Measuring leakage currents in electromedical devices in accordance with IEC EN 62353

White Paper

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Introduction

The measurement of leakage currents in electromedical devices and systems (hereinafter EM), in accordance with the IEC EN 62353:2010-10 Standard "Electromedical devices - Periodic checks and tests after repairs on electromedical devices," (hereinafter the Standard), provides for the use of three methods: direct, alternative and differential. The measurements to be performed are then classified into leakage current in the device and leakage currents in the parts applied, as defined in the Standard.

Where possible, the direct method is preferred, since it is more similar to the measurement approach in the product standard IEC 60601-1-XX. We will indicate below the criteria for selecting the measurement method according to the mains supply characteristics and the installation conditions of the EM device or system.

One of the most severe errors committed in the execution of electrical safety checks is to neglect the following fundamental aspects:

- Failure to remove ground connections results in measurements generally equal to zero for the measured currents.
- A power supply from the isolation transformer reduces the currents to negligible values because the voltages on the two supply polarities are equal, and with opposite signs, compared to the housing connected to ground.

A particular case to take into consideration is the existence, in some hospitals and in some parts of the LV network, of a distribution system with only three active distributed conductors and phase-to-phase voltage of 230 V. (The neutral is not distributed and the power supply voltage of the EM devices or systems is 230 V phase/phase.)

It should be noted, finally, that the same standard states if the power supply voltage of the device is $U_0 \neq 230$ V, the values measured with the different methods must be multiplied by $230/U_0$ to be more correctly compared with the limits indicated in the Standard.

Therefore, the variables in the leakage current measurement system are: type of system, EM installation and measurement method.

Type of mains supply

The mains supply types, in order of importance for the purposes of periodic checking, are:

- TN-S with four active distributed conductors and voltage 400/230 V
- TT with four active distributed conductors and voltage 400/230 V
- IT-M 230 V
- TN-S with three active distributed conductors and phase-to-phase voltage of 230 V
- TT with three active distributed conductors and phase-to-phase voltage of 220 V

The TN-S system with four active distributed conductors 400/230 V (Fig. 1) is generally present in all large public and private health care facilities. The TT system with four active distributed conductors 400/230 V (Fig. 2) is generally present in small public and private health care facilities that require less than approx. 100 kW.

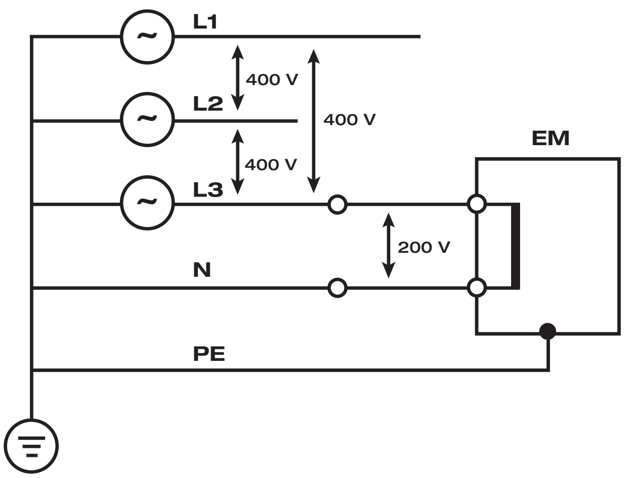


Figure 1: Electrical diagram for -TN-S type system with four active distributed conductors and voltages of 400/230 V.

The system of type IT-M (Fig. 3), i.e. with an isolation transformer, voltage 230 V and isolation detector is required in all Group II medical rooms.
In some hospitals, the distribution is of the type -TN-S with three active distributed conductors and phase-to-phase voltage of 230 V (Fig. 4).

Some parts of the LV system are still managed with the TT system with three active distributed conductors and phase-to-phase voltage of 230 V (Fig. 5).

