

SNI IEC 60601

Safety and Essential Performance of Medical Electrical Equipment

Regulatory Training on Medical Device-Related Standards and Guidance

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Hazards of Medical Electrical Equipment

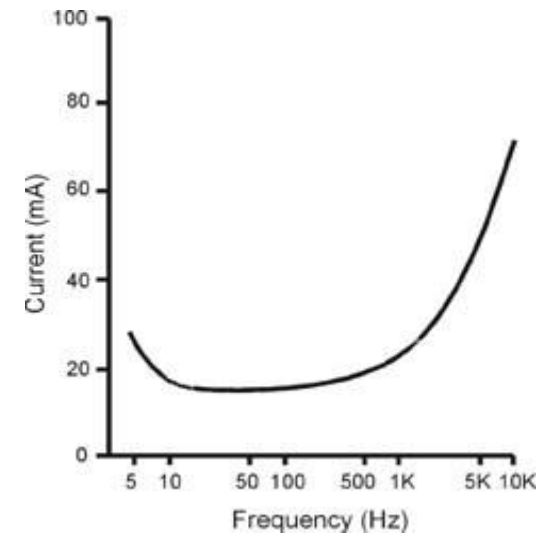
1. Risk of fire or explosion (e.g. short circuit, particularly presence of oxygen or nitrous oxide)
2. Absence of Function (e.g. ECG in vital sign monitor)
3. Excessive or insufficient output (e.g. surgical diathermy)
4. Misuse (e.g. poor user instructions → included in IEC 60601)
5. Risk of exposure to spurious electric currents

to the patient, the user, or to service personnel

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Physiological Effects of Electricity

- Burns (skin / tissue)
- Muscle cramps
- Respiratory arrest (intercostal muscles)
- Cardiac arrest
- Ventricular fibrillation*
- Effect of frequency on neuro-muscular stimulation
- Natural protection factors



*70 mA flowing from hand to hand across the chest, or 20 μ A directly through the heart may cause ventricular fibrillation. Most deaths from electric shock are attributable to the occurrence of ventricular fibrillation.

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Peralatan elektromedik - Bagian 1 : Persyaratan umum keselamatan dasar dan kinerja esensial

(IEC 60601-1: 2005, IDT)

IEC 60601

- IEC60601 is a series of technical standards for the safety and essential performance of medical electrical equipment, published by the International Electrotechnical Commission.
- The scope of IEC 60601-1 identifies which devices are not included in the IEC 60601 series: in vitro-diagnostic equipments (IEC 61010) and implantable parts of active implantables (ISO 14708 series)
- SNI IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- 60601-X: Collateral standard, e.g.:
 - 60601-1-2: Electromagnetic disturbances - Requirements and tests
 - 60601-1-3: Radiation protection in diagnostic X-ray equipment
- 60601-2-X: Particular standard, e.g.:
 - 60601-2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

IEC 60601 (contd.)

- If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.
- In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.
- Members of IEC and ISO maintain registers of valid International Standards. Users of this standard should consult these registers to determine which particular standards have been published.

SNI IEC 60601-1: 2014

- Standar Nasional Indonesia (SNI) IEC 60601-1: 2014 *Peralatan elektromedik - Bagian 1 : Persyaratan umum keselamatan dasar dan kinerja esensial* is the translated version of IEC 60601-1:2005 Medical electrical requirement - Part 1 : General requirement for basic safety and essential performance.
- It was agreed in a consensus meeting on 21 - 23 May 2012 attended by stakeholders, including government, testing laboratories, medical equipment manufacturers, consumers, experts, and universities.
- If any doubts about this standard, it is recommended to refer back to the standard IEC 60601-1:2005 *Medical electrical requirement - Part 1 : General requirement for basic safety and essential performance*.

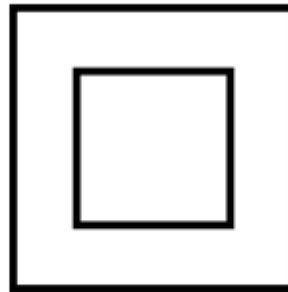
Medical Electrical (ME) Equipment

- Definition: electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:
 - a. provided with not more than one connection to a particular SUPPLY MAINS; and
 - b. intended by its MANUFACTURER to be used:
 - a. in the diagnosis, treatment, or monitoring of a PATIENT; or
 - b. for compensation or alleviation of disease, injury or disability
- For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded:
 - 250 V for HAND-HELD ME EQUIPMENT;
 - 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA; or
 - 500 V for all other ME EQUIPMENT and ME SYSTEMS.

Classification of Electrical Equipment



Class I (1)



Class II (2)



Class III (3)

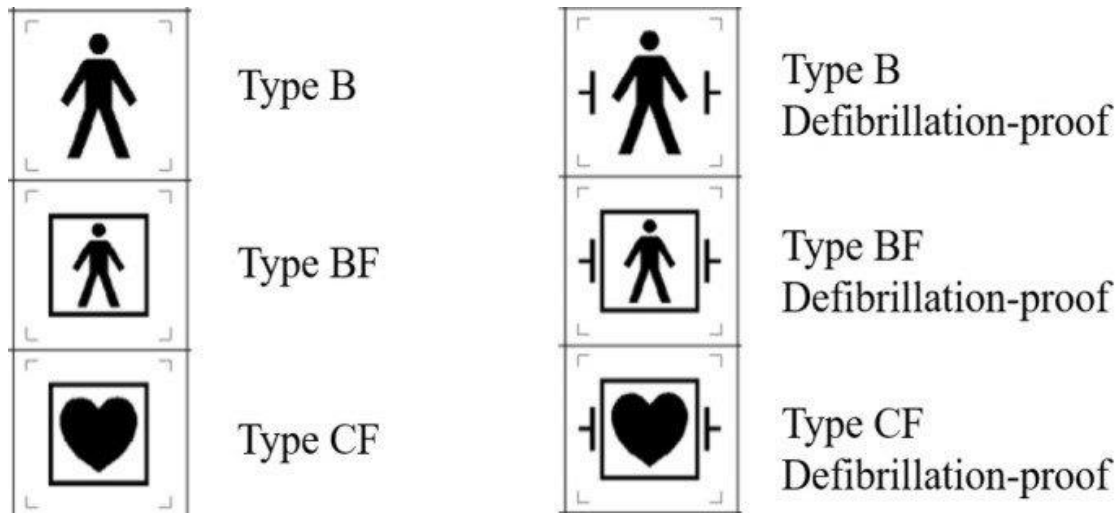
Classification of Electrical Equipment (contd.)

- Class I:
 - refers to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED.
- Class II:
 - refers to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.
- Class III:
 - no voltages higher than safety extra low voltage (SELV) are present. SELV is defined in turn in the relevant standard as a voltage not exceeding 25V ac or 60V dc. In practice such equipment is either battery operated or supplied by a SELV transformer. If battery operated equipment is capable of being operated when connected to the mains (for example, for battery charging) then it must be safety tested as either class I or class II equipment. The current IEC standards relating to safety of medical electrical equipment do not recognise Class III equipment since limitation of voltage is not deemed sufficient to ensure safety of the patient.

E-Life Solutions

Medical Equipment Types

- Type B → Equipment providing a particular degree of protection against electric shock, particularly with regard to allowable leakage currents
- Type BF → As type B but with isolated or floating (F-type) applied parts
- Type CF → Equipment providing a higher degree of protection against electric shock than BF, particularly regarding allowable leakage currents. Has F-type applied parts.



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Electrical Safety Tests

- Visual Inspection
- Protective Earth Continuity
- Insulation Resistance*
- Earth Leakage current
- Touch current
- Patient Leakage current
- Patient Auxiliary current

Visual Inspection

- Housing Enclosure – Look for damage, cracks etc.
- Contamination – Look for obstruction of moving parts, connector pins etc.
- Cabling (supply, Applied Parts etc.) – Look for cuts, wrong connections etc.
- Fuse rating – check correct values after replacement
- Markings and Labelling – check the integrity of safety markings
- Integrity of mechanical parts – check for any obstructions

