



- Brief review of the Leakage Current Test
- General Patient Leakage Current
- Patient Auxiliary Leakage Current
- Mains on Applied Park Leakage Testing
- Medical Device Leakage Testing Considerations



**Bishan Patel**

Presenter  
Applications Engineer



**Syed Abidi**

Panelist  
Applications Leader



**Amanda Boothe**

Organizer  
Marketing Assistant



# Webinar Notes

Please use the Q & A utility to ask us any questions concerning the material being presented.

You can find a recording of this webinar and presentation on our Webinar Archive page, [www.arisafety.com/webinars/archived-webinars/](http://www.arisafety.com/webinars/archived-webinars/)

Please contact Amanda Boothe– on the chat line or email [amanda.boothe@ikonixusa.com](mailto:amanda.boothe@ikonixusa.com) if you have any connection issues.



# Learning Objectives

## Touch Current

- Touch Current
- Patient Leakage
- Patient Auxiliary Leakage
- Mains on Applied Part Leakage

## Leakage Current

- Description
- Network and MD

## IEC 60601-1

- IEC 60601-1 3<sup>rd</sup> Edition and the leakage current tests
- Tests called out for in the standard

## Testing Examples

- IEC 60601-1 discussion and reference diagrams
- Leakage testing video examples

# Leakage Current Types

## Leakage Current Types

- Electric current through a human body when it touches one or more accessible parts of an installation or surface of electrical equipment<sup>1</sup>
- Also called Enclosure Leakage Current.

## Patient Leakage Current

- Current flowing from the patient connections via the patient to earth
- Current originating from the unintended appearance of a voltage from an external source on the patient and flowing from the patient via the patient connections of an F-Type applied part to earth.

## Patient Auxiliary Current

Current flowing in the patient in normal use between any patient connection and all other patient connections (and not intended to produce a physiological effect)<sup>2</sup>.

## Mains on Applied Part

Application of mains voltage on an applied part or patient lead.

1 – IEC 60990 2<sup>nd</sup> edition: Methods of Measurement of Touch Current and Protective Conductor Current

2 – IEC 60601-1 3<sup>rd</sup> edition: Medical Electrical Equipment

# Patient Lead Types

## Patient Leads

**F-Type:** APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT

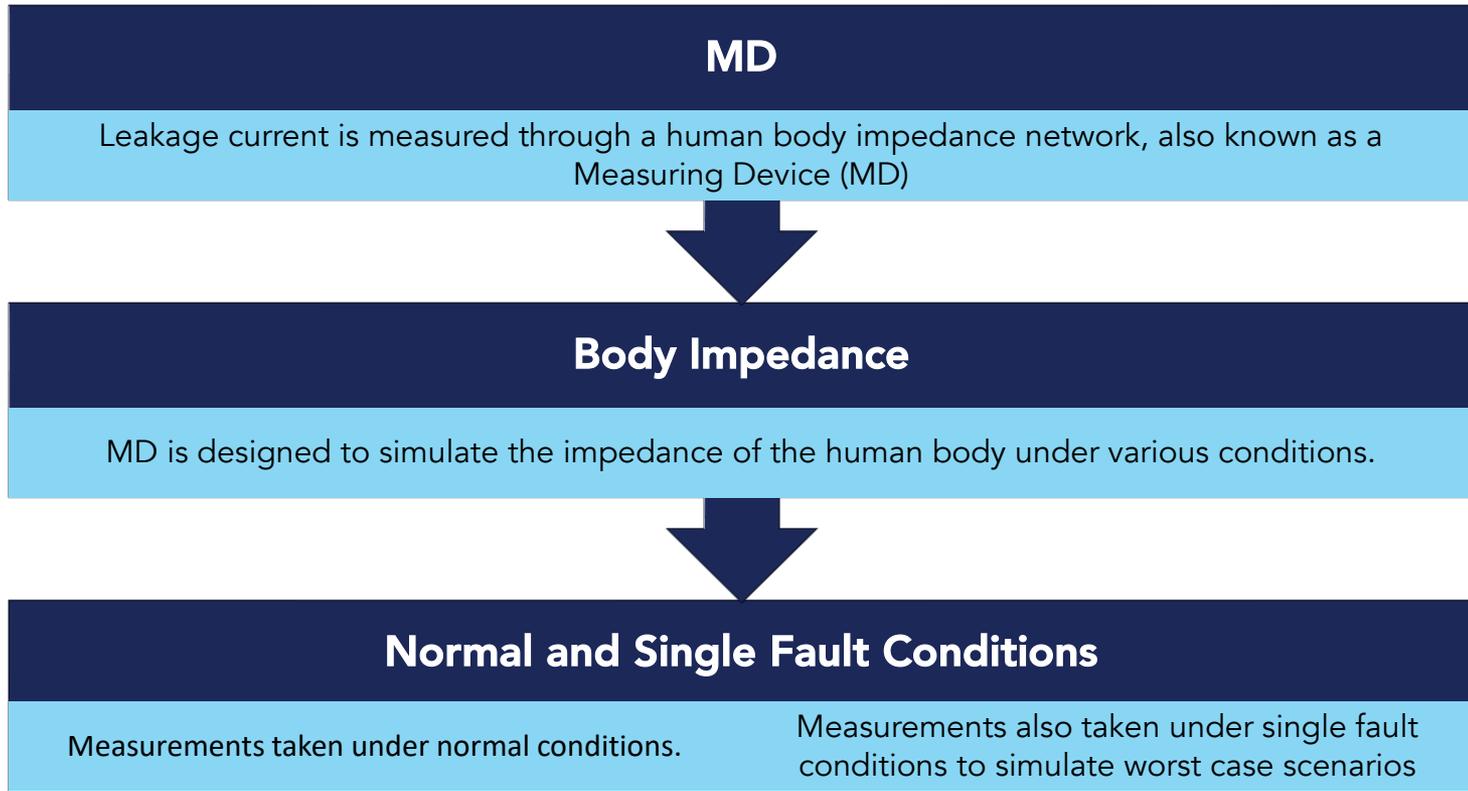
**B Type:** APPLIED PART that provides protection against electric shock

