

# SAFETY OF BIOMEDICAL INSTRUMENTS

## Lecture Notes

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Hospitals are confronted with the difficult problem of creating a safe electric environment for the care and comfort of the patients.

The patient is part of an electrical system which needs to have a well established safety conventions.

The patient is wired for collecting data important for diagnosis and therapy whose presence in the system requires refined safety concepts.

Electrical currents are administered intentionally in the following cases:

- i) for the measurement of respiration rate by impedance method, a small current at high frequency is made to flow between the electrodes applied on the surface of the body,
- ii) high frequency currents are also passed through the body for therapeutic and surgical purposes,
- iii) when recording signals like ECG and EEG, the amplifiers used in the preamplifier stage may deliver small currents themselves to the patient. These are due to bias currents.

Accidental transmission of electrical current can take place because of

- 1 a defect in the equipment,
- 2 excessive leakage currents due to defect in design,
- 3 operational error,
- 4 (human error) and simultaneous use of other equipment on the patient which may produce potentials on the patient circuit.

Other aspects of safety in biomedical devices and instrumentation are concerned about *biocompatibility* including issues as *cytotoxicity*, *hemocompatibility*, *carcinogenicity* and *material degradation*.

Also there are hazardous substances and energy forms available in the hospital environment which can lead to injury if not properly managed. Some of these are fire, air, earth, water, chemicals, drugs, vermin, waste, microorganisms, sound, electricity, gravity, natural and unnatural disasters, surroundings, mechanical stress, x-rays, ultrasound, magnet UV light, and laser.



## Electric Shock Hazards

- i) A patient may not be able to react because of illness, unconsciousness, anaesthetization or strapping on the operating table before any danger occurs.
- ii) The patient or the operator may not realize that a potential hazard exists because small potential difference and high frequency ionizing radiations are not directly indicated.
- iii) Human skin provides a considerable natural protection and barrier to electric current. In certain applications, natural resistance of the skin may be bypassed as in the case of a catheter patient's body.
- iv) Electromedical equipment, such as pacemakers used either temporarily or permanently whose interruption in the power supply or failure may give rise to hazards which may cause injuries or even fatality.
- v) Medical instruments often used in conjunction with several other instruments and equipment which become a combination of high power equipment and extremely sensitive low signal equipment. Although they may be safe in themselves, they can be dangerous when used in conjunction with others.
- iv) The environmental conditions in the hospitals, particularly in the operating theatres, cause an explosion or fire hazards due to the presence of anaesthetic agents, humidity and cleaning agents, *etc.*

## Electric Shock Hazards

1 Macro Shocks (Gross Shocks)

2 Micro Schocks

Parameters determining the effects of shocks;

- i) the intensity and duration of the current,
- ii) the pathway of the current passing especially in relation to heart,
- iii) whether the current is DC or AC.

Skin resistance at 50/60 Hz is between  $15\text{ K}\Omega$  to  $1\text{M}\ \Omega$  per  $\text{cm}^2$  depending on the region.

If a wound, a jel or wetness exists on the surface, it can reduce to 100 to  $1000\ \Omega$ .

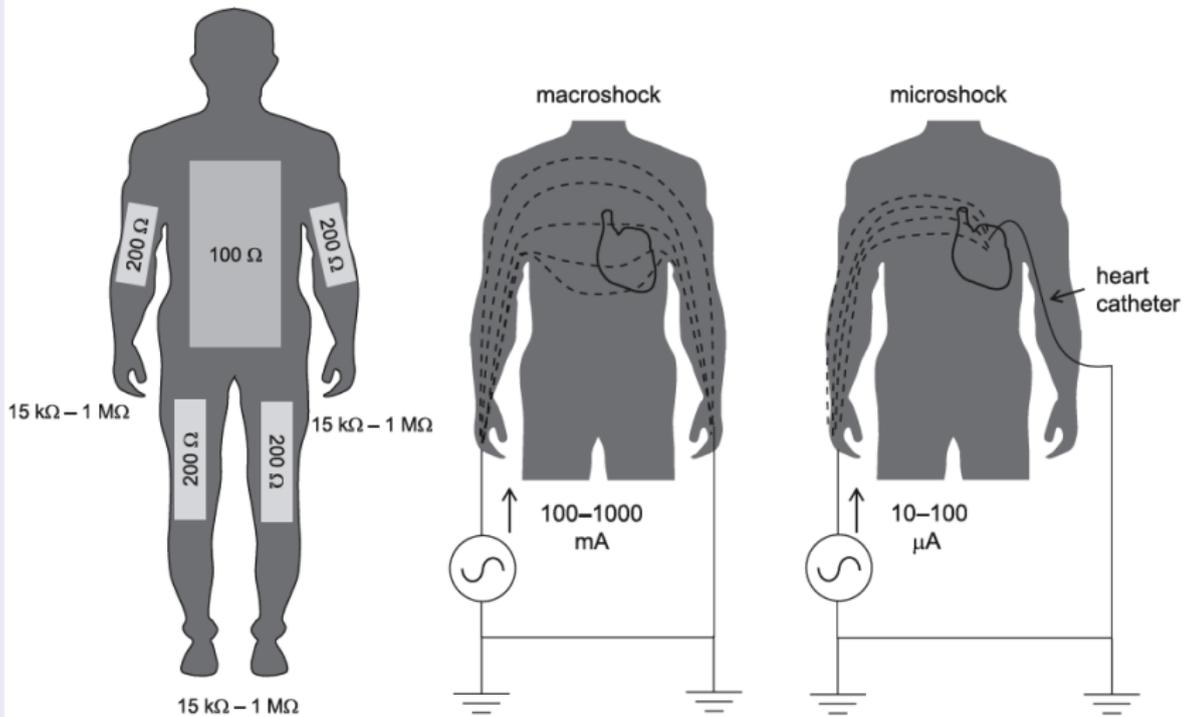
A 40 mA pulse of 250 ms duration can stop the heart or a pulse of 200 mA for a 50 ms duration can cause ventricular fibrillation or asphyxia due to tetanic contraction of respiratory muscles.

