Electrical Safety Analysers

Electrical Safety analysers are useful for testing both medical facility power systems and medical appliances. These analysers range in complexity from simple conversion boxes used any volt-ohm meter to computerized automatic measurement systems with bar code readers that generate written reports of test results. The features to consider are accuracy, ease of use, testing time and cost. The analysers also reduce errors caused by incorrect test setups and reduce the risk of shock to the person performing tests such as applying line voltage to patient leads to test isolation.

The Analyser is intended for use by trained service technicians to perform periodic inspections on a wide range of medical equipment. The testing procedures are menu-driven, and simple to operate. The Product is an electronic signal source and measurement device for verifying the electrical safety of medical devices. The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology. This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment. It is intended for over the counter use.

Electrical Safety Measurements and Testing

To help verify the functionality and safety of medical devices, electrical safety standards have been established in the United States, European countries, and other parts of the world. The standards differ in criteria, measurements, and protocol. The International Organization for Standardization (ISO) and the International Electro-Technical Commission (IEC) organizations based in Europe provide standards worldwide in partnership with the World Trade Organization. These include standards for electro-medical equipment. There are general and specific standards for medical device electrical safety. IEC60601 AAMI/NFPA 99 The primary standard for medical devices is IEC 60601. General requirements for protection against electric shock hazards are covered in IEC 60601.1, Section 3.

In this standard, each instrument has a class:

- Class I—Live part covered by basic insulation and protective earth
- Class II—Live part covered by double or reinforced insulation
- Class IP—Internal power supply

Each patient applied part or patient lead has a type:

- Type B—Patient applied part earthed
- Type BF—Patient applied part floating (surface conductor)
- Type CF—Patient applied part floating for use in direct contact with the heart

Leakage measurement limits have been developed for equipment types and measurements. They include:

- NC—normal conditions
- SFC—single fault conditions

Applied Parts:

Any conductive components that are intended to contact the patient in normal use. Examples: connectors for ECG or EEG electrodes, defibrillator pad connectors or paddles, active or return ESU electrodes.

Earth Leakage Current:

Current that flows in the Earth wire of a protectively earthed device.

Enclosure Leakage Current (Touch or Chassis leakage):

Current that flows to earth from any exposed conductive part of the enclosure other than through the protective earth wire.

Patient Leakage Current (Lead to Ground Current):

Current that flows to earth through a patient connected to an applied part or parts.

Patient Auxiliary Current:

Current that flows between applied parts which serves no design purpose.

Isolation Leakage Current (Mains-on-Applied-Parts Current):

Current that flows to earth through the applied parts (connected as one) when momentarily connected to the mains voltage.

Single Fault Condition:

A condition in which a normal connection (Earth or L2) is open.

The terminology used in IEC 60601.1 3rd Edition includes:

- Protective earth resistance
- Earth leakage current
- Touch current (formerly enclosure leakage current)
- Patient leakage current
- Patient auxiliary current
- Mains on applied part (MAP)

IEC60601	AAMI/NFPA 99
Protective Earth Resistance	Ground Wire Resistance
Earth Leakage Current	Ground Wire Leakage Current
Touch or Enclosure Leakage Current	Chassis Leakage Current
Patient Leakage Current	Lead to Ground Leakage Current
Patient Auxiliary Leakage Current	Lead to Lead Leakage Current
Mains on Applied Part (MAP) Leakage Current	Isolation Leakage Current

Leakage current (µA)		Earth leakage current mA	Touch current (µA)	Patient leakage current AC (µA)	Patient leakage current DC (µA)	Patient leakage current mains on applied (µA)	Patient auxiliary current (µA)
Type B	NC	5	100	100	10	–	100
	SFC	10	500	500	50	–	500
Type BF	NC	5	100	100	10	–	100
	SFC	10	500	500	50	5000	500
Type CF	NC	5	100	10	10	–	10
	SFC	10	500	50	50	50	50

Testing Procedure

- **Physical Inspection**: Inspect the power cord, especially the plug. Inspect the patient interface components: cables, tubing, pads, cuffs, etc. Anything that is damaged or beyond cleaning for reasonably good appearance should be replaced.
- **Configure the Safety Analyzer**: Select the standard that you will be using, then verify if the device to be tested is used in the patient care vicinity (defined in IEC 60601), and whether it is a Class I (line-powered) or Class II (double insulated) device
- **Mains Voltage**: Measure the voltage from Hot to Neutral, from Neutral to Ground, and from Hot to Ground. The voltage from Hot to Neutral and from Hot to Ground should be within +/- 10% of nominal. On 120v wiring, there should be no more or less than 3.6v from Neutral to Ground.
- **Ground Wire (Protective Earth) Resistance**: NFPA-99 and AAMI ES-1 set the maximum acceptable resistance at 0.50 Ω. It is a good practice (in fact specified in most standards) to stress the power cord at both connector ends while testing, in order to detect any incompetency of the ground wire continuity.
- **Ground Wire (Protective Earth) Leakage Current**: The analyzer is configured to measure the current in the Ground Wire.
- **Touch or Chassis (Enclosure) Leakage Current**: The analyzer measures current from the device's enclosure; usually, the "ground pin" is the best option. In the absence of a ground pin, you may connect to any conductive feature likely to be contacted by the patient or user, and which is continuous with the enclosure.
- **Patient (Applied Part to Ground) Leakage Current**: This measures the current between any and all conductive components which necessarily come in contact with the patient in normal use. Measurements are taken from each applied part, and from all applied parts connected together, Auxiliary ("Lead to Lead") Leakage Current:
- **Auxiliary ("Lead to Lead") Leakage Current**: The analyzer is configured to determine the current between any two applied parts or any combination of applied part groups, user-selectable on the analyzer.
- **Isolation (Mains-on-Applied-Parts) Leakage Current**: In order to verify that the isolation of the applied parts is competent, this test exposes the applied parts, connected together, to the mains voltage created by an isolation transformer within the analyzer.