

BIOMEDICAL & CLINICAL ENGINEERING

Medical Equipment Preventive Maintenance and Electrical Safety Test

Dr. Eng. Ibrahim Andijani

Within the 21st International Operations
& Maintenance Conference in the Arab Countries

An Initiative by



Organized by



Collaborators



دكتور مهندس إبراهيم نعمة الله أندجاني

استشاري هندسة طبية

مدير إدارة سلامة المنشآت بمدينة الأمير سلطان الطبية العسكرية بالرياض.

عضو ونائب رئيس مجلس إدارة الجمعية العلمية السعودية للهندسة الطبية

عضو لجنة الاعتماد المهني بالهيئة السعودية للمهندسين.

رئيس شعبة الهندسة الطبية الحيوية بالهيئة السعودية للمهندسين.

رئيس اللجنة العلمية المؤتمر الدولي للهندسة الطبية والاكلينيكية في الدول العربية.

مقيم مستشفيات معتمد في أمن وسلامة المرافق المجلس المركزي لاعتماد المنشآت الصحية سابقاً.

ضابط اتصال لبلاغات الأجهزة والمنتجات الطبية ومحقق حوادث أجهزة طبية. الهيئة العامة للغذاء والدواء

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International Accreditation Body

J.C.A.H.O. (Joint Commission on Accreditation of Healthcare Organization)

N.C.Q.A. (National Committee for Quality Assurance)

I.S.O. (International Standard Organization)

JCIA (Joint Commission International Accreditation)

A.C.H.S. (Australian Council on Healthcare Standards)

CCHSA Canadian Healthcare Accreditation Body

National Accreditation Body

CBAHI:
Central Board for Accreditation of Health care Institutions

GAHAR:
General Authority for Healthcare Accreditation & Regulation

ECRI Institute Accreditation



CBAHI FMS Standards Overview

- [FMS.1 – FMS.10]

Facility Safety



- [FMS.11 – FMS.13]

Security



- [FMS.14 – FMS.15]

Hazardous Materials



- [FMS.16 – FMS.17]

Emergency Preparedness and Plans



- [FMS.18 – FMS.24]

Fire Safety



- [FMS.25 – FMS.27]

Medical Equipments



- [FMS.28 – FMS.39]

Utility Systems



FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.1 The hospital has adequate number of qualified biomedical staff.
- FMS.25.2 There is a written biomedical equipment plan that covers the following:
 - FMS.25.2.1 A comprehensive inventory of medical equipment with their corresponding locations.
 - FMS.25.2.2 Preventive maintenance program that conforms with the manufacturer's instructions.
 - FMS.25.2.3 The program specifies, for each equipment, the frequency of checks, methods of checks, acceptance criteria, and actions to be taken in the event of unsatisfactory results.

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.2.4 The program includes the process for investigation and follow-up of equipment failure that addresses reporting of failure, immediate remedial actions, assessment of the failure effect on reported results and services (needs alignment), and requalification of the equipment.
- **FMS.25.2.5 Electrical safety testing for patient related equipment.**
- FMS.25.2.6 History record for the maintenance schedule, failure incidence, and repairs done.

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.3 Technical service manuals for all equipment are available at the biomedical workshops.
- FMS.25.4 Operator manuals are available at all departments using the equipment.
- FMS.25.5 The hospital ensures that all maintenance works are conducted by qualified and trained staff.
- FMS.25.6 Equipment maintenance and repairs are documented to help in the decision making for replacement.
- FMS.25.7 Investigation procedures conform to manufacturer's instructions.
- FMS.25.8 There is an equipment recall system that is implemented.
- FMS.25.9 Each department has a back-up or alternative for each critical equipment to cover for prolonged downtime.
- FMS.25.10 Preventative Maintenance data are used for upgrading/replacing of equipment.

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

- FMS.26.1 There is a policy to perform inspection on all new equipment for conformity before commissioning including those brought for "demos".
- FMS.26.2 There is a written policy for tagging medical equipment as follows:
 - FMS.26.2.1 Preventive maintenance with testing date and due date.
 - FMS.26.2.2 Inventory number.
 - FMS.26.2.3 Removal from service.
 - FMS.26.2.4 Electrical safety check.
- FMS.26.5 There is a policy to eliminate the use of extension cords.
- FMS.26.6 There is a policy to restrict the use of cellular phones in the intensive care units, operating room, and cardiology units, as needed.

FMS.27 Hospital staff are trained on safe operation of medical equipment.

- FMS.27.1 Hospital staff are trained to operate safely all medical equipment.
- FMS.27.2 The training includes physicians, nurses, and paramedics.
- FMS.27.3 The training considers the following:
 - FMS.27.3.1 New equipment.
 - FMS.27.3.2 Staff transferred from a department to another.
 - FMS.27.3.3 New staff hired.
 - FMS.27.3.4 Recurrent misuse of equipment.

- Medical Equipment Inventory
- DOCUMENT OF MEDICAL EQUIPMENT



Riyadh Military Hospital
 Department of Biomedical Engineering
 Tel: 4777714 Ext. 25469

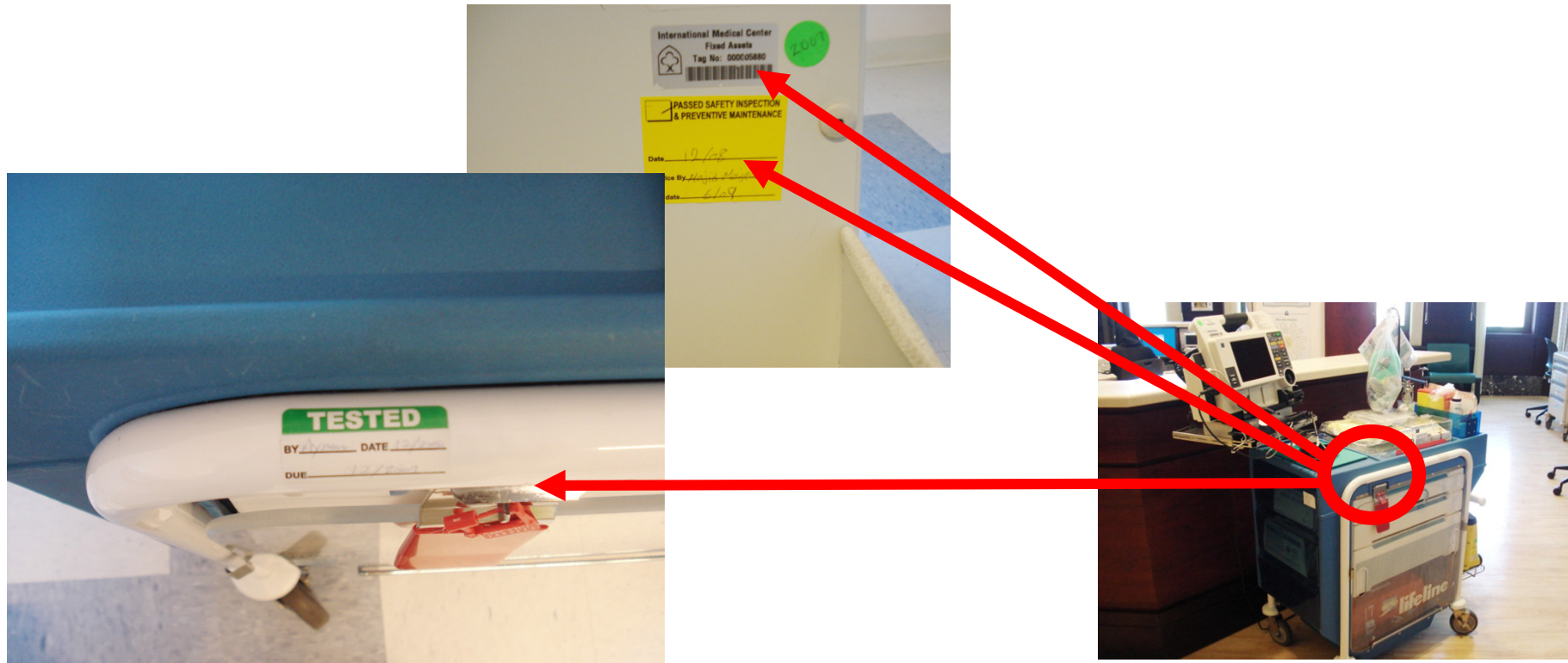
مستشفى القوات المسلحة
 إدارة الهندسة الطبية الحيوية
 ت/ 4777714 تحويلة / 25469