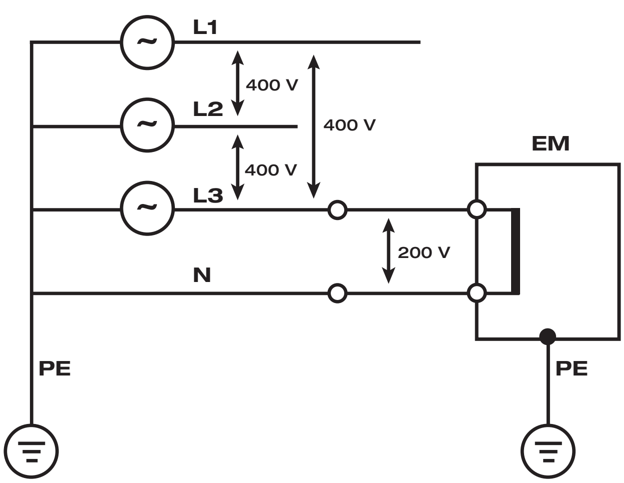


Figure 2: Electrical diagram for -TT type system with four active distributed conductors and voltages of 400/230 V.

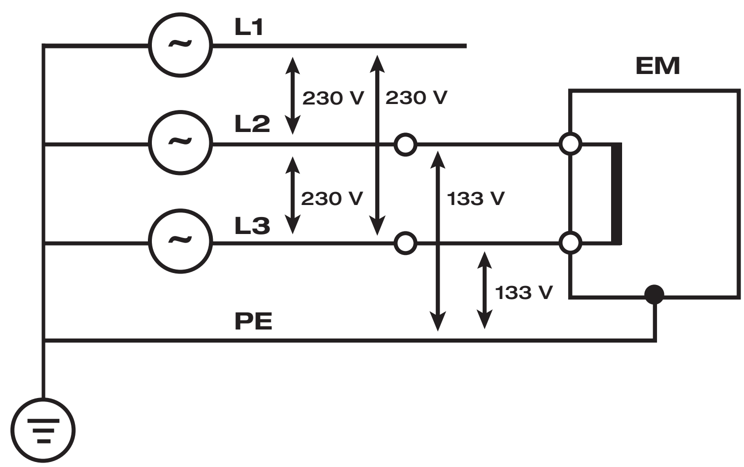


Figure 4: Electrical diagram for -TN-S type system with three active distributed conductors and phase-to-phase voltages of 230 V.

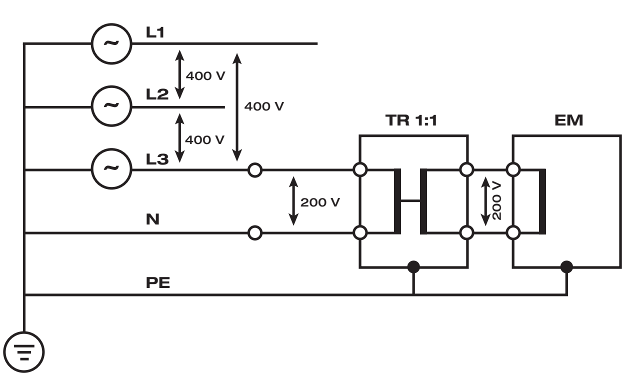


Figure 3: Electrical diagram for IT-M system.

