



Courtesy Dr Sung

9.1 Introduction and scope

Sect 710 Section 710 'Medical locations' is incorporated in Part 7 (Special Installations or Locations) of BS 7671:2008 of Amendment No. 3:2015.

The section is based on the published standard IEC 60364-7-710:2002 as modified by CENELEC standard HD 60364-7-710 (March 2012), plus additional regulations and provisions to satisfy the UK Healthcare requirements.

Note: This section should be read in conjunction with Parts 1-6 of BS 7671:2008 incorporating Amendment No. 3 (2015) and other relevant chapters of Guidance Note 7 where applicable.

701.1 This section applies to electrical installations in medical locations to ensure the safety of patients and medical staff.

These requirements, in the main, refer to hospitals, private clinics, medical and dental practices, healthcare centres and dedicated medical rooms in the workplace.

This section also applies to electrical installations in locations designed for medical research.

The requirements of this section do not apply to medical electrical (ME) equipment, which is covered by the BS EN 60601 series of documents.

The use of ME equipment can be split into three categories; some brief examples are listed below:

- (a) Life support:** infusion pumps, ventilators, anaesthetic equipment and monitors etc.
- (b) Diagnostic:** X-ray machines, CT scanners, magnetic resonance imagers, blood pressure monitors, electroencephalograph (EEG) and electrocardiograph (ECG) equipment.
- (c) Treatment:** surgical diathermy, defibrillators, haemodialysis machines and radiotherapy equipment etc.

Note: Some diagnostic equipment may also be used in the treatment of patients. Equipment such as X-ray, CT and MR may be used to perform interventional procedures.

710.56 Patients undergoing acute care require enhanced reliability and safety of the electrical installation in hospitals to ensure the security of supplies and minimise the risk of electric shock.

Notes:

- (a)** A source of additional guidance on the electrical installations of medical locations can be found in *Health Technical Memorandum (HTM) 06-01 (Part A)*, published by the Department of Health (where the term HTM is used, this will also relate to SHTM for Scotland) and IET publication *A Guide to Electrical Installations in Medical Locations*. For additional published guidance from the Department of Health, refer to 9.21.1.
- (b)** Where the designer and the client agree, this Standard can also be used in veterinary clinics.
- (c)** It may be necessary to modify the existing electrical installation, in accordance with this Standard, when a change of utilization of the location occurs. Special care should be taken where intracardiac procedures are performed in existing installations.
- (d)** Care should be taken so that other installations do not compromise the level of safety provided by installations meeting the requirements of this section of BS 7671.
- (e)** For medical electrical equipment and medical electrical systems, refer to the BS EN 60601 series of standards.

9.2 The risks

In medical locations stringent measures are necessary to ensure the safety of patients likely to be subjected to the application of medical electrical equipment.

Shock hazards due to bodily contact with the 50 Hz mains supply are well known and documented. Currents of the order of 10 mA passing through the human body can result in muscular paralysis followed by respiratory paralysis depending on skin resistances, type of contact, environmental conditions and duration. Eventual ventricular fibrillation can occur at currents just exceeding 20 mA. These findings are listed in IEC/TR2 60479-1 *Effects of current on human beings and livestock – General aspects*.

The natural protection of the human body is considerably reduced when certain clinical procedures are being performed on it. For example, patients undergoing treatment may have their skin resistance broken or their defensive capacity either reduced by medication or nullified while anaesthetised. These conditions increase the possible consequences of a shock under fault conditions.

In patient environments where intracardiac procedures¹ are undertaken, the electrical safety requirements are more stringent. Prolonged loss of the mains supply may put the patient's life at risk. Patient leakage currents from applied parts introduced directly to the heart can interfere with cardiac function at current levels that would be considered safe under other circumstances. In order to protect the patient against 'microshock' the requirements of the medical equipment are enhanced.

Patient leakage current that can flow into an earthed patient is normally greatest when the equipment earth is disconnected (single fault condition). A limit is set to the amount of leakage current that can flow in the patient circuit when the protective earth conductor is connected or disconnected. Patients' leakage currents² of the order of 10 μA have a probability of 0.2 per cent for causing ventricular fibrillation or pump failure when applied through a small area of the heart. At 50 μA (microshock), the probability of ventricular fibrillation increases to the order of 1 per cent (refer to BS EN 60601-1).

Equipment constructed to the BS EN 60601 series of standards ensure the leakage currents produced by medical equipment meet the required levels to ensure patient safety, which is why only ME equipment meeting the standards should be used clinically. It should also be noted that the allowable levels of patient leakage current depend on the classification of the applied parts B, BF or CF, the strictest being CF (cardiac floating) parts as these are expected to be used inside (intracardiac) or near the heart.

Additional to the consideration of risk from electric shock, some kinds of electrical equipment (life-support equipment, surgical equipment) perform such vital functions that loss of supply would pose an unacceptable risk to patients. Medical locations where such equipment is used require secure supplies. This has implications not only for the provision of safety (emergency) power supplies, but can also render some conventional protective measures unsuitable. Hence, for example, when protecting circuits supplying critical medical equipment, restrictions are stipulated on the use of RCDs.

Notes:

- (a) Further guidance on modelling of shock to the human body can be found in IET publication *A Guide to Electrical Installations in Medical Locations*.
- (b) Where the requirements of Section 710 are properly fulfilled, the risk of a dangerous touch leakage current occurring inadvertently, from medical staff simultaneously touching an intracardiac conductor and the electrical installation earth (e.g. via the enclosure of ME equipment), are negligible.

1 A procedure whereby an electrical conductor is placed within the heart of a patient or is likely to come into contact with the heart, such conductor being accessible outside the patient's body. In this context, an electrical conductor includes insulated wires such as cardiac pacing electrodes or intracardiac ECG electrodes, or insulated tubes filled with conducting fluids (catheter).

2 'Patient leakage current': current flowing from a medical electrical equipment applied part via the patient to earth.

Part 2 **9.3 Definitions**

9.3.1 Medical location

Location intended for purposes of diagnosis, treatment including cosmetic treatment, monitoring and care of patients.

9.3.2 Patient

Living being (person or animal) undergoing a medical, surgical or dental procedure. Also, a person undergoing treatment for cosmetic purposes may be regarded as a patient.

9.3.3 Medical electrical equipment (ME equipment)

Electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and that is:

- (a) provided with not more than one connection to a particular supply mains; and
- (b) intended by the manufacturer to be used:
 - (i) in the diagnosis, treatment or monitoring of a patient; or
 - (ii) for compensation or alleviation of disease, injury or disability.

