

Chroma Systems Solutions, Inc.

Leakage Current Part II

19032 Safety Analyzer

Keywords: Human Body Impedance, IEC60601-1, Earth Leakage Current, Enclosure Leakage Current, Patient Leakage Current, Patient Auxiliary Current.

Title:

Leakage Current Part II

Product Family: 19032 Safety Analyzer

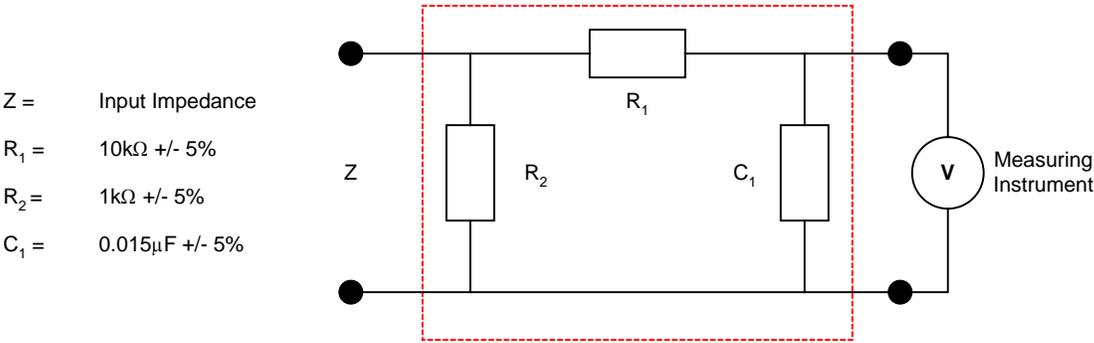
Scope

Part 1 of this two-part reference on leakage current discussed the terms and definitions associated with leakage current and the two classes that electronic medical products are divided into per IEC60601-1. Part 2 builds on those basic principles and details the IEC60601-1 measurement circuits for Earth, Touch/Chassis and Patient leakage current tests.

Rules of Leakage Current Measurement

There are some general rules that should be followed when performing a leakage current measurement. The product being tested should be placed on an insulating surface and significantly far away, 20cm, from any earthed metal surface. The measurement circuit and cables should be positioned as far away from unscreened power supply leads as possible and significantly far away from any earthed metal surface.

Recall from Part 1 the human body impedance circuit as illustrated in Figure 1. This circuit is represented as MD in the circuit diagrams for Earth, Touch/Chassis and Patient leakage current tests.



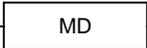
This figure is equivalent to  in IEC60601-1 Leakage Circuit Diagrams

Figure 1.0: Equivalent Circuit - Human Body Impedance

Table 1 lists the LC Test figure numbers for this application note and IEC60601-1.

Table 1.0: Reference Figures for LC Tests

Leakage Current Test	App Note Figure #	IEC60601-1 Figure #
Earth	2.0	12
Touch/Chassis (Enclosure)	3.0	13
Patient, Applied Part to GND	4.0	14
Patient, F-TYPE Applied Part to GND	5.0	15
Patient, Applied Part to GND by SIP/SOP	6.0	16
Patient Auxiliary	7.0	17

Earth Leakage Current

One of the most important of the leakage current tests for Class I products is earth line leakage. The earth leakage current test measures the leakage current flowing back through the protective earth conductor of the power cord. This is the total leakage current from all protectively earthed parts of the product. This test is only applicable to protectively earthed products that have a three-prong power cord.

Figure 2 illustrates the basic connections to a medical product for earth leakage measurements. The actual leakage current is measured in the box marked **MD**. This is a point in the protective earth conductor between the products protective earth terminal and reference ground. Depending upon the configuration reference ground can also be mains supply ground. Earth leakage measurements are normally made under the following mains supply conditions:

Normal Mains: S5 down position

Reverse Mains: Hot and Neutral reversed S5 up position as shown

Single Fault – Normal: Neutral open S1 open and S5 down

Single Fault – Reverse: Hot and Neutral reversed with Neutral open S1 open and S5 up

For medical devices touch/chassis leakage current is normally performed with signal inputs and outputs connected to a voltage using a separate transformer. The voltage supplied to the signal inputs and outputs is either based upon the voltage rating supplied by documentation from the manufacturer or 110% of the mains supply voltage. This is shown as T2 in Figure 3.

