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Introduction to Electrical Safety Testing: Part I

White Paper

Electro-Medical Devices are powered by the mains or an internal power source (batteries) and often attached to the patient by wires. Some of these devices have active parts inserted into the patient body and may come in direct contact with the heart. There is a risk to the patient in the event of current leaking from the device. Current can also be transmitted through a caregiver such as a nurse in contact with an electronic device near the patient. Electrical shock can cause disruptions during health care procedures and result in injury or death. This makes electrical safety a topic of very high importance in medical device quality assurance.

Physiological effects of electrical shock range from a tingling sensation to serious burns and electrocution. Excitable human tissue is very sensitive to current in the frequency range of electrical power systems worldwide (50 Hz to 60 Hz). The figure below shows the effects of current flowing from one skin contact point to another.

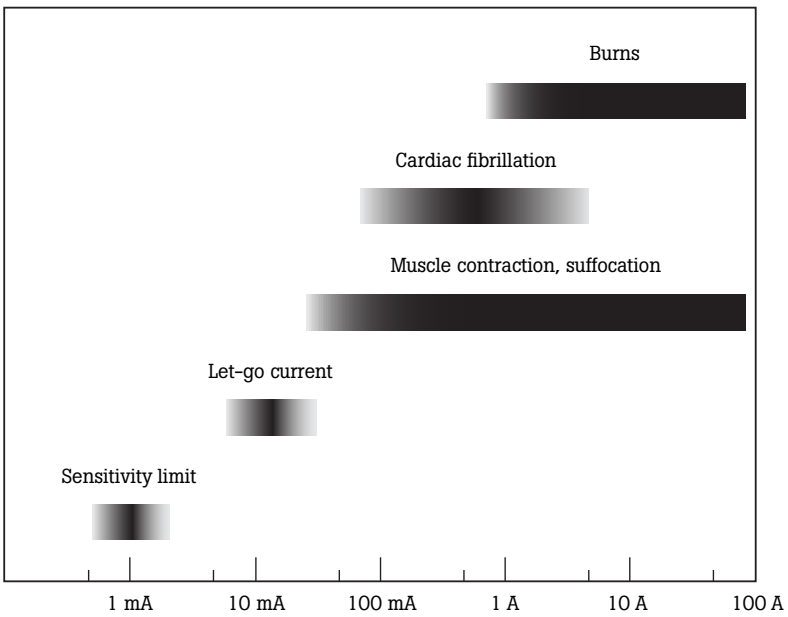

Figure 1: Effects of current flowing from one skin contact point to another.

Electrical safety takes on added significance in electrically-susceptible patients. For cardiac procedures, electrically-conductive catheters may be placed into the heart while the patient is connected to medical equipment. This procedure puts patients at risk for ventricular fibrillation. Skin exhibits a high electrical resistance, but internal body components such as blood and muscle have a low electrical resistance. In fact, currents as low as 20 microamps have caused ventricular fibrillation in experiments conducted with dogs when a conductor made direct contact to the heart.

The term macroshock describes electrical current applied externally. On the other hand, the term microshock is used to describe direct shocks to the cardiac muscle. As a result of data collected regarding macroshock and microshock, worldwide standards have been established to limit leakage current.

In equipment designed for low resistance direct contact with patients, such as indwelling catheters, electrical isolation techniques are used to reduce the current flowing to the patient to minimal levels. In the event of a device failure or short-circuit condition, the patient is protected from microshock. These techniques may utilize isolation transformers and optical circuits. Thus, electrical safety standards specify low microampere limits for direct patient contact equipment.

To reduce leakage current to negligible levels, chassis grounding is utilized to shunt any leakage or fault current to ground rather than to the patient or staff. Figure 1 demonstrates the hazard current from the electrical failure being safety shunted to ground through this alternative pathway. Effective grounding can only be achieved with very low resistance pathways to ground on the order of tenths of an ohm. Grounding is another measurement specified in electrical safety standards for medical devices.