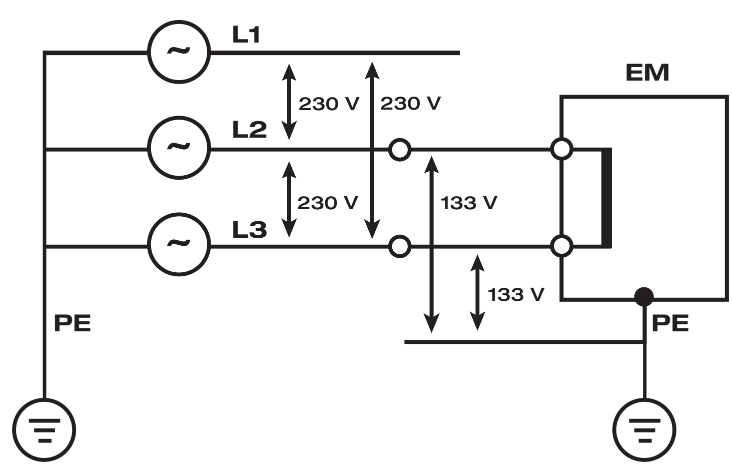


Figure 5: Electrical diagram for -TT type system with three active distributed conductors and phase-to-phase voltages of 220 V.

Type of installation and power supply

The connection of the EM devices and systems to their power supply can be:

- Movable single-phase/three-phase equipment (with the possibility of being completely isolated from the ground during the measurement) with connection to the power supply through a plug/socket connection
- Movable single-phase/three-phase equipment with permanent connection (without plug/socket connection to the power supply)
- Fixed single-phase/three-phase equipment (which cannot be completely isolated from the ground during the measurement) with connection to the power supply through a plug/socket connection
- Fixed single-phase/three-phase equipment with permanent connection (without a plug/socket connection to the power supply)
- Internal electrical power source.

Measurement methods

All three leakage current measurement methods required by the Standard are generally possible with the measuring instruments available in the market, but only for EM devices and EM systems with a single-phase power supply. With existing instruments, it is possible to measure both the equipment leakage current of the devices and the applied part leakage currents.

Direct method

Using the direct method, the device under test is powered and the leakage currents are measured from accessible parts and applied parts with interruption of the protective ground. The power supply is then inverted between the two poles and the highest value is recorded.

Alternative method

With the alternative method, the two ELM power supply poles are short-circuited to create the same voltage between them and either the parts are connected or disconnected from the protection circuit. In this situation, isolations are strained at a double voltage (or better with the same voltage in both polarities) compared to what they are subjected to in the case of a device that is normally powered.

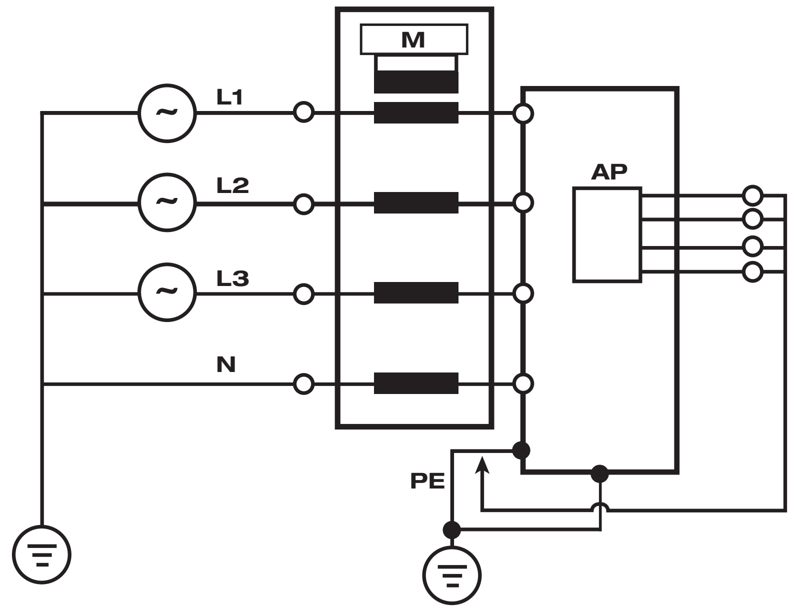


Figure 6: Electrical diagram for measuring the leakage current in a three-phase EM device or system.

Differential method

This leakage current measurement method for the device involves the use of a toroid traversed by all of the active conductors of the power supply circuit of the EM device or EM system. The toroid gives a signal proportional to the differential current flowing through it.