Notes:

- (a) ME equipment includes those accessories as defined by the manufacturer that are necessary to enable the normal use of the ME equipment.
- (b) This equipment should meet the requirements of the BS EN 60601-1 series of standards.

9.3.4 Applied part

Part of medical electrical equipment that in normal use necessarily comes into physical contact with the patient for the ME equipment or an ME system to perform its function.

9.3.5 Group 0

Medical location where no applied parts are intended to be used and where discontinuity (failure) of the supply cannot cause danger to life.

9.3.6 Group 1

Medical location where discontinuity of the electrical supply does not represent a threat to the safety of the patient and applied parts are intended to be used:

- (a) externally; or
- (b) invasively to any part of the body, except where Group 2 applies.

9.3.7 Group 2

Medical location where applied parts are intended to be used, and where discontinuity (failure) of the supply can cause danger to life, in applications such as:

- (a) intracardiac procedures; and
- (b) vital treatment and surgical operations.

9.3.8 Medical electrical system (ME system)

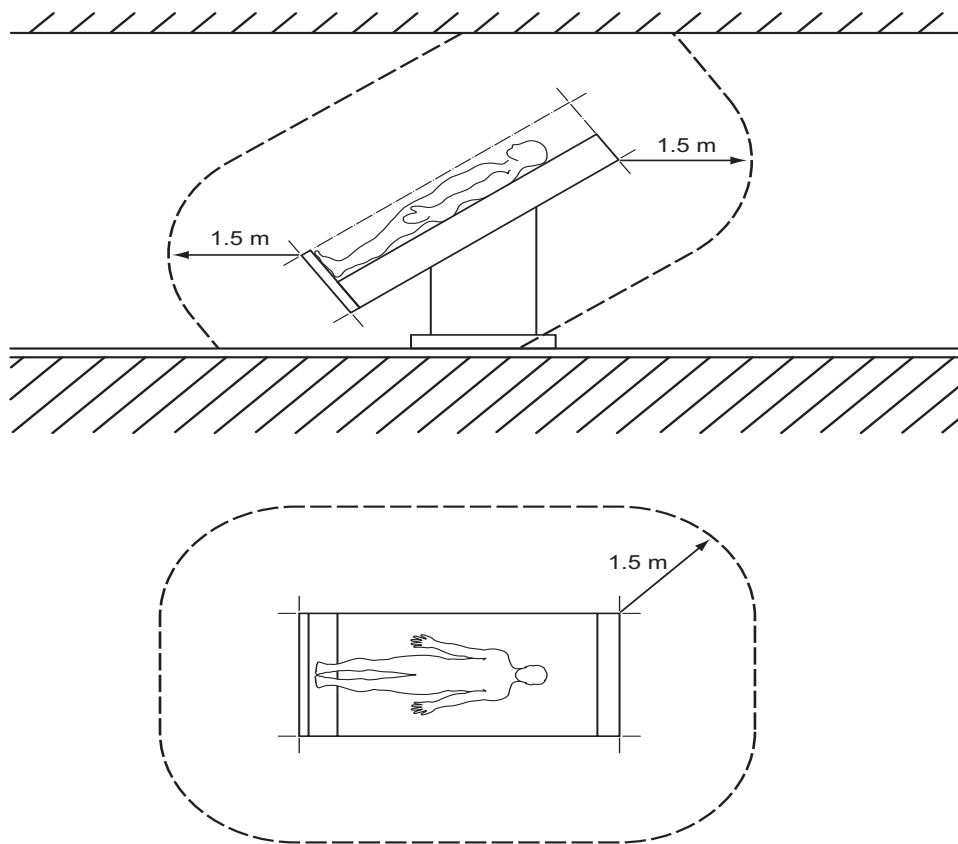
Combination, as specified by the manufacturer, of items of equipment, at least one of which is medical electrical equipment to be interconnected by functional connection or by use of a multiple socket-outlet.

Note: The system includes those accessories which are needed for operating the system and are specified by the manufacturer.

9.3.9 Patient environment

Any volume in which intentional or unintentional contact can occur between a patient and parts of the medical electrical equipment or medical electrical system or between a patient and other persons touching parts of the medical electrical equipment or medical electrical system (for illustration see Figure 9.1).

▼ **Figure 9.1** Patient environment (BS EN 60601-1:2006)



Note: The dimensions in the figure show the minimum extent of the patient environment in a free surrounding. It applies when the patient's position is predetermined; if not, all reasonably practicable patient positions should be considered.

9.3.10 Medical IT system

IT electrical system fulfilling specific requirements for medical applications.

Notes:

- (a) The combination of an IT system and an Insulation Monitoring Device (IMD) is referred to as a medical IT system.
- (b) These supplies are also known as isolated power supply systems (IPS).
- (c) Currently, many medical IT systems are backed-up by Uninterruptible Power Supplies (UPS). Refer to Figure 9.4 for a typical arrangement.

9.4 Assessment of general characteristics

710.3 In order to determine the classification and group number of a medical location, it is necessary that the relevant medical staff indicate which medical procedures will take place within the location. Based on the intended use, the appropriate classification for the location shall be determined.

Notes:

- (a) Classification of a medical location is related to the type of contact between applied parts and the patient, the threat to safety of the patient owing to a discontinuity (failure) of the electrical supply, as well as the purpose for which the location is used.
- (b) Guidance on the allocation of a group number and classification of safety services for medical locations is shown in Table 9.1.
- (c) To ensure protection of patients from possible electrical hazards, additional protective measures are applied in medical locations. The type and description of these hazards can vary according to the treatment being administered. The purpose for which a location is to be used may justify areas with different classifications (Group 0, 1 or 2) for different medical procedures.
- (d) Applied parts are defined by the particular standards for ME equipment.
- (e) The possibility that certain medical locations could be used for different purposes may require a higher group allocation (guidance shown in Table 9.1).