DOCUMENT OF MEDICAL EQUIPMENT

Bio-Eng Code:		
PC No.:		
Equipment Type:		
Safety Class: I B <input type="checkbox"/> II B <input type="checkbox"/> I BF <input checked="" type="checkbox"/> II BF <input type="checkbox"/> I CF <input type="checkbox"/> II CF <input type="checkbox"/>	PPM interval:	
Model No.		Serial No.:
Manufacture:		Functional Class:
Department:		Location:
Purchase Order:		MRF:
Cost in S.R.:		Contract No.
Warranty Length:		
Start:	End:	
Vendor:	Phone No.:	
Pre Issue Date:	Inspected By:	
Funct'l Cl:		
Comment:		

Medical Equipment Tagging policy



Medical Equipment Tagging policy

The Preventive Maintenance Sticker is Yellow safe for use & indicates the next due date for PM_ ملصق أصفر للصيانة الوقائية

PASSED SAFETY INSPECTION
& PREVENTIVE MAINTENANCE

Date ~ _____

Serviced by _____

Due date _____

The equipment which need a functional test the appropriate tag will be the Tested one ملصق يبين عمل الفحص وتاريخ الفحص القادم

TESTED

BY _____ DATE _____

DUE _____

Equipment Relocation

- The hospital departments to perform the proper use of the medical equipment to transfer or to relocate medical equipment from department to another.

This procedure it must be done in presents of biomedical engineer/technician.

إدارة ضبط الممتلكات
PROPERTY CONTROL DEPARTMENT
أمر نقل معدات

NO.:

R.K.H.
EQUIPMENT TRANSFER / STORAGE AUTHORIZATION

TAG NO. : _____ رقم الجرد
تالف نقل تخزين صرف
REJECTED TRANSFER STORAGE RELEASE

وصف / نوع القطعة
ITEM DESCRIPTION : _____
رقم نموذج الصيانة رقم الهندسه الاحيائية
REJECTION FORM NO. : _____ BIO - ENG. CODE _____
رقم التسلسل للقطعة رقم الاصل
ITEM SERIAL NO. : _____ CAPITAL NO. : _____

الموقع القديم المبنى الطابق الغرفة
OLD LOCATION : BUILDING : _____ FLOOR : _____ ROOM : _____
الادارة
تحويله
DEPARTMENT : _____ COST CODE _____ EXT.#: _____
اسم الشخص المسلم للطلب التوقيع التاريخ
PERSON RELEASED : NAME : _____ SIGNED : _____ DATE : _____

الموقع الجديد المبنى الطابق الغرفة رقم المستودع
NEW LOCATION : BUILDING : _____ FLOOR : _____ ROOM : _____ STORE # _____
الادارة
تحويله
DEPARTMENT : _____ COST CODE _____ EXT.#: _____
اسم الشخص المستلم للطلب التوقيع التاريخ
PERSON RECEIVED : NAME : _____ SIGNED : _____ DATE : _____

الحاله
CONDITION: تعمل لاتعمل اتلاف اخرى
WORKING NOT WORKING FOR DISPOSAL OTHERS

الاسباب / ملاحظات
REASON / REMARKS: _____
التاريخ التوقيع
DISTRIBUTED BY : NAME : _____ SIGNED : _____ DATE : _____
التاريخ التوقيع
COMPUTER INPUT : NAME : _____ SIGNED : _____ DATE : _____
التاريخ التوقيع
بأمر _____ SIGNED : _____ DATE : _____

D. PC-100.1
Printing Press

Planned Preventive Maintenance

- Preventive Maintenance Program (PPM) as per manufacturer recommendations
- Deferred Planned Maintenance and Safety Checking of Medical Equipment



مستشفى القوات المسلحة بالرياض
RIYADH MILITARY HOSPITAL

RMH DEPARTMENT OF MEDICAL PHYSICS, CLINICAL AND BIOENGINEERING
BIOENGINEERING SECTION

**DEFERRED PLANNED MAINTENANCE AND SAFETY CHECKING
OF MEDICAL EQUIPMENT**

To: _____ Ward/Dept.: _____
Equipment: _____ Code: _____
Type: _____ Date: _____
Serial No.: _____

The above piece of equipment was not found/available for Planned Safety and Preventive Maintenance procedures between ___/___/___ and ___/___/___.

Please make the equipment available as soon as possible, contact the Bioengineering Section on Ext. _____ before continuing clinical use.

The Bioengineering Section cannot be responsible for the continued safety and performance of medical or laboratory equipment if not made available for preventive maintenance. If the equipment is no longer in use, has been withdrawn from service, or has been stolen, etc., please confirm this in writing so our records can be amended. For any further information, please contact the Senior Medical Physicist on Extension 25471.

Signed:

Dr. Ibrahim Andijani
Bioengineering Section

cc: Property Control Department

Planned Preventive Maintenance

- Preventive Maintenance Program (PPM) as per manufacturer recommendations
- **2nd Request Notice** Deferred Planned Maintenance and Safety Checking of Medical Equipment



مستشفى القوات المسلحة بالرياض
RIYADH MILITARY HOSPITAL
DEPARTMENT OF MEDICAL PHYSICS, CLINICAL AND BIO-ENGINEERING
BIO-ENGINEERING SECTION

DEFERRED PLANNED MAINTENANCE AND SAFETY CHECKING OF MEDICAL EQUIPMENT

To: Ward/Dept.:

Equipment: Code:

Type: Date:

Serial No.: **SECOND REQUEST NOTICE**

The above piece of equipment was **still** not found/available for Planned Safety and Preventive Maintenance procedures between ____/____/____ and ____/____/____ .

Please make the equipment available as soon as possible, contact the Bio-Engineering Section on Ext. _____ before continuing clinical use.

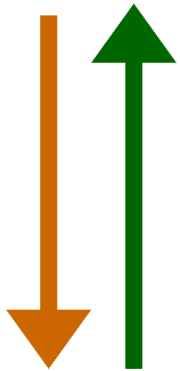
Please note that this is the second request to conduct Planned Safety and Preventive Maintenance procedures.

The Bio-Engineering Section cannot be responsible for the continued safety and performance of medical or laboratory equipment if not made available for preventive maintenance. If the equipment is no longer in use, has been withdrawn from service, or has been stolen, etc., please confirm this in writing so our records can be amended. For any further information, please contact the Senior Medical Physicist on Extension 5471.

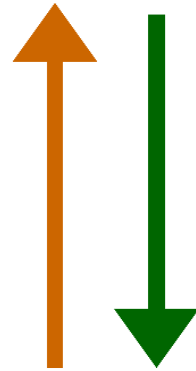
Signed:

