International Standard for Routine Electrical Safety Testing of Medical Electrical Equipment

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Introduction

In the UK, there is no specific guidance for the routine testing of medical electrical equipment. Mostly, service organisations perform tests that have become custom and practice over many years, mainly modelled on the tests set out in the IEC60601 series of standards for ‘type testing’. The inclusion of these tests in the repertoire of commercial testers has consolidated the position. Although there have been attempts by individuals and interest groups to undertake a risk analysis to establish the value of all this testing and of specific tests, little has been achieved. That may be about to change, since a draft IEC Standard (IEC62353) is now nearing completion that specifies test methods and procedures for routine testing and testing after repair. This is likely to be accepted soon by the IEC and then become a British Standard before the end of 2007. We understand that the UK voted against acceptance of the current draft, and although there was UK representation on the drafting committee, it seems that there was little or no consultation with the obvious other interested parties (such as the IPEM). Senior IPEM members active in equipment management only became aware of the proposal at the voting stage, early in 2006. This new standard will obviously have an impact on practices in UK hospitals, on commercial service organisations, and on test equipment manufacturers.

Draft IEC62353

It could be argued that the IEC should have no particular interest in how equipment in the UK is tested for safety in the field, since the methods we might use in a particular UK hospital have no affect on competitive international trade. However, a key reason for producing such a standard is to provide manufacturers of test equipment with a specification for their future products, since trade in such test equipment is international. Some countries (e.g. Germany) have long had a National Standard for routine testing of Medical Electrical Equipment (VDE751), and the tests and philosophy of that standard are very evident in the draft IEC62353. From the resulting document, it would appear that a compromise could not be reached on several issues, and thus there are two alternative methods of protective earth resistance measurement, and three methods of leakage current measurement.

General proposals in the standard

The draft provides for a basic set of non-destructive tests to be applied to all medical electrical equipment, taking account of class of enclosure and of type of patient applied part. The tests include the familiar protective earth resistance, mains part and patient part insulation resistance measurements, and a suite of a.c. leakage current tests in some rather unfamiliar configurations. It is only applicable to equipment already complying with IEC60601 Standards. The default test protocol is to be overridden by any specific recommendations (do’s or don’ts) by the manufacturer, including frequency of tests. A risk analysis method is proposed to set testing intervals between 6 and 36 months, and not more than 24 months for any higher-risk equipment.

There are new or revised definitions, such as ‘touch current’ in place of enclosure leakage, and some resistance and leakage current limits are not the same as the 601 limits. Reference (ideally the first) values for all measurements should be recorded. If reference values for leakage current are over 90% of the allowable values, then the trend must be investigated. Differences between 60601-1:1988 (2nd edition) and 60601-1:2006 (3rd edition) result in some extra test configurations, in particular different test circuits for enclosure leakage current.

Specific test protocols

The tests after inspections, in the order recommended, are as follows.

Protective earth resistance

This may be performed either according to 60601 (25 A+,
Leakage currents

Three methods are suggested:

- The direct method, which uses a 60601 leakage current load and circuit to measure directly, as in 60601.
- The differential method, which uses a current transformer (clamp ammeter) around the mains lead (excluding earth) to measure the ‘missing’ current not returned in the neutral wire.
- The ‘alternative’ method, which uses a low-power 250-V generator with output current limited to 3.5 mA; all tests are performed without applying power to the equipment. Allowable limits are all doubled for this method.

Essentially, there are only two leakage current measurements, although the configuration varies slightly with the class of enclosure, and whether the equipment complies with 60601 2nd or 3rd edition.

- Equipment leakage current: The three approaches are illustrated in figure 1, which shows ‘equipment leakage current’ for a generic Class 1 item. A single fault (disconnecting the earth) is applied and the mains plug reversed ‘if applicable’. Figure 2 shows the configurations for a generic Class 2 item.
- Patient leakage current: This is a ‘mains on applied part test’ applied in all three leakage current methods, obviously only for F-type connections. In the alternative method, this is performed without the equipment energised. The configuration for the alternative method is shown in figure 3 for a Class 1 item. No patient leakage current measurement is made with Type B
connections, except that they are included in the equipment leakage current above.

Insulation resistance
This has three pass limits, these being:
- 2 MΩ between mains part and enclosure (Class 1) and also to Type B applied parts
- 7 MΩ between mains part and parts separated by double insulation, including some Type B applied parts
- 70 MΩ between mains and Type F applied parts

Discussion
Neither the Department of Health (Medicines and Healthcare Products Regulatory Agency, MHRA), nor the professions (e.g. IPEM) have provided adequate guidance on field safety testing for medical electrical equipment so far. Indeed, the MHRA has just published the latest guidance on managing medical devices [DB2006(05)], which replaces DB98016 and its supplements. The revised guidance omits all of the previous technical guidance on acceptance testing and commissioning. The previous guidance did not extend to routine testing, but at least set out a rationale for a simplified test set.

It seems likely that in the vacuum so created, any guidance henceforth may simply point to compliance with IEC62353.

So, does this take us forwards or backwards? It certainly does not provide a single agreed method, and still leaves much choice (and responsibility) to the technician or department. It is possible that there will now be a greater divergence of methods than at present, or more likely, most departments will just continue with their current methods. Nor does it fully clarify the situation fully for test equipment manufacturers. For instance, should a compliant tester be able to perform all of the tests, or just a selection, e.g. omitting the 25-A protective earth resistance test, or the differential leakage current method?

There is still an opportunity here for the MHRA, IPEM or other body to make recommendations about implementation of the standard in the UK, e.g. to advise on the two methods for protective earth resistance measurement. As anyone who regularly performs this test knows, low-current tests fail older equipment, presumably because of tarnishing of plug contacts. However, the same equipment passes at high current. As regards the leakage current tests, it seems unlikely that the alternative or differential methods will find much support in the UK. Surely, leakage current measurement needs the equipment to be energised. Furthermore, more equipment is appearing with ‘latching’ power supplies, such that internal parts are just not connected unless the equipment is energised.

It seems a pity that the drafting committee could not have eliminated the insulation resistance test, since earth wire leakage current in energised apparatus is a more comprehensive test of insulation (i.e. a.c. and d.c.). Also, if one is to use a mains-on-applied-part test in the field, then why not forego the corresponding insulation resistance test? Once again, the a.c. test is a more comprehensive test.

Conclusion
The draft IEC62353 seems likely to become an IEC Standard and then a British Standard, and this will have consequences for medical equipment management in the UK. It will not provide the specific test and test frequency guidance that we need, but it may be a step in the right direction. Interested parties now need to respond with recommendations about its implementation in the UK.

References
5. DB2006(05). Managing medical devices, guidance for healthcare and social services organisations.