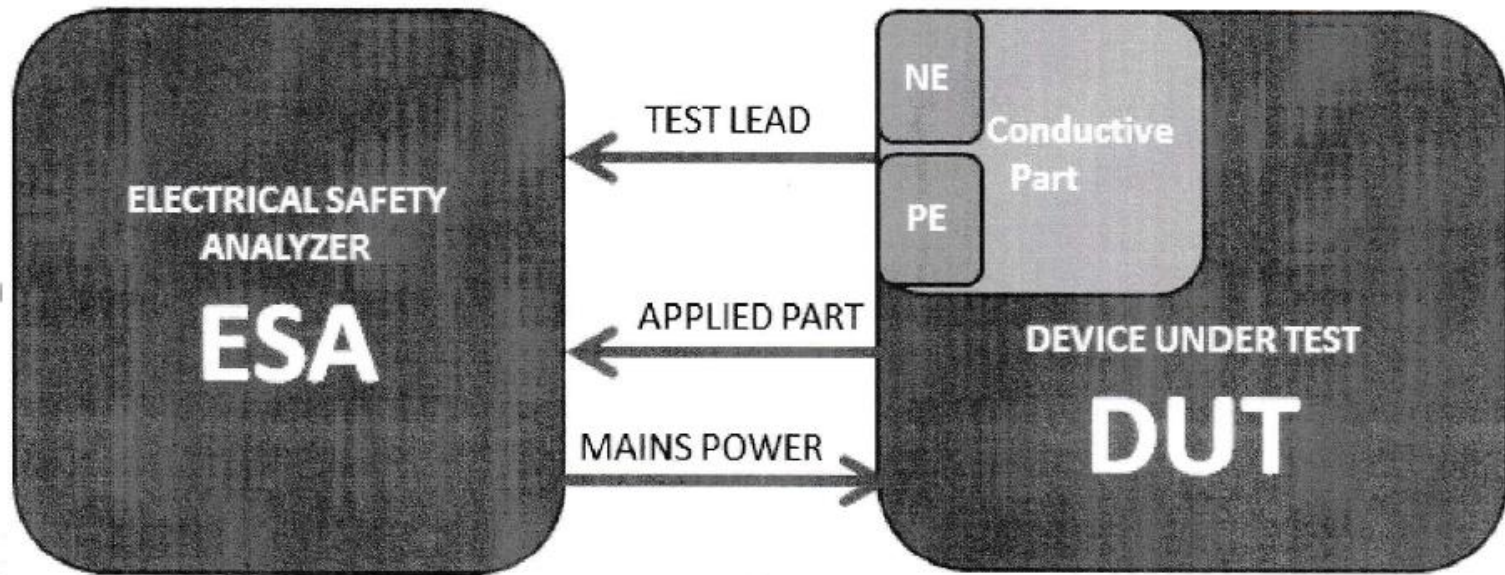
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Normal Condition (NC) – Single Fault Condition (SFC)

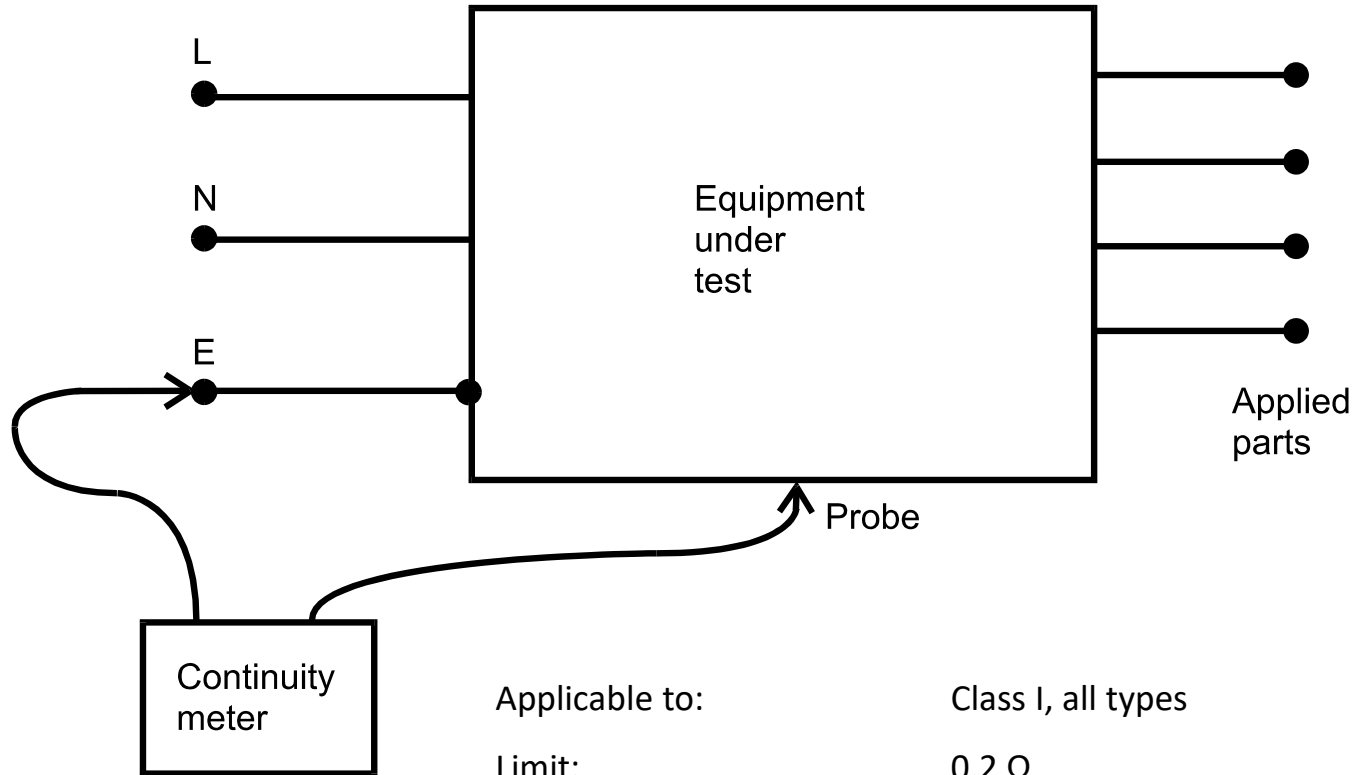
- Normal condition includes
 - Reversed mains
- SFC's include
 - Interruption of supply conductor
 - Interruption of protective earth
 - External voltage on applied part

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ESA and DUT



PE Continuity



Applicable to:

Class I, all types

Limit:

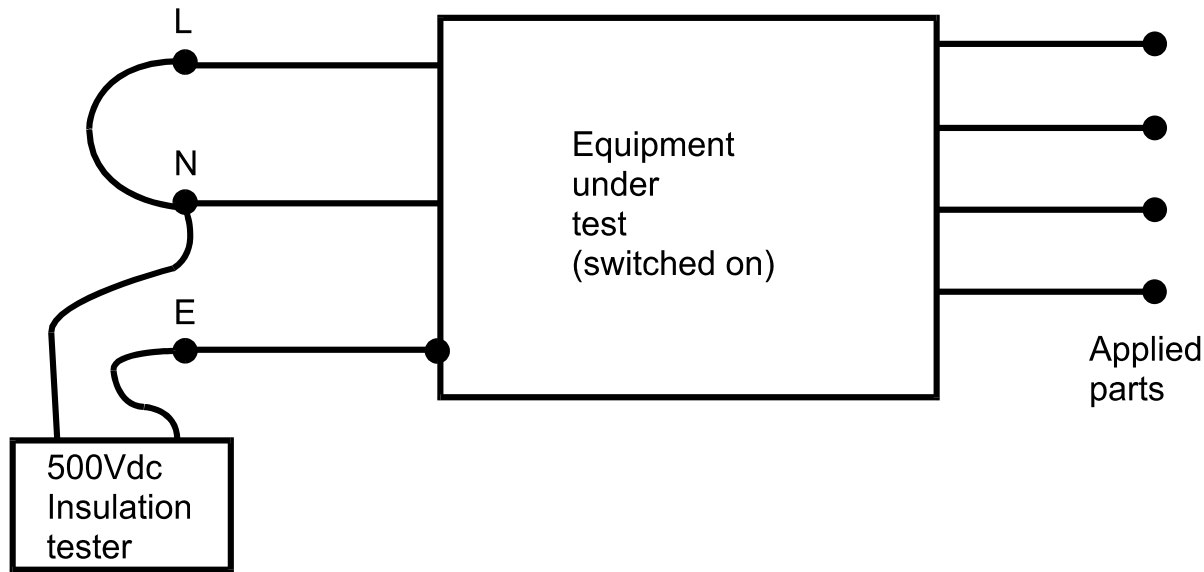
0.2 Ω

Notes:

Ensure probe is on a protective earth

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Insulation Resistance (Class I)



Applicable to:

Class I, all types

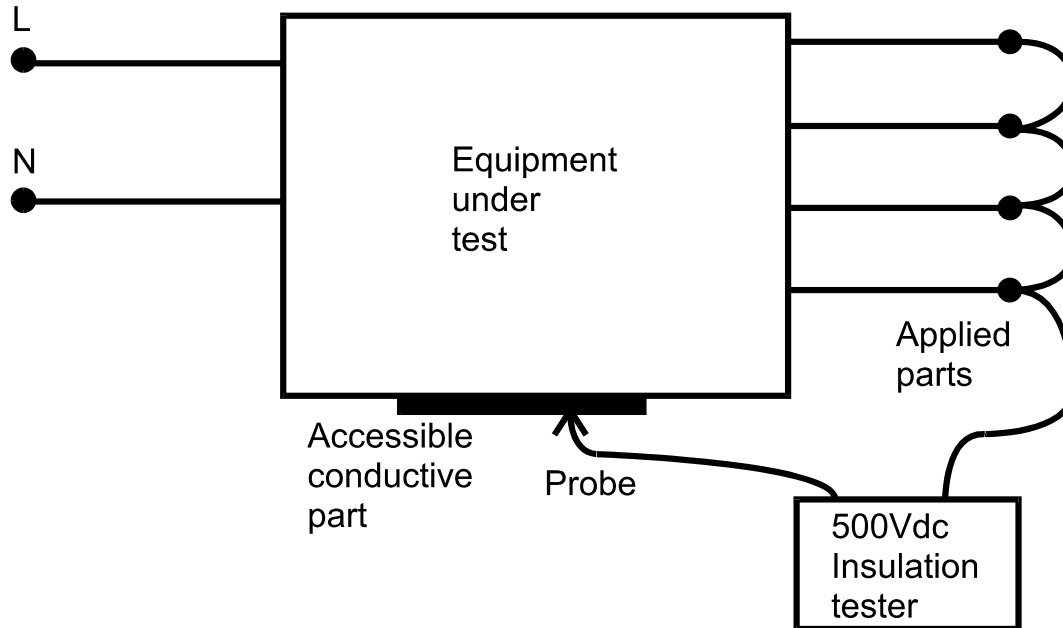
Limit:

Not less than 50MΩ*

Notes: Equipment containing mineral insulated heaters may give values down to 1MΩ. Check equipment is switched on.

