ASSOCIATED RESEARCH
A DIVISION OF IKONIX USA

- Electrical Safety Tests Overview
- Medical Device Testing Requirements per IEC 60601-1 3rd edition
- Medical Device Testing Application Overview

Webinar Notes

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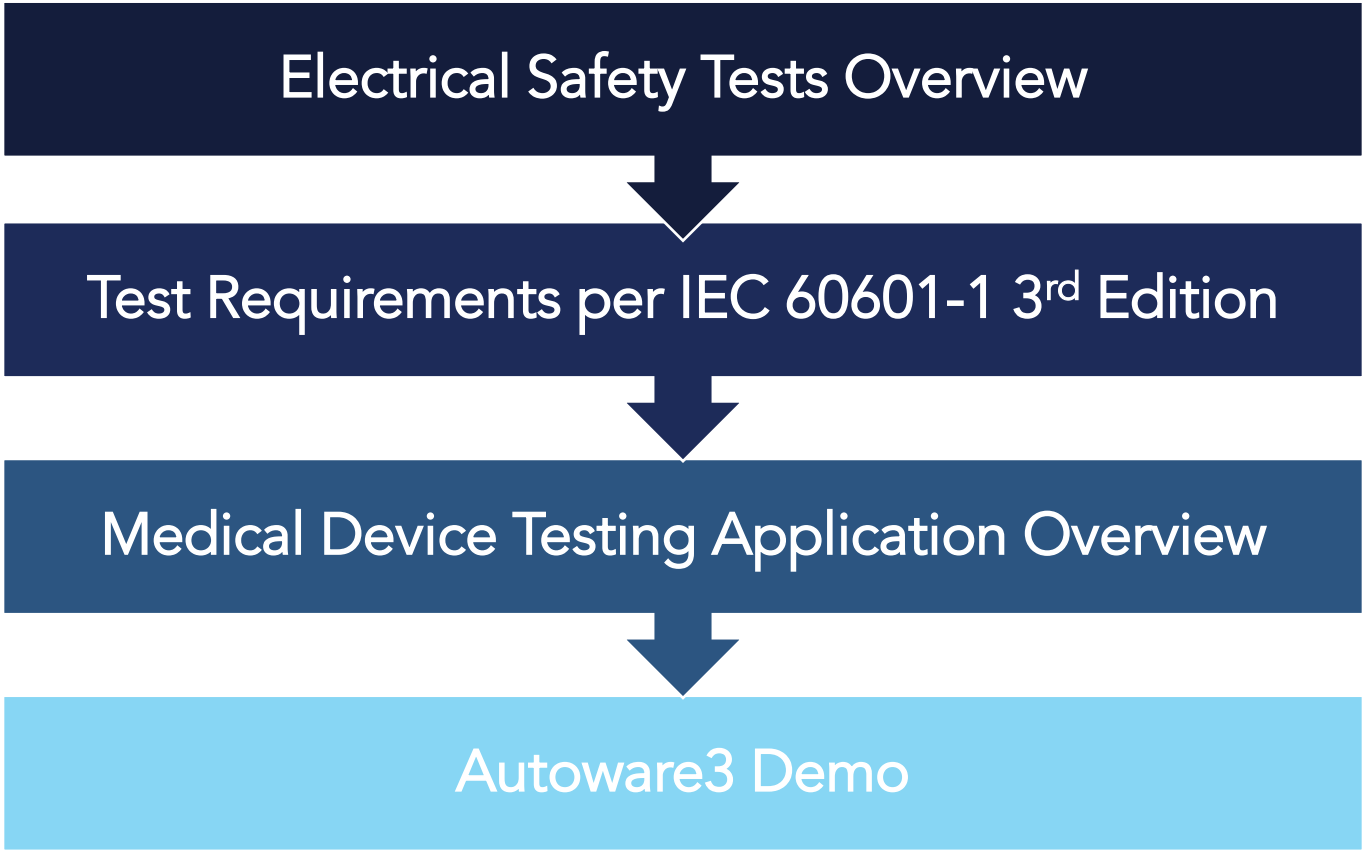
Learning Objectives



Common Medical Electrical Safety Tests

AC Hipot

DC Hipot

Ground Bond

Leakage Current

What is Good Ground?

National Electrical Code	• NFPA 70 • Protect people and property from electrical hazards
NEC 250-45	• "Any exposed non-current carrying metal parts of cord & plug connected equipment which may become energized shall be grounded."
NEC 250-51	• Permanent and Continuous • Capacity to conduct fault current • Low impedance to limit voltage to ground.

NFPA (National Fire Protection Agency) stipulates the NEC which is adopted in all 50 U.S. States. The NEC gives requirements for grounding products and installations. The NEC defines a "good" ground.

Ground Bond Test

GB test verifies the integrity of the ground connection between exposed metal and ground wire of the power cord.

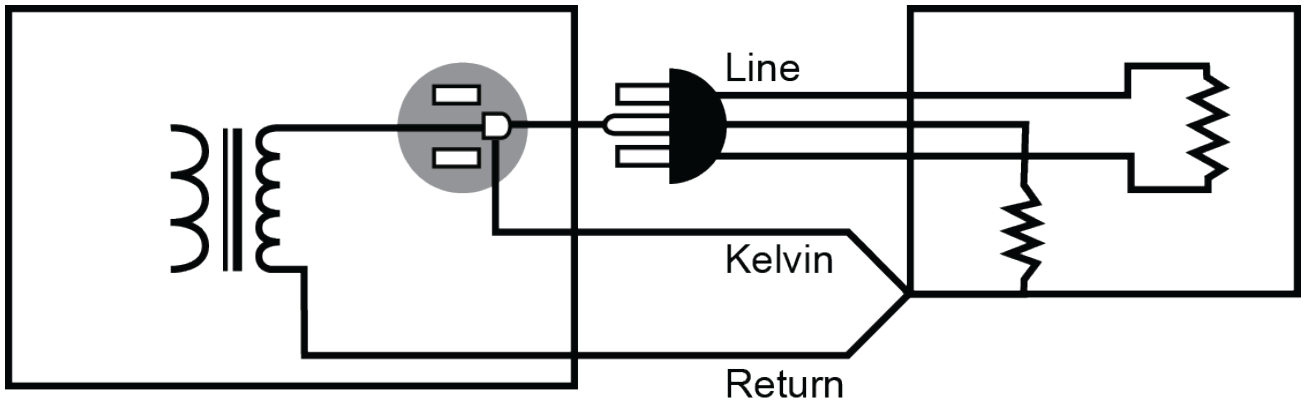
High current is injected into the ground pin of the product's power cord which flows through the chassis and is returned on an accessible grounded part.

