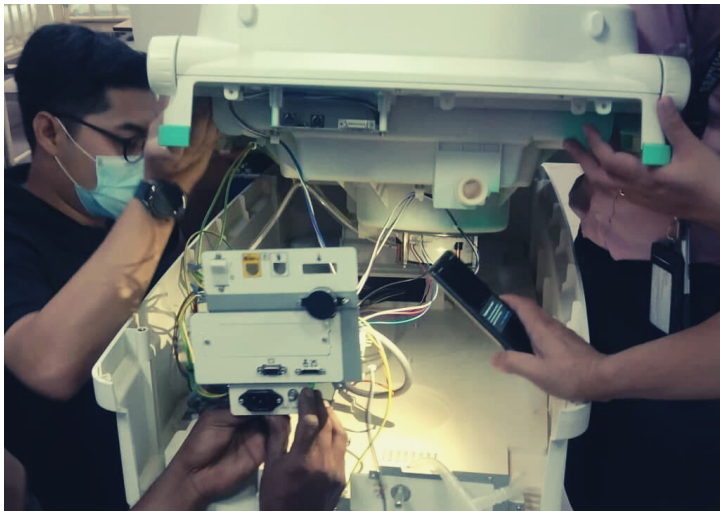
PREFACE

This ebook provides a foundation for biomedical engineering standard and regulation knowledge and professional practices that will be used and applied to medical equipment and human body as well. Globally recognized standard and regulation medical engineering is becoming the key issue for the electrical safety procedure test that meet the safety level of users and patients physiological effect. It helps on health system develop and assess important topics such as infection prevention and control, medical equipment maintenance and prevention & precaution maintenance.

Through lectures, medical workshops, and laboratory experiments, students will gain standard knowledge and practice skills in areas such as medical good practices standards from the International Electrotechnical Commission (IEC) and Underwriters Laboratories (UL), leakage currents, electrical safety test procedures and hazards in hospitals, and so on.

Biomedical engineering is a specialized field that has developed over centuries of practice. This eBook will teach you the fundamentals of electrical safety testing of medical equipment and how to apply what you've learned to improve the quality of services you give to the public.

The Electrical Safety Tests and Standards are intended to protect us against the natural tendency of complicated systems to go wrong at some point. The use of these electrical medical equipment requires strict adherence to these guidelines. At the end of the day, all of this testing and compliance isn't about product quality or mindless adherence to legislated protocols; it's about the value of human health and safety, which is what the medical sector is all about.



CONTENT

CHAPTER 1

“ People say that accidents are due to human error, which is like saying falls are due to gravity”.

Trevor Kletz

CHAPTER 1
MEDICAL DEVICES SAFETY STANDARD

INTRODUCTION

A medical device is any product used to diagnose, cure, or treat a condition, or to prevent disease. They range from small and simple, like a blood glucose meter, to large and complicated, like a ventilator.

To use medical devices safely. Medical devices shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

What medical device means?

In general terms, a medical device is any device that is intended for medical purposes. These devices help healthcare providers to diagnose and treat patients, helping patients to overcome illness or disease and improving quality of life.

Medical Electrical Equipment

A device (include applied parts) connected to a particular mains supply of power that uses the transfer of energy to or from the patient or displays an energy transfer of this sort in order to diagnose, treat or monitor the patient

- THERAPEUTIC EQUIPMENT
- DIAGNOSTIC EQUIPMENT
- RADIOLOGY EQUIPMENT
- LIFE-SUPPORT EQUIPMENT
- IMAGING EQUIPMENT
- LABORATORY EQUIPMENT

Medical Electrical System

Combination of equipment of which at least one is classed as medical electrical equipment, and such as specified by the manufacturer to be connected by functional connection or use of a multiple portable socket-outlet.

EXERCISE

1. Name the type of equipment below :
   a) Operating Light
   b) Ultrasound
   c) Patient monitor
   d) Centrifuge

2. What is a different between MEE and MES?

SAFETY STAGES FOR MEDICAL EQUIPMENT

1 DESIGN (IEC60601)

- Subject to initial & clinical trials
- Electronic & Mechanical design of product must be in line with IEC60601

2 TYPE TEST (IEC60601)

- Hardware & Software of the product verified against design
- Product can be marked after CE marks is obtained

3 END OF LINE TEST (Production)

- The product being assembled,tested & inspected
- Release into market place

4 ACCEPTANCE (T&C)

- Verify the device delivered in acceptable condition, without available with accessories
- Product can be marked after CE marks is obtained

5 OPERATOR TRAINING (user training)

- How to operate the device with the correct way. Reference: user manual.
- Safety Alert

6 MAINTENANCE (IEC62353)

Planned Preventive Maintenance (PPM) referred as Pro Active Maintenance

- Scheduled inspections & test to verify the safety & operation are within acceptable level.

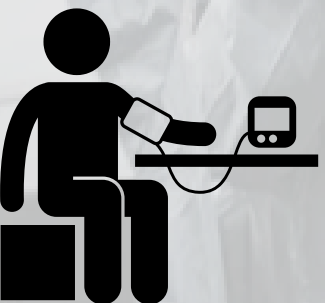
7 REPAIR (IEC62353)

- Referred as Re-Active Maintenance
- Device create a fault or require an upgrade, then it will susceptible to further inspections and testing

8 DECOMMISSIONING

- Device (depends on its function & material content) required to follow a recycling process
- Device can be made available to other organisations

(2nd lifecycle can start at the acceptance stage)



Standard Requirement for Medical Devices

1. International Electrotechnical Committee: IEC 60601, IEC 61010, IEC 62353 and etc
2. Malaysian Standards : MS 2058 Code of practice for good maintenance active medical device
3. Medical Device Act and Regulation 2012 (Act 737)
4. International Standardization Organization: ISO 13485 Medical devices
5. Good Distribution Practice for Medical Devices 2015 (GDPMD)

LET'S DISCUSS

Why IEC standard is required?

1 IEC 60601

2 IEC 61010

3 IEC 62353

- IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment, published by the International Electrotechnical Commission. First published in 1977.

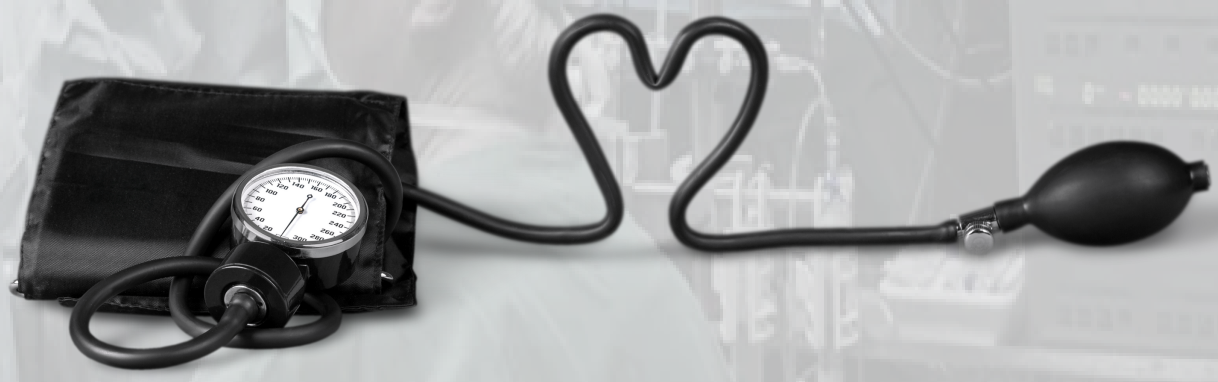
- is a family of standards whose scope covers the safety, essential performance and electromagnetic compatibility of Medical Electrical Equipment and Systems.

IEC

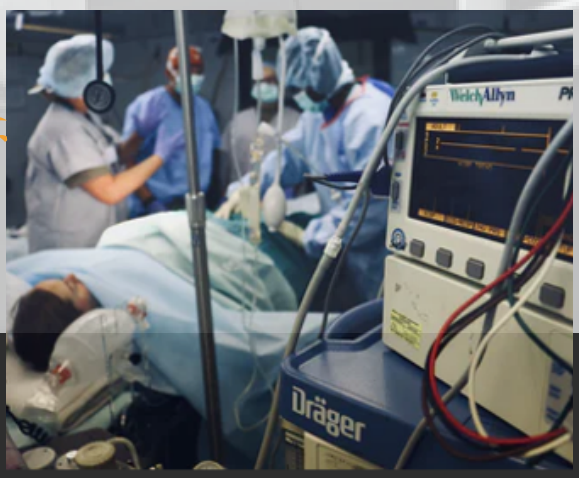
INTERNATIONAL ELECTROTECHNICAL COMMITTEE

Equivalent Standard

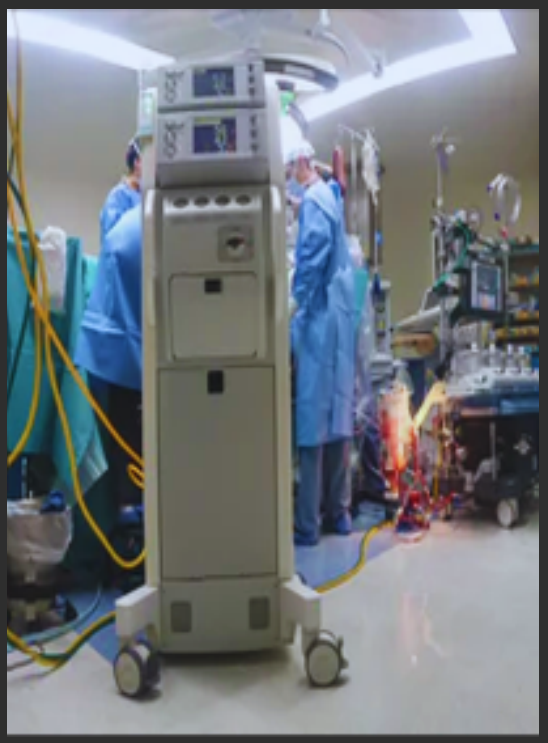
- EN 60601 – Europe
- BS EN 60601 – UK
- UL2601 - USA
- CSA C22.2 – Canada
- AS/NZ 3200-1 - Australia /New Zealand
- OEVE-MG 601 part 1 - Austria
- SFS 3720 (with dev)- Finland
- NF C74-011 – France
- VDE 0750 teil 1 - Germany
- CEI 62.5 - Italy
- NEN - Netherlands



IEC 60601 : MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR SAFETY (1977)



- Widely known as IEC 601.
- Manufacturers of medical equipment are required to test to IEC 601 to ensure that the design of the equipment is intrinsically safe.
- The standard specifies the type testing requirements for protection against potential electric hazards including protective earthing (earth continuity), earth leakage current, patient leakage current and patient auxiliary current.
- As a type-testing standard, it describes a range of measures that are intended to prove the safety of an item of electromedical equipment during its expected useful life.

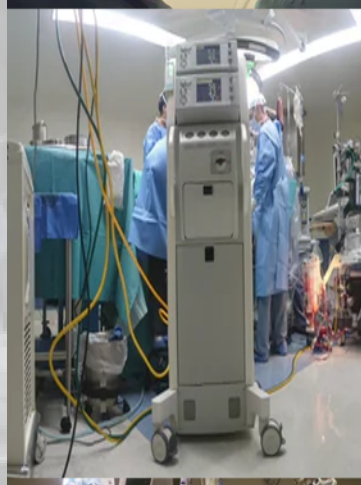


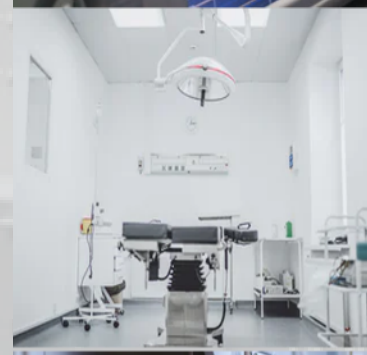
LET'S DISCUSS

Is IEC 60601 mandatory?

What does IEC 60601-1 compliant mean?

IEC 62353 : Medical Electrical Equipment – recurrent test and test after repair of medical electrical equipment (2007)

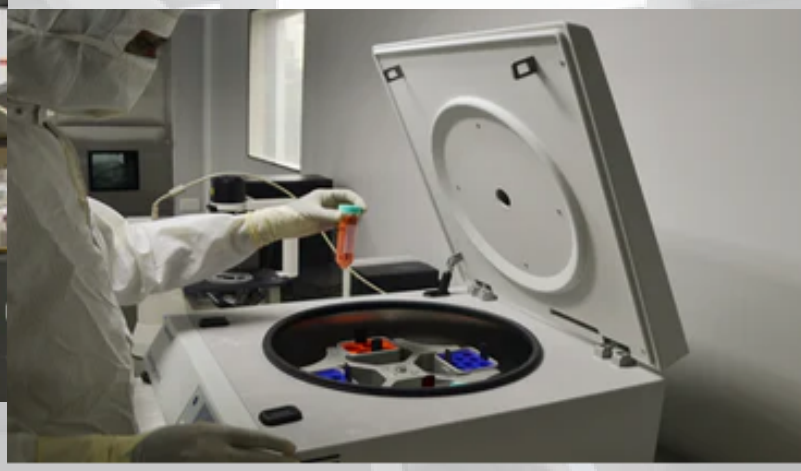




- To provide a uniform standard that ensures safe practice and reduces the complexity of the current IEC 60601-1 standard.
- Ensuring the in-service electrical safety of electromedical equipment and systems
- The standard is an attempt at harmonizing the safe operation and testing of ME Equipment and ME Systems, whilst respecting local requirements and meeting increasing demands for risk management.
- IEC 62353 summarized electrical safety testing into a clearly defined structure, testing for leakage resulting of potential failures on the input (power supply) and output (applied parts). All tests are carried out under single fault condition only, such as open earth (class 1 equipment only), mains on applied parts (applied part leakage) and open neutral (alternative method).

