

Chroma Systems Solutions, Inc.

Multiple Patient Leakage and Mains on AP Leakage Measurements with the 19032 and 5000-03 Scanner

19032 Series Electrical Safety Analyzer, 5000-03 Scanner

Keywords: 19032 Series Electrical Safety Analyzer, dielectric withstand, leakage current, mains hipot, AP hipot, enclosure leakage, patient leakage, patient aux leakage, IEC60601-1, 5000-03 Scanner, class I medical devices, earth line leakage

Title:

Multiple Patient Leakage and Mains on AP Leakage Measurements with the 19032 and 5000-03 Scanner

Product Family: **19032 Series Electrical Safety Analyzer, 5000 Scanner**

Summary

The 19032 series can be used with an external 5000-03 Scanner to accomplish testing on Class I medical devices per IEC 60601-1. Tests include: Earth Line Leakage, Patient Leakage, Mains to Enclosure Hipot, AP to Protective Earth PE Hipot and F-Type Mains to AP. The external scanner is used to switch between the various points for leakage, and hipot on a medical device that has multiple applied parts. This application note describes how this can be accomplished without the need to change cable to the device during testing.

Solution

The 19032 series has internal measurement circuits or measurement devices MD that meets the requirements of various standards such as IEC60601-1. When performing leakage current measurements, for single phase products, the 19032 series can create single fault neutral open by opening or closing S1. The mains input power to the device can be switched between normal and reverse as designated by S5. The switching is all done automatically via relays within the 6000-07 scanner of the 19032 series. For Class I products the Ground Switch GS designated by S7 is used to open and close protective earth.

The 19032 series can also control several external scanners. This application note uses one 5000-03 scanner which has 8 channels which can be switched high, low or no connect and utilizes high voltage reed relays which can operate to 4500VAC. The 5000-03 scanner is configured so that Patient leakage, mains to AP or AP to PE hipot can be measured on up to 8 points. See Diagram 1.

Note: if Mains to AP hipot is required, disconnect the ground and sense lead from the G30 Corded product adapter at the Drive – or Sense – connections to prevent damage to the 19032 series during

hipot testing in this configuration. This would require a pause step to switch cables or change connections.

