

## IEC 62353: Standards for the Safety and Efficacy of Medical Electrical Equipment

### Introduction

It might, perhaps, be a little too self-evident to say that there is no industry that is expected to require higher standards for safety procedures than the medical industry. The unbridled advancement of modern medicine has made hospitals and other medical facilities into one of the culture's paramount embodiments of a safe haven; between the extraordinary life-saving skills of the staff, the particular assistances received during times of crisis, and the remarkably powerful equipment, these facilities have come to rise even above their designed functionalities as symbols of how much their communities value human life and health. But as mankind's capabilities progress, so too do his machines, presenting new complexities to the system, and with them, newer and greater dangers. Most of the individuals passing through these medical facilities do so with little, if any, thought about the proceedings that protect them from potential harm by way of technical malfunction; it is therefore feasible to declare that the standard procedures of maintenance of these medical electrical devices and the professionals who perform them are among the great unsung heroes of the general public.

The International Electrotechnical Commission, or IEC, has done the industry a great service by introducing a series of standards for the safety and efficacy of medical electrical equipment, better known as IEC 60601. As IEC 60601 was put into practice, though, experts observed that these standards overlooked the necessity of ongoing testing of the equipment after it had entered the field. Thus, a new set of standards for this very purpose was introduced: IEC 62353.

### About

This article was written to correspond with an article titled *Testing Electrical Medical Devices - IEC 62353*, written by Mr. Dieter Feulner, GMC-I Product Manager. Mr. Feulner is a German national expert and Member of IEC TC 62A WG 14, IEC 62353, as well as a German national expert and Member of IEC TC 85 WG 8, and IEC 61557.

### IEC 60601 vs. IEC 62353

IEC 60601, "Medical Electrical Equipment—General Requirements for Safety" was introduced in 1977 and put forth a set of requirements for the manufacturers of medical equipment. These requirements were designed to detect and eradicate any potential electric hazards presented by the equipment being produced (e.g. leakage currents, protective grounding, etc.). Assuming the equipment was utilized properly for the duration of its lifespan, these tests were meant to curb possible defects later on. They were further utilized on equipment already in service as a means of routine tests and after-repair tests; however, this practice presented some unforeseen difficulties. For example, IEC 60601 outlines type-testing in laboratory conditions, but often those conditions are not available or applicable once the device is already in use. And so, thirty years after IEC 60601 appeared on the scene, in 2007, IEC 62353, "Medical Electrical Equipment—Recurrent Test and Test After Repair of Medical Electrical Equipment" emerged to accommodate the needs of in-service devices. IEC 62353 is specifically designed around testing equipment in the field, and is therefore more practical, more effective, and more safe than using IEC 60601 in those particular circumstances.

## What, When, Who, How

### *What is an electrical medical device?*

An electrical medical device is a device (including its application parts) connected to a particular mains supply of power that uses the transfer of energy to or from the patient or displays an energy transfer of this sort in order to diagnose, treat, or monitor the patient.

Electrical medical devices are often combined into “systems,” and these systems can be tested just like devices. The IEC 62353 standard only applies to electrical medical devices or systems and their

components that comply with IEC 60601. All devices within a certain proximity of the patients must also comply with IEC 62353 standards.

### *When are the tests specified by IEC 62353 performed?*

IEC 62353 requires testing before initial start-up, after repair, and periodically. The manufacturer is obligated to provide information about the testing of the device, with which the operator of the testing should carefully comply.

### *Who should perform these tests?*

Tests of device safety must be performed by qualified electricians who have received adequate training for attending to devices under testing conditions. “Qualified” in this case is defined as including technical training, knowledge and practical experience, and keen awareness and familiarity of all relevant technologies, standards, and local regulations. Individuals who perform safety tests must be able to recognize any threats posed by devices that do not meet safety standards.

Please take note that most of those individuals who are qualified for testing devices are not necessarily qualified for testing systems, and that testing systems requires additional test instruments.