Germany & Austria – IEC 62353 has replaced the previous editions of VDE/ODE 751-1.

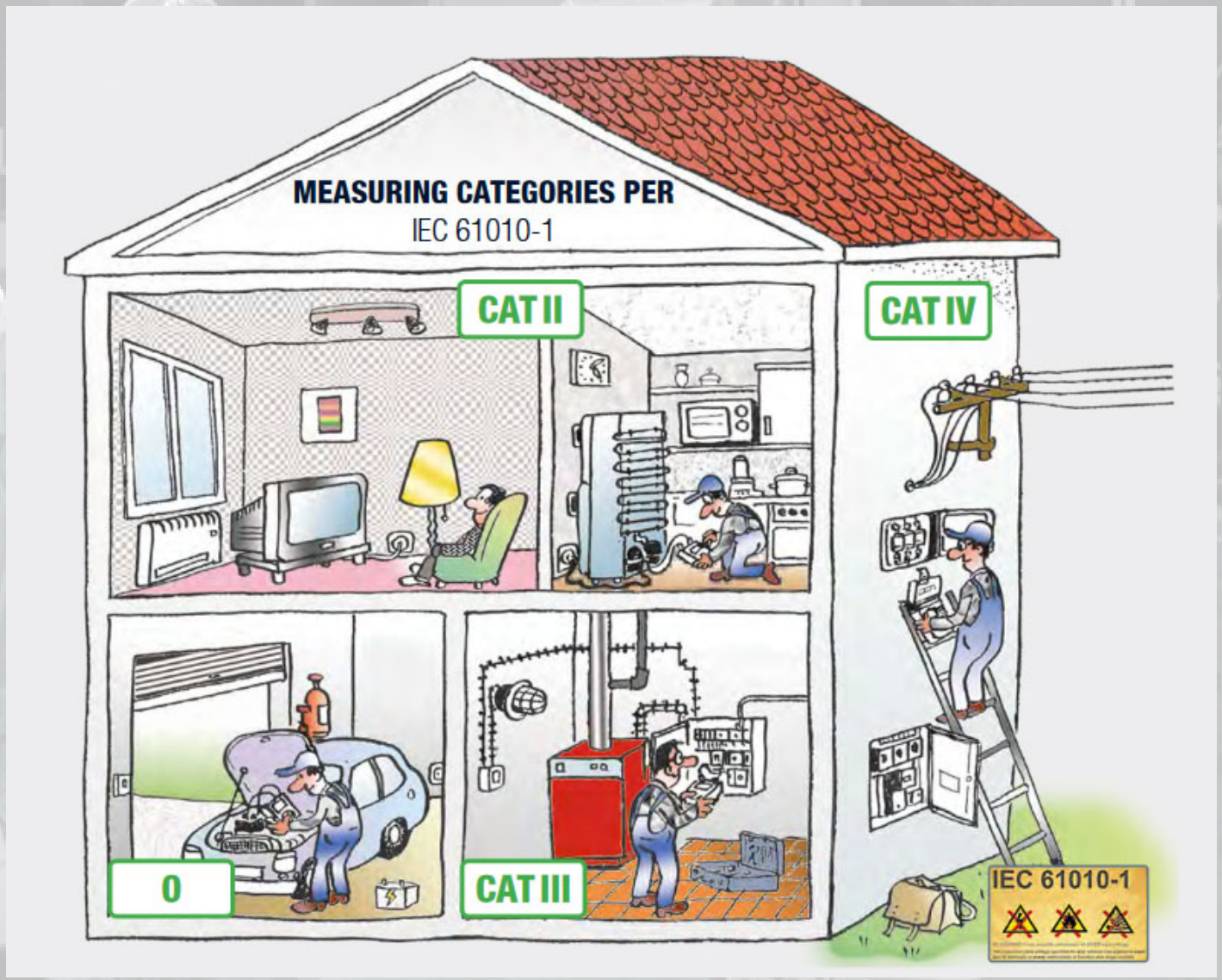
Ministry of Health has adopted IEC 62353 (MS 62353) in its Medical Device Act as the minimum test requirement for medical electronic device.



IEC 61010

Safety requirements for electrical equipment for measurement, control and laboratory use

The purpose of the standard is to minimize hazards to operators and the surrounding environment and equipment.



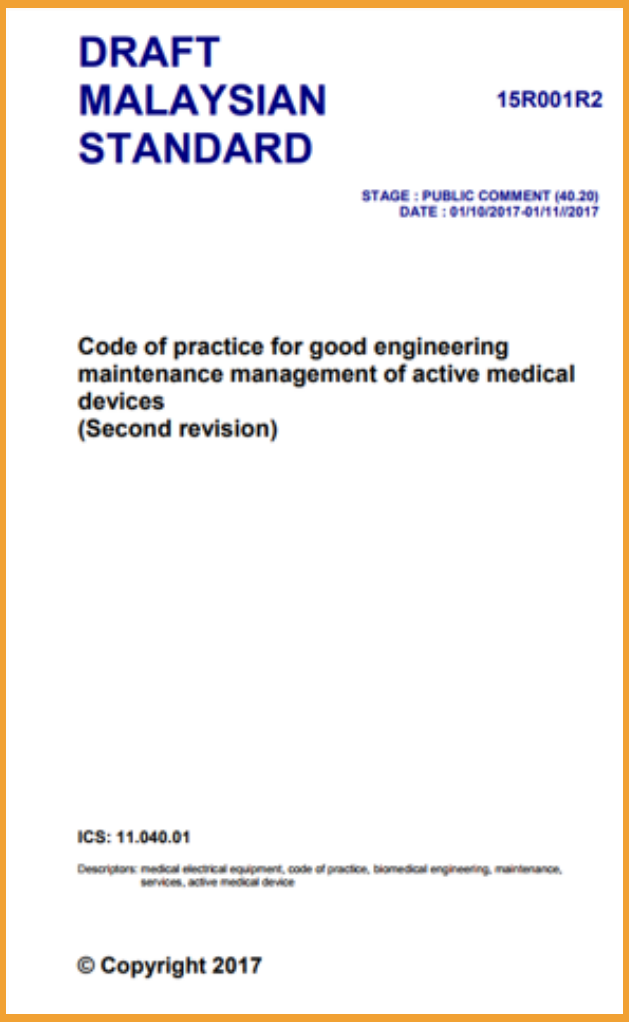
Malaysian Standards

MS 2058 : Code of practice for good maintenance active medical device

Scope

This Malaysian Standard prescribes the active medical devices placed for use in any healthcare facility or any other facility which requires maintenance.

This standard is not applicable to any medical device placed and used in any facility not intended to be used on human



DRAFT
MALAYSIAN
STANDARD

15R001R2

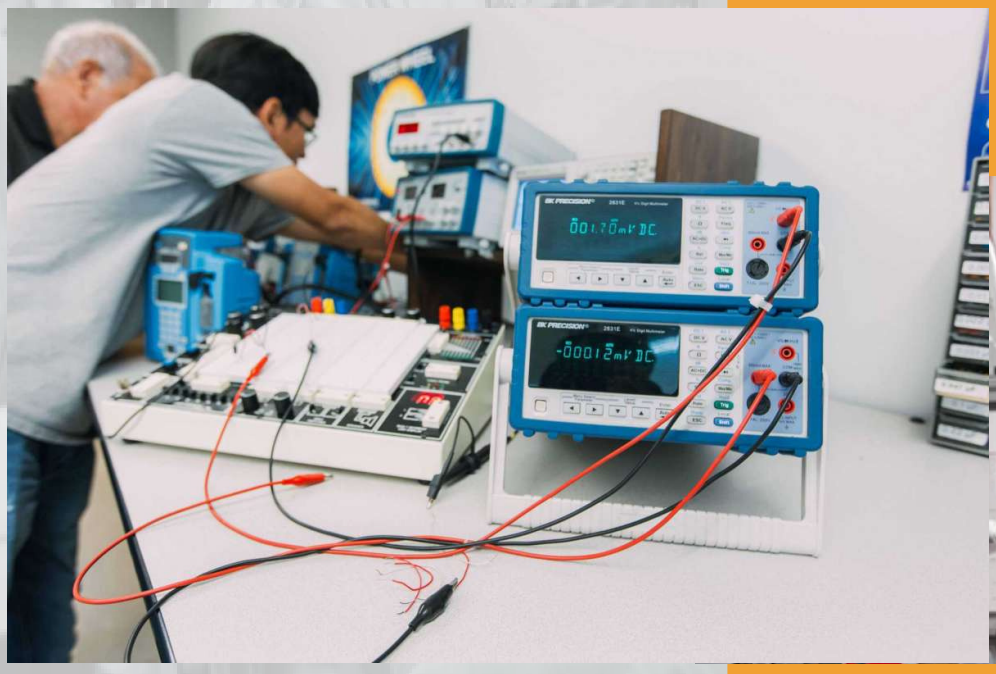
STAGE : PUBLIC COMMENT (40.20)
DATE : 01/10/2017-01/11//2017

Code of practice for good engineering maintenance management of active medical devices
(Second revision)

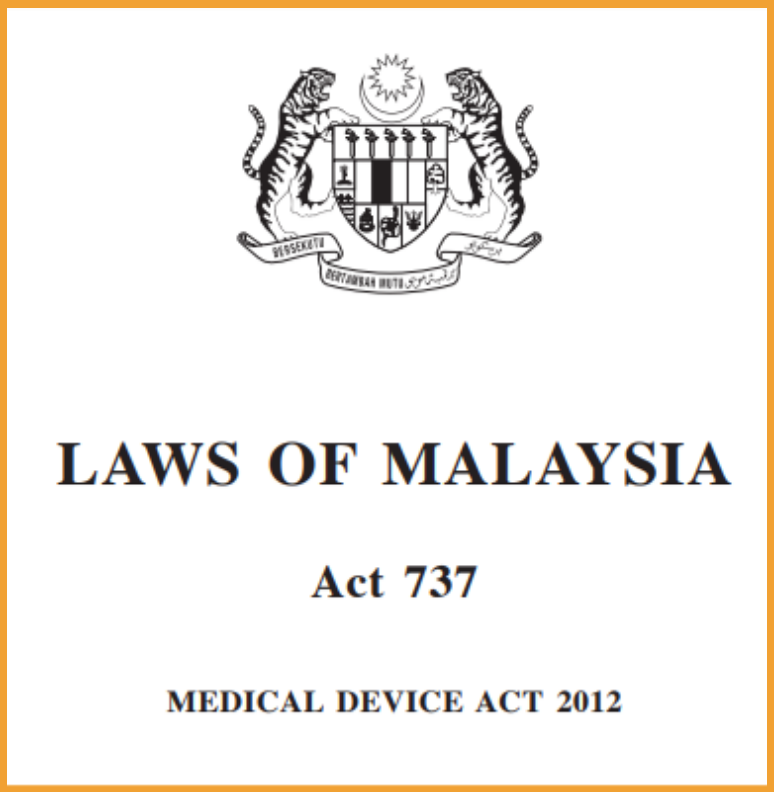
ICS: 11.040.01

Descriptors: medical electrical equipment, code of practice, biomedical engineering, maintenance, services, active medical device

© Copyright 2017



Medical Device Act and Regulation 2012 (Act 737)



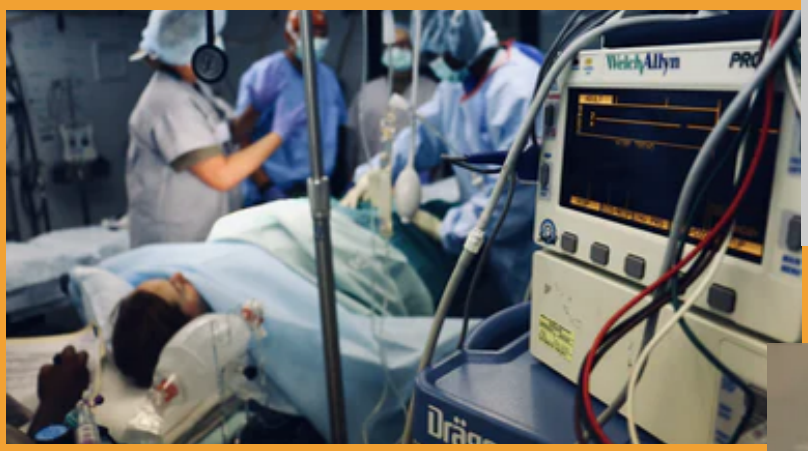
LAWS OF MALAYSIA

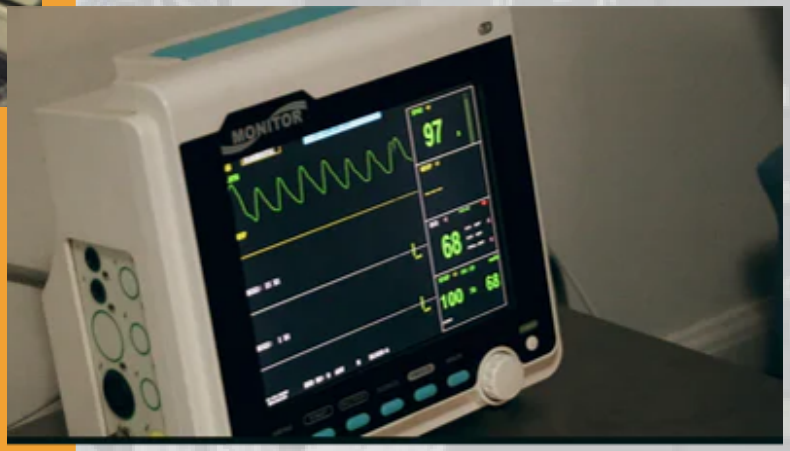
Act 737

MEDICAL DEVICE ACT 2012

Contents :

1. Registration of Medical Device and Conformity Assessment Body
2. License and Permit
3. Appeal
4. Enforcement





International Standardization Organization

Medical devices — Quality management systems(QMS) : Requirements for regulatory purposes

A QMS conforming with ISO 13485 requirements is a documented set of interrelated processes, including any forms or templates, that establish, implement, and maintain the provisions outlined in the requirements of the standard with the aim of meeting customer and applicable regulatory requirements for businesses operating in the medical device sector.

