

# Medical Device Installation Safety

The following was produced by AXREM (Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care) in response to the death of a patient following the disconnection of the mains supply to an interventional x-ray system. Information about this incident can be found in the Prevention of Future Deaths Report:

<https://www.judiciary.uk/prevention-of-future-death-reports/jean-dye-prevention-of-future-deaths-report/>

The Society of Radiographers (SoR) also published some information and lessons learned:

<https://www.sor.org/news/health-safety/mains-electricity-wiring-issues-with-medical-radio>

## Requirements

For electrically powered medical devices, known as Medical Electrical Equipment (ME Equipment) or Medical Electrical System (ME System), to operate safely it is vital that the requirements for the installation meet the specifications set out in the *ACCOMPANYING DOCUMENTS*. In this regard it is also important to understand the demarcation of responsibilities between the medical device and the installation.

The responsibility for the ME Equipment or ME System starts at the connection to the mains supply or connection point for any other services required for operation, such as water, drainage, air, etc. Everything before the supply connection is **not** the responsibility of the medical device manufacturer/supplier.

The responsibility for the ME Equipment or ME System mains electrical supply, supporting UPS and batteries, electrical switchgear and accessories, environment (temperature, humidity, airflow, etc.), and associated services to enable the operation of the medical device falls to the *RESPONSIBLE ORGANISATION*. Even if the medical device is part of a turnkey solution the post warranty service, maintenance, and testing rests with the *RESPONSIBLE ORGANISATION*.

For patient safety adhere to the following:

- When commissioning new or replacement equipment, healthcare estates, designers, and clinical staff should collaborate from the earliest planning stages and include the medical device supplier/manufacturer. The NHS England [HTM 06-01](#) document provides information on the design, installation and testing of all fixed wiring and integral electrical equipment used for electrical services and the need to establish an Electrical Safety Group (ESG). For NHS Scotland see [SHTM 06-01](#).
- The electrical installation should meet the current version of BS 7671, including section 710 (medical locations), and fulfil all the requirements specified for the medical device. All required certifications and reporting documents, according to part 6 of BS 7671 (Electrical Installation Certificate and Electrical Installation Condition Report), should be provided to the medical device manufacturer/supplier and *RESPONSIBLE ORGANISATION*.
  - BS 7671 section 710 includes requirements for diagrams and documentation that should be provided, along with a model form for recording the supplementary protective equipotential bonding.
  - The current version of BS 7671 must be used when refurbishment is undertaken, or a change in clinical use alters the medical location group number. This is crucial to patient safety.
  - The lifespan of all electrical components must be assessed to determine if reuse is acceptable. Worn socket-outlets, switches, relays, control-gear, or contactors could result in a loss of supply, inadequate earth connections, or faults in a medical device.

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- The impact on medical devices from the loss of mains supply must be assessed (BS 7671) to determine the medical location group number and the measure that will be required to mitigate such power loss. Mitigations can include:
  - A medical IT system to prevent loss of supply for multiple devices when a first fault to earth occurs on one device (e.g., when spilt liquid ingresses a device).
  - Use of emergency generators or UPS to maintain the supply.
  - Providing separate circuits for socket-outlets, so if one circuit fails devices can be transferred to the other circuit.
- Loss of supply could also affect lighting, which may be essential to patient safety. Consider if supplemental battery-operated emergency lighting is required in high risk (group 2) locations, above the existing requirements set out in section 710 of BS 7671.
- Care should be taken to ensure electromagnetic (EMI/RFI), or electrostatic discharge (ESD) interference does not affect the medical device. For example, EMI may originate from high current cables for mains supplies running too close to cabling for the medical device, or RFI from ineffective Faraday cage screening or an MRI scanner. ESD from low humidity or lack of ESD flooring may interfere with equipment (ECG, EEG, etc.) or result in damage to equipment.
- There should be periodic testing, maintenance, and inspection of the electrical installation, including all supporting equipment, such as:
  - Uninterruptable Power Supplies (UPS) and associated indicators (especially those used by the medical device operators).
  - Automatic transfer switches (ATS) and associated indicators.
  - Medical IT Systems (IPS) and associated monitoring and indication systems.
  - Supply power ON/OFF controls and associated supply indicator lights.
  - Supply Emergency Power Off (EPO) buttons (also called REPO when used for UPS shutdown).
- There should be periodic testing, maintenance, and inspection of all environmental systems (heating, cooling, air circulation, etc.), as these may affect the safe operation of the medical device or associated electrical installation (e.g., UPS batteries may fail if kept above 25 C for long periods).
- Staff (medical device operators) should receive training on the aspects of the electrical installation that can affect safety, such as how to restore power after accidental operation of an emergency power off (EPO) button, including restoration of UPS power. Documentation should be provided for reference and training (e.g., within standard operating procedures).