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Insulation Resistance (Class II)



Applicable to:

Class II, all types having applied parts

Limit:

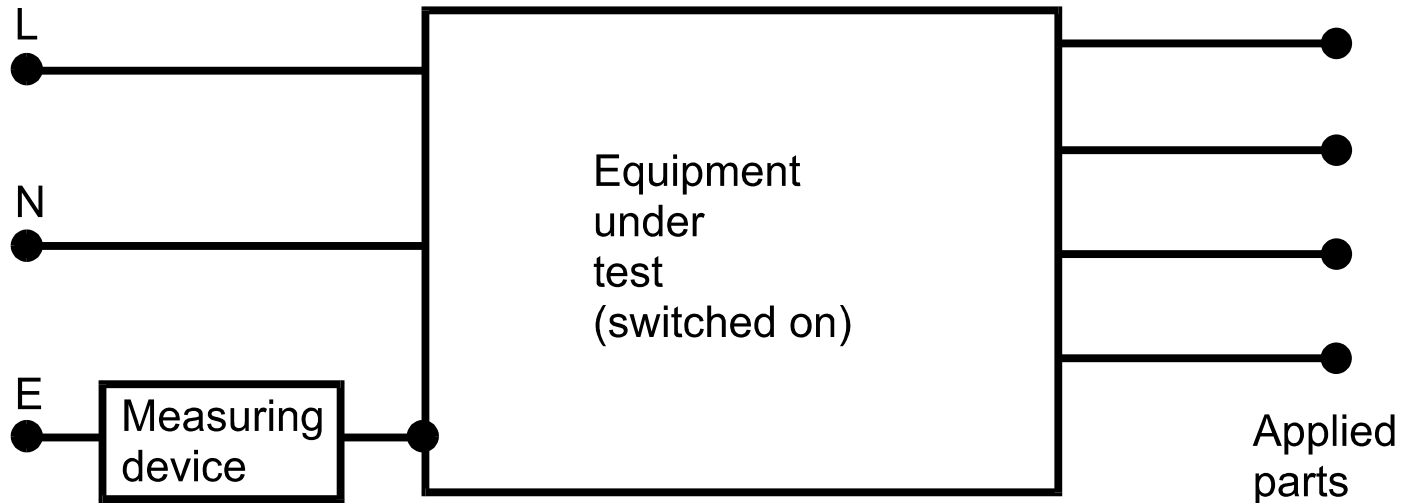
not less than 50M Ω .

Notes:

Move probe to find worst case.

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Earth Leakage Current



Applicable to:

Class I equipment, all types

Limits:*

0.5mA in NC, 1mA in SFC or 5mA and 10mA

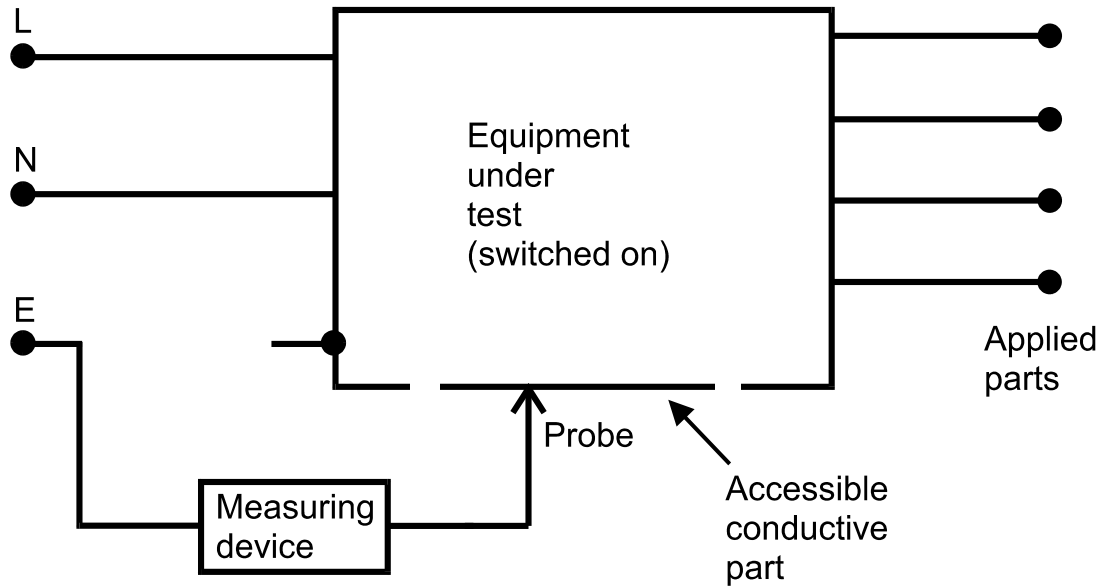
*For equipment designed to IEC60601-1 2nd Edition & 3rd Edition respectively

Notes:

Measure with mains normal and reversed.
Ensure equipment is switched on.

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Touch Current (Earth Leakage Current)



Applicable to:

Class I and class II equipment, all types.

Limits:

0.1mA in NC, 0.5mA in SFC

Notes:

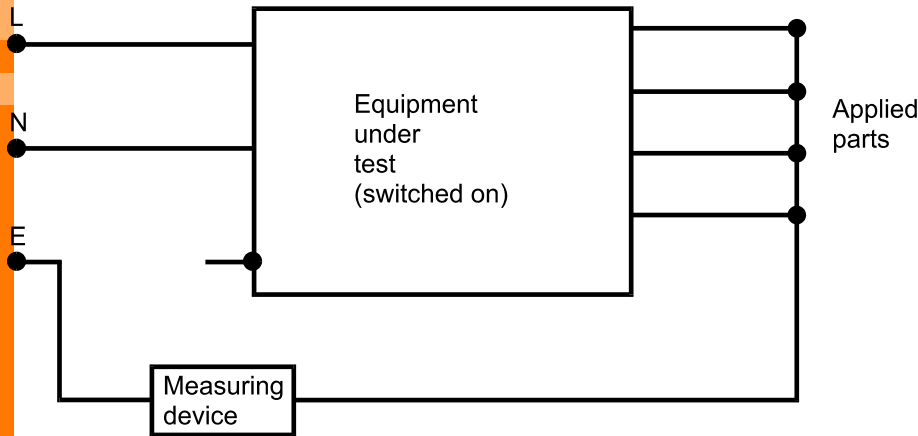
Ensure equipment switched on.

Normal and reverse mains.

Move probe to find worst case.

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Patient Leakage Current

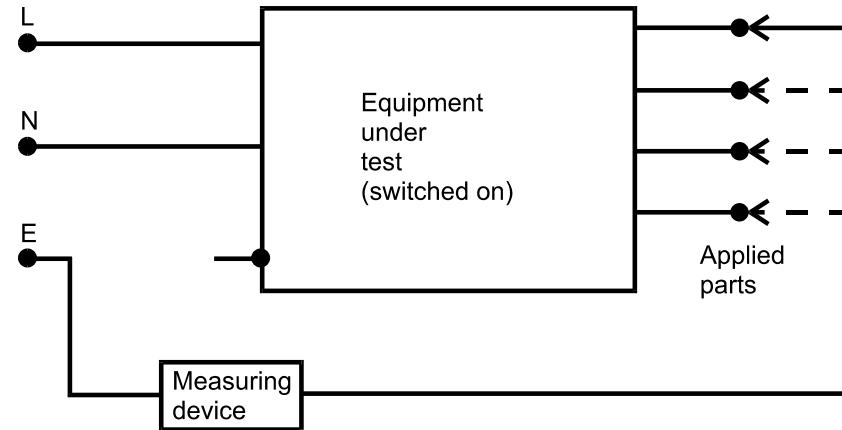


Applicable to: All classes, type B & BF equipment having applied parts.

Limits: 0.1mA in NC, 0.5mA in SFC.

Notes: Equipment on but outputs inactive.

Normal and reverse mains.



Applicable to: Class I and class II, type CF (B & BF under DB9801 only) equipment having applied parts.