## Macro Shocks

Macro shock occurs by an accidental contact with the electric wiring at any point on the surface of the body. The majority of electric accidents involve a current pathway through the victim from one upper limb to the feet or to the opposite upper limb and they generally occur through intact skin surfaces.

Three phenomena can occur;

- i) Electrical stimulation of the excitable tissues, nerves and muscles.
- ii) Resistive heating of tissue.
- iii) Electrochemical burns and tissue damage for direct current and very high voltages.



Resistance of different body parts

## Effects of Electric Current on Human Body

*Threshold of Perception* : Smallest felt sensation when a subject is in contact with electrified surface is 0.5 mA for 50Hz and 2-10 mA for DC current.

*Let-go Current* : It is the maximum amount of current that can allow a subject to release gripping a conductor. It is about 16 mA for males and is 10.5 mA for females.

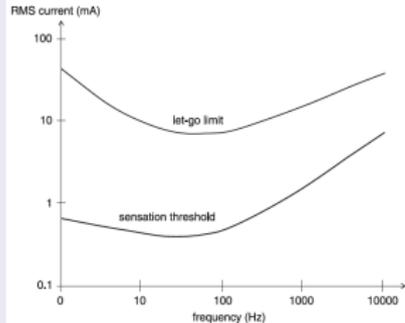
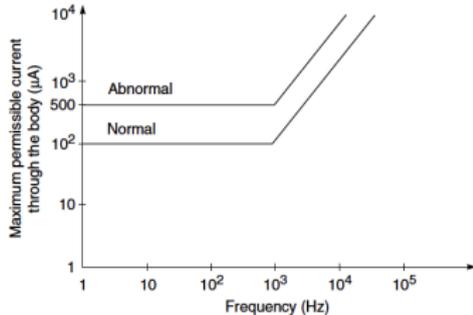
*Physical Injury and Pain* : Current levels higher than the let-go current renders the subject unable to control one's own muscle actions. Being unable to release grip on the electrical conductor can cause accident by currents in the range of 20-100 mA. Although it causes fatigue, the heart and respiratory functions usually continue.

*Ventricular Fibrillation* : Any current above 100 mA can cause derangement of ventricular contraction which can lead to death in 2 to 4 min if it is not cardioverted.

*Sustained Myocardial Contraction* : Currents in the range of 1 to 6 A can contract the entire heart muscle. Although the heart stops beating while the current is applied, it may revert to a normal rhythm if the current is discontinued in time. The damage is reversible if the shock duration is only of a few seconds and it may be accompanied by respiratory paralysis.

*Burns and Physical Injury* : Currents more than 6 can cause temporary respiratory paralysis and also of serious burns. Voltages higher than 230 V can cause skin puncture. If the duration is only a few seconds, then the heart may return to normal functioning as in the case defibrillation.

# Maximum Permissible Leakage Currents



Effect	
<b>Macroshock current</b>	
1 mA	Perception threshold
5 mA	Maximum 'harmless' current
10–20 mA	Let-go current before sustained muscle contraction
50 mA	Mechanical injury and pain
	Heart and respiratory functions maintained
100–300 mA	Ventricular fibrillation
>1 A	Sustained myocardial contraction
	Respiratory paralysis
	Tissue burns
<b>Microshock current</b>	
100 µA	Ventricular fibrillation

Effects of Current Flow on Body for 1 sec.

Minimum let-go current thresholds occur around 50/60 Hz, exactly where many problems exist due to coupling with power lines.

If the patients are anesthetized sedated or pain medicated, they may not feel the current which increases the risk of injury.

