A PRACTICAL GUIDE TO IEC 62353

RIGEL

WORLD LEADERS IN SAFETY TEST & MEASUREMENT

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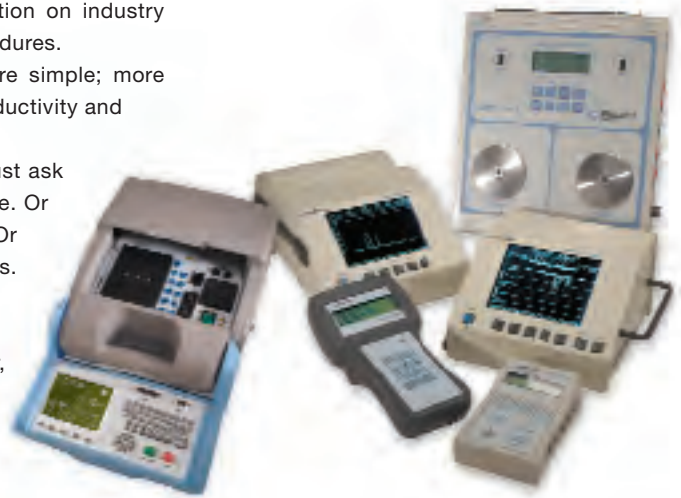

FOREWORD

This booklet is written as a guideline for people involved in testing medical electrical equipment and cannot be considered to replace the IEC 62353 standard.

Although all reasonable care has been taken to ensure accuracy of the information and reference figures and data have been taken from the latest versions of various standards, guidance notes and recognised 'best practices' to establish the recommended testing requirements, Rigel Medical, their agents and distributors, accept no responsibility for any error or omissions within this booklet, or for any misinterpretations by the user. For clarification on any part of this booklet please contact Rigel Medical before operating any test instrument.

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1. INTRODUCTION TO IEC 62353

As its full name implies, IEC 62353 Medical Electrical Equipment – recurrent test and test after repair of medical electrical equipment, is proposed to define the requirements of ensuring the in-service electrical safety of electromedical equipment and systems.

The IEC 62353 standard is an attempt to harmonise the various local standards and practices to ensure safe operation and testing of ME Equipment and ME systems.

In meeting this requirement the IEC 62353 incorporates tests beyond those of type testing. Specifically it seeks to provide a uniform and unambiguous means of assessing the safety of medical equipment, whilst maintaining the relation to IEC 60601-1 and minimising the risks to the person conducting the assessment.

Importantly, the new standard recognises that the laboratory conditions described in the IEC 60601-1 cannot always be guaranteed when in-service testing of medical devices is undertaken. As a result, test measurements that require certain environmental conditions may not always be applicable or consistent for the testing of equipment that is already in use. Another factor raised is that equipment could potentially be damaged by applying type test specifications when in service and could therefore represent a potential danger to users.

2. HOW DOES IEC 62353 COMPARE WITH IEC 60601?

Although IEC 60601 is a type test standard governing the safety of the design and manufacture of medical electrical equipment, most biomedical and clinical engineering departments and medical service companies use it as the basis for regular testing of medical devices or after service or repair.

However this is likely to change with the introduction of the proposed IEC 62353 which is currently being developed by the IEC to specifically describe the test requirements for the in-service testing of medical devices.

So what will the implications of IEC 62353 be and how will it differ from the very well established and widely understood requirements of IEC 60601?

2.1. IEC 60601

Introduced by the International Electrotechnical Committee to govern the design and development of medical equipment, the international safety standard IEC 60601 Medical Electrical Equipment – General Requirements for Safety was first published in 1977 and became widely known in shorthand form as IEC 601.

Manufacturers of medical equipment are required to test to IEC 601 to ensure that the design of the equipment is intrinsically safe. The standard specifies the type testing requirements for protection against potential electric hazards including protective Earthing (Earth continuity), Earth leakage currents, patient leakage current and patient auxiliary currents.

As a type testing standard it describes a range of measures that are intended to prove the safety of an item of electromedical equipment during its expected useful life. These measures include a combination of stress and destructive tests that must be undertaken under certain environmental conditions.

In many cases IEC 60601 has been translated into local national standards for use in certain countries. Examples are EN 60601 (EC), ES 60601, UL2601-1 (USA), CSA C22.2 (Canada) and AS/NZ 3200-1 (Australia/ New Zealand).

Clearly, safety testing at the design stage and at the end of the production line is vitally important, but what about when the equipment enters service? In the absence of a recognised international standard for in-service testing, a number of countries have already introduced their own national test recommendations.

For example, some countries have produced their own technical standards or guidelines for safety testing of newly delivered medical devices (sometimes referred to as acceptance testing), others have specified the tests at regular intervals, (also referred to as preventive maintenance) and some have testing requirements directly following service or repair. Some examples are MDA DB9801 (UK), VDE 750/751 (Germany), AS/NZ 3551 (Australia/New Zealand), NFPA-99 (USA).

In essence all these standards are linked by the aim to control the safety of medical devices used the treatment, care and diagnosis of patients and or individuals.

However, in those countries without any national guidance or code of practice on in-service testing, the convention has been to follow the manufacturer's instructions which invariably require that IEC 60601-1 test requirements and limits be repeated.

2.2. IN-SERVICE TEST REQUIREMENTS

As a type testing electro-technical standard, the current IEC 60601-1 does not provide any guidance in harmonising test requirements once an

item of medical electrical equipment leaves the production line.

Once a medical device enters into service, a number of potential test scenarios arise.

These are:

Acceptance Test also referred to as an Initial or Reference Test. This test is carried out prior to a new medical device being authorised for use and is undertaken to ensure correct and complete delivery. Acceptance Testing is often not limited to an electrical safety test, with some basic function tests being applied to verify correct performance.

Routine Testing also referred to as PPM, Preventative Product Maintenance. This form of testing is often conducted at fixed time intervals, which vary between types of equipment, manufacturer's recommendations and risk assessment procedures undertaken by individual BME or medical physics departments. Routine testing is not limited to safety testing and often includes the verification of correct functionality.

After Service & Repair Testing is carried out following a repair or product upgrade. It is often part of a service carried out by in-hospital mechanical or clinical engineering teams. In many cases, more rigorous electrical safety testing is needed after the replacement of components or reconfiguration of medical devices.

2.3. TECHNICAL CONSIDERATIONS

The main aim of IEC 62353 is to provide a uniform standard that ensures safe practice and reduces the complexity of the current IEC 60601-1 standard.

For example, one of the main differences will be in Earthbond testing, where the new standard will specify a minimum Earthbond test current of 200mA instead of the required 25A in IEC 60601-1.

In terms of assessing leakage currents, IEC 62353 incorporates a number of different measurement methods to help guarantee safer practice and the repeatability of measurements.

