Electrical Safety of Medical Equipment
An Experimental Approach

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Abstract

Electrical safety is a very important factor that needs to be tested: (a) On newly acquired equipment prior to being accepted for use, (b) during routine planned preventative maintenance and (c) after repairs have been carried out on equipment. The purpose of this article is (a) to inform scientific community about the electrical safety tests of Medical Equipment and the serious consequences for the patient, the medical staff as well as others when it is not properly and regularly performed, (b) present the current status in the Greek Hospitals' regarding the electrical safety tests and (c) the presentation of the experimental setups, measurements and tests that were performed on every medical equipment of five fully operational operating theaters of a Greek hospital in Athens. Tests and measurements were performed according to the international protocols IEC 60601 and IEC 62353 (which is valid for medical devices). Results revealed that some multi-socket power lines, as well as some power cords were outside of the limits provided by the international protocols. All tests results as well as the conclusions are graphically presented and analyzed.

Key words: Electrical Safety, Electrical Safety Analyzer, IEC 60601, IEC 62353, Rigel 288.

Introduction

Contemporary hospital, with the increased entry of advanced biomedical technology, involves a number of risks that threaten the physical integrity of both patients and users of various medical devices and equipment. These risks may be relatively small and not directly threaten patients, but they can also be fairly serious, in a way that they can cause serious injuries or even death. In each case the sources of such risks must firstly be identified and then encountered [2].

A patient is surrounded by many electrical sources, and most often connected to electrical medical equipment. Many medical actions require invasive intervention on the patient which makes him very sensitive to electric currents that move within the body and particularly around the heart. An additional risk is the electric current in places where anesthetic gases are used, which can cause fire [2].

In general, electrical medical devices are a potential source of risks and accidents. Both patients and medical staff in many medical applications can form involuntarily part of an electrical circuit. As a result to that, they suffer from the consequences of electric current passing through their bodies [3].

The electrical medical devices and the applied parts are categorized according to the type of protection and the degree of protection against electrical accidents. There are the following categories:

I. Class I. Class I category, includes equipment that in addition to basic insulation, provides permanent connection of the protective earth conductor and of the metallic parts, as an additional mean of protection. This connection must be in such way that the metal parts do not become active in case of destruction of the basic insulation.
II. Class II. Class II category, includes equipment that in addition to basic insulation, provides double or reinforced insulation as an additional mean of protection.
III. Class III. Class III category, includes devices that receive power from internal power source.

Types of medical equipment

- **Type B Equipment:** Class I, II or III. Includes devices that provide a certain degree of security that is mainly related to the permitted leakage current and the reliability of the connections of protective earth conductor. Suitable for external use and internal applications except catheterization [5].
- **Type Bf Equipment:** Refers to floating isolated applied parts. It is only intended for connection to patient's skin but has floating input circuits. There are no connections between patient and earth [5].
- **Type Cf Equipment:** Class I, II or III providing a higher protection against shock intended for direct cardiac applications [5].

Table 1 shows the types, symbols and definitions of medical equipment.

Table 1. Types, symbols and definition of medical equipment [7].

Type	Symbol	Definition
Type B		Non-Isolated Applied Part
Type BF		Isolated Applied Part
Type CF		Isolated Applied Part. Suitable for direct cardiac application
Type F		Fixed Device
Type T		Transportable Device

Figure 1a and Figure 1b show the symbols that can be seen on a medical electrical device, indicating the category in which it belongs.

Figure 1a. Class I Symbols [7].

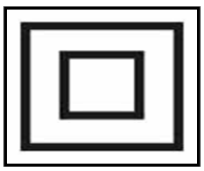

Figure 1b. Class II Symbol [7].

Materials and Methods

The main instrument (Electrical Safety Tester) as well as the equipment used is shown in Figure 3. Rigel 288 is a hand-held medical electrical safety analyzer manufactured by Seaward Electronic Ltd, Bracken Hill, South West Industrial Estate Peterlee, Country Durham, SR8 2SW, England. It combines the features of an automatic / manual tester with a data Logging / asset management facility. The tester was recently calibrated in order to keep the accuracy of the results in the highest standards [1].

