Chroma Systems Solutions, Inc.

19032 for Measurement of Leakage Current, Mains Hipot and AP Hipot on Class II Medical Appliances

19032 Series Electrical Safety Analyzer

Keywords: 19032 Series Electrical Safety Analyzer, dielectric withstand, leakage current, mains hipot, AP hipot, class II medical appliances, enclosure leakage, patient leakage, patient aux leakage, IEC60601-1

Title:

19032 for Measurement of Leakage Current, Mains Hipot and AP Hipot on Class II Medical Appliances

Product Family: **19032 Series Electrical Safety Analyzer**

Summary

The 19032 Series Electrical Safety Analyzer can be used with external 5000-03 Scanners to accomplish testing on Class II medical appliances per IEC 60601-1. Tests include Enclosure Leakage, Patient Leakage, Patient Aux Leakage, Mains to Enclosure Hipot, Mains to AP Hipot, and AP to Enclosure Hipot. The external scanners are used to switch between the various points for leakage, and hipot on a medical appliance that has multiple applied parts, SIP/SOP and enclosure points. This application note describes how this can be accomplished without the need to change cable to the appliance 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 appliance 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 II products the Ground Switch GS designated by S7 is not used. Class II products do not have a protective earth ground.

The 19032 series can also control several external scanners. This application note uses 5000-03 scanners which have 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 scanners are configured so that one scanner switches patient probe #1 and #2 for leakage current measurements and the other scanner switches high voltage or ground return for hipot testing. See Figure 1. Note it is very important not to connect

the ground or sense leads from the G30 Corded product adapter to the Drive – or Sense – leads to prevent damage to the 19032 series during hipot testing in this configuration.

Each section below will show the appropriate figure from IEC60601-1 standard for the test being performed, the setup of the 19032 series and a table showing the settings of all scanner channels.