In addition to the direct leakage method as used in IEC 60601-1, IEC 62353 also provides for differential leakage measurement (also referred to as residual current in some standards) and the 'alternative' method. All these tests offer a variety of advantages and disadvantages. (See 8.1 for more details).

2.4. PREPARATION VITAL

Although the new IEC 62353 standard and local adaptations are expected to be published in 2007, all involved in the planning, management and implementation of electrical safety testing procedures for medical equipment should start to think about the possible implications now.

Although the onus will inevitably fall on the manufacturers of medical devices to advise on appropriate in-service test procedures for their own equipment, the new standard will clearly have an impact on medical service companies, Biomed's, medical physics, clinical engineering and other technical departments.

To help all those likely to be affected by the introduction of the new IEC 62353 standard, a summary of the test requirements is provided in this IEC 62353 guidance booklet. This guidance booklet is intended for general information only and is not intended for use as a replacement of the full version of the standard.

3. COMMONLY USED DEFINITIONS WITHIN IEC 60601 – IEC 62353

Equipment Under Test
The equipment (EUT) which is the subject of testing.

Device Under Test
The equipment (DUT) which is the subject of testing.

Applied Part
Part of the medical equipment which is designed to come into physical contact with the patient or parts that are likely to be brought into contact with the patient.

Patient Connection
Individual physical connections and / or metal parts intended for connection with the patient which form (part of) an Applied Part.

Patient Environment
Volumetric area in which a patient can come into contact with medical equipment or contact can occur between other persons touching medical equipment and the patient, both intentional and unintentional (see Appendix E).

F-Type Applied Part
Applied Part which is electrically isolated from Earth and other parts of the medical equipment i.e. floating F-type Applied Parts are either type BF or type CF Applied Parts.

Type B Applied Part
Applied Part complying with specified requirements for protection against electric shock. Type B Applied Parts are those parts, which are usually Earth referenced. Type B are those parts not suitable for direct cardiac application.

Type BF Applied Part
F-Type Applied Part complying with a higher degree of protection against electric shock than type B Applied Parts. Type BF Applied Parts are those parts not suitable for direct cardiac application.

Type CF Applied Part
F-Type Applied Part complying with the highest degree of protection against electric shock. Type CF Applied Parts are those parts suitable for direct cardiac application.

Medical Electrical Equipment
Electrical equipment designed for treatment, monitoring or diagnoses of patients, powered from not more than one connection to mains supply and which are not necessarily in physical or electrical contact with the patient or transfers energy to or from the patient or detects such energy transfer to or from the patient.

Medical Electrical System
Combination of equipment of which at least one is classed as medical electrical equipment and is specified by the manufacturer to be connected by functional connection or use of a multiple portable socket-outlet.

Class I
Equipment protection against electric shock by

(Earthed) additional protection to basic insulation through means of connecting exposed conductive parts to the protective Earth in the fixed wiring of the installation.

Class II

Also referred to as Double Insulated. Equipment protection against electric shock by additional protection to basic insulation through means of supplementary insulation are provided, there being no provision for the connection of exposed metalwork of the equipment to a protective conductor and no reliance upon precautions to be taken in the fixed wiring of the installation.

NOTE: CLASS II EQUIPMENT MAY BE PROVIDED WITH A FUNCTIONAL EARTH TERMINAL OR A FUNCTIONAL EARTH CONDUCTOR.

4. SYMBOLS AND MARKINGS

The IEC 60601 has defined the requirements for information / data to be present on the medical equipment's nameplate, in order to form an unambiguous identification of the equipment.

Information must include: Manufacturer's name, model number, serial number, electrical requirements etc.

The IEC 60601 standard refers to a large variety of symbols for use on medical equipment, medical systems, accessories and other related parts. A full overview of the symbols used in IEC 60601 is provided in the standard, table D1.

For the purpose of this booklet, a selection of the most commonly used symbols is displayed below:


Class I


Class II


Earth Reference point


i.e. "Conformité Européenne"


Type B Applied Part


Defibrillation proof type B Applied Part


Type BF Applied Part


Defibrillation proof type BF Applied Part


Type CF Applied Part


Defibrillation proof type CF Applied Part

5. VISUAL INSPECTION

The process of visual inspection is not clearly defined by IEC 60601, however visual inspections form a critical part of the general safety inspections during the functional life of medical equipment. In most cases, 70% of all faults are detected during visual inspection.

Visual inspection is a relatively easy procedure to make sure that the medical equipment in use still conforms to the specifications as released by the manufacturer and has not suffered from any external damage and/or contamination.

These can include the following inspections:

- Housing Enclosure – *Look for damage, cracks etc*
- Contamination – *Look for obstruction of moving parts, connector pins etc*
- Cabling (supply, Applied Parts etc) – *Look for cuts, wrong connections etc*
- Fuse rating – *check correct values after replacement*
- Markings and Labelling – *check the integrity of safety markings*
- Integrity of mechanical parts – *check for any obstructions*

6. EARTHBOND TESTING

Earthbond Testing, also referred to as Groundbond Testing, tests the integrity of the low resistance connection between the earth conductor and any metal conductive parts, which may become live in case of a fault on Class I medical devices.

Although many Class I medical devices are supplied with an Earth reference point, most if not all medical devices require multiple Earthbond tests to validate the connections of additional metal accessible parts on the enclosure.

The test current is applied between the Earth pin of the mains supply plug and any accessible metal part (including Earth reference point) via a dedicated Earthbond test lead (clip/probe). Figure 1 shows a representation of the Earthbond test.

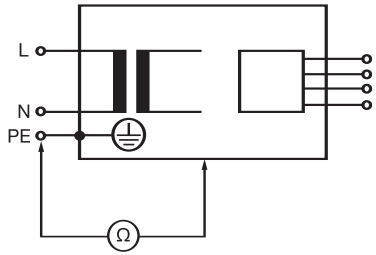


Figure 1: Earthbond test in Class I equipment

For fixed installations a Point-to-Point continuity measurement can be made by fitting a second lead into the Aux Earth socket. The resistance is then measured between the two leads.

The IEC 62353 requires a minimum test current of 200mA, either AC or DC. When using a DC test current, the resistance must be tested in both polarities of the test current. The highest reading will determine the PASS or FAIL result of this test.

The open circuit voltage of the current source should not exceed 24V.

The Test limits in IEC 62353 are set to:

100mΩ for a detachable power cable up to 3 metres

300mΩ for a Class I device including power cable (not exceeding 3 metres)

500mΩ for a Medical System consisting of several Medical and Non-Medical pieces of Equipment. See definition of Medical System in IEC 60601-1: 2005

6.1. EARTHBOND TEST CONSIDERATION

High Test Currents (10A or more) might potentially be destructive to parts of the DUT which are connected to the protective Earth but have a functional purpose (e.g. screening). As such, consideration should be given to the test current.