Is ISO 13485 a regulation or standard?

ISO 13485 is the main Quality Management System (QMS) standard for medical devices, although several countries have their own set of regulations. As an example, the United States plans to harmonize the Food and Drug Administration (FDA) requirements for medical devices with ISO 13485. ... It is NOT a standard for products.

Good Distribution Practice for Medical Devices 2015 (GDPMD)

Objective

to ensure the quality, safety and performance of medical device during all aspects of medical device supply-chain, which include, but not limited to, product sourcing and procurement; transportation and delivery; storage; installation, commissioning, service and maintenance, calibration and after sales service; tracking, documentation and record-keeping practices.

The GDPMD requirements consists of 6 parts:

With the effective date (1 July 2013) of Act 737 and Medical Device Regulations 2012, manufacturers and distributors of medical devices are required to apply for their establishment licence to continue carrying out their manufacturing, distribution or importing activities.

Manufacturers require ISO13485 Medical Devices Quality Management System certification whereas Distributors and Importers require Good Distribution Practice for Medical Devices (GDPMD) certification prior to applying for their Establishment Licence, as provided in Section 80, Act 737.
(source: www.mdb.gov.my)

EXERCISE

1. What are the IEC categories?
2. What are IEC standards and IEC ratings?
3. What is a collateral standard for IEC60601?
4. What is the current version of IEC 60601-1?
5. What IEC 61010?
6. Explain briefly about the challenges and changes of IEC 61010?
7. Why do you need ISO 13485?
8. How many sections does ISO 13485 have?
9. Does ISO 13485 replace ISO 9001?
10. List the benefits of GDPMD Certification
11. How to apply the Good Distribution Practice for Medical Devices (GDPMD)?

PICK 5 QUESTIONS AND DISCUSS THE ANSWER WITH YOUR LECTURER. SCAN THE QR CODE

CHAPTER 2

“For safety is not a gadget but a state of mind.” –

Eleanor Everet

CHAPTER 2

ELECTRICAL SAFETY TESTING OF MEDICAL EQUIPMENTS

INTRODUCTION

Medical technology has substantially improved health care in all medical specialties and has reduced morbidity and mortality for critically ill patients.
However, the increased complexity of medical devices and their utilization in more procedures result in about 10,000 device- related patient injuries in USA.

RESULTS & DISCUSSION

Most of these injuries are attributable to:

- ***improper use of devices;***
- ***as a result of inadequate training;***
- ***lack of experience;***
- ***Medical personnel rarely read user manuals until a problem has occurred;***
- ***Furthermore, medical devices eventually fail;***
- ***so engineers must develop fail-safe designs.***

PATIENT SAFETY

A fundamental component for Universal Health Coverage

HEALTHCARE ECOSYSTEM

Successful healthcare delivery depends both on the availability of medical personnel and health technologies. Medical devices are an important cog in the healthcare delivery system. They equip health service providers with the necessary tools to perform their job of providing quality healthcare effectively.

HAZARDS!!

A hazard is any biological, chemical, mechanical, environmental or physical agent that is reasonably likely to cause harm or damage to humans, other organisms, or the environment in the absence of its control.

1 HAZARDS ON MEDICAL EQUIPMENTS

- Medical electrical equipment can present a range of hazards to the patient, the user, or to service personnel.
- The root causes for injures involving medical equipment include Human Error, Faulty Equipment Design & Poor Maintenance.

2 COMMON HAZARDS OF MEDICAL EQUIPMENTS

- These can range from insecure fittings of controls to loose fixings of wheels on equipment trolleys.
- The enclosure of the device must be sufficiently strong to retain its integrity under conditions of normal wear and tear.
- Moving parts which could produce a safety hazard must be suitable guarded to prevent access.
- Sharp Edges - The device must not have sharp edges, corners, etc.
- Stability - Medical devices must not overbalance when tilted to an angle of 10°.

3 FIRE OR EXPLOSION

- All mains powered electrical equipment can present the risk of fire such as internal or external short circuits faults.
- In certain environments, such fires may cause explosions. Many of the medical gases in use vigorously support combustion.

4 EXCESSIVE OR INSUFFICIENT OUTPUT

- In order to perform its desired function equipment must deliver its specified output either too high or too low an output for surgical diathermy or therapy units
- It would clearly be hazardous or inadequate therapy, cause patient injury or delay patient recovery.
- Medical electrical equipment is life-supporting or monitors vital functions, the absence of function could threaten life.
- This recommends the use of proper test equipment to verify the correct operation of the equipment.

5 INFECTION

- Medical equipment that has been inadequately decontaminated after use may cause infection through the transmission of microorganisms to any person who subsequently comes into contact with it.

6 MISUSE

- Misuse of equipment is one of the most common causes of adverse incidents involving medical devices. Such misuse may be a result of inadequate user training or of poor user instructions.
- Do not modify or alter devices, unless in the instructions.

7 RADIATION

- The medical use of ionizing radiations (diagnosis or therapy) may not only result in irradiation but may also result in some degree of exposure others
- Although many patients benefit from radiation's ability to destroy cancer cells or capture real-time images of the human body, radiation can harm healthy cells wherever it enters the body.

8 SPURIOUS ELECTRIC CURRENTS

- Electrical hazards such as leakage current shock are common to all types of medical electrical equipment and can minimize the use of safety testing regularly.

Safety in Clinical Environment

•Electrical hazards:
Electrical shocks (micro and macro) due to equipment failure, failure of power delivery systems, ground failures, burns, fire, etc.

•Mechanical hazards:
mobility aids, transfer devices, prosthetic devices, mechanical assist devices, patient support devices

•Environmental hazards:
Solid wastes, noise, utilities (natural gas), building structures, etc.

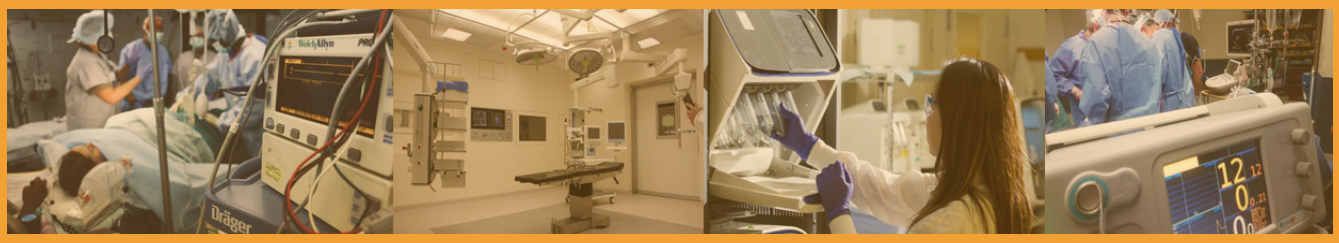
•Biological hazards:
Infection control, viral outbreak, isolation, decontamination, sterilization, waste disposal issues

•Radiation hazards:
Use of radioactive materials, radiation devices (MRI, CT, PET), exposure control

TERMINOLOGY

LEAKAGE CURRENT (UL)

"Electric current which flows through a person upon contact, between accessible parts of an appliance and (1) ground, or (2) other accessible parts of the appliance."



"Electric current through a human body or an animal body when it touches one or more accessible parts of an installation or of equipment."

TOUCH CURRENT (IEC 60990)

PHYSIOLOGICAL EFFECT OF ELECTRICITY ON HUMAN BODY

- Electrical stimulation !
- Resistive heating !
- Electrochemical burns!

- **Uncontrollable muscle contraction or unconsciousness**
- **Ventricular fibrillation**
- **Injury to tissues**
  - **– Electrical burns**
  - **– Chemical burns (for dc currents)**
  - **– Muscular paralysis, injuries, pain and fatigue**
  - **– Breaking the bones and tendons**
- **Secondary (side) effects as falling of the ladder or spilling hot oil etc.**

Important Factors

(Neuro-muscular)

· **Threshold of Perception:**
Minimal current
that an individual can detect.

· **Let go current:**
Maximal current at which a person can let go voluntarily

· **Factors involved:**
– Frequency of current density
– Duration of application
– Body size
– Point of entry
– Gender (male or female)

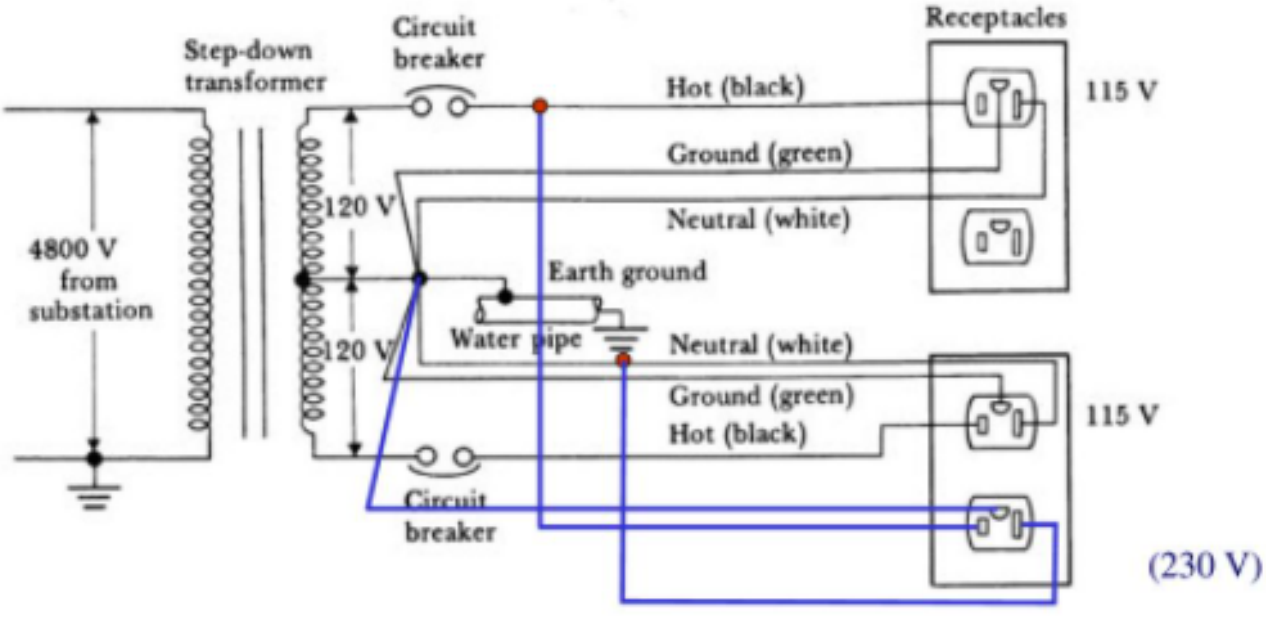
- Electrolysis: (nearly d.c.)
- Neuromuscular effect: (10-100Hz)
- Heating: (100kHz-30MHz)

10,000 DEVICE RELATED INJURIES IN THE US EVERY YEAR! TYPICALLY DUE TO!!