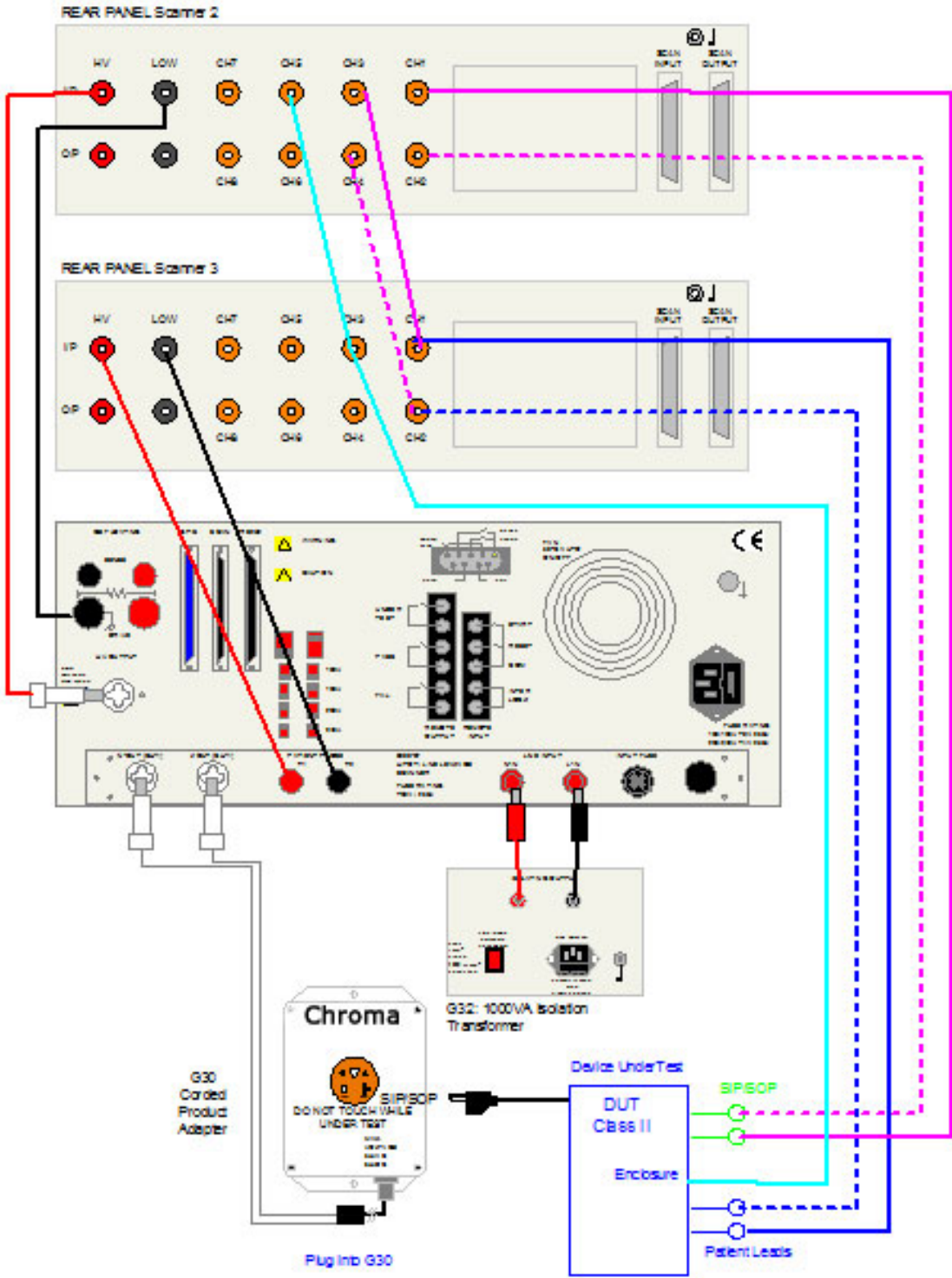


Diagram 1 Connection of 19032 and 5000-03 Scanner

Earth Line Leakage Class I

Earth Leakage measures the leakage current from the accessible metal parts that are protectively earthed. The scanner is not used for Earth Line Leakage. The Earth Line Leakage is the leakage current returning to the Drive – and Sense – leads. The leakage current would then be measured for all combinations of S1 and S5.

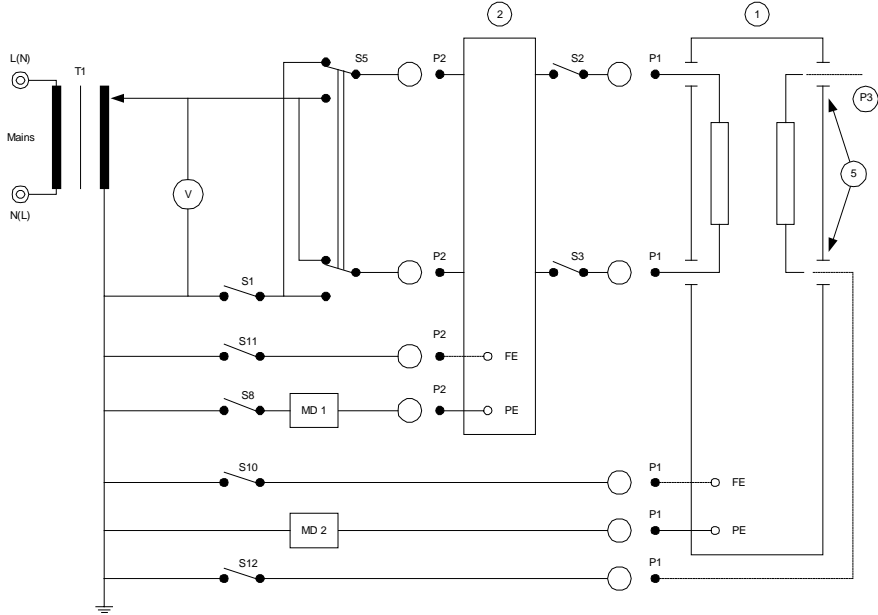


Figure 2-21a: SM937 Earth Leakage Class I

STEP SETTING					STEP SETTING								
01. Test Step	:	1		SETUP	01. Test Step	:	7						
02. Test Mode	:	LC			02. Test Mode	:	LC						
03. Device	:	UL2601			03. Device	:	UL2601						
04. Line Input	:	NORMAL			SETUP SCANNER - 1								
05. GB Switch	:	OPEN			1	2	3	4	5	6	7	8	NEXT BOX
06. Meter	:	L - G			X	X	X	X	X	X	X	X	
07. High Limit	:	0.3mA											
08. Low Limit	:	OFF											
09. Power	:	VOLTAGE											
10. Test Time	:	3.0s			10. Test Time	:	3.0s						
11. CHNL (H-L)	:	OFF			11. CHNL (H-L)	:	OFF						EXIT
PRESS FUNCTION KEY					PRESS NUMBER KEYS								
			Remote	Lock	Offset	Error				Remote	Lock	Offset	Error