Tests were performed on both Class I and Class II equipment such as Anaesthesia machines, Patient Monitors with Applied Parts, Electrical Injection Syringes and Pumps, Operating-tables, Defibrillators, Suctions and Electrosurgery Units. A total number of 58 medical devices, 58 power cords and 17 multi-socket power lines were tested. In more detail there were six (5) Anaesthesia machines, ten (12) Patient Monitors with Applied Parts, twenty (21) Electrical Injection Syringes and Pumps, six (5) Operating-tables, four (4) Defibrillators, five (5) Suctions and five (6) Electrosurgery Units tested.

Some of the performed tests were: (a) Protective Earth Continuity, (b) Insulation Tests, (c) Leakage Current Tests (Earth Leakage Current, Enclosure Leakage Current, Patient Leakage Current), (d) Mains on Applied Parts etc.

All tests were performed according to the sequence of Single Fault Condition (Normal Supply, Normal Supply Open Earth SFC (for class I equipment only), Normal Supply Open Neutral (Power Break), Reversed Supply (Power on), Reversed Supply Open Earth (for Class I equipment only), Reversed Supply Open Neutral (Power Break).

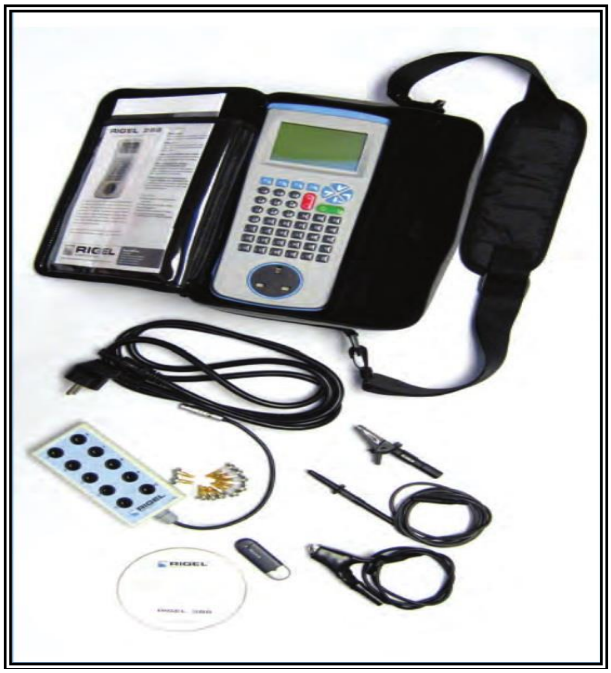

Figure 3. Rigel 288 electrical safety analyser with its carrying case, including earth bond test probe with clip, earth bond clip lead, Patient applied part module, 10 applied part adaptors, detachable 2 meter mains cable, Blue tooth USB dongle, Electronic instruction manual and removable ‘quick start’ card [4].

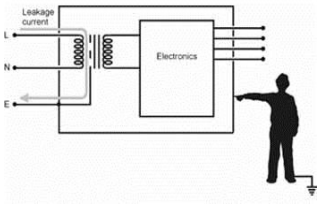

Figure 4. Earth Leakage Current path [6].

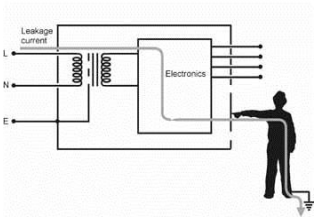

Figure 5. Enclosure Leakage Current path [6].

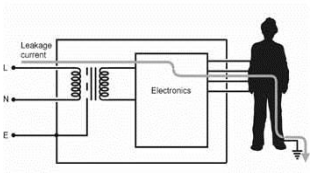

Figure 6. Patient Leakage Current path from equipment [6].

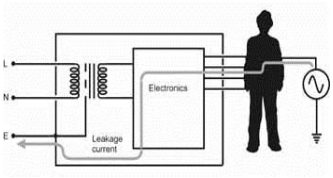

Figure 7. Patient Leakage Current path to equipment [6].