▼ **Table 9.1** Group number and classification of safety services for medical locations

| | Medical location | Group | | | Classification (see 9.18.1) | |
|----|--|-------|----------------|---|-----------------------------|------------------|
| | | 0 | 1 | 2 | ≤ 0.5 s | > 0.5 s ≤15 s |
| 1 | Massage room | X | X | | | X |
| 2 | Bedrooms | | X | | | X |
| 3 | Delivery room | | X | | X ^a | X |
| 4 | EKG, EEG, EHG room | | X | | | X |
| 5 | Endoscopic room | | X ^b | | X | X ^b |
| 6 | Examination or treatment room | | X | | X | X |
| 7 | Urology room | | X ^b | | X | X ^b |
| 8 | Radiological diagnostic and therapy room | | X | X | X | X |
| 9 | Hydrotherapy room | | X | | | X |
| 10 | Physiotherapy room | | X | | | X |
| 11 | Anaesthetic area | | | X | X ^a | X |
| 12 | Operating theatre | | | X | X ^a | X |
| 13 | Operating preparation room | | | X | X ^a | X |
| 14 | Operating plaster room | | | X | X ^a | X |
| 15 | Operating recovery room | | | X | X ^a | X |
| 16 | Heart catheterization room | | | X | X ^a | X |
| 17 | Intensive care room | | | X | X ^a | X |
| 18 | Angiographic examination room | | | X | X ^a | X |

| | Medical location | Group | | | Classification (see 9.18.1) | |
|----|---------------------------------------|-------|---|---|--------------------------------|------------------|
| | | 0 | 1 | 2 | ≤ 0.5 s | > 0.5 s ≤15 s |
| 19 | Haemodialysis room | | X | | | X |
| 20 | Magnetic resonance imaging (MRI) room | | X | X | X | X |
| 21 | Nuclear medicine | | X | | | X |
| 22 | Premature baby room | | | X | X ^a | X |
| 23 | Intermediate Care Unit (IMCU) | | | X | X | X |

Notes on Table 9.1:

- (a) Luminaires and life-support ME equipment requiring a power supply within 0.5 s or less.
 (b) Not being an operating theatre.

Notes:

- (i) A definitive list of medical locations showing their assigned group and classification is impracticable. The above list is a **guide only** and should be read in conjunction with 9.4.
 (ii) Changes to the above list based on 'Risk Assessment', and agreed locally by clinicians and management, are also acceptable provided that all relevant risks associated with the installation are mitigated by an appropriate measure.
 (iii) Further guidance on the application of Table 9.1 and grouping and classification of haemodialysis rooms can be found in IET publication *A Guide to Electrical Installations in Medical Locations*.

9.5 Types of system earthing

710.312.2 PEN conductors shall not be used in medical locations and medical buildings downstream of the main distribution board.

Note: In Great Britain, Regulation 8(4) of the ESQCR 2002 (as amended) prohibits the use of PEN conductors in a consumer's installation.

9.6 Supplies

710.313.1 In medical locations, the distribution system shall be designed and installed to facilitate the automatic changeover from the main distribution network to the electrical safety source feeding essential loads, as required by Regulation 560.5.

710.512.1.2 9.6.1 Power supply for medical locations of Group 2

In the event of a first fault to earth, a total loss of supply in Group 2 locations shall be prevented.

Note: This is not solely referring to medical IT supplies, it applies equally to the level of resilience a designer must apply to the distribution circuits supplying a Group 2 location. For example, that the loss of one distribution circuit through fault or fire will not cause total loss of supply to that location.

9.7 Protection against electric shock

710.410.3.5 Protective measures providing basic protection (protection against direct contact) utilizing obstacles or placing out of reach (see Section 417) are not permitted.

710.410.3.6 Protective measures of a non-conducting location (see Regulation 418.1), earth-free local equipotential bonding (see Regulation 418.2) or electrical separation for the supply of more than one item of current-using equipment (see Regulation 418.3) are not permitted.

Notes:

- (a) Only protection by insulation of live parts or by the use of Class II equipment are permitted.
- (b) A medical IT system does not use electrical separation as the sole means of protection against electric shock (refer to 9.8.5).

9.8 Requirements for fault protection (protection against indirect contact)

9.8.1 Automatic disconnection in case of a fault

710.411.3.2.1 Care shall be taken to ensure that simultaneous use of many items of equipment connected to the same circuit cannot cause unwanted tripping of the residual current device (RCD).

Notes:

- (a) This applies to all circuits (including lighting circuits) supplied by a TN or TT system.
- (b) Designers should take note of the inherent high protective conductor (earth leakage) currents associated with a variety of electronic equipment. Examples of these are information technology equipment and mobile X-ray equipment, which can produce a higher allowable earth leakage current than normal medical electrical equipment.

710.411.3.2.1 In Group 1 and Group 2 medical locations, where RCDs are required, only type A (complying with BS EN 61008 or BS EN 61009) or type B (complying with IEC 62423) shall be selected, depending on the possible fault current arising. Type AC RCDs shall not be used.

Notes:

- (a) This applies to all circuits (including lighting circuits) supplied by a TN-S system.
- (b) Type A RCDs ensure tripping for:
 - (i) residual sinusoidal alternating currents.
 - (ii) residual pulsating direct currents.
 - (iii) residual pulsating direct currents superimposed by a smooth direct current of 6 mA, with or without phase-angle control, independent of the polarity.
- (c) Type B RCDs ensure tripping for Type A and:
 - (i) residual sinusoidal currents up to 1000 Hz.
 - (ii) residual sinusoidal currents superimposed by a pure direct current.
 - (iii) pulsating direct currents superimposed by a pure direct current.
 - (iv) residual currents resulting from various configurations of rectifier circuits.

For example, a typical X-ray generator uses a rectifier circuit to generate a d.c. intermediate voltage. Due to this, equipment manufacturers often advise the use of a Type B RCD.

(d) Type AC RCDs ensure tripping for **only** residual sinusoidal alternating currents.

710.411.3.2.5 In Group 1 and Group 2 medical locations, the following shall apply:

- (a)** for IT, TN and TT systems, the voltage presented between simultaneously accessible exposed-conductive-parts and/or extraneous-conductive-parts shall not exceed 25 V a.c. or 60 V d.c.; and
- (b)** for TN and TT systems, the requirements of Table 9.2 shall apply.

▼ **Table 9.2** Maximum disconnection times for TN and TT systems in Group 1 and Group 2 medical locations

| System | 25 V < U ₀ ≤ 50 V | | 50 V < U ₀ ≤ 120 V | | 120 V < U ₀ ≤ 230 V | | 230 V < U ₀ ≤ 400 V | | U ₀ > 400 V (seconds) | |
|--------|------------------------------|------|-------------------------------|------|--------------------------------|------|--------------------------------|------|----------------------------------|------|
| | (seconds) | | (seconds) | | (seconds) | | (seconds) | | | |
| | a.c. | d.c. | a.c. | d.c. | a.c. | d.c. | a.c. | d.c. | a.c. | d.c. |
| TN | 5 | 5 | 0.3 | 2 | 0.3 | 0.5 | 0.05 | 0.06 | 0.02 | 0.02 |
| TT | 5 | 5 | 0.15 | 0.2 | 0.05 | 0.1 | 0.02 | 0.06 | 0.02 | 0.02 |

Note: In TN systems, a value of 25 V a.c. or 60 V d.c. **may** be met with protective equipotential bonding, complying with the disconnection time in accordance with Table 9.2 (refer also to the notes associated with 9.12.1).