	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6	Ch 7	Ch 8
Scanner 1	X	-	X	-	-	-	-	-
Scanner 2	X	X	X	X	X	X	X	X

Patient Leakage Channel 1

Patient Leakage measures the leakage current from each patient connection. The scanner is configured so that Patient Probe #2 is connected through scanner 2 to Channel 1 which connects to the AP on the device. Channel 2 could also be used to measure the patient leakage to the other applied part. The leakage current would then be measured for combinations of S1 S5 and S7.

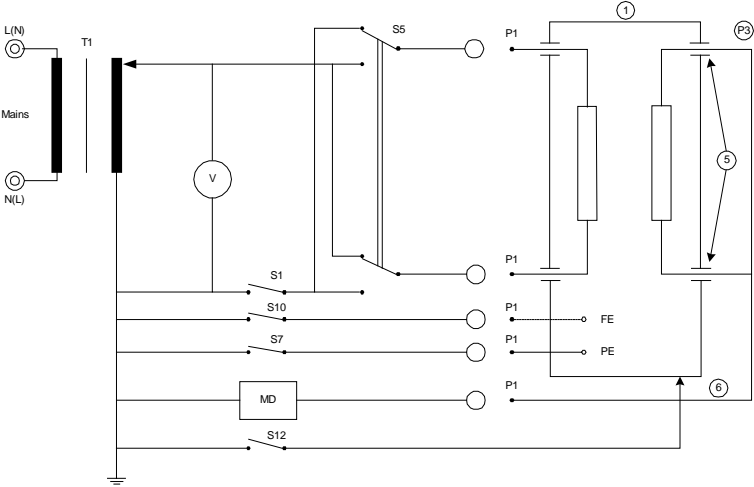


Figure 2-23a: SM940 Patient Leakage

STEP SETTING					STEP SETTING								
01. Test Step	:	1		SETUP	01. Test Step	:	7						
02. Test Mode	:	LC			02. Test Mode	:	LC						
03. Device	:	UL2601			03. Device	:	UL2601						
04. Line Input	:	NORMAL			SETUP SCANNER - 1				NEXT BOX				
05. GB Switch	:	CLOSED			1	2	3	4	5	6	7	8	
06. Meter	:	L - P2			X	X	X	X	X	X	X	X	
07. High Limit	:	0.01mA											
08. Low Limit	:	OFF			10. Test Time	:	3.0s						
09. Power	:	VOLTAGE			11. CHNL (H-L)	:	OFF					EXIT	
10. Test Time	:	3.0s			PRESS FUNCTION KEY					Remote	Lock	Offset	Error
11. CHNL (H-L)	:	OFF			PRESS NUMBER KEYS					Remote	Lock	Offset	Error

	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6	Ch 7	Ch 8
Scanner 1	X	-	X	-	-	-	-	-
Scanner 2	L	X	X	X	X	X	X	X

F-Type Mains on AP

The connections shown in Figure 2.24a are the required connections for performing the F-Type Leakage Test only. This may be a standalone test or may be part of a series of tests that are performed on your medical device. The other tests may include AC Hipot, Earth Leakage Current, Ground Bond, etc... The only test that requires T2 is this F-Type Leakage test.

What is an F-Type Leakage Test and how is one performed using the Guardian 6100 Electrical Safety Analyzer? The answer to these questions and more is right here. At first glance, the text of the international medical standard, IEC 60601-1, can be confusing yet by concentrating on a specific test the rationale becomes clearer.

Consider first the requirements of the IEC 60601-1 standard for an F-Type Leakage Test. Secondly, analyze the application of the Guardian 6100 Electrical Safety Analyzer. Can it accurately perform an F-Type leakage measurement? Once these two queries are solved, examine the practical part of this equation – just how is the Guardian 6100 instrument connected and how is it programmed? F-Type Leakage Measurements are easier than you think.