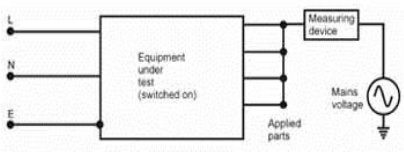

Figure 8. Patient Leakage F-Type (or else Mains on Applied Parts) Measurement arrangement [6].

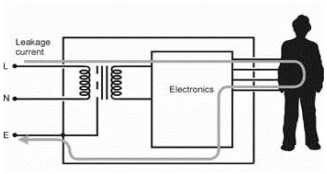

Figure 9. Patient Auxiliary Current path [6].

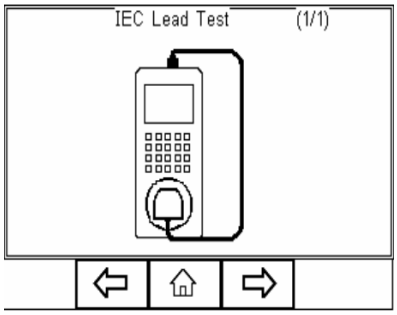

Figure 10. IEC Lead Test [1].

Results and Discussion

Figure 4 shows the Earth Leakage Current path. Earth leakage current is the current that normally flows in the earth conductor of a protectively earthed piece of equipment.

Figure 5 displays the Enclosure Leakage Current path. Enclosure Leakage current is the current that would flow if a person came into contact with the housing (or any accessible part not intended for treatment or care) of the appliance.

The Patient Leakage Current path from equipment and the Patient Leakage Current path to equipment are shown in Figure 6 and Figure 7 respectively. This is the current flowing from the Applied Part via the patient to earth or flowing from the patient via an Applied Part to earth, which originates from an unintended voltage appearing on an external source.

The Patient Leakage F-Type Measurement arrangement (also known as mains on Applied Parts test) is shown in Figure 8. This figure displays the current that would flow if a mains potential was applied to the Applied Part which was attached to a patient (i.e. a single fault condition).

Figure 9 displays the Patient Auxiliary Current path. This is the leakage current that would flow between Applied Parts under normal and fault conditions.

Figure 10 shows the IEC Lead Test. This test provides a means of testing the Load current in Amps and power in KVA.

Our results indicate that 95% of the equipment tested, passed all the electrical safety tests and 3% of them failed. This failure can be attributed to the inappropriate connection of the tested equipment in multisocket power lines. Finally 2% of the tested devices didn't pass the earth bond test mainly due to damages in the power cords.

Figure 11 presents graphically the results of the measurements performed.

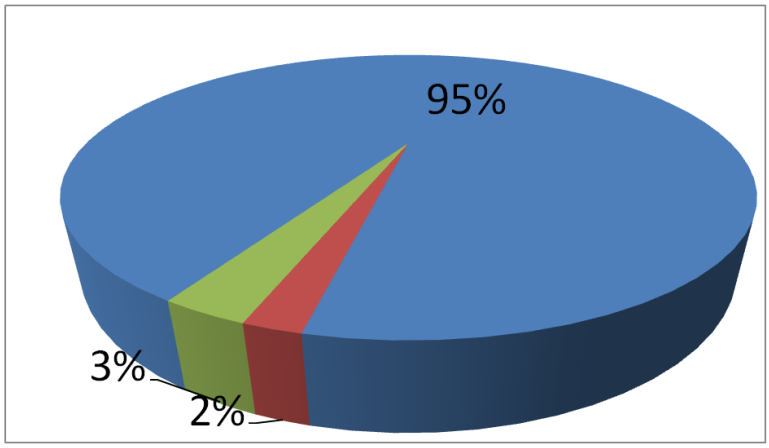

Figure 11. Graphical presentation of the results acquired in our survey.

Conclusion

Our results demonstrate that some multi-socket power lines, as well as some power cords were outside of the limits provided by the international protocols. Failures were quite limited mainly due to hospital policy regarding EST tests, which are performed on a yearly basis for all biomedical equipment. It is highly profound that equipment found to be out of the EST limits should be tested more often than a yearly basis and proceed with their replacement once they do not pass the tests.

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