Low Test Currents (<8A) could potentially influence the reading as contact resistance is influenced by a number of factors (Constriction, Pressure, Film resistance). Higher Test Currents overcome the contact resistance where lower currents show a relatively higher reading, thus potentially causing unnecessary failures.

More on High vs Low Test Currents can be obtained in an application note on Earthbond testing. Simply email **info@rigelmedical.com** to receive your free copy.

7. INSULATION RESISTANCE TEST

Unlike the standard IEC 60601-1 tests, the IEC 62353 does provide a method of testing the Insulation of the Medical Device.

The methods of testing insulation are separated into:

- Insulation between Mains Parts and Earth (7.1)
- Insulation between Applied Parts and Earth (7.2)
- Insulation between Mains Parts and Earth (7.3)

7.1. INSULATION RESISTANCE EUT TO EARTH

This test is used to verify that the mains parts are adequately insulated from Earth (Class I) or the Enclosure (Class II). Figures 2A and 2B show a representation of the Insulation Test.

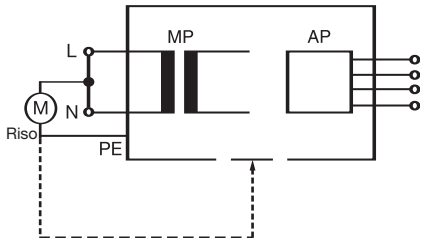


Figure 2A: Insulation EUT Test on Class I equipment

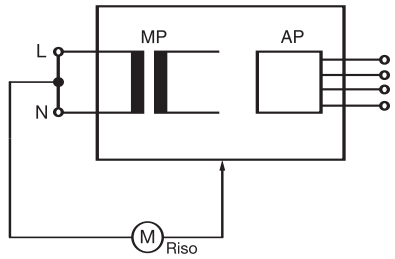


Figure 2B: Insulation EUT Test on Class II equipment

⚠ **During this test, 500V D.C. is applied between the Earth pin and both the Live and Neutral pins of the appliance mains supply plug.**

For both Class I and Class II appliances plug the DUT into the Safety Analyser. Class II equipment requires an auxiliary lead to be connected to the enclosure of the equipment. This can be done by wrapping the enclosure in aluminium foil and connecting to the auxiliary lead via an alligator clip.

7.2. INSULATION RESISTANCE APPLIED PARTS

This test is used to verify that the Applied Parts are adequately insulated from Earth (Class I) or the Enclosure (Class II). This test is applicable to Class I and Class II, BF and CF equipment only. Figures 3A and 3B show a representation of this Insulation test.

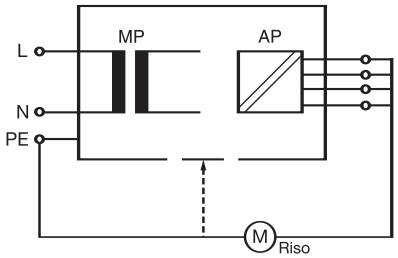


Figure 3A: Insulation AP Test on Class I equipment

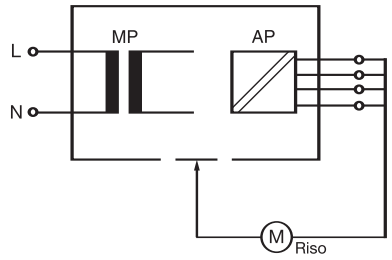


Figure 3B: Insulation AP Test on Class I equipment

⚠ **During this test, 500V D.C. is applied between the Earth pin (Class I) or the Enclosure (Class II) and all the Applied Parts combined.**

For both Class I and Class II appliances, connect the Patient Connections or Applied Parts to the corresponding terminals of your safety analyser. For Class I equipment, plug the mains plug into the safety analyser. Class II Equipment requires an auxiliary lead to be connected to the enclosure of the equipment. This can be done by wrapping the enclosure in aluminium foil and connecting to the auxiliary lead via an alligator clip.

7.3. INSULATION RESISTANCE APPLIED PARTS TO MAINS

This test is used to verify that the Applied Parts are adequately insulated from the mains parts and is applicable to Class I and Class II BF and CF equipment only. Figure 4 show a representation of the Applied Parts to Mains Insulation test.

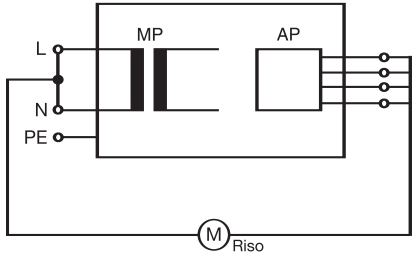


Figure 4: Insulation AP to Mains Test on Class I and Class II equipment

⚠ **During this test, 500V D.C. is applied between all the Applied Parts combined and both the live and neutral pins of the appliance mains supply plug.**

For both Class I and Class II appliances, connect the Patient Connections or Applied Parts to the

corresponding terminals of your safety analyser and connect the mains plug into the safety analyser.

8. IEC 62353 LEAKAGE MEASUREMENTS

Research has shown that current not voltage is often the source of injury or death. It takes only a small amount of current to cause major consequences.

When an electrical current flows through the human body the effect is influenced by two main factors. Firstly the amount of current and secondly the length of time the current flows.

For example, the heart stops if the current persists for:

a) 250mS at 40mA
b) 100mS at 100mA
c) 50mS at 200mA

Consider the following examples of the effect of current on the human body when applied to the skin (non invasive);

0.9–1.2mA	Current just perceptible
15.0–20.0mA	Release impossible: cannot be tolerated over 15 minutes
50.0–100.0mA	Ventricular fibrillation, respiratory arrest, leading directly to death
100.0–200.0mA	Serious burns and muscular contraction of such a degree that the thoracic muscles constrict the heart

Compare these values to the fact that 250mA of current is required to power a 25 watt lamp.

For this reason, the IEC 60601 committee has set stringent rules on the design of medical equipment so as to prevent any patient or operator being exposed to currents not part of the functional operation of the device. These currents are referred to as leakage currents.

IEC 62353 defines two different kinds of Leakage Current Tests;

- **Equipment Leakage Current** – total leakage deriving from the Applied Parts, Enclosure and Mains Parts combined to real Earth
- **Applied Part Leakage Current** – total leakage deriving from the combined Patient Connections within an Applied Part to Earth and any conductive or non conductive parts on the enclosure

The IEC 62353 describes the following methods to measure these Leakage Currents;

- **Direct Leakage;** Current flowing down the protective Earth conductor of the mains inlet lead
- **Differential Leakage;** The result of imbalance in current between the Live conductor and the Neutral conductor
- **Alternative Method;** Current flowing through a person to earth from the Applied Part or current flowing from a person to Earth via the Applied Part by applying unintended voltage from an external source

8.1. METHOD CHARACTERISTICS

8.1.1. Direct Leakage Provides:

The Direct Leakage Method is identical to the method used in the IEC 60601-1 standard, measuring the true leakage through a body model (Measuring Device) to Earth.