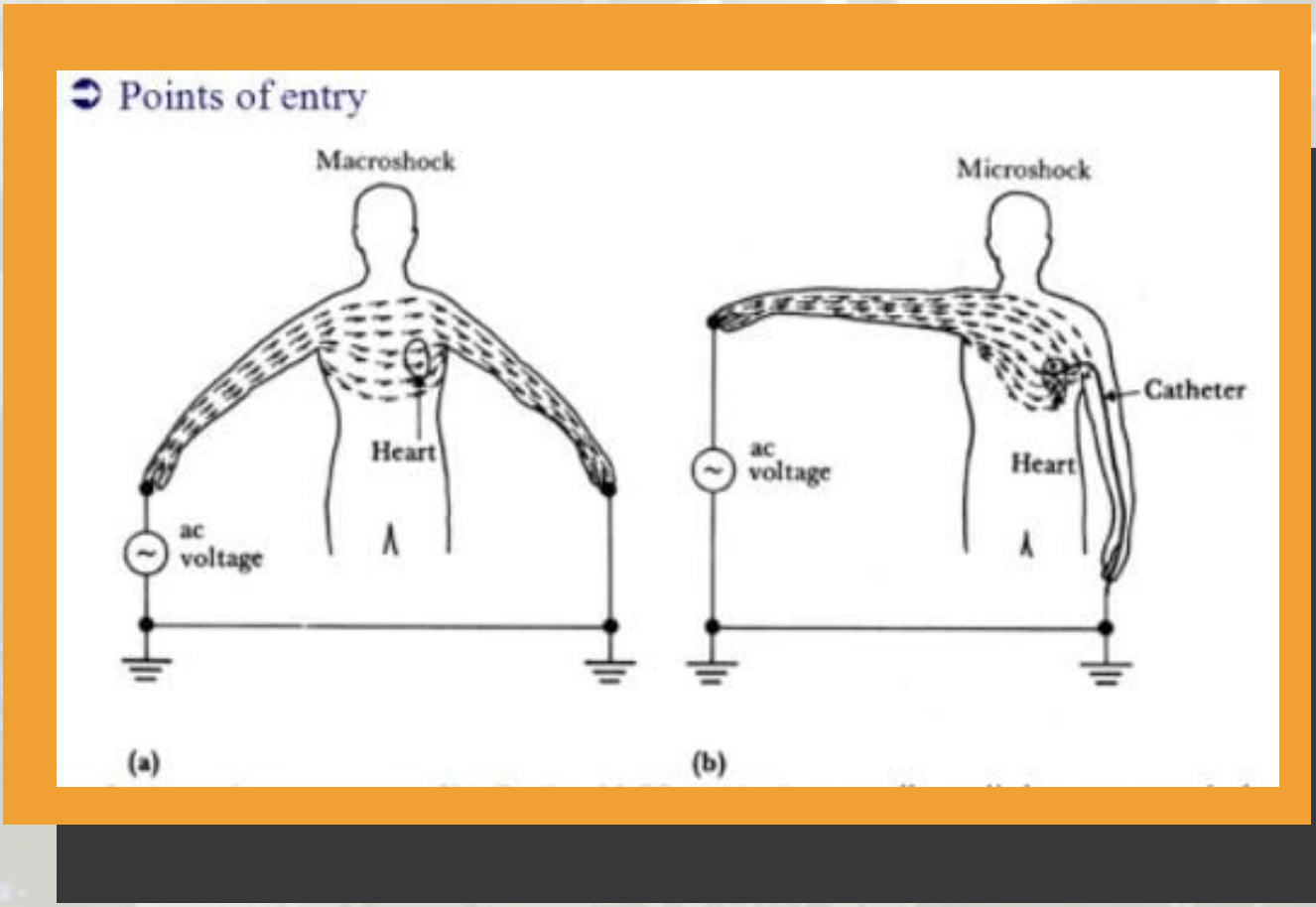
- Improper use
- Inadequate training
- Lack of experience
- Improper (lack of) use of manuals
- Device failure

PROTECTION: POWER DISTRIBUTION

- Grounding system
- Isolated power distribution system
- Ground-fault circuit interrupters



Simplified electric-power distribution for 115 V circuits. Power frequency is 60 Hz



A) "MACROSHOCK"
(ELECTRICAL SHOCK- NON INVASIVE)

• 2 points of body contact (skin surface of the body)

• Many devices have metal chassis or cabinet that can be touched dangerous.

.The safety limit is below 5 mA

•High value current level

(> 5mA – feeling pain)

>50mA – cause VF

.

B) "MICROSHOCK"
(CARDIAC SHOCK -INVASIVE)

• If the connection is insulated all the way except at the heart, a very small current can induce ventricular fibrillation thru catheter

• Current density at the point of entry can be quite high, a current level as low as more than 20 uA can induce ventricle fibrillation

•The widely accepted safety limit is less than 10 uA

Physiological Effect	Gender	DC	60Hz AC	10 kHz A
Slight sensation	Men	1 mA	0.4 mA	7 mA
	Women	0.6 mA	0.3 mA	5 mA
Threshold of perception	Men	5.2 mA	1.1 mA	12 mA
	Women	3.5 mA	0.7 mA	8 mA
Pain, voluntary muscle control "Let-go"	Men	62 mA	9 mA	55 mA
	Women	41 mA	6 mA	37 mA
Pain, involuntary muscle control	Men	76 mA	16 mA	75 mA
	Women	51 mA	10.5 mA	50 mA
Severe pain, difficulty breathing, 99.5% percentile muscle control lost	Men	90 mA	23 mA	94 mA
	Women	60 mA	15 mA	63 mA
Ventricular fibrillation (3 seconds)	Men	500 mA	100 mA	
	Women	500 mA	100 mA	

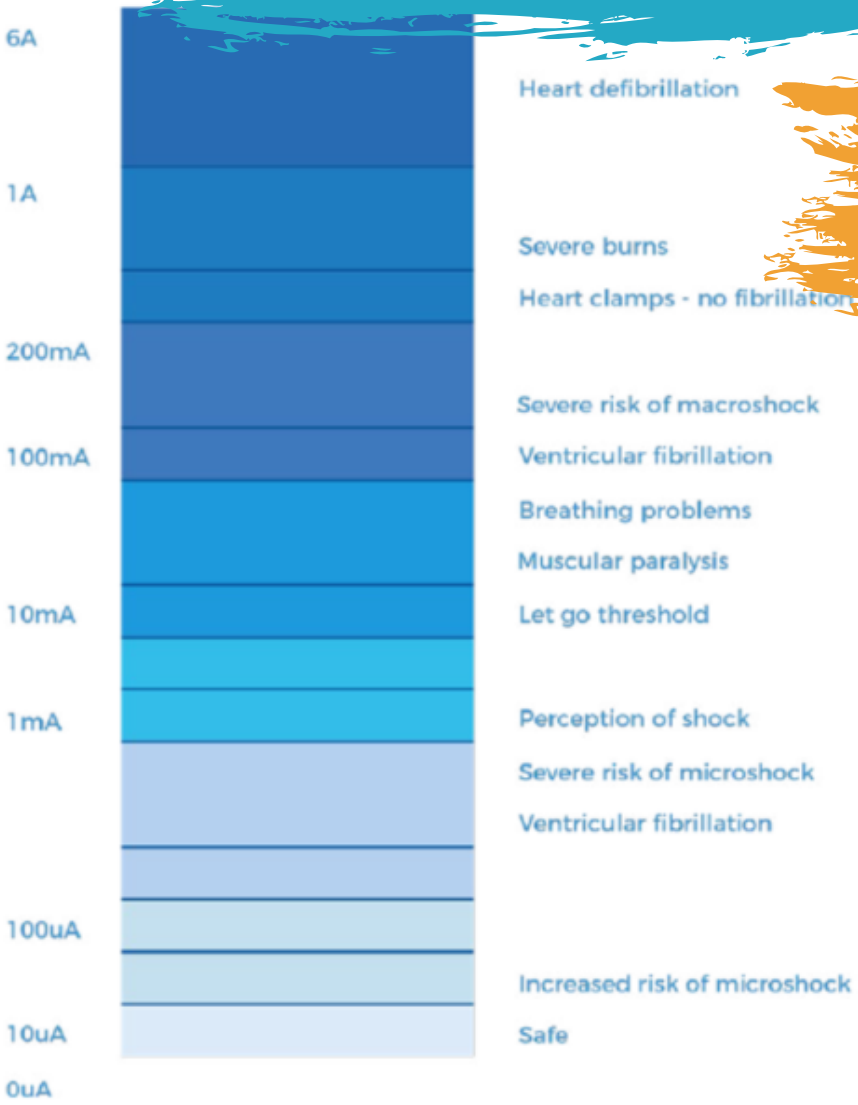
MACROSHOCK

MACRO-SHOCK OCCURS WHEN CURRENT PASSES THROUGH THE BODY VIA CONTACT WITH THE SKIN AND THIS ASPECT APPLIES TO ALL TYPES OF ELECTRICAL SAFETY OF ME

EXTERNAL DRY SKIN HAS HIGH RESISTANCE, WHICH LIMITS CURRENT FLOW THROUGH THE BODY. MANY MEDICAL PROCEDURES INVOLVE MOISTENING THE SKIN, WHICH LOWERS SKIN RESISTANCE SIGNIFICANTLY, SUCH AS ULTRASOUND GEL AND SURGICAL APPLICANTS.

MICROSHOCK

Case Brief



Micro-shocks occur when invasive patient connections are placed across or in close proximity to myocardial tissue and nerves and blood components have relatively low resistance. Therefore, very small levels of electrical current can induce ventricular fibrillation because tissue impedance below the skin surface is low and current is focussed at an invasive location.

Challenges:There are two distinct types of electrocution which need to be considered in healthcare environments: macro-shock and micro-shock.

Several corresponding studies have recognised the physiological effects of electrical current under macro-shock and micro-shock conditions, and international standards reflect these results in their safety criteria. In 1971 “Ralph Nader’s Most Shocking Exposé,” revealed that about 1,200 people a year were dying in hospitals from the effects of micro-shock. Several years later, in 1977, the safety standard IEC 60601 was formed and parts of it have survived to this day. Further developments and revisions have led to year on year reductions in death from both macro and micro-electrocution.

Macroshock: Patients are often in constant physical contact with medical electrical (ME) equipment, both directly and indirectly e.g., electrical monitoring systems and electrically powered beds. The results from macro-shock lead to loss of voluntary muscle control at currents as low as 10mA and ventricular fibrillation at currents of approximately 100mA.

Microshock: Death by micro-shock is known as micro-electrocution and both catheters and pacemakers carry this risk. It has been repeatedly estimated that currents of over 20 microamps can lead to micro-electrocution.

Physiological Effects of Touch Current

(sinusoidal, rms, 60 Hz)

- PERCEPTION (MICROAMPERES TO 0.5 MILIAMP)
- STARTLE REACTION – PAIN (> 0.5 MILIAMP)
- MUSCLE TETANIZATION (INABILITY TO LET GO) (> 5 MILIAMP)
- VENTRICULAR FIBRILLATION (> 50 MILIAMP)
- ELECTRICAL BURNS (> 70 MILIAMP)

PROTECTION !

Equipment Design

PATIENT'S ELECTRICAL ENVIRONMENT

Creating a Innovation and Smart Medical Device

- Reliable grounding for equipment
- Reduction of leakage current
- Double-insulated equipment (ground + insulated chassis)
- Operation at low voltages (battery powered Vs < 10V)
- Electrical Isolation through using isolated amplifiers
- Isolated heart connection

1. Electric Shock
   - Shock hazard exists between two conductors supplying either a 240 V or a 120-V appliance
   - A connection between hot conductor and any grounded surface poses a shock hazard since neutral is grounded

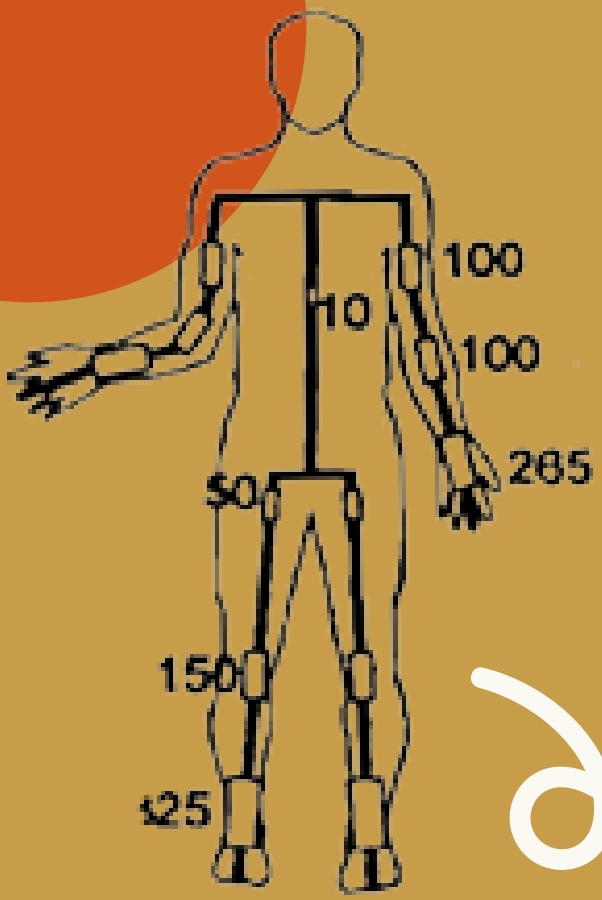
2. Microshock can also occur if sufficient potentials can exist between exposed conductive surfaces in the patient's environment.