9.8.2 Additional protection

710.411.3.3 Where a medical IT system is used, additional protection by means of an RCD shall **not** be used.

9.8.3 TN systems

710.411.4 In final circuits of Group 1 medical locations rated up to 63 A, RCDs with a rated residual operating current not exceeding 30 mA and meeting the requirements of Regulation 415.1.1 shall be used.

Note: Regulation 415.1.1 states that the use of RCDs with a rated residual operating current ($I_{\Delta n}$) not exceeding 30 mA and an operating time not exceeding 40 ms at a residual current of 5 $I_{\Delta n}$ is recognized in a.c. systems as additional protection in the event of failure of the provision for basic protection and/or the provision for fault protection or carelessness by users.

In final circuits of Group 2 medical locations (except for the medical IT system), RCDs having the characteristics specified in Regulation 415.1.1 shall be used in circuits for:

- (a)** the supply of movements of fixed operating tables;
- (b)** X-ray units; and
- (c)** large equipment with a rated power greater than 5 kVA.

Notes:

- (i)** The list of circuits (a) to (c) above is not exhaustive. This implies that the designer is not restricted to providing only medical IT final circuits in a Group 2 medical location, but should also consider the wider implications of Group 2 medical location design.

- (ii) The requirement in (b) of the listed circuits is mainly applicable to mobile X-ray units brought into the patient environment. Correct selection of the RCD that is insensitive to leakage spikes caused by capacitance will meet the requirement for mobile X-ray units. The maximum leakage current in normal condition, as defined in BS EN 60601-2-54, is 2.5 mA for a mobile X-ray unit and 5 mA for a permanently installed X-ray unit.
- (iii) Other items of equipment include mobile imaging and diagnostic equipment brought into the patient's environment. These types of equipment may draw a substantially high current and, if connected to the IT system, have been known to overload the IT transformer (see 9.9).
- (iv) Equipment supplied by RCD-protected circuits provides adequate safety to the user and patient where the supply failure, caused by a single fault to earth, does not present danger to the patient's life.
- (v) Whilst Residual Current Monitoring is not mandated, insulation monitoring may be considered appropriate. In using this type of monitoring, designers will need to consider the threshold of alarm and how this alarm will be identified/acted upon.
- (vi) Designers and stakeholders have to ascertain the suitability of any electrical equipment brought into the patient environment and whether it is connected to an IT, TN or TT system, where the latter should be RCD protected. Special consideration should be given when current-carrying equipment possessing non-specified leakage currents is permanently installed in a Group 2 medical location.
- (vii) Designers must fully consider the impact of assigning medical IT circuits for use in non-life support applications. That is, not all socket-outlets in a theatre environment need to be connected to the IT system; for example, supplies to shavers, music systems, computerised records (PACS) etc. These may be required to be supplied by UPS. However, for simplicity designers may wish to provide non-IT circuits that are UPS backed.

9.8.4 TT systems

710.411.5 In Group 1 and Group 2 medical locations, RCDs shall be used as protective devices and the requirements of 9.8.3 apply.

9.8.5 IT system

710.411.6 In Group 2 medical locations, an IT system shall be used for final circuits supplying
710.411.6.3.1 medical electrical equipment and systems intended for life support, surgical applications and other electrical equipment located within the 'patient environment'.

Note: Any non-medical electrical equipment located or brought into the patient environment has to be assessed for its suitability for use in this environment.

For each group of rooms serving the same function, at least one IT system is necessary. The IT system shall be equipped with an insulation monitoring device (IMD) in accordance with BS EN 61557-8:2007, with the following additional specific requirements:

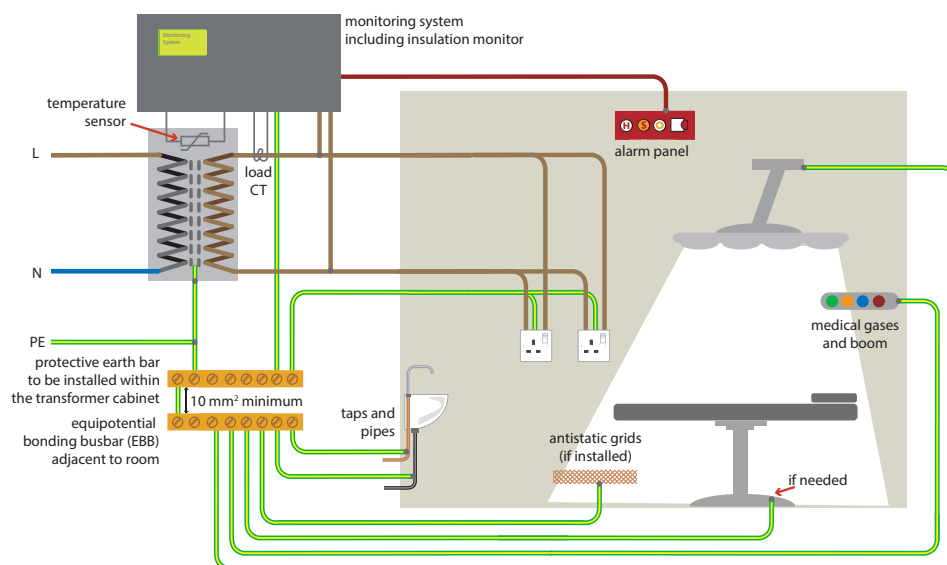
- (a) a.c. internal impedance shall be $\geq 100 \text{ k}\Omega$;
- (b) internal resistance shall be $\geq 250 \text{ k}\Omega$;
- (c) test voltage shall be $\leq 25 \text{ V d.c.}$;

- (d) injected current, even under fault conditions, shall be ≤ 1 mA peak;
- (e) indication shall take place at the latest when the insulation has decreased to 50 k Ω . If the response value is adjustable, the lowest decreased possible set point value shall be ≥ 50 k Ω . A test device shall be provided; and
- (f) response and alarm-off time shall be ≤ 5 s.

Notes:

- (i) An indication is recommended if the protective earth (PE) or wiring connection of the IMD is lost.
- (ii) For further technical clarification on medical IT systems, refer to IET publication *A Guide to Electrical Installations in Medical Locations*.