Determines if the safety ground wire is capable of handling excessive current flow in case a fault occurs and the product's insulation fails.

Ground Bond Test

40A

Example Circuit for Ground Bond Test



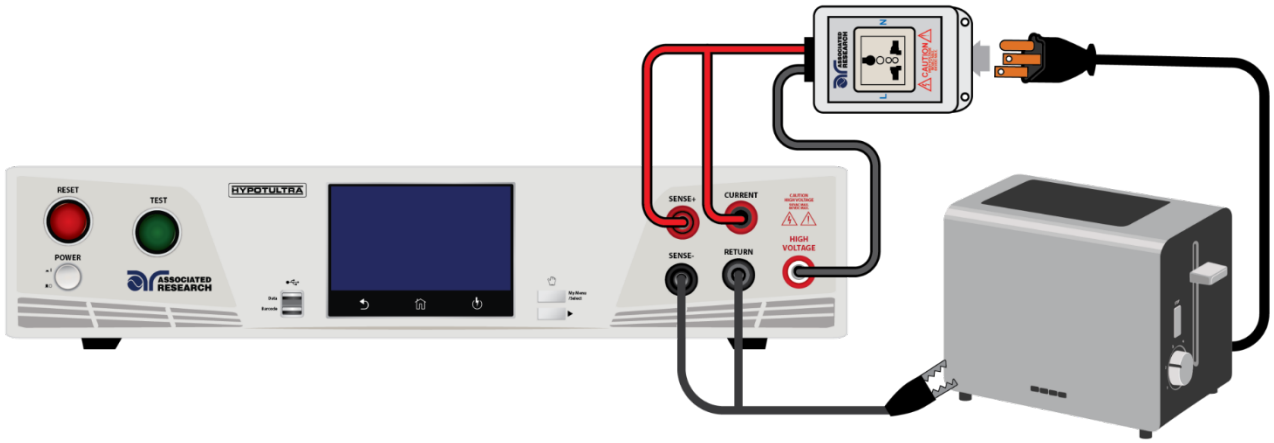
Ground Bond Test

40A

Ground Bond test is commonly considered a Type test and is generally performed *before* the Hipot test.

The results of this test are displayed in Ohms (Ω).

The ground conductor of a product must have a low enough impedance to handle any fault current.



Ground Bond Test

Test parameters for Ground Bond test vary from standard to standard.

Manufacturers must consult the safety standard which they are trying to comply with before setting test parameters.

IEC/UL 60601-1 3rd Edition

8.6.4 Impedance and Current Carrying Capability (AC Ground Bond Test)	
REQUIREMENT	**PASS CRITERIA**
Current = 25 A OR 1.5 * highest rated current (whichever is greater ±10%) passed through protective earthing circuit. Frequency = 50 or 60 Hz, no load voltage ≤ 6 V	Impedance protective earthing circuit on the DUT ≤ 100 mΩ For DUTs with non-detachable supply cord, impedance for DUT ≤ 200 mΩ

Dielectric Withstand Test

Also referred to as Hipot test, it is used to determine whether the insulation of a product is able to withstand an over-voltage condition for a period of time without breaking down.

It is a deliberate application of high voltage potential between the mains input and any exposed dead-metal.

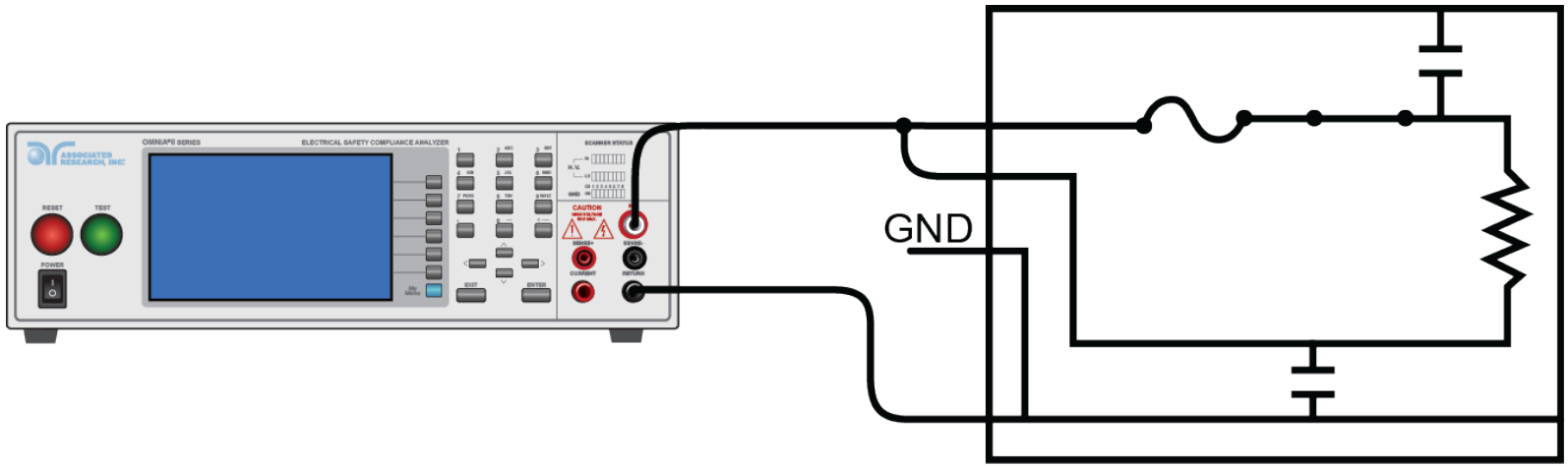
The resulting leakage current (due to the application of high voltage) is measured to determine whether a product's insulation is able to withstand the high voltage without breaking down.