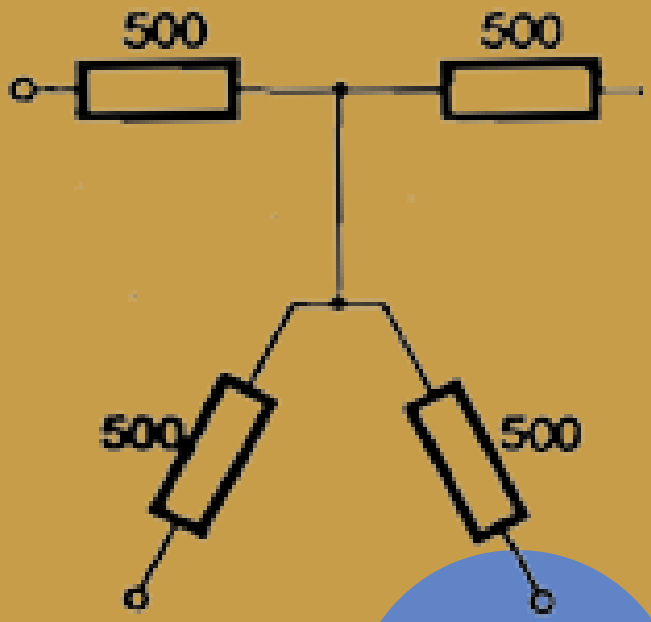
3. Maximal potentials permitted between any exposed conductive surfaces:
   - General-care areas: 500 mV under normal operation
   - Critical-care areas: 40 mV under normal operation

4. Each receptacle must be grounded

INTERNAL BODY RESISTANCE

Distribution of natural body resistance protection and a simplified equivalent diagram



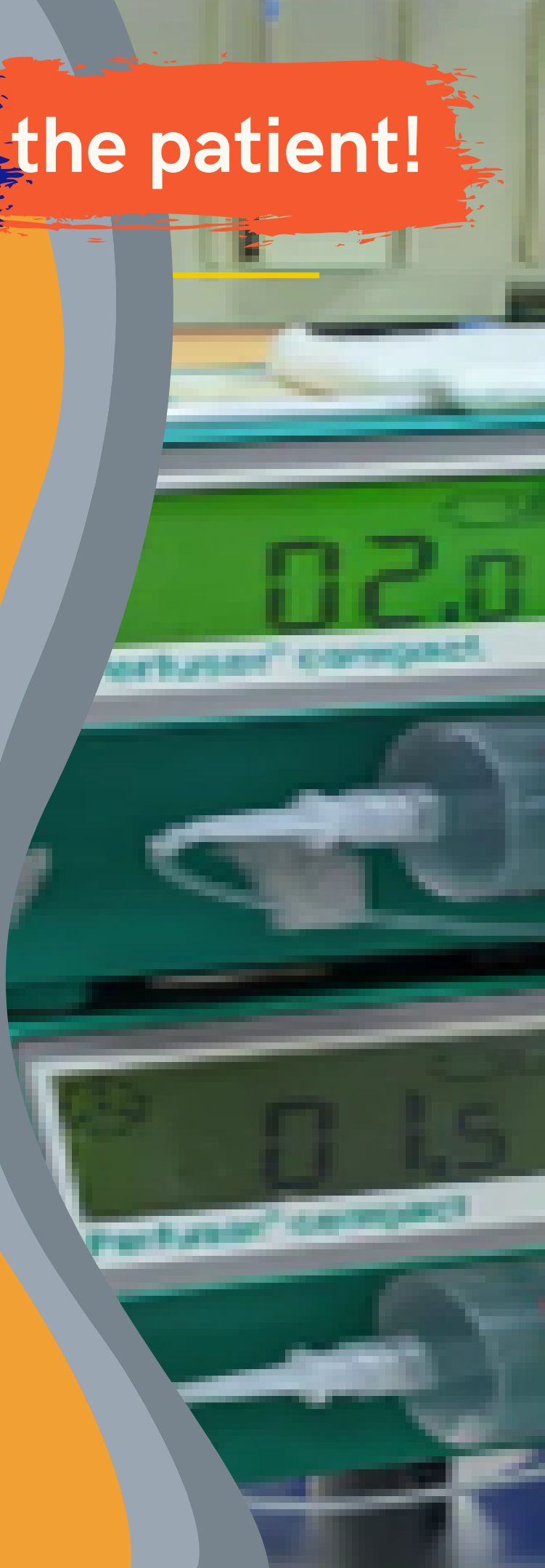


- Intact skin, Rk = 2-5kohm
- Damage skin, Ro (injuries, surgical skin) = 100 ohm - 1kohm

A hazard to the patient!

Isolated systems are now commonly used to protect against electrical shock in many areas, among them:

- intensive care units (ICUs)
- coronary care units (CCUs)
- emergency departments
- special procedure rooms
- cardiovascular laboratories
- dialysis units
- various wet locations



*1.***Earth leakage current** — Earth leakage current flows in the earth conductor of a protectively grounded piece of equipment.

2.Enclosure leakage current — Enclosure leakage current flows from an exposed conductive part of the enclosure to earth through a conductor other than the normal ground conductor.

Leakage Current Classifications

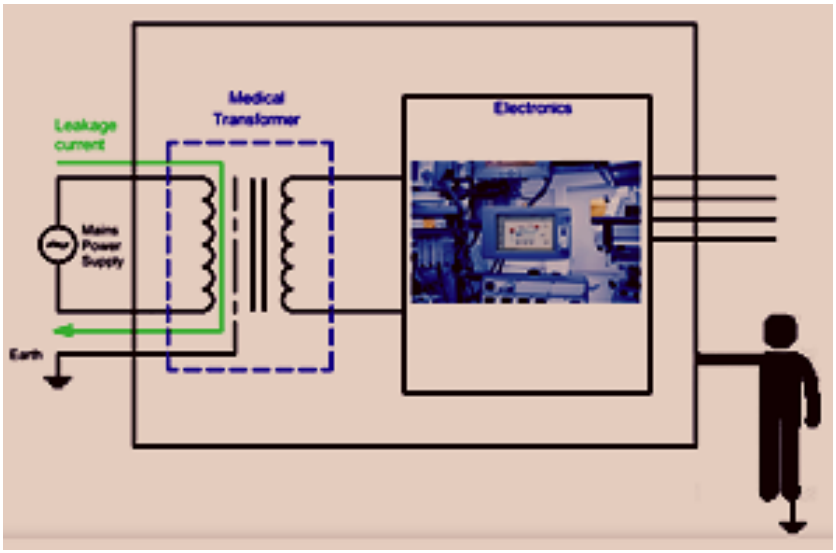
3.*Patient leakage Current* — Patient leakage current is the leakage current that flows through a patient connected to an applied part or parts.

4.*Patient auxiliary current* — Patient auxiliary current is the current that normally flows between parts of the applied part through the patient, which is not intended to produce a physiological effect.

Leakage Current Causes

Medical equipment that has direct physical contact with patients must limit its leakage current to the lowest prescribed levels in term of:

- **Earthed connections - touchable, conductive/metallic parts**
- **Insulation -**
  1. **Basic - providing sufficient dielectric strength**
  2. **Supplementary - additional second layer**
- **Current breakers**
- **Fuses**
- **Electrical safety testing**

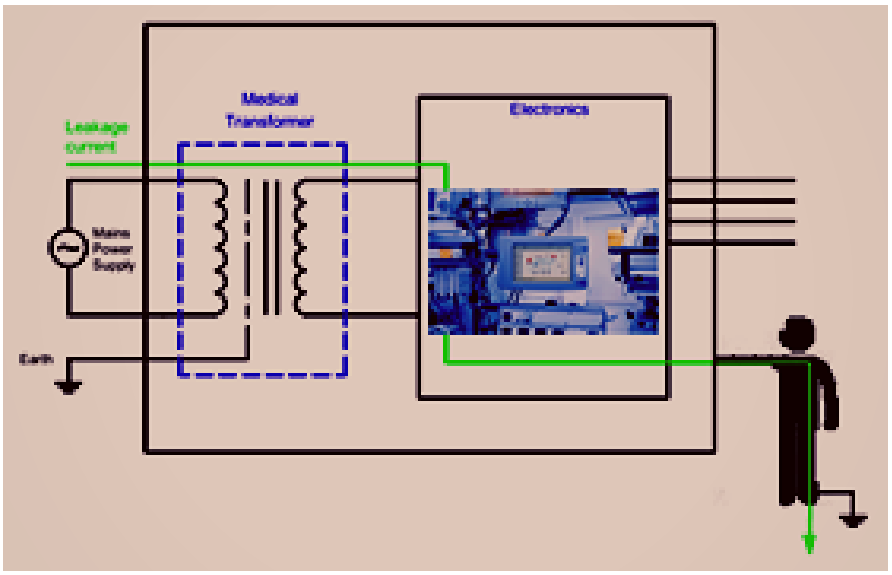


EARTH LEAKAGE CURRENT

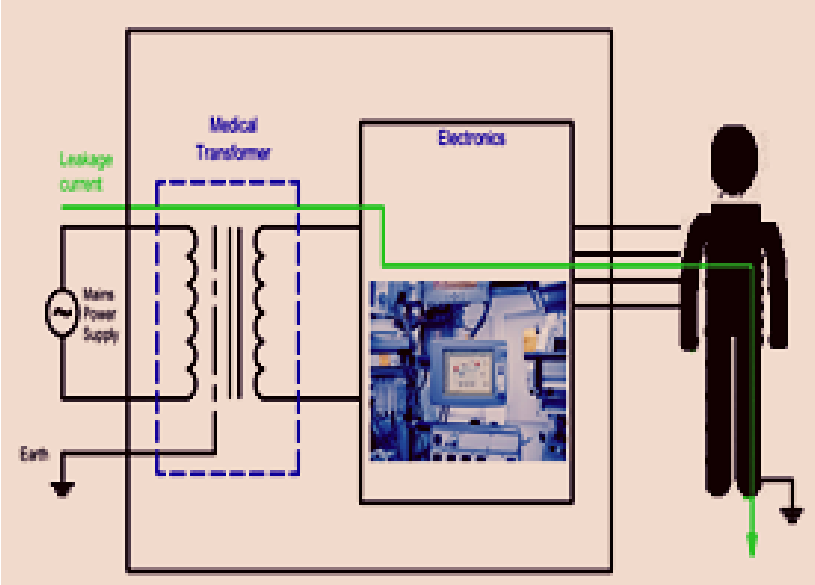
As long as the connection to earth remains closed, a person coming into contact with the metal enclosure of the equipment would be safe. Otherwise, the impedance to earth through the person becomes much lower, thus creating a shock hazard.

ENCLOSURE LEAKAGE CURRENT

Testing is usually conducted on points of the enclosure that are not intended to be protectively grounded to cover the unlikely possibility that a fault may exist.

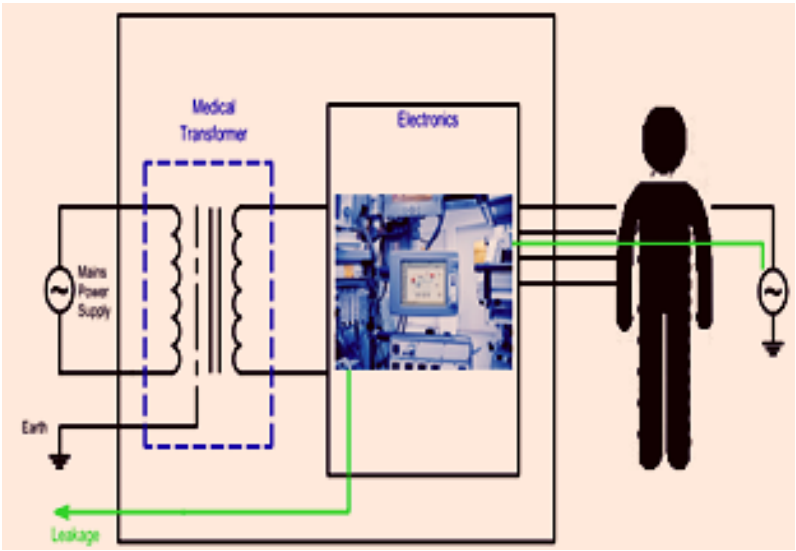


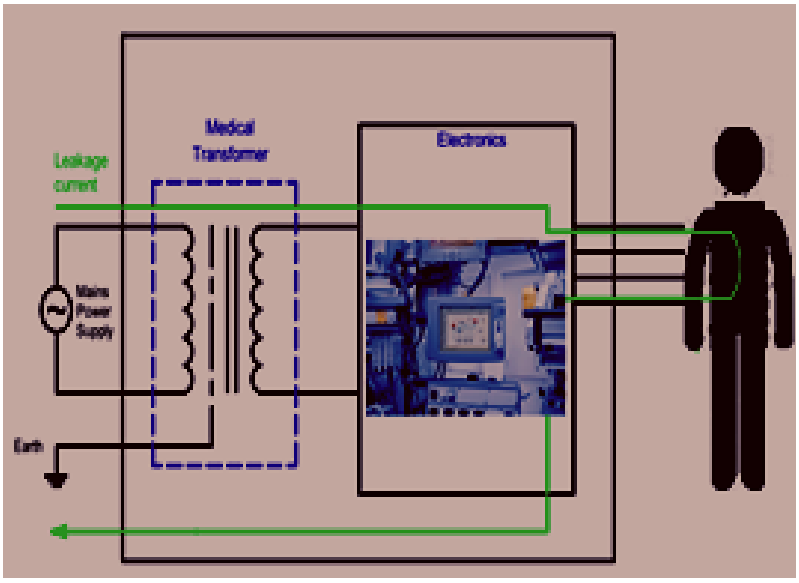
A. PATIENT LEAKAGE CURRENT PATH FROM EQUIPMENT



It can either flow from the applied parts via the patient to earth or from an external source of high potential via the patient and the applied parts to earth. As shown in figure A and B

B. PATIENT LEAKAGE CURRENT PATH TO EQUIPMENT





PATIENT AUXILIARY CURRENT

Patient auxiliary current is the current that normally flows between parts of the applied part through the patient, which is not intended to produce a physiological effect.

UL

THE OFFICIAL REGULATORY BODY FOR THE UNITED STATES, AS IT WAS APPOINTED BY THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA) TO BOTH TESTS AND CERTIFY ALL ELECTRONIC EQUIPMENT.