Measurement of Touch/Chassis (enclosure) leakage is performed under the following conditions:

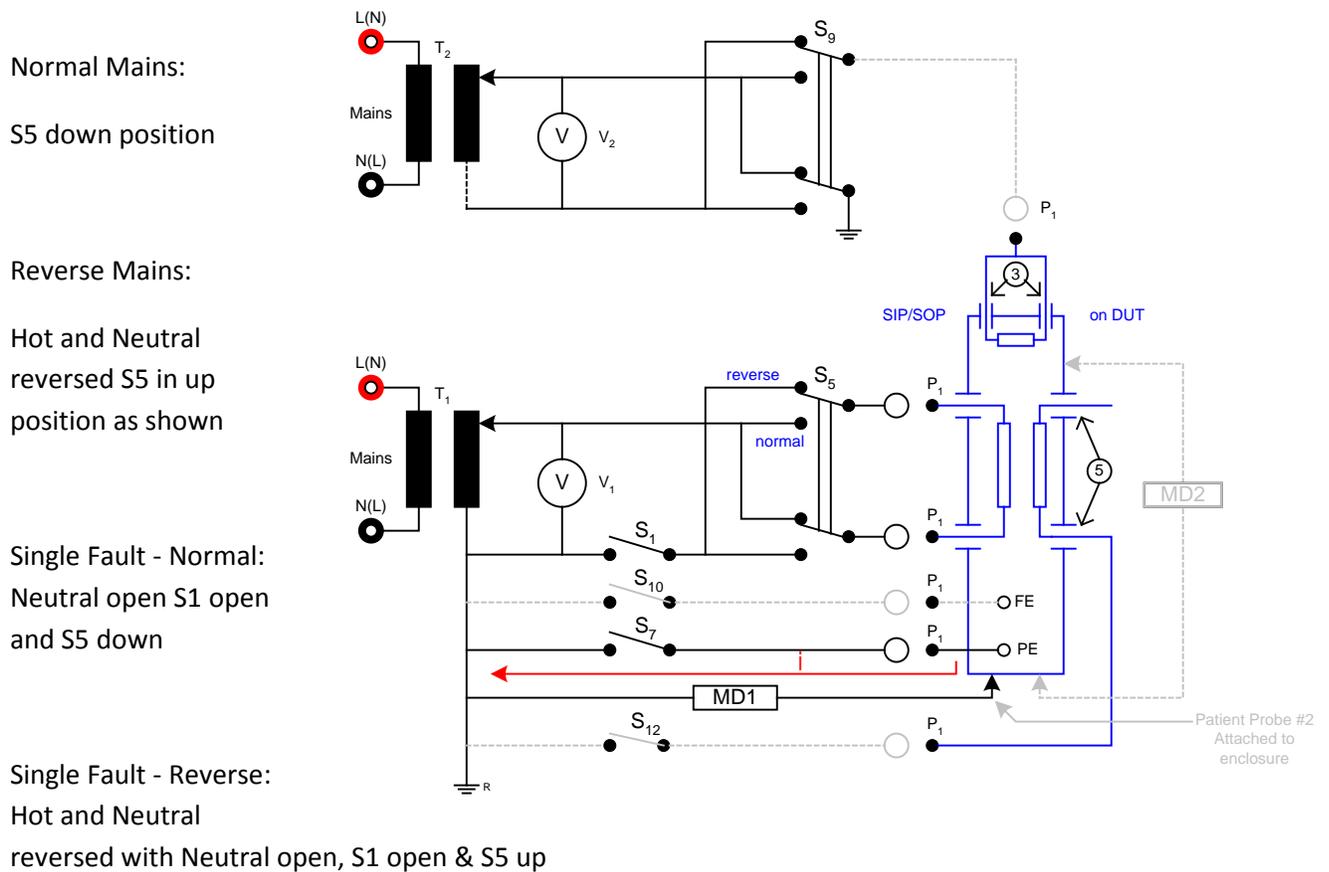


Figure 3.0: Enclosure (Touch/Chassis) Leakage Current (Figure 13 of IEC60601-1)

Patient Leakage Current – Applied Part to Supply Ground

Patient leakage current is only a requirement for medical devices. Patient leakage current measures the leakage between any applied part(s) and reference ground using the same standard measuring device MD. The leakage current measurement device MD is connected between supply ground and any exposed metal on applied part. To achieve measurements on products that have an applied part made

of insulating material, a piece of conductive foil no larger than 20cm x 10cm is placed in direct contact with the surface of the applied part or a saline solution in which the applied part is immersed maybe used.