PPM Vs CM

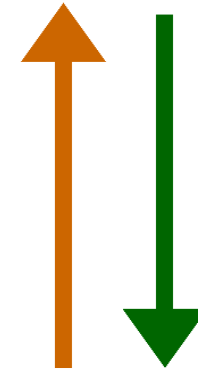
PPM



CM



ACCEDINETS



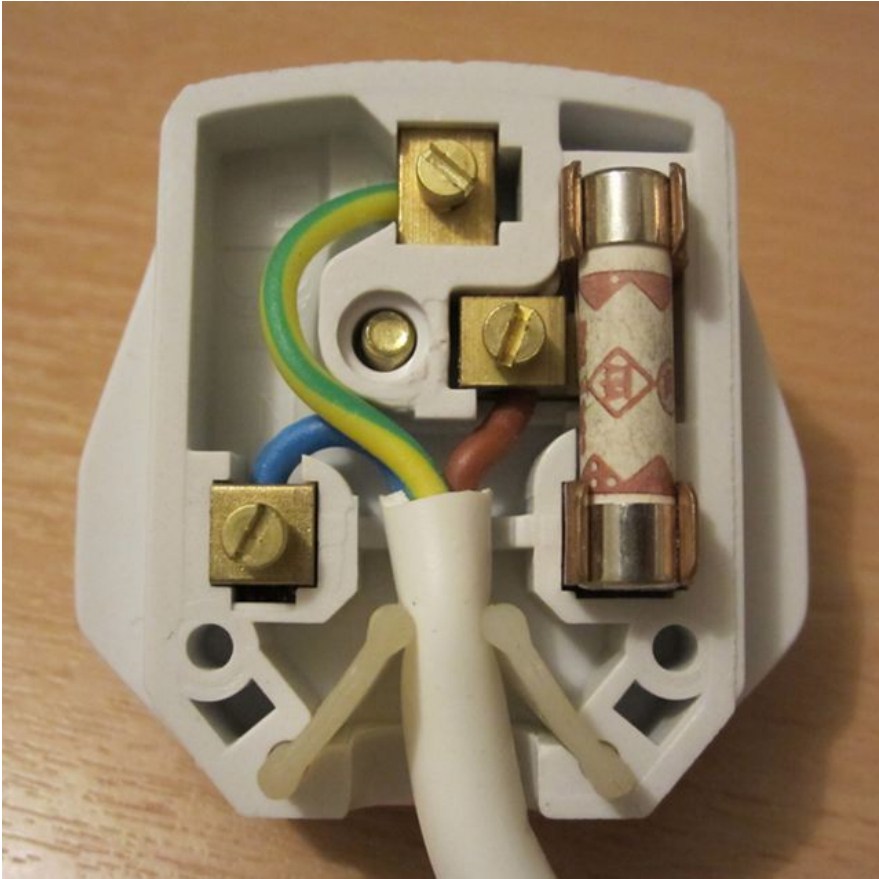
Plan Preventive maintenance of medical equipment procedure consist of the following:

- ❖ **Visual Inspection.**
- ❖ **Functional Test.**
- ❖ **Electrical Safety Test.**

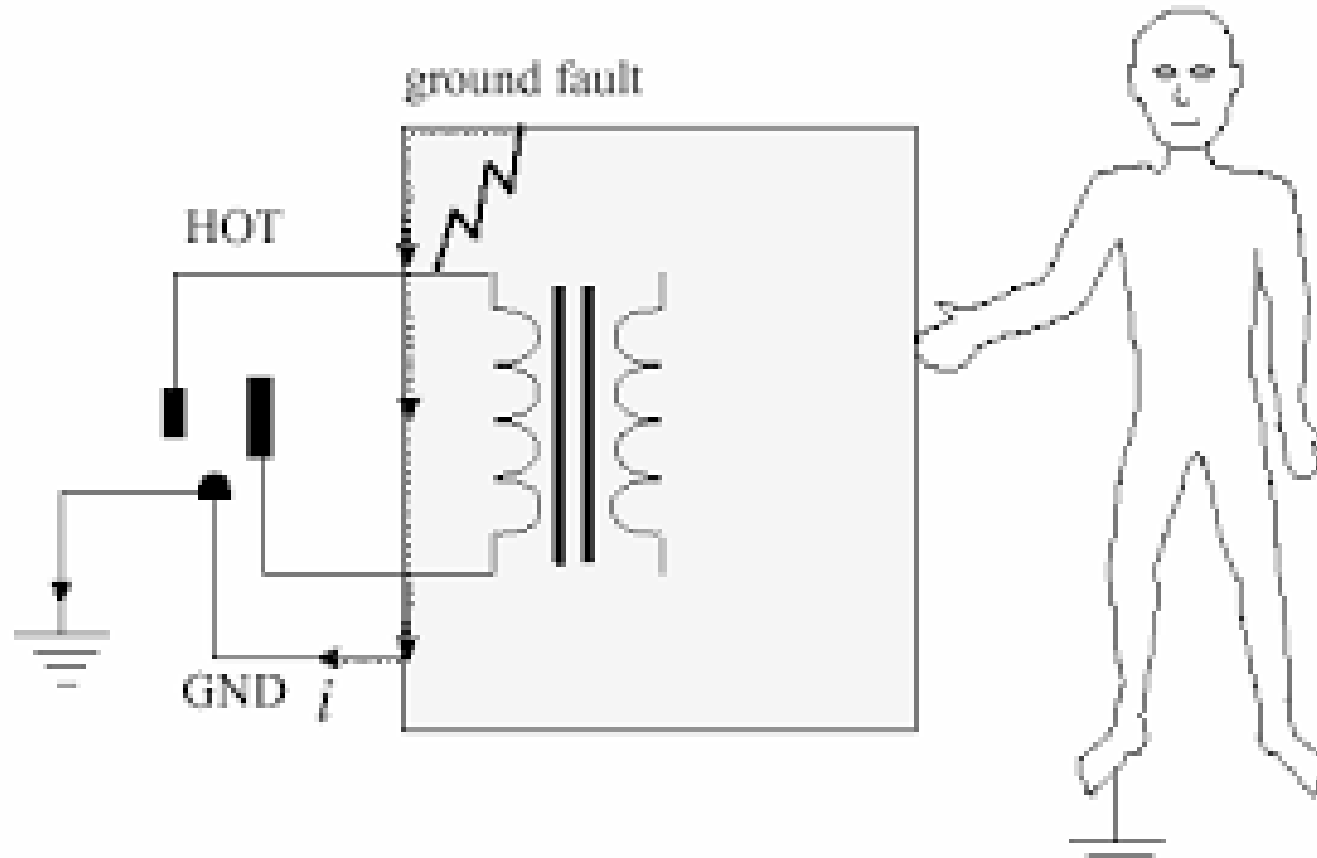
■ Class I Medical Equipment:

- Equipment in which protection against electric shock does not rely on basic insulation but also provided by connecting all accessible conductive parts into protective earth conductor on the mains wiring, so these parts can not become live in case of failure of basic insulation.
- Protective Earth Conductor: the conductor to be connected to the protective earth terminal & external protective earthing system.