Benefits

- Means of measuring both AC and DC leakage current
- Highest accuracy compared to other methods
- Potential leakage through a human body via measuring device
- Direct comparison with measurements made in accordance with IEC 60601-1

To consider

- The 1kΩ resistor forming the Measuring Device is interrupting the low resistance Protective Earth Conductor, thus causing a potential hazard when testing faulty equipment
- Secondary Earth path(s). The EUT / DUT must be positioned electrically isolated from Earth during the measurement. A lower leakage might be measured as not all leakage is measurable in the earth conductor
- Secondary connections are typical with:
  - Equipment bolted to steel enforced concrete floor (e.g. dentist chairs, MRI)
  - Equipment connected to gas or water supply
  - Equipment that is part of a Medical Electrical System
  - Equipment connected to PC / Printer
- A difference in Polarity of the Live and Neutral conductors might alter the leakage readings, as such leakage measurements must be done in each polarity of mains supply
- A TN (Terre – Neutral) system is required to ensure that the measurements are done at maximum Live to Earth voltage. Any voltage between Neutral and Earth might result in a lower reading, potentially passing faulty equipment

8.1.2. Differential method

The Differential Leakage Method measures the leakage current as a result of an imbalance in current between the Live conductor and the Neutral conductor.

Potential secondary Earth connections are included in the total measurement and the EUT doesn't need to be positioned in isolation from Earth.

Low leakage currents of less than 75µA are difficult to measure using the Differential Leakage method. The Differential Leakage method is deemed unsuitable for measuring conductive Un-Earthed parts and in those instances where leakages are expected to be below 75µA.

Benefits

- The measurements are not influenced by secondary Earth connections
- It measures the total equipment leakage current
- The Measuring Device (1kΩ resistor) is no longer in series with the Earth conductor, thus providing a low resistance Protective Earth

To consider

- The Differential Leakage measurement is less suitable to accurately measure lower leakage currents (<100µA)
- The measurements can be influenced by external magnetic fields or the analyser's own internal magnetic fields
- The measurements can be influenced by high current consumption of the DUT
- The measurements have limited frequency response

- A difference in Polarity of the Live and Neutral conductors might alter the leakage readings. Leakage measurements must be done in each polarity of mains supply
- Both Direct and Alternative methods provide higher accuracy and broader frequency response which is required for measuring trends in low leakage conditions

8.1.3. Alternative method

The Alternative Method is similar to a Dielectric Strength Test at mains potential, using a current limited voltage source at mains frequency.

The Live and Neutral conductors are shorted together and the current limited voltage is applied between the mains parts and other parts of the equipment.

Due to the current limiting resistor(s), the actual measuring voltage is dependent on the test load. The measured leakage current is scaled in proportion to the actual output voltage to predict the actual leakage current flow at full mains potential.

Benefits

- As Live and Neutral are combined, the mains polarity has no influence. Only one measurement is required
- The DUT is disconnected from the mains thus providing a high level of safety for the test engineer
- TN-System is not required due to mains free application
- Measurements are not influenced by secondary earth connections
- Tests can be performed from a battery powered instrument
- Measurements are highly repeatable and provide a good indication of deterioration in the dielectrics of the medical device under test

To consider

- Equipment will not be activated thus preventing the measurement of actual leakage currents on equipment with switched circuits
- The Alternative Method is not directly comparable with the IEC 60601 test results

8.2. IEC 601 BODY MODEL

To ensure a traceable simulation of current as if passing through a human body, measurement circuits have been designed to simulate the average typical electrical characteristics of the human body. These measurement circuits are referred to as Body Models or Measuring Device (MD in IEC 60601-1).

Some standards such as the NFPA-99 and the IEC 61010 (electrical equipment for measurement, control and Laboratory use) specify different electrical characteristics to that of the IEC 60601-1.

The IEC 60601-1 Body Model or measuring device is shown in Appendix B.

8.3. EQUIPMENT LEAKAGE

The Equipment Leakage Test measures the total leakage deriving from the Applied Parts, Enclosure and Mains Parts combined to Real Earth. The Equipment Leakage Test is applicable to Class I and II, B, BF and CF equipment.

Leakage measurements to IEC 62353 are done using the RMS value instead of the separate AC and DC values used in the IEC 60601-1 standard.

The IEC 62353 specifies three different methods of measuring the Equipment Leakage Current;

- **Direct Method**
- **Differential Method**
- **Alternative Method**

8.3.1. Equipment Leakage Direct method

The Direct Method is identical to the method used in the IEC 60601-1.

Figures 5A and 5B show a representation of the Direct Method.

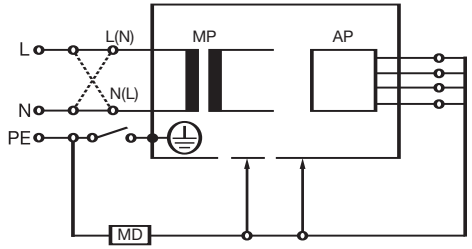


Figure 5A: Equipment Leakage Direct - Class I

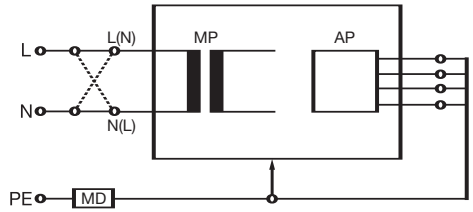


Figure 5B: Equipment Leakage Direct – Class II

The DUT must be positioned floating to avoid secondary Earth connections influencing the measuring process.

All **Applied Parts** (B, BF & CF) and **Earthed** (eg enclosure Class I) and **Non-Earthed** accessible conductive parts or non-conductive accessible parts (enclosure Class II) are **grouped together** and connected to earth via the 1kΩ Measuring Device (Body Model).

The 1kΩ Measuring Device (MD – equivalent to that used in the IEC 60601 standard – see Appendix B) is positioned in the leakage return path to Earth.

The test is conducted with the **protective earth connection interrupted** to ensure the measurements are done under worst conditions. As such, any Earth leakage current will be measured as part of the enclosure (or touch) leakage.

Measurements are done in **both polarities** of the incoming mains with the protective Earth to the EUT interrupted.