This test verifies that the insulation of a product is capable of protecting the user from any leakage currents as a result of an electrical fault within the product.

Dielectric Withstand Test

Can be a Type test or a Routine test.

Used to detect possible defects in the design of a product and workmanship defects such as inadequate creepage and clearance distances.



Dielectric Withstand Test

Test is performed on both Class I and Class II products.

Test can be performed in both AC and DC mode based on the safety standard, however AC hipot test is more stressful than the DC hipot test.

Test voltage and trip settings must be specified by the manufacturer in accordance with the safety standard.

Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage may be used.

The test voltage, for the WORKING VOLTAGE to which the insulation is subjected is greater than or equal to the value specified in Table 6.

b) *During the test, breakdown constitutes a failure. Insulation breakdown is considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner, that is, the insulation does not restrict the flow of the current. Corona discharge or a single momentary flashover is not regarded as insulation breakdown.*

Means of Protection

MOP is divided into two categories

MOOP- Means Of Operator Protection

MOOP is applied to situations where the equipment will not come into contact with the patient at all. For example, IVD (in-vitro diagnostic) devices which are used only in medical laboratories, such as centrifuges, are often classified as requiring MOOP only

MOPP- Means Of Patient Protection

Any equipment that is used in a medical environment, in an area which means patients could come into contact with it, requires at least one means of patient protection (MOPP). This includes everything from hospital beds and lighting to ultrasound scanners and MRI machines, to defibrillators and dialysis machines. The highest level of protection specified in the standard requires at least two MOPPs.

Dielectric strength test requirements differ between these two categories with MOOP being more liberal.

Voltage requirements are listed in table 6 of IEC 60601-1 “AC test voltages in V rms”

Test Voltages For Solid Insulation MOP

Peak working voltage (U) V peak	Peak working voltage (U) V d.c.	A.C. test voltages in V r.m.s.							
		Means of operator protection				Means of patient protection			
		Protection from mains part		Protection from secondary circuits		Protection from mains part		Protection from secondary circuits	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOPP	Two MOPP	One MOPP	Two MOPP
U < 42,4	U < 60	1 000	2 000	No test	No test	1 500	3 000	500	1 000
42,4 < U ≤ 71	60 < U ≤ 71	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
71 < U ≤ 184	71 < U ≤ 184	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
184 < U ≤ 212	184 < U ≤ 212	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
212 < U ≤ 354	212 < U ≤ 354	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
354 < U ≤ 848	354 < U ≤ 848	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
848 < U ≤ 1 414	848 < U ≤ 1 414	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
1 414 < U ≤ 10 000	1 414 < U ≤ 10 000	See Table 7	See Table 7	See Table 7	See Table 7	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
10 000 < U ≤ 14 140	10 000 < U ≤ 14 140	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
U > 14 140	U > 14 140	If necessary, to be prescribed by particular standards							

It's up to the manufacturer to decide whether the equipment only requires MOP for the operator (MOOP), or whether the more stringent patient levels are required (MOPP). If the manufacturer decides MOOP is enough, it will have to back up its reasoning with a risk assessment as per ISO 14971, which examines how likely it is that a patient will come into contact with the equipment.

3rd EDITION REQUIREMENTS BY CLASSIFICATION			
Classification	Isolation	Creepage	Insulation
One MOOP	1500 V ac	2.5mm	Basic
Two MOOP	3000 V ac	5mm	Double
One MOPP	1500 V ac	4mm	Basic
Two MOPP	4000 V ac	8mm	Double

Leakage Current Test

Line Current Test are performed on electrical products to measure the leakage current which could flow through a person while the product is operating.

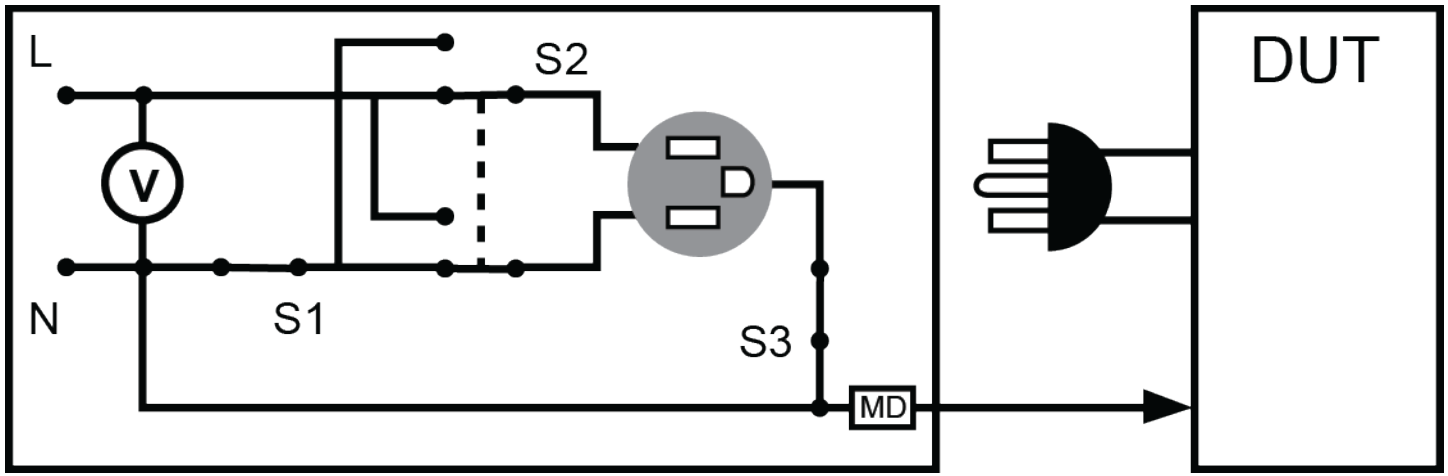
A measuring device (MD) is used to simulate the impedance of the human body under different conditions depending upon the application of the product.