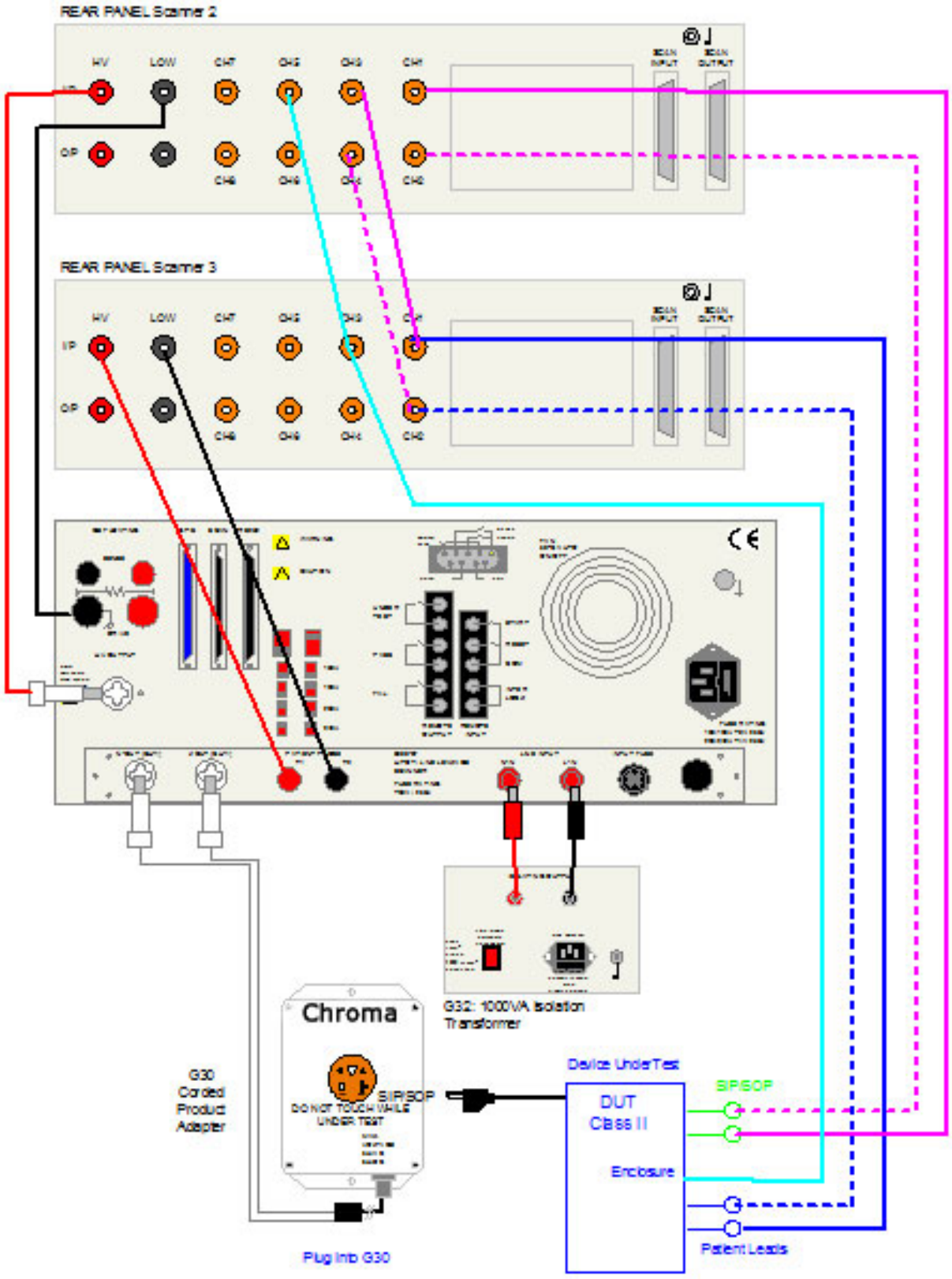


Figure 1. 19032 connections for Hipot and Leakage on Class II Appliances

Enclosure Leakage Class II

Enclosure Leakage measures the leakage current from the enclosure. The scanners are configured so that Patient Probe #2 is connected through scanner 3, channel 3 to the enclosure of the appliance. The leakage current would then be measured for all combinations of S1 and S5.

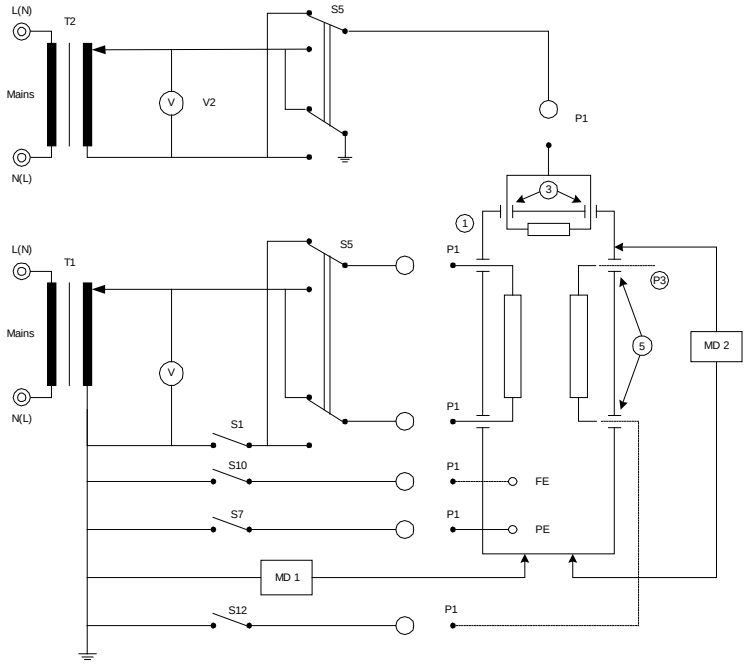
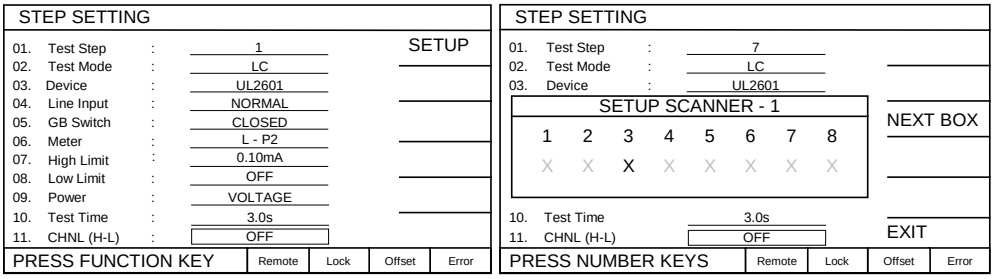