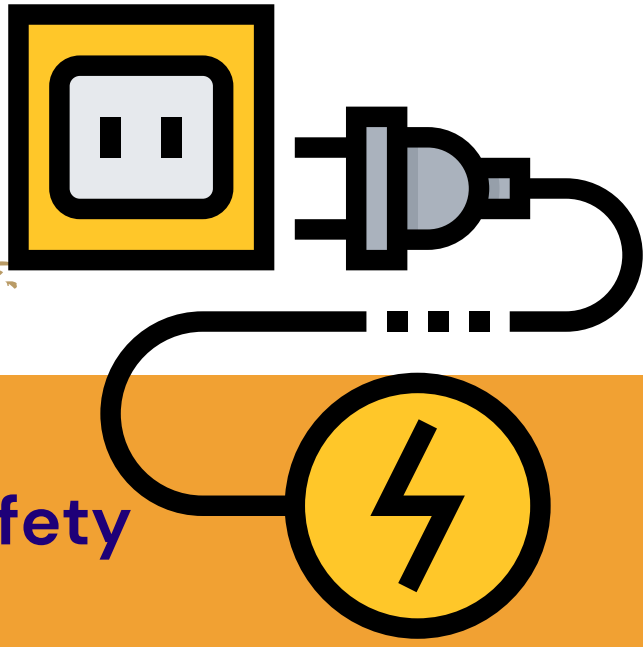
IEC

THE STANDARDS BODY IN EUROPE, WORKING CLOSELY WITH EACH NATION'S OWN NATIONAL LABORATORY. UL 60601-1 IS A STANDARD THAT HAS BEEN HARMONIZED WITH IEC 60601-1.

Today, the International Electrotechnical Commission (IEC) and Underwriters Laboratories (UL) are the two main regulatory bodies that determine and publish minimum safety standards for electronics products, including medical transformers.

ELECTRICAL SAFETY TESTING

WHY DO WE NEED ELECTRICAL SAFETY ?



1. **Ensure patient safety**

- Protect against macroshock
- Protect against microshock

2. **Test for electrical internal breakdown / damage to power cord, AC mains feed, acceptance, PPM, post repair etc.**

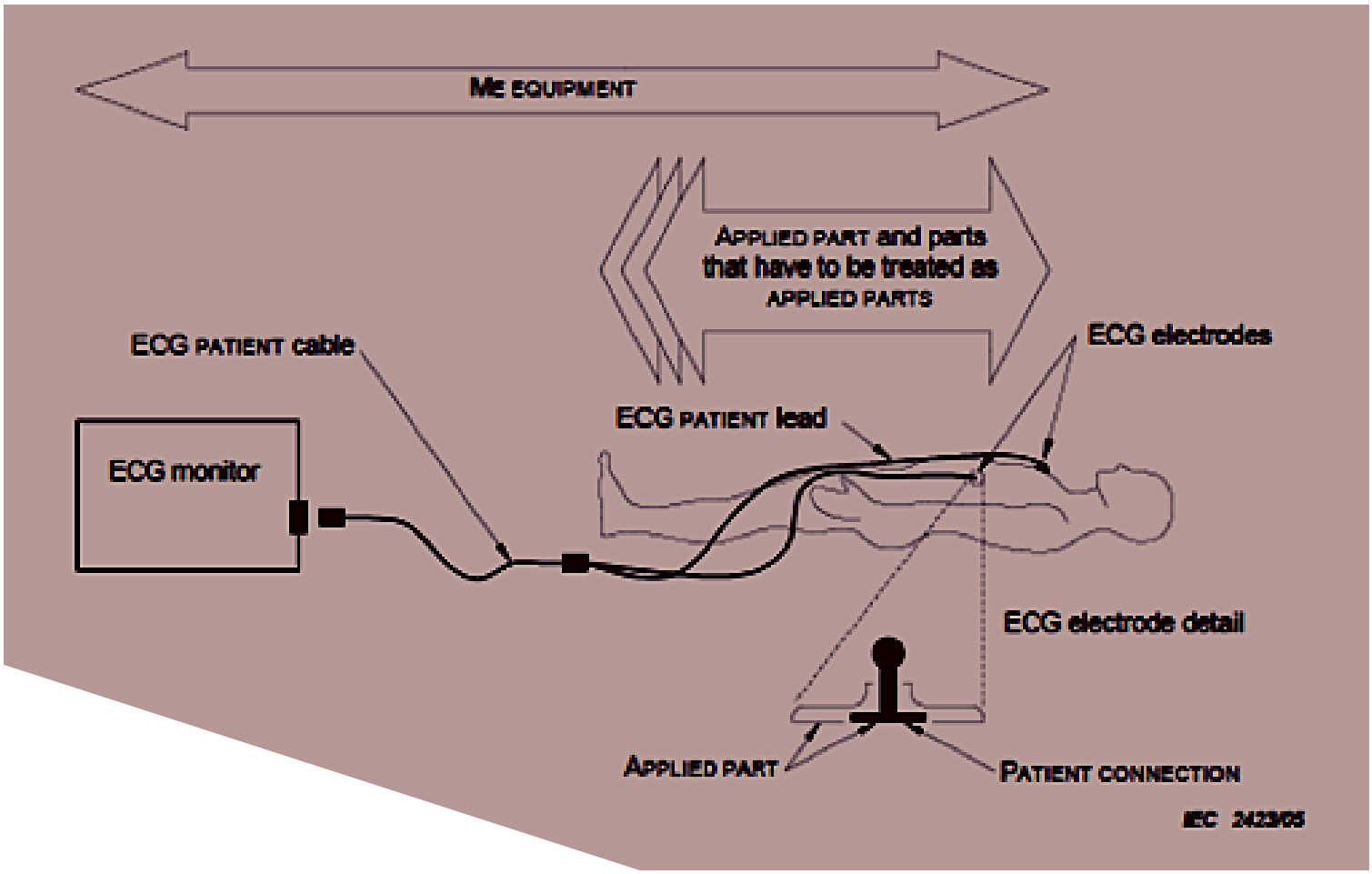
3. **Meet codes & standards: AAMI, IEC, UL, NFPA, etc.**

4. **Protect against legal liability**

Patients, staff and visitors

REMEMBER! TERMINOLOGIES OF ELECTRICAL SAFETY TEST

- Classes and Types
- L1 - Hot
- L2 - Neutral
- Earth - Ground
- Mains Line - Voltage
- Enclosure/Case - Chassis
- Protective Earth -Ground Wire
- Earth Leakage Current Leakage in Ground Wire
- Enclosure Leakage - Chassis Leakage
- Patient Leakage - Lead Leakage
- Patient Auxiliary - Leakage between Patient Leads
- Mains on Applied Parts - Lead Isolation
- Insulation Resistance - Dielectric Strength or Insulation Resistance between Hot and Neutral to Ground
- Earth Resistance - Ground Wire Resistance



APPLIED PARTS

DEF: "An APPLIED PART is “part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function.”

In the other words:
IT can be brought into contact with the patient; or needs to be touched by the patient

An APPLIED PART can be a blood pressure cuff or a SpO2 sensor of a multi-parameter monitor, the tabletop of an MRI, and many other parts of ME EQUIPMENT that manufacturers intend to come into contact with a PATIENT during NORMAL USE.

ELECTRICAL-MEDICAL DEVICES CAN HAVE DIFFERENT TYPES OF APPLIED PARTS OR MORE THAN ONE OF THE SAME TYPE (E.G., MULTI-PARAMETER MONITORS FREQUENTLY HAVE TEMPERATURE SENSORS, AND BLOOD PRESSURE MONITORING COMPONENTS IN THE BASE CONFIGURATION AND OTHER APPLIED PARTS CAN BE ADDED)

APPLIED PARTS can have six different classifications: TYPE B, BF, or CF (and each can be DEFIBRILLATION PROOF). Each of these classifications also has an associated symbol

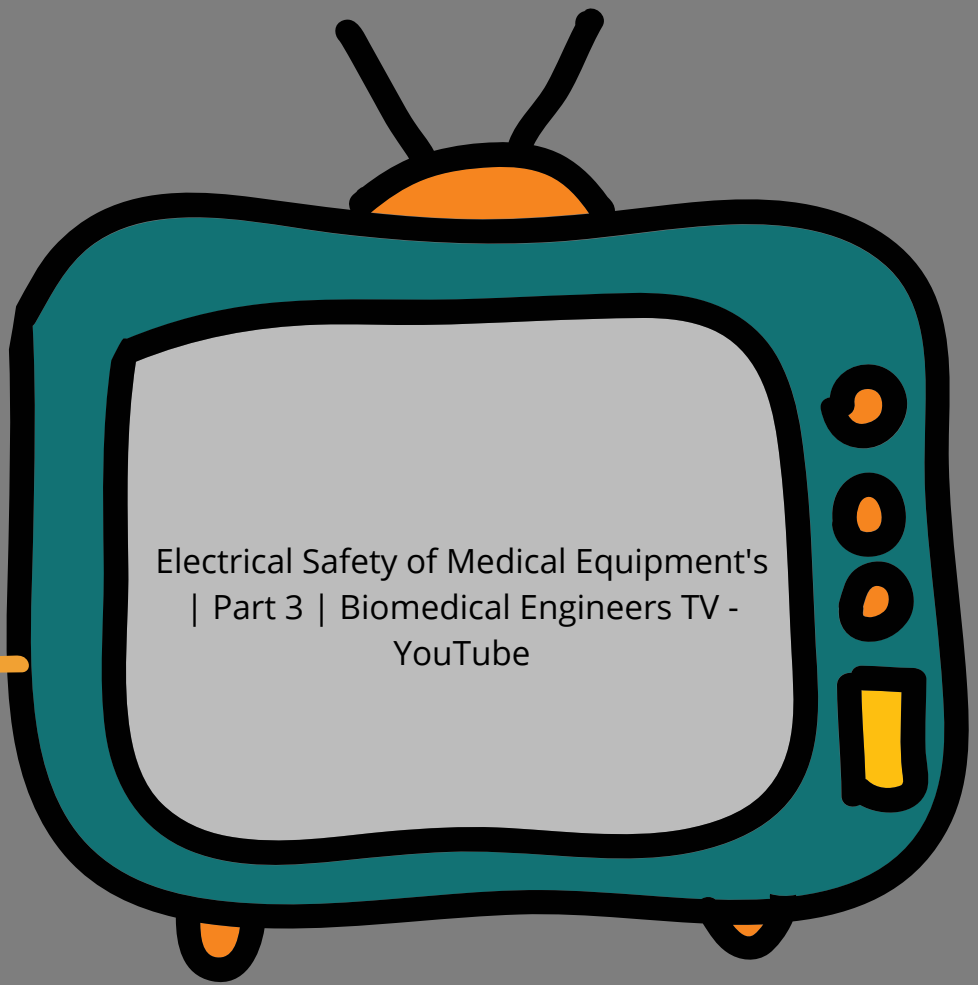
(Notes: Accessible part: Accessible Parts are Parts of equipment that can be touched without the use of a tool. • EXAMPLE: Illuminated push-buttons;Indicator lamps ; Recorder pens; Parts of plug-in modules ;Batteries;etc)

MEDICAL EQUIPMENT: CLASS & TYPE

1. EQUIPMENT CLASS {I, II, III}
“METHOD OF PROTECTION AGAINST ELECTRIC SHOCK“

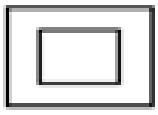
2. EQUIPMENT TYPE {B, BF, CF}
“DEGREE OF PROTECTION“

here



ME CLASS & TYPE

Class I (1)



Class II (2)

Class III (3)

B type

a)

BF type

b)

CF type

c)

CLASS I

Class I equipment has a protective earth. Protection relying on fault currents to Earth.

CLASS II

Protection against electric shock either double insulation or reinforced insulation.

CLASS III

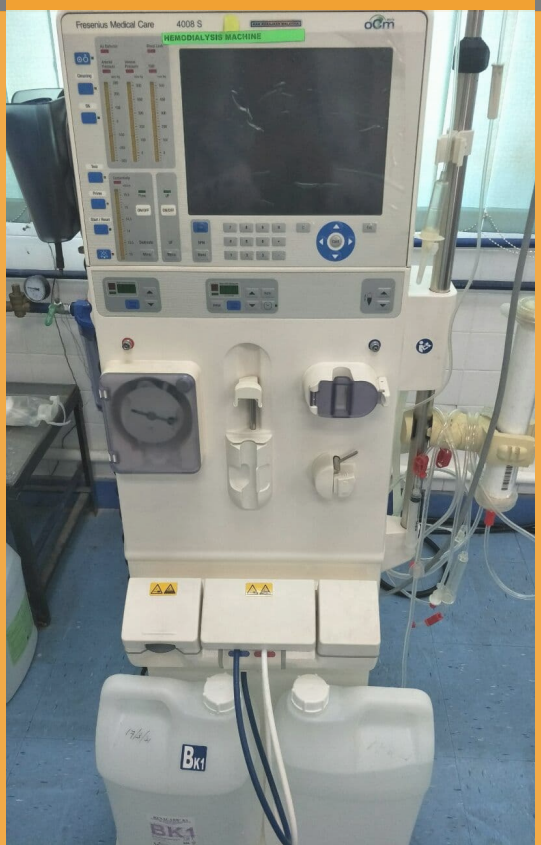
protection against no voltages higher than safety extra low voltage (SELV) are present (<25V ac or 60V dc. Eg battery or SELV transformer.

Type B (body)

The least stringent classification and earth referenced. Thia type is normally not conductive, non invasive and the patient can immediately release them. Examples are: LED operating lighting, medical lasers, MRI body scanners, hospital beds.

Type BF (body float)

This classification is generally used for conductive contact with the patient, non invasive or having medium or long term contact with the patient. Circuits in connection with the patient are floating. Examples are: def. paddle, ECG monitors, incubators, SPO2 probe and ultrasound equipment.



TYPE CF

The most stringent classification. It is used for cardiac that may come in direct contact with the heart, such as dialysis machines, infusion device or invasive blood pressure monitors. Circuits in connection with the patient are floating. The limits for leakage current are below the microshock limit both during normal operation and in case of a single fault.