IEC 60601-1 Requirements

IEC 60601-1 requires Medical Electrical Equipment supplied with an F- Type Isolated (Floating) Applied Part, BF or CF, to pass the F-Type Leakage Test (110% Mains on Applied Part).

Per IEC 60601-1, Section 1, Sub-clause 2.1.7, an F-Type Isolated (Floating) Applied Part is defined as: “Applied Part isolated from other parts of the equipment to such a degree that no current higher than the Patient Leakage Current allowable in Single Fault Condition flows if an unintended voltage originating from an external source is connected to the patient, and thereby applied between the Applied Part and earth.”

The rationale behind this requirement is that the medical device attached to a patient should not provide a current path if the patient were to become in contact with Mains Voltage.

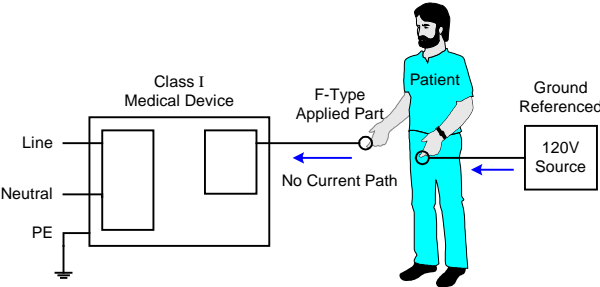


Figure 1.0: Isolated Patient Circuit

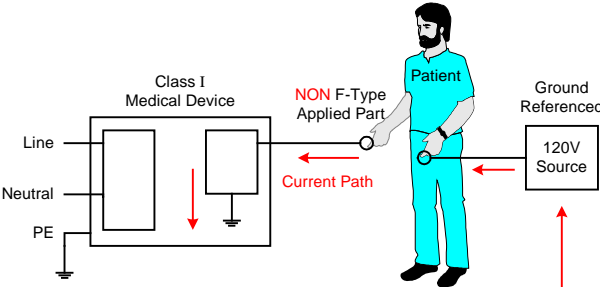


Figure 2.0: NON-Isolated Patient Circuit

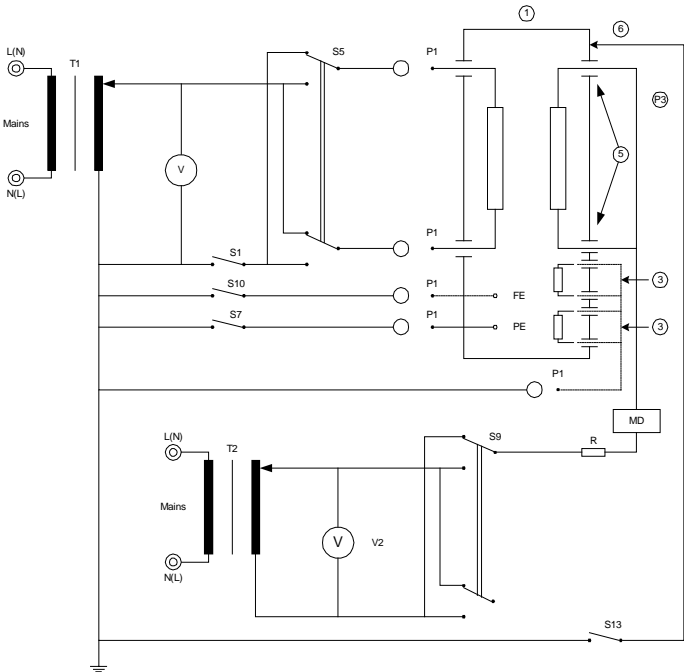


Figure 2-24a: SM941

STEP SETTING					
01. Test Step	:	1			SETUP
02. Test Mode	:	LC			
03. Device	:	UL2601			
04. Line Input	:	NORMAL			
05. GB Switch	:	CLOSED			
06. Meter	:	P1 - P2			
07. High Limit	:	0.05mA			
08. Low Limit	:	OFF			
09. Power	:	VOLTAGE			
10. Test Time	:	3.0s			
11. CHNL (H-L)	:	OFF			
PRESS FUNCTION KEY		Remote	Lock	Offset	Error

STEP SETTING					
01. Test Step	:	7			
02. Test Mode	:	LC			
03. Device	:	UL2601			
SETUP SCANNER - 1					
		1	2	3	4
		X	X	X	X
		5	6	7	8
		X	X	X	X
10. Test Time	:	3.0s			
11. CHNL (H-L)	:	OFF			EXIT
PRESS NUMBER KEYS		Remote	Lock	Offset	Error

	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6	Ch 7	Ch 8
Scanner 1	X	-	X	-	-	-	-	-
Scanner 2	L	X	X	X	X	X	X	X

Mains to PE Hipot at 1500VAC

Dielectric withstand would be checked between Mains LP(MP) and any accessible metal parts that are connected to protective earth. This test is typically performed at 1500VAC. Channel 1 on scanner 1 applies high voltage to the mains. Scanner 2 is not used.