And in the case of permanently installed equipment, especially interventional systems, include:

- When any permanently installed medical device is replaced the electrical installation must meet the current requirements of both BS 7671 and the replacement medical device specification. Reuse of electrical switchgear and controls (EPO buttons, contactors, relays, isolators, etc.) should **not** be considered, as continued safety and reliability is not assured.
- Any switchgear and control gear assemblies should meet the current version of BS EN 61439. Markings should meet IEC 60417, and signs ISO7010.
- Any electrical installation remotely operated mains supply ON/OFF control buttons should be located near the medical equipment power controls, which is usually in the control room or exam room, and include illuminated indication of power state and labelling. Where loss of supply to the medical equipment is not obvious the exam room should include a supply indicator.
  - Permanently installed X-ray equipment often requires emergency power off (EPO) mushroom buttons as an emergency measure to stop radiation in the event of a fault, so a motorised switch disconnect or, if permitted, contactor is provided. The ON/OFF


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- button to control this circuit must be easily accessible to the operator so they can restore power if an EPO has been used (and subsequently reset).
  - Automatic restoration of power, except when an EPO has been activated, is often required for medical devices (e.g., to maintain device internal temperatures).
  - The ON/OFF push buttons should be clearly labelled (e.g., ‘X-RAY SYSTEM MAINS SUPPLY’ along with ‘ON’ and ‘OFF’ words or standard power symbol markings).
- The status of the emergency power supply and any associated UPS should be visible within the clinical area (exam room).
  - For interventional imaging equipment this is mandated by IEC 60601-2-43 (clause 201.12.4.101.4 – Indications of emergency power supply). This indicator may be provided on a monitor screen that is part of the medical equipment, so will be lost if an EPO is operated. Therefore, separate indicator lights displaying mains power, UPS power and System power are recommended to allow determination of when the EPO circuit has been activated (all lights except mains power will be out).
- Where provided, any emergency power off buttons (EPO) must be located in accordance with the medical device manufacturer instructions and be clearly labelled (see [AXREM guidance](#) for recommended labels). Shrouded buttons are recommended to prevent accidental activation, and the supply must not be restored simply by releasing the button.
- Where a UPS that is dedicated to one medical device is located remotely from the medical device either a UPS remote reset facility or UPS bypass switch (may be built into the UPS) must be provided within the medical device control room, clinical room, or readily accessible (e.g., adjacent) technical room (where ME Equipment and ME System cabinets and supporting equipment, such as chillers, UPS, and batteries, are located). When the UPS is bypassed, any use of medical equipment with patients should only be in emergency situations, as any subsequent loss of supply would result in loss of medical device operation. The medical device operator should be provided with guidance on how to respond to a UPS fault.
- Medical device operators (staff) should report any defects in the electrical installation or supporting infrastructure (heating, cooling, ventilation, etc), including indicator lights that are not working, immediately and the facilities management should rectify promptly.

**NOTE:** Some aspects of testing the electrical installation may require support from the medical device operators or manufacturer/supplier to prevent damage or data loss (e.g., testing EPO or UPS function).

The need for maintenance of medical devices is well understood and documented in publications such as the [MHRA Managing Medical Devices](#) guidance. However, the same applies for the electrical installation and other building services that support the healthcare organisations activities. This is backed up by legislation including, The Electricity at Work Regulations 1989, The Provision and Use of Work Equipment Regulations 1998, and the Health and Safety at Work Act. Therefore, it is vital that both the installation and the medical device are covered by appropriate maintenance arrangements.