Figure 2-21a: SM938A Enclosure Leakage Class II



	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
Scanner 3	X	X	L	X	X	X	X	X

Patient Leakage Channel 1

Patient Leakage measures the leakage current from each patient connection. The scanners are configured so that Patient Probe #2 is connected through scanner 3, channel 1 to one of the applied parts on the appliance. Channel 2 could also be used to measure the patient leakage to the other applied part. The leakage current would then be measured for all combinations of S1 and S5.

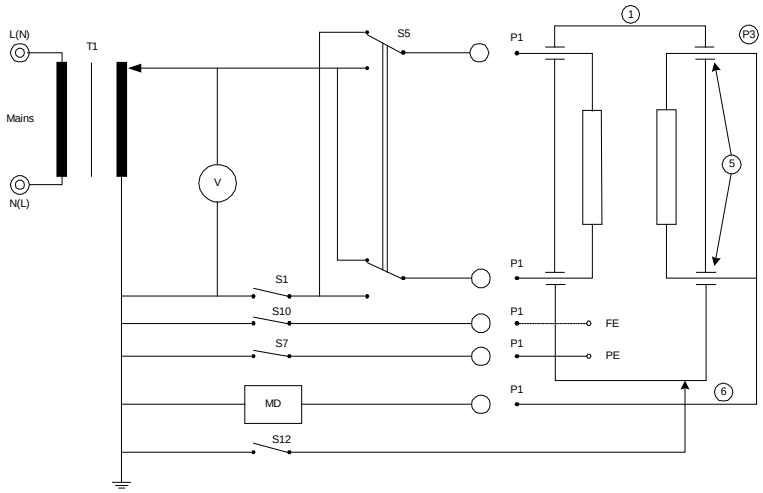
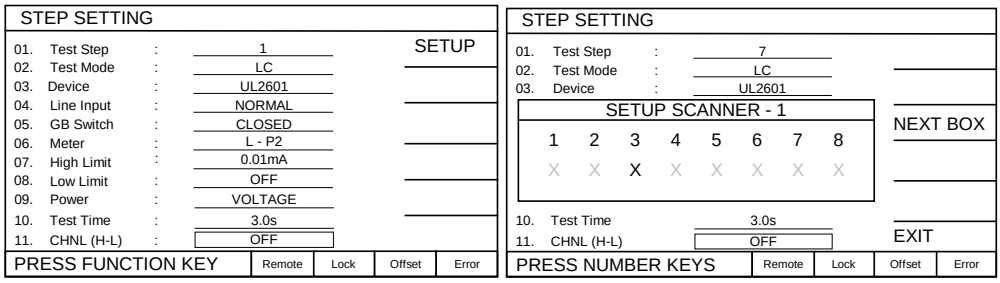


Figure 2-23a: SM940 Patient Leakage Class II



	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**
Scanner 3	**L**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

Patient Auxiliary Leakage

Patient Leakage measures the leakage current from between patient connections. The scanners are configured so that Patient Probe #2 is connected through scanner 3, channel 1 to one of the applied parts on the appliance and Patient Probe #1 is connected through scanner 3, channel 2 to other applied part on the appliance. The leakage current would then be measured for all combinations of S1 and S5.