EM devices with internal power source

The leakage current in the device is not applicable to devices with an internal electrical power source. However, it is necessary to correctly measure the applied part leakage current if the applied part is floating. This will be discussed later.

The Standard, and all of the electrical safety analyzers' user manuals, demonstrate the electrical diagrams of the various measurement methods.

According to the IEC EN 62353 standard, if the system is built and maintained in compliance with the requirements of IEC 60346-7-710 (Italian CEI 64-8), there is no need to check the equipment's leakage current if the device is permanently installed.

However, the measurement of the leakage current of the EM device or EM system, especially if powered with a three-phase supply, may be necessary to check its compatibility with the differential protection upstream. This can be done with a differential clamp-on ammeter, with frequency characteristics similar to the MD (measuring device), on all active conductors that supply the device (see Figure 6).

Selection criteria for the measurement method

The first factor to consider is the type of system. Many electrical safety testers, including the Fluke Biomedical ESA612, ESA620 and ESA615, perform a measurement of the voltages phase 1-phase 2, phase 1-ground and phase 2-ground, while also warning the technician to pay attention to unconventional situations. Conventional is considered to be phase-to-neutral voltage close to 230 V, phase-to-phase close to 230 V, and ground potential close to zero.

Each technician must check these voltages, and if an IT-M type system is identified, it is necessary to give it close attention. The presence of the isolation transformer has always been a problem for the correct execution of the electrical safety measurements, also performed with procedures based on the IEC EN 60601-1 standard. The recommended solutions are to use a device powering the system through the “radiology socket”, (dedicated to power on equipment with high consumption), which is not generally supplied by the IT system. Or, supply the device via an extension from a socket outside of the room, again not powered through the insulation transformer.

With the IEC EN 62353 standard, this is no longer necessary if using the alternative method, which is also independent of any grounding of the device through additional connections other than PE. The only limitation on the application of the alternative method is the presence of an electronic switch. In this case, the execution of the measurements is not possible by supplying the electrical safety tester in these conditions.

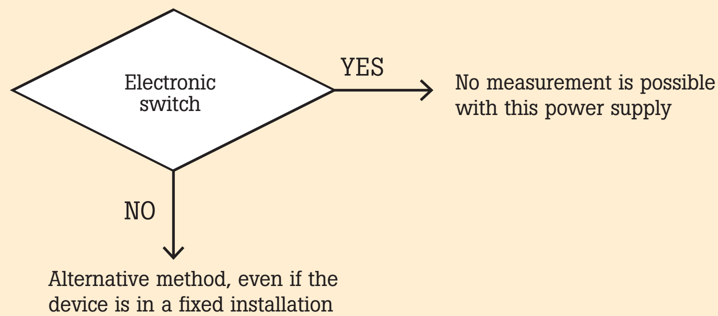
If the power supply is of the types TN-S or TT 400/230 V with four active distributed conductors, it is advised to proceed with the direct method if the device is isolated from the ground. In all other situations, it is possible to use the alternative method (only if the electronic switch is absent), or the differential method.

If the system is of the types TN-S 230 V phase/phase or TT 220 V phase/phase with three active distributed conductors, you can continue to perform the measurements described in the direct method. However, you must take into account that the values to be compared with the limits set in the Standard are the measured values multiplied by $\sqrt{3}$ because the power supply voltages of the device referenced to ground are reduced by a factor of $\sqrt{3}$.

