Medical Electrical Installations

Guidance for Healthcare Staff Involved in Commissioning of New or Refurbished Clinical Areas Containing Mains Powered Medical Devices

Purpose

This document has been produced to compliment and explain the changes that have come about with the publication of BS EN 7671 (2018) - known as the IET Wiring Regulations. One major change simplifies the previous processes for risk assessment of a medical location. A medical location (see BS7671) can be an area or a room.

It also aims to clarify what clinical staff need to undertake in cooperation with the Estates or installing contractors.

The last section is to assist with post installation testing especially for medical radiological equipment and other high-risk areas such as theatres. Experience has shown that checks are required over and above those that the installing electrician is obliged to undertake. These extra tests help to achieve the highest standards in order to reduce risks to the patient and business.

1 Determine the use of the location

Estates should engage clinical staff to ascertain if and what medical devices will be used in that location. This governance process is described in the Department of Health and Social care guidance - HTM 06-01. In the case of independent healthcare providers, the clinical staff still need to decide if devices with applied parts are used or not. The type of applied part is listed in a field on the medical device CE marking label.

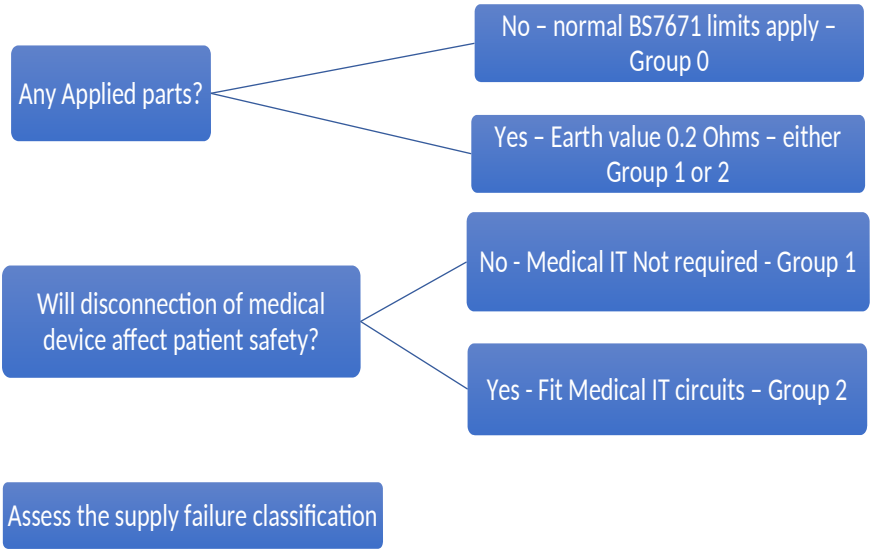
https://www.gov.uk/government/publications/guidance-on-electrical-services-supply-and-distribution-within-healthcare-premises

Determining the use will inform Estates colleagues about the medical location Group designation which is the basis for the electrical design.

Record this decision with the room drawings – as described in HTM 06-01 para 16.36.

Since the introduction of BS7671 (2018) of which fully applies from January 2019, the process is much simpler because you only need to decide if applied parts are fitted to the mains powered medical device. There is no longer a need to decide what **type** of applied parts are used because the maximum earth resistance value for Group 1 and Group 2 medical locations is now the same (0.2 Ohm).

Flow chart for the medical location group category decision.



Supply failure classification refers to a loss of the supply - not disconnection (see section 6). The classification is about how long the medical location and its equipment can be without the supply. This decision is agreed at the design stage by the Electrical Safety Group or local team. The governance process will identify devices or equipment that need a continuous supply or will the back-up generator be sufficient. Refer to HTM 06-01 for more detail.

2 Contracts

Use your contract to ensure the turn-key stakeholder or installing contractor is clear that you want the medical location installed to comply with BS EN 7671 (2018), IET Guidance note 7 (Special Locations) and the Dept. of Health and Social Care guidance HTM 06-01. Also state the medical location group number.

This way, if you find any non-compliance during the testing phase, which can be checked by trained staff, the installing contractor will be obliged to rectify the non-compliant issues. Refer to the attached testing guidance and advice for clinical staff.

It is the clinical staff that determine the **use** of the medical location not Estates. The electrical designers will then specify the location accordingly.

No specific statutory regulation applies to medical electrical installations and instead relies on the duty of care approach using the BS7671 and HTM 06-01 guidance. The guidance will be used in a court of law if a death or injury occurs as a result of non-compliance or lack of risk assessment for derogations.