Class I Medical Equipment



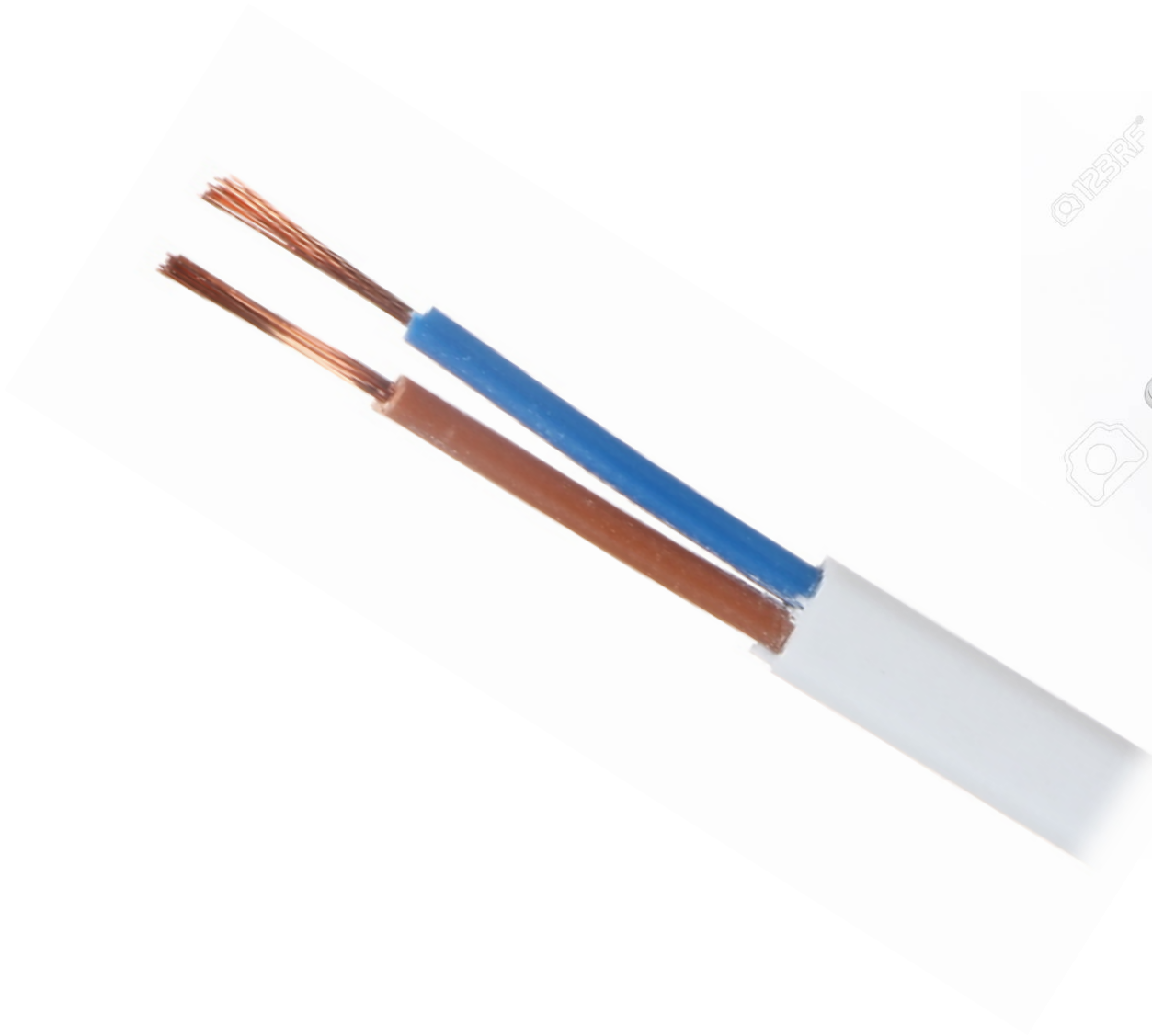
Class I Medical Equipment

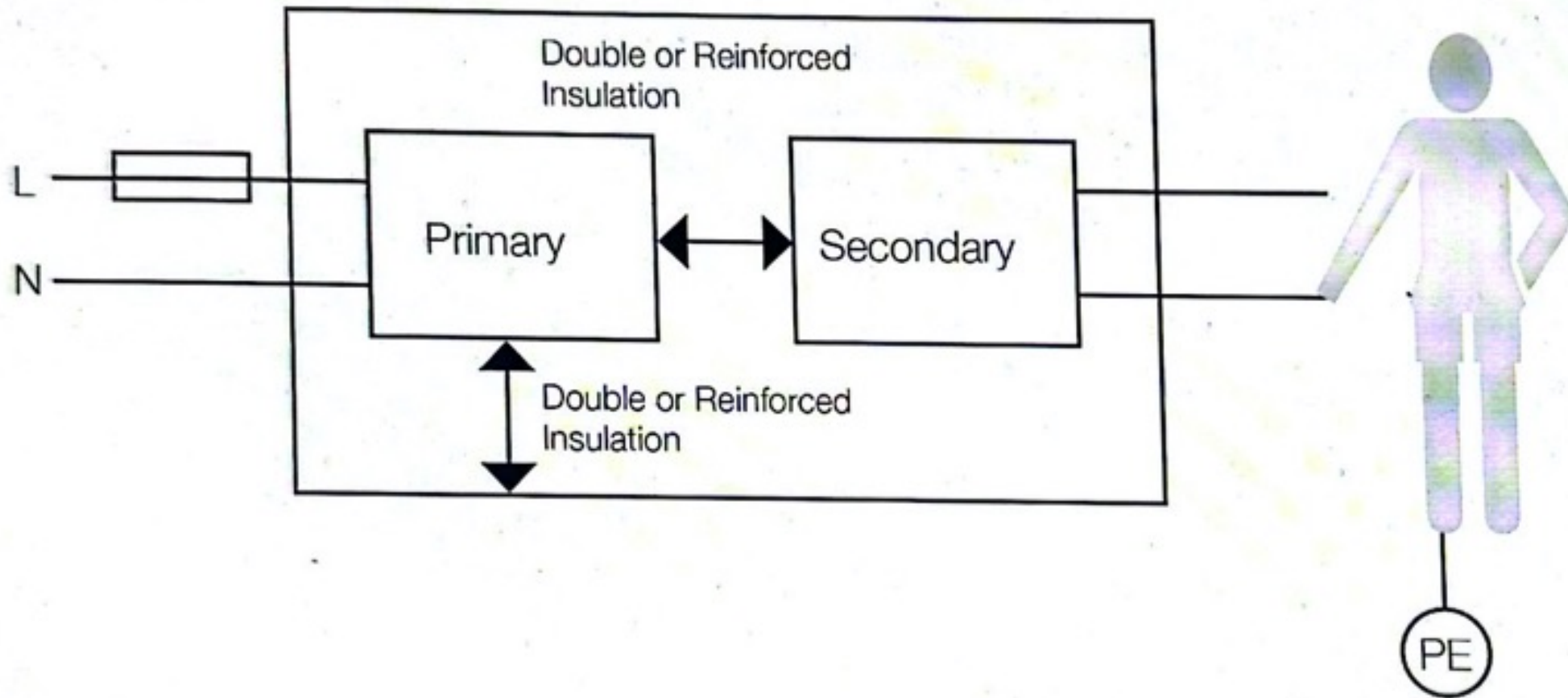


■ Class II Medical Equipment:

- Equipment in which protection against electric shock depends on the provision of additional insulation. This protection is double insulation where there are two layers on insulation between any live parts and accessible parts of the equipment.

■ Class II Medical Equipment:





■ Class III Medical Equipment:

- Equipment operating on SELV(Safe Extra-Low Voltage).
- SELV is a voltage which does not exceed (25VAC / 60VDC).

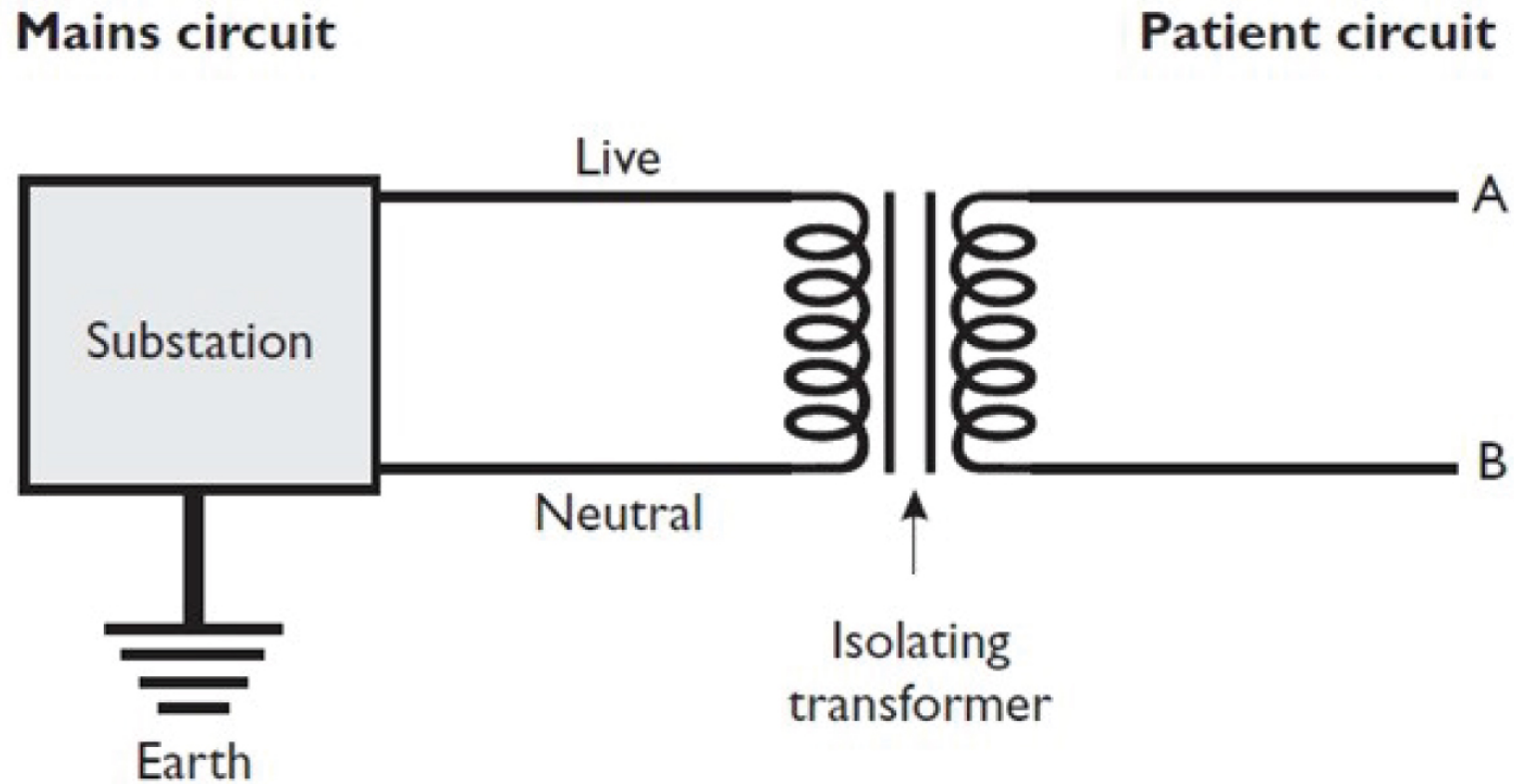
■ Type B Medical Equipment:

- Accepted protection against electric shocks with regards to leakage current & reliability.