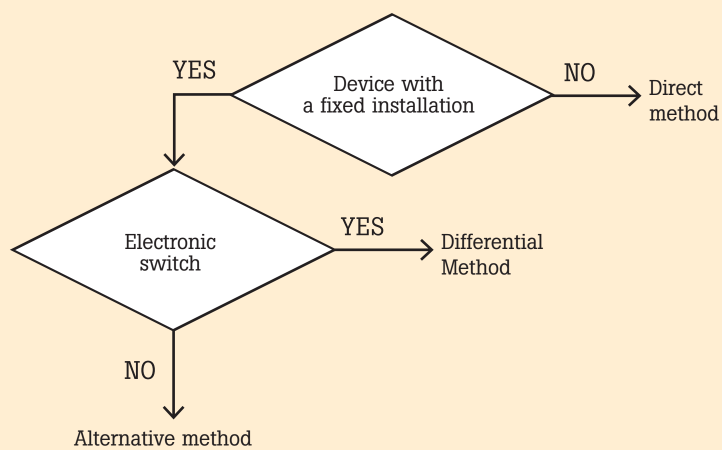
Again, the direct method is only possible if the device under test is isolated from the ground. If the device is a fixed installation, it is possible to use the two other methods: the alternative method (only if the electronic switch is absent) or differential method. In these two cases, the value of the current will be identical to that measured with the TN-S or TT system, without any effect of the $\sqrt{3}$ factor.

The following diagrams may be used to make the correct selection of the measurement method

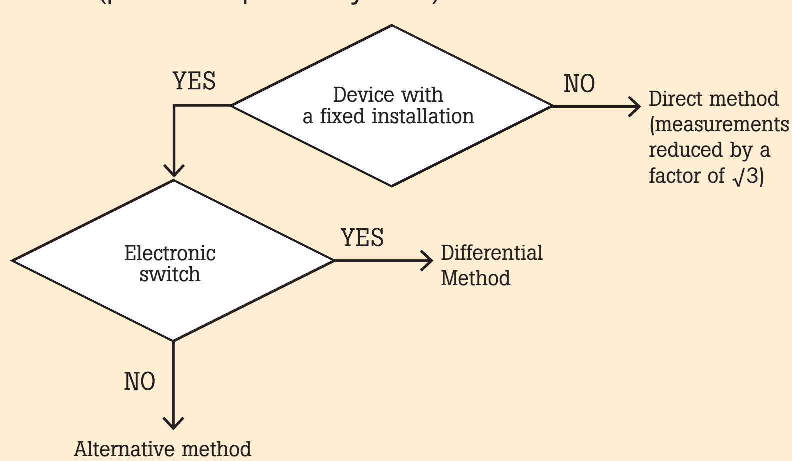
IT-M system (simplified: IT system)



System of types TN-S or TT (phase-to-neutral system)



TN-S type system with phase-to-phase voltages of 230 V or TT type with phase-to-phase voltage of 220 V (phase-to-phase system)



In the case of measurements on three-phase equipment with a plug/socket combination, all of the previously mentioned considerations apply. It is possible to perform the measurement with an appropriate adapter connected to the electrical safety tester, which inserts the MD in series with the protective ground conductor using the direct method. Additionally the measurement can be performed using a differential clamp-on ammeter that is connected to the active conductors using the differential method.
The alternative method is not applicable to devices with a three-phase power supply.

Measurement of the leakage currents in the applied parts

The IEC EN 62353 standard also states requirements for the measurement of applied parts leakage currents performed by the application of mains voltage to the patient connections short-circuited "by function".

For the measurement of current in applied parts, both the power supply circuit and any ground connections not removed have no effect on the result. This is because the electrical safety tester always applies a voltage of 220 V between the applied parts and the housing, independently of the choice of the alternative or direct methods, not depending on whether the device has a single-phase or a three-phase power supply, or if it is isolated from ground or in a fixed installation. Note that even if a device is permanently installed and has floating applied parts, such as the detection electrodes of the ECG waveform in an angiography system, this test must always be performed without powering up the device under test via the electrical safety tester.

This test is the only measurement to be performed on devices with an internal power supply.

The following table shows the measurements of equipment leakage currents performed on an operating table using the Fluke Biomedical ESA615 tester powered by the three types of mains supply discussed above. The results confirm the effect of the power supply type on the values of the leakage current.