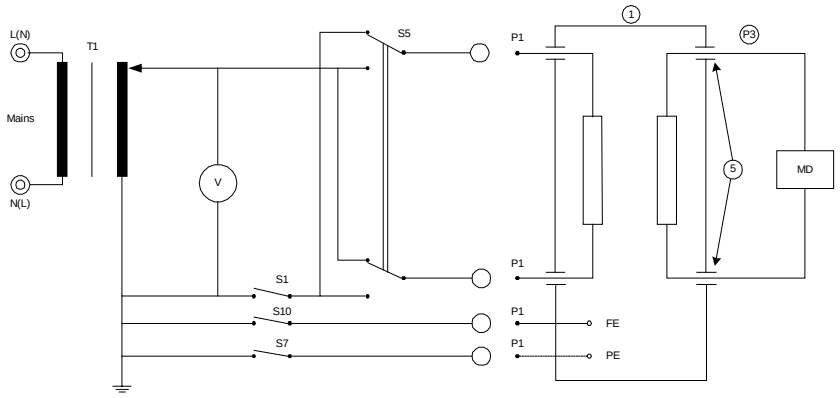
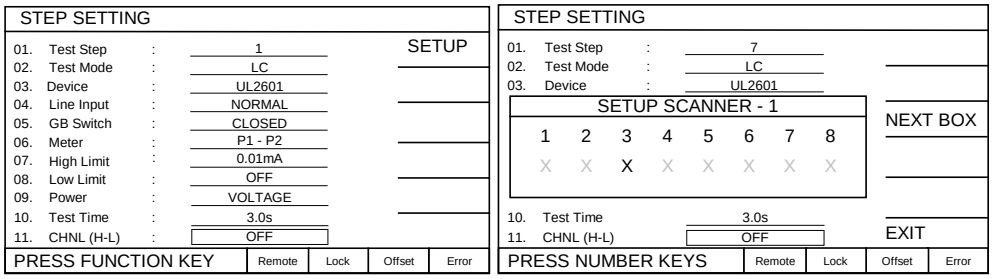


Figure 2-30a: SM934 Patient Auxiliary



	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
Scanner 3	L	H	X	X	X	X	X	X

Mains to Patient Hipot at 4000VAC

Dielectric withstand would also checked between Mains LP(MP) and the applied part AP. This test is typically performed at 4000VAC. Channel 1 on scanner 1 applies high voltage to the mains and scanner 2 channels 3 and 4 are set low which connects applied parts to ground return.

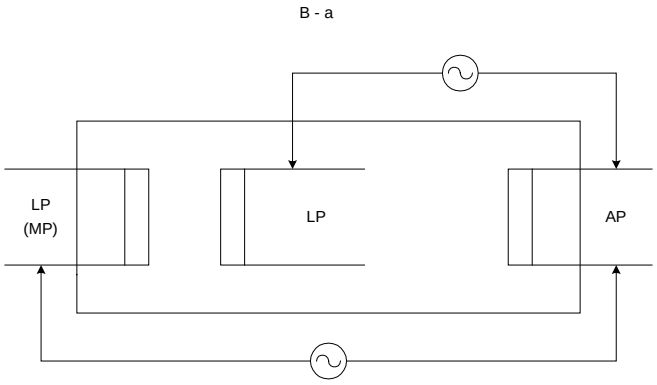
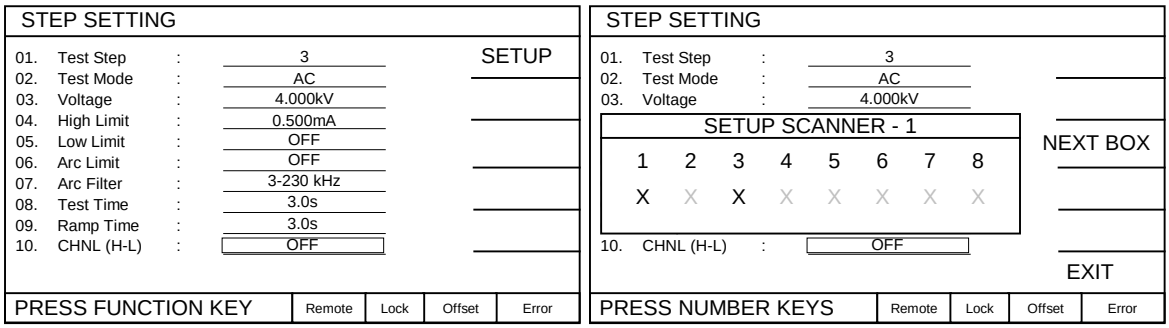