■ Type BF Medical Equipment:

- Floated isolated applied parts from patient body.
- It's only intended for applying to patient's skin but has floated input circuits. No connection between patient & earth.

Type BF Medical Equipment



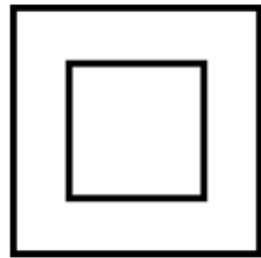
■ Type CF Medical Equipment:

- Floated isolated applied parts from patient cardiac parts.
- Provides a higher protection against electrical shock .
- It's only intended for applying to direct cardiac application.

Medical Device Electrical Safety Symbols



Class I (1)



Class II (2)



Class III (3)

TYPE B
APPLIED PART



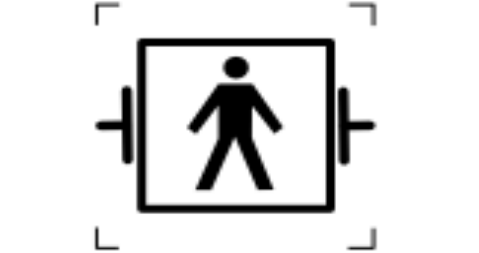
TYPE B
APPLIED PART
DEFIBRILLATION PROOF



TYPE BF
APPLIED PART



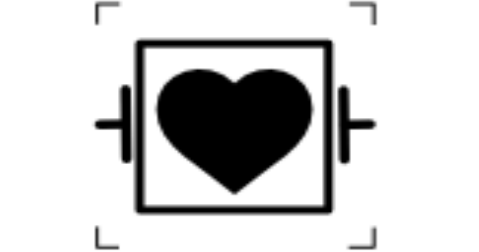
TYPE BF
APPLIED PART
DEFIBRILLATION PROOF



TYPE CF
APPLIED PART



TYPE CF
APPLIED PART
DEFIBRILLATION PROOF



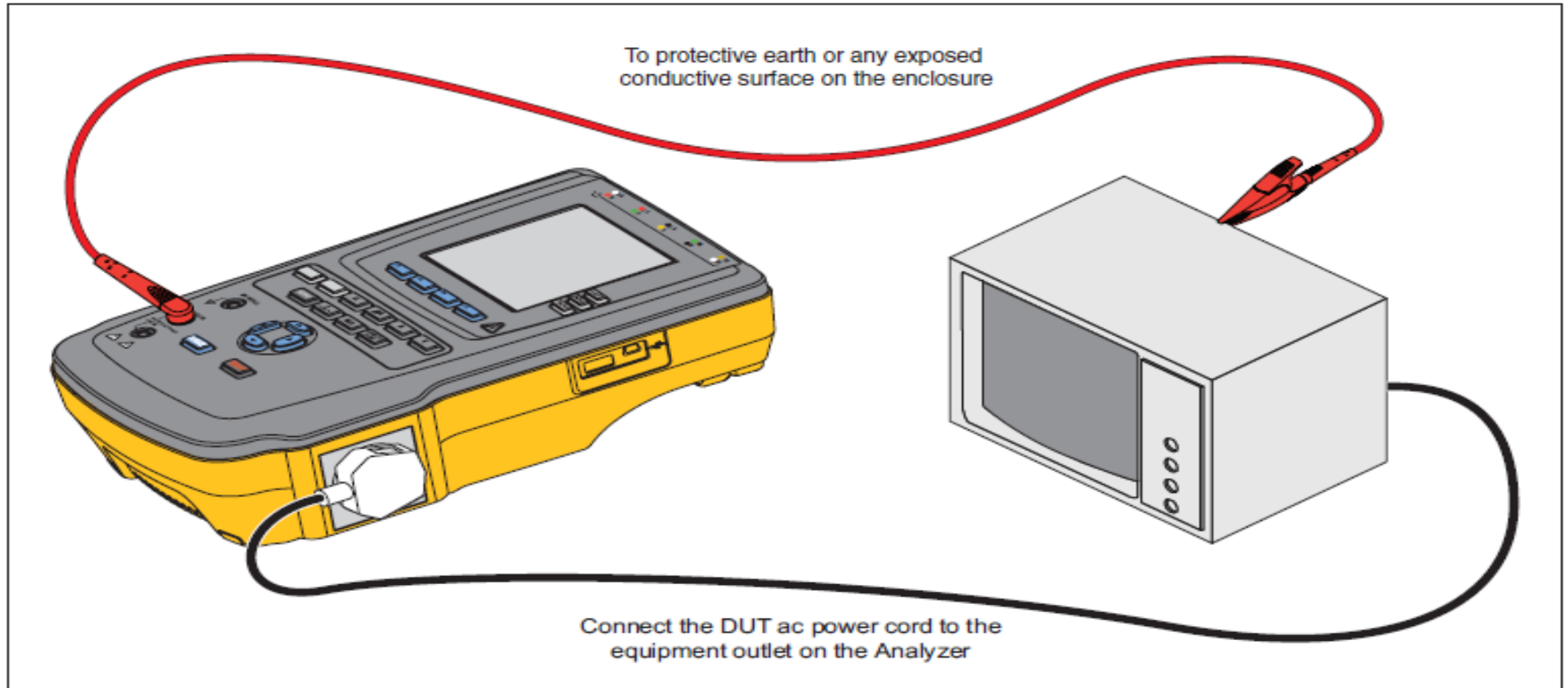
Safety Testing of medical equipment should be performed as follow:

- ❖ **Periodically – PPM (Periodic Preventive Maintenance).**
- ❖ **Post Acceptance Test – Pre-Issue Check.**
- ❖ **Post Repair – after carrying out any corrective maintenance.**

■ Protective Earth Resistance (Ω):

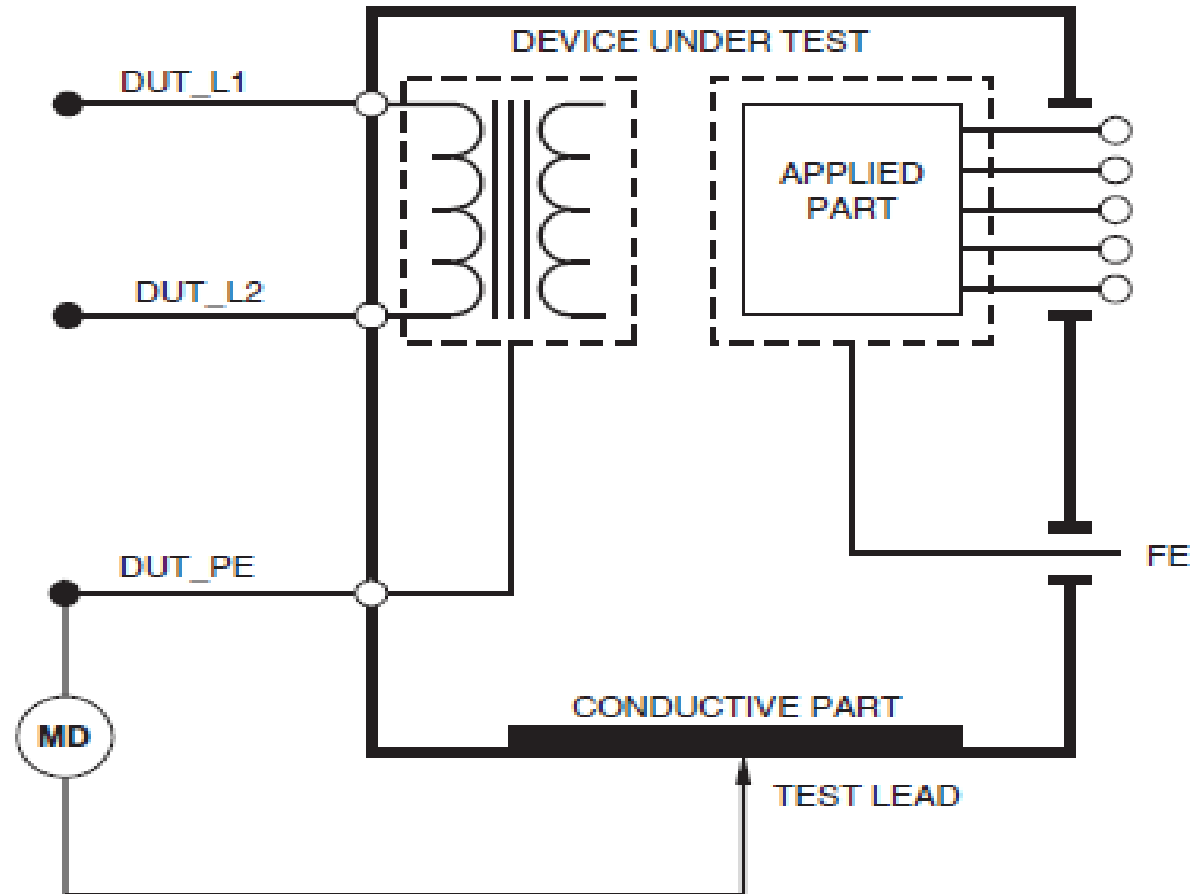
- By definition it's the resistance between protective earth plug & protective conductive parts.
- Under NC (Normal Condition) of operation the resistance should be $< 0.2\Omega$.
- For Class II medical equipment this resistance is not measured or this test is N/A(not applicable).