Current in µA (RMS)	APPLIED PART		
	B	BF	CF
Equipment leakage – direct or differential method			
Class I Equipment	500µA	500µA	500µA
Class II Equipment (touch current)	100µA	100µA	100µA

8.3.2. Equipment Leakage Differential method

Figures 6A and 6B show a representation of the Differential Method.

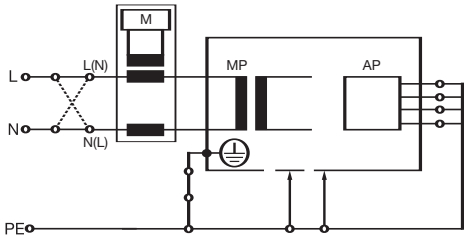


Figure 6A: Equipment Leakage Differential – Class I

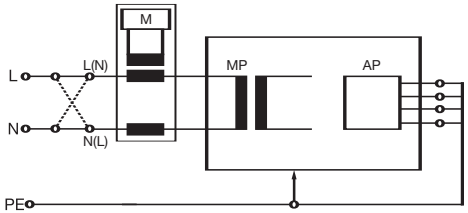


Figure 6B: Equipment Leakage Differential – Class II

Potential secondary Earth connections are included in the total measurement and the DUT is not required to be isolated from Earth.

All **Applied Parts** (B / BF & CF) and **Earthed** (e.g. enclosure Class I) and **Non-Earthed** accessible conductive parts or non-conductive accessible parts (enclosure Class II) are **grouped together** and connected to Earth to allow the Differential circuit to measure the total leakage current.

Unlike the Direct Method, the Differential method does not measure via the standard IEC 60601 Body Model in the Earth conductor. The MD is part of a differential current measurement between the Live and Neutral conductors. The frequency response of the measurement is similar to the Body Model used in the IEC 60601.

The test is conducted with the **protective Earth connection closed** for protection of the user.

Measurements are done in **both polarities** of the incoming mains with the protective Earth to the EUT interrupted.

Low leakage currents of less than 75µA are difficult to measure using the Differential Leakage method. The Differential Leakage method is unsuitable for measuring conductive Un-Earthed parts and in those instances where leakages are expected to be below 75µA.

Current in µA (RMS)	APPLIED PART		
	B	BF	CF
Equipment leakage – direct or differential method			
Class I Equipment	500µA	500µA	500µA
Class II Equipment (touch current)	100µA	100µA	100µA

8.3.3. Equipment Leakage Alternative method

This method is in fact similar to a dielectric test between the mains parts and all accessible parts (conductive and non-conductive) including the Applied Parts connected together. Figures 7A and 7B show a representation of the Alternative Method.

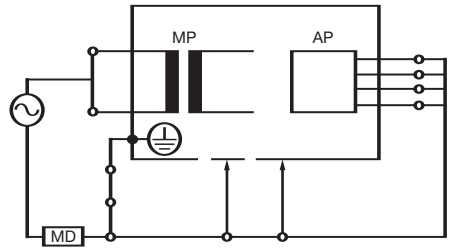


Figure 7A: Equipment Leakage Alternative – Class I

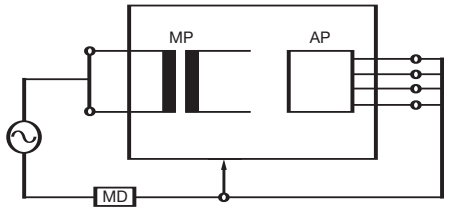


Figure 7B: Equipment Leakage Alternative – Class II

The test is performed using current limited (3.5mA) mains potential sinusoidal 50Hz signal (60Hz where this is the mains frequency).

As Live and Neutral are shortened, the DUT is not directly connected to the mains potential. Mains reversal is not applicable and the EUT does not need to be positioned isolated from Earth.

All **Applied Parts, Earthed** (e.g. enclosure Class I) and Non-Earthed accessible conductive parts or non-conductive accessible parts (enclosure Class II) are **grouped together** and connected to the mains parts via the 1kΩ Measuring Device (Body Model) and voltage source.

The 1kΩ measuring Device (equivalent to that used in the IEC 60601 standard – see Appendix B) is positioned directly after the voltage source.

The test is conducted with the **protective Earth connection closed** for protection of the user.

Current in µA (RMS)	APPLIED PART		
	B	BF	CF
Equipment leakage – alternative method			
Class I Equipment	1000µA	1000µA	1000µA
Class II Equipment (touch current)	500µA	500µA	500µA

8.4. APPLIED PART LEAKAGE

The Applied Part Leakage Test measures the total leakage deriving from the combined Patient Connections within an Applied Part to Earth and any conductive or non conductive parts on the enclosure (either connected or isolated from Earth) under the fault condition Mains on Applied Parts.

The Applied Part Leakage Test is applicable to **Floating type (BF & CF)** Applied Parts only either Class I or II.

All Patient Connections of a single function within an Applied Part shall be connected together (BF & CF) and measured one at the time.

Applied Parts (and Patient Connections) not part of the measurement shall be left floating i.e. not connected to real Earth.

The test is conducted by applying a current limited (3.5mA) mains potential sinusoidal 50Hz signal (60Hz where this is the mains frequency) between the Applied Part and the Enclosure and Earth connection of the EUT connected to real Earth.

Leakage measurements to IEC 62353 are done using the RMS value instead of the separate AC and DC values used in the IEC 60601-1 standard.

The IEC 62353/Applied Part Leakage can be performed in two different methods;

- **Direct Method**
- **Alternative Method**

8.4.1. Applied Part Leakage Direct method:

Figures 8A and 8B show a representation of the Direct Method.

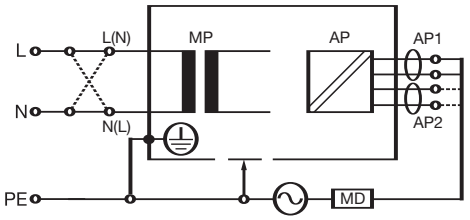


Figure 8A: Applied Part Leakage Direct – Class I

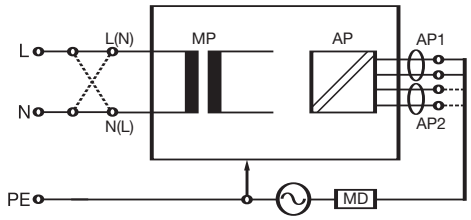


Figure 8B: Applied Part Leakage Direct – Class II

The DUT must be positioned floating to avoid secondary Earth connections influencing the measuring process.

All floating type Patient Connections in each Applied Part (BF & CF) are connected together. Each Individual **Applied Part** is measured in turn and grouped with all **Earthed** (e.g. enclosure Class I) and **Non-Earthed** accessible conductive parts or non-conductive accessible parts (enclosure Class II). These are **grouped together** and connected to Earth via the 1kΩ Measuring Device (Body Model).