Figure 2-9a: SM927 Mains to AP Hipot



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

Mains to Enclosure Hipot at 4000VAC

Dielectric withstand would also checked between Mains LP(MP) and the enclosure. This test is typically performed at 1500VAC. Channel 1 on scanner 1 applies high voltage to the mains and scanner 2 channel 5 is set low which connects the enclosure to ground return.

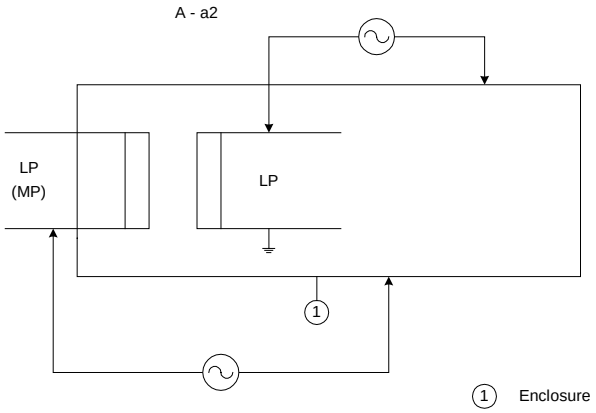
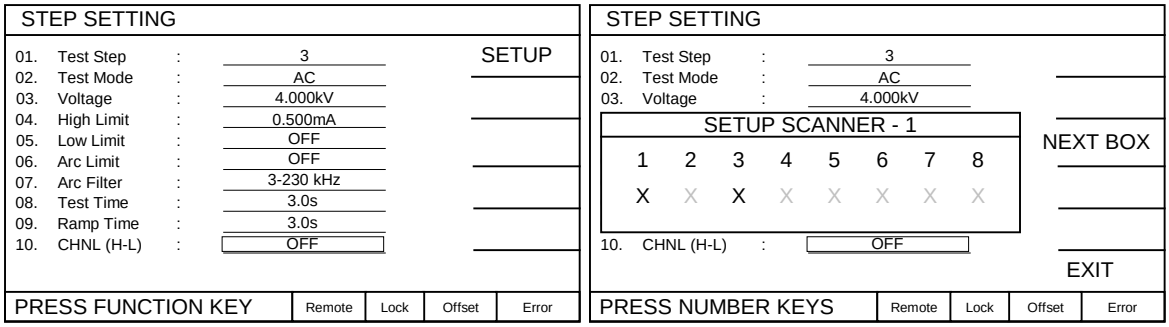


Figure 2-7: SM917 Mains to Enclosure not PE



	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**	**L**	**X**	**X**	**X**
Scanner 3	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

AP to Enclosure Hipot 1500VAC

Dielectric withstand would also checked between Applied parts (AP) and the enclosure. This test is typically performed at 4000VAC. Channel 3 on scanner 1 applies high voltage to scanner 2 and scanner 2 channels 3 and 4 are set high applying high voltage to both applied parts AP and scanner 2 channel 5 is set low which connects the enclosure to ground return.