▼ **Figure 9.2** Typical theatre layout of medical IT system with insulation monitoring



For each medical IT system, an acoustic and visual alarm system incorporating the following components shall be arranged at a suitable place so that it can be permanently monitored (via audible and visual signals) by the medical staff and, furthermore, is reported to the technical staff:

- (g) a green signal lamp (light) to indicate normal operation;
- (h) a yellow signal lamp (light) that illuminates when the minimum value set for the insulation resistance is reached. It shall not be possible for this light to be cancelled or disconnected;
- (i) an audible alarm that sounds when the minimum value set for the insulation resistance is reached. This audible alarm may be silenced; and
- (j) the yellow signal shall go out on removal of the fault and when the normal condition is restored.

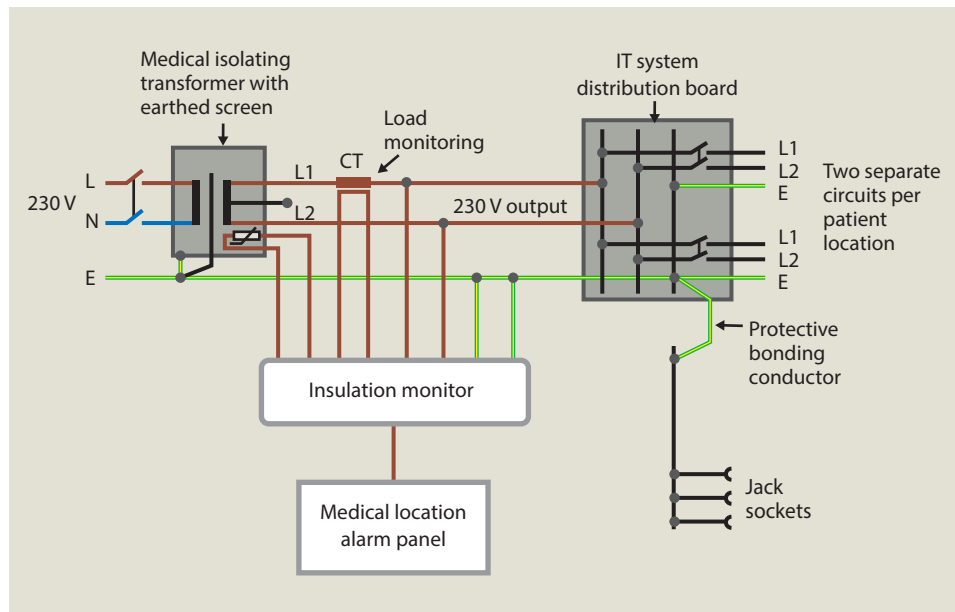
Documentation shall be easily readable in the medical location and shall include:

- (k) the meaning of each type of signal; and
- (l) the procedure to be followed in case of an alarm at first fault.

Notes:

- (a) These colours only apply to the visual alarm system associated with the medical IT system. The colour of indicator lights for medical equipment is given in BS EN 60601-1. Care should be taken over the selection of any indicator lights visible within the patient environment to avoid any confusion by medical staff.
- (b) A system constructed to the requirements of 9.8.5 is referred to as a medical IT system.
- (c) For illustration of a typical theatre layout refer to Figure 9.2.
- (d) For illustration of a typical medical IT system arrangement refer to Figure 9.3.

▼ **Figure 9.3** Typical medical IT system arrangement



710.411.6.3.2 Monitoring of overload and high temperature for the IT transformer is required.

Note: This would result in an early alarm to avoid unnecessary tripping of the IT transformer. The alarm is raised when the load current exceeds the rated output of the transformer. However, if it is within the specification of the equipment to adjust the set point, then it is desirable that the alarm is raised earlier, say at 10 per cent below the rated output.

710.411.6.3.3 In addition to an insulation monitoring device, consideration shall be given to the installation of fault location systems, which localize insulation faults in any part of the medical IT system. The insulation fault location system shall be in accordance with BS EN 61557-9.

9.9 Transformers for IT systems

710.512.1.1 Transformers shall be in accordance with BS EN 61558-2-15, installed in close proximity to the medical location and with the following additional requirements:

- (a) The leakage current of the output winding to earth and the leakage current of the enclosure, when measured in no-load condition and the transformer supplied at rated voltage and rated frequency, shall not exceed 0.5 mA.
- (b) At least one single-phase transformer per room or functional group of rooms shall be used to form the IT systems for mobile and fixed equipment, the rated output of which shall be not less than 0.5 kVA and not more than 10 kVA.

Where two or more transformers are needed to supply equipment in one room, they shall not be connected in parallel.

- (c) If the supply of three-phase loads via an IT system is also required, a separate three-phase transformer shall be provided for this purpose.

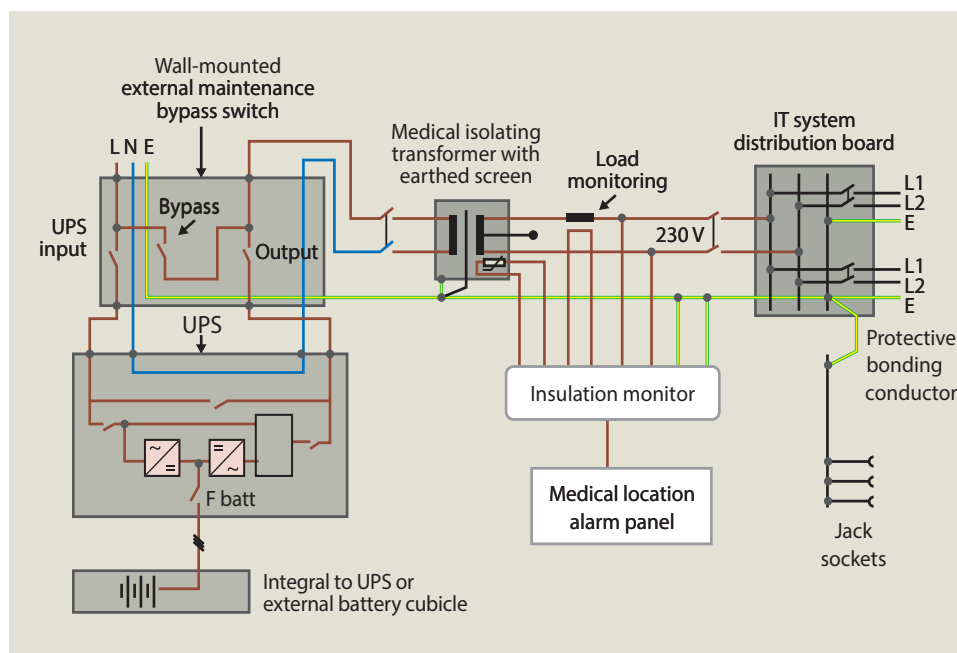
For monitoring refer to 9.8.5.