Gross shock hazards are usually caused by electrical wiring failures, which allow personal contact with a live wire or surface at the power line voltage.

The most vulnerable part in the system of electrical safety is the cord and plug. Broken plugs, faulty sockets and defective power cords must be immediately replaced.

Commonly found fluids in medical practice such as blood, urine, intravenous solutions, etc. can conduct electricity to cause temporary short circuits if they are accidentally spilled into normally safe equipment. The cabinets of many electrically operated equipment have holes and vents for cooling that provide access for spilled conductive fluids, which can cause potential electric shock hazard.

The frequency with which such errors create hazards has prompted the designing of many testers for checking outlets or appliances.

The length should be standardized, say at 3 m. This should be shielded and a low dielectric loss insulation be used. Extension cords introduce needless risk. They should be avoided as far as possible.

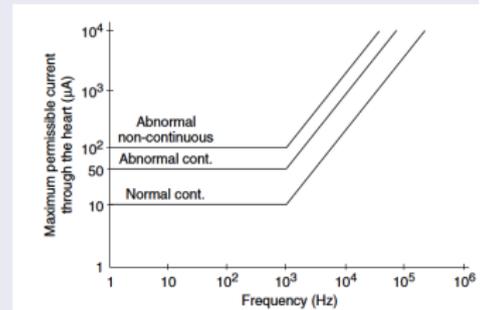
## Micro Shocks

A cardiac catheter connected to an electrical circuit for the measurement of pressure provides a conductive fluid connection directly to the heart. This makes the patient highly vulnerable to electric shock because the protection from layers of intact skin and tissue between the heart and the outside electrical environment has now been bypassed by the fluid column within the heart or blood vessels.

If a far smaller percentage of electric current passing through the body flows through the arterial system to the heart, it may produce ventricular fibrillation in patients with a catheter in the heart.

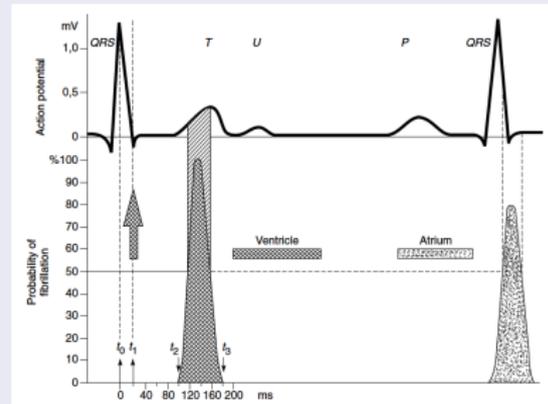
10 mA has been postulated as the safe upper limit for a frequency range of 0 to 1KHz.

In abnormal situations, the maximum value may be 50mA for continuously flowing and 100mA for noncontinuously flowing current through the patients heart. Current limits increase proportionally for frequencies above 1 KHz.



Ventricular fibrillation is produced more spontaneously when current passes directly through the heart during *vulnerable period* which occurs during the upstroke of the T wave of ECG when a single impulse lasting for less than 0.1 s could cause ventricular fibrillation.

Probability of the heart getting into fibrillation during various phases of the cardiac cycle.  
Risk decreases with shorter durations and higher frequencies.  
Fibrillation threshold for current increases with body weight.  
Above 100kHz muscle contraction and shock sensation are replaced by tissue overheating.



## Hospital Electrical Supply

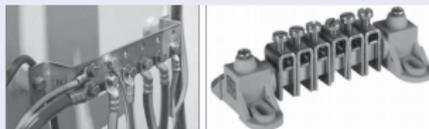
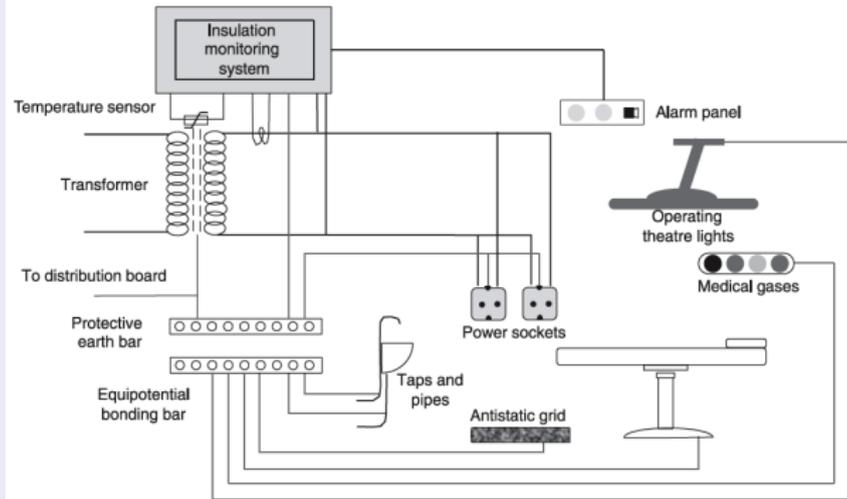
Energy requirement of hospitals are significantly higher than the other kind of buildings of similar size because of

- High energy equipment as CT, MRI , PET, Gamma Camera *etc.*
- Higher exchange rate of air ventilation and stable acclimatization,
- Large number of receptacles in enclosed areas,
- High power illumination accessories for surgery, examination and medical procedures.