TEST TYPES

TESTING

IEC 60601-1 Electrical Tests

- Earth Bond Test (high current - 25A Manufacturer's Conformance Test)
- Insulation Test
- Leakage Tests (SFC's): o Earth o Enclosure / Touch o Patient (AC / DC) o Patient Auxiliary (AC / DC) o Patient type F

IEC 62353 Electrical Tests

- Earth Bond Test (low current - 200mA in Service Testing is toward lower current tests)
- Insulation Test
- Leakage Test

THESE REMINDERS ARE FOR EVERYONE'S SAFETY.

For further questions, please approach Senior Bioengineer or manual from manufacturing.

IEC 60601 VS 62353 SAFETY TESTS

IEC 60601

- Earth Bond Test
- Leakage Tests - Single Fault Conditions (SFC)
  - Earth
  - Enclosure / Touch
- Applied Patient Leakage (SFC)
  - Patient (AC / DC)
  - Patient Auxiliary (AC / DC)
  - Patient type F

IEC 62353

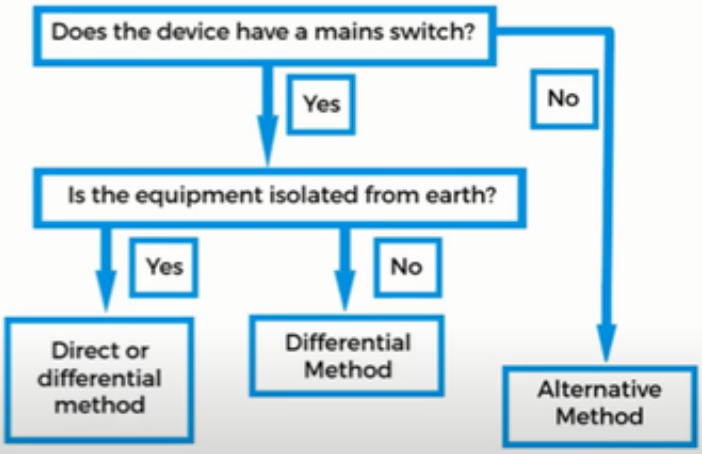
- Earth Bond Test
- Insulation Test
- Leakage Tests
  - Direct
  - Differential
  - Alternative
- Applied Patient Leakage
  - Direct patient leakage
  - Alternative patient leakage

Single Fault Condition (SFC) in IEC60601:

- Open earth
- Reversed mains supply
- Open neutral
- Mains on applied parts
- mains on signal input/output

62353 Leakage Methods?

- Direct Method
- Differential Method
- Alternative Method

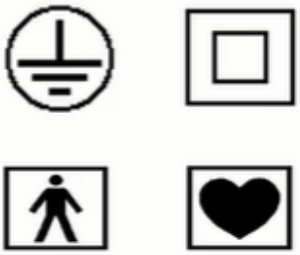


IEC 62353 Visual Test

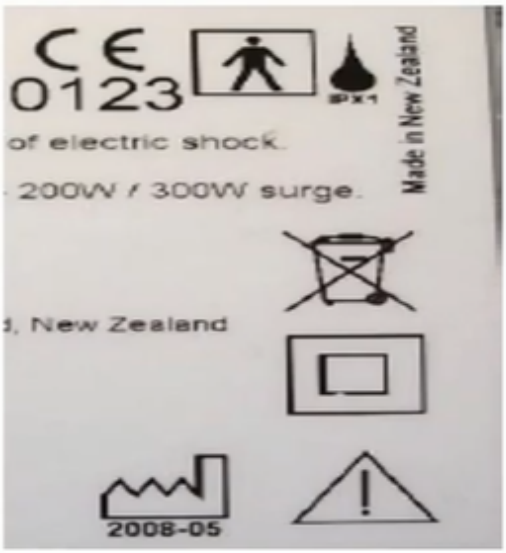
- Housing – Enclosure
  - Including (de-)contamination
- Electrical Connections
  - (supply, Applied Parts etc)
- Appropriate fuse rating
- Safety markings and labelling
- Integrity of mechanical parts
- Common sense is your best tool
- 70% of all faults are detected during a visual inspection

IEC 62353 Leakage Tests

- Equipment Leakage (input safety, MOOP)
- Applied Part Leakage (output safety, MOPP)
  - Different Methods
  - Common Patient Connections
  - Total Leakage
  - Compare



Medical Device Labels



COMPARISON NUMBER OF MEASUREMENTS

IEC 60601 vs 62353 (Class 1, 10CF)

IEC 62353

- No of measurements;

1.	Equipment Leakage (Dir / Diff)	2
2.	Applied Part Leakage (Dir)	2
	Total (excl. earth bond)	4

IEC 60601

No of measurements;

1.	Earth Leakage		4
2.	Enclosure Leakage		6
3.	Patient Leakage	(6 x 10 x 2)	120
4.	Patient Aux Leakage	(6 x 10 x 2)	120
5.	Patient Type F Leakage	(4 x 10)	40 +
	Total (excl. earthbond)		290 !!!

IEC 60601	AS/NZ 3551	NFPA 99	IEC 62353
Earth Bond	Protective Earth	Ground Bond	Earth Bond
Earth leakage	Earth leakage	Ground Wire Leakage	Equipment Leakage DIRECT / DIFFERENTIAL
Earth Leakage SFC Neutral open	Earth Leakage SFC Neutral Open	Ground Wire Leakage SFC Neutral Open	Equipment Leakage ALTERNATIVE
Enclosure Leakage	Touch Leakage	Chassis Leakage	Equipment Leakage DIRECT / DIFFERENTIAL
Enclosure leakage SFC earth	Touch Leakage SFC earth	Chassis Leakage SFC earth	Equipment Leakage DIRECT / DIFFERENTIAL
Patient Leakage	Patient Leakage	Lead to Ground Leakage	Equipment Leakage (enclosure pro disconnected)
Mains on Applied Parts	Mains voltage on applied parts	Isolation Leakage	Applied Part Leakage
Measured values	Measured values	Measured values	Some are calculated
Only direct method	Only direct method	Only direct method	Direct/Differential/Alternative

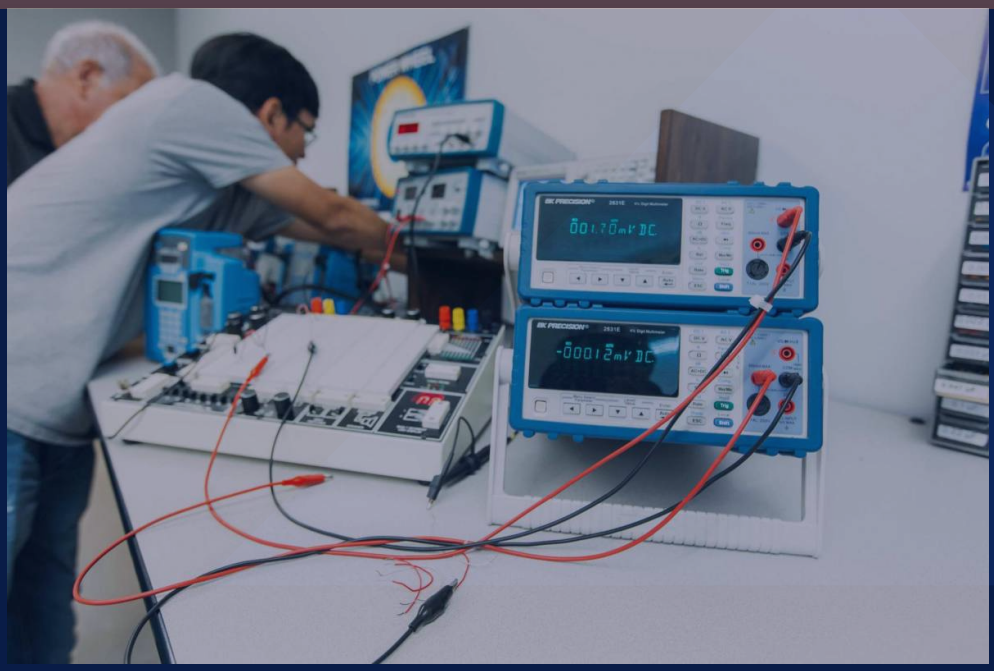
ALWAYS FOLLOW THE USER MANUAL

ELECTRICAL SAFETY TESTING PROCEDURES

PPM & SEQUENTIAL TESTING

PPM & Sequential Testing

- Objective is to prevent or find potential faults
- Visual Inspection
- Testing means of protection
  - Earth bonding
  - Insulation
- Testing effectiveness of protection
  - Leakage currents
- Testing the performance
- Reporting and analyses leads to prevention



60601 Limits 3rd Edition

Excluding power cord			< 0.1 Ω			
Including power cord			< 0.2 Ω			
	Type B Applied Parts		Type BF Applied Parts		Type CF Applied Parts	
Leakage Current Type	NC	SFC	NC	SFC	NC	SFC
Earth Leakage (3rd edition)*	5000µA	10000µA	5000µA	10000µA	5000µA	10000µA
Earth Leakage (General)	500µA	1000µA	500µA	1000µA	500µA	1000µA
Enclosure Leakage	100µA	500µA	100µA	500µA	100µA	500µA
Patient Leakage (dc)	10µA	50µA	10µA	50µA	10µA	50µA
Patient Leakage (ac)	100µA	500µA	100µA	500µA	10µA	50µA
Patient Leakage (F-Type)	NA	NA	NA	5000µA	NA	50µA
Patient Leakage (Mains on SIP/SOP)	NA	5mA	NA	NA	NA	NA
Patient Auxiliary Current (dc)	10µA	50µA	10µA	50µA	10µA	50µA
Patient Auxiliary Current (ac)	100µA	500µA	100µA	500µA	10µA	50µA

*The pass fail limit for Earth Leakage in the 3rd edition of IEC 60601 has been increased from 500µA under normal condition to 5000µA for class I equipment with NO exposed metal parts that may become live when a fault appears

SAY NO TO HAZARD!

IEC 62353 Leakage Limits

Current µA	APPLIED PART B	BF	CF
Equipment leakage current – direct or differential method			
Equipment leakage current Class I	500	500	500
Equipment leakage current Class II	100	100	100
Equipment leakage current – alternative method			
Equipment leakage current Class I	1000	1000	1000
Equipment leakage current Class II	500	500	500
Applied Part leakage current – direct or alternative method			
Applied Part leakage current (Class I and II)		5000	50
NOTE 1 This standard does not provide measuring methods and allowable values for equipment producing DC leakage currents. In such a case, the manufacturer should give information in accompanying documents. NOTE 2 Particular standards may allow different values of leakage current			

MUST FOLLOW THE STANDARD LEAKAGE LIMITATION VALUE !!

MEDICAL ELECTRICAL SAFETY TESTING

PROCEDURES; CIRCUIT DIAGRAMS; TABLES.

- How testing is performed
- Documentation
- Visual Inspection
- Earth Resistance Test
- Insulation Test
- Leakage Current Test

Visit web: ELECTRICAL SAFETY TRAINING FOR MEDICAL EQUIPMENT https://www.slideshare.net/MEHABOOBRAHMAN/electrical-safety-training-73060578 for more information about the questions.

SELF EVALUATION

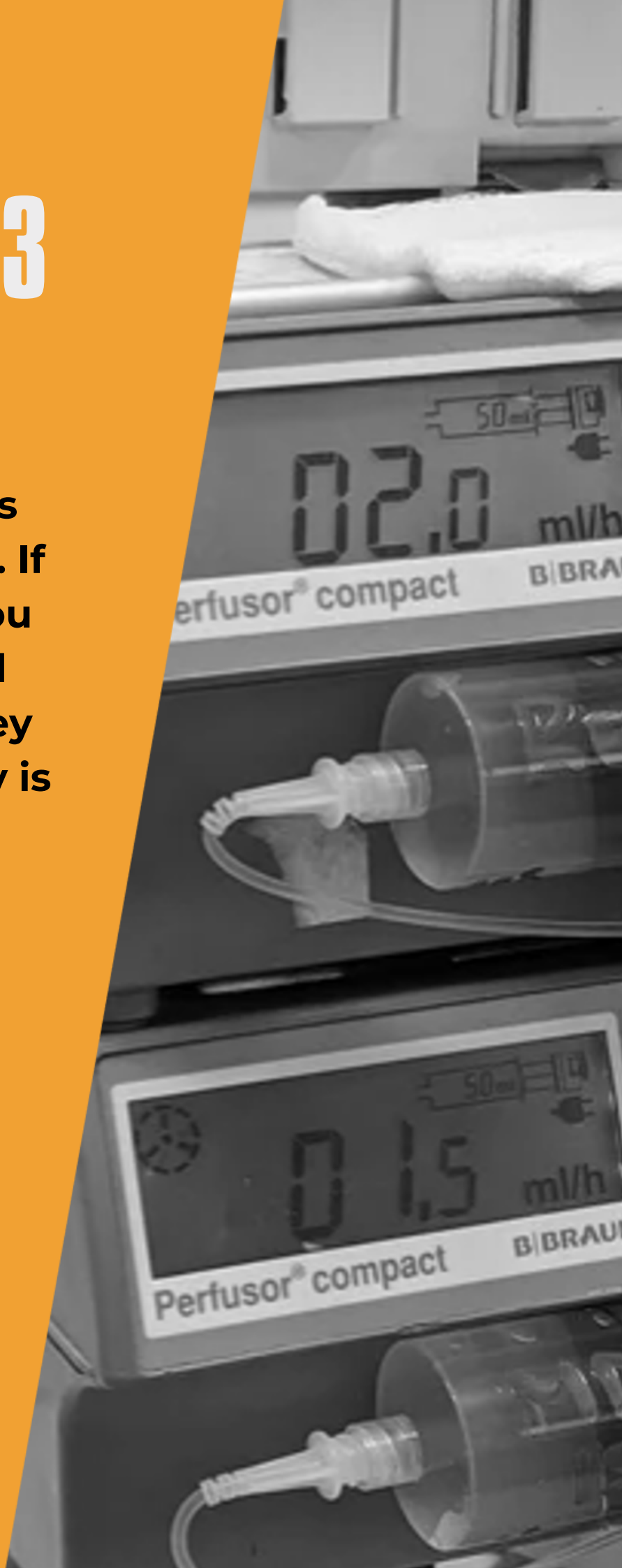
LEAVE YOUR COMMENT AT THE LINK BELOW

(SCAN THE QR CODE)

CHAPTER 3

"Your employees learn by example. If they don't see you practicing good safety habits, they won't think safety is important."