Test is run under both normal and single fault conditions and reversed polarity on the input line power at 110% of rated input.

Most commonly performed on medical equipment.

Leakage Current Test

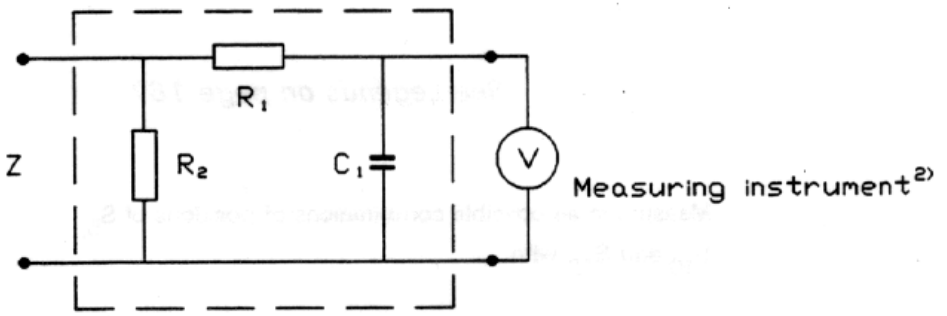
Typical circuit for Leakage Current test



Leakage Current Test

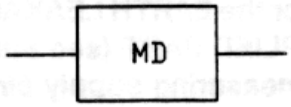
The MD can vary from standard to standard.

Measuring device for EN 60601-1 Medical Electrical Equipment.



R_1 = 10kΩ ± 5% 1)
R_2 = 1kΩ ± 1% 1)
C_1 = 0.015μF ± 5% 1)

1) Non-inductive components
2) Impedance » measuring impedance Z



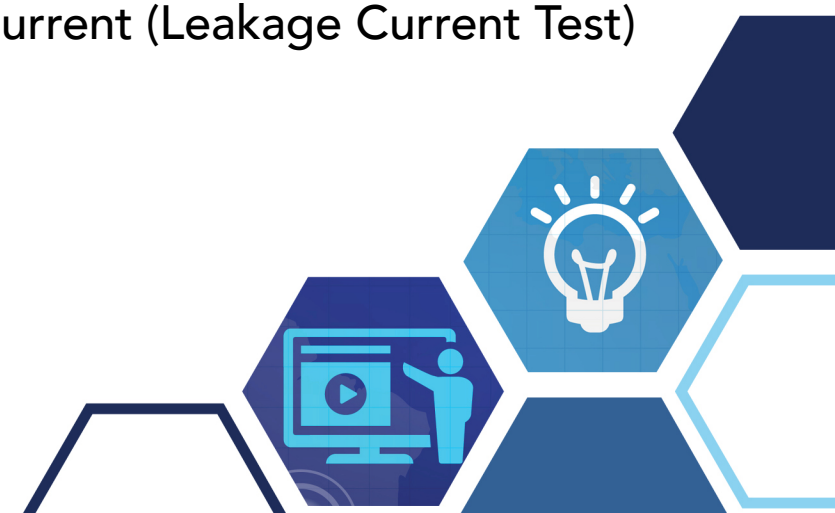
Equivalent to the above in subsequent figures.

Medical Device Testing Requirements

- IEC 60601-1 3rd Edition – Medical Electrical Equipment
  - Collateral Standards (60601-1-X)
  - Particular Standards (60601-2-X)

- Safety Tests Requirements

- Type and Routine Testing
  - Impedance and Current Carrying Capabilities (AC Ground Bond Test)
  - Dielectric Strength (Hipot Test)
  - Leakage Current and Patient Auxiliary Current (Leakage Current Test)



Ground Bond Test

8.6.4 Impedance and Current Carrying Capability (AC Ground Bond Test)	
REQUIREMENT	**PASS CRITERIA**
Current = 25 A OR 1.5 * highest rated current (whichever is greater ±10%) passed through protective earthing circuit. Frequency = 50 or 60 Hz, no load voltage ≤ 6 V	Impedance protective earthing circuit on the DUT ≤ 100 mΩ For DUTs with non-detachable supply cord, impedance for DUT ≤ 200 mΩ

- 25 A of current passed through the ground circuit
- Resistance of the ground circuit to be ≤ 100 mΩ or ≤ 200mΩ
- Frequency of 50 or 60 Hz

Dielectric Withstand Test

8.8.3 **Dielectric Strength** (Hipot Test)	
REQUIREMENT	**PASS CRITERIA**
Test voltage - Refer to tables 6 and 7 Test time = 10 sec ramp up, 60 sec dwell & 10 sec ramp down Tested at 50Hz, 60Hz or DC equivalent (1.414 * AC test voltage)	No dielectric breakdown If DUT enclosure is non-conductive, use metal foil as conductive medium for return point.

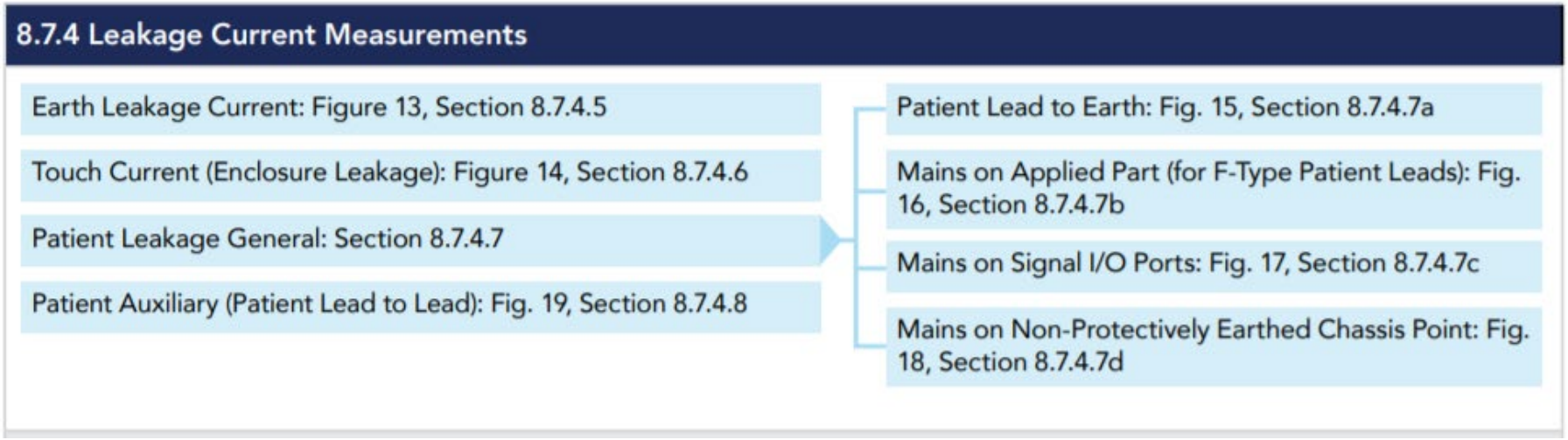
- Test voltage depends on two factors
  - Peak Working Voltage
  - Means of Protection, MOP (Operator) or MOPP (Patient)
- Dielectric breakdown is considered a failure
- For example, 240 V mains input requires 1500 V AC Test voltage