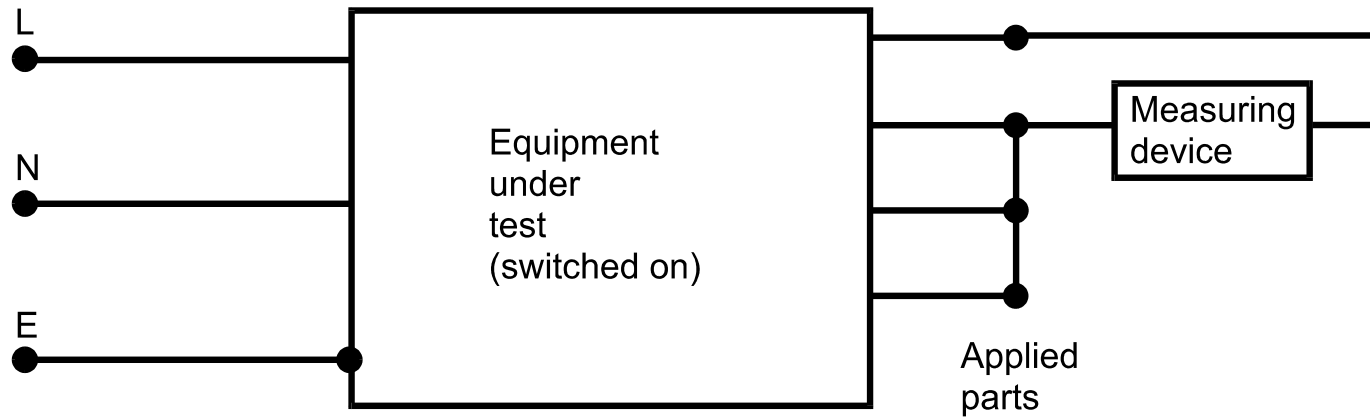
Limits: 0.01mA in NC, 0.05mA in SFC.

Notes: Equipment on but outputs inactive.

Normal and reverse mains.
Limits are per electrode.

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Patient Auxiliary Current



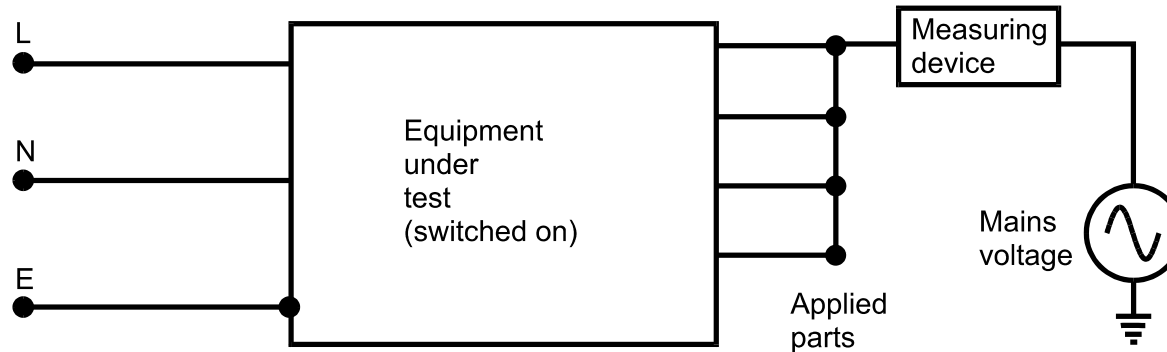
Applicable to: All classes and types of equipment having applied parts.

Limits: Type B & BF - 0.1mA in NC, 0.5mA in SFC.
Type CF - 0.01mA in NC, 0.05mA in SFC.

Notes: Ensure outputs are inactive.
Normal and reverse mains.

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Mains on Applied Parts



Applicable to:
having applied parts.

Limits:
per electrode.

Notes: Ensure outputs are inactive. Normal and reverse mains. Caution required, especially on physiological measurement equipment.

Class I & class II, types BF & CF

Type BF - 5mA; type CF - 0.05mA

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Allowable values for leakage currents from IEC 60601-1

Current in mA

	Type B		Type BF		Type CF		
	N.C.	S.F.C.	N.C.	S.F.C.	N.C.	S.F.C.	
EARTH LEAKAGE CURRENT general	0,5	1 ^a	0,5	1 ^a	0,5	1 ^a	
EARTH LEAKAGE CURRENT for EQUIPMENT according to notes ^b and ^d	2,5	5 ^a	2,5	5 ^a	2,5	5 ^a	
EARTH LEAKAGE CURRENT for EQUIPMENT according to note ^c	5	10 ^a	5	10 ^a	5	10 ^a	
ENCLOSURE LEAKAGE CURRENT	0,1	0,5	0,1	0,5	0,1	0,5	
PATIENT LEAKAGE CURRENT according to Note ^e	d.c	0,01	0,05	0,01	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5	0,01	0,05
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the signal input part or signal output part)	–	5	–	–	–	–	
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)	–	–	–	5	–	0,05	
Patient auxiliary current according to Note ^g	d.c	0,01	0,05	0,01	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5	0,01	0,05

Example of Test Report Form

Testing organisation:		Test before putting into service (reference value) <input type="checkbox"/>	
Name of testing person:		Recurrent test <input type="checkbox"/>	
Test after repair <input type="checkbox"/>			
Responsible organization:			
Equipment:		ID-Number:	
Type:		Production No./Serial Nr.:	
Manufacturer:		Class of protection: I II Battery	
Applied part type: 0 B BF CF		Mains connection: ¹⁾ PIE NPS DPS	
Accessories:			
Test:		Complies:	
Measurement equipment:		Yes	No
Visual inspection:		<input type="checkbox"/>	<input type="checkbox"/>
Measurements:		measured value	
Protective earth resistance	_____ Ω	<input type="checkbox"/>	<input type="checkbox"/>
Equipment leakage current (according to Figure ___)	_____ mA	<input type="checkbox"/>	<input type="checkbox"/>
Patient leakage current (according to Figure ___)	_____ mA	<input type="checkbox"/>	<input type="checkbox"/>
Insulation resistance (according to Figure ___)	_____ MΩ	<input type="checkbox"/>	<input type="checkbox"/>
Functional test (parameters tested):		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

Deficiency / Note:

Overall assessment:

- f No safety or functional deficiencies were detected!
- g No direct risk, deficiencies detected may be corrected on short term!
- h Equipment shall be taken out of operation until deficiencies are corrected!
- i Equipment does not comply - Modification / Exchange of components / Taking out of service - is recommended!

Next recurrent test necessary in 6 / 12 / 24 / 36 months!

Name: _____ Date / Signature: _____

¹⁾ PIE Permanent installed equipment
 NPS Non- DETACHABLE POWER SUPPLY CORD
 DPS DETACHABLE POWER SUPPLY CORD



Table of Safety Electrical Tests

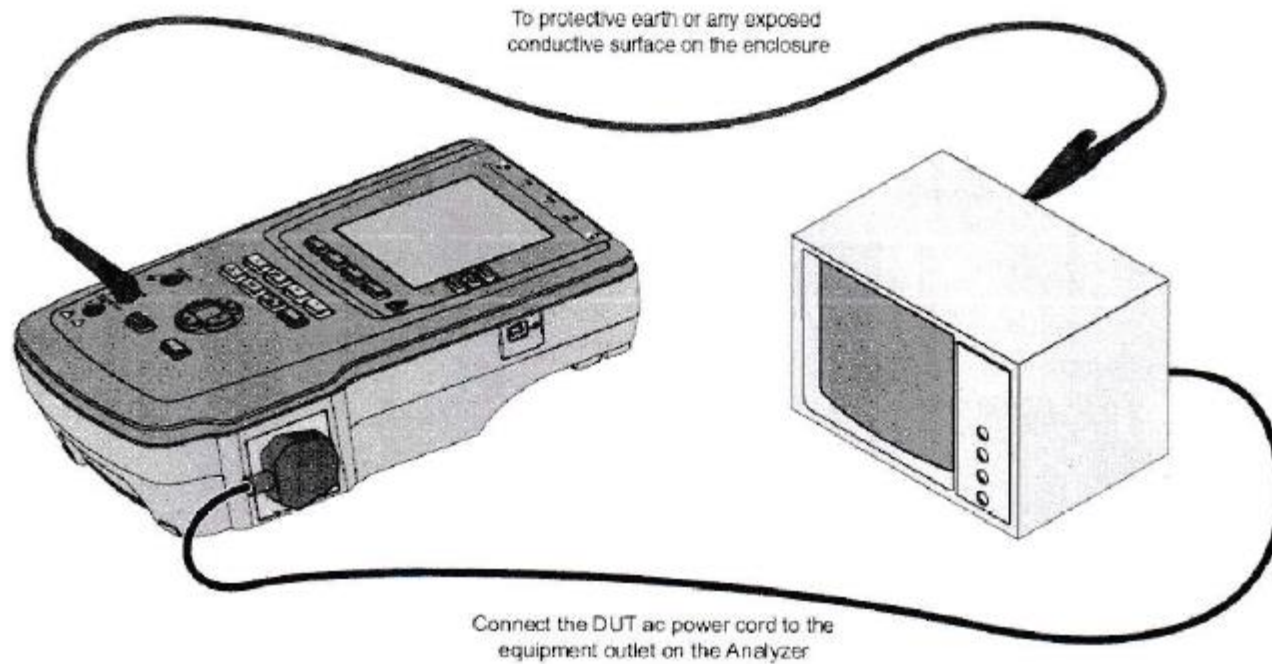
	Current in mA/ Ω		Remarks	
	Measure	Limits	PASS	FAIL
Mains Voltage - Live to Neutral - Live to Earth - Neutral to Earth Protective Earth Connection				
Insulation Resistance Test - Live and Neutral to Protective Earth - Applied Part to Protective Earth - Mains to Applied Part - Mains to Non-Earth Conductive Part - Applied Port to Non-Earth Conductive Part				
Earth Leakage Test - Normal Polarity - Normal Polarity, Open Neutral - Reversed Polarity - Reversed Polarity Open Neutral				
ENCLOSURE LEAKAGE CURRENT - Normal Polarity - Normal Polarity, Open Neutral - Normal Polarity Open Earth - Reversed Polarity - Reversed Polarity, Open Neutral - Reversed Polarity, Open Earth				
PATIENT LEAKAGE CURRENT - Normal Polarity - Normal Polarity, Open Neutral - Normal Polarity, Open Earth - Reversed Polarity - Reversed Polarity, Open Neutral - Reversed Polarity, Open Earth				