Patient leakage is measured under the same normal and fault conditions as outlined in touch/chassis leakage current. Depending upon the Type of patient connection depends upon the number of measurements required. For example leakage current shall be measured from all B-Type applied parts tied together where for products with CF-Type applied parts leakage current has to be measured to each CF-Type applied part separately.

There are a number of considerations when it comes to patient leakage current measurements. If the medical device contains an F-Type Applied Part then the device is tested according to Figure 5 (Figure 15 from IEC601-1) with all signal input and outputs tied to ground.

If the medical device does not have F-Type Applied Parts but contains signal inputs and outputs then the device is tested according to Figure 6.0 (IEC60601-1, Figure 16). In this case the patient leakage current is measured between the applied part(s) and supply ground with all signal inputs and outputs connected to a voltage using a separate transformer. The voltage supplied to the signal inputs and outputs is either based upon the voltage rating supplied by documentation from the manufacturer or 110% of the mains supply voltage. This is shown as T2 in Figure 6.0.

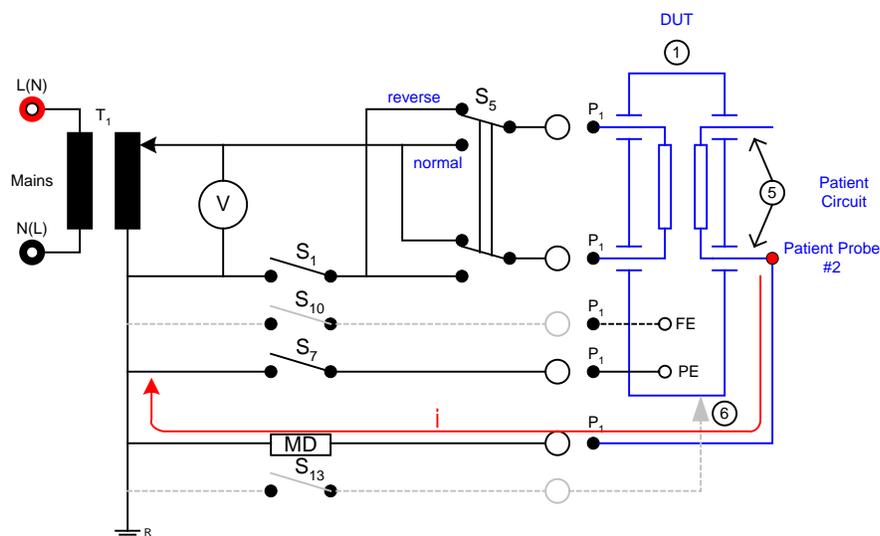


Figure 4.0: Patient Leakage - Applied Part to Ground (Figure 14 of IEC60601-1)

Patient Leakage Current – Applied Part to Supply Ground

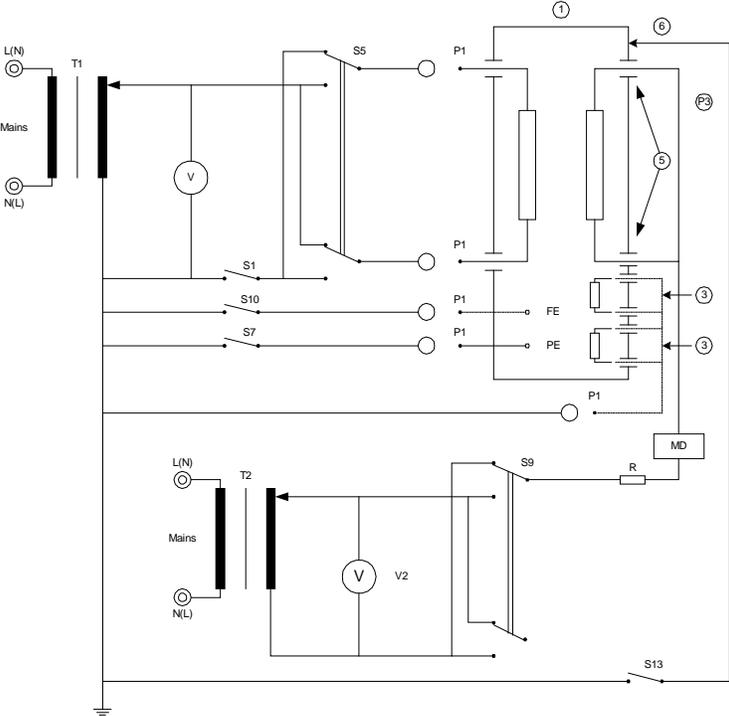


Figure 5.0: Patient Leakage – F-TYPE Applied Part to Ground (Figure 15 of IEC60601-1)