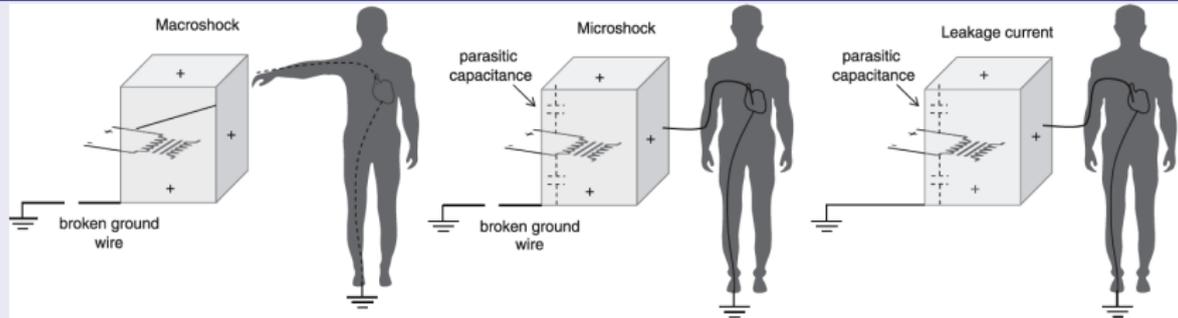
Emergency power requirements call for generators having a capacity to provide 50% to 60% of its total power needs indefinitely.

# Hospital Electrical Supply

4800 V is stepped down to 240/120 V inside the building.



## Shocks and Leakage Currents



If ground is broken the chassis of device will have a higher potential than ground and a current will flow through the patient.

The chassis can have a capacitive coupling with power lines and existing high potential can cause a current flow through patient if a ground failure occurs.

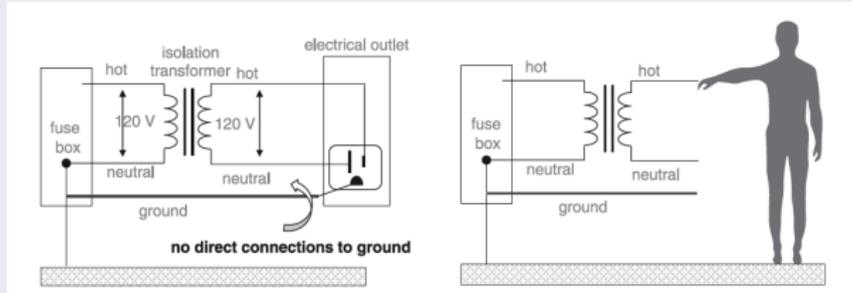
Even though there is no ground failure, if there is a direct connection to the heart, a leakage current may pass through the patient.

## Protection Against Macroshocks

Two methods:

- 1 Isolate the patient from any grounded surface and all current sources which is implemented in operating theatre using isolation transformers
- 2 Maintain all surfaces within patient's reach at the same potential using equipotential bonding bars.

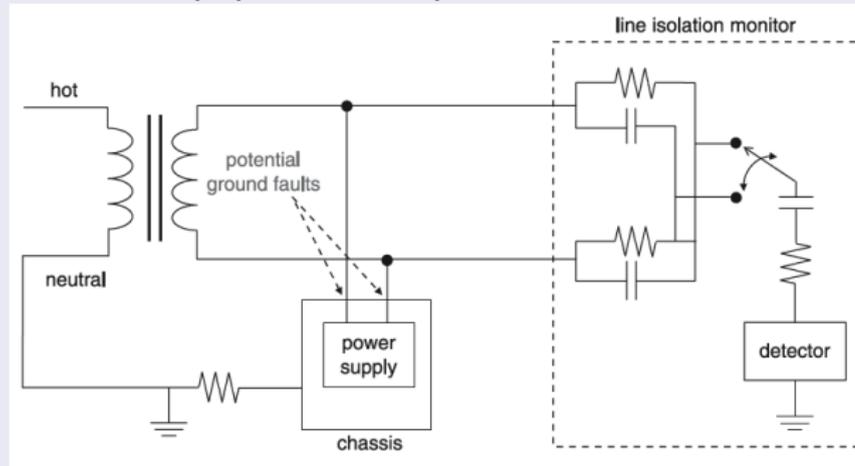
## Isolated Power Systems



Even if the patient touches a surface at high potential, there is no path for the current to flow to ground.