Capacitors shall not be used in transformers for medical IT systems.

Notes:

- (a) When selecting circuit-breakers, designers need to take into account possible high inrush currents associated with the IT transformer and, in particular, inrush currents associated with equipment connected to final circuits on the output of the IT transformer. In this instance, Regulation 533.2.1 applies which calls for consideration of peak load current values rather than just steady-state values. BS EN 61558-2-15 states that the maximum inrush current of the IT transformer shall not exceed 12 times the peak value of the rated input current.
- (b) Neither CENELEC HD 60364-7-710 (2012) nor BS 7671:2008+A3:2015 refer to the use of Uninterruptible Power Supplies (UPS) as safety back-up to the IPS system in Group 2 medical locations where the latter serves life-support equipment. The required safety has been generally provided by standby generators and embedded equipment batteries. However, static UPS units are being used frequently to provide such safety back-up. This is recommended by the Department of Health guidance (HTM 06-01 Part A). It ensures a back-up supply is continuously available to cover a variety of treatment options. Please refer to Figure 9.4 for a typical arrangement of the UPS supply.
- (c) For further detailed arrangements of the UPS system refer to IET publication *A Guide to Electrical Installations in Medical Locations*.
- (d) By convention, both conductors constituting the output of the secondary of the medical IT transformer (Fig. 9.2) are considered 'live' and carry a significant potential (by capacitive coupling) with respect to earth. It is recommended that both output conductors from an IPS circuit should be coloured brown and identified as L1 and L2. Composite cable conductors can be sleeved brown at their terminations.

▼ **Figure 9.4** Typical arrangement of a UPS back-up to a medical IT system



9.10 Functional extra-low voltage (FELV)

710.411.7 In medical locations, functional extra-low voltage (FELV) is **not** permitted as a method of protection against electric shock.

9.11 Protection by SELV and PELV

710.414.1 When using SELV and/or PELV circuits in Group 1 and Group 2 medical locations, the nominal voltage applied to current-using equipment shall not exceed 25 V rms a.c. or 60 V ripple-free d.c. Protection by basic insulation of live parts, as required by Regulation 416.1 or by barriers or enclosures as required by Regulation 416.2, shall be provided.

710.414.4.1 In Group 2 medical locations, where PELV is used, exposed-conductive-parts of equipment, e.g. operating theatre luminaires, shall be connected to the circuit protective conductor.

9.12 Supplementary equipotential bonding (additional protection)

710.415.2.1 In each Group 1 and Group 2 medical location, supplementary equipotential bonding shall be installed and the supplementary bonding conductors shall be connected to the equipotential bonding busbar for the purpose of equalizing potential differences between the following parts, which are located, or that may be moved into, the 'patient environment':

- (a) protective conductors;
- (b) extraneous-conductive-parts;
- (c) screening against electrical interference fields, if installed;
- (d) connection to conductive floor grids, if installed; and
- (e) metal screen of isolating transformers, via the shortest route to the earthing conductor.

Supplementary equipotential bonding connection points for the connection of medical electrical equipment shall be provided in each medical location, as follows:

- (f) Group 1: one per patient location; and
- (g) Group 2: a minimum of four, but not less than 25 per cent of the number of medical IT socket-outlets provided per patient location.

Notes:

- (a) Fixed conductive non-electrical patient supports, such as operating theatre tables, physiotherapy couches and dental chairs, should be connected to the equipotential bonding conductor unless they are intended to be isolated from earth.
- (b) In medical locations the equipotential bonding busbar (EBB) historically was referred to as the earth reference bar (ERB).

9.12.1 Resistance of protective conductors in Group 1 medical locations

710.415.2.2 In Group 1 medical locations:

- (a) the resistance of the protective conductors between the earth terminal of any socket-outlet (or fixed equipment) and any exposed-conductive-part and/or extraneous-conductive-part shall be such that the voltages given in 9.8.1 (Regulation 710.411.3.2.5 indent (i)) are not exceeded; and
- (b) the measured resistance between the earth terminal of any socket-outlet (or fixed equipment) and any extraneous-conductive-part shall not exceed 0.7 ohm.

Notes:

- (a) TN systems in Group 1 locations should be protected by RCDs designed to operate within 0.3 s.
- (b) Designers should ensure that in TN and TT systems, touch voltages of 25 V a.c. or ripple-free 60 V d.c. under single fault conditions are not exceeded (this is the voltage between exposed-conductive-parts and/or extraneous-conductive-parts and should **not** be confused with any values referenced in IEC/TR2 60479-1 *Effects of current on human beings and livestock - General aspects*).

This may be obtained by the provision of protective equipotential bonding in conjunction with circuit protective conductors for the particular circuit. In the case of TT systems, a satisfactory value of R_A will also be required.

- (c) The value of 0.7 ohm is a maximum, as calculation would be impossible since the protective conductors are not part of the circuit (where the protective device value is known). As a practical application, in general a value of 0.35 ohm can be expected between the EBB and the earth terminal of any socket-outlet (or fixed equipment) and any exposed-conductive-part and/or extraneous-conductive-part.
- (d) Designers generally aim to achieve figures below 0.7 ohm.

9.12.2 Resistance of protective conductors in Group 2 medical locations

710.415.2.2 In Group 2 medical locations, the resistance of the protective conductors, including the resistance of the connections, between the terminals for the protective conductor of socket-outlets and of fixed equipment or any extraneous-conductive-parts and the equipotential bonding busbar shall not exceed 0.2 ohm.

Notes:

- (a) Condition (a) of 9.12.1 is also applicable to Group 2 medical locations.
- (b) TN systems in Group 2 medical locations should be protected by RCDs designed to operate within 0.3 s.
- (c) The 0.2 ohm (subject to device characteristics) serves to limit any potential difference between the exposed-conductive-parts of ME equipment and the EBB. Any such potential difference should remain within the limits designed for Group 2 locations under fault conditions. As a practical application, in general a value of 0.1 ohm (subject to device characteristics) can be expected between the EBB and the earth terminal of any socket-outlet (or fixed equipment) and any exposed-conductive-part and/or extraneous-conductive-part.
- (d) Additional technical clarification is contained within IET publication *A Guide to Electrical Installations in Medical Locations*.

9.12.3 Specification of the equipotential bonding busbar

710.415.2.3 The equipotential bonding busbar shall be located in or near the medical location. Connections shall be so arranged that they are accessible, labelled, clearly visible and can easily be disconnected individually.