<p>PATIENT AUXILIARY CURRENT</p> <p>Combination 01</p> <ul style="list-style-type: none"> - Normal Polarity - Normal Polarity, Open Neutral - Normal Polarity, Open Earth - Reversed Polarity, Open Neutral - Reversed Polarity, Open Earth <p>Combination 02</p> <ul style="list-style-type: none"> - Normal Polarity - Normal Polarity, Open Neutral - Normal Polarity, Open Earth - Reversed Polarity, Open Neutral - Reversed Polarity, Open Earth <p>Combination 03</p>				
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<p>MAINS ON APPLIED PART</p> <ul style="list-style-type: none"> - Normal - Reversed 				
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An example: EKG

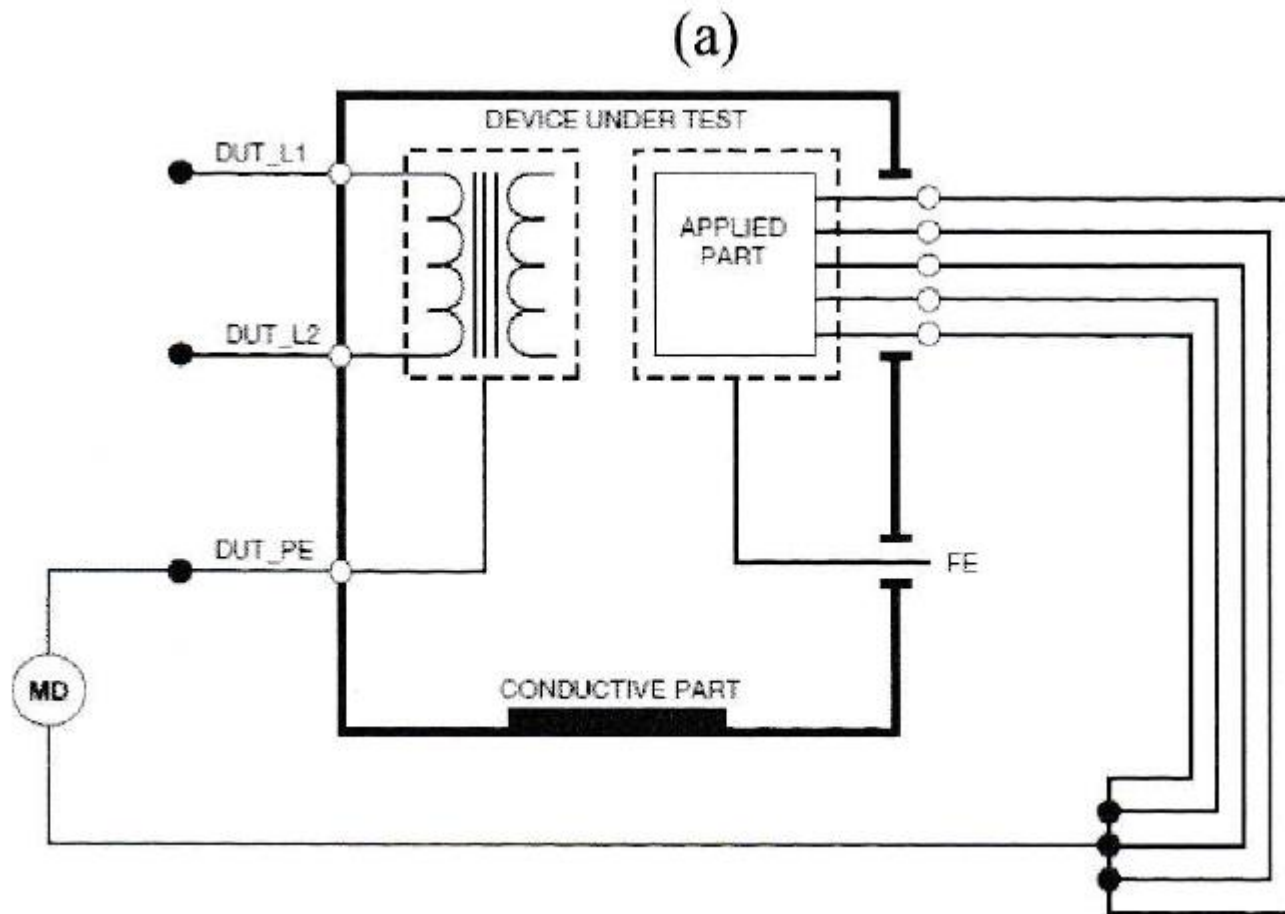
PE Resistance



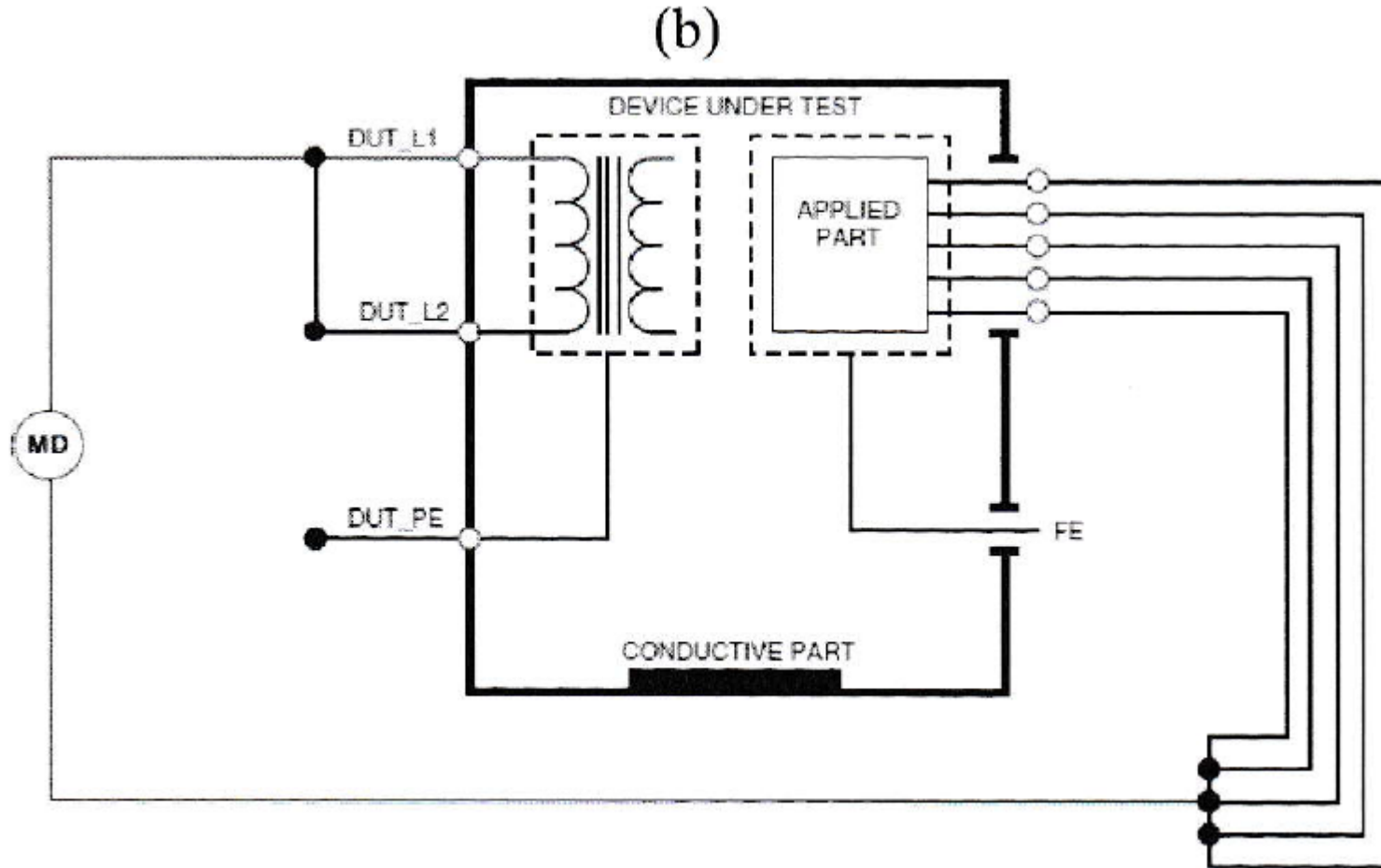
Insulation Resistance

- (a) Applied Parts to Protective-Earth Insulation
- (b) Mains to Applied Parts Insulation
- (c) Mains to Non-Earth Accessible Conductive Points
- (d) Applied Parts to Non-Earth Conductive Points