## Line Isolation Monitor (LIM)

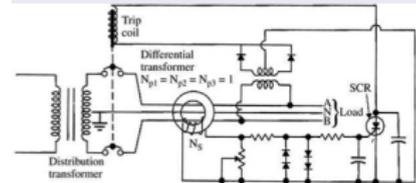
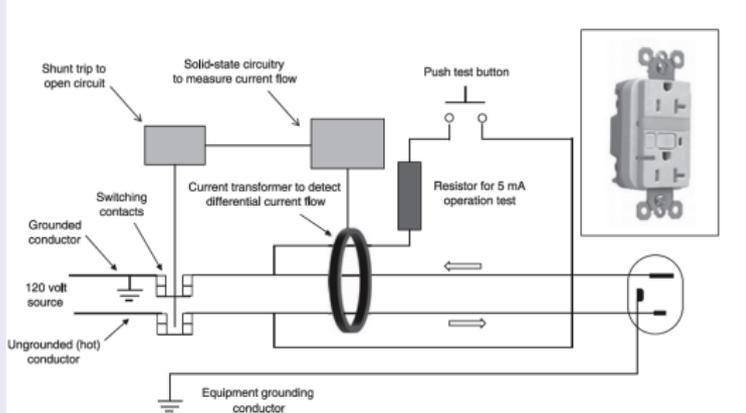
It is an additional safety device to prevent leakage and coupling between equipment and power lines.



The switch continuously monitors any leakage in the power lines and sets up an artificial ground fault if the other line has an actual ground fault. It sets off an alarm indicating the level of leakage current ( $> 5\text{mA}$ ) without shutting of the electric supply.

## Ground Fault Circuit Interrupters (GFCI)

It compares the current flowing in the hot and neutral wires of a grounded power system. If a macroshock occurs, current in the hot wire exceeds the one in the ground and GFCI shuts off power when it is more than 5 mA.



The disadvantage of GFCI is the danger of losing power to life support equipment so they are not typically used in ICU.

## Protection Against Microshocks

Microshock is produced by currents as  $100\mu\text{A}$  passing directly through heart can cause ventricular fibrillation.

They usually arise from three conditions;

- 1 a cardiac ECG lead acts as a current source and transfers the current to the catheter,
- 2 cardiac ECG lead acts as a current sink and flows to a pacemaker lead,
- 3 a ground loop occurs when a patient is connected to two grounded devices, one with a pacemaker lead and then a third faulty device not connected to the patient is hooked up to the same power outlet which sends a high leakage current to the catheter.

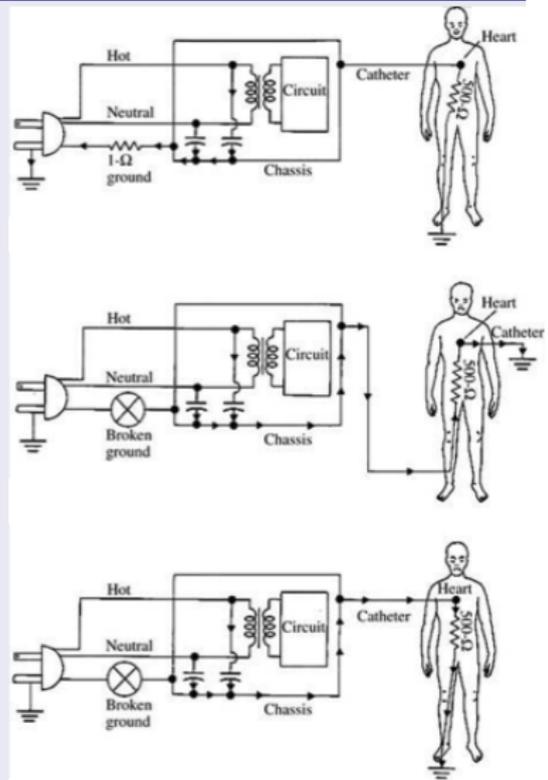
The maximum allowable current leakage through electrodes or catheters contacting heart is  $10\mu\text{A}$ .



Leakage current flowing to the chassis flow safely to ground if a low resistance ground is available.

If the ground wire is broken, the chassis potential rises above ground and a patient who touches the chassis and a grounded electrical connection to the heart may receive a microshock.

If there is a connection from chassis to patient's heart, and a connection to ground anywhere on the body, it can cause a microshock.



## Protection Against Microshocks

Pacemaker wires and modules are carefully isolated by the manufacturers. Residual current devices (RCD) detect leakage currents  $> 10$  mA and shut off power supply to the equipment within 40 ms.

Low leakage power chords using insulation materials that reduce stray capacitance between wires and chassis.

Equipotential earthing is installed in rooms to minimize voltage difference between devices and other exposed metals in the room.

Operation at low voltages by using solid state electronic equipment powered by voltage batteries ( $< 10$  V) or low voltage isolation transformers.