**Type BF:** F-TYPE APPLIED PART provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

**Type CF:** F-TYPE APPLIED PART provide a highest degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

IEC 60601-1 3<sup>rd</sup> edition: Medical Electrical Equipment

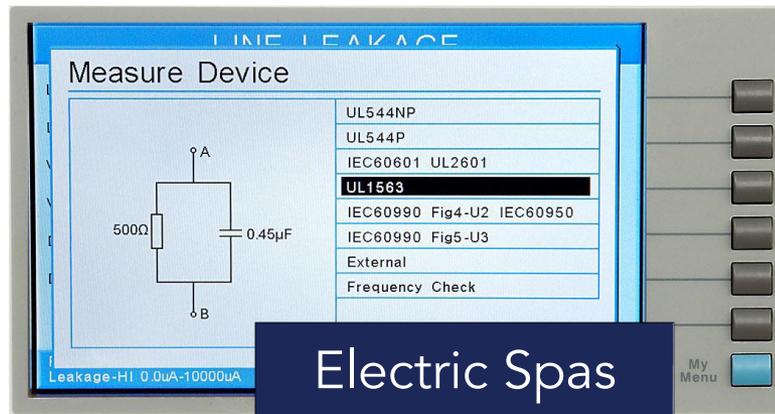
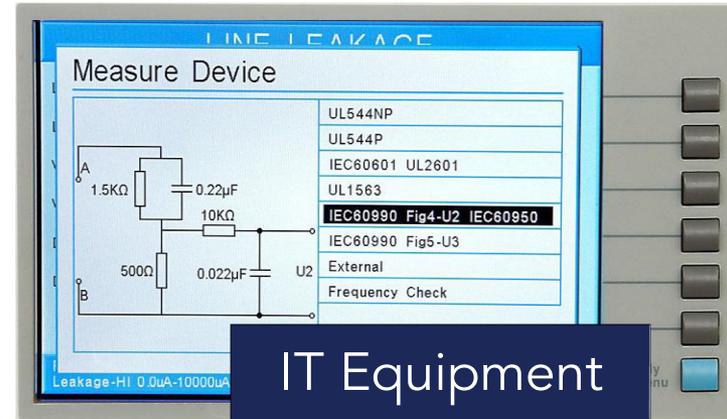
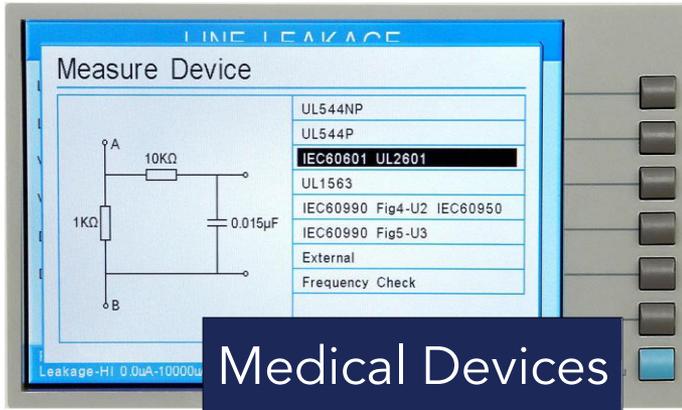
# How Is It Measured?