If the safety of the device while it is being tested cannot be assured, it must be accordingly identified, and the responsible organization must be notified in writing of the resultant hazard.

### *How is testing performed?*

Before testing, accompanying documentation must be examined, and accordingly, manufacturer recommendations of maintenance and repair taken into account. Whenever and wherever possible, the device must be disconnected from the mains supply power; otherwise, special measures must be implemented for the prevention of hazards resulting from working on live devices.

## Documentation

All tests carried out must be documented in depth. Testing documents must at the very least contain the following entries:

- Designation of the test location (e.g. company, department, authority)
- Name of the person(s) who performed and evaluated the test
- Designation of the tested device and accessories (e.g. type, serial number, inventory number)
- Executed tests including measured values, measuring methods and utilized measuring instruments
- Function test
- Final evaluation
- Date and signature of the person who prepared the evaluation
- Identification of the tested device (if required by the operating service provider)

The methods of measurement used before initial start-up and the results of those measurements should be documented for the purpose of comparison with the results of later measurements. This comparison is recommended if the measured value amounts to more than 90% of the limit value. With regard to systems, initial start-up testing must be performed every time the system is altered (such as modified configuration or replacement of components), and the changes and new measurements must be documented as well.

## Visual Inspection

This is a fairly easy and very effective portion of the procedure; the human eye must not be forgotten as a crucial tool that an operator of testing has available. The legibility of safety-relevant labeling is inspected, as well as the device’s compliance with the manufacturer’s specifications.

## Electrical Measurement Tests

### *Protective Conductor Resistance Measurement*

Protective conductor resistance measurements are performed on Class I devices to ensure that all accessible conductive parts (which, in the event of a fault, may become live) are appropriately secured to the protective conductor terminal. All devices must conform to the following protective conductor connection limit values:

Devices with a removable mains power cable (measurement without mains power cable)	0.2 $\Omega$
Devices including mains power cable	0.3 $\Omega$
Mains power cable (all available mains power cables are tested)	0.1 $\Omega$
Systems with multiple electrical outlets	0.5 $\Omega$

Connector cables such as data transmission lines and functional earth cables may simulate protective conductor connections, and should be disconnected if possible before testing is started. The disconnection of protective conductors is not called for with permanently connected devices.

### *Leakage Current Measurement*

Leakage current measurement requirements only apply universally to AC components; DC leakage current measurements must be determined and explicitly expounded upon in accompanying documentation by manufacturers (complying also with IEC 60601 DC limit values).

The measured value must be corrected to the value which corresponds to the measurement at nominal line voltage.

## The following leakage currents are measured:

<p><b>Device Leakage Current</b></p> <p><b>Device Leakage Current (Continued)</b></p>	<p>Device leakage current is the sum of all possible leakage currents which could flow over the user or the patient in the event of an interrupted protective earth conductor. (For this reason, current in the protective conductor, as well as from the application parts and accessible conductive parts, must be acquired during measurement.)</p> <p>In the IEC 60601-1 standard, this measurement corresponds to earth leakage current with grounded application parts and housing components. In the case of protection class II devices, current corresponds to contact current.</p> <p>This leakage current will be designated housing leakage current in the second edition of IEC 60601-1.</p>
<p><b>Leakage Current from the Application Part</b></p>	<p><b>Testing is only performed on type F application parts.</b> (Testing is usually not required for type B application parts, because it's included in device leakage current. However, the manufacturer may require an additional leakage current measurement for type B application parts.) Depending upon device layout, testing can be performed by means of direct measurement (mains to application part) or alternative measurement. If <b>alternative measurement</b> is used, test voltage equal to nominal line voltage is applied between the application part to be measured and all mains power cables which are connected to each other (L, N and PE). In the case of <b>direct measurement</b>, test voltage equal to nominal line voltage is applied between the application part to be measured and PE while the test object is being supplied with power from the mains. Application parts of identical type can be connected to each other during measurement, or the manufacturer's instructions must be followed. If different application parts are included, they must be connected and measured individually, one after the other. Application parts which are not included in the measurement are not connected.</p> <p><b>This leakage current will also be designated "patient leakage current with single fault condition mains on application part in IEC 60601.</b></p> <p><b>On some equipment it is required to measure patient leakage current on Type B applicatrion parts according to IEC 60601. This current is measured from the application part to ground and DC components will also be taken into consideration.</b></p>