Electrical safety Test



Ground Wire (Protective Earth) Resistance Measurement Connections

Protective Earth Resistance Test



Ground Wire (Protective Earth) Resistance Measurement Schematic

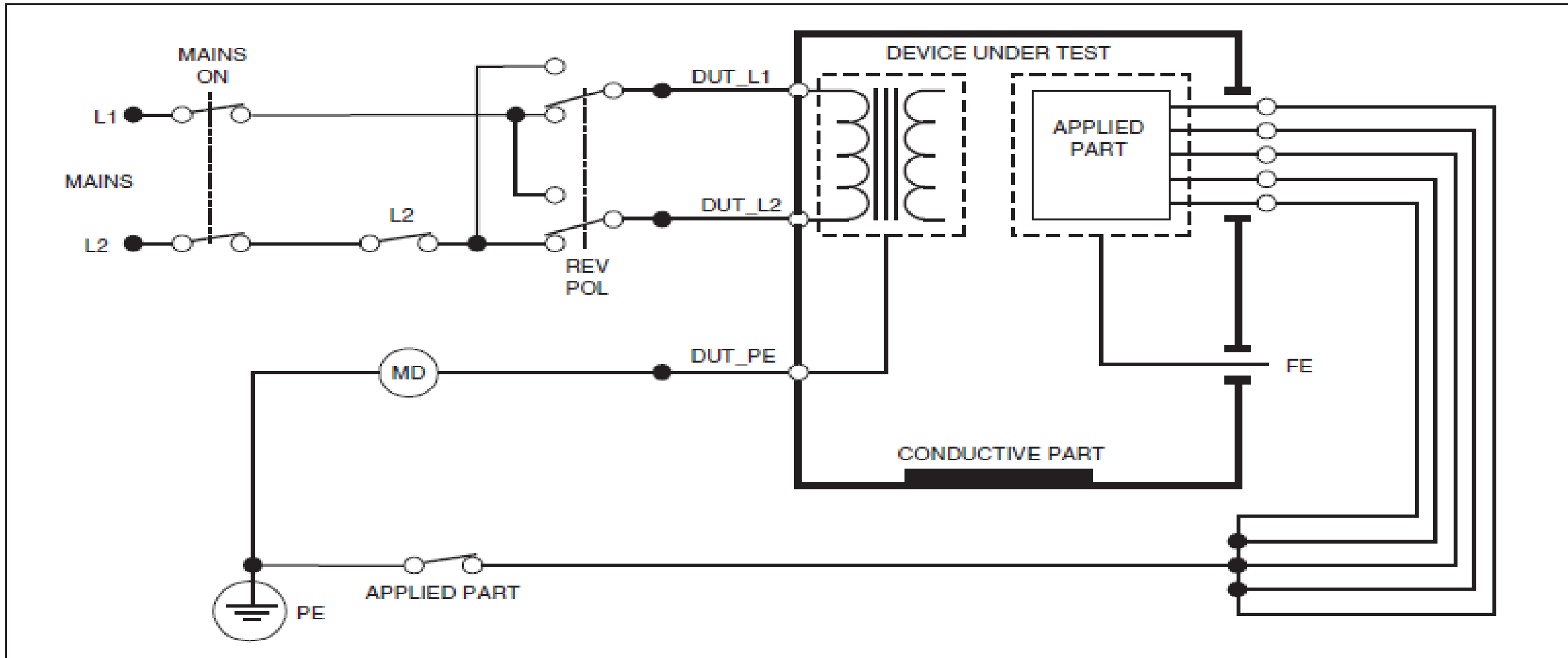
■ Leakage Current(μ A):

- The following types of Leakage Current is measured under the safety test procedures:

A. Protective Earth Leakage Current:

- it's the current which normally flows in the earth conductor of a protective earth conductor of the equipment.

Earth Leakage Current Test

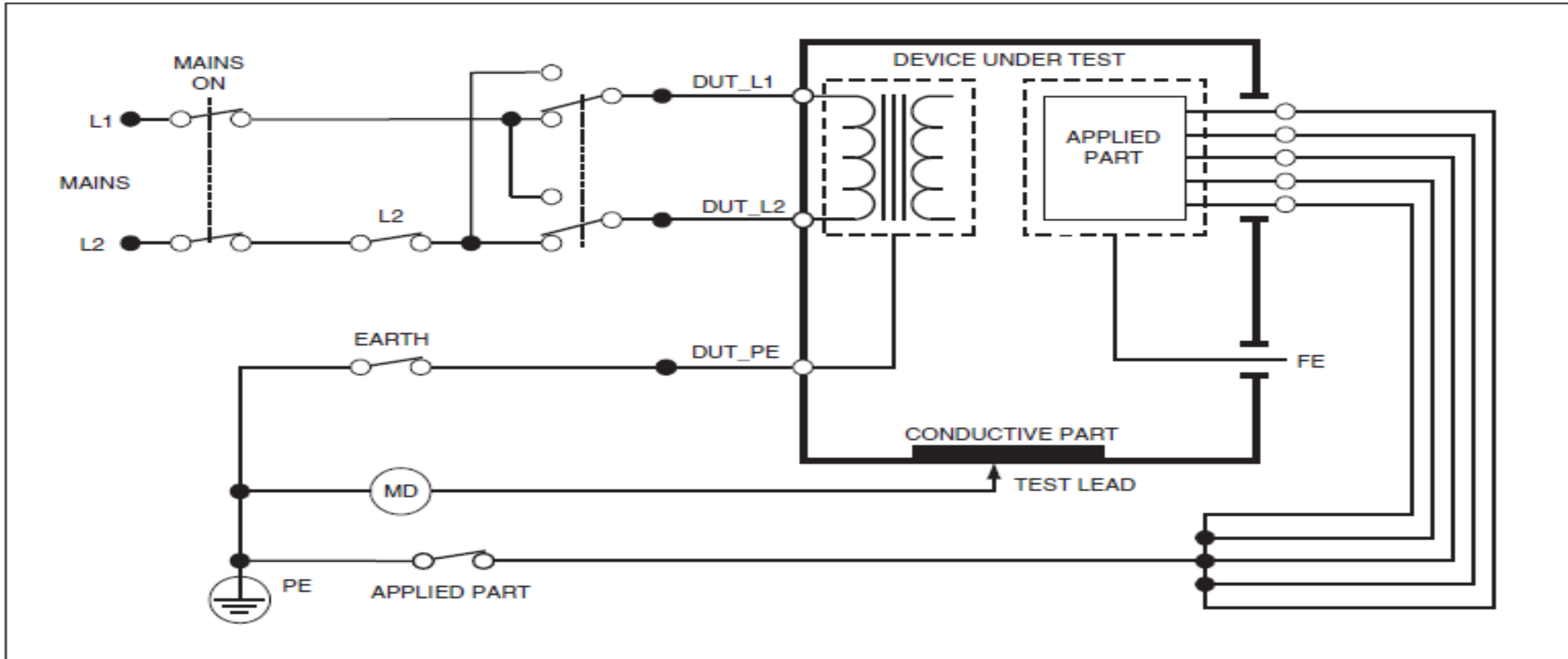


Earth Leakage Current Test Schematic

B. Enclosure Leakage Current:

- it's the current which flows from the exposed conductive parts of the equipment into the earth through a conductor other than the protective earth conductor.