Notes:

- (a) The EBB is located within the vicinity of the Group 2 location (see (b) below) to allow short lengths of bonding cables to be connected (for example, 6 mm²), so the resistive values remain within the 0.2 ohm. Where the additional protective earth bar is located some distance away, within the vicinity of the distribution board of the IT transformer panel, the connection between the EBB and this panel is by a larger size earthing cable (for example, 10 mm²). Refer to Figure 9.2. All related circuits must be isolated before these conductors are disconnected.
- (b) It is recommended as general guidance that:
 - (i) the EBB is located within or directly adjacent to the location, with adequate access to carry out any maintenance and periodic inspection/testing etc.;
 - (ii) the EBB enclosure should be permanently labelled for the location and the group number; and
 - (iii) record drawings should be marked with the location of the EBB.
- (c) It is recommended that radial wiring patterns are used to avoid 'earth loops' that may exacerbate electromagnetic disturbances.

9.13 Distribution boards

710.511.1 Distribution boards shall meet the requirements of the BS EN 60439 series.

Distribution boards for Group 2 medical locations should be installed in close proximity to the locations they serve and be clearly identified.

9.14 Explosion risk

710.512.2.1 Electrical devices, e.g. socket-outlets and switches, installed below any medical-gas outlets for oxidizing or flammable gases shall be located at a distance of at least 0.2 m from the outlet (centre to centre), so as to minimise the risk of ignition of flammable gases.

Note: Requirements for medical electrical equipment for use in conjunction with flammable gases and vapours are contained in BS EN 60601-1.

9.15 Wiring systems in Group 2 medical locations

710.52 Any wiring system within Group 2 medical locations shall be exclusively for the use of equipment and accessories within those locations.

Note: This is to ensure that any faults and/or electromagnetic disturbances in wiring and equipment not meeting the requirements of medical locations cannot affect the safety of the medical location.

9.15.1 Protection of wiring systems in Group 2 medical locations

710.531.1 Overload current protection shall not be used in either the primary or secondary circuit of the transformer of a medical IT system.

Overcurrent protection against short-circuit and overload current is required for each final circuit.

Notes:

- (a) Overcurrent protective devices (e.g. fuses) may be used in the primary circuit of the transformer for short-circuit protection only.
- (b) Refer to Figure 9.3 for a typical medical IT system arrangement.

9.16 Lighting circuits

710.559 In Group 1 and Group 2 medical locations, at least two different sources of supply shall be provided. One of the two sources shall be connected to the electrical supply system for safety services.

9.16.1 Safety lighting

710.560.9.1 In the event of mains power failure, the changeover period to the safety services source shall not exceed 15 s. The necessary minimum illuminance shall be provided for the following:

- (a) emergency lighting and exit signs (to BS 5266).
- (b) locations for switchgear and controlgear for emergency generating sets, and for main distribution boards of the normal power supply and for power supply for safety services.
- (c) rooms in which essential services are intended. In each such room at least one luminaire shall be supplied from the power source for safety services.
- (d) locations of central fire alarm and monitoring systems.
- (e) rooms of Group 1 medical locations. In each such room at least one luminaire shall be supplied from the power supply source for safety services.
- (f) rooms of Group 2 medical locations. A minimum of 90 per cent of the lighting shall be supplied from the power source for safety services.

The luminaires of the escape routes shall be arranged on alternate circuits.

9.17 Socket-outlets

9.17.1 Circuits protected by RCDs

710.531.2.4 For each circuit protected by an RCD with a rated residual operating current not exceeding 30 mA and meeting the requirements of Regulation 415.1.1, consideration shall be given to reduce the possibility of unwanted tripping of the RCD due to excessive protective conductor currents produced by equipment in normal operation.

9.17.2 Socket-outlet circuits in the medical IT system for Group 2 medical locations

710.553.1 Socket-outlets intended to supply medical electrical equipment shall be unswitched.

At each patient's place of treatment, e.g. bedheads, the configuration of socket-outlets shall be as follows:

- ▶ each socket-outlet supplied by an individually protected circuit; or

- ▶ several socket-outlets separately supplied by a minimum of two circuits.

Socket-outlets used on medical IT systems shall be coloured blue and be clearly and permanently marked 'Medical Equipment Only'.

Notes:

- (a) The two circuits are normally fed from the same IT transformer, where each circuit is individually protected.
- (b) The designer shall consider the use of the socket-outlets and any equipment connected including the assessment of any loads and their associated inrush currents (refer to Note (a) of 9.9).

9.18 Safety services

- 710.56 A power supply for safety purposes is required which will maintain the supply for continuous operation for a defined period within a pre-set changeover time.

The safety power supply system shall automatically take over if the voltage of one or more incoming live conductors at the main distribution board of the building has dropped for more than 0.5 s and by more than 10 per cent in regard to the nominal voltage.

710.560.4 9.18.1 Classification of safety services for medical locations

Classification of safety services is listed in Regulation 560.4.1 (refer to Table 9.3).

▼ **Table 9.3** Classification of safety services necessary for medical locations

| Classification | Changeover time (s) | Description |
|------------------|---------------------|--|
| No-break | 0 | Automatic supply available with no break |
| Very short break | 0.15 | Automatic supply available within 0.15 s |
| Short break | 0.5 | Automatic supply available within 0.5 s |
| Medium break | 15 | Automatic supply available within 15 s |
| Long break | >15 | Automatic supply available in more than 15 s |

Notes:

- (a) Mains-floating UPS sources satisfy the 'No-break' classification requirement. Other types of UPS sources can satisfy the 'Very short break' classification.
- (b) Safety services provided for locations having differing classifications should meet that classification which gives the highest security of supply. Refer to Table 9.1 for guidance on the association of classification of safety services with medical locations.

9.18.2 General requirements for safety power supply sources of Group 1 and Group 2 medical locations

- 710.560.5.5 Primary cells are not allowed as safety power sources.

An additional main incoming power supply, from the general power supply, is not regarded as a source of the safety power supply.

The availability (readiness for service) of safety power supply sources shall be monitored and indicated at a suitable location.

9.18.3 Failure of the general power supply source

710.560.5.6 In case of a failure of the general power supply source, the power supply for safety services shall be energized to feed the equipment stated in 9.18.5.1, 9.18.5.2 and 9.18.5.3 with electrical energy for a defined period of time and within a predetermined changeover period.

9.18.4 Socket-outlets

710.560.5.7 Where socket-outlets are supplied from the safety power supply source they shall be readily identifiable according to their safety services classification.