## Permissible Values for Leakage Current Measurements:

<p><b>Device Leakage Current</b></p> <p>Direct or differential measurement: alternative measurement:</p>	<p>At protection class I parts</p> <p>0.5 mA 1.0 mA</p>	<p>At protection class II parts</p> <p>0.1 mA 0.5 mA</p>
<p><b>Leakage Current from the Application Part</b></p> <p>Type BF: Type CF:</p>	<p>5.0 mA 0.05 mA</p>	
<p><b>Patient leakage current according to IEC 60601 Type B, BF or CF (normal condition)</b></p>	<p>0.1 mA</p>	

Because cables and wiring (such as mains power cables, measurement cables, and data transmission lines) have an enormous influence on the leakage current measurements, they must be arranged in such a way as to minimize their interference.

Permanently connected devices need not be tested for leakage current measurements if the location is in accordance with IEC 60364-7-710 (“Medical locations”), and is regular tested according to this standard.

There are three methods to choose from for measuring leakage current; selection of which should be based on the design of the device:

<b>Alternative method</b>	Cannot be used for devices for which insulation in the power pack is not included in the measurement (e.g. due to a relay which is only closed in the operating state). If the measured value resulting from equivalent measurement exceeds 5 mA during testing of 3-phase devices, the test must be performed using the direct or differential method.
<b>Direct method</b>	Cannot be used in IG (Isolated Ground) systems. This method may not be used if the device under test cannot be isolated from ground. The protective conductor is interrupted when this measuring method is used, for which reason it’s essential not to come into contact with accessible conductive parts during testing, because danger of electrical shock would otherwise exist.
<b>Differential Current method</b>	Cannot be used in IG systems. Measuring instrument specifications must be observed when measuring small leakage currents with this method. As a rule, the method is only conditionally suitable for current values of less than 100 $\mu$ A.

### *Insulation Resistance Measurement*

Insulation resistance is a helpful measurement to find insulation faults caused by dust, wetness or pollution but the measurement may be forbidden by some manufacturers to avoid damage on sensitive parts. Furthermore, there is no limit value specified in IEC 62353, but the following values can serve as a reliable guideline:

Protection class I (LN to PE)	Protection class II (LN to accessible conductive part or type BF application part)	(LN to type CF application part)
2 M $\Omega$	7 M $\Omega$	70 M $\Omega$

### **Function Test**

Function tests regarding safety will be specified by the manufacturer, and should be executed accordingly. Function tests also fall under “essential performance characteristics” and “special requirements” of IEC 60601. Most of the time, additional test instruments will be required (such as with infusion pumps and defibrillators).

## Restoration to Operable State

Once testing is complete, the device must be restored to an operable state. This includes reconnection of power cables, data transmission lines and alarm devices, and general setup, etc., so that the device is in the same state as it was prior to the testing.

## Conclusion

IEC 62353 is a series of standards designed to protect us from the natural proclivity of complex systems to eventually go awry. Adherence to these standards is a crucial element in the operation of these electrical medical devices. At the end of the day, all of this testing and these standards are not about product quality or thoughtless conformity to mandated procedures; what it's really about is what the whole medical industry is about: The value of human health and safety.

For more information about IEC 62353 or any other electrical test or power-related issue, please contact Dranetz at 1-800-372-6832 or e-mail [sales@Dranetz.com](mailto:sales@Dranetz.com).

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