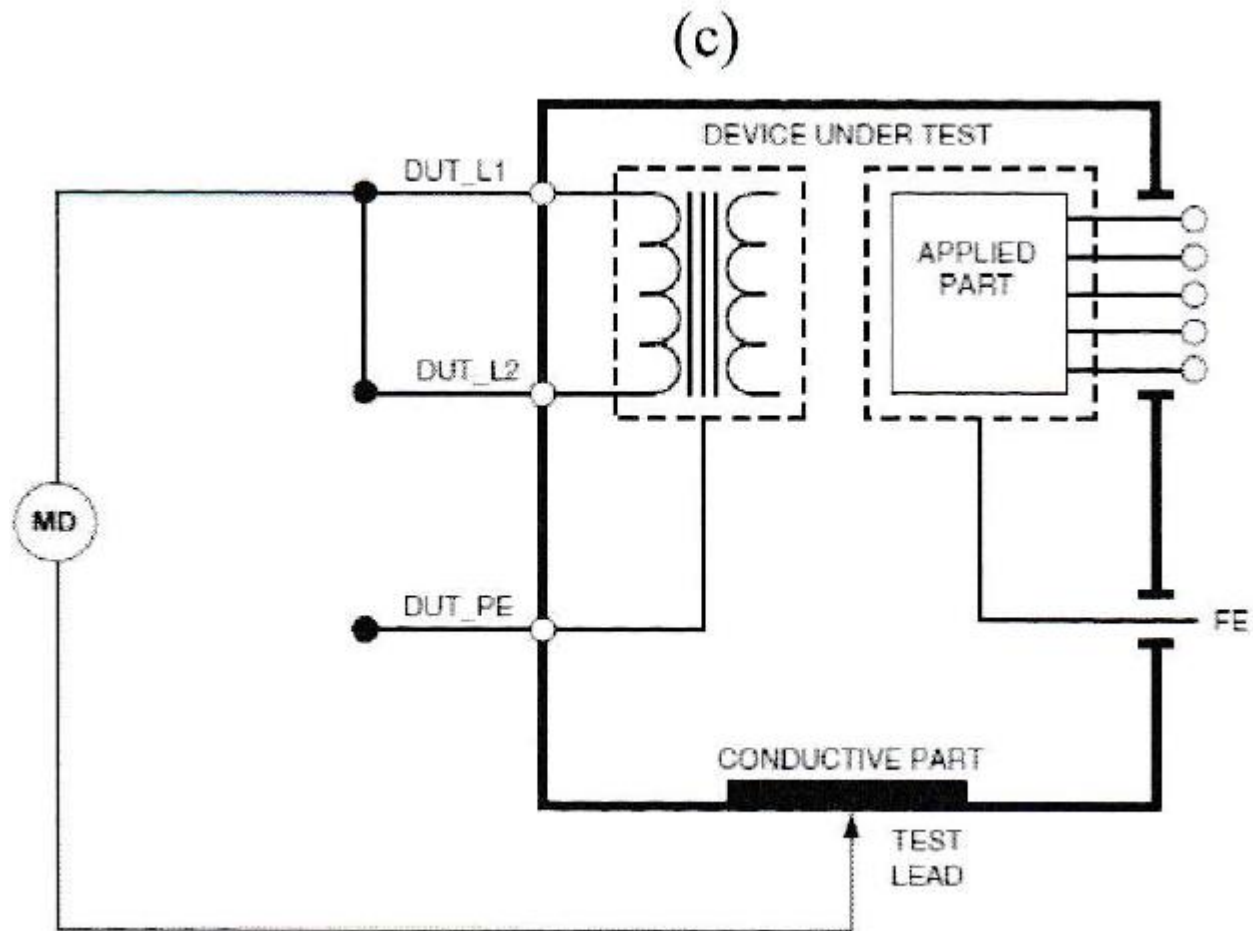
Insulation Resistance (Applied Parts to Protective-Earth Insulation)



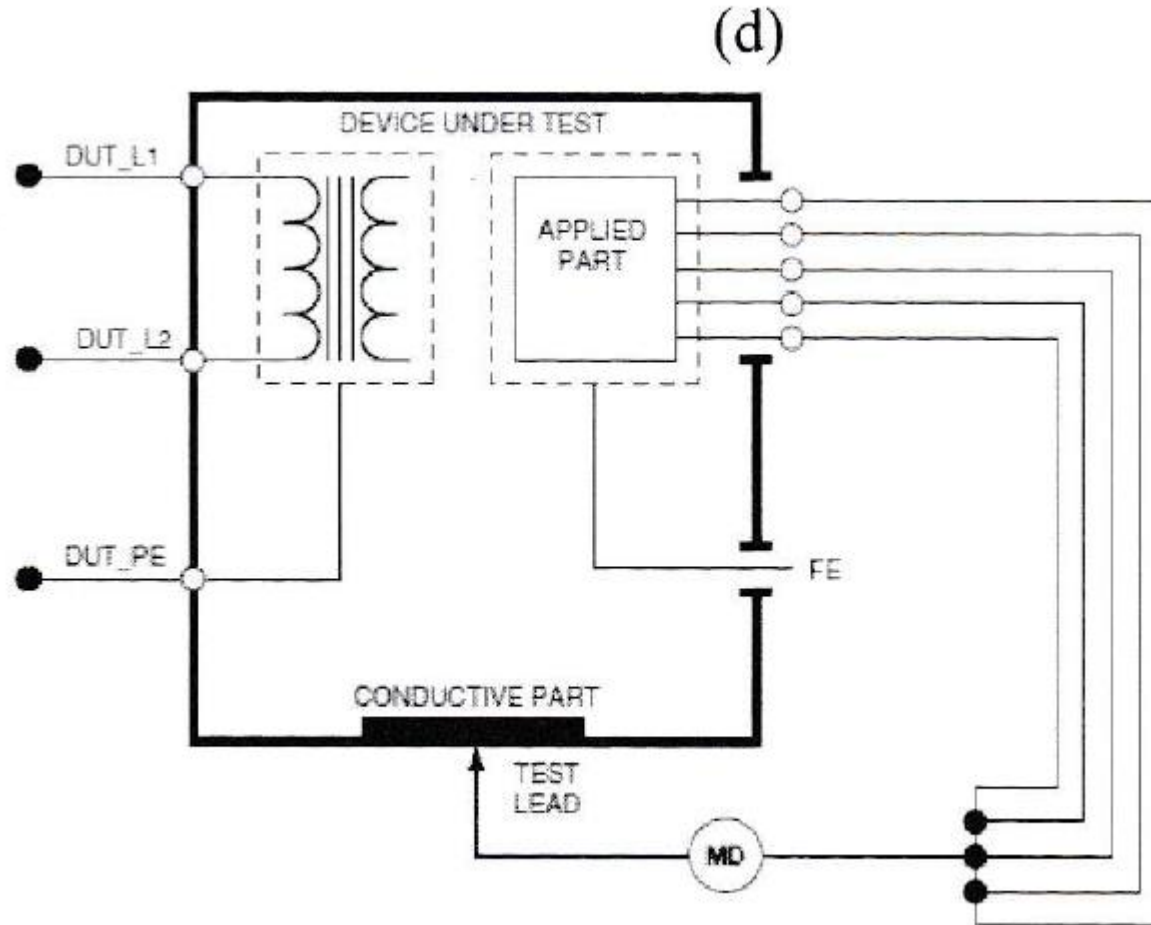
Insulation Resistance (Mains to Applied Parts Insulation)



Insulation Resistance (Mains to Non-Earth Accessible Conductive Points)



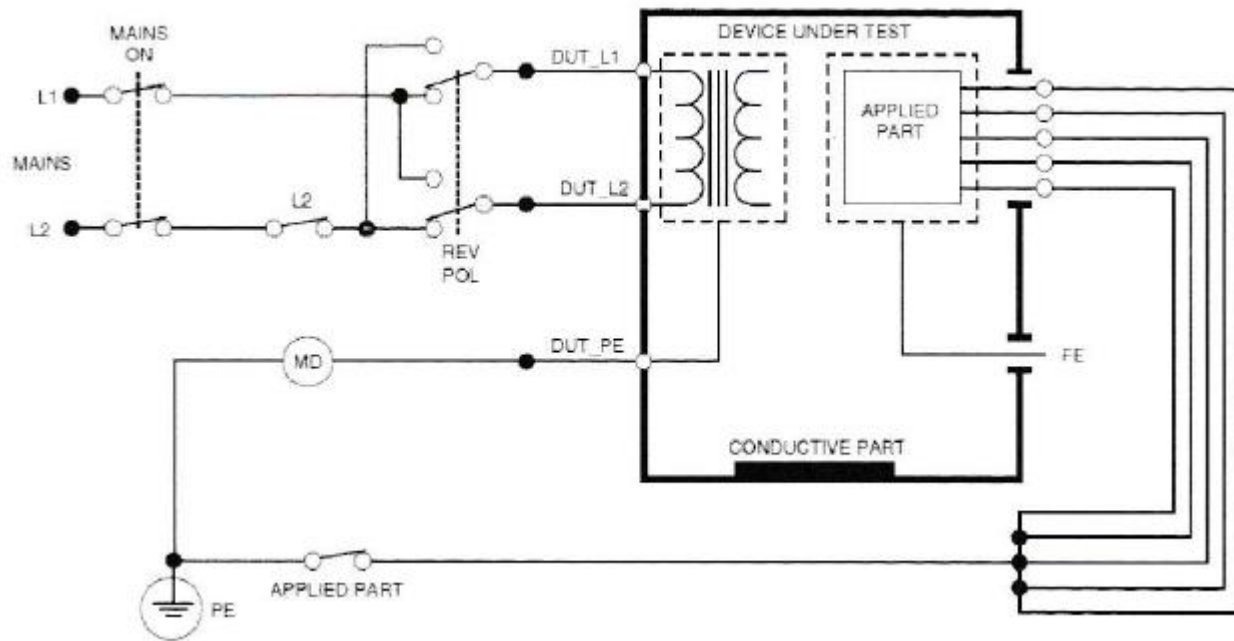
Insulation Resistance (Applied Parts to Non-Earth Conductive Points)