Leakage Current Test

8.7 Leakage Current and Patient Auxiliary Current* (Leakage Current Test)	
REQUIREMENT	**PASS CRITERIA**
Tested in Normal Conditions (NC) & Single Fault Conditions (SFC) Tested with supply at 110% highest rated mains voltage Tested at highest rated supply frequency	Earth Leakage Current ≤ 5 mA (NC) or 10 mA (SFC) Touch Current ≤ 100 µA (NC) or 500 µA (SFC) Patient Leakage Current - Refer to Tables 3 and 4

- Normal and Single Fault Conditions
- Mains supply at 110% voltage
- Placement of the Measuring Device (MD)

Leakage Current Test



- Example of different type of leakage current test called out in the standard
- Required test vary depending on the type of medical device and inclusion of any patient applied parts

Leakage Current Test

Table IV

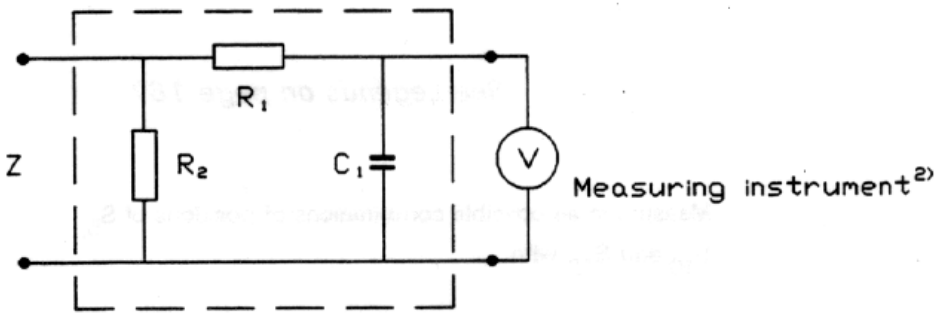
***Allowable values of continuous LEAKAGE and PATIENT AUXILIARY CURRENTS, in milliamperes**

Current		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[1)]	0,5	1[1)]	0,5	1[1)]
EARTH LEAKAGE CURRENT for EQUIPMENT according to notes [2)] and [4)]		2,5	5[1)]	2,5	5[1)]	2,5	5[1)]
EARTH LEAKAGE CURRENT for EQUIPMENT according to note [3)]		5	10[1)]	5	10[1)]	5	10[1)]
ENCLOSURE LEAKAGE CURRENT		0,1	0,5	0,1	0,5	0,1	0,5
PATIENT LEAKAGE CURRENT	d.c.	0,01	0,05	0,01	0,05	0,01	0,05
according to note 5)	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	d.c.	0,01	0,05	0,01	0,05	0,01	0,05
according to note 5)	a.c.	0,1	0,5	0,1	0,5	0,01	0,05

Leakage Current Test

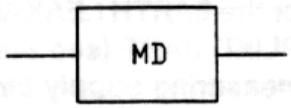
The MD can vary from standard to standard.

Measuring device for EN 60601-1 Medical Electrical Equipment.



R_1 = 10kΩ ± 5% 1)
R_2 = 1kΩ ± 1% 1)
C_1 = 0.015μF ± 5% 1)

1) Non-inductive components
2) Impedance » measuring impedance Z



Equivalent to the above in subsequent figures.