Applied Parts and Patient Connections not part of the measurement shall be left floating.

The 1kΩ Measuring Device (MD - equivalent to that used in the IEC 60601 standard – see Appendix B) is positioned between the Applied Part and Voltage Source.

The test is conducted with the **protective Earth connection closed** for protection of the user.

Measurements are done in **both polarities** of the incoming mains with the protective Earth to the EUT interrupted.

⚠ **Warning:** This Applied Part Direct Leakage test is similar to that of the F-Type leakage test according to IEC 60601 using an equivalent current limited voltage source to produce the mains potential. Both sources depend on a current limiting resistor which could cause a significant voltage drop.

Unlike the IEC 60601-1 requirements, the voltage drop caused by the current limiting resistor **is compensated for** in the IEC 62353 thus potentially resulting in a higher reading than the typical IEC 60601-1 F-type test. Please refer to the manufacturers recommendations.

Current in µA (RMS)	APPLIED PART		
	B	BF	CF
Patient leakage current – direct method (a.c.)			
Class I & II		5000µA	50µA

8.4.2. Applied Part Leakage Alternative method

This method is in fact similar to a dielectric test between the Applied Part and all mains parts, EUT Earth and Enclosure connected together. Figures 9A and 9B show a representation of the Alternative Method.

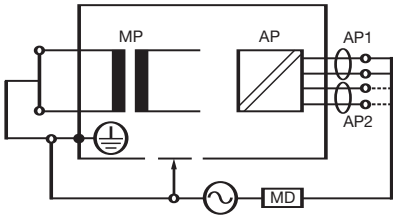


Figure 9A: Applied Part Leakage Alternative – Class I

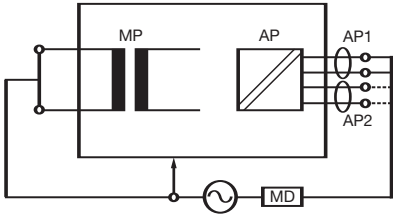


Figure 9B: Applied Part Leakage Alternative – Class II

As Live and Neutral are shortened, the DUT is not directly connected to the mains potential. Therefore, mains reversal is not applicable and the EUT does not need to be positioned in isolation from Earth.

All floating type Patient Connections in each Applied Part (BF & CF) are connected together. Each Individual **Applied Part** is measured in turn and connected via the 1kΩ Measuring Device (Body Model) to the voltage source and **Earthed** (e.g. enclosure Class I) and **Non-Earthed** accessible conductive parts or non-conductive accessible parts (enclosure Class II) **grouped together**.

Applied Parts and Patient Connections not part of the measurement shall be left floating.

The 1kΩ Measuring Device (MD - equivalent to that used in the IEC 60601 standard – see Appendix B) is positioned between the Applied Part and Voltage Source.

The test is conducted with the **protective Earth connection closed** for the protection of the user.

Current in µA (RMS)	APPLIED PART		
	B	BF	CF
Patient leakage current – alternative method (a.c.)			
Class I & II		5000µA	50µA

9. RECORD KEEPING

Overall, the area of risk assessment and the creation of risk management files has become a growing feature of routine safety testing decisions, with different organisations and departments drawing-up individual plans to deal with specific safety hazards. Comparison with previous test results will therefore allow you to monitor deterioration of the Device Under Test and prevent potential failure before a fault occurs.

Electrical safety testing is only part of the total service carried out on medical equipment. Once the safety has been proven, the functionality is verified and recorded before the equipment is returned for use on patients.

This functional testing can be a combination of simulations and functional measurement such as measuring the output energy of defibrillators, the infusion rate of infusion pumps and syringe drivers, the flow rate and frequency of ventilators and the energy output of surgical instruments. Patient monitors are designed to take a variety of physiological conditions to monitor the patient's vital signs. To ensure patient monitors are displaying the correct readings, a verification of the individual parameters is required.

Such verifications are typically done by specialised equipment such as an Oxygen Saturation Simulator (SPO2), Non-Invasive Blood Pressure (NIBP) Simulator, Temperature Simulator, ECG Simulator, Ventilator Tester, Infusion Pump Tester etc.

To ensure proper record keeping is maintained it is important to provide a procedure in which data is collected regarding:

- Inspection Date
- Visual Inspection
- Electrical Safety
- Functional Testing
- Next Inspection Date

The IEC 62353 provides a guideline in collecting such information with the purpose of developing consistency in data collection and management. By doing so, trends can be monitored to benefit:

- Identifying common faults
- Detect component deterioration (preventative maintenance)
- Develop efficient re-test periods

For the future, determining the appropriate levels of both electrical and functional testing will be central to the introduction of cost effective yet reliable preventative maintenance campaigns.

10. CONCLUSION

Electrical safety testing of medical electronic devices remains a crucial part of the overall safety validation of medical devices and requires specialised test equipment.

The IEC 62353 standard will provide;

- Global test reference to allow uniform testing
- Development tools for saver and suitable test sequences
- A method of record keeping and maintenance procedures

When choosing your future electrical safety analyser, ensure that it can be used to test in accordance with the IEC 62353 requirements and secondly that your analyser will enable you to accurately and repeatedly produce the results you require.

10.1 CONSIDERATIONS AND RECOMMENDATIONS

1. Ensure that the operator of the safety test equipment is properly trained on both the safety analyser and Device Under Test to prevent unneccessary danger during the safety test
2. Always ensure that the Device Under Test does not pose any danger to the user and/or people within the vicinity to the safety test (e.g. moving parts, open conductors, Live components, heat etc.)
3. Ensure that Leakage Measurements are performed whilst the equipment is in full operation mode, including its sub-systems or components
4. Ensure high accuracy and repeatability of leakage measurement readings (some manufacturers might specify full scale accuracy which will affect the accuracy of low leakage measurements)
5. Ensure that contact resistance is taken into account when measuring the Earth continuity at low currents (<8A). Contact resistance can influence the readings and cause unnecessary failures of the Device Under Test. Ask for an application note on low current testing via info@rigelmedical.com (subject: low current testing)
6. When determining the correct means of testing a specific item of Medical Equipment, ensure that the chosen safety test procedures are applicable to the Device Under Test and are clearly documented for future use

Rigel Medical offers a range of test equipment in line with IEC 62353 and IEC 60601 requirements. Please visit our website www.rigelmedical.com for a full overview of our product offering or register online for our free newsletter on future product releases and product innovations.