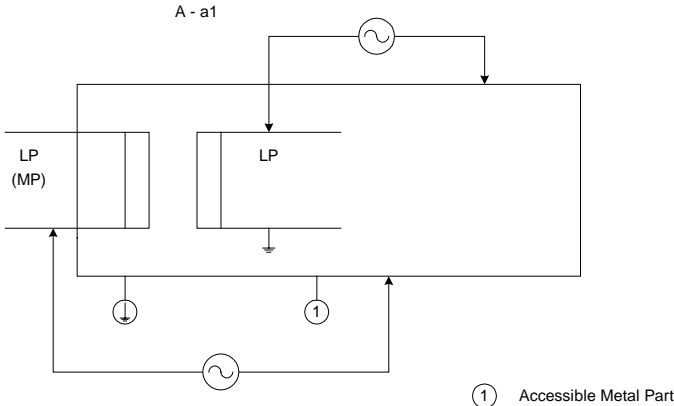


Figure 2-6a: SM916A

STEP SETTING					STEP SETTING				
01. Test Step	:	3		SETUP	01. Test Step	:	3		
02. Test Mode	:	AC			02. Test Mode	:	AC		
03. Voltage	:	1.500kV			03. Voltage	:	1.500kV		
04. High Limit	:	0.500mA			SETUP SCANNER - 1				NEXT BOX
05. Low Limit	:	OFF			1	2	3	4	5
06. Arc Limit	:	OFF			H	X	X	X	X
07. Arc Filter	:	3-230 kHz							
08. Test Time	:	3.0s			10. CHNL (H-L)	:	OFF		
09. Ramp Time	:	3.0s			EXIT				
10. CHNL (H-L)	:	OFF			PRESS NUMBER KEYS				
PRESS FUNCTION KEY					Remote	Lock	Offset	Error	

	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6	Ch 7	Ch 8
Scanner 1	H	-	X	-	-	-	-	-
Scanner 2	X	X	X	X	X	X	X	X

F-Type AP to accessible metal parts that are protectively earthed Hipot 1500VAC

Dielectric withstand would also checked between F-Type Applied parts (AP) and accessible metal parts that are protectively earthed.. This test is typically performed at 1500VAC for Class 1 products. Channel 3 on scanner 1 applies high voltage to scanner 2 and scanner 2 channels 1 and 2 are set high applying high voltage to both applied parts AP. Channels 3 to 8 could be set for additional AP connections if necessary.

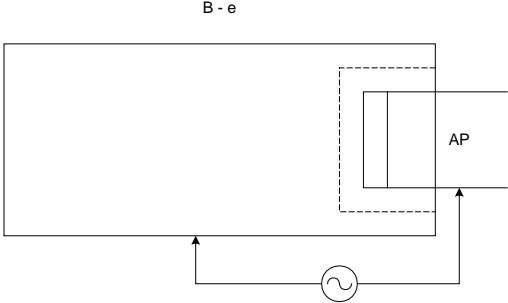


Figure 2-17a: SM931 Hipot AP to PE

STEP SETTING					STEP SETTING																												
01. Test Step	:	3		SETUP	01. Test Step	:	3																										
02. Test Mode	:	AC			02. Test Mode	:	AC																										
03. Voltage	:	1.500kV			03. Voltage	:	1.500kV																										
04. High Limit	:	0.500mA			<table border="1"> <thead> <tr> <th colspan="8">SETUP SCANNER - 1</th> </tr> <tr> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th> <th>6</th> <th>7</th> <th>8</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>X</td> <td>H</td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> </tr> </tbody> </table>					SETUP SCANNER - 1								1	2	3	4	5	6	7	8	X	X	H	X	X	X	X	X
SETUP SCANNER - 1																																	
1	2	3	4	5	6	7	8																										
X	X	H	X	X	X	X	X																										
05. Low Limit	:	OFF																															
06. Arc Limit	:	OFF																															
07. Arc Filter	:	3-230 kHz																															
08. Test Time	:	3.0s																															
09. Ramp Time	:	3.0s																															
10. CHNL (H-L)	:	OFF																															
PRESS FUNCTION KEY					PRESS NUMBER KEYS																												
	Remote	Lock	Offset	Error		Remote	Lock	Offset	Error																								