Earth Leakage

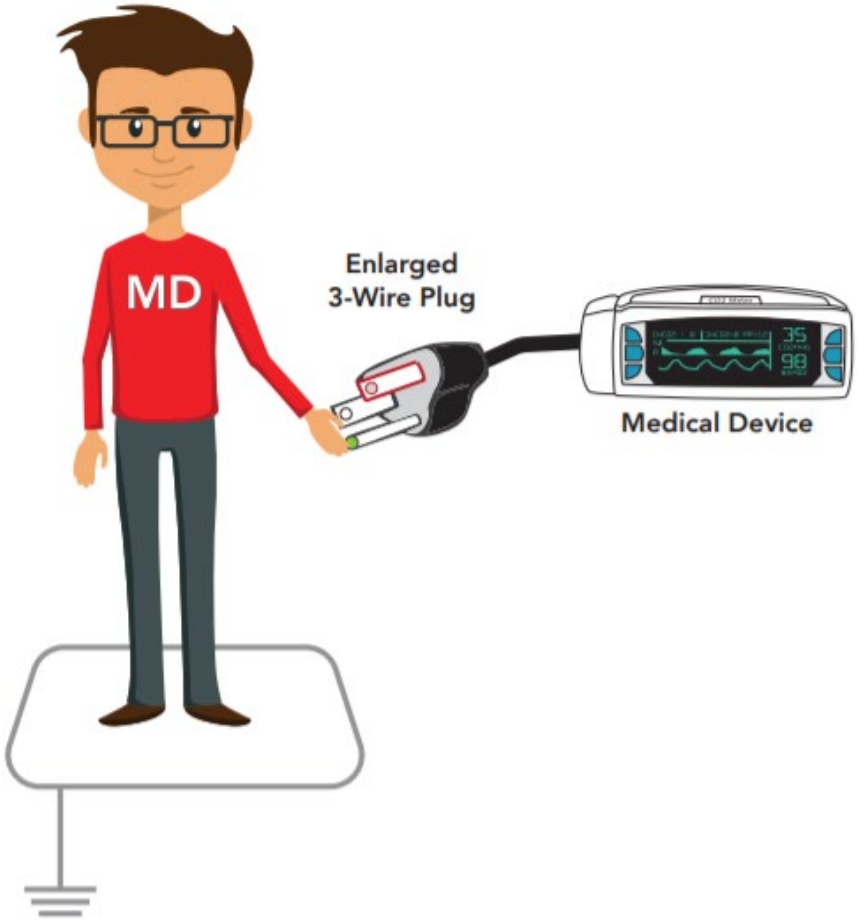


Figure 3 Earth Leakage Test

Enclosure Leakage

