ELECTRICAL SAFETY TESTING ACCORDING TO IEC 62353

R. Ciorap*, C. Corciova
Faculty of Medical Bioengineering, University of Medicine and Pharmacy "Grigore T. Popa", Iasi, Romania
*E-mail: radu.ciorap@bioinginerie.ro

Electrical safety is an area of concern related to medical devices. Electrical shock can cause disruptions during healthcare procedures, injury, and death. Physiological effects range from a tingling sensation to serious burns and electrocution.

Electrical safety standards have been developed 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 Electrotechnical Commission (IEC) based in Europe are organizations that provide standards worldwide in partnership with the World Trade Organization. These standards include those for electromedical equipment. There are general and specific standards for medical device electrical safety. The primary standard for medical devices has been IEC 60601.

A new IEC standard is used for medical device testing in hospitals. IEC standards 62353 applies to testing of medical equipment and medical electrical systems, which comply with IEC 60601-1. 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 include those prior to use on patients, during schedule periodic testing, and after repair. Thus, this standard is for hospitals and does not address equipment design.

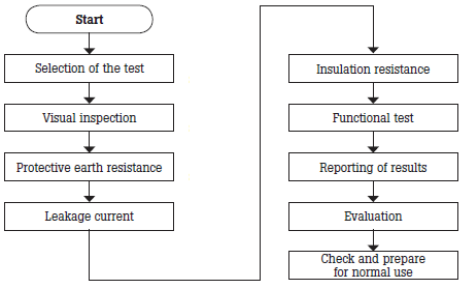

Figure 1. Testing requirements and sequence according to IEC 62353

Documentation requirements for IEC 62353 include: Identification of the testing group (hospital department, independent service organization, manufacturer); Names of the persons, 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. The device fields must be standardized.

IEC 62353 goes on to further specify that safety related functions of the equipment are to be inspected. The standard does not specify which functions need to be tested or how often, only that the device functionality should be tested. The standard also specifies that safety inspections need to be documented.

[1] IEC 60601-1. *Medical Electrical Equipment – Part 1: General Requirements for Safety*, 2nd ed. (Geneva: International Electrotechnical Committee, 1988).

[2] IEC 62353. *Medical Electrical Equipment - Recurrent Test and Test after Repair of Medical Electrical Equipment*, (Geneva: International Electrotechnical Committee, 2009).