Isolation Amplifier:

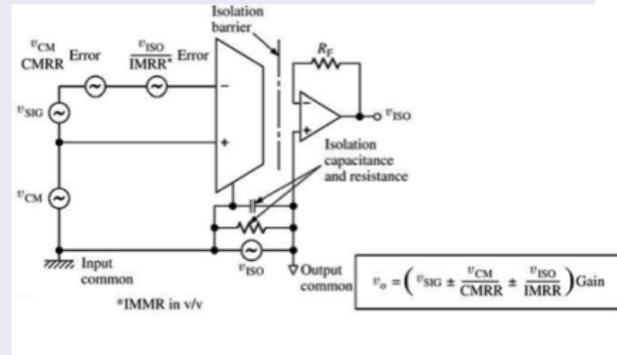
Very high isolation barrier

is denoted by isolation capacitance and resistance.

$v_{ISO}$ : potential (1-10 KV) that exists between the I/O commons.

Isolation mode rejection ratio specifies the rejection of this voltage.

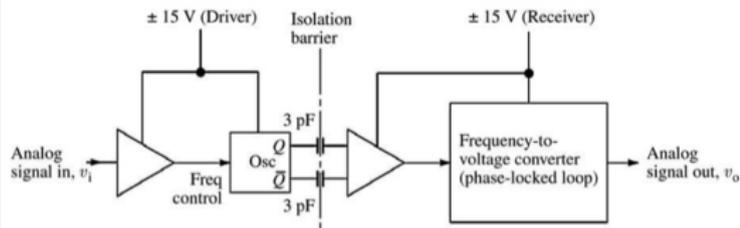
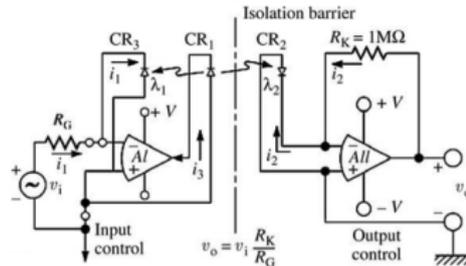
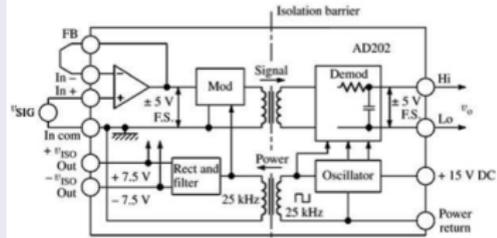
Typical features:  $v_{ISO} = 1$  KV,  
Isolation Impedance (10 M $\Omega$ ),  
CMRR  $> 100$  dB.



Transformer Type:  
 Uses FM or PWM with bandwidths up to 30 KHz.  
 Uses DC to DC converter composed of 25 KHz oscillator, transformer, rectifier and filter.

Optical Type :  
 Uses a LED and PD,  
 Signal is transmitted in DC optically.

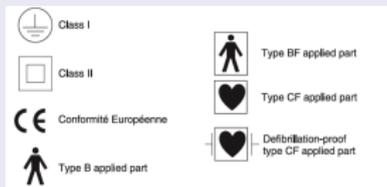
Capacitive mode:  
 Uses digital encoding of input voltage and FM to send the signal across a differential ceramic capacitive barrier.  
 Peak isolation voltage is 8 KV and BW is 70 KHz.



## Classification of Medical Devices

- *Body Protected Areas* : places designed in which patients are connected to equipment that lowers skin resistance using electrode gels, conductive fluids entering body, metal needles and catheters. RCD's, isolation transformers, and LIM's are used to reduce the chance of shocks from leakage currents.
- *Cardiac Protected Areas* : places in which procedures involving an electrical conductor to be placed inside or near the heart. Electrical conductors used are cardiac pacing electrodes, intracardiac ECG electrodes and intracardiac catheters.

Equipotential grounding with RCD or LIM is used to provide protection against microshocks.



Stickers attached to a medical device to identify its class and type.

*Defibrillation proof* means the device can be attached to the patient even if cardiac defibrillation is required.



## Classes of Equipment

*The class of equipment* refers to method by which the device is protected against electrical shocks.

- *Class I* : fitted with a three core power cable that contains a protective earth wire.

Any exposed metal parts on Class I device is connected to earth wire.

Class I device has fuses at the device end of the power cables in both alive and neutral conductors.

If a fault develops inside the equipment and the exposed metal comes into contact with the power supply, the earthing conductor diverts the fault current to the ground which blows the fuse and disables the circuit to prevent electric shock.

Maximum standard resistance between protective earth plug pin and the conductive components is  $0.2 \Omega$ .



## Classes of Equipment

- *Class II* : enclosed within a double insulated case and does not require earthing conductors.

If an internal electric failure occurs, double insulation prevents the external parts having a high potential to cause a hazardous current flow through the subject.