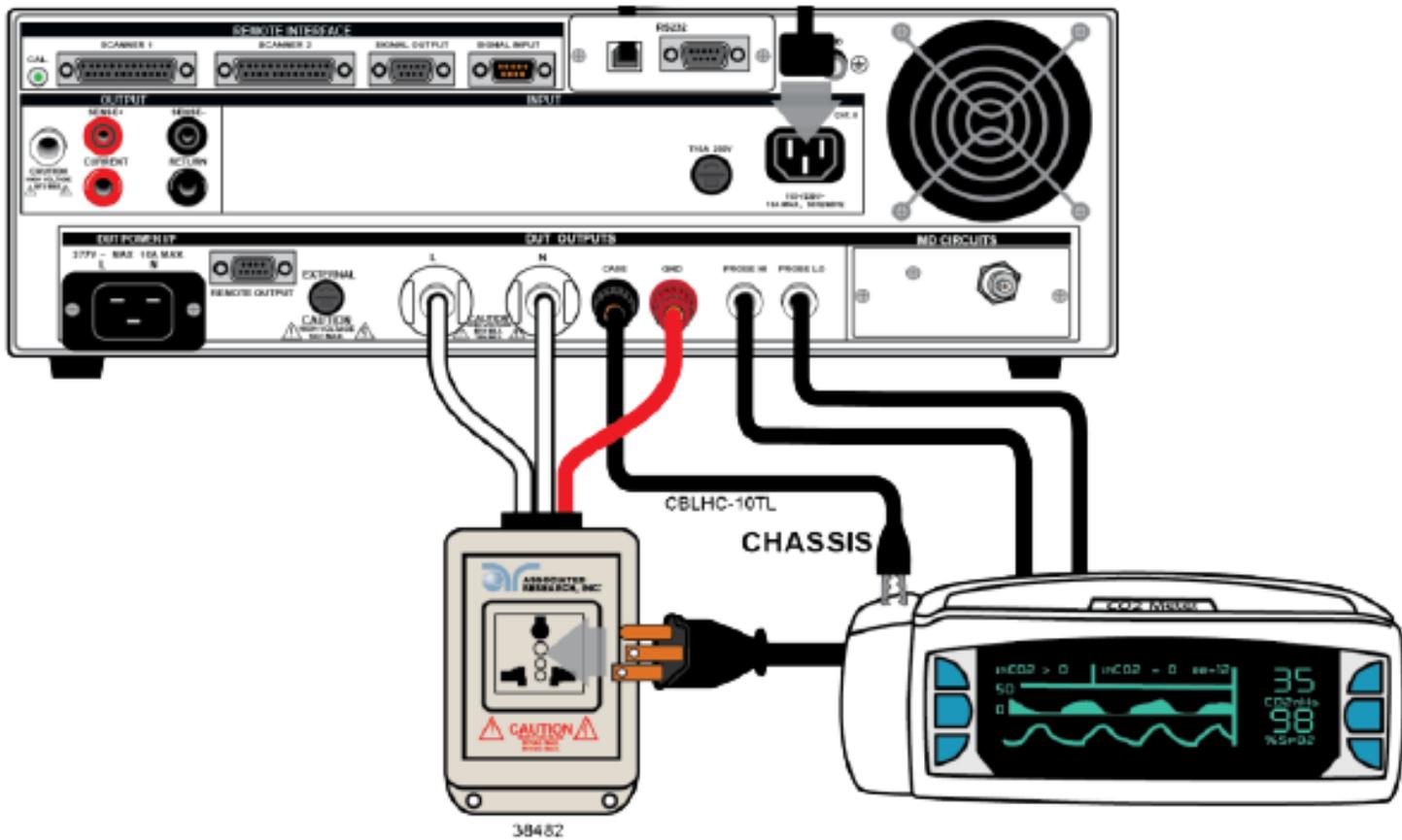
## THE MAIN QUESTION TO ASK

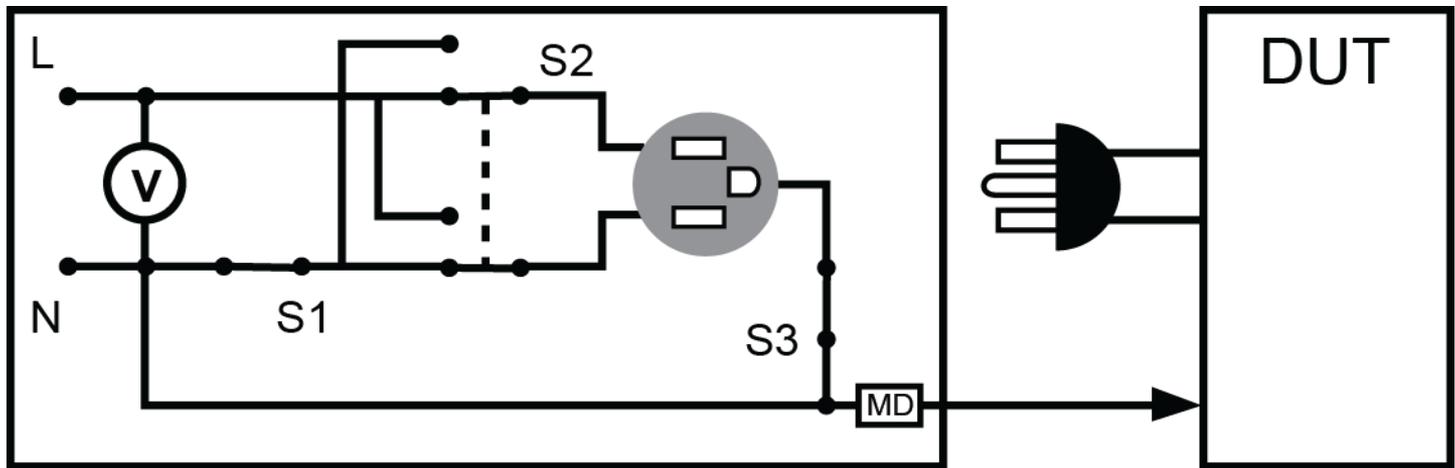
What is the severity of electric current someone would be exposed to if they were to touch the DUT under such conditions?