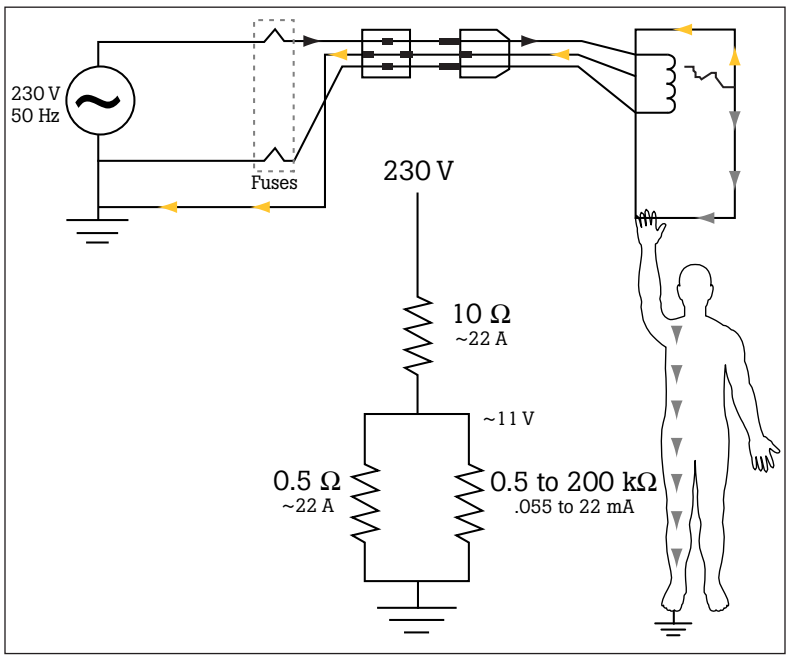

Figure 2: Hazard current from electrical failure being safety shunted to ground through an alternative pathway.

Basic electrical safety tests include:

- Visual inspection of cables, plugs and connectors
- Measurement of ground wire resistance
- Measurement of chassis and patient lead/contact isolation

Electrical safety standards

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

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)

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)	Patient auxiliary current (µA)	Patient auxiliary current (µA)
Type B	NC	5	100	100	10	—	100	10	100
	SFC	10	500	500	50	—	500	50	500
Type BF	NC	5	100	100	10	—	100	10	100
	SFC	10	500	500	50	5000	500	50	500
Type CF	NC	5	100	10	10	—	10	10	10
	SFC	10	500	50	50	50	50	50	50

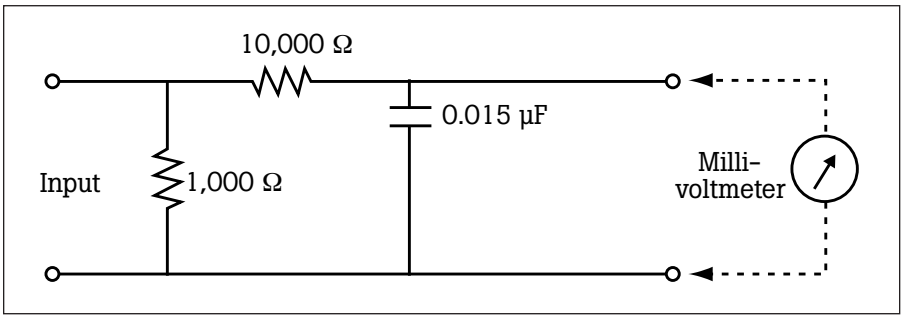

Figure 3. Impedance of a patient test load.

The figure above represents the impendence of a patient test load. Leakage current measuring devices use this impedance circuit for measurements.

Additional important points regarding IEC 60601.1 include:

- The use of up to 25 amperes ac for protective earth testing (this is a type-test and generally suitable for manufacturers)
- Leakage current is measured at 100 percent of mains voltage
- Performance of dielectric strength/insulation testing is measured at 110 percent of mains voltage.

A new IEC standard, IEC 62353, is used for medical device testing in hospitals. IEC 62353 was developed because IEC 60601.1 is a type-testing standard with no risk management criteria and is impractical for testing in the hospital environment.

IEC 62353 tests are performed on equipment prior to use on patients, during schedule periodic testing, and after repair. Thus, this standard is for field (hospital) testing and does not address equipment design. In Annex E of the document, the manufacturer is requested to provide information on testing interval and procedure based on risk, typical usage, and device history. The minimum testing requirement for life support and other critical equipment is every 24 months.

In the United States, there are several primary and secondary organizations setting standards:

1. **National Fire Protection Association (NFPA):** NFPA 99 Standard for Health Care Facilities is the primary standard addressing electrical safety testing required in health care institutions. Other publications include NFPA 70, National Electrical Code, and NFPA 70E, Electrical Safety in the Workplace.
2. **Association for the Advancement of Medical Instrumentation (AAMI):** ANSI/AAMI ES1 Safe Current Limits for Electro-medical Apparatus is another commonly-accepted standard.
3. **Underwriters Laboratories (UL):** UL544, Medical Equipment requirements is a standard for manufacturers, not hospitals. These standards may be referenced by accreditation, code or regulatory organizations such as the Joint Commission, Occupational Health and Safety Administration or other organizations monitoring health care institutions in the United States.
4. **Canadian Standards Association (CSA):** CAN/CSA C22.2 NO. 60601-1-08 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12)

Global harmonization of standards has led to the development of worldwide standards. Equipment in the regions listed below must be certified to the IEC60601-1 standard or the device cannot be sold in that country.