For further questions or comments relating to this booklet or the Rigel Medical product offering, please contact John Backes at johnb@seaward.co.uk

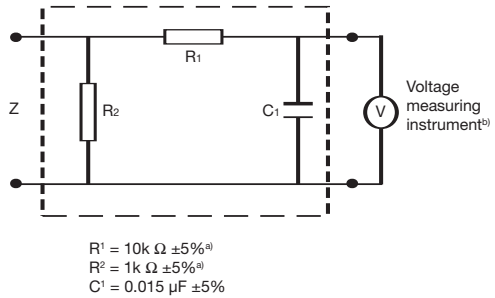
APPENDIX A: PASS/FAIL LIMITS OF IEC 62353

Current in µA (RMS)	APPLIED PART		
	B	BF	CF
Equipment Leakage – alternative method			
Class I Equipment	1000µA	1000µA	1000µA
Class II Equipment	500µA	500µA	500µA
Equipment leakage – direct or differential method			
Class I Equipment	500µA	500µA	500µA
Class II Equipment (touch current)	100µA	100µA	100µA
Patient leakage current – alternative method (AC)			
Class I & II		5000µA	50µA
Patient leakage current – direct method (AC)			
Class I & II		5000µA	50µA

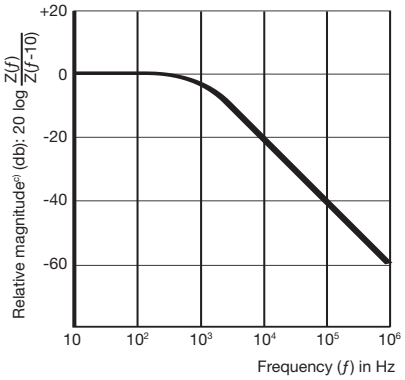
NOTE 1: This IEC 62353 standard does not provide measuring methods and allowable values for equipment producing DC leakage currents. In such a case the manufacturer should give information in accompanying documents.

NOTE 2: Particular standards may allow different values of leakage current. For a list of particular standards, please refer to Appendix D.

APPENDIX B: IEC 60601-1 MEASURING DEVICE



a) Measuring Device



b) Frequency Characteristics

Note: The network and voltage measuring instrument above is replaced by the symbol —[MD]— in the following figures.

[a] Non-inductive components
[b] Impedance >> measuring impedance Z
[c] $Z(f)$ is the transfer impedance of the network, i.e. $V_{out/in}$, for a current frequency f.

Example of a measuring device MD according to IEC 60601-1 and its frequency characteristics

APPENDIX C: IEC 60601-1 COLLATERAL STANDARDS

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IEC 60601-1-1	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY 1: COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS
IEC 60601-1-2	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY –REQUIREMENTS AND TESTS
IEC 60601-1-3	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY – COLLATERAL STANDARD: GENERAL REQUIREMENTS FOR RADIATION PROTECTION IN DIAGNOSTIC X-RAY EQUIPMENT
IEC 60601-1-4	MEDICAL ELECTRICAL EQUIPMENT: PART 1-4: GENERAL REQUIREMENTS FOR COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS
IEC 60601-1-6	MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY
IEC 60601-1-8	MEDICAL ELECTRICAL EQUIPMENT - PART 1-8: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: GENERAL REQUIREMENTS, TESTS AND GUIDANCE FOR ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS
IEC 60601-1-9 (CDIS)	MEDICAL ELECTRICAL EQUIPMENT - PART 1-9: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR ENVIRONMENTALLY CONSCIOUS DESIGN
IEC 60601-1-10 (ADIS)	MEDICAL ELECTRICAL EQUIPMENT - PART 1-10: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR THE DEVELOPMENT OF PHYSIOLOGIC CLOSED-LOOP CONTROLLERS
IEC 60601-1-11 (ANW)	MEDICAL ELECTRICAL EQUIPMENT - PART 1-11: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEM USED IN HOME CARE APPLICATIONS

APPENDIX D: IEC 60601-2 PARTICULAR STANDARDS

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IEC 60601-2-1	MEDICAL ELECTRICAL EQUIPMENT – PART 2-1: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTRON ACCELERATORS IN THE RANGE 1 MEV TO 50 MEV
IEC 60601-2-2	MEDICAL ELECTRICAL EQUIPMENT – PART 2-2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH FREQUENCY SURGICAL EQUIPMENT
IEC 60601-2-3	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SHORT-WAVE THERAPY EQUIPMENT
IEC 60601-2-4	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CARDIAC DEFIBRILLATORS AND CARDIAC DEFIBRILLATORS MONITORS
IEC 60601-2-5	MEDICAL ELECTRICAL EQUIPMENT – PART 2-5: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ULTRASONIC PHYSIOTHERAPY EQUIPMENT
IEC 60601-2-6	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MICROWAVE THERAPY EQUIPMENT
IEC 60601-2-7	MEDICAL ELECTRICAL EQUIPMENT – PART 2-7: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH-VOLTAGE GENERATORS OF DIAGNOSTIC X-RAY GENERATORS
IEC 60601-2-8	MEDICAL ELECTRICAL EQUIPMENT – PART 2-8: PARTICULAR REQUIREMENTS FOR THE SAFETY OF THERAPEUTIC X-RAY EQUIPMENT OPERATING IN THE RANGE 10 KV TO 1 MV
IEC 60601-2-9	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF PATIENT CONTACT DOSEMETERS USED IN RADIOTHERAPY WITHELECTRICALLY CONNECTED RADIATION DETECTORS
IEC 60601-2-10	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF NERVE AND MUSCLE STIMULATORS
IEC 60601-2-11	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF GAMMA BEAM THERAPY EQUIPMENT
IEC 60601-2-12	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF LUNG VENTILATORS FOR MEDICAL USE
IEC 60601-2-13	MEDICAL ELECTRICAL EQUIPMENT – PART 2-13: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ANAESTHETIC WORKSTATIONS
IEC 60601-2-14	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCONVULSIVE THERAPY EQUIPMENT
IEC 60601-2-15	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CAPACITOR DISCHARGE X-RAY GENERATORS
IEC 60601-2-16	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HAEMODIALYSIS EQUIPMENT
IEC 60601-2-17	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF REMOTE-CONTROLLED AUTOMATICALLY DRIVEN GAMMARAY AFTER-LOADING EQUIPMENT
IEC 60601-2-18	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT
IEC 60601-2-19	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS OF SAFETY OF BABY INCUBATORS
IEC 60601-2-20	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF TRANSPORT INCUBATORS
IEC 60601-2-21	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT RADIANT WARMERS
IEC 60601-2-22	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF DIAGNOSTIC AND THERAPEUTIC LASER EQUIPMENT
IEC 60601-2-23	MEDICAL ELECTRICAL EQUIPMENT – PART 2-23: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF TRANSCUTANEOUSPARTIAL PRESSURE MONITORING EQUIPMENT
IEC 60601-2-24	MEDICAL ELECTRICAL EQUIPMENT – PART 2-24: PARITCULAR REQUIREMENTS FOR THE SAFETY OF INFUSION PUMPS AND CONTROLLERS
IEC 60601-2-25	MEDICAL ELECTRICAL EQUIPMENT – PART 2-25: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHS
IEC 60601-2-26	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROENCEPHALOGRAPHS
IEC 60601-2-27	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT
IEC 60601-2-28	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY SOURCE ASSEMBLIES AND X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS
IEC 60601-2-29	MEDICAL ELECTRICAL EQUIPMENT – PART 2-29: PARTICULAR REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY SIMULATORS
IEC 60601-2-30	MEDICAL ELECTRICAL EQUIPMENT – PART 2-30: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT
IEC 60601-2-31	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EXTERNAL CARDIAC PACEMAKERS WITH INTERNAL POWER SOURCE
IEC 60601-2-32	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ASSOCIATED EQUIPMENT OF X-RAY EQUIPMENT
IEC 60601-2-33	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL DIAGNOSIS
IEC 60601-2-34	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT
IEC 60601-2-35	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF BLANKETS, PADS AND MATTRESSES, INTENDED FOR HEATING IN MEDICAL USE