# How Is It Measured?

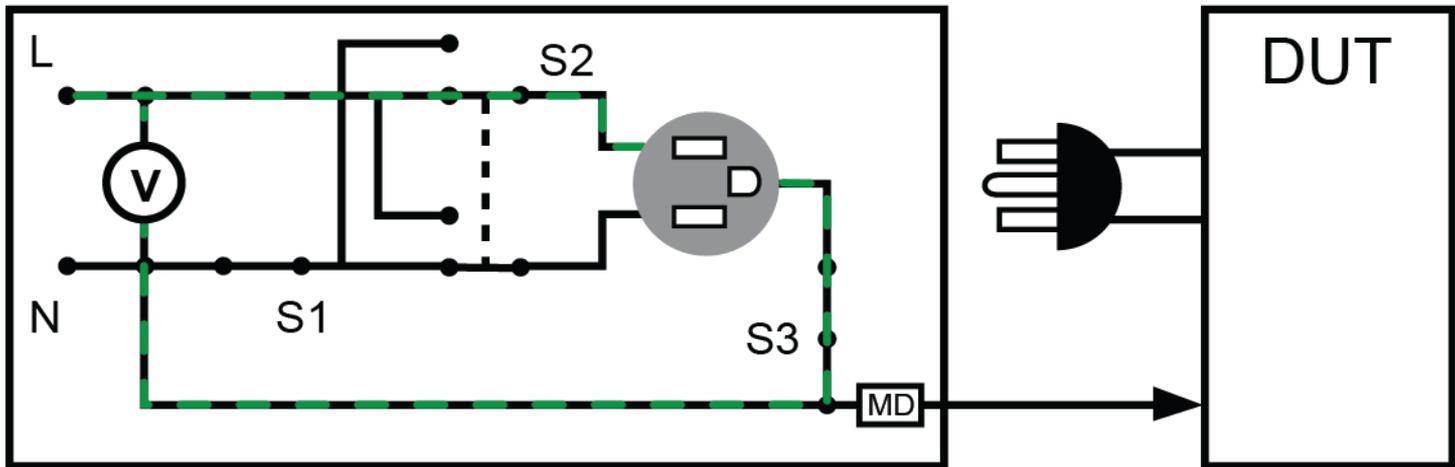


MD will vary by product standard. Most MDs are derived from IEC 60990-1

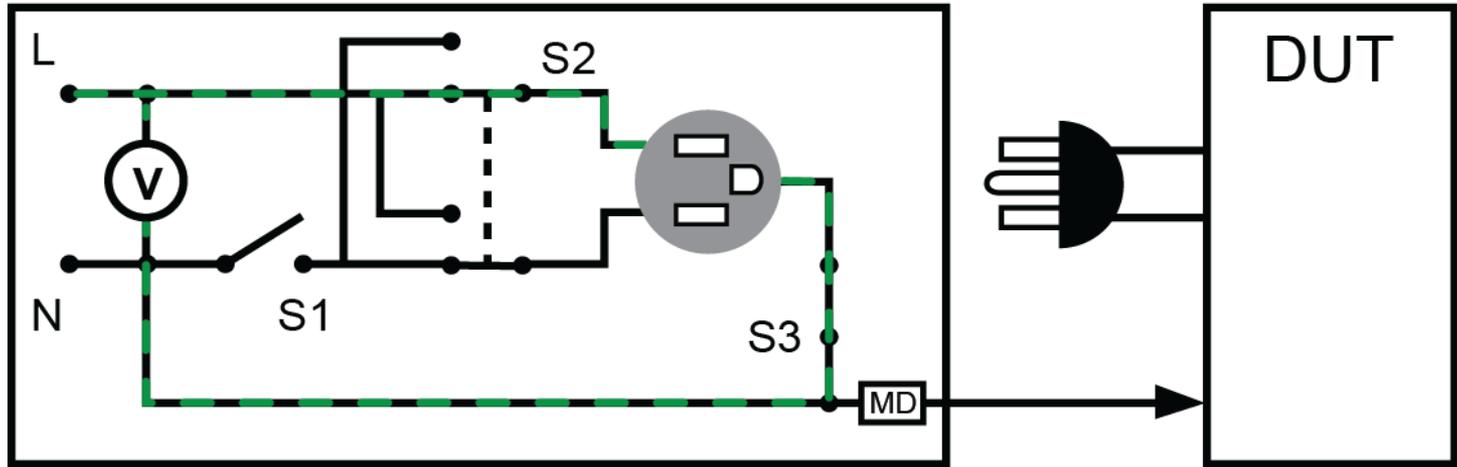




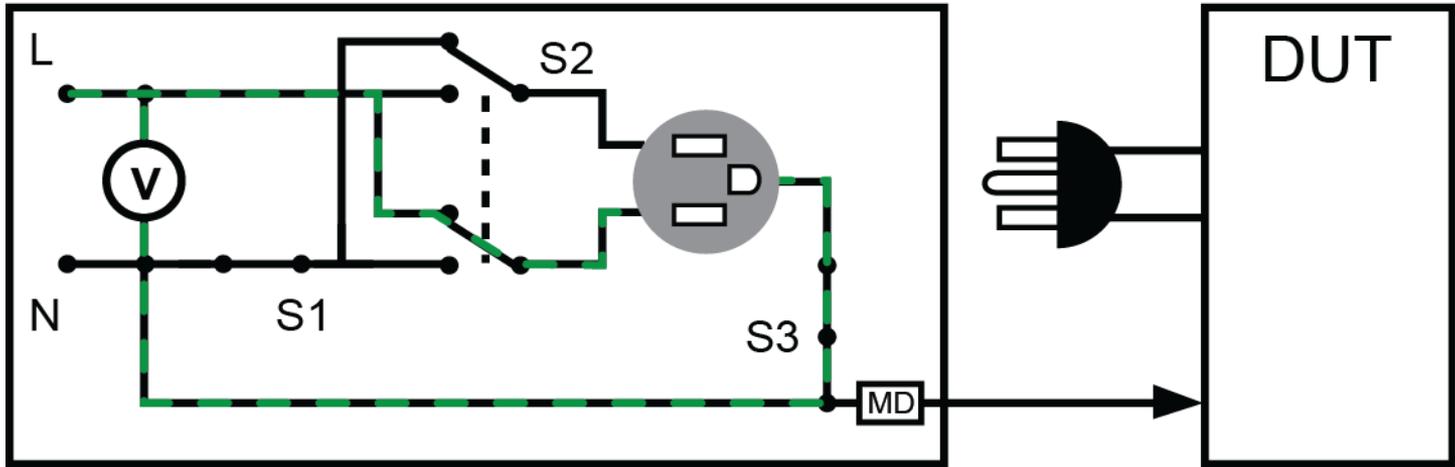
### Normal Conditions



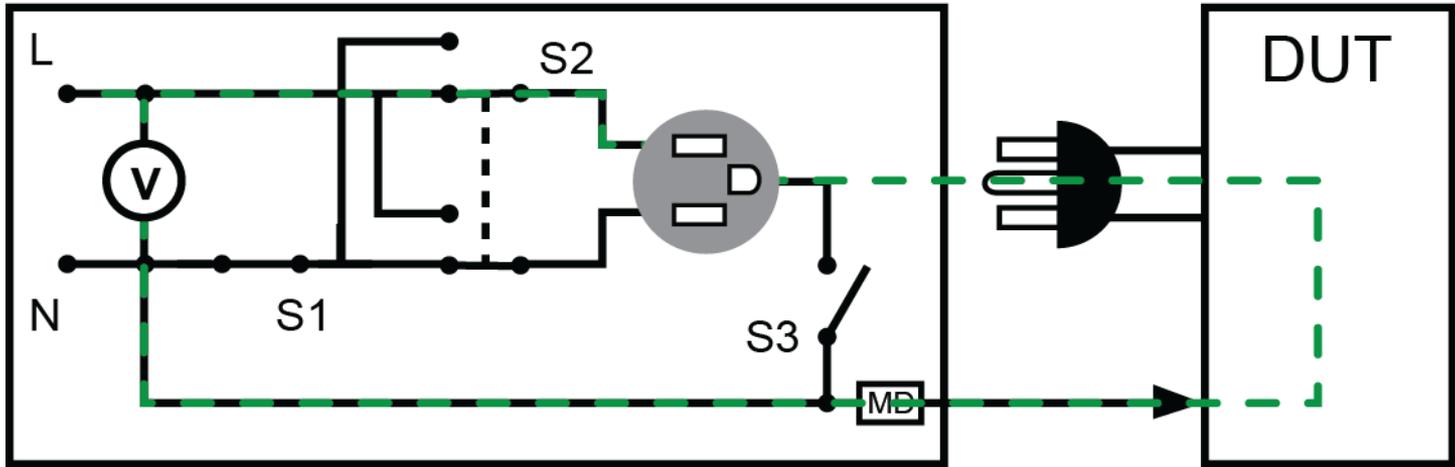
# Open Neutral



### Reverse Polarity



Open Ground



# Poll Question

Question Goes Here

- A. Answer Choice A
- B. Answer Choice B
- C. Answer Choice C
- D. Answer Choice D

# IEC 60601-1 Medical Equipment

## 8.7 Leakage Current and Patient Auxiliary Current\* (The Leakage Current Test)

OMNIA® II 8206, 8207



LINECHECK® 620L



### REQUIREMENT:

Tested in Normal Conditions (NC) & Single Fault Conditions (SFC)  
Tested with supply at 110% highest rated mains voltage  
Tested at highest rated supply frequency

### PASS CRITERIA:

Earth Leakage Current  $\leq 5$  mA (NC) or 10 mA (SFC)  
Touch Current  $\leq 100$   $\mu$ A (NC) or 500  $\mu$ A (SFC)  
Patient Leakage Current - Refer to Tables 3 and 4