Enclosure Leakage Current Test

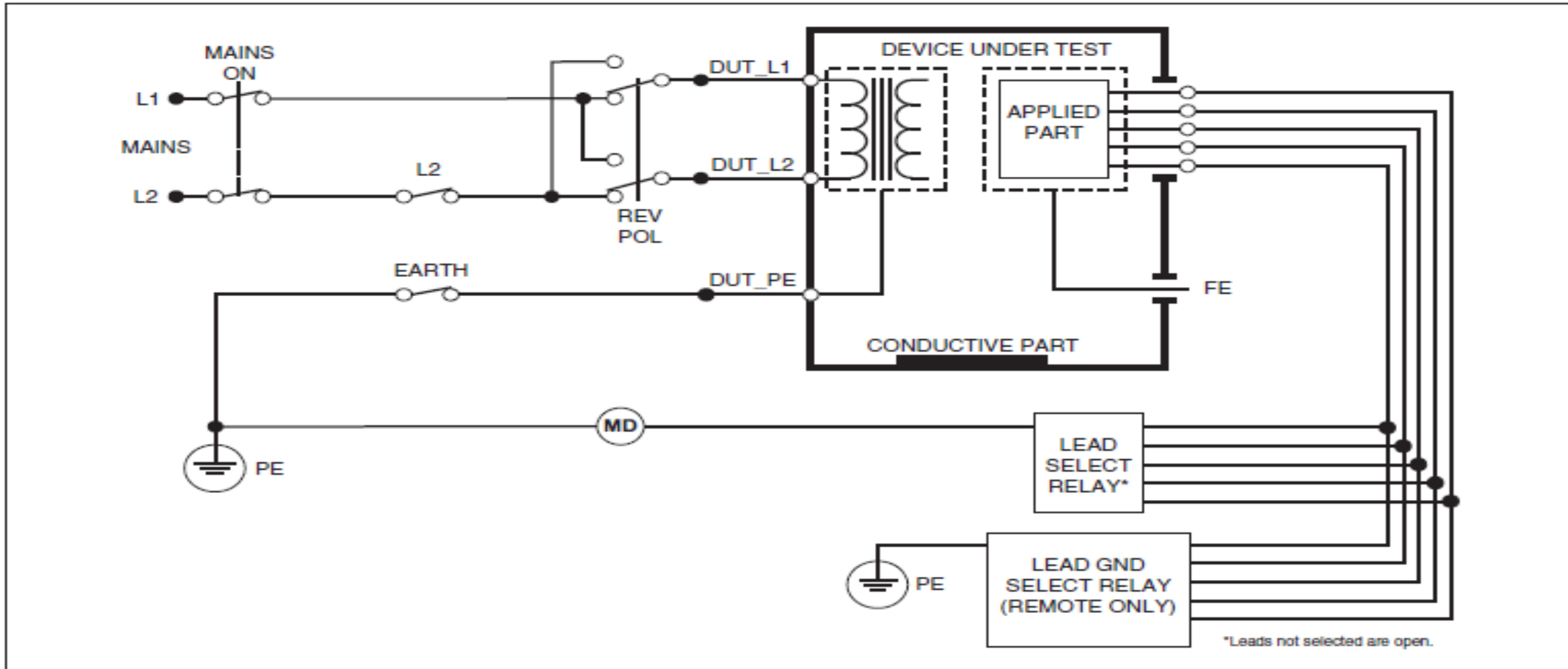


Enclosure Leakage Current Test Schematic

C. Patient Leakage Current:

- it's the current flows through the patient body by mean of any connected applied parts and then into the earth.

Patient Leakage Current Test

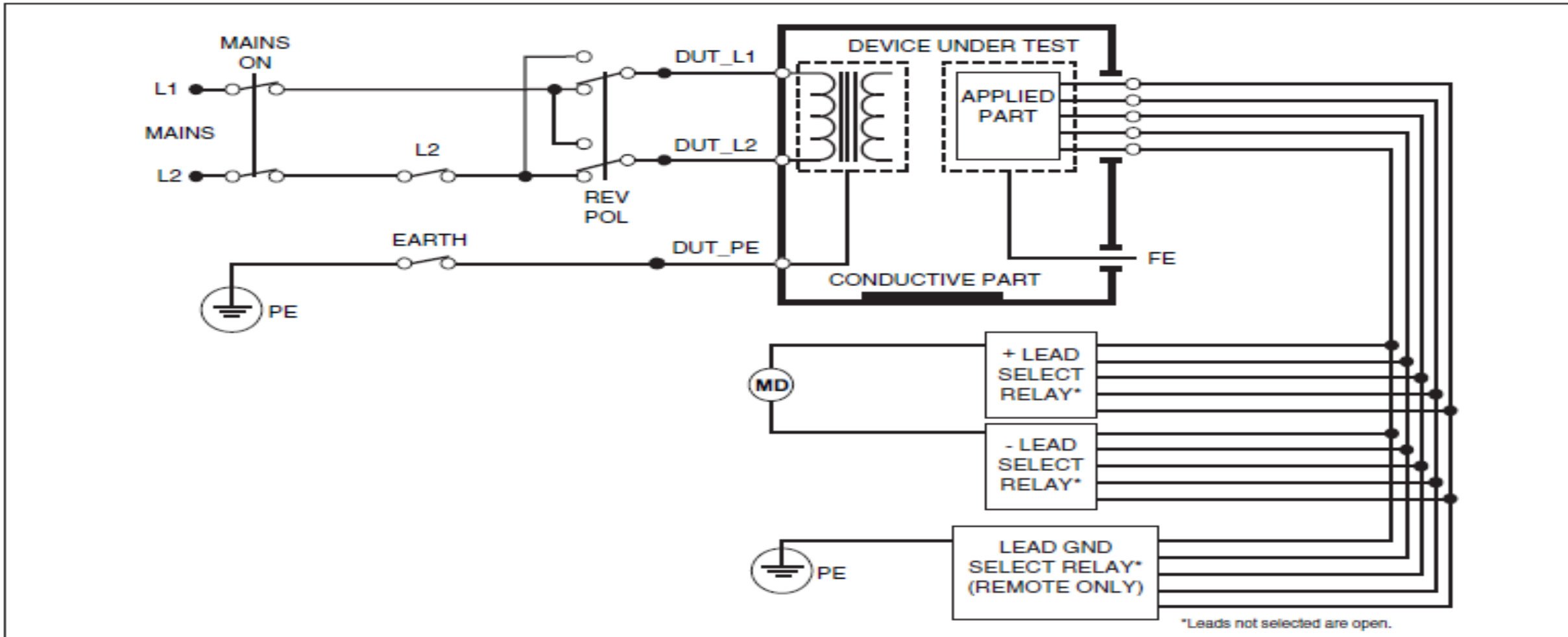


Lead-to-Ground (Patient) Leakage Current Test Schematic

D. Patient Auxiliary Leakage Current:

- it's the current flows through the patient body between any of the connected applied parts .