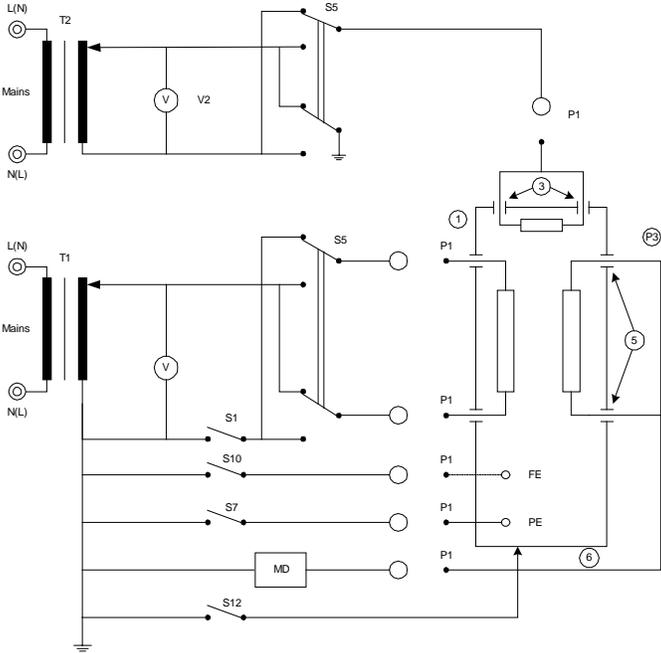


Figure 6.0: Patient Leakage - Applied Part to Ground by SIP/SOP (Figure 16 of IEC60601-1)

Patient Auxiliary Current

Patient Auxiliary current measures the leakage current between one applied part and all others for all possible combinations. The IEC 60601-1 measuring circuit for the patient auxiliary current test is illustrated in Figure 7.0. All of the same normal and fault conditions as outlined in touch/chassis leakage current.

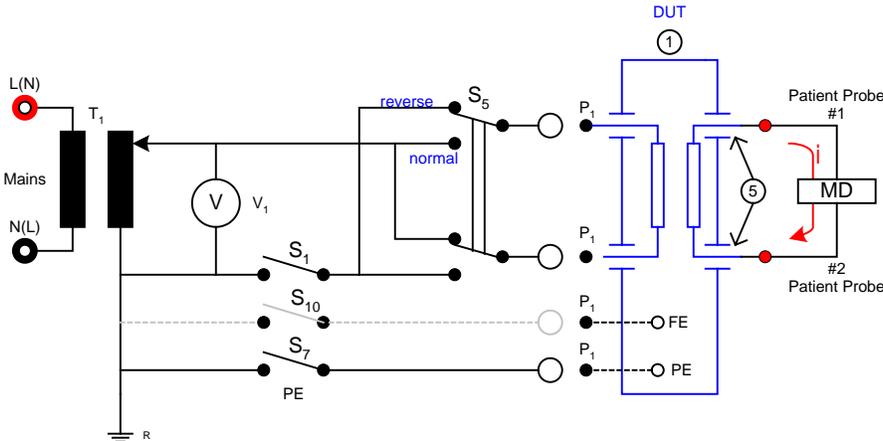


Figure 7.0: Patient Auxiliary Current (Figure 17 of IEC60601-1)

This installment (#7) of the IEC60601-1 Series has illustrated the types of leakage tests performed on electronic medical devices. Tune in next time when the discussion will focus on national deviations to IEC60601-1, like AAMI, ES-1 and NFPA 99.



To find out more about IEC60601-1 and classification please contact Eisner Safety Consultants at (503)-244-6151 visit us on the web at <http://www.eisnersafety.com/> or e-mail us at Leo@EisnerSafety.com. Eisner Safety Consultants specializes in assisting clients with product evaluation to safety standards, Agency coordination, CE Mark, Quality Systems and training.

For complete product specifications on the 19032 Series Electrical Safety Analyzers or any of Chroma’s products, visit us at www.Chromausa.com. Do you have an application specific testing need? Call us at

Application Note

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