\*Section 8.7 consists of a number of various leakage tests. Further details are given in the below diagram

## 8.7.4 Leakage Current Measurements

OMNIA® II 8206, 8207



LINECHECK® 620L



OPTIONAL APT POWER SOURCE SC6540

&



Earth Leakage Current: Figure 13, Section 8.7.4.5

Touch Current (Enclosure Leakage): Figure 14, Section 8.7.4.6

Patient Leakage General: Section 8.7.4.7

Patient Auxiliary (Patient Lead to Lead): Fig. 19, Section 8.7.4.8

Patient Lead to Earth: Fig. 15, Section 8.7.4.7a

Mains on Applied Part (for F-Type Patient Leads): Fig. 16, Section 8.7.4.7b

Mains on Signal I/O Ports: Fig. 17, Section 8.7.4.7c

Mains on Non-Protectively Earthed Chassis Point: Fig. 18, Section 8.7.4.7d

# Patient Leakage Current

**Table 3 – \* Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION**

Current in  $\mu\text{A}$

Current	Description	Reference	Measuring Circuit		TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
					NC	SFC	NC	SFC	NC	SFC
PATIENT AUXILIARY CURRENT		8.7.4.8	Figure 19	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7 a)	Figure 15	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c)	Figure 17	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT *	With the same types of APPLIED PART connected together	8.7.4.7 a) and 8.7.4.7 h)	Figure 15 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c) and 8.7.4.7 h)	Figure 17 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100

# Patient Leakage Current

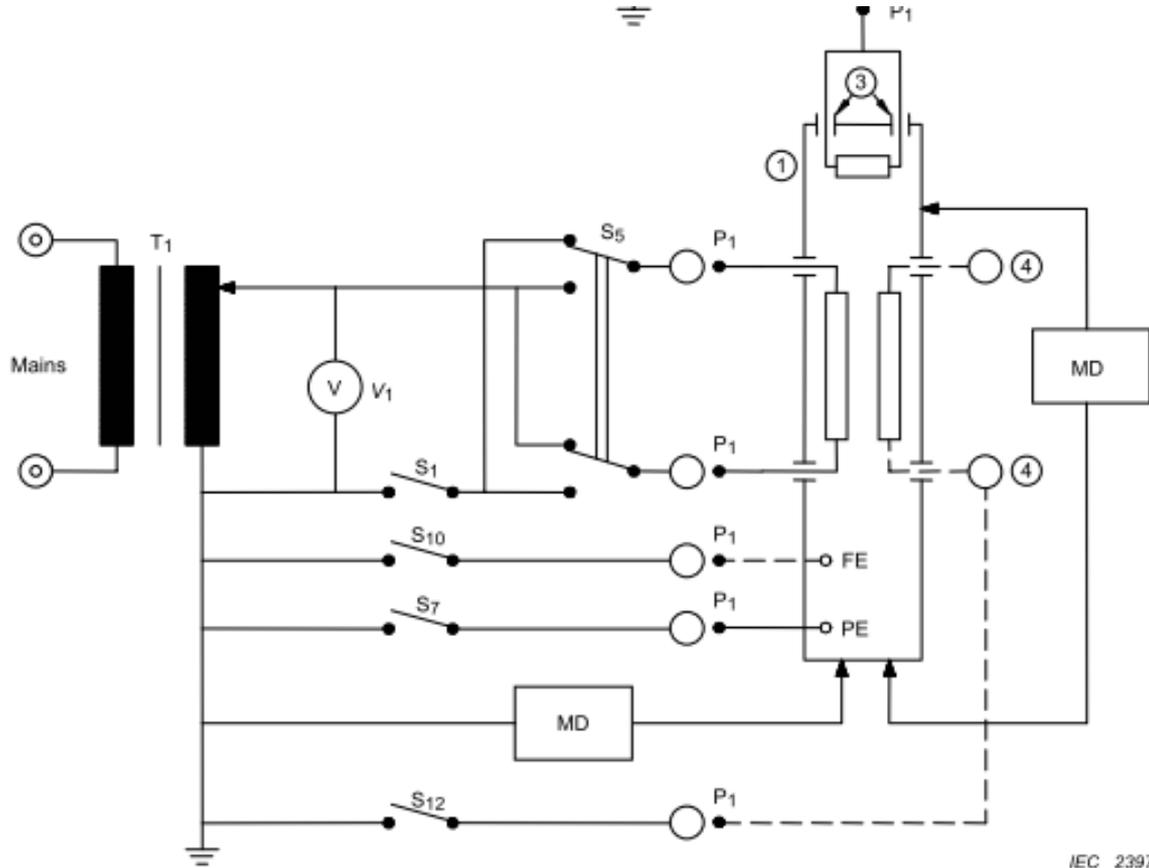
Table IV

\*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 <sup>1)</sup>	0,5	1 <sup>1)</sup>	0,5	1 <sup>1)</sup>	
EARTH LEAKAGE CURRENT for EQUIPMENT according to notes <sup>2)</sup> and <sup>4)</sup>	2,5	5 <sup>1)</sup>	2,5	5 <sup>1)</sup>	2,5	5 <sup>1)</sup>	
EARTH LEAKAGE CURRENT for EQUIPMENT according to note <sup>3)</sup>	5	10 <sup>1)</sup>	5	10 <sup>1)</sup>	5	10 <sup>1)</sup>	
ENCLOSURE LEAKAGE CURRENT	0,1	0,5	0,1	0,5	0,1	0,5	
PATIENT LEAKAGE CURRENT according to note 5)	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 OF SIGNAL OUTPUT PART)	–	5	–	–	–	–	
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)	–	–	–	5	–	0,05	
PATIENT AUXILIARY CURRENT according to note 5)	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