IEC 60601-2-36	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EQUIPMENT FOR EXTRACORPOREALLY INDUCED LITHOTRIPSY
IEC 60601-2-37 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT – PART 2-37: PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE OF ULTRASONIC MEDICAL DIAGNOSTIC AND MONITORING EQUIPMENT
IEC 60601-2-38	MEDICAL ELECTRICAL EQUIPMENT – PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTRICALLY OPERATED HOSPITAL BEDS
IEC 60601-2-39	MEDICAL ELECTRICAL EQUIPMENT – PART 2-39: PARTICULAR REQUIREMENTS FOR THE SAFETY OF PERITONEAL DIALYSIS EQUIPMENT
IEC 60601-2-40	MEDICAL ELECTRICAL EQUIPMENT – PART 2-40: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELETROMYOGRAPHS AND EVOKED RESPONSE EQUIPMENT
IEC 60601-2-41	MEDICAL ELECTRICAL EQUIPMENT – PART 2-41: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS
IEC 60601-2-43	MEDICAL ELECTRICAL EQUIPMENT – PART 2-43: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR INTERVENTIONAL PROCEDURES
IEC 60601-2-44	MEDICAL ELECTRICAL EQUIPMENT – PART 2-44: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY
IEC 60601-2-45	MEDICAL ELECTRICAL EQUIPMENT – PART 245: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAMMOGRAPHIC X-RAY EQUIPMENT AND MAMMOGRAPHIC STEREOTACTIC DEVICES
IEC 60601-2-46	MEDICAL ELECTRICAL EQUIPMENT – PART 2-46: PARTICULAR REQUIREMENTS FOR THE SAFETY OF OPERATING TABLES
IEC 60601-2-47	MEDICAL ELECTRICAL EQUIPMENT – PART 2-47: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS
IEC 60601-2-49	MEDICAL ELECTRICAL EQUIPMENT – PART 2-49: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MULTIFUNCTION PATIENT MONITORING EQUIPMENT
IEC 60601-2-50	MEDICAL ELECTRICAL EQUIPMENT – PART 2-50: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT PHOTOTHERAPY EQUIPMENT
IEC 60601-2-51	MEDICAL ELECTRICAL EQUIPMENT – PART 2-51: PARTICULAR REQUIREMENTS FOR SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS
IEC 60601-2-52 (ACDV)	MEDICAL ELECTRICAL EQUIPMENT – PART 2-52: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF MEDICAL BEDS
IEC 60601-2-53 (PWI)	MEDICAL ELECTRICAL EQUIPMENT, PART 2-53: PARTICULAR REQUIREMENTS FOR THE SAFETY AND ESSENTIAL PERFORMANCE OF A STANDARD COMMUNICATIONS PROTOCOL FOR COMPUTER ASSISTED ELECTROCARDIOGRAPHY
IEC 60601-2-54 (ANW)	MEDICAL ELECTRICAL EQUIPMENT – PART 2-54: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF X-RAY EQUIPMENT FOR RADIOGRAPHY AND RADIOSCOPY
IEC 60601-2-56 (1CD)	MEDICAL ELECTRICAL EQUIPMENT – PART 2-56: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF SCREENING THERMOGRAPHS FOR HUMAN FEBRILE TEMPERATURE SCREENING
IEC 60601-2-57 (ANW)	PARTICULAR REQUIREMENTS FOR THE SAFETY AND ESSENTIAL PERFORMANCE OF INTENSE LIGHT SOURCES USED ON HUMANS AND ANIMALS FOR MEDICAL AND COSMETIC PURPOSES
IEC 60601-2-58 (ANW)	MEDICAL ELECTRIC EQUIPMENT – PART 2-58 – PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF LENS REMOVAL AND VITRECTOMY DEVICES FOR OPHTHALMIC SURGERY

APPENDIX E: PATIENT ENVIRONMENT

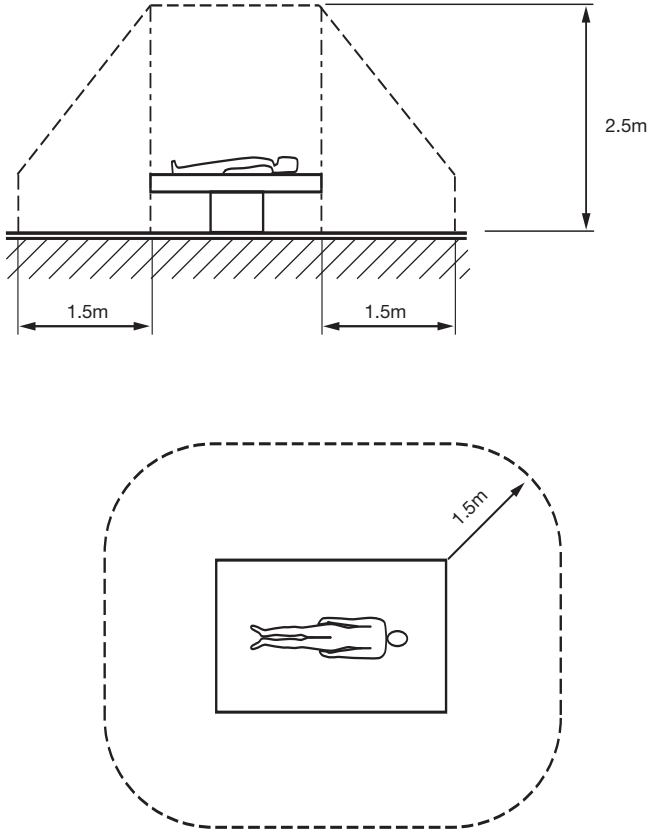

Figure G1: Patient Environment