Electrical Construction & Maintenance



PRACTICAL WORK 1

INTRODUCTION TO MEDICAL EQUIPMENT

Hi !Do you know how to identify Class and Type of medical equipment?

PRACTICAL WORK 1

APPARATUS

MEDICAL EQUIPMENT

Defibrillator
Infusion Pump
Non Invasive Blood Pressure
Hemodialysis
Anesthesia Unit
Infant Warmer
Electrosurgical Unit
Patient Monitor

1

- Brand
- Model
- Serial Number
- Function of the equipment
- Analyzer for performance test

2

Sketches class and type of medical equipment according to IEC 60601 standards

PRACTICAL WORK 1

DEMONSTRATION

CLASS N TYPE OF MEDICAL EQUIPMENT - YouTube

The demonstration on identifying Class and Type of Medical Equipment

PRACTICAL WORK 1

RESULT AND ANALYSIS

Explain your results and interpret those results in the context existing theory and knowledge that you have learn before.

Identify and comment on any trends you have observed

TELL US YOUR EXPERIENCE !

ELECTRICAL SAFETY TEST FOR CLASS 1 MEDICAL EQUIPMENT

PRACTICAL WORK 2

Get the standard checklist and DUT's user manual in your hand first.

POLITEKNIK MALAYSIA
SULTAN SALAHUDDIN ABDUL AZIZ SHAH

CHECKLIST FOR ELECTRICAL SAFETY TEST (IEC 62353)

DEFIBRILLATOR

(Estimated Time: 60 minutes)

EQUIPMENT INFORMATION

Manufacturer: Model:
Serial No: Location:
Frequency: 6 monthly ☐ 12 monthly ☐

TEST INFORMATION

Test equipment needed: Electrical Safety Analyzer / Defibrillator Analyzer

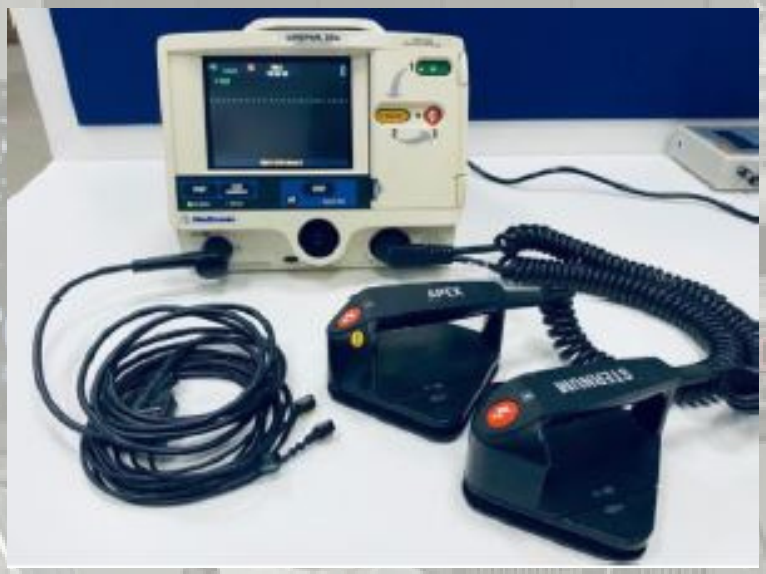
			TEST RESULT			
			Measured Value	Pass	Fail	Not Applicable
ELECTRICAL SAFETY						
Mains Voltage (V) - *(UUT Power OFF)*		Live-Neutral (L1-L2)				
		Live-Earth (L1-GND)				
		Neutral-Earth (L2-GND)				
Protective Earth (PE) Resistance (Ω)	<0.3Ω	*(UUT Power OFF)*				
Insulation Resistance (MΩ) - *(UUT 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)*				
REMARK						

COMPLETED BY: *DATE:*

Don't Forget PARAMOUNT SAFETY!

PRACTICAL WORK 2

APPARATUS



DEFIBRILLATOR CLASS 1 TYPE CF

ELECTRICAL SAFETY ANALYZER

Use the AR application by scanning the image of ESA

-You have to download the blippAR Application-

code : 12345

blippAR

PRACTICAL WORK 2

Prepare the connection of device under test (DUT) and ESA

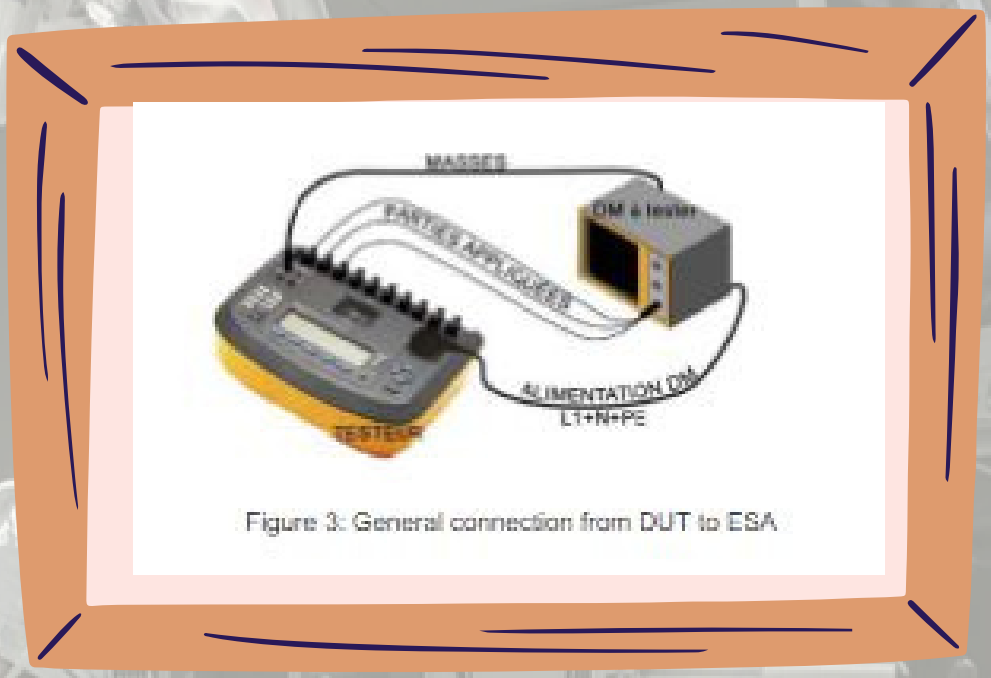


Figure 3: General connection from DUT to ESA

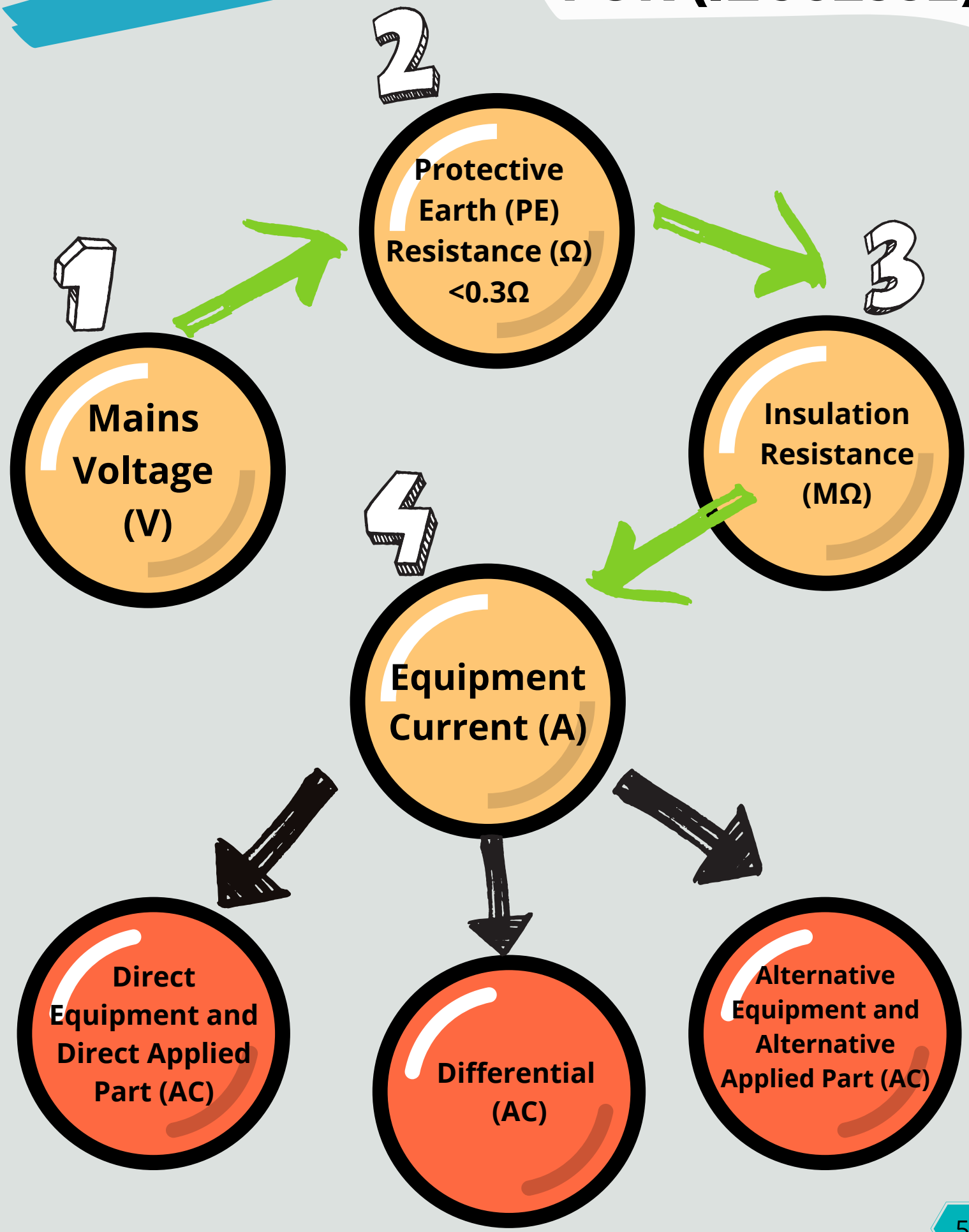
1. Connect the power cord DUT to ESA

2. Connect the ground DUT to the input 2 wire Electrical Safety Analyzer (Make sure to zeroing the ground lead first.)

3. Connect all applied parts to the ESA

PRACTICAL WORK 2

ESA TESTING FOR (IEC62352)



PRACTICAL WORK 2

DEMONSTRATION

PRACTICAL WORK 2

RESULT AND ANALYSIS

Explain your results and interpret those results in the context existing theory and knowledge that you have learn before.

Identify and comment on any trends you have observed

TELL US YOUR EXPERIENCE !

REFFERENCES

1. DIETER FEULNER (2013). IEC62353 STANDARD FOR SAFETY AND EFFICACY OF MEDICAL ELECTRICAL EQUIPMENT, GOSSEN METRAWATT, APPLICATION NOTE.

2. AN INTRODUCTION TO ELECTRICAL SAFETY TESTING IN ACCORDANCE WITH IEC62353, RIGEL MEDICAL. (2015)

3. IEC 60601-1:2012. MEDICAL ELECTRICAL EQUIPMENT–PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE. GENEVA, SWITZERLAND: INTERNATIONAL ELECTROTECHNICAL COMMISSION.

4. ALEX GROB (2020). SETTING STANDARDS: THE IEC 60601 SERIES: QUICK-USE GUIDE. BIOMED INSTRUM TECHNOL 54 (3): 220–222.

5. CODE OF PRACTICE ENGINEERING MAINTENANCE MANAGEMENT OF ACTICE MEDICAL DEVICES – MALAYSIA STANDARD MS2058:2017 (SECOND REVISION)

6. HOW TO APPLY FOR MEDICAL DEVICE REGISTRATION UNDER MEDICAL DEVICE. ACT 2012 (ACT 737). [REGULATION 8 MEDICAL DEVICE REGULATION 2012].

7. ISO 13485:2016 - MEDICAL DEVICES - A PRACTICAL GUIDE. PUBLICATION 2017, EDITION 1

8. GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD), SIRIM QAS INTERNATIONAL .GDPMD BROCHURE (2015)

"Doctors are the brain of the hospital. Nurses are the heart of the hospital. Here comes Biomedical Engineers are the nerves of the hospital."

by Suji

WE ARE PROUD TO BE A BIOMEDICAL ENGINEER

Terbitan:

POLITEKNIK MALAYSIA
SULTAN SALAHUDDIN ABDUL AZIZ SHAH

e ISBN 978-967-2044-69-7

9 789672 044697