Leakage Current

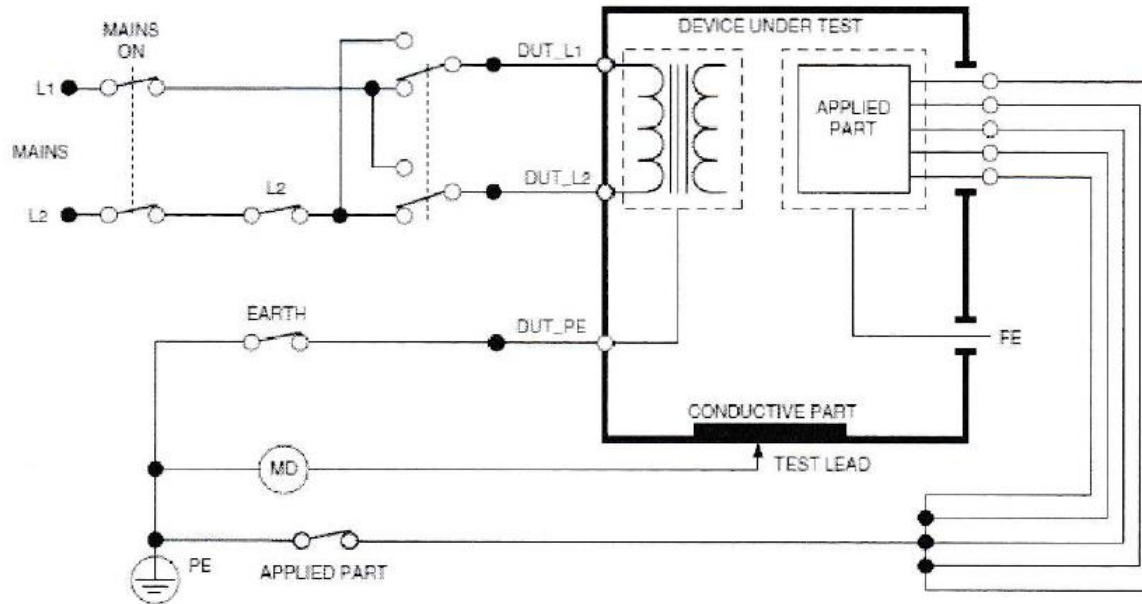
- IEC60601 lists six leakage current test:
 - Protective Earth Resistance
 - Earth Leakage Current
 - Touch or Enclosure Leakage Current
 - Patient Leakage Current
 - Patient Auxiliary Leakage Current
 - Mains on Applied Part (MAP) Leakage Current

Earth Leakage Current



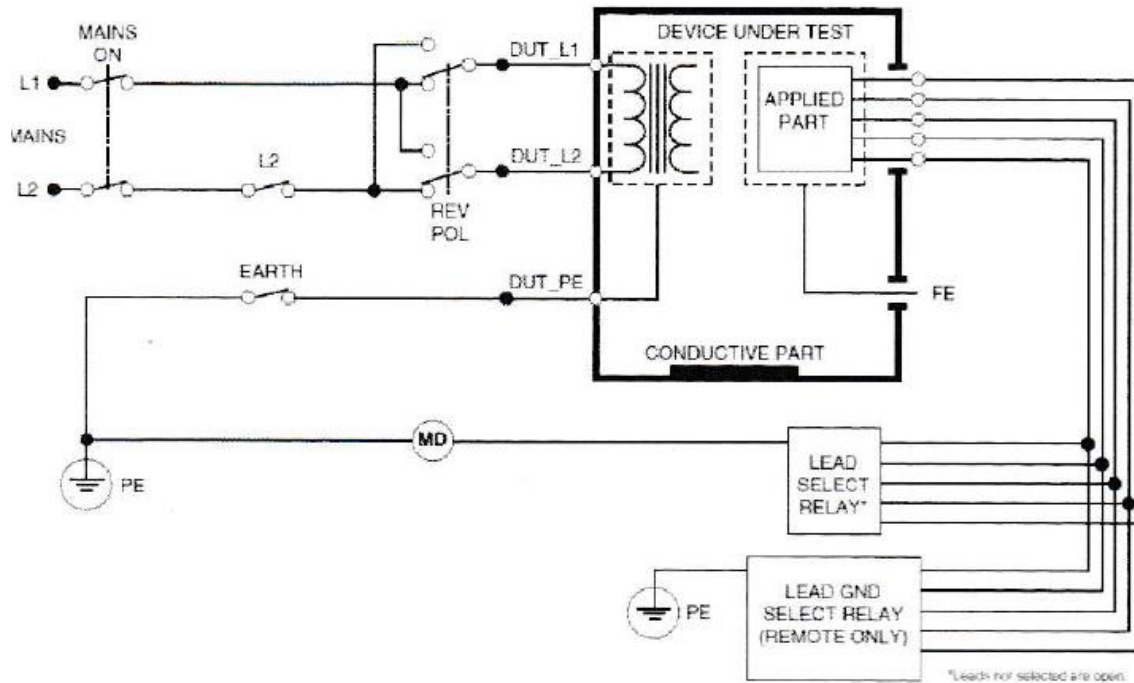
- The following outlet conditions apply when performing this test:
 - Normal Polarity
 - Normal Polarity, Open Neutral
 - Reversed Polarity
 - Reversed Polarity, Open Neutral

Chassis (Enclosure) Leakage



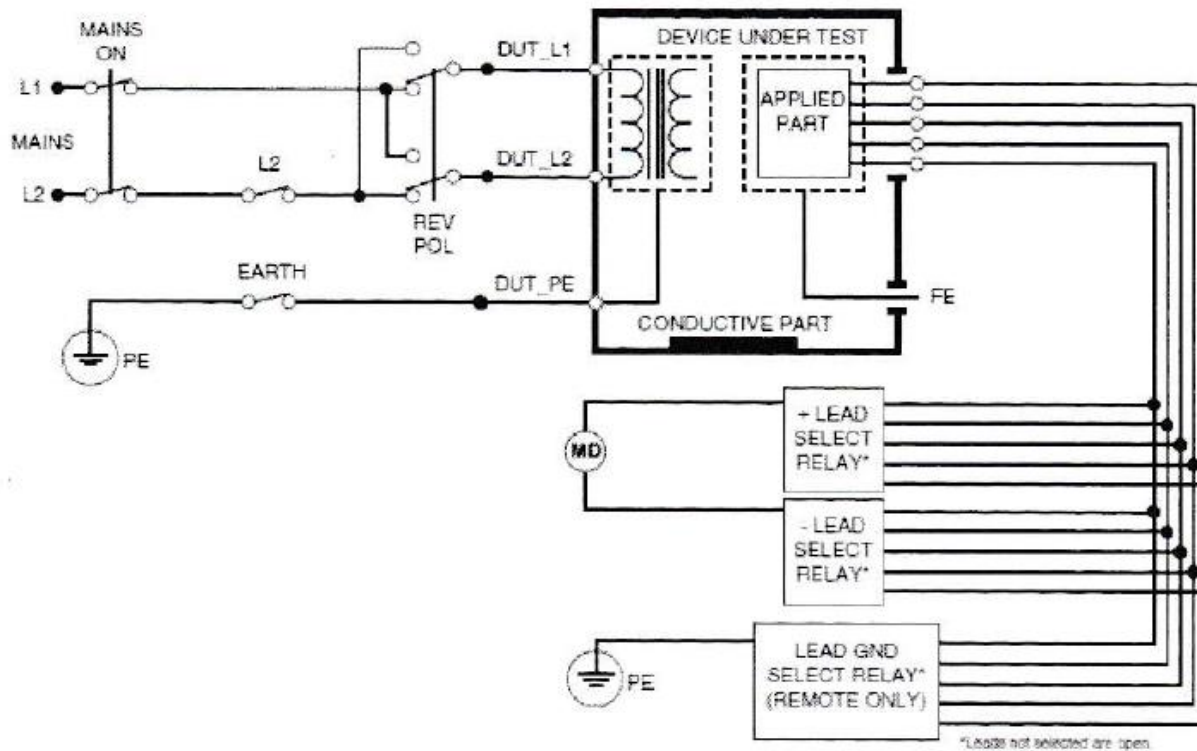
- The following outlet conditions apply when performing this test:
 - Normal Polarity
 - Normal Polarity, Open Earth
 - Normal Polarity, Open Neutral
 - Reversed Polarity
 - Reversed Polarity, Open Earth
 - Reversed Polarity, Open Neutral