9.18.5 Electrical sources for safety services

9.18.5.1 Power supply sources with a changeover period not exceeding 0.5 s

710.560.6.1.1 In the event of a voltage failure on one or more line conductors at the distribution board, a safety power supply source shall be used and be capable of providing power for a period of at least 3 h for:

- (a) luminaires of operating theatre tables;
- (b) medical electrical equipment containing light sources being essential for the application of the equipment, e.g. endoscopes, including associated essential equipment, e.g. monitors; and
- (c) life-supporting medical electrical equipment.

The duration of 3 h may be reduced to 1 h for (b) and (c) if a power source meeting the requirements of 9.18.5.2 is installed.

The normal power supply shall be restored within a changeover period not exceeding 0.5 s.

9.18.5.2 Power supply sources with a changeover period not exceeding 15 s

710.560.6.1.2 Equipment meeting the requirements of 9.16.1 and 9.18.7 shall be connected within 15 s to a safety power supply source capable of maintaining it for a minimum period of 24 h, when the voltage of one or more live conductors at the main distribution board for the safety services has decreased by more than 10 per cent of the nominal value of supply voltage and for a duration greater than 3 s.

9.18.5.3 Power supply sources with a changeover period greater than 15 s

710.560.6.1.3 Equipment, other than that covered by sections 9.18.5.1 and 9.18.5.2, which is required for the maintenance of hospital services, may be connected either automatically or manually to a safety power supply source capable of maintaining it for a minimum period of 24 h. This equipment may include, for example:

- ▶ sterilization equipment;
- ▶ technical building installations, in particular air conditioning, heating and ventilation systems, building services and waste disposal systems;
- ▶ cooling equipment;
- ▶ catering equipment; and
- ▶ storage battery chargers.

9.18.6 Circuits of safety services

710.560.7 The circuit that connects the power supply source for safety services to the main distribution board is considered a safety circuit.

Note: Regulation 560.7 of BS 7671 details the requirements associated with circuits for safety services.

9.18.7 Other services

710.560.11 Other services that may require a safety service supply with a changeover period not exceeding 15 s include, for example, the following:

- ▶ selected lifts for firefighters;
- ▶ ventilation systems for smoke extraction;
- ▶ paging/communication systems;
- ▶ medical electrical equipment used in Group 2 medical locations and which serves for surgical or other procedures of vital importance. Such equipment will be defined by responsible staff;
- ▶ electrical equipment of medical gas supply including compressed air, vacuum supply and narcosis (anaesthetics) exhaustion as well as their monitoring devices;
- ▶ fire detection and fire alarms;
- ▶ fire extinguishing systems.

9.19 Diagrams and documentation

710.514.9.1 Plans of the electrical installation together with records, drawings, wiring diagrams and modifications relating to the medical location, shall be provided.

Information provided shall include but not be limited to:

- (a) overview diagrams showing the distribution system of the normal power supply and power supply for safety services, in a single-line representation;
- (b) distribution board block diagrams showing switchgear and controlgear and distribution boards in a single-line representation;
- (c) schematic diagrams of controls;
- (d) the verification of compliance with the requirements of standards; and
- (e) functional description for the operation of the safety power supply services and of the safety power supply system.

710.6 9.20 Inspection and testing

Note: The testing of equipment connected to the electrical installation is outside the scope of this document. For ME equipment refer to BS EN 62353.

9.20.1 Initial verification

710.61 The dates and results of each verification shall be recorded.

Chap 61 The tests specified below under items (a) to (c) shall be carried out, both prior to commissioning and after alteration or repairs and before re-commissioning:

- (a) complete functional tests of the insulation monitoring devices (IMDs) associated with the medical IT system, including insulation failure, transformer high temperature, overload, discontinuity and the acoustic/visual alarms linked to them;
- (b) measurements of leakage current of the output circuit and of the enclosure of the medical IT transformers in no-load condition (refer to 9.9); and
- (c) measurements to verify that the resistance of the supplementary equipotential bonding is within the limits stipulated by 9.12.1 and 9.12.2.

Note: The tests specified within HTM 06-01 (Part A) may also be required as part of client requirements.

710.62 9.20.2 Periodic inspection and testing

Chap 62 Notes:

- (a)** In addition to the requirements of Chapter 62 of BS 7671, the following procedures are recommended at the given intervals:
- (i)** annually – complete functional tests of the insulation monitoring devices (IMDs) associated with the medical IT system including insulation failure, transformer high temperature, overload, discontinuity and the acoustic/visual alarms linked to them;
 - (ii)** annually – measurements to verify that the resistance of the supplementary equipotential bonding is within the limits stipulated by 9.12.1 and 9.12.2; and
 - (iii)** every 3 years – measurements of leakage current of the output circuit and of the enclosure of the medical IT transformers in no-load condition (refer to 9.9).
- (b)** Guidance on periodic inspection and testing is given in HTM 06-01 (Part B; also refer to 9.21.1 Note (a)). Client or local Health Authority requirements, if any, may apply.

9.21 Further recommended guidance

9.21.1 The Department of Health

The Department of Health provides medical, building and engineering guidance through its *Health Technical Memoranda (HTM)* series of documents and other documents. Five documents are specifically related to electrical engineering issues.

Notes:

- (a)** In Scotland these documents are referred to as ‘Scottish Health Technical Memoranda’ (SHTM).
- (b)** Some HTM guidance documents may have been produced before the publication of Section 710, as amended, and might contain some outdated information.

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| HTM 06-01 Part A | Electrical Services supply and distribution; Design considerations (2006) |
| HTM 06-01 Part B | Electrical Services supply and distribution; Operational management (2007) |
| HTM 06-02 | Electrical Safety Guidance for low voltage systems (2006) |
| HTM 06-02 | Electrical Safety Handbook |
| HTM 06-03 | Electrical Safety Guidance for high voltage systems (2006) |
| Model Engineering Specification (MES) C44 | |
| Activity Data Base series | |

HTM 06-01 Part A provides guidance for all works on the fixed wiring and integral electrical equipment used for electrical services within healthcare premises. The document should be used for all forms of electrical design work ranging from a new greenfield site to modifying an existing final circuit.

HTM 06-01 Part B addresses the operational management and maintenance of the electrical services supply distribution within a healthcare facility.

HTM 06-02, together with its associated *Safety Guidance Handbook*, gives operational guidance on electrical safety requirements for low voltage systems in healthcare premises.

HTM 06-03 gives operational guidance on electrical safety requirements for high voltage systems in healthcare premises.

9.21.2 IET publication

IET publication *A Guide to Electrical Installations in Medical Locations*.