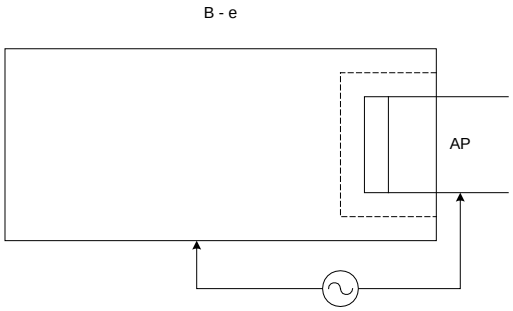
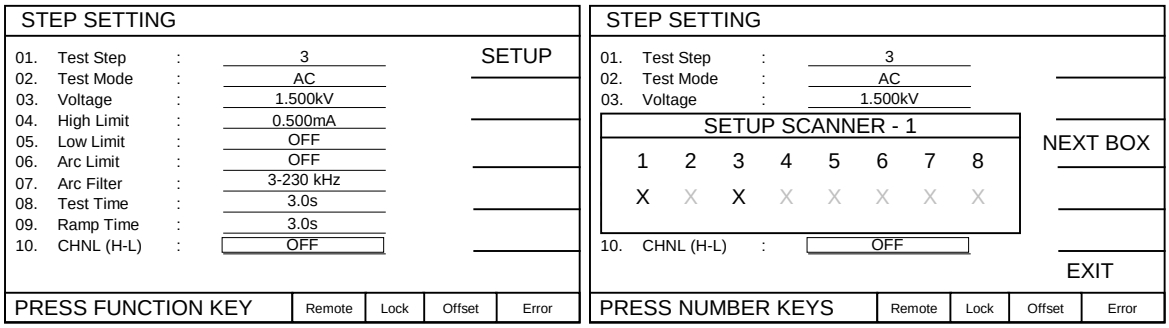


Figure 2-17a: SM931 Hipot AP to Enclosure



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

Mains to SIP/SOP Hipot 1500VAC

Dielectric withstand would also checked between Mains LP(MP) and the SIP/SOP parts. This test is typically performed at 1500VAC. Channel 1 on scanner 1 applies high voltage to mains and scanner 2 channels 1 and 2 are set low which connects the SIP/SOP parts to ground return.

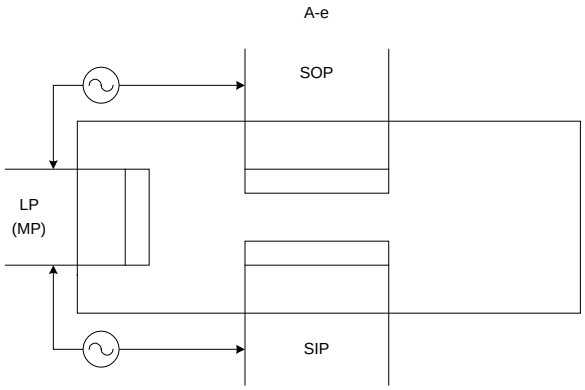
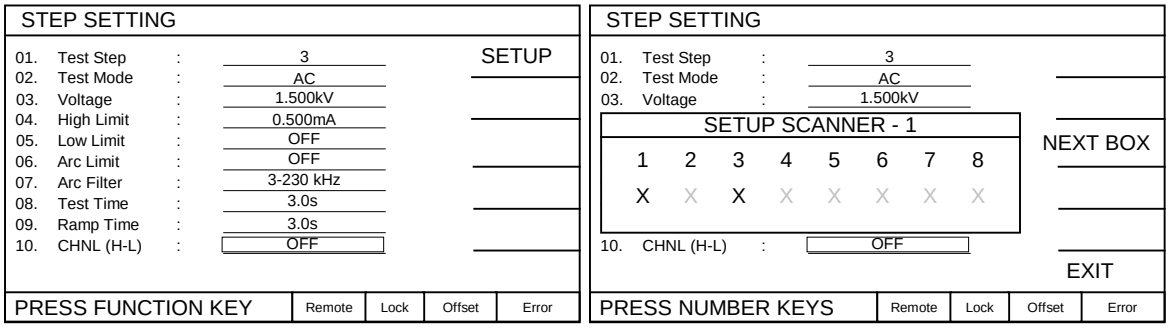


Figure 2-10a: SM921 Mains to SIP/SOP



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

Conclusion

The19032 can be used for measurement of enclosure leakage, patient leakage and patient auxiliary leakage on a medical device with up to 7 patient connections. Hipot Mains to AP, Mains to Enclosure and AP to enclosure hipot can also be done without changing cables during testing.

UL60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety