

# Medical Electrical Installation Guidance Notes

# **‘MEIGaN’**

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Boxed text represents background information

Other text sets out requirements that can be invoked in a contract.

Document hyperlinks appear as [blue text](#).

## 3 Introduction

### 3.1 Background

This guidance document supplements the following, all relevant requirements of which apply:

- BS 7671:2001 Requirements for electrical installations. IEE Wiring Regulations. Sixteenth edition, including amendment No. 1 2002 and No. 2 2004 [1]
- NHS Estates HTM 06-01 Electrical services, supply and distribution [2]
- BS EN60601-1-1:2006 Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems [3].

Annex 1 of this document is based on IEC 60364-7-710 [4] and IEE Guidance Note 7 [5]. It will be incorporated in a subsequent revision of HTM 06-01 [2].

This document, in conjunction with the above, replaces the electrical requirements of TRS 89, which are no longer valid.

The text within this document has been produced by the MHRA and representatives from the Department of Health's Estates and Facilities Division, the Scottish, Welsh and Northern Ireland administrations, NHS electrical experts, medical device suppliers and pre-installation companies.

### 3.2 Document scope

This document is intended to be used by healthcare organisations and medical device suppliers responsible for permanent electrical installation of medical devices and associated equipment in diagnostic imaging and radiotherapy rooms/suites. This includes dental X-ray equipment, ultrasound, nuclear medicine, bone density, MR, CT, PET, as well as conventional radiotherapy, radiographic and fluoroscopic equipment. Its requirements are intended for application by staff with electrical knowledge.

Healthcare organisations can include as a condition of contract that ‘the electrical installation shall meet the requirements of BS7671 IEE Wiring Regulations [1], MEIGaN and BS EN60601-1-1:2006 [3].’

A complete set of paper commissioning records, sufficient to show compliance with the MEIGaN guidance shall be made available to the owner at handover.

This document may also be of use to persons installing permanently installed medical devices in other clinical areas, but has not yet been agreed by interested parties concerned with installations other than for imaging and radiotherapy.

This guidance covers the electrical wiring and installation up to the terminals of permanently installed medical devices and to the supply outlets for other medical devices, and is intended to improve the reliability and resilience of the power supplies used in diagnostic imaging and radiotherapy rooms/suites as well as their electrical safety.

Although this is a guidance document, the word ‘shall’ has been used to emphasise the importance of complying with its content.

Modern mobile X-ray units are designed to operate from a standard 13 A socket outlet. However, where a socket is supplied by means of a long run of cable, the total mains resistance may exceed the maximum permitted value. The mains resistance (and also the earth bonding resistance) of all mains outlet sockets that are intended to be used to power mobile X-ray units shall be measured to ensure that the value does not exceed that quoted by the equipment supplier. Where the value is found to be too high, the wiring to the socket may have to be upgraded.

### 3.3 Use of the document

**This guidance is for new buildings, refurbished or upgraded rooms including transportable diagnostic or treatment rooms and is not retrospective except where major items of equipment such as the X-ray table or generator are replaced.**

Purchasers and suppliers shall not change the original text. Any changes shall be listed in an addendum.

#### **Document support**

Feedback and enquiries about this document are welcome at all times. E-mail to: [devices@mhra.gsi.gov.uk](mailto:devices@mhra.gsi.gov.uk)

The electronic version of this document (in PDF format) can be found on the MHRA website: [www.mhra.gov.uk](http://www.mhra.gov.uk)

## 4 Mains supply

If both three-phase and single-phase supplies are needed in the same location, they shall be derived from the same source. (A sub-station containing a number of cross-bonded transformers is considered to be a single source).

All single-phase TN-S supplies within a medical location shall be from the same phase. The declared voltages in the UK are:

230 V (single-phase)	+10%	253.0V
	-10%	207.0V
400 V (three-phase)	+10%	440.0V
	-10%	360.0V

### 4.1 Mains cables

Mains cables shall be armoured or double insulated except where they are installed in enclosed containment that provides mechanical and electrical protection.

The steel wire armour (SWA) is intended to provide mechanical and electro-magnetic compatibility protection; it shall not be used as the main earth conductor. Connection to earth shall be achieved by means of a copper conductor, having a cross sectional area (CSA) greater than or equal to that of the phase conductors. Where the medical device supplier specifies a greater cross sectional area, the supplier's instructions shall be followed. The copper earth conductor shall be connected to the source of the supply unless it can be shown that a more local distribution panel can provide a copper conductor of adequate CSA from the earth reference bar (ERB) to the earth distribution bar of the sub-station (verify by inspection).

The cable supplying power to a three-phase installation shall be a five core cable, and the cable supplying power to a single-phase installation shall be a three core cable. Where an existing four core SWA cable is to be used to provide a three-phase supply, an additional copper earth conductor of the same CSA as the phase conductors can be strapped externally to the existing SWA cable.

If the medical device manufacturer stipulates an electromagnetic interference (EMI) screen for the mains supply cables, the SWA shall be terminated with a zoned earthing and neutral (ZEN) gland. The SWA shall be earthed only at the distribution board unless that would conflict with the equipment manufacturer's instructions for earthing arrangements for electromagnetic compatibility (EMC).

The use of standard glands is not practical as the SWA gland is used to hold the cable in position with respect to the metal isolator/enclosure.

The conductors of three-phase cables shall be permanently identified as: L1, L2 and L3, neutral as N, and the earth by green/yellow insulation, as specified in amendment No.2 2004 of BS 7671 Table 7A, Appendix 7 [1]. The phase conductor of the single-phase supply shall also be identified as coming from either L1, L2 or L3, and the neutral as N. The earth shall be identified as yellow/green.

Room lighting or power cables shall not be included in the medical device cable containment except where the lighting is controlled by the installed medical device.

## 4.2 Mains supply quality

Any of the following mains supply quality parameters that are specified by the medical device manufacturer shall be checked for consistency with the manufacturer's specification:

- supply frequency
- RMS phase voltage range
- voltage sags
- voltage surges
- voltage unbalance
- harmonic voltage distortion
- voltage waveform profile.

The reliability and proper functioning of electrical equipment will be compromised if the electrical supply delivered to it does not fall within the power quality parameters for which it is designed. For 'new-builds' the supply parameters of typical imaging equipment of the type to be installed should be obtained early in the design stage, and the electrical system designed and constructed to meet the worst case scenario. It should be noted that the peak power drawn from the supply may be 50% higher than the maximum rated output of the X-ray generator, so that a 50 kW generator may draw 75 kW peak from the mains.

When upgrading an existing installation, the power quality should be monitored over an extended period (7 days including a weekend) using an appropriate power quality monitor, and the electrical system upgraded to meet the demands of the new installation. It is important that the quality of the electrical supply be compatible with the newly installed medical devices. The specification will be provided by the medical device manufacturer; the installer shall be responsible for meeting this specification. Any voltage unbalance greater than 2% should be investigated.

## 4.3 Mains supply impedance

Where equipment is to be connected to an existing supply, the mains impedance shall be measured (up to the room mains isolator) at the earliest opportunity, so that the figure is available when reviewing the specification of any imaging equipment on offer. When the installation is to be a new-build, typical values of mains impedance for the type of equipment to be installed shall be obtained from prospective suppliers, and the electrical system designed to meet the lowest value quoted by the prospective equipment suppliers.

## 4.4 Crimped connections

In order to ensure consistent values of resistance, tin plated copper crimp terminals shall be used on all terminations in the mains supply and earth systems. A ratchet type crimping tool and die set compatible with the crimp terminals shall be used. The crimp terminal shall be the correct size for the conductor cross sectional area. The crimp terminal mounting hole shall be the correct size for the securing stud, which shall be of a CSA sufficient to carry the full load current. The crimped terminals shall be attached



to the connection bars with brass studs and flat brass washers; they shall all be of matching size.

#### 4.5 Mains supply isolator and contactor

A means of isolating and switching electrical supplies to all of the installed device(s) and mains outlet sockets in the medical location shall be provided, sited in a position readily accessible to the operator, in accordance with IEE Wiring Regulations BS 7671 [1]. The isolator shall include a means to lock it in the off position.

A remotely operated electromechanical contactor shall be fitted in the mains supply of three-phase medical devices, with the controls sited in a position readily accessible to the operator. This contactor shall isolate all three-phase contacts and be capable of interrupting maximum load currents. The contactor control circuit shall be the same phase as the room socket outlets except where a separate extra low voltage supply (SELV, <25 V rms) is used for the control circuitry.

The primary means of removing the mains supply to the installation shall be labelled 'emergency off'. In the case of energy storage X-ray units, activation of the emergency off shall remove the mains supply from the charging circuit, together with the inverter supply to the X-ray generator.

Where equipment is provided with an internal uninterruptible power supply or other power source (power storage capacitors, external generators, batteries etc.) clear signage warning of the dangers shall be provided at all points of isolation for the equipment both as a part of the fixed electrical installation and internal isolation within the equipment. The signage shall also indicate the source and nature of the risk, capacitor, battery, generator etc. and any time delay between switch-off and the equipment becoming safe.

Where a manually operated mains switch is provided as the primary means of turning the system on and off, it shall be of a grade suitable for frequent use. Where an electromechanical contactor is provided this shall be the primary means of turning the system on and off.

Where equipment is installed in a separate equipment room, but the mains isolator/contactor is located in the diagnostic or treatment area, the medical device supplier shall install emergency off/stop switches in a position accessible to a person working in the equipment room.

#### 4.6 Contactor control circuit

All three-phase equipment shall be supplied via a contactor that is switched on by a green momentary push button using a self-holding circuit. This self-holding circuit shall be disconnected by means of a red push button or failure of the incoming supply.

At least one red emergency off button shall be provided in the contactor control circuit. Additional emergency off buttons may be added to the circuit as necessary. These buttons may incorporate protective shrouds to prevent accidental activation and a twist-to-release mechanism. One contact of the red emergency off button shall be normally closed and part of the self-holding circuit. Other contacts may be needed, as specified by the medical device supplier.

The emergency off button shall override all other functions of the installed imaging equipment, remove the mains supply to the room or location and terminate radiation.

Some manufacturers require additional contacts in order to initiate a graceful switch-off to maintain data integrity. This involves maintaining the supply to parts of the equipment for long enough to store data in a non-volatile memory.

Label the contactor on/off switches as '**main equipment on/off**'

Label the red emergency switches '**emergency off**'

When more than one medical device system is located in the same room/area/location, there shall be one mains contactor controlling the supply to the entire room, labelled 'emergency off'. Where individual equipment on/off controls are also provided they shall be suitably located and clearly identified to discriminate between the systems.

#### 4.7 Over-current protection

Over-current protective devices or fuses shall be rated to protect conductors on the load side of the protective device. They shall also have a time/current characteristic specified by the medical device manufacturer. The supplier shall quote the medical device manufacturer's time/current characteristics.

See [Appendix 1](#) for more information on fuses and over-current protection

#### 4.8 Mains supply monitoring

It is recommended that three-phase supplies feeding medical devices have a phase rotation and voltage monitoring device installed, except where such a device forms part of the installed equipment. This device shall prevent the contactor from energising with:

- under- or over-voltage condition on any phase
- incorrect phase sequence
- phase loss
- neutral loss
- phase-neutral faults.

The under- and over-voltage limits shall be provided by the equipment manufacturer. The monitoring device shall be interlocked to prevent disconnection of the supply during an exposure.

The monitoring device will also prevent damage caused by incorrect connection of the phase or neutral conductors. The identification colours for electric cables were changed on 31 March 2004. The changes are covered in amendment No. 2 (2004) of BS 7671:2001 'Requirements for Electrical Installations' [1]. It allows wiring with the new colours to be connected to wiring with the old colours, and calls for warning labels to be fixed close to the point of interconnection.

## 5 Earthing and equipotential bonding

### 5.1 General

The earthing and equipotential bonding conductors terminating on the ERB shall not intentionally carry load or control currents.

The impedance from phase to neutral and phase to earth of the supply shall be equal to or less than the impedance between phases.

### 5.2 Equipotential bonding system

Equipotential bonding and protective earth continuity between equipment and the associated mains supply isolator(s) shall not depend solely upon the continuity of conduits, cable braiding, ducts or trunking; it shall be achieved by means of a dedicated copper earth cable connected with brass or copper fittings.

### 5.3 Supplementary equipotential bonding

Supplementary equipotential bonding conductors shall be installed as specified in section 2.13 of Annex 1 (see separate document).

Equipotential bonding is necessary to prevent significant touch voltages within the patient environment. See section 2.4.9 'Patient Environment' in Annex 1 and drawing C 'Example of patient environment' also in Annex 1.

### 5.4 Earth Reference Bar (ERB)

An earth reference bar (ERB) shall be provided. The ERB installation shall comply with the following requirements:

1. The mains supply protective earth conductor entering the location shall be terminated at the ERB.
2. The ERB shall be close to the mains supply isolator except with MRI units.
3. The ERB shall be installed in an accessible position, to facilitate easy visual inspection and testing, not higher than 1.8 m and not lower than 1 m measured from the floor. The ERB shall not be fitted where other equipment, such as medical device cabinets or furniture, restricts visual inspection.
4. The ERB shall be installed in a dedicated enclosure, with a cover that requires a tool to open it and is permanently marked 'Earth Reference Bar' or 'ERB'.
5. The ERB shall contain one or more (see Figure 1) copper connection bar(s) insulated from the building earth, having a cross sectional area capable of carrying the maximum predicted short circuit current. The connection bars shall be connected to the incoming earth conductor by means of flexible removable links, which will facilitate the use of a current-measuring probe. The links shall have a

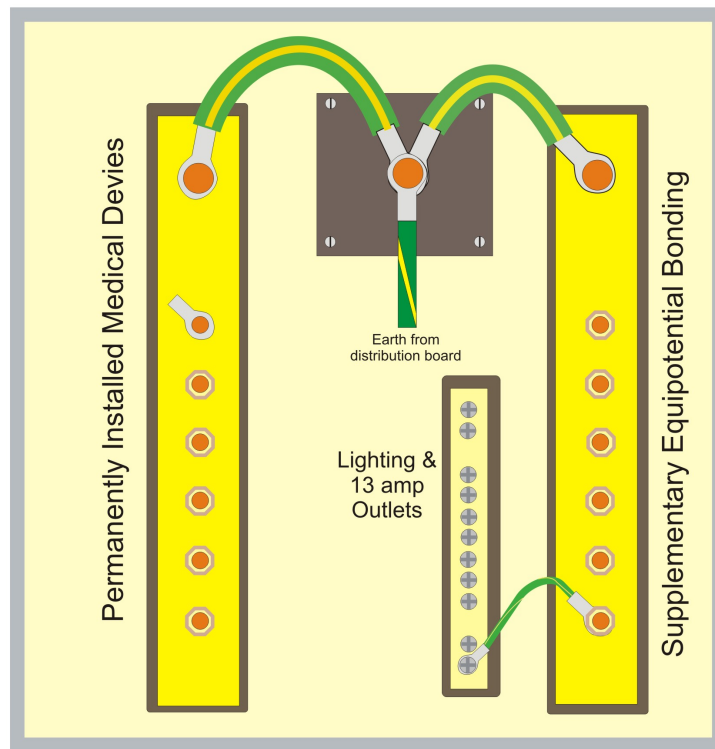
cross sectional area sufficient to carry the maximum rated current. The additional smaller bar (see Figure 1) to accommodate the protective earth and equipotential bonding conductors from the socket outlets shall be rated to carry the maximum short-circuit current of the socket outlet supply.

6. Each protective earth and equipotential bonding conductor shall be separately terminated and connected to the relevant connection bar.
7. Crimped connections of circuit protection and potential equalisation conductors shall comply with [section 4.4 'Crimped connections'](#) of this document.
8. All circuit protective earth and equipotential bonding conductors shall be identified and a list of connections made, a copy of which shall be available in the ERB cabinet. Protective earth and equipotential conductors from the socket outlets shall be identified as either 'Medical Location of Group 1' or 'Medical Location of Group 2', as appropriate.

Group 0 is a medical location where no applied parts are intended to be used.  
Group 1 is a medical location where discontinuity of supply is not a threat to life.  
Group 2 is a medical location where discontinuity of supply can cause danger to life.

9. All exposed conductive surfaces of installed equipment shall be earthed to the ERB. This includes the enclosures of warning lights, injectors, water baths, contrast media warming equipment, viewing boxes, powered drug cabinets surgical lamps etc. All such items shall be returned to the ERB by means of a cable having a cross sectional area sufficient to ensure that the bonding resistance between the ERB and the earth connection on any installed device is less than  $0.1 \Omega$  (this includes the earth receptacle of all 13 A mains outlets) or as specified by the equipment manufacturer. Also see [section 5.6 'Connections to the ERB'](#).
10. All fixed non-powered equipment with metal surfaces (extraneous conductive surfaces) shall be similarly bonded to the ERB. This includes protective screens (including wings), metal sinks and work surfaces, air transfer grills, medical gas outlets, heating pipes and radiators, water pipes, drug cupboards, ceiling mounted hardware, conduits, trunking and cable trays, steelwork above the ceiling line (Unistrut or Marstrut for example) (cross-bonded), steel or wire basket cable trays, steel floor ducts (lids to be fly-lead tagged), steel floor plates (in or below floor line), metal support plates, metal cable outlet plates, metal suspended ceiling tiles (cross-bonded), 'computer' flooring (cross-bonded). All such items shall be returned to the ERB by means of a cable having a cross sectional area sufficient to ensure that the bonding resistance between any two conductive surface in the room is less than  $0.2 \Omega$ . Earthing by means of trunking, conduits or screening alone is not permitted, a copper conductor shall be provided.

Where possible, the lead screening installed to provide radiation protection for the room should be earthed by connecting it back to the ERB, even when the lead is covered by wood or plaster board. This is to ensure that any objects mounted on the walls do not become interconnected via the fixings.  
Existing installations may be difficult to earth, but where new builds are planned, it is recommended that provision be made for the lead panels to be earthed by means of copper braiding (min 5 x 0.7 mm) during the course of installation.



Left Earth Bar	Lighting & 13 amp Outlets	Right Earth Bar

**Figure 1: Typical Earth Reference Bar layout**

## 5.5 Construction of the ERB

Where more than one protective earth or equipotential bonding conductor is required for a medical device or complete medical device system, the insulated copper connection bars shall be provided as specified below:

### **1<sup>st</sup> earth connection bar:**

Equipotential bonding and protective earth conductors from all permanently installed medical device(s) or modules of a system.

### **2<sup>nd</sup> earth connection bar:**

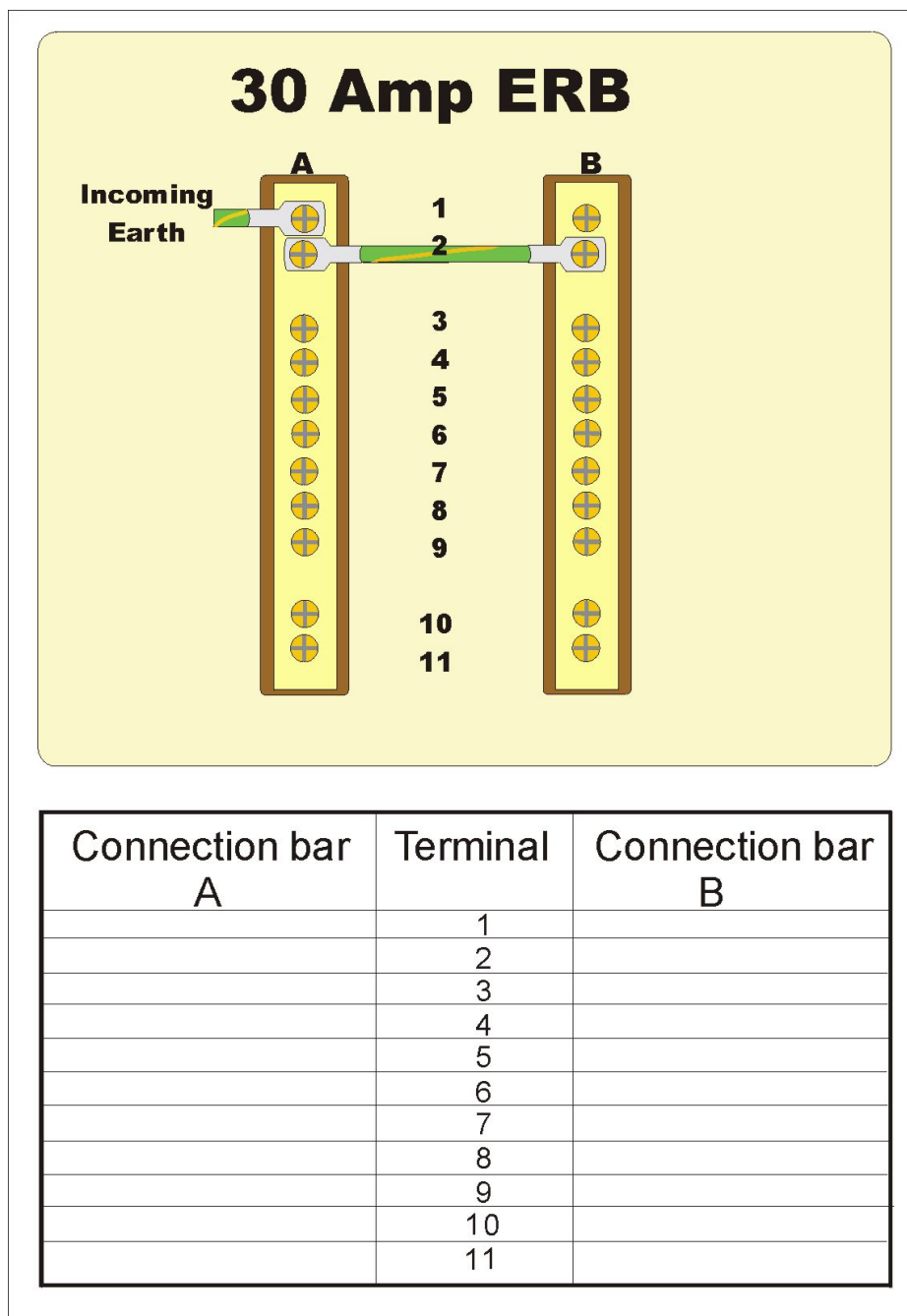
All equipotential bonding and protective earths other than the installed medical device(s). A smaller supplementary connection bar can be connected to this bar to accommodate protective earths and equipotential bonding conductors from socket outlets.

### **3<sup>rd</sup> short earth connection bar or isolated brass earth stud:**

Incoming mains supply protective conductor.

The links shall be configured to allow the earth leakage currents to be measured either by breaking the connection between either the earth connection bar and the incoming earth conductor or by means of a current probe.

In many cardiac or angiographic installations the installed equipment connected to the 1<sup>st</sup> earth bar will be isolated from earth, and will be earthed only via the ERB. This is to prevent circulating currents from the building earths from flowing through the network of earth conductors that make up the complete installation.



**Figure 2: A 30 A Earth Reference Bar**

Figure 2 shows a suggested design for a simplified ERB suitable for use in a mammography or dental room, for example. In many installations of this type, the imaging equipment will have only one connection to earth, which would be taken to terminal 3A. The other installed devices, for example the dental engine, etc. would also be earthed to the terminals on connection bar A. The equipotential conductors and earths from the socket outlets would be taken to connection bar B.

## 5.6 Connections to the ERB

Each equipotential conductor and protective conductor shall be individually permanently labelled and identified. A record sheet shall be prepared, which may be used to identify each connection to the connection bars.

The copper connection bars shall be of sufficient cross sectional area to carry the maximum predicted short circuit current, and shall have tapped holes able to take studs mechanically and electrically compatible with the peak current and cable size.

Crimped connections shall comply with [section 4.4 'Crimped connections'](#). The crimped terminals shall be attached to the connection bars with brass studs or machine screws and flat brass washers; they shall all be of matching size.

The mains supply circuit protective conductor shall be connected to the mains supply distribution board at the source of supply at one end, and the ERB at the other. Connection to the source of supply can be via a local distribution board, providing there is a continuous copper conductor of sufficient CSA from the local board back to the source of the supply.

The earth impedance between the earth connection of installed equipment, the earth pin of any socket outlet earth and the ERB shall not exceed 0.1  $\Omega$ . Refer to [section 11 'Testing and verification'](#).

The ERB is to be mounted in an enclosure that can only be opened by means of a tool. The enclosure shall be labelled 'ERB' or 'Earth Reference Bar'. If a metal enclosure is used, both the door and the enclosure shall be earthed to tags on the equipotential earthing bar via a copper braid or a flexible cable.

The connection of installed equipment to the ERB shall be in accordance with the manufacturer's instructions. Where the manufacturer has specified that installed equipment be earthed only via the ERB, suitable insulation materials shall be used to isolate the installed equipment from earth. On completion of the mounting of the equipment, the link to earth shall be removed, and the insulation resistance to earth measured. The resistance value shall be measured using a 250 V high resistance ohmmeter.

## 5.7 Socket outlet equipotential bonding

The installation of socket outlets shall ensure that the circuit protective conductors together with the equipotential bonding conductor achieve an earth resistance value of less than 100 milliohms between any socket outlet and the ERB.

Providing these resistance values are less than 100 milliohms, ring-type mains are permitted, provided that both ends of the ring are terminated at separate terminals on the ERB. The use of dual earth sockets will aid connecting the larger earth conductors that may be required.



## 5.8 Magnetic resonance requirements

The ERB shall be located on the equipment room side of the Faraday cage at the earth connection point specified by the manufacturer. The brass stud used to connect each side of the Faraday cage is deemed to be the incoming earth to the diagnostic room. This stud shall be securely connected to the Faraday cage. The ERB enclosure shall be non-metallic to prevent interaction with the high magnetic field. The supply-side conductor shall be one cable directly connected to the incoming supply equipotential conductor.

A distributor connection bar shall be installed to facilitate equipotential bonding in the diagnostic room. See Figure 14 in the Glossary.

## 5.9 Ancillary electrical equipment

All ancillary electrical equipment with accessible metal parts shall be earthed to the ERB by means of a cable. Earthing by means of trunking or conduits alone is not acceptable.

## 5.10 Medical gases

Where a medical gas pendant is installed within the patient environment then an equipotential bonding conductor shall be connected between the incoming gas supply and the ERB. For further information see Annex 1, Part 3, diagram C (separate document).

# 6 Socket outlets

## 6.1 Numbers and positions of socket outlets

**Domestic extension mains leads shall not be used in any part of the installation.**

An assessment shall be made of the number of socket outlets needed for the medical procedures which may take place in the area of the fixed installed medical equipment. This assessment shall be undertaken in consultation with installation, clinical and engineering staff.

The number and location of socket outlets, including those in the control area and any other equipment rooms, shall be sufficient to avoid the need for extension leads and trailing wires, taking account of possible extra equipment such as computers that act as part of the hospital information technology system and image display equipment. The assessment shall also establish how many of the socket outlets need to be on isolated power supply (IPS) circuit(s) and how many on the normal TN-S supply. Either un-switched or double-pole socket outlets shall be used in conjunction with IPS circuits. See Annex 1 section 2.22.1 (separate document).

The maximum permitted rated output of a medical IPS is 10 kVA, and so the total loading on the supply shall be calculated assuming that the normal range of devices are in use in the location. Where this value is within 20% of the maximum output of the

IPS, a second IPS shall be provided, the output sockets being divided between the two IPS units.

More information on IPS/UPS systems can be found in [Appendix 4](#).

For circuits protected by residual current devices (RCD) consideration shall be given to the risk that aggregation of leakage currents from many items of equipment connected to the same circuit may cause unwanted tripping of the RCD. For further details refer to Annex 1 section 2.9.1.1.2 (separate document).

More detailed information on the use of RCDs is provided in [Appendix 2](#).

From the design assessment, design guidance shall be followed in accordance with Annex 1 (see separate document) and the other documents referred to in [section 3.1](#) for the installation of socket outlets.

Tower-mounted socket outlets shall be mounted at least 100 mm from the floor to the bottom edge of the lowest socket outlet.

Tower-mounted socket outlets may be the best way of providing sufficient socket outlets close to the patient position, for example, in cardiac catheter labs, where a device such as a c-arm may be obstructed by ceiling-mounted socket outlets.

It is recommended that the IPS socket outlets shall be double pole or un-switched, clean earth sockets, colour-coded blue, engraved in white lettering 'Medical equipment only'. If white sockets are preferred, they shall be mounted on a blue background, approximately 2 cm larger than the socket. The socket to be engraved 'Medical equipment only' in blue. The use of these socket outlets to connect equipment not complying with IEC 60601-1 (BS EN 60601-1) [3] in the patient environment is to be avoided. The non-compliant equipment can possess high earth leakage currents resulting in a higher risk to patients.

## 6.2 Back-boxes

Plastic back-boxes shall be used in diagnostic or treatment rooms for 13 A socket outlets in order to isolate the mains earth connection from the building earth. Where existing metal back boxes are to be used, 'Clean earth sockets' shall be fitted.

More detailed information on 'clean earth' sockets is found in [Appendix 3](#). It is essential that the correct type of socket is used, since not all so-called 'clean earth' sockets are capable of achieving the desired isolation.

## 6.3 Socket outlet cable(s)

Socket outlet earth cabling shall be of sufficient size to ensure that the earth impedance is less than 0.1  $\Omega$  from socket outlet to ERB. The cable run shall be as short as possible.

It should be noted that if standard 2.5 mm twin-and-earth cable is used, the resistance of the earth conductor will be in the order of 8 milliohms per meter, giving a maximum run length of 12 m for a radial or 24 m for a ring, providing that both ends are connected to the ERB. It is recommended that a minimum of 6 mm<sup>2</sup> earth cable is used, which will reduce the cable resistance to 3 milliohms per meter. This will give a maximum run length of 33 m for a radial or 66m for a ring.

## 6.4 MR diagnostic rooms

Reference shall be made to section 607 of BS 7671 [1], re filter installation and high leakage circuits. If IPS systems are to be installed, they should be limited to two socket outlet sub-circuits, to minimise system to earth capacitance levels. Designers/installers shall provide the IPS supplier with filter capacitance system-earth values and any bleed (discharge) resistors (quantity of and resistance values) which may be fitted within IPS sub-circuit filters. IPS suppliers shall be requested to provide confirmation that the IPS insulation monitors will be able to function correctly (without nuisance alarms) with the installed filters.

## 6.5 Device mounted socket outlets

Where device mounted socket outlets are provided as part of the medical device, the socket outlets shall, wherever possible, be on the same phase as the room socket outlets. Where this is not possible, signage warning of the voltage likely to be encountered should be mounted close to the socket. The supply to these socket outlets shall be via the device on which they are mounted, so that they do not remain live when the device is switched off.

Devices such as contrast injectors controlled by other medical devices shall be powered by a dedicated supply, via the controlling medical device.

# 7 Equipment wiring installation

## 7.1 Flexible power cables

Unenclosed flexible power cables shall be double insulated and shall be provided with effective strain relief. The unenclosed cables shall be of adequate length to prevent strain arising with articulated systems or equipment movements. It should be noted that increasing the length of the flexible power cable will increase the bonding resistance of the device that is being supplied.

## 7.2 Emergency off and emergency stop controls

The 'emergency off' switch shall remove all power to equipment in the room except for those situations outlined in [section 4.5](#).

The 'emergency stop' is a safety feature of the medical device, and its function will be determined by the manufacturer.

### 7.3 Illuminated X-ray warning signs

Illuminated warning signs as required by the Ionising Radiation Regulations 1999 [6] shall have both lamps supplied from the same phase. This should be the same phase as other single-phase devices within the medical location, except where the supply is derived from a transformer that forms part of the X-ray generator or when a SELV supply is used to power the lamps. Each door warning light box shall have an earth connected to the ERB of the room that it is associated with.

The switching arrangements, location, height, and number of illuminated warning signs shall be agreed with the local radiation protection advisor (RPA).

A fluorescent lamp shall not be used in the 'X-rays on' section of the sign, but may be used in the 'Controlled area' section.

## 8 Transportable diagnostic or treatment rooms

### 8.1 General requirements

This is intended for static vehicle use and does not apply to ambulances.

If a medical device is installed in a vehicle or built into a container that can be transported between sites, the environment is classed as a diagnostic or treatment room and is subject to the same requirements as a static room plus the additional points in this section

Electrical services associated with the vehicle or container shall be installed, tested and commissioned in accordance with all current legislation, standards, codes of practice and guidelines.

Mains wiring within the transportable room shall be finely stranded or Tri-rated

Tri-rated cables conform to BS6231 (BSI, UK) [7], type TEW (CSA, Canada) [8] and styles 1015, 1028 or 1283 (UL, USA) [9].

Where wiring passes through partitions or enclosures, the cable insulation shall be protected against the effects of vibration.

Transportable diagnostic or treatment rooms may be powered by an external generator, an internal generator or a fixed supply.

### 8.2 External electrical supply

The external mains supply source supplying the transportable room shall be TN-S, terminated in a BS EN 60309-2 [10] compliant switched socket outlet, which shall be housed in a suitable weather protective lockable enclosure (minimum IP44). The mains impedance to the socket outlet shall be measured and the value recorded. A label shall be fixed to the enclosure giving the mains impedance and voltage and current rating of the supply. Any power consumption meters shall also be housed in an appropriate enclosure.

The mains isolator shall be operated to isolate the transportable room before inserting or removing the mains plug to the external supply. A notice warning of the requirement to isolate the transportable room from the supply before connecting or disconnecting the room from the supply shall be fixed close to the stowage of the mains lead.

External electrical supply shall be in accordance with IEE Special Locations Guidance Note 7 chapter 17 [5].

The equipment supplier shall confirm that imaging equipment can operate correctly on the impedance measured.

### 8.3 Mains supply lead

The transportable room supplier shall provide a double-insulated mains lead that is of sufficient length, terminated with an impact resistant connector (minimum IP44). It is permitted to fit a mains lead with connectors at each end to facilitate rapid mains lead replacement as well as deployment and stowage. Alternatively, a cable storage drum may be provided to facilitate cable withdrawal and retrieval into the storage enclosure.

Three-phase systems require a five-wire supply cable; single-phase systems require a three-wire supply cable.

The supply lead and connector rating shall be of sufficient size to prevent significant voltage drop with instantaneous loads (e.g. X-ray exposure) along with other constant loads. The mains supply impedance shall meet the values specified by the medical device manufacturer.

The supply lead and connector will also be supplying the domestic load, which will be made up of air conditioning, heating, lighting and ancillary equipment, in addition to the medical device load.

Mains leads shall be routed to prevent entrapment from moving trailer parts such as the fold-away trailer sides.

The mains lead and its connectors form part of the overall electrical system. Changing the length and/or cross sectional area without the supplier's agreement could influence the mains impedance and thus prevent the medical devices from functioning correctly. The advice of the equipment supplier should be sought before changing the length or CSA of the mains lead.

The mains lead is not intended to withstand the wear and tear of traffic passing over it. If necessary, portable protective ramps, catenary system or other means shall be provided to protect the lead where it traverses roads or pathways in accordance with BS 7671 [1].

A label shall be provided on the connecting box, adjacent to the cable socket, indicating the measured mains impedance, a similar label shall be attached to the vehicle adjacent to the mains lead stating the maximum impedance that the vehicle can operate on, this value shall be specified by the equipment supplier.

## 8.4 Generator supply

When a new transportable room is to be constructed, incorporating a single-phase X-ray generator, a single-phase generator shall be specified that is capable of providing both the constant load of the domestic supply and the impulse load of the X-ray generator. This will ensure that there is only a single-phase supply throughout.

## 8.5 External mains supply: protective devices

The power supply to the transportable diagnostic or treatment room shall include an RCD. The RCD shall have attached to it a blue label bearing the inscription 'Press the RCD TEST button every time the unit is connected' in large white font.

If an exposed-conductive part is not connected to a circuit protective conductor, in the event of a fault, even if the circuit is protected by a 30 mA RCD, the fault will not be cleared until the equipment is touched. This puts a person's life at risk, staked against the reliable operation of the RCD.

## 8.6 Earthing of transportable diagnostic or treatment rooms

A low impedance earth from the mains supply or from the generator shall be provided via the mains cable. Earth rods, i.e. metal rods inserted into the ground to connect a cable to ground potential, shall not be used.

In order to provide a low impedance earth path that will enable the RCD to operate in the event of a fault, a small CSA ( $\sim 10 \text{ mm}^2$ ), double insulated, high flexibility cable shall be connected between the trailer and the mains supply outlet, before the mains cable is plugged in.

The continuity and quality of earth shall be tested at least whenever the transportable room is moved to a new location.

Both the continuity and quality of the earth shall be tested and the results recorded, as part of the maintenance of the transportable room. An earth-neutral loop test may be carried out to test the earth provision.

# 9 Application of standards

## 9.1 Interconnected medical devices

This section applies if the main medical device:

- supplies power (at mains voltage or any other voltage) to any separate items of medical or non-medical electrical equipment; or
- has signal connections (direct or via a network) to any separate items of medical or non-medical electrical equipment.

If all such items are supplied by the manufacturer of the main medical device and are intended by the manufacturer to be assembled into a system, the power and/or signal connections shall be made in accordance with the manufacturer's instructions.

In this case, the manufacturer is responsible for the safety of the assembled system. Manufacturers can generally be expected to apply BS EN 60601-1-2006 [3], but are entitled to achieve safety in other ways if they choose.

In all other cases the installer shall make the power and signal connections in accordance with the requirements of BS EN 60601-1-2006, Section 14 [3].

## 10 Data network connections

### 10.1 Background

This section refers to a data communication system that exchanges data with the medical device. The manufacturer is responsible for any issues inside supplied equipment that is CE marked to the Medical Devices Directives [11]. Currently, IT equipment such as a PC will not be classified as a medical device although it can be, if the manufacturer so desires. Software such as the Patient Records or Radiology Information System (RIS) is not covered by any single regulatory body.

### 10.2 Data connections to medical devices

If the medical device is to be connected to a data network, the device installer shall ensure that the network data connection point is in accordance with relevant information provided by the device manufacturer, that the network data connection point itself satisfies any requirements specified by the device manufacturer and ensure that the requirements of BS EN 60601-1-2006 [3] are satisfied. In particular see guidance in the standard BS EN 60601-1-4:1997 'General requirements for programmable electrical medical systems' [12].

Under CE marking medical device manufacturers will provide sufficient information for preventing any adverse effects on the safety, functions or performance of the medical device resulting from connection to a data network. Such information may include the characteristics of the network necessary for the medical device to perform as intended, and information on potential hazards if the network fails to provide these specified characteristics.

Where a medical device is to be connected to an external network, an isolator compliant with EN 60601-1 [3] may be required in order to provide the necessary degree of isolation. In some cases isolators may also need to be inserted into USB, RS232, and printer connections. A range of suitable products are available, capable of operating at up to 1,000 Mbits/s.

## 11 Testing and verification

### 11.1 General

Testing and verification shall be carried out by a Competent Person in accordance with BS 7671 'Requirements for electrical installations' [1], including Amendment No. 2 2004 (the form in [section 11.10](#) in this document may be of value).

Results of the testing may be recorded in paper or electronic form, but in either case the information shall be available to the healthcare organisation responsible for the equipment before the first use of the equipment/installation and throughout the life of the installation.

### 11.2 Cable terminations (crimps)

Every crimped termination that is part of the medical device electrical installation (covered by this document) shall be inspected to ensure that it is terminated in a manner that will ensure that the minimum resistance will be added to the circuit.

Check that all cable ends have been crimp tagged using a compatible ratchet crimp tool. Where barrel terminations are provided, bootlace terminations should be fitted.

Inspect each crimp – the cable ends shall not be folded back. Crimp tags should be of the correct size to enable all conductors to be included in the crimp. The tags should be firmly tightened on the appropriate terminating studs, which shall be of brass, and fixed via tapped holes to the connecting bar with brass nuts and washers. Bolts, studs and tags should be of matching size. See [sections 4.4](#) and [5.6](#).

### 11.3 Phase rotation

Medical devices and associated circuits may be phase sensitive and confirmation of the direction of phase rotation shall be ascertained as early as is possible.

Where necessary, the three-phase supply shall be tested for phase rotation, using a phase rotation meter, at the mains supply terminals of the medical device on completion of the pre-installation phase. The medical device installer shall also complete this test.

If phase rotation is incorrect, the pre-installer shall take action to ensure the phase rotation is correct by altering the cable connections at the load side of the Isolator. Phase rotation shall then be re-checked, and the results recorded.

This will ensure the phase relationship is correct at the medical device mains supply terminals.



## 11.4 Mains supply voltage

On completion of the pre-installation, the mains supply voltage phase-to-phase and each phase to neutral shall be measured and the results recorded.

## 11.5 Mains phase impedance

Imaging equipment will normally require the mains impedance to be accurately measured in order to ensure that the specified performance of the unit is met. This shall be done on completion of the pre-installation work.

For a three-phase unit the mains supply impedance between each phase combination (L1-L2, L2-L3, L3-L1 together with the L1 to N, L2 to N, and L3 to N.) shall be measured and recorded. In the case of single-phase supplies, the impedance from the phase to neutral shall be measured. If the measured value is outside the range specified by the medical device manufacturer, action shall be taken to bring the supply impedance into the specified range. This will usually involve increasing the cross sectional area of the mains supply cable.

## 11.6 Single-phase supplies within the diagnostic or treatment area

Test that all TN-S single-phase supplies in the diagnostic or treatment room or area are connected to the same phase; where possible this should include socket outlets mounted on any equipment. One socket outlet in the room shall be deemed as a reference socket outlet for the purpose of this test.

Where the single-phase supply is protected by an RCD, the RCD shall be tested as part of the normal routine maintenance procedure. The RCD should be tested by pressing the 'Test' button. Any RCD that does not terminate the supply when the button is pressed shall be replaced.

**Note** There will be a phase difference between the live of the TN-S supply and either side of the IPS supply.

## 11.7 Earthing and supplementary equipotential bonding

Earthing and equipotential bonding connections shall be inspected and tested to verify that the requirements set out in this document have been satisfied.

The measurement of resistance alone does not prove compliance, because paths additional to that deliberately provided through the network could exist and could obscure the fact of inadequate conductivity in the qualifying path. Inspection of design and construction is an essential step in the verification process.

The resistance shall be measured with an earth continuity tester between each protective earth terminal, socket outlet or every accessible metal part and the ERB. The maximum acceptable resistance in this test shall be 100 milliohms  $\pm$  10%. A minimum current of 0.1 A shall be used.

Testing of the socket outlets can be achieved by using a meter lead connected to the earth pin of a 13 A plug to check the total resistance (including insertion resistance) of the socket outlet (the other meter lead shall be connected to the ERB). The resistance value obtained using a standard earth pin may be different to that obtained by inserting a test probe into the socket.

### Touch voltages

The voltage between the ERB and every accessible conductive surface (referred to as the touch voltage) at the patient location shall be measured using a high impedance digital voltmeter:

1. with the medical device switched off
2. with the medical device switched on
3. with radiation exposure with X-ray equipment (high load)

X-ray units draw very little current when in standby but this can increase to over 400 A during a maximum rating exposure. This high current can induce voltages in the earth cables of certain devices, which will only be present for the duration of the high current pulse. In order to show up these high touch voltages, a long duration mid-range exposure, for example 80 kV, 1.0 s, 50% of the maximum mA, should be made. In order to keep the number of exposures down to an acceptable number, the tests can be limited to only those conductive surfaces within the patient location. The operator will need to pause between each exposure in order to let the tube cool down.

**Note:** A person competent to operate an X-ray unit shall be present in order to carry out this part of the test.

The measured values shall not exceed 100 mV DC/AC 50 Hz except in the case of a location that may be used on a patient undergoing a procedure that involves the placing of a catheter, guide-wire or pacing lead into the central circulatory system, where the maximum is **10 mV**. However it should be noted that this can include the most basic type of imaging equipment, if it is being used to examine patients on life support.

These touch voltage values include the accessible metal parts of any socket outlets such as the mounting screws and front plates (not the socket outlet contacts).

The aim of this test is to check whether any significant voltages exist between metal parts in the patient environment and the ERB. The MHRA has evidence of inadequate earth bonding of medical devices. In one example, the high touch voltage was due to the room mains supply and the installed medical device supply coming from two different sub-stations.

One common cause of excessive touch voltages may be a neutral-to-earth fault at some point in the mains supply system, resulting in the creation of an inadvertent TN-C-S supply.

A TN-C-S system is one in which earth and neutral are common over part of the system. In many cases this arises due to a fault in some remote location. The effect of this is to inject part of the load current into the earth system, which will result in potential differences occurring between various earth points; this will vary depending on the amount of current flowing at the time, and will give rise to a fluctuating high touch voltage. See entry in the glossary under '[Electrical systems](#)' for more details.

## 11.8 MR diagnostic rooms

The measurement of touch voltage and bonding resistance, together with visual inspection of the electrical installation, shall take place before the magnetic field is energised, in order that any alterations in the wiring that may be needed can be performed. The measurements shall be repeated once the installation is finalised, using the procedure outlined in [Appendix 5](#). The same method shall be used when carrying out the annual checks. The bonding resistance shall be less than 100 milliohms from the earth stud on the scanning room side of the RF screen and all accessible conductive surfaces in the room, and similarly less than 100 milliohms from the ERB to all accessible conductive surfaces in the equipment room. (The resistance from the ERB and the earth stud on the scanning room side of the screen can be expected to be less than 10 milliohms). Where the installation is to be used for patients likely to be on life support or undergoing an interventional procedure, the touch voltages shall be less than 10 millivolts. Otherwise a maximum touch voltage of 100 millivolts is permitted.

There is likely to be a small window of opportunity between the completion of the installation and the magnetic field being energised when any changes to the wiring that are needed may be carried out by the installer. Work of this nature is very difficult once the magnet is switched on. Battery operated milliohmmeters are available that are capable of functioning in association with MRI units running at below 1.5 T. But the use of these instruments should be limited to trained personnel.

## 11.9 Authorised and Competent Persons

The inspection and testing of the installation shall be carried out by a suitably appointed 'Competent Person'.

This person shall be assessed and appointed in writing by the 'Authorised Person (LV)' who shall verify that the proposed Competent Person possesses the necessary technical knowledge, skills and experience relevant to the nature of the installation to be tested and includes a knowledge of the requirements of the MEIGaN document.

## 11.10 Form 1 Example test sheet collection form

Details of all measurements are to be recorded and stored on site on the following form

**Site name**

**Room**

	<b>Pass</b>	<b>Fail</b>	<b>Failure description</b>	<b>Final pass</b> (use if all pass first time)	<b>Reference documents</b> (insert doc name & ref)
BS7671 2001 (2004)					
Additional requirements of IPS circuits if installed					
Touch voltages					
Phase rotation					
Equipotential bonding					
Cable crimps					
Specific tests Door warning lights on same phase (e.g. X-ray/laser)					
Socket outlets and lighting on same phase					

Testing electrician details

Name:

Job title:

Employer's details:

BS7671 2001 (2004):

Competency passed and up to date?

YES / NO (circle one)

Certificate number:

Issued by:

Signature:

Date:

Final pass (or no fails during first test)

**Signature:**

**Date:**

## 12 Mechanical and engineering requirements

### 12.1 Guidance concerning pre-installation work

The installing company shall specify to the purchaser any required pre-installation work by way of and including, for example, working drawings showing the provision of electrical and other supply points, electrical interconnections, ceiling fixings and floor mountings, and all features necessary to enable the installation to comply with MEIGaN.

**Note:** Several of the requirements in MEIGaN relate to features of installations which in certain cases will properly form part of the pre-installation work. The responsibility of the pre-installation contractor for compliance with such requirements shall be discharged wholly or in part by the appropriate specification of pre-installation work. Items that are not included in the specification for pre-installation work will be the responsibility of the **installing company**.

#### 12.1.1 Room preparation

All room preparation that may result in the generation of significant amounts of dust, including cement work, plastering, painting and decorating, sanding down, shall be completed before the equipment to be installed is unpacked. Where this is not possible, the equipment shall be sealed in plastic sheeting, until such time as the work has ceased and the dust has been eliminated.

#### 12.1.2 Pre-installation work inspection

The installing company shall inspect the pre-installation work and shall not proceed with the installation if it is believed or suspected that its condition is incompatible with the safety or reliability of the completed installation. The installing company may consult MHRA in the event of difficulty in reaching agreement with the purchaser on measures to be taken to enable installation to proceed.

#### 12.1.3 Drawings and documents

Copies of all documentation and drawings relating to the installation and pre-installation work shall be made available to the purchaser in a form that is accessible to the purchaser.

### 12.2 Mechanical safety

The installation shall comply with BS EN 60601-1:2006 'General requirements for basic safety and essential performance' [3].

#### 12.2.1 Components

All components and materials to be used for installation and pre-installation work shall be specified by the installing company. Consultation with the pre-installation contractor may be appropriate.

#### 12.2.2 Security

The security of all attachments and fastenings **shall** be safeguarded by the use of locking devices to prevent them from loosening or becoming detached after assembly.

### **12.2.3 Protection against corrosion**

All components that are susceptible to corrosion shall be suitably protected.

## **12.3 X-ray room provision**

Main doors into the X-ray room shall be provided with self-closing mechanisms in order to comply with radiation protection requirements. The same doors may also require stay-open detents to assist in the movement of patients in wheelchairs and beds into the rooms.

### **12.3.1 Ceiling mounted equipment**

The equipment supplier/installing company shall provide a full specification for the installation of ceiling mounted equipment, giving the total weight to be supported, location and mechanical specification of fixing points and all relevant tolerances. Ceiling mounted equipment shall be installed in such a way as to ensure that no uncontrolled movement will take place when the mains supply is turned off.

### **12.3.2 Cooling and ventilation**

Equipment shall be installed in such a manner as to ensure that the ventilation holes or grills are not obstructed, and so that any filters can be removed for inspection and cleaning without difficulty. Where equipment is installed in a separate equipment room attention shall be paid to the pattern of airflow in the equipment room to ensure that localised overheating cannot occur.

## **12.4 Mechanical inspection**

The installation shall be inspected on completion to ensure that there are no sharp edges or burrs that could cause harm to either patients or staff.

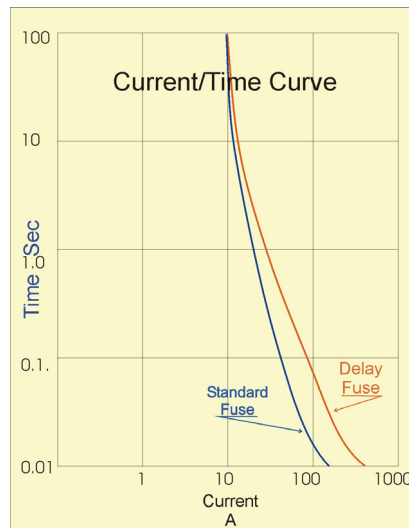
## Appendix 1 Over-current protection

Over-current protection is achieved by means of either a fuse or a miniature circuit-breaker (MCB). It should be noted that both of these devices limit the time for which over-current can flow. They do not limit the current.

In its simplest form, a fuse is simply a short length of wire of a cross sectional area much less than that of the wiring downstream from the fuse. Current flowing through the fuse will heat up the fuse wire to a temperature greater than that of the wiring. If sufficient current flows, the fuse wire will melt and the circuit will be broken. The fuse can be repaired by replacing the wire with a new length of similar CSA. Many household fuse boxes use simple rewireable fuses of this type, although it is prone to abuse, the householder using any available length of wire with little regard for the correct CSA.

More accurate fusing is possible using a cartridge fuse, in which the fusible element is enclosed in an insulated tube. By selecting not only the CSA of the wire but also the length, material and shape of the fusible element, the characteristics of the fuse can be tailored to meet the requirements of the application. The graph in Figure 3 shows the time/current curve for two typical cartridge fuses, the blue line representing the standard fuse and the red line, a delay fuse. Both fuses have a nominal rating of 10 A. It can be seen that at a current of 10 A the fuse will not blow, but if the current is increased to about 20 A, the fuses will both blow after a couple of seconds.

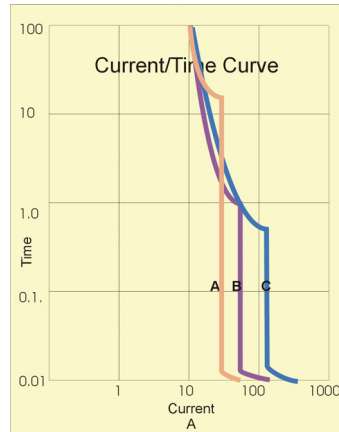
For a current of 50 A, the standard fuse will fail after about 0.1 s, whereas the delay fuse will continue to function for approximately 1.0 s. If the fuse is protecting a circuit that has a high inrush current, the standard fuse may well cause nuisance failure due to the high current that can occur should the switch-on point coincide with the peak of the supply voltage.



**Figure 3: Cartridge fuse time/current curve**

This is much less likely to occur when a delay fuse is fitted, since the fuse can carry a much higher current for a short time. At currents close to the maximum rated value both fuses will fail at about the same time.

Miniature circuit-breakers are available having similar characteristics. The characteristic curves are classified as type A, B or C. The diagram in Figure 4 shows a comparison of the three curves. Type A is in effect a rapid action device, the type B MCB can be considered to be a general purpose device, and type C a delay device. Although the shape of the curves for MCBs is different to that of fuses, in operation the results are much the same.



**Figure 4: Miniature circuit breaker time/current curve**

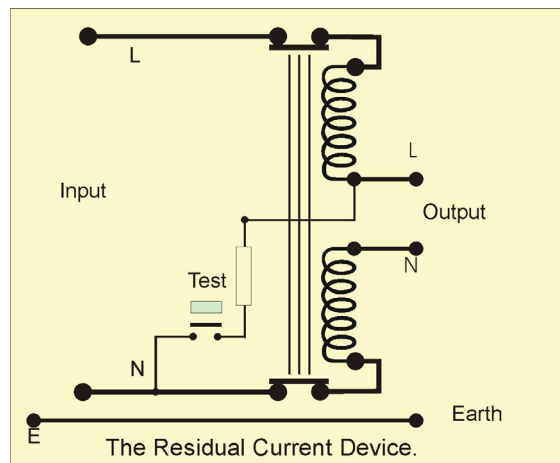
In order to provide over-current protection it is essential that the correct type of fuse or MCB is fitted. Fitting an incorrect type can either damage the device or cause unnecessary failures. MCBs have the advantage that they can be reset by simply pressing the button, so that there is less chance of an incorrect fuse being fitted. On the other hand, the user may not always report a fault, until it has occurred a number of times since it is easier to simply reset the MCB each time that it trips.



## Appendix 2 Residual current device

A residual current device (RCD) is a switching device that is activated by a difference in the current flowing in the live and neutral conductors. Any imbalance will cause the device to trip, disconnecting the supply.

Figure 5 shows a simplified diagram of the construction. The two windings produce opposing magnetic fields that will cancel out, giving zero net magnetisation. If the current flowing in the live winding exceeds the current flowing in the neutral winding by more than a predetermined amount, the contacts will snap open and remain open until the RCD is manually reset.



**Figure 5: Simplified diagram of an RCD**

The test button connects a resistor between the live conductor and neutral of a value designed to give a current flow just above the operating threshold of the RCD. This will cause the device to trip. The operating tolerance of an RCD is wide; it should not operate at 50% of the rated current but should operate within 300 ms at a current equal to the rated current and within 40 ms at a current equal to five times the rated current. In order to minimise the chances of unnecessary tripping the expected earth leakage current (which will be the total leakage currents of the group of devices that are supplied via the RCD) should be less than 25% of the rated operating current.

The main equipment manufacturers will normally specify the characteristics of the RCD associated with their own areas of the complete installation. It should be noted that every device connected to the supply can be expected to have a certain leakage current, so that adding additional devices to a circuit will increase the normal leakage current and can lead to unnecessary tripping of the RCD. In order to prevent this, the circuit may need to be subdivided and a number of RCDs used.

RCDs should be tested by means of a suitable tester at least once per year. This will bring two benefits. First of all it will detect any RCD that is likely to fail. Secondly it will, by exercising the RCD mechanism, tend to keep it operating at the correct current.

In the United States, RCDs are known as ground fault circuit interrupters (GFCIs). In some instances the RCD is combined with an MCB (miniature circuit breaker) giving an RCBO. It should be noted that in this case the current rating of the MCB and the tripping current for the leakage current are specified separately.

### Appendix 3 Clean earth sockets

The 16<sup>th</sup> edition of the IEE Wiring Regulations (BS EN 7671 amendment No.2 [1]) require the fixing screws of all mains sockets to be earthed. This is normally achieved by a link that connects a metal insert in the fixing holes of the socket to the earth pin connection.

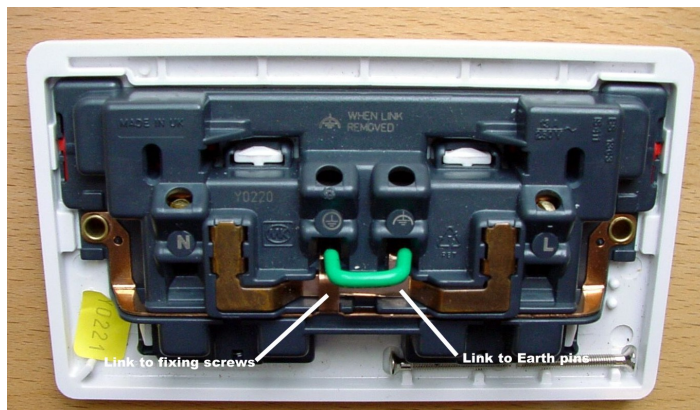
If a metal back-box is used that is in contact with the building earth, a large amount of current can flow through this path if there is a significant difference in potential between the earth reference bar and the building earth at that point. This problem is more likely to occur in an old building where there may be a link between earth and neutral somewhere in the wiring. The fault current can inject large amounts of noise into the equipment that is being fed from the supply.

The presence of this fault can often be demonstrated by measuring the touch voltage between the ERB and the earth of the portable device. This should be done using a digital volt meter without an IEC filter (see Glossary, Figure 15) (an IEC filter is not used when measuring noise). Anything greater than 10 mV should be investigated using an oscilloscope.

The problem can be reduced by eliminating the current path between the ERB and the building earth provided by the earth connection in the mains socket. This can be done in two ways:

1. The metal back-box can be replaced by a plastic one, so that the only earth connection will be via the earth conductor that goes back to the ERB.
2. By fitting a clean earth socket.

Figure 6 is a photograph of an example of a good clean earth socket. It can be seen that there is a link (green in this photograph) joining the earth pin to the connection bar between the fixing screws. When used with a plastic back-box this link should be left in place, so that the fixing screws are earthed. However, when a metal back-box is used the link should be removed and the fixing screws and back-box earthed separately back to the ERB. It should be done by means of an actual copper conductor and should not depend on the conductivity of the trunking or conduit.



**Figure 6: Example of a good clean earth socket**

Some of the devices that are sold as clean earth sockets are in fact double earth sockets, there are two earth conductor receptacles provided, which makes it easier to fit 2 x 6 mm<sup>2</sup> earth conductors. However, inspection will reveal that there is no means of separating the earths of the fixing screws and the earth pins. If this type of socket is used because of the need to use thicker earth conductors, plastic back-boxes shall be used if isolation of the mains earth from the building earth is required.

## Appendix 4 Uninterruptible power supply (UPS) and isolated power supply (IPS) systems

Although seen as a single unit, often referred to as an IPS/UPS system, they are made up of two separate units that have different functions. The UPS is an uninterruptible power supply, essentially a battery charger that converts the incoming AC supply to DC and uses it to charge a battery. The output from the battery is converted back to 50 Hz AC, which can then be distributed to essential items of equipment.

Since the purpose of the UPS is to ensure continuity of supply, provision is made to bypass the UPS in the event of failure or overload. In order to ensure that the UPS really is more reliable than the normal mains supply, the UPS shall be subject to regular preventative maintenance, and so shall also have provision for manual bypass, in order that the unit can be removed from service for regular inspection and testing to take place. The least reliable components are likely to be the batteries; the expected life of the batteries is stated in the manufacturer specification so that a planned replacement program can be set up. The specification will also give details of the operating temperature range. If the batteries are operating outside the temperature range stated, the operational life of the batteries will be reduced. The UPS may be powered from either the single-phase or the three-phase supply; the output will be single-phase. Although some early UPS systems used rotary converters, the devices now use much more efficient solid-state inverters. In addition, these devices are able to generate an accurate 50 Hz sine wave with a low harmonic content that is less likely to cause problems with sensitive equipment.

The amount of power available will depend on the capacity of the batteries used. Since the most appropriate battery for this type of application is still the lead-acid battery, the size and weight of the batteries required can be considerable, and shall be taken into consideration when designing an installation.

The incoming supply is monitored, so that an alarm is triggered in the event of supply failure. An alarm is also triggered if the unit goes into bypass. A further monitoring circuit triggers an alarm before the battery power is exhausted, so that there is some warning before the final failure of the supply.

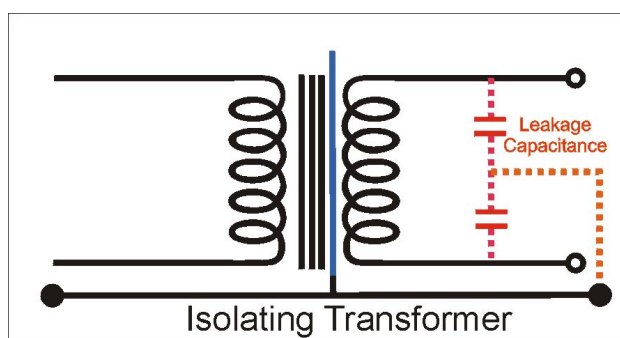
The output from the UPS can be used to power a number of isolated power supply (IPS) units. The medical IPS system will be equipped with an insulation monitoring device in accordance with IEC 61557-8 Electrical Safety in Low Voltage Distribution Systems [13] with the following additional requirements:

- the internal impedance shall be at least 100 k $\Omega$ .
- the test voltage shall not be greater than 25 V DC
- the test current shall, even under fault conditions, not be greater than 1 mA peak.
- indication shall take place before the insulation resistance has decreased to 50 k $\Omega$  for which a test device shall be provided.

Although more complicated than a simple isolating transformer, a medical IPS should always be used to provide an isolated supply in medical locations. This is because an isolating transformer will provide very little additional protection against both shock and failure of the supply. In some cases the addition of an isolating transformer can even reduce supply resilience.

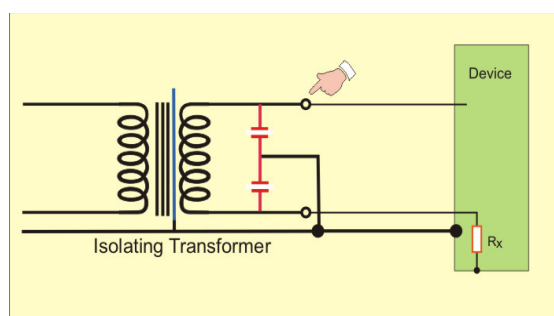
It should be understood that the output of an IPS is not, and cannot be, completely isolated from earth. There will always be some capacitance between both the transformer secondary plus the external wiring, and earth. It is usual for an isolating transformer to have a shield (shown blue in Figure 7) in the form of an insulated copper foil, between the primary and secondary winding, the purpose being to reduce the interference that is passed between the two windings. There will inevitably be some capacitance between this shield and the secondary windings.

**Figure 7: An isolation transformer showing the leakage capacitance**



There will also be a certain amount of capacitance between the wiring from the IPS to the outlet sockets and earth. All together, this is shown as the red capacitors in Figure 7. As a result, if a measurement is made using a digital multimeter, between either leg of the transformer and earth, a reading of approximately 50% of the transformer output will be recorded. The current flowing to earth will be low, since the capacitive reactance will be high at mains frequency. Although it will be possible to receive a painful shock if either side of the output is touched, there will not be sufficient current to cause electrocution, particularly where the current flow is hand to hand or hand to foot. However, if this current were to be conducted to the heart via a catheter or guide wire, there would be more than enough current to trigger ventricular fibrillation.

The biggest danger when depending on a simple isolating transformer to prevent shock is that it is possible for a fault to develop in the device being supplied by the transformer that increases the current flowing to earth ( $R_x$  in Figure 8).



**Figure 8: Isolation transformer under single fault condition**

The device may continue to function normally, and there will be no indication of the presence of the fault. If the top end of supply is touched, it would now be possible to receive a shock, where the current is that flowing through the resistor  $R_x$ . In order to ensure that this will not happen with a medical-grade isolated power supply, the insulation between the transformer secondary and earth is continuously monitored by superimposing a low voltage DC waveform upon the 50 Hz supply. If the insulation

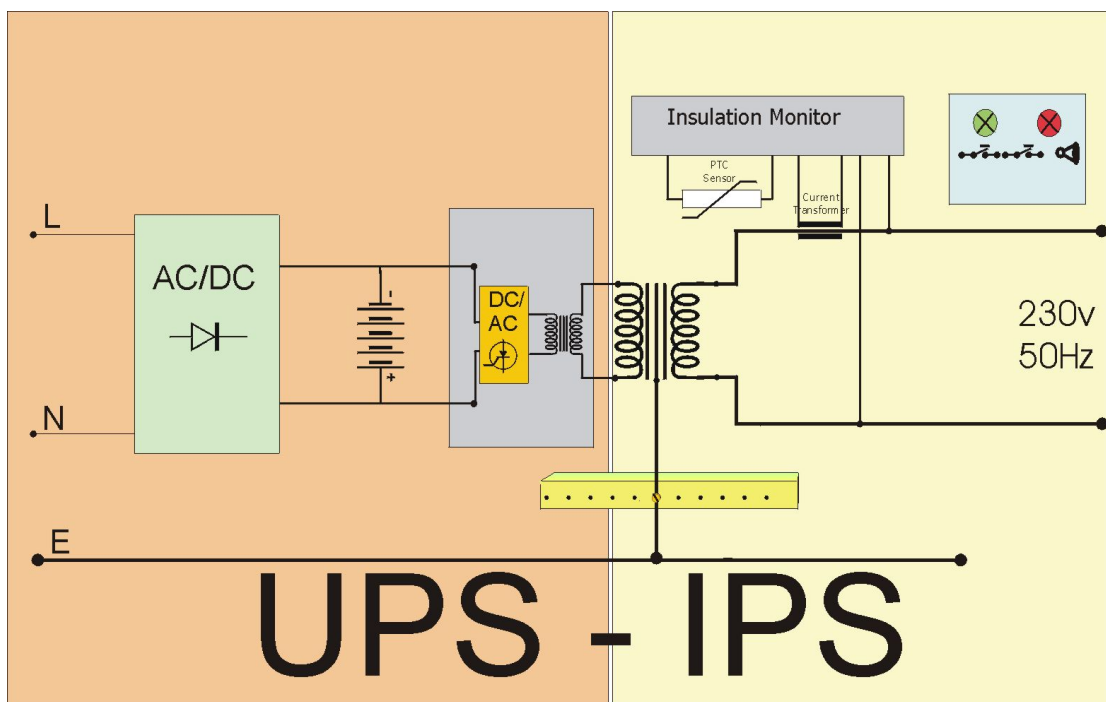
resistance falls to below a certain pre-set value, an alarm is triggered although the supply is not interrupted. The user is able to mute the alarm and continue working if this is deemed safe. Alternatively, the device that is causing the alarm to trigger can be removed and replaced should this seem to be the safest course of action.

Ideally the alarm should be triggered as soon as earth leakage current is detected, but in reality every mains powered device will have some earth leakage current, provided that a protective earth is connected. In principle, the more power the device consumes the greater will be the earth leakage current. Since it is usual to supply a number of devices from each IPS, the earth leakage current will increase according to the number of devices being supplied. In order to ensure that the alarm is triggered as soon as a real fault is detected, while at the same time avoiding false alarms, the maximum power output is limited to 10 kVA, in accordance with IEC 61558-2-15 [14], although a number of IPS systems can be driven from the same UPS.

Where there is the possibility of more than 10 kVA being required in a given location, two or more IPS units may be provided, with the mains socket outlets being interleaved, so that adjacent sockets are supplied from different IPS units. This has the advantage of further increasing the resilience of the supply. A practical IPS unit will also monitor the temperature of the transformer and the output current, triggering an alarm if the pre-set limits are exceeded.

Should the demand exceed the maximum output of the unit, an automatic by-pass will come into operation, ensuring continuity of supply, even though the overload alarm will be operating. Whenever the alarm system is triggered the cause should be investigated, and steps taken to prevent future incidents of the same type.

Figure 9 shows a simplified diagram of a typical UPS-IPS



**Figure 9: Simplified diagram of a UPS/IPS system**

Consideration should be given to the limited capacity of the IPS unit, since the number and complexity of the items of electrically operated equipment used in medical locations increases year by year. The situation is aggravated by the increasing use of switch-mode power supplies in individual pieces of equipment and of toroidal transformers used to power trolley-mounted equipment stacks (medical electrical systems) in order to reduce leakage currents. Both of these types of input circuit can result in high inrush currents, sufficient to trip out the IPS supply and sound the alarm. This situation will often occur at switch-on when a number of items of equipment have been left switched on and plugged into the mains, and the whole arrangement turned off by turning off the IPS. It is best practice to turn off and unplug each item of equipment individually before turning off the supply and then reverse the action by turning on the IPS supply before plugging in each piece of equipment and turning it on, starting with any medical electrical system, before moving on to the next item of equipment. In this way any equipment that has a fault will be more easily identified.

The problems caused by high inrush currents can be particularly troublesome when a small IPS transformer is used since the transformer may not be capable of supplying the inrush current demanded. As a result, turning on one item of equipment can cause a fall in voltage that can then cause other equipment that is supplied from the same IPS to drop out.

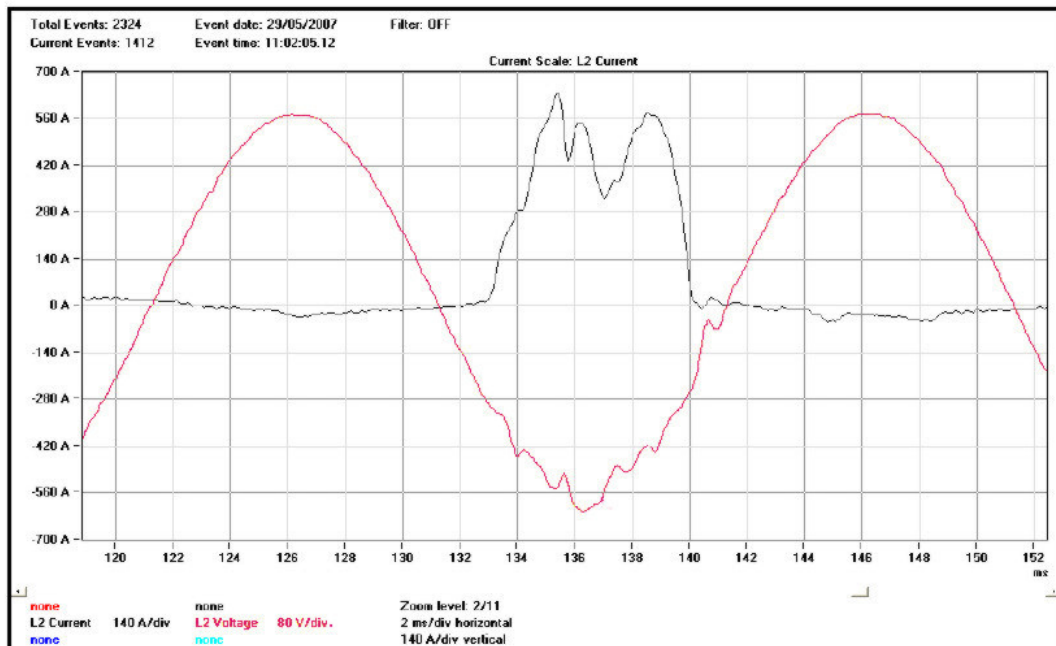
When assembling a trolley-mounted equipment stack the specification of the separation transformer should be chosen with care. The inrush current can in the case of toroidal transformers be up to 30 times the maximum primary current, which is likely to cause problems if this transformer is fed from an IPS. The Inrush current will depend on the characteristics of the primary of the transformer, and not necessarily on the secondary loading. In order to keep the inrush current down to an acceptable value, the rating of the transformer should be not more than 1 kVA. Where the stack system is to be plugged into an un-switched mains socket, an ON/Off switch should be fitted to the transformer, so that any arcing as the mains plug is inserted under load is avoided.

### **Uninterruptible power supplies for angiographic systems**

There appears to be a growing demand for uninterruptible power supplies that are capable of maintaining full functionality of angio-cardiographic X-ray systems in the event of a power failure. In the majority of angio-cardiographic installations, should the hospital mains supply fail during the course of an examination, the examination would have to be abandoned and all unsaved data would be lost.

In contrast to the type of UPS used in association with a medical IPS, the UPS needed to provide full functionality would have to be capable of supplying the full three-phase power requirements of the system when in acquisition mode, which could be up to the maximum rating of the tube, typically 100 kW or more. Taking into account the efficiency of the X-ray unit this could amount to something in the order of 700 A peak. See graph of UPS output voltage and current below (Figure 10).



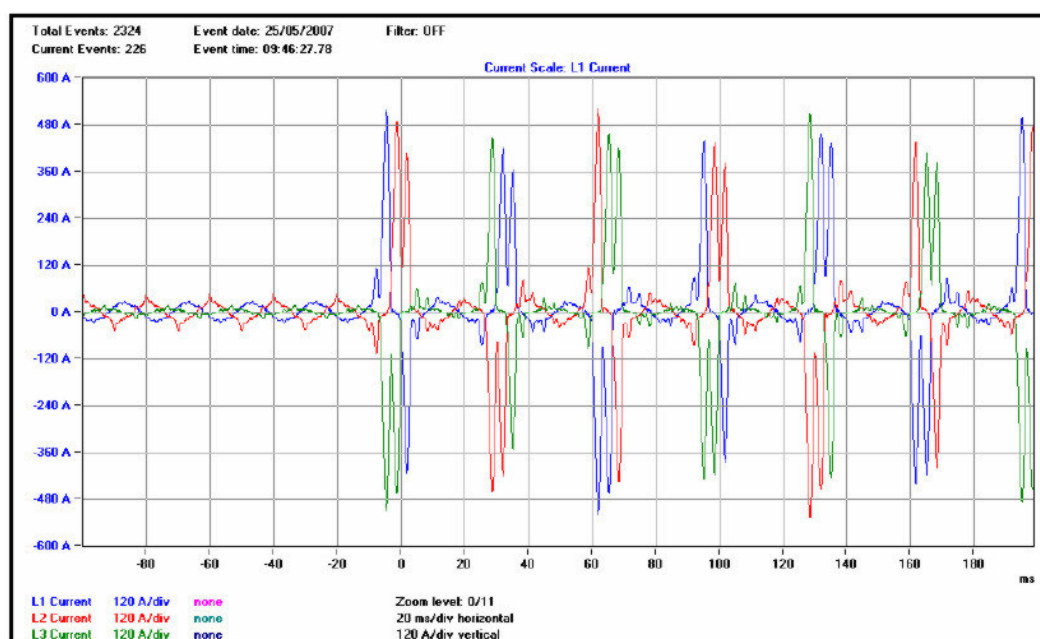


**Figure 10: Trace given by a mains analyser showing the voltage (red) and current (black) during a single acquisition exposure**

The duration of this high current pulse would be less than one half-cycle, so that the total power consumption would be only about 50-60 kW. When in standby, the X-ray unit will consume something like 15 kW.

The complete sequence would be as follows:

When turned on, the unit would be in standby mode for most of the time, drawing about 15 kW. When an examination gets under way, there will be a number of sequences in which the unit will be put into fluoroscopy mode for a couple of minutes at a time, when the power demanded will increase to about 30-40 kW, interspersed with short bursts of high current pulses at a rate of about 10-25 pulses per second. Figure 11 shows the three phase current drawn by the X-ray unit during the fluoroscopy and acquisition modes. Acquisition mode is on the right of the graph in Figure 11. The train of pulses can last for up to 10 seconds. The power demanded for each pulse during acquisition mode will be determined by the automatic exposure circuit but could be up to the maximum determined by the tube rating.



**Figure 11: Trace showing the three-phase current waveform during a burst of acquisition exposures**

When specifying a UPS capable of maintaining full functionality of the complete angio-cardiographic system it is essential that the UPS be capable of supplying the high current pulses that will be drawn when in acquisition mode, together with the sustained lower current demands of the unit when it is in fluoroscopy and standby modes, for long enough to allow the procedure to be completed.