**NOTE:** Failure in duty of care could result in corporate manslaughter/homicide charges.

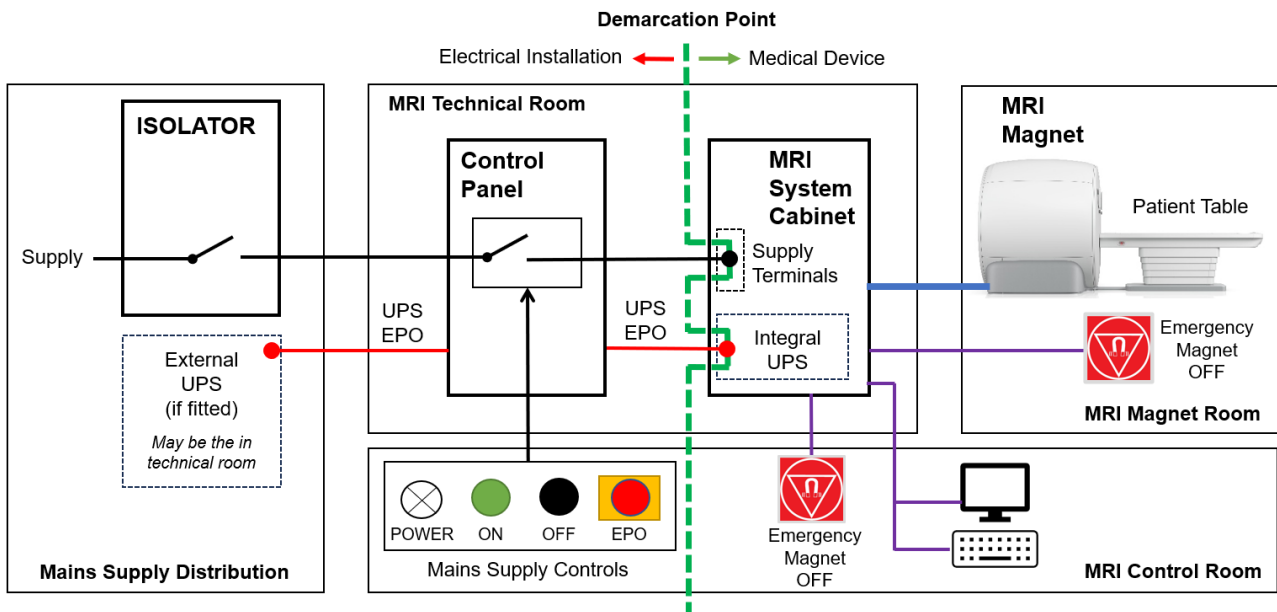
	<p><b>Consider the need to provide alternative arrangements where failure of the installation supporting infrastructure or the ME Equipment or ME System (medical device) could endanger a patient.</b></p>
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## Typical Permanently Installed Equipment Arrangements

It is important to understand the demarcation of responsibilities between the medical device and the installation.

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Below is an example showing the demarcation point and basic electrical supply control arrangement for a typical MRI system:

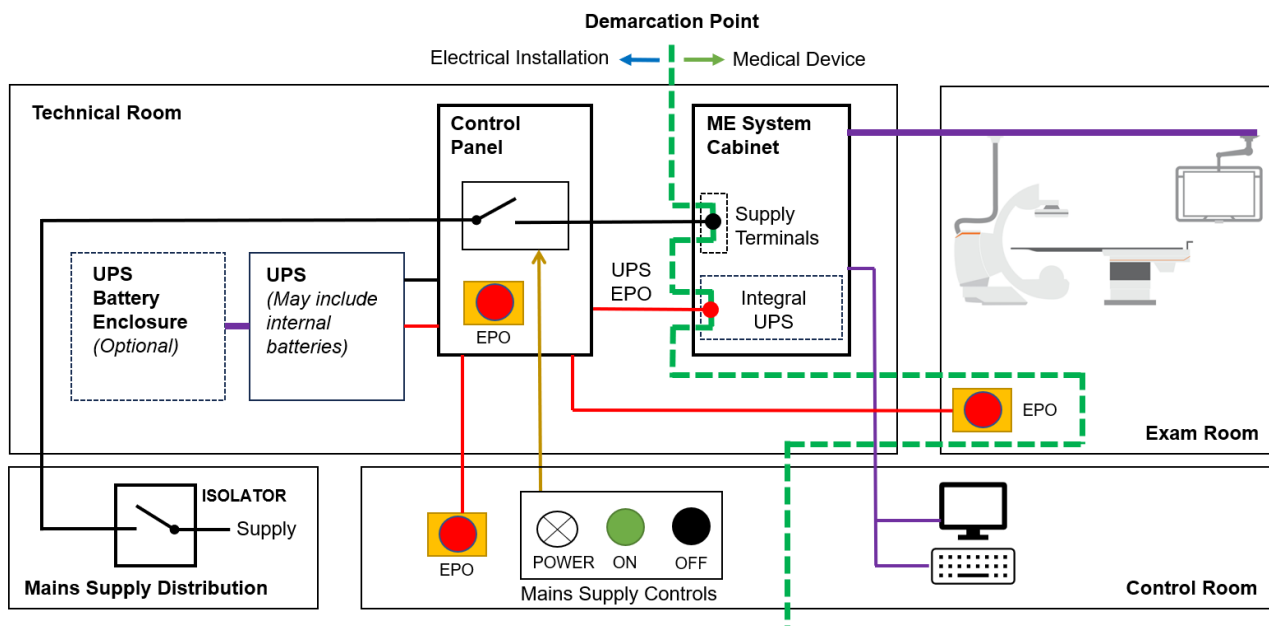


**NOTE 1:** An EPO button may be provided in the magnet room but is still part of the electrical installation. All EPO buttons may support additional separate (isolated) contacts for a UPS REPO function, which can include any internal UPS forming part of the MRI system (medical device). Internal (part of the medical device) UPS provided with a REPO function will be tested as part of the medical device maintenance, but not any other part of the electrical installation or associate control gear.