Measurement from system Ground-Neutral										
Test results ESA615 direct method				Test results ESA615 alternative method			Test results ESA615 differential method			
Test	Value	High value	Result	Value	High value	Result	Value	High value	Low value	Result
Protective earth resistance	0.079 ohm	0.3	P	0.080 ohm	0.3	P	0.079 ohm	0.3	-	P
Mains voltage			P			P				P
Live to neutral	236.3 V	-	P	236.0 V	-	P	235.8 V	-	-	P
Ground to neutral	237.2 V	-	P	237.2 V	-	P	237.1 V	-	-	P
Ground to live	1.8 V	-	P	1.7 V	-	P	1.9 V	-	-	P
Current consumption	0.3 A	-	P	0.3 A	-	P	0.3 A	-	-	P
Direct device dispersion			P			P				P
Open ground	23.1 uA	500	P	48.5 uAAC	1000	P	22 uA	500	-	P
Open ground-reverse polarity	22.0 uA	500	P				21 uA	500	-	P
Measurement from IT System										
Test results ESA615 direct method				Test results ESA615 alternative method			Test results ESA615 differential method			
Test	Value	High value	Result	Value	High value	Result	Value	High Value	Low value	Result
Protective earth resistance	0.079 ohm	0.3	P	0.079 Ohm	0.3	P	0.079 Ohm	0.3	-	P
Mains voltage			P			P				P
Live to Neutral	239.5 V	-	P	239.5 V	-	P	239.4 V	-	-	P
Ground to Neutral	122.7 V	-	P	122.7 V	-	P	123.0 V	-	-	P
Ground to Live	116.9 V	-	P	116.9 V	-	P	117.0 V	-	-	P
Current consumption	0.3 A	-	P	0.3 A	-	P	0.3 A	-	-	P
Direct device dispersion			P			P				P
Open ground	2.1 uA	500	P	48.7 uAAC	1000	P	0 uA	500	-	P
Open ground-reverse polarity	1.0 uA	500	P				0 uA	500	-	P

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Measurement from system Ground-Ground										
Test results direct method				Test results ESA615 alternative method			Test results ESA615 differential method			
Test	Value	High value	Result	Value	High value	Result	Value	High value	Low value	Result
Protective earth resistance	0.079 ohm	0.3	P	0.079 ohm	0.3	P	0.079 ohm	0.3	-	P
Mains Voltage			P			P				P
Live to Neutral	238.5 V	-	P	238.2 V	-	P	239.4 V	-	-	P
Ground to Neutral	137.7 V	-	P	137.6 V	-	P	123.0 V	-	-	P
Ground to Live	137.4 V	-	P	137.3 V	-	P	117.0 V	-	-	P
Current consumption	0.3 A	-	P	0.3 A	-	P	0.3 A	-	-	P
Direct device dispersion			P			P				P
Open ground	13.3 uA	500	P	48.7 uAAC	1000	P	21 uA	500	-	P
Open ground-reverse polarity	12.9 uA	500	P				22 uA	500	-	P

About Fluke Biomedical ESA615 Electrical Safety Analyzer

The ESA615 performs all primary electrical safety tests, ECG simulation, point-to-point voltage, leakage and resistance tests to the latest electrical safety standards. The ESA615 has automation inside that lets you test in minutes to the electrical safety standard of your choice. Reduce test time, eliminate errors and standardize testing with the latest innovation in electrical safety analyzers. To learn more about the ESA615 or any other electrical safety analyzer mentioned in this white paper, **click here** or visit flukebiomedical.com.

About the author, Vincenzo Ventimiglia

Vincenzo Ventimiglia is an electrical engineer with a strong background in biomedical specialization. A renowned professional in the biomedical business since 1991, Ventimiglia studied at the Polytechnic University of Milan and has since developed a business of biomedical technician quality assurance training. He has been a member of the Italian Electrical Committee for over twenty years and is currently a member of the IEC SC62A Working Group 14.

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