The cost of such a large UPS will be high and so in some cases a smaller UPS will be provided which has the capacity to provide sufficient power to enable fluoroscopy to be performed for long enough for the catheters to be withdrawn, although acquisition exposures will be blocked during the failure of the incoming mains supply. An alternative option would be to simply provide a small UPS that would have the capacity to maintain the X-ray unit in standby mode for 30 minutes or more, and so prevent the loss of unsaved data, while at the same time reducing the time taken for the unit to restart once the incoming supply is restored.

Where a common UPS is required to supply a suite of two or more rooms, the UPS must be capable of supplying the maximum current demanded by all of the rooms simultaneously, as it is impractical to arrange that simultaneous acquisition exposures will not be made.

It should be noted that there is no changeover to the UPS. The supply to the X-ray generator always comes from the secondary of the UPS output transformer. All that happens when the incoming supply fails is that there is no longer any charging current to the battery.



## Appendix 5 Electrical safety checks on MR systems

Interventional procedures are increasingly being performed using MR systems, so that measurements of bonding resistance and touch voltages should be performed on MR units, just as they are on conventional radiographic systems.

There will need to be some differences in procedure, because of the strong magnetic field within the scanning room, but the general principles will be the same.

Touch voltages should be measured using a conventional auto-ranging digital multimeter, equipped with a set of test leads long enough for the meter to be sited outside the scanning room. One lead should be attached to the Earth Reference Bar, and the other lead, fitted with a sharp pointed probe used to check for touch voltages on any of the accessible conductive surfaces within the scanning room. The probe should be tested to ensure that it does not contain any significant amount of magnetic material by running a test magnet over it.

Measurements shall also be made between the earth point on all mains sockets in the scanning room and the ERB. If any devices are plugged into sockets outside the scanning room and then used within the scanning room, these should be supplied from the same phase as any sockets within the scanning room, and the touch voltage on the earths of these sockets also measured. The touch voltage should be less than 10 mV, AC or DC. If a voltage greater than 10 mV is found, the measurement should be repeated using an IEC filter. If the touch voltage is still above 10 mV, the source of the voltage should be investigated.

Once it has been established that there are no significant touch voltages present, the bonding resistance should be measured. A battery operated four-wire milliohm meter should be used, in order that the meter can be kept at a safe distance from the midline of the field during the measurement. The meter shall have a resolution better than 10 milliohms, and be capable of performing the measurement at a current greater than 100 mA.

The resistance between the ERB and all accessible conductive surfaces of installed equipment should be less than 100 milliohms. The resistance between the earth point of all mains sockets and the ERB should also be less than 100 milliohms.

Any portable devices shall be plugged directly into a conveniently located hardwired socket. Extension mains leads shall not be used within the scanning room.

## Glossary

### **Authorised Person**

An individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the authorising engineer to be responsible for the practical implementation and operation of management's safety policy and procedures on defined electrical systems (see [section 11.9](#)).

### **Competent Person**

An individual who in the opinion of an Authorised Person has sufficient technical knowledge and experience to prevent danger while carrying out work on a defined electrical system (see HTM 06-02 [15]).

### **Contactors**

A remotely operated single or three-phase electromechanical switch.

### **Diagnostic or treatment area**

The room or area, where a medical device is permanently located and permanently connected to the mains supply.

### **Earth Reference Bar (ERB)**

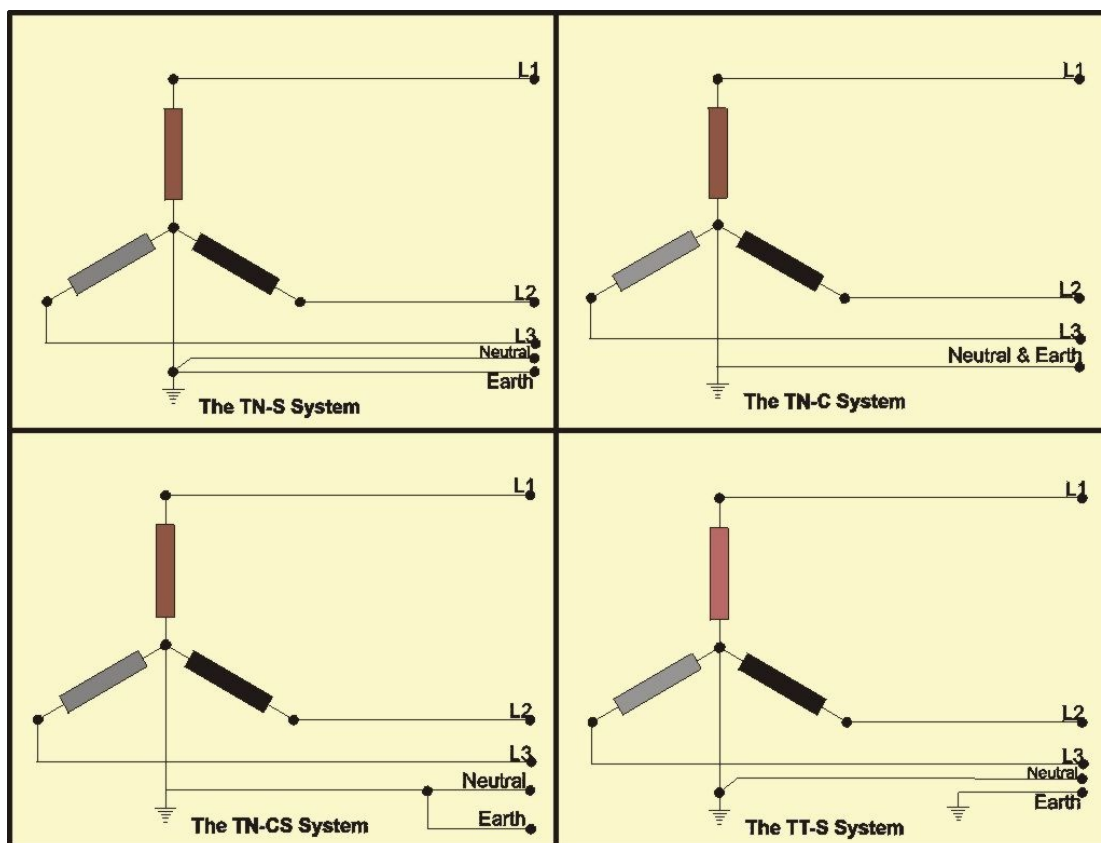
One or more copper connection bars installed in an enclosure forming part of the protective earth system in a room and designated as a reference or datum for the purpose of defining and measuring resistance values. Earth connection bars connect to the incoming earth supply with a solid copper link. The term busbar is not used because this implies that a voltage is present and is often relative to earth.

### **Electrical equipment room**

A separate room from the diagnostic or treatment room that contains the electrical control equipment supplied as part of the medical device.

### **Electrical systems**

An electrical system consists of a single source of electrical energy and an installation. The types of system are identified by the relationship between the source of supply and earthing of exposed conductive parts of the installation. The diagram in Figure 12 shows the secondary of a three-phase substation transformer. Only the TN-S system is permitted in medical locations.



**Figure 12: Electrical systems**

### Emergency off

The 'Emergency off' button must remove all power to the medical device. In some circumstances removing power from a device may result in damage to the equipment (e.g. the crystal of a gamma camera can fracture if a sudden change in temperature occurs as the result of the loss of temperature control equipment. Similarly, some direct digital panels may take some time to stabilise if the temperature control system is turned off). In this case, the control used to turn off the mains supply to the major part of the system should be labelled 'Emergency stop'. A second switch labelled 'Emergency off' should also be installed, located where it is accessible to a person standing in the operator's position. This may be mounted in a 'Break glass' enclosure if activation of the control could result in the equipment malfunctioning. See Regulation 12 of the Electricity at Work Regulations 1989 [16].

### Emergency stop

The emergency stop button is used to arrest the system to a safe condition as defined by the manufacturer. The manufacturer is responsible for which functions of the device are terminated.

### ERB

See earth reference bar.

### Flexible power lead specification

The specification of some commonly used flexible power leads is given in the table below. The cable resistance is of particular significance when determining the earth bonding resistance.

CSA (mm <sup>2</sup> )	Current rating (A)	Resistance per metre (mΩ)
0.25	1	83.6
0.50	3	40.1
0.75	6	24.7
1.50	13	13.7

### Installer

The person who installs, erects or assembles a permanently installed medical device(s).

### IP number (IP44)

The IP number indicates the degree of environmental protection of the device and is made up of two numbers. The first number (4) indicates that the device is protected against solid objects with a diameter greater than 1 mm. If this number were 6, it would indicate that the device was totally dust-proof.

The second number indicates the degree of protection against liquids. The number 4 indicates that it would be protected against a water spray from any direction. A limited ingress of water is permitted. If this number were 8, it would be protected against immersion in water for long periods.

### Mains impedance

It is convenient to consider the mains voltage to have been supplied by a constant-voltage source, and all the resistances and impedances to be lumped together. It will include all of the wiring, connections, switch-gear and transformers back to, and including, the alternator. In practical terms this value will usually come to between 0.1 and 0.5 ohms total.

It should be remembered that the total mains resistance will be that of both the out and return path, that is the value of the resistance in ohms per metre **multiplied by the length of run X 2**.

The table below gives the total resistance for the out and return path for a range of cable CSAs. The CSA of the cable used will be determined by the length of run and not the current rating.

CSA of cable (mm <sup>2</sup> )	Resistance R <sub>Cu</sub> out & return (mΩ/m)
25	1.40
35	1.00
50	0.70
70	0.50
95	0.38
120	0.30
150	0.24

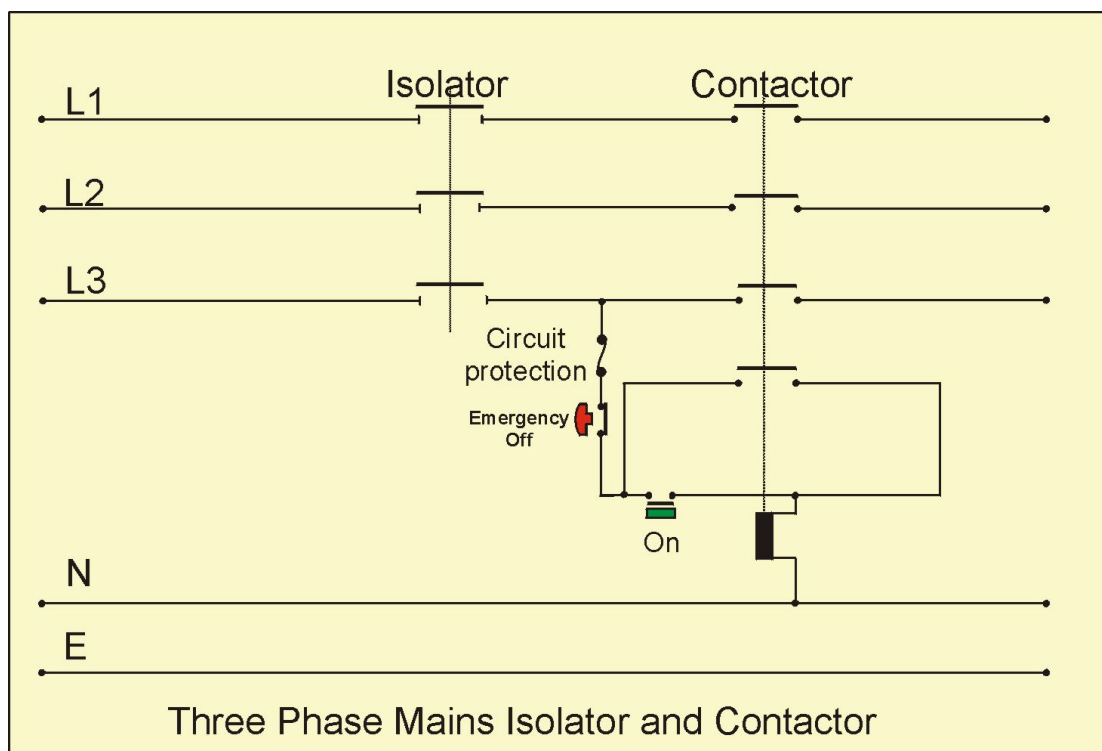
### Mains supply

A single-phase 230 V ±10%, 50 Hz AC or three-phase 400V ±10%, 50 Hz AC supply.

### Mains supply isolator

A single or three-phase isolating switch or fused switch. The on/off switching circuit shall comply with BS EN 7671 [1]. The isolator shall be capable of being locked in the

off position. The minimum air gap between the phase contacts when in the off position shall be not less than 3 mm. A solid state device shall not be used (see Figure 13).



**Figure 13: Simplified circuit of a three-phase mains isolator and contactor**

#### **Manufacturer**

The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

#### **Medical device**

Any instrument, apparatus, appliance, material or any other article, whether used alone or in combination including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease.

(This text is quoted verbatim from the Medical Devices Directive [13].)