**NOTE 2:** Any optional integral UPS is normally only for protection of the data (saving images) in the event of a supply loss. It is not intended to enable continued use of the system.

**NOTE 3:** The 'Emergency Magnet Off' (quench) buttons form part of the medical device (emergency field shutdown unit) and **not** the electrical installation.

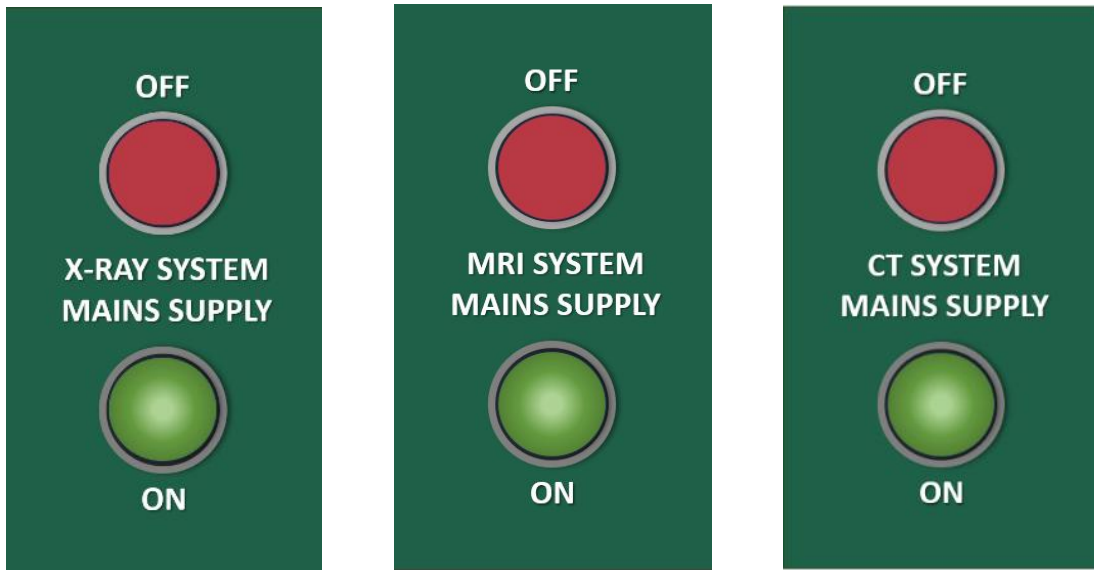
Below is an example showing the demarcation point and basic electrical supply control arrangement for a typical interventional system:



**NOTE:** A UPS might have some other connections to the ME Equipment or ME System for both power and signalling (e.g., UPS active).

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Below show typical remote mains supply ON/OFF push button controls with a power indicator light within the ON button:



**NOTE:** The power OFF button may also be black in colour, and the ON button may be white in colour. It is normally located near the medical device power controls, which is normally in the medical device control room. The text should make it clear as to what equipment is being controlled, e.g., as shown for an X-ray, MRI, and CT system.

Below is an image of a typical indicator panel to display the UPS and power status located in the examination room:



**NOTE 1:** In accordance with IEC 60601-2-43, emergency power supply (UPS) indicators may be provided on a monitor screen in the examination room, so will normally be unavailable (off) if an EPO is operated.

**NOTE2:** In accordance with IEC 60601-1 a red indicator is used to indicate a hazardous situation that could cause death or serious injury. The colour red is used only for a control where a function is interrupted in case of emergency, such as the red EPO button).

Below is a typical emergency power off (EPO) button and label (for an X-ray system):

**NOTE:** The actuator of the emergency button will be coloured red on a yellow background according to standards such as ISO 13850 or IEC 60601-1.

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Below is a typical mains supply panel (isolator and control) for an interventional system with external UPS:



**NOTE:** Panels like this may be installed in a separate technical room or in the control room. If mounted in the examination room it should ideally be located outside the patient environment (see IEC 60601-1 or BS 7671, Figure 710.1). The UPS bypass switch may be mounted in a separate enclosure or part of the UPS. Panel controls and indicators will vary depending on the equipment that is being supported.

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## Definitions

The following definitions, taken from IEC 60601-1 (BS EN 60601-1), have been used in this document.

### **ACCOMPANYING DOCUMENT**

*document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANISATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE.*

### **RESPONSIBLE ORGANISATION**

*entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM.*

*NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANISATION can be one and the same person.*

*NOTE 2 Education and training is included in “use.”*

### **OPERATOR**

*Person handling equipment*

**Disclaimer:** AXREM accepts no liability for any actions or inactions resulting from the information provided. The information provided may change without prior notice due to legal, technical, or organisational changes.