	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6	Ch 7	Ch 8
Scanner 1	X	-	H	-	-	-	-	-
Scanner 2	H	H	X	X	X	X	X	X

Mains to Patient Hipot at 4000VAC

Dielectric withstand would also be checked between Mains LP(MP) and the applied part AP. This test is typically performed at 4000VAC. One way of performing this test is to disconnect all Drive and Sense connections. Once these are disconnected, high voltage can be safely applied between the AP and Mains.

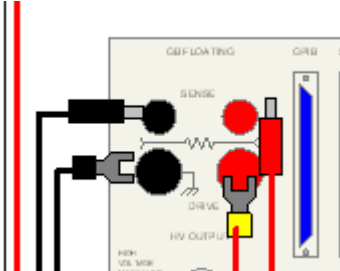


Diagram 2. Disconnect Drive and Sense Connections

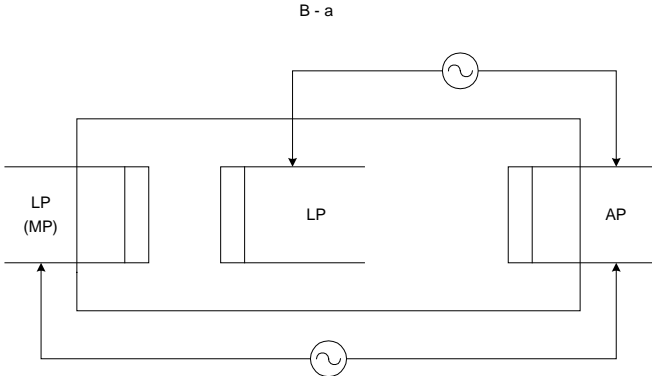


Figure 2-9a: SM927 Mains to AP Hipot

STEP SETTING					STEP SETTING								
01. Test Step	:	3	SETUP		01. Test Step	:	3						
02. Test Mode	:	AC			02. Test Mode	:	AC						
03. Voltage	:	4.000kV			03. Voltage	:	4.000kV						
04. High Limit	:	0.500mA			SETUP SCANNER - 1								
05. Low Limit	:	OFF			1	2	3	4	5	6	7	8	NEXT BOX
06. Arc Limit	:	OFF			X	X	X	X	X	X	X	X	
07. Arc Filter	:	3-230 kHz											
08. Test Time	:	3.0s											
09. Ramp Time	:	3.0s											
10. CHNL (H-L)	:	OFF			10. CHNL (H-L)	:	OFF			EXIT			
PRESS FUNCTION KEY					PRESS NUMBER KEYS								
Remote	Lock	Offset	Error		Remote	Lock	Offset	Error					

	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6	Ch 7	Ch 8
Scanner 1	H	-	L	-	-	-	-	-
Scanner 2	L	X	X	X	X	X	X	X

To implement this test within a series of tests, include this test as a Step within a Test Setup. For example, Step 1 might be Ground Bond, Step 2 AC Hipot, Step 3 Earth Leakage Current, then Step 4 F-Type Leakage Test, Step 5 Pause (Pause is inserted to display instructions that tell the user to change connections for F-Type Mains to Patient Hipot Test), and Step 6 Main to AP hipot.

Conclusion

The 19032 series can be used for measurement of Earth Line Leakage, patient leakage and F-Type Mains on AP leakage on a medical device with up to 8 patient connections when used in combination with the 5000-03 Scanner. Mains to PE Hipot and AP to PE hipot can also be done without changing cables during testing. The only test that requires changing or disconnecting cables is Mains to AP hipot which is performed at 4000VAC. A pause step can be used prompt the operator to perform the required changes to cabling.

This combination makes a very economical solution to testing Class I Medical Products.

REFERENCES:

[UL60601-1 MEDICAL ELECTRICAL EQUIPMENT, PART 1: GENERAL REQUIREMENTS FOR SAFETY](#)