#### **Medical location**

An area intended for the purpose of diagnosis, treatment, monitoring or care of patients. A room may be divided into a number of locations, not all of which are used for the purposes outlined above.

#### **Macro-shock**

A big shock, the passage of any current greater in magnitude than 1mA, and which can be perceived as an electric shock.

#### **Micro-shock**

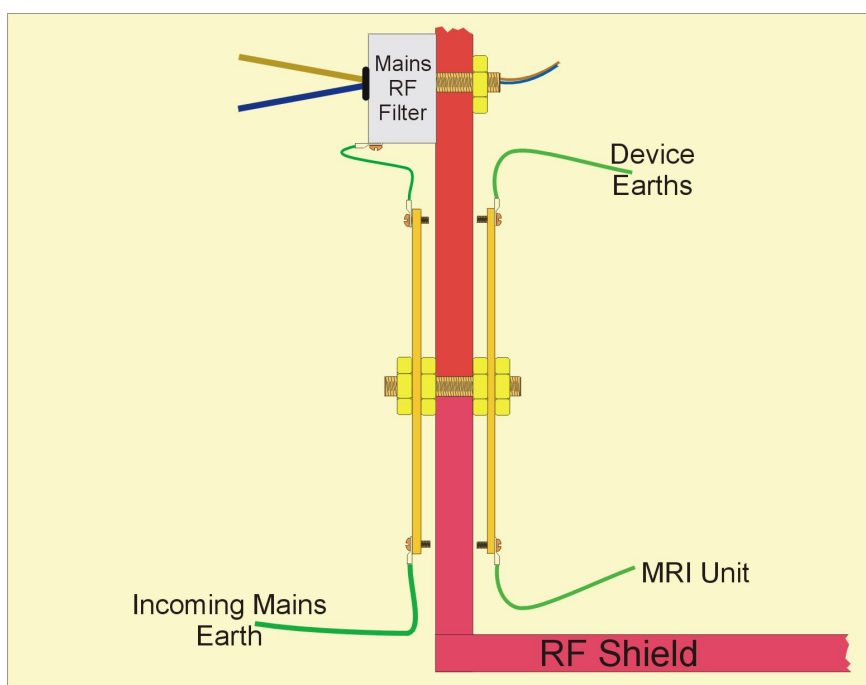
Micro-shock is the passage of a low level of electricity through the body, which causes no perceptible sensation. The threshold of sensation is at about the 1 mA level. The subject cannot detect currents below this level. These low-level events are of no

consequence unless the current passes through the cardiac conductive tissue, in which case ventricular tachycardia or ventricular fibrillation may be triggered. Currents of the order of 10  $\mu$ A can be enough to initiate ventricular fibrillation.

A patient undergoing any procedure that involves the placing of an electrical conductor in the central circulatory system is particularly at risk. In this context, an electrical conductor includes insulated wires such as cardiac pacing electrodes or intracardiac ECG electrodes or an insulated tube (catheter) filled with conducting fluid inserted into the central circulatory system.

### **MRI earthing system**

The manufacturer's instructions for the earthing of the MRI installation shall be closely followed, but the general principle is shown in Figure 14. Care shall be taken to ensure that any mains outlet sockets installed within the Faraday cage are wired correctly. Extension mains leads shall never be used.



**Figure 14: Diagram showing the earthing arrangements for a MR room**

### **Permanently installed equipment**

Equipment electrically connected to the mains supply by means of a permanent connection that can be only disconnected by the use of a tool.

### **Phase rotation**

This document refers to the phase denotations of L1, L2 and L3 (L1 leads L2 and L2 leads L3).

### **Power quality monitor**

Also known as a power quality analyser.

A meter that is capable of measuring and recording a range of parameters relating to the mains supply, over an extended period. A suitable instrument will measure voltage, current, frequency, power, harmonics and flicker on all three phases and neutral. It should be able to display trends, sags, swells, surges, interruptions, spikes and

transients, and register and store deviations from the preset limits unattended over a period greater than seven days.

### **Pre-installer**

The person responsible for carrying out whatever mechanical or electrical work is needed to prepare the location so that the installation of the defined medical device(s) can take place.

The pre-installer is to be provided with a specification which defines the work to be carried out, and is responsible for ensuring that the conditions of the specification are met before handing over the site.

### **Radiation protection advisor (RPA)**

A radiation protection advisor shall: either hold a Radiation Protection level 4 National or Scottish Vocational Qualification (N/SVQ) issued not more than five years previously; or hold a valid certificate of core competence from an organisation recognised as an assessing body by the Health and Safety Executive for this purpose.

### **Shall**

A requirement for compliance with these guidance notes.

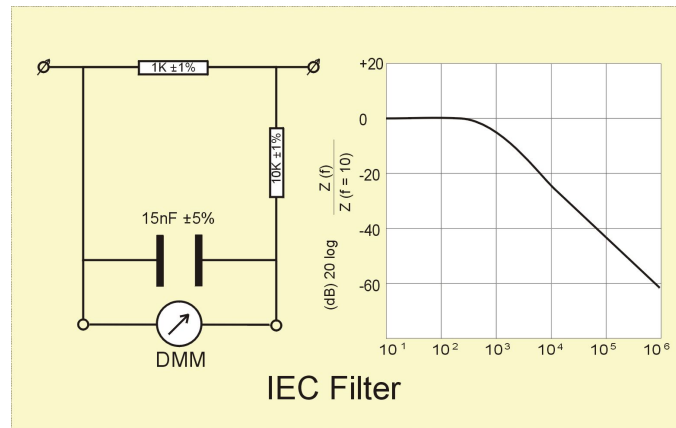
### **Touch voltage measurement**

The voltage between the ERB and every accessible conductive surface is measured in order to ensure that there is not a potential present that could harm either patients or staff. The measurement may also be useful in tracing sources of interference.

The greatest danger is that the voltage could be conducted to the heart muscle by means of a catheter, guide wire, pacing lead or endoscope. The heart is particularly sensitive to alternating voltages of a frequency similar to that found in normal mains supplies (~50 – 60 Hz). A voltage of 10 mV can be sufficient to trigger ventricular fibrillation.

Measurements should be made first of all with the mains supply to the unit turned off, then repeated with the mains turned on and the unit in standby, and finally during a mid-range exposure of about 1 s duration. The test should first be performed using a normal digital multimeter. Measure the touch voltage between the ERB and all accessible conductive surfaces, paying particular attention to the area shown as the 'Patient environment' in drawing C of Annex 1 (separate document). The meter should be switched between AC and DC at each measuring point. If no significant voltage is measured, proceed to the next stage of the test procedure.

If a value of 10 mV or above is found, the measurement should be repeated using an IEC filter (see Figure 15). As the graph shows, high frequencies will be attenuated, as these are less likely to trigger ventricular fibrillation. If the touch voltage is now below 10 mV, the system can be considered safe to use for interventional procedures. However, if significant amounts of high frequencies are present, this can have an adverse effect on the performance of some equipment; in particular it may result in poor image quality on a digital imaging system. When in doubt a cordless oscilloscope should be used to display the complete voltage waveform between the ERB and the earths on the equipment under test, paying particular attention to the earths on any input/output ports. The source of the waveform should be investigated and steps taken to bring the touch voltage to below the critical value. This may involve running supplementary earth conductors, installing isolators in the data lines, and altering the run of some earth conductors in order to minimise coupling.



**Figure 15: Circuit diagram of an IEC filter**

### **Transportable diagnostic or treatment rooms**

This can be either an enclosed structure mounted on or transported by a vehicle or a portable building intended for transportation by crane and HGV to a temporary site. The term includes the structure, accommodation, associated engineering and building services.

### **Voltage between phases**

The voltage between any two phases is the voltage between phase and neutral, multiplied by 1.732 ( $\sqrt{3}$ ). For a voltage between phase and neutral of 240 V the voltage between any two phases will be 415.68 V.



## References

- 1 BS 7671:2001 Requirements for electrical installations. IEE Wiring Regulations. Sixteenth edition (incorporating Amendments 1 & 2, 2004). BSI 2001.  
<http://www.bsonline.bsi-global.com>
- 2 Department of Health: Estates and Facilities Division. HTM 06-01 Electrical services supply and distribution. The Stationery Office, 2007.  
[http://195.92.246.148/nhsestates/knowledge/knowledge\\_content/home/home.asp](http://195.92.246.148/nhsestates/knowledge/knowledge_content/home/home.asp)
- 3 BS EN 60601-1:2006 Medical electrical equipment. General requirements for basic safety and essential performance. BSI, 2006.
- 4 IEC 60364-7-710:2002 Electrical installations of buildings - Part 7-710: Requirements for special installations or locations - medical locations. Note: the MHRA and DH Estates and Facilities Division recommend that MEIGaN is used.
- 5 The Institution of Engineering and Technology IEE Guidance Note 7: Special Locations, 2nd Edition. IEE Publications, 2004.  
<http://www.theiet.org/publishing/books/wir-reg/19284.cfm>
- 6 Statutory Instrument 1999 No. 3232 The Ionising Radiation Regulations 1999. HMSO 1999.  
<http://www.opsi.gov.uk/si/si1999/19993232.htm>
- 7 BS 6231:2006 Electric cables. Single core PVC insulated flexible cables of rated voltage 600/1000 V for switchgear and controlgear wiring. BSI, 2006.
- 8 Canadian Standards Association. C22.2.127-99 Equipment and lead wires. CSA, 1999.
- 9 Underwriters Laboratories Inc. UL 758 Appliance wiring material, 2nd edition. UL, 2007.
- 10 BS EN 60309-2:1999, IEC 60309-2:1999 Plugs, socket-outlets and couplers for industrial purposes. Dimensional interchangeability requirements for pin and contact-tube accessories. BSI, 1999.
- 11 Medical Devices Directives. Council of the European Communities. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. OJ L169: 1-43. 1993.  
[http://ec.europa.eu/enterprise/medical\\_devices/legislation\\_en.htm](http://ec.europa.eu/enterprise/medical_devices/legislation_en.htm)
- 12 BS EN 60601-1-4:1997, BS 5724-1.4:1997, IEC 60601-1-4:1996 Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for programmable electrical medical systems. BSI, 1997.
- 13 IEC 61557-8 Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 8: Insulation monitoring devices for IT systems.  
<http://webstore.iec.ch/webstore/webstore.nsf/artnum/037457>

- 14 IEC 61558-2-15 Safety of power transformers, power supply units and similar - Part 2-15: Particular requirements for isolating transformers for the supply of medical locations. May 1999.  
<http://webstore.iec.ch/webstore/webstore.nsf/artnum/023605>
- 15 Department of Health: Estates and Facilities Division. HTM 06-01 Electrical services supply and distribution. The Stationery Office, 2007.  
[http://195.92.246.148/nhsestates/knowledge/knowledge\\_content/home/home.asp](http://195.92.246.148/nhsestates/knowledge/knowledge_content/home/home.asp)
- 16 The Electricity at Work Regulations. Statutory Instrument 1989 No. 635. ISBN 011096635X.  
[http://www.opsi.gov.uk/si/si1989/Uksi\\_19890635\\_en\\_1.htm](http://www.opsi.gov.uk/si/si1989/Uksi_19890635_en_1.htm)

## Bibliography

Great Britain. Health and Safety at Work Act 1974. London: HMSO; 1974.

Guidance notes for NHS trusts on requirements for mobile trailers for breast screening - 03043. MHRA; June 2003.

<http://www.pasa.doh.gov.uk/evaluation/publications/dier/details.asp?id=390>

Guidance notes on electrical safety in rooms used for colposcopy and the safe use of electrosurgery for LLETZ procedures. NHSCSP Equipment Report 0401 Dec 2004.

<http://www.cancerscreening.nhs.uk/cervical/publications/0401.html>

Statutory Instrument 2002 No. 2665 The Electricity Safety, Quality and Continuity Regulations 2002. HMSO; 2002.

<http://www.opsi.gov.uk/si/si2002/20022665.htm>

Medical and Dental Guidance Notes. Institute of Physics and Engineering in Medicine; 2002.

[http://www.ipem.ac.uk/ipem\\_public/article.asp?id=366&did=49&aid=628&st=&oaid=-1](http://www.ipem.ac.uk/ipem_public/article.asp?id=366&did=49&aid=628&st=&oaid=-1)

Statutory Instrument 2002 No. 618 The Medical Devices Regulations 2002.

HMSO; 2002.

[www.legislation.hmsso.gov.uk/si/si2002/20020618.htm](http://www.legislation.hmsso.gov.uk/si/si2002/20020618.htm)

Waste Electrical and Electronic Equipment Regulations (draft).

<http://www.dti.gov.uk/innovation/sustainability/weee/page30269.html>

BS EN 60309-1:1999, IEC 60309-1:1999 Plugs, socket-outlets and couplers for industrial purposes. General requirements. BSI, 1999.

This is the second version of the MEIGaN document.

We would value additional input from users of the document.

It will be reviewed in six months' time, and updated where necessary.

In the meantime your comments would be appreciated

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