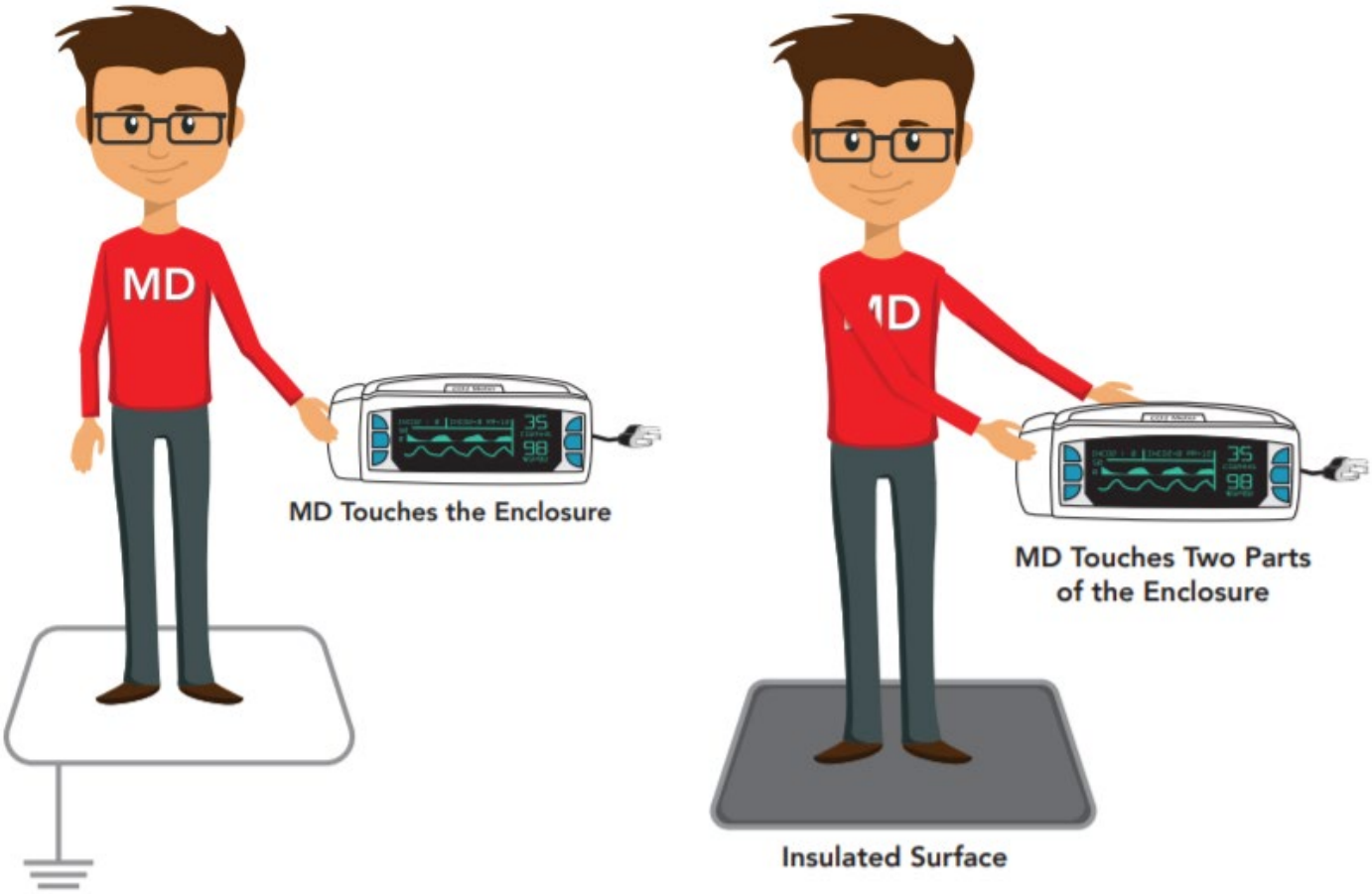
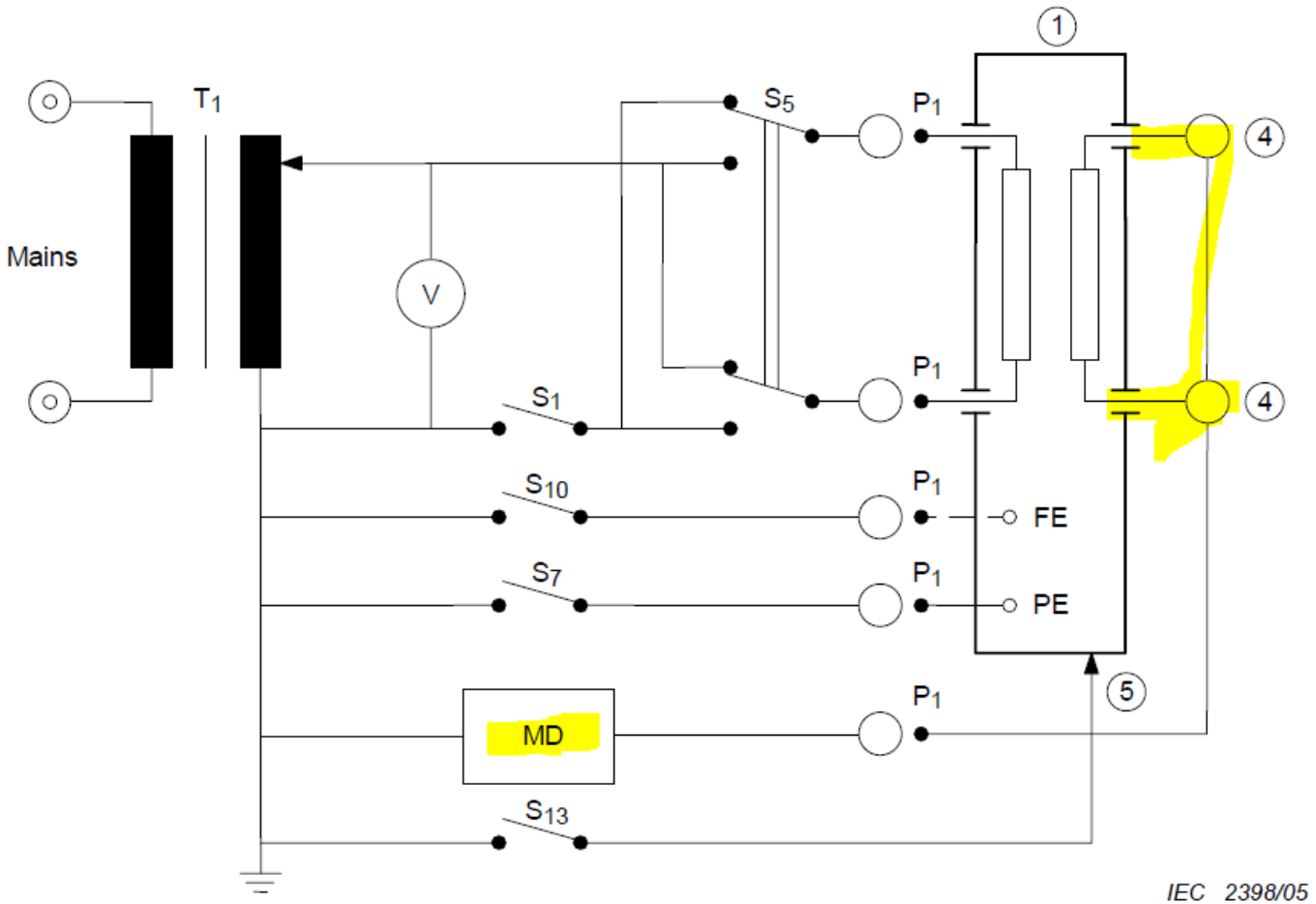
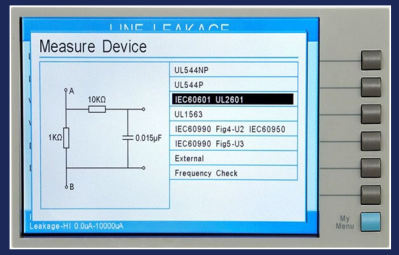