Patient Auxiliary Leakage Current Test



Lead-to-Lead (Patient Auxiliary) Leakage Current Test Schematic

■ Insulation Resistance ($M\Omega$):

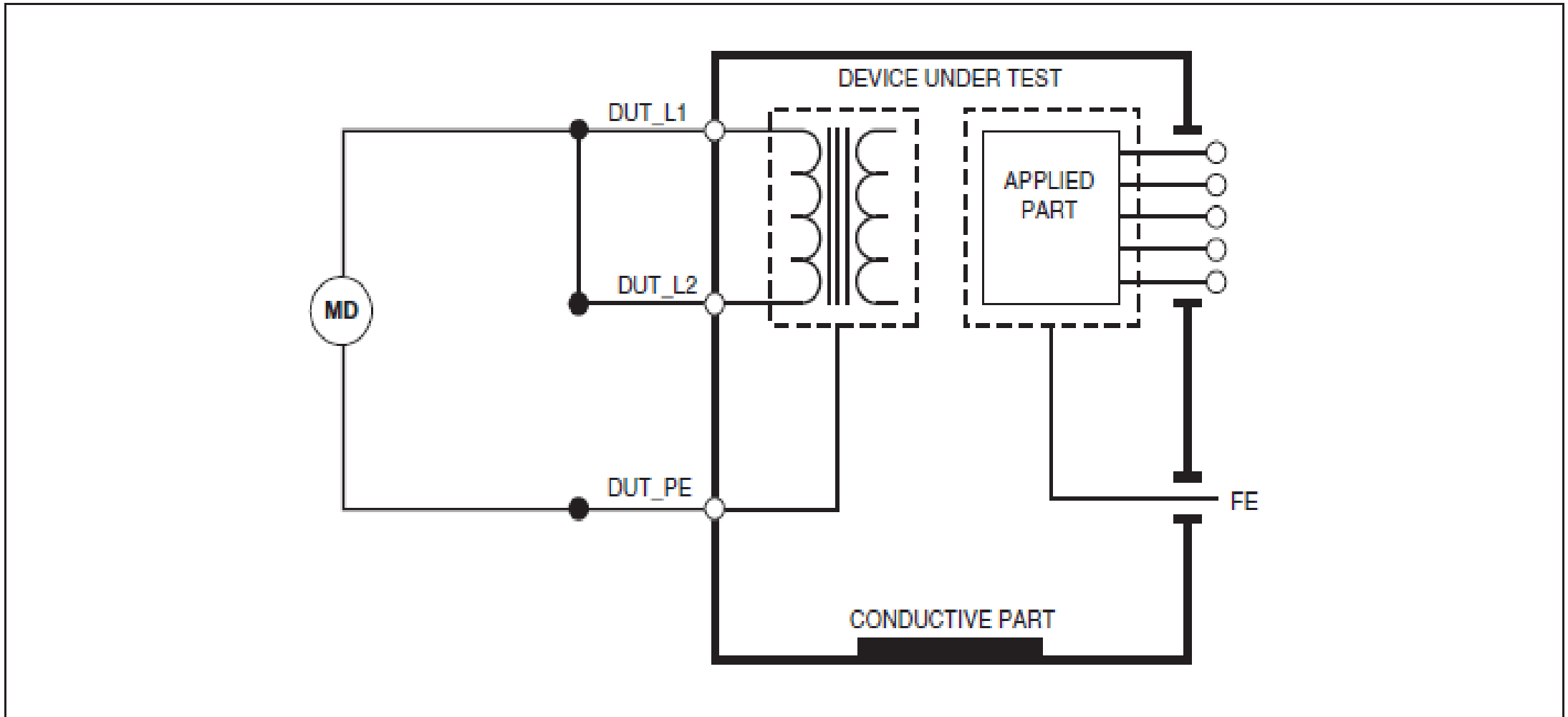
- The following types of Insulation Resistance is measured under the safety test procedures:

A. Protective Earth Insulation Resistance

(Mains on Protective Earth Resistance):

- it's the resistance between the Mains ($L + N$) / ($L1+L2$) shorted together & the Protective Earth.

Protective Earth Insulation Resistance Test

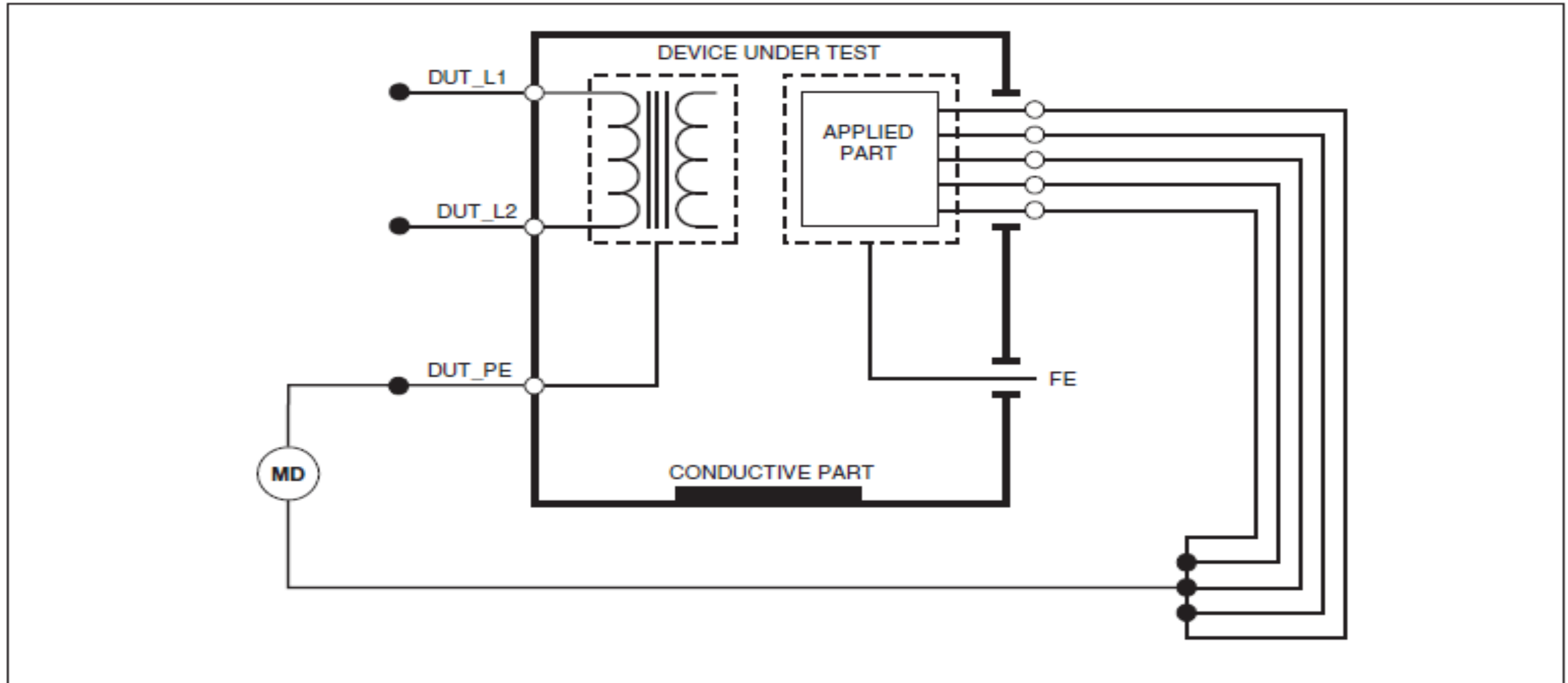


Mains to Protective-Earth Insulation Resistance Test Schematic

B. Applied Parts Insulation Resistance (Mains on A.P. Resistance):

- it's the resistance between the Mains (L + N) / (L1+L2) shorted together & the Applied Parts.

Applied Parts Insulation Resistance Test



Applied Parts to Protective-Earth Insulation Test Schematic

Electrical safety Test Limits

IEC 601 Test Standards

Description	Polar-ity	Circ-uit	Class I			Class II		
			B	BF	CF	B	BF	CF
Protective Earth Continuity Ω	N/A	OFF	0.2	0.2	0.2	NT	NT	NT
Insulation Resistance L1-L2-Case M Ω	N/A	OFF	2	2	20	NT	NT	NT
Enclosure Leakage μA	Norm	Norm	100	100	100	100	100	100
Enclosure Leakage μA	Norm	No L2	500	500	500	500	500	500
Patient Leakage Current μA	Norm	Norm	100	100	10	100	100	10
Patient Leakage Current μA	Norm	No L2	500	500	50	500	500	50
Earth Leakage μA	Norm	No E	500	500	500	NT	NT	NT
Earth Leakage μA	Norm	No E No L2	1000	1000	1000	NT	NT	NT

NT: No Test is available for this particular class/type. NL: No Limit

**KEEP CALM!
AND GET
ELECTRICAL
SAFETY TEST**



BIOMEDICAL & CLINICAL ENGINEERING

THANK YOU!

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An Initiative by



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