Lead-to-Ground (Patient) Leakage



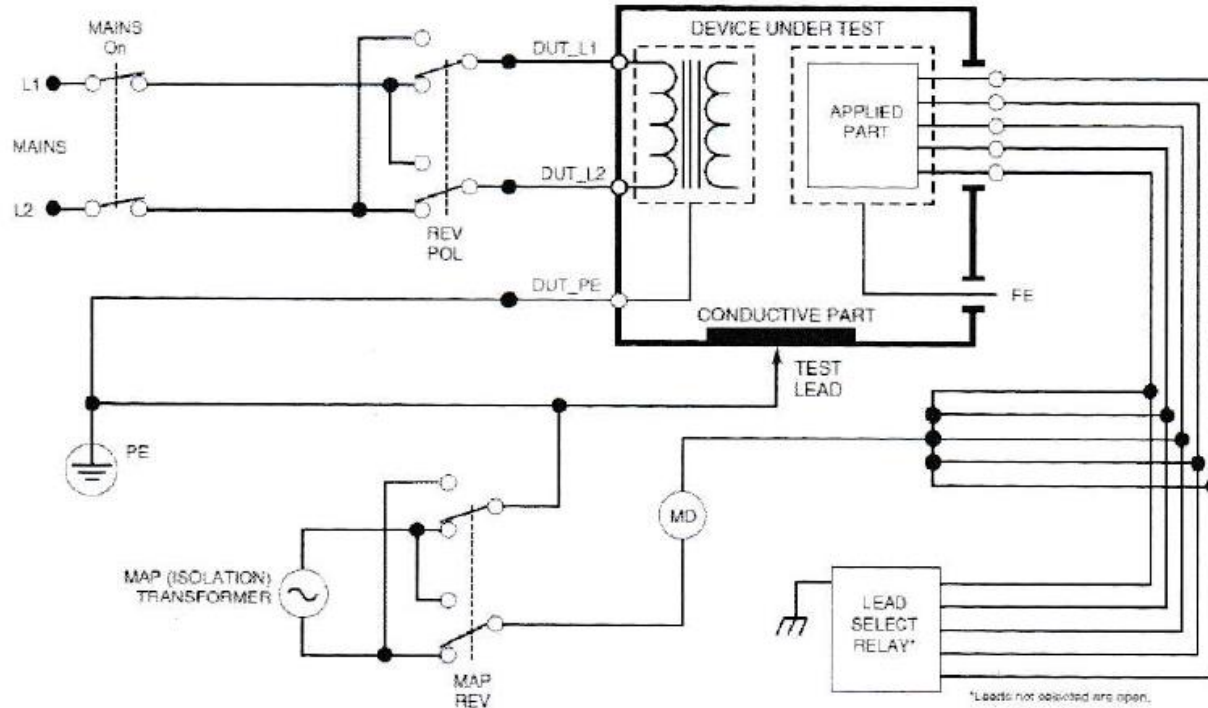
- Normal Polarity
- Normal Polarity, Open Neutral
- Normal Polarity, Open Earth
- Reversed Polarity
- Reversed Polarity, Open Neutral
- Reversed Polarity, Open Earth

Lead-to-Lead (Patient Auxiliary) Leakage



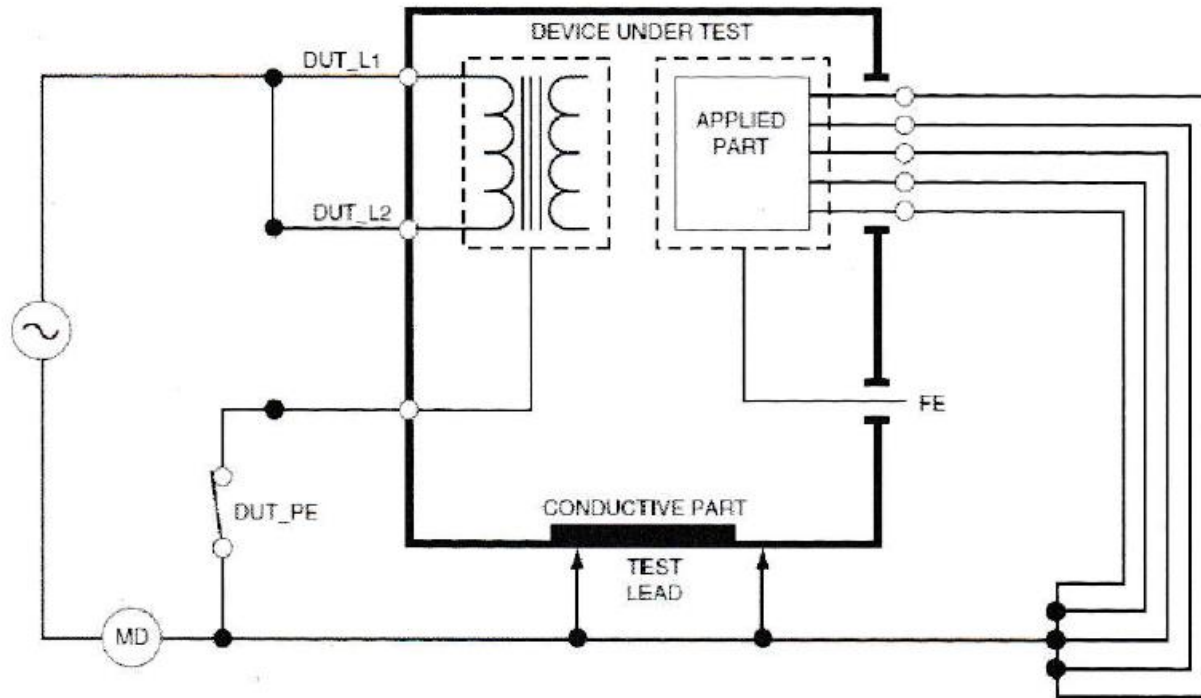
- Normal Polarity
- Normal Polarity, Open Neutral
- Normal Polarity, Open Earth
- Reversed Polarity, Open Neutral
- Reversed Polarity, Open Earth

Lead Isolation (Mains on Applied Part) Leakage



- Normal Polarity
- Reverse Polarity

Alternative Equipment Leakage



- Closed Earth
- Open Earth

Example

ELECTRICAL TESTS								
Test Title		Standard		Measurement			Pass/ Fail	
Mains supply	L1 – L2	240V ± 10%						
	L1 – Gnd	0V ± 5V						
	L2 – Gnd	240V ± 10%						
Earth continuity		≤ 0.2Ω						
Enclosure leakage current (External)	Normal/ Reverse	≤ 10 uA	Normal		Reverse			
	Gnd Open	≤ 500 uA	Gnd Open		Gnd Open			
Earth leakage current (Gnd Conductor)	Normal/ Reverse	≤ 500 uA	Normal		Reverse			
	Gnd Open	≤ 1000 uA	Gnd Open		Gnd Open			
Patient Leakage Current (Individual Leads to Gnd)	Normal/ Reverse	≤ 10 uA	RL	Normal		Reverse		
				Gnd Open		Gnd Open		
			RA	Normal		Reverse		
				Gnd Open		Gnd Open		
				LA	Normal		Reverse	
					Gnd Open		Gnd Open	
	Gnd Open	≤ 50 uA	LL	Normal		Reverse		
				Gnd Open		Gnd Open		
			V1- V6	Normal		Reverse		
				Gnd Open		Gnd Open		
Patient Auxiliary Current (Interlead)	Normal/ Reverse	≤ 10 uA	RA	Normal		Reverse		
			- LA	Gnd Open		Gnd Open		
	Gnd Open	≤ 50 uA	RA	Normal		Reverse		
			-RL	Gnd Open		Gnd Open		
			LA	Normal		Reverse		
			-RL	Gnd Open		Gnd Open		
Isolation Test		Normal/ Reverse	≤ 50 uA	Normal		Reverse		

Example: SNI IEC 60601-2-51

TESTING REPORT FORM

VISUAL INSPECTION						
Subject			Comment			
Accessories condition						
Cable condition						
Plug condition						
Fuses presence						
ELECTRICAL TESTS (ref. to electrical safety testing result)						
FUNCTIONAL TEST						
	Set			Measurement /status		
Paper speed (mm/sec)	10	25	50			
Sensitivity (mm/mV)	5	10	20			
Lead off detection warning? (Y/N)						
Recording Check:						
i) is R wave positive on I, II, and III? (Y/N)						
ii) is R wave <u>has</u> the highest amplitude on lead II (compared to I and III)? (Y/N)						
iii) is R wave is inverted on the aVR trace? (Y/N)						
Does each recorded trace started by a 1mV square wave pulse? (Y/N)						
Waveform check:						
2.0 Hz square wave, 1mVpp	Amplitude 1mVpp? (Y/N)					
2.0 Hz square wave, 1mVpp	Under damped/ <u>well adjusted</u> / over damped?					
10 Hz sine wave, 1mVpp	<u>Bandpass</u> works? (Y/N)					
40 Hz sine wave, 1mVpp	-3dB works? (Y/N)					
50 Hz sine wave, 1mVpp	Notch filter works? (Y/N)					
100 Hz sine wave, 1mVpp	-3dB works? (Y/N)					
2.0 Hz triangle wave, 3mVpp	Signal linear? (Y/N)					
30 BPM (Bit Per Minute) NSR (Normal Sinus Rhythm) waveform, 1mV _{peak}	Rate = ... Alarm works? (Y/N)		Rate = ...			
60 BPM NSR waveform, 1mV _{peak}	Rate = ... Alarm works? (Y/N)		Rate = ...			
120 BPM NSR waveform, 1mV _{peak}	Rate = ... Alarm works? (Y/N)		Rate = ...			
180 BPM NSR waveform, 1mV _{peak}	Rate = ... Alarm works? (Y/N)		Rate = ...			
240 BPM NSR waveform, 1mV _{peak}	Rate = ... Alarm works? (Y/N)		Rate = ...			
General Comments:					Tested by:	

Thank You