A typical Class II device is a *cardiac monitor*.

- *Class III* : no voltage higher than 25V AC or 60V DC (Safe Extra Low Voltage or SELV) is present in the device. The equipment is powered by a battery or a SELV transformer. Examples include *implantable pacemakers* and *automated external defibrillators*.

## Types of Equipment

*Type of Equipment*: defined in terms of maximum permitted leakage current from the equipment.

- *Type B (body) equipment* : includes Class I,II and III equipment and a maximum leakage current is  $100\mu\text{A}$ .

This type of equipment cannot be directly connected to the heart.

Type B applied parts may be connected to earth ground;

Typical Type B devices are *medical lasers, MRI scanners* and *phototherapy equipment*.

- *Type BF (body floating) equipment* : refers to a floating, isolated component and is generally used for applied parts that have a medium or long term conductive contact with the patient.

Type BF devices can be attached to skin but has a floating input circuit *ie.* there is no physical connection between the body and the ground.

A Typical BF device is a *blood pressure monitor*.



- *Type CF (Cardiac Floating) equipment* : refers to the most stringent classification and used for applied parts that may come into direct contact with the heart.

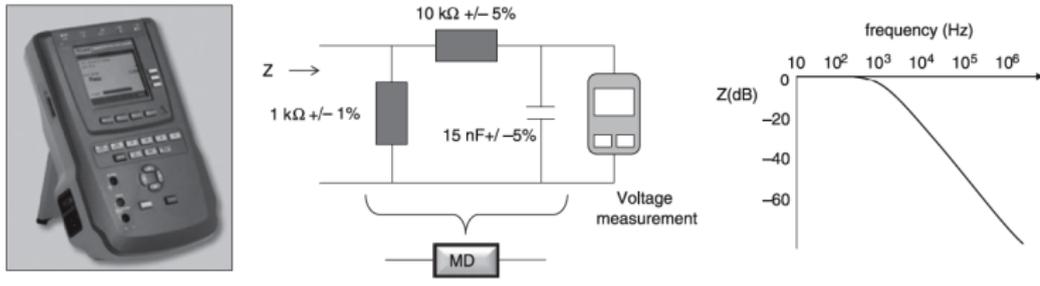
The maximum leakage current is  $10 \mu\text{A}$ .

The minimum resistance between the mains lead and ground is  $20\text{M } \Omega$  and between the mains lead and the components connected to the patient is  $70 \text{ M}\Omega$ .

A typical CF equipment is a *dialysis machine*.

## Testing the Electric System

Around 70 % of electric faults can be detected by visual inspection as the cracks in the equipment housing, cuts in the cables and fuses replaced with one with too low a rating.



A safety testing apparatus measures four different parameters;

- i) *Line (mains) voltage*
- ii) *Ground wire (protective earth) resistance*
- iii) *insulation resistance*
- iv) *device current and patient lead leakage*

For tests in iv), the RC impedance is chosen as to mimick the human body with a constant impedance from DC to 1KHz.

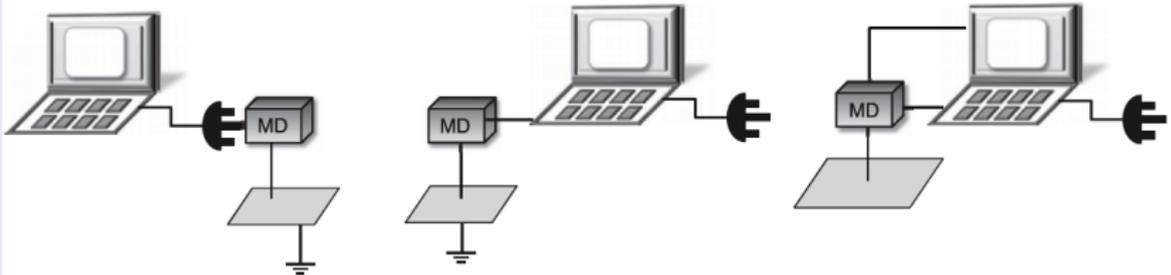
## Leakage Current Measurements

Leakage Currents are measured under two conditions:

- i) *normal conditions* (NC) : cases in which all protections are intact and device is operated in standby and in normal full operational modes.
- ii) *single fault conditions* (SFC) : includes open circuiting the protective ground and open circuiting each conductor on the mains supply one by one time.

During tests the medical device is connected to conductive point being measured.

## Earth and Enclosure Leakage Current Measurements



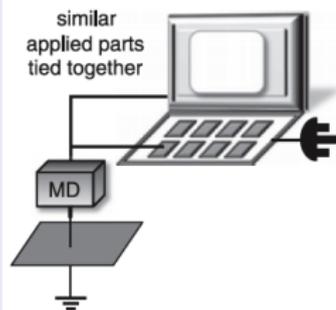
*Earth Leakage Current* : flows from the protective earth of the device through the patient back to the protective earth of the power cord. This type of measurement is required for Class I devices.