- USA uses UL2601-1 or ANSI/AAMI ES601
- Europe uses EN60601-1
- Canada uses CAN/CSA-C22.2 No. 601.1-M90

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

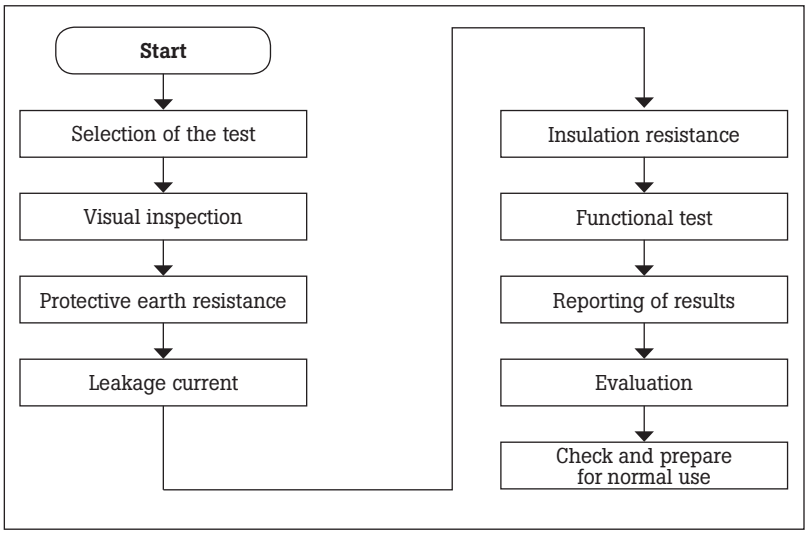

Figure 4: Testing requirements and sequence according to IEC 62353 Annex C.

Electrical safety testing

Testing requirements and sequence according to IEC 62353 Annex C are shown below. Only measurement equipment that meets IEC 61010-1 should be used. The sequence outlined in the figure below should be followed. For example, protective earth resistance should be measured prior to leakage current measurements.

General connections to an electrical safety analyzer (ESA) are shown in Figure 5-5. Consult the operational manual for specifics for your electrical safety analyzer. Documentation requirements for IEC 62353 include:

- Identification of the testing group (hospital department, independent service organization, manufacturer)
- Names of the person(s), who performed the testing and evaluation(s)
- Identification of the equipment/system (e.g. type, serial number, inventory number) and the accessories tested
- Tests and measurements
- Date, type, and outcome/results of:
  - Visual inspections
  - Measurements (measured values, measuring method, measuring equipment)
  - Functional testing
- Concluding evaluation
- Date and signature of the individual who performed the evaluation

Computerized record-keeping systems are greatly preferred for data storage, search, review, and analysis. Note the device fields must be standardized.

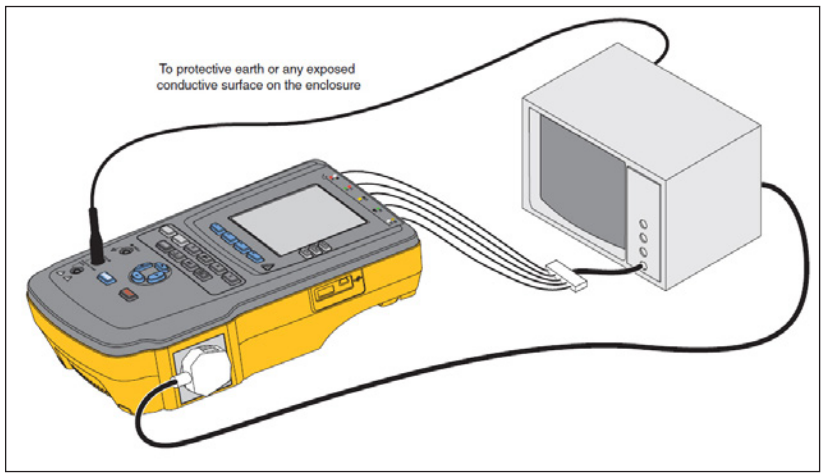

Figure 5. General connections to an electrical safety analyzer.

Basic electrical safety testing with the ESA609

The ESA609 integrates all functions needed to test medical devices when patient lead testing is not required, including:

- Line (mains) voltage
- Ground Wire (or protective earth) resistance
- Equipment current
- Ground wire (earth) leakage
- Chassis (enclosure) leakage
- Direct equipment leakage
- Point to point leakage and resistance

Versatile to global electrical safety standards of choice, the ESA609 tests to ANSI/AAMI ES1, NFPA-99, and parts of IEC62353 and IEC60601-1. To learn more about the ESA609 Electrical Safety Analyzer or any other Fluke Biomedical analyzer, click here or visit **www.flukebiomedical.com/ESA609**.

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Do you want to learn more about electrical safety? Stay tuned for Introduction to Electrical Safety—Part II.

Introduction to Introduction to Electrical Safety—Part II will cover:

- How to perform various required electrical safety tests using an Electrical Safety Analyzer
- How to test according to IEC62353
- How to select an electrical safety analyzer to perform prescribed tests

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