Figure 4 Enclosure Leakage Test

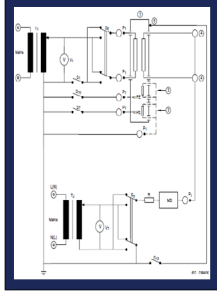
Patient Leakage



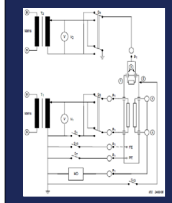
Additional Tests



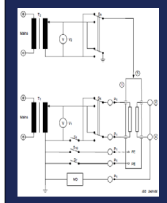
Leakage current



Mains Voltage on Applied Part
Figure 16

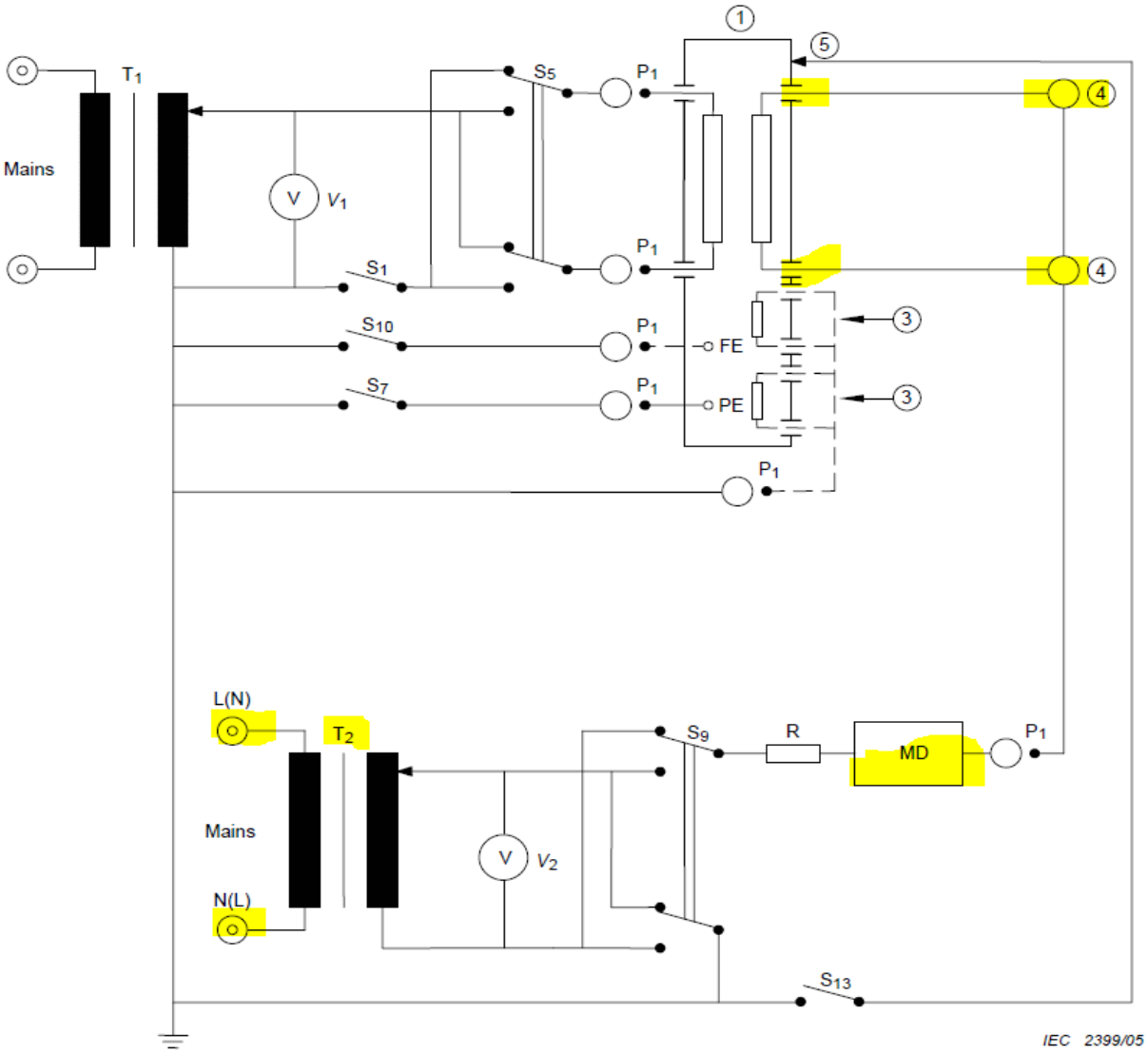


External voltage on SIO
Figure 17

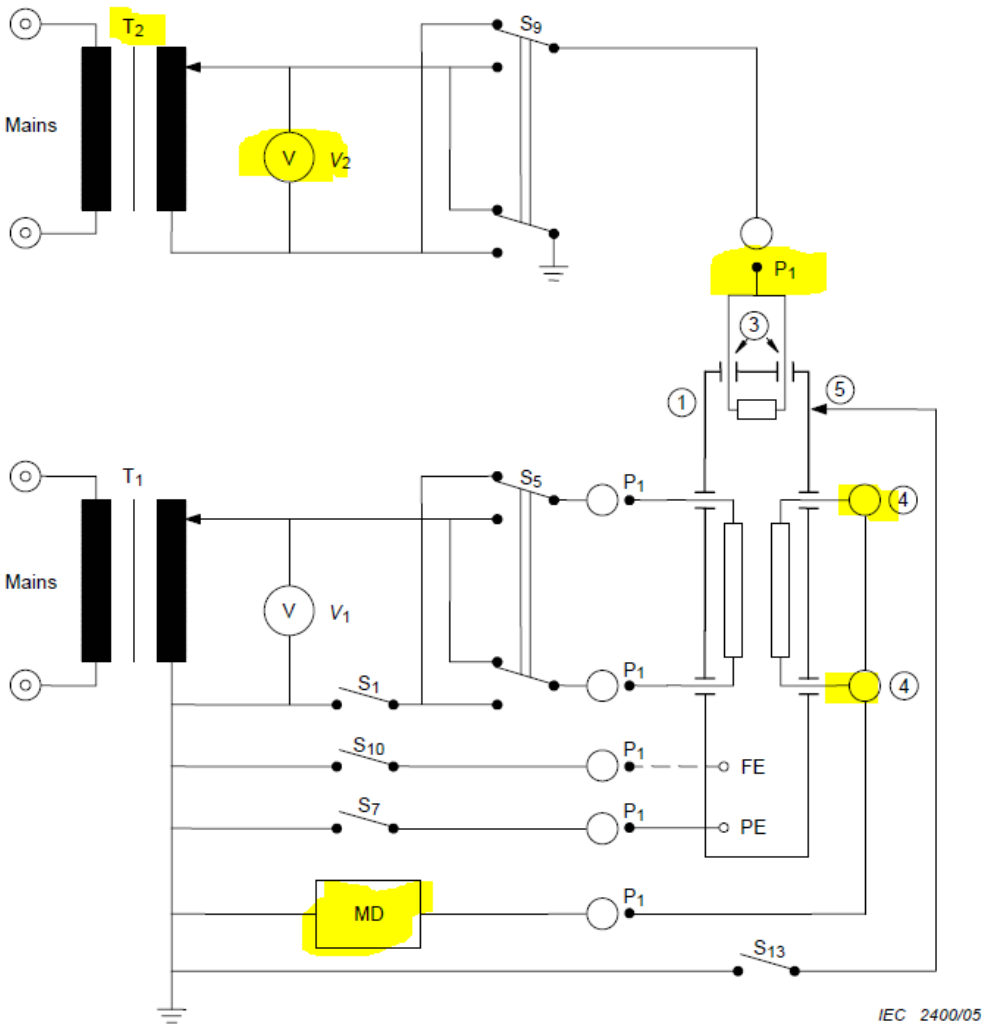


External voltage on metal accessible part that is not PE
Figure 18

MOAP


1
5
T1
Mains
V
V1
S5
P1
S1
S10
S7
4
3
FE
PE
L(N)
T2
Mains
N(L)
V
V2
S9
R
MD
S13
IEC 2399/05

Mains on SIP/SOP



Medical Device Testing Application Overview

ASSOCIATED RESEARCH

This Application note provides an example of how to test a medical device per IEC/UL 60601-1 3rd Edition using the Associated Research MedTEST System.

Table 1 lists all the instruments shown in the test setup used as an example in this document.

ction.

Table 1

APPLICATIONS CONSULTING

A DIVISION OF IKONIX USA

We can help you ensure your company is meeting industry standard testing requirements while minimizing risks for your employees in the lab and on the production line.

Operator Education

Employ best practices to comply with agency required regulations and train operators on proper testing protocols.

Safe Workstation

Ensure work areas are safe to avoid fines, litigation, and most importantly, prevent injury or fatality.

System Validation

Create IQ/OQ documentation to validate your test system and ensure that you pass your next regulatory audit.

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