*Enclosure leakage current* : current that would flow if a person were to come in contact with housing or any accessible part of the equipment. It can be between any part of enclosure and earth or it can be between any two parts of the enclosure.

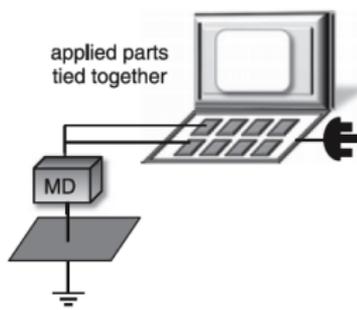
## Patient Leakage Current: Normal and F-Type

Patient Leakage Current is very important since directly affects patient safety. It originates from unintended voltage appearing on an external source.

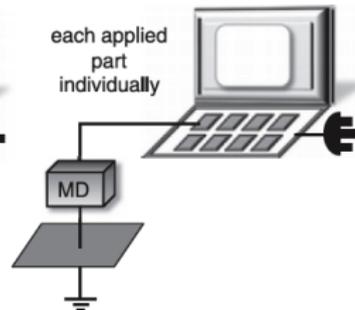
Depending upon type (B, BF, CF) of applied part, test requirements and conditions vary.



Leakage current for Type B applied parts is measured between all applied parts tied together and ground.



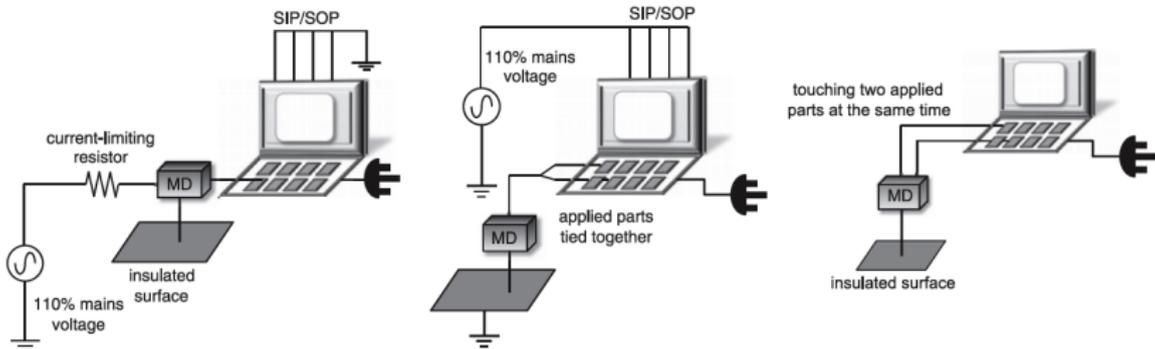
Type BF applied parts are separated into groups with different functions. Leakage current is measured between all similar applied parts and ground.



Leakage current for Type CF applied parts is measured from each applied part to ground individually.

## Maximum Leakage Currents (mA) for Different Medical Devices under Normal (NC) and Single Fault (SFC) Conditions (from IEC 60601-1)

	Type B		Type BF		Type CF	
	NC	SFC	NC	SFC	NC	SFC
Earth	0.5	1	0.5	1	0.5	1
Enclosure	0.1	0.5	0.1	0.5	0.1	0.5
Patient (DC)	0.01	0.05	0.01	0.05	0.01	0.05
Patient (AC)	0.1	0.5	0.1	0.5	0.01	0.05
Patient (F-type)	–	–	–	5	–	0.05
Patient (mains on SIP/SOP)	–	5	–	–	–	–
Patient auxiliary (DC)	0.01	0.05	0.01	0.05	0.01	0.05
Patient auxiliary (AC)	0.1	0.5	0.1	–	0.01	0.05



Type F applied parts must have additional requirements. Leakage current of each applied part is measured while applying 110% of nominal line voltage by current limiting resistor and signal I/O parts are tied to ground and leakage is measured for normal and reversed mains polarity.

Type B applied parts must have an additional SFC of 110 % of nominal mains voltage applied to all signal I/O parts during patient leakage measurements.

Patient auxiliary leakage current flows between any single applied part and all other applied parts tied together and is measured under both NC and SFC.

## Earthbond Testing

Earthbond or groundbond testing is used to check the integrity of the low resistance connection between the earth connector and any conductive metal parts that may become live if there is a fault on a piece of Class I medical equipment.

The test involves applying a test current of 25 A (or one and a half times the maximum current rating of the device, whichever is higher) at 50/60 Hz between the earth pin of the mains supply plug and any metal part of the medical equipment that is accessible to the patient, including its earth reference point.

Majority of earthbond failures arise from detachable power cords which are also checked for their resistance values which must be kept below  $0.2 \Omega$ .