# Touch Current

60601-1 – Figure 14

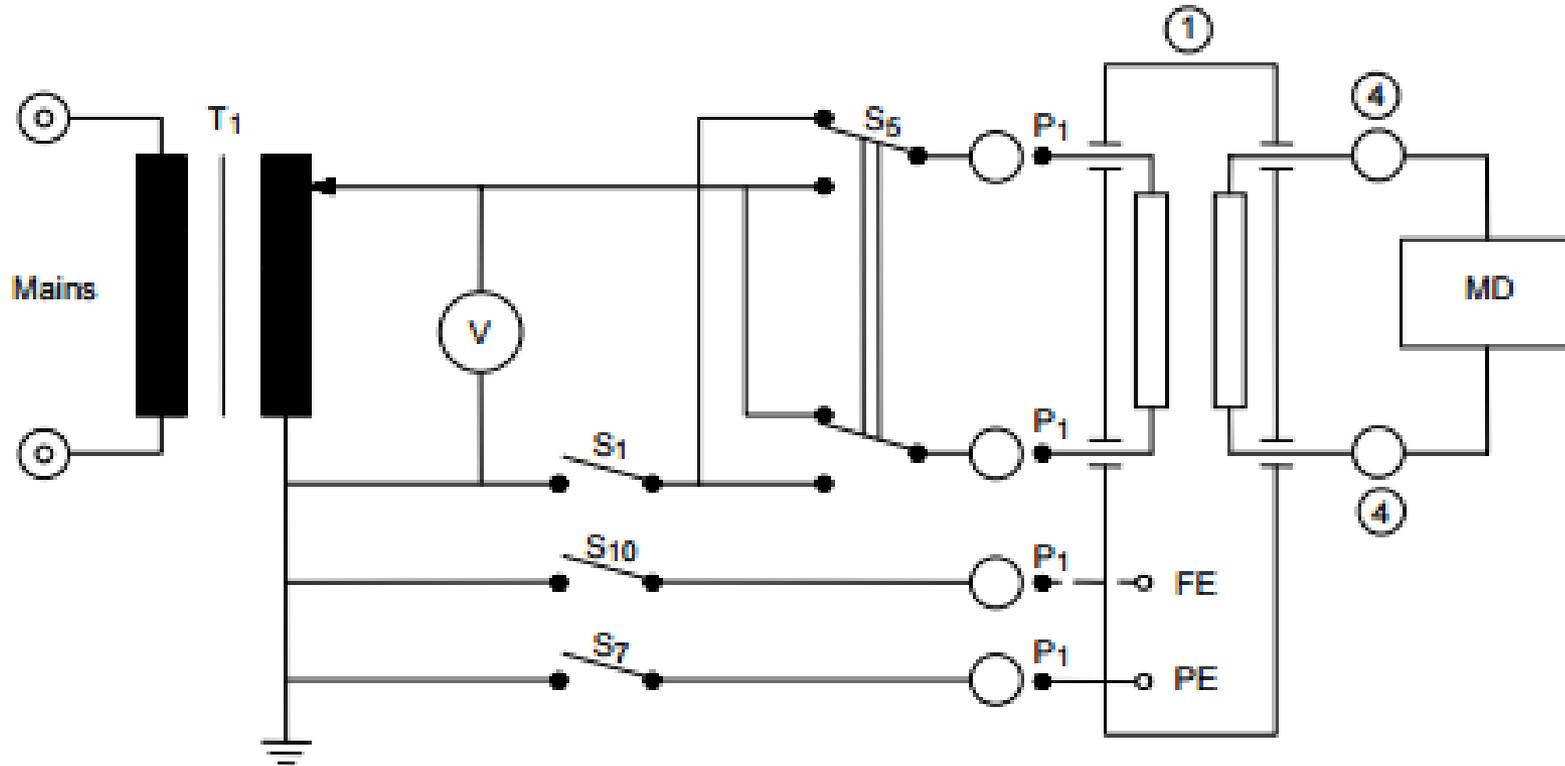




# Video Demonstration

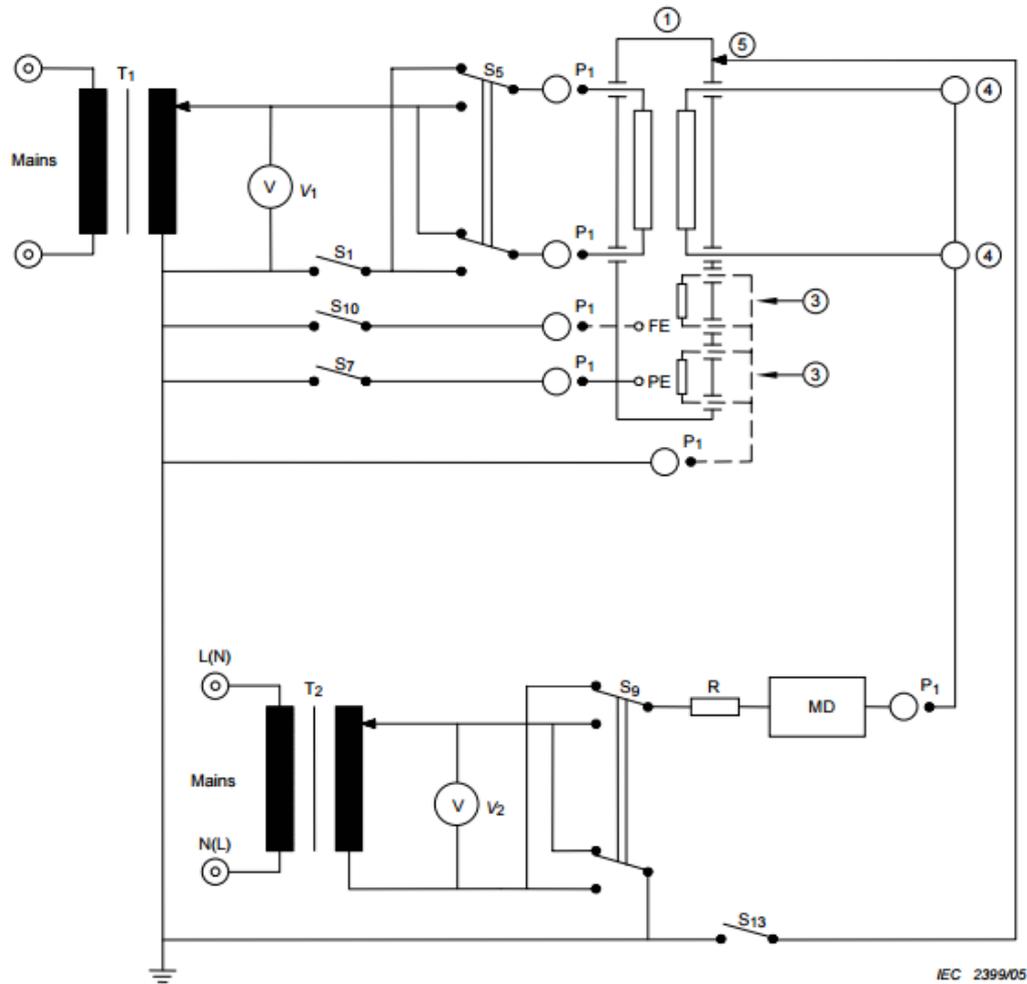


# Patient Auxiliary Current



IEC 2402/05

# Mains on Applied Part

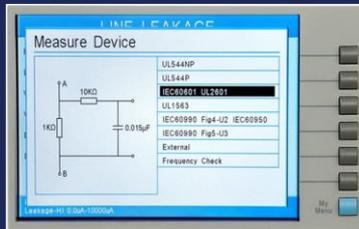


# Poll Question

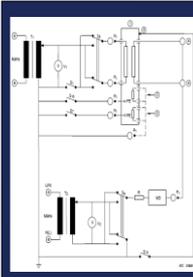
Question Goes Here

- A. Answer Choice A
- B. Answer Choice B
- C. Answer Choice C
- D. Answer Choice D

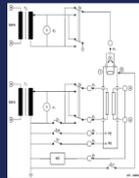
# Additional Tests and Considerations



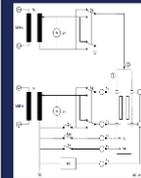
Leakage current



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

# Educational Resources

Visit us online to view all of our Educational Resources  
[arisafety.com/support/educational-resources/](https://www.arisafety.com/support/educational-resources/)



**Nobody Understands Electrical Safety  
Testing Better Than We Do.**



## **SAFETY**

Safe Workstations. Safe Products. Safe Customers. Conform to OSHA.



## **EDUCATION**

Educate your operators on best practice.



## **PRODUCTIVITY**

We'll help you improve throughput on your production line.

**Ready to Improve Your Production Line?**

Visit [ikonixusa.com/consulting](http://ikonixusa.com/consulting) Contact [applications@ikonixusa.com](mailto:applications@ikonixusa.com)

**Custom packages available to meet your needs.**

# Contact Us

You can find a recording of this webinar and presentation on our Webinar Archive page, [arisafety.com/webinars/archived-webinars/](https://www.arisafety.com/webinars/archived-webinars/)

Check out our website for more information [arisafety.com](https://www.arisafety.com)

For any questions about our webinars send an email to Amanda at [amanda.booth@ikonixusa.com](mailto:amanda.booth@ikonixusa.com)