3 What clinical users should also discuss with Estates

Check that somebody checks the adequacy of the local existing earth cable for refurbished rooms if a new earth isn't being installed.

Determine how many socket-outlets of each type are required. (Blue and White).

If you want USB charging in Group 1 and 2 areas, only use those built to IEC 60601. These must be stand-alone and not within a socket-outlet. Refer to HTM 06-01.

Consider installing a cleaner's socket-outlet using a unique identifier such as a unique colour of the socket-outlet (grey?).

Consider if a mobile x-ray unit will be used in the location as it may need an allocated circuit (numerous reasons).

Check that the supplier quotes the required maximum power requirements (120kVA for an 80KW X-ray generator) and the maximum mains resistance. Note - if the mains cables are too small you won't get the maximum mA!

Training:

- Train staff on the Medical IT alarm indicators and circuit identification markings so they can differentiate circuits in the event of one circuit failing (difficult with frequently changing staff).

Testing:

- Regular electrical testing is required by HTM 06-01.
- Consider independent inspection of an installation or produce a test protocol that the installer fills in.
- Always test the trailer supply and earth connections every time a mobile scanner etc is brought onto site.

4 For MPEs, theatre staff, radiographers and Biomedical/Clinical Engineers - the relevant paragraphs in HTM 06-01 are:

4.11 – 4.30 Assessment process - noting 4.22 specifically lists some radiology rooms as Grade A risk. (group 2)
13.18 The Equipotential Bonding Busbar (EBB) - consider the number of busbars because radiology equipment has a number of earth cables.
15.15 Alarm indicator training.
15.21 Extension lead use (none in Groups 1/2).
15.28 Identification of Medical IT socket-outlets.
15.45 Mobile X-ray unit plugs.
15.53 Liaison.

15.54 Supplier to provide mains supply power and impedance values.
15.59 – 15.63 Emergency Power Off.
16.36 Record the decision for the Medical Location Group
17.74 – 17.77 Testing.

5 Differences between Medical Location Groups

Group 0. No Medical Devices with **Applied Parts** are used.	**Group 1.** Medical devices with **Applied Parts** are used. As group 0 plus:	**Group 2.** Medical Devices with **Applied Parts and patient risk with disconnection.** As Group 1 plus:
No PEN (Protective Earth/Neutral).	EBB Required.	EBB within vicinity.
No EBB	Fit one Supplementary Equipotential Bonding (SEB) point per location.	SEB points - At least four or 25% of the number of the total Medical IT socket-outlets.
Auto Changeover from distribution network to generator	Earth resistance to EBB is 0.2 Ohms (0.1 Ohm design target suggested).	Fit dual circuit Medical IT socket-outlets within location.
Reduce the risk of RCD tripping.	RCD (A/B) or RCBO required for TN socket-outlets. Dual circuits preferred.	Wiring system exclusively within location trunking.
	25V AC touch limit.	RCD use for devices > 5kVA.
	Fit RCD for TT supply.	

* Once this is achieved, assess the business and patient risk for supply FAILURE, to determine if a UPS is required (Classification).

6 Supply Disconnection and Failure

Medical IT socket-outlets are fitted to reduce the risk of DISCONNECTION. They are not installed for any other reason. This is because the risk of an RCD tripping is too high for life-critical devices. It has nothing to do with shock risk reduction – even though the supply is isolated.

Clinical staff need to be involved with the commissioning requirements for supply failure. Back-up generators are generally available but some devices require no break in the supply and therefore, an uninterruptable power supply needs to be specified.

This should be discussed at the Electrical Safety Group.

7 Equipment Safety

The sole aim of Supplementary Equipotential Bonding (SEB) (extra separate earth wire) is to act as a back-up connection should the medical device mains flex earth should fail. Although hospitals should have a mains flex checking schedule, a cable failure can still occur but if an SEB cable is connected, the risk is significantly reduced.

Use SEBs where required and make sure the cables are kept nearby or with the medical device. Battery powered devices don't need an SEB cable.

Note – all dental x-ray units need to be hard-wired by means of an isolator and radial feed as per the requirements of BS7671 (2018) for Group 1 medical Locations including a single EBB. This is because it has a type-B applied part (look on the CE mark label). The exception is when an intra-oral unit is marketed with it mounted on a wheeled stand or is hand-held. DEXA Scanners should also be on a radial spur with a single EBB point - this is because the patient table is an applied part (IEC 60601 sub-clause 3.8 applied parts). Fit an SEB cable to either of the above because a flexible mains cable is used.

8 Guidance for Testing Medical Locations

Scope

This Guidance is for healthcare establishments who wish to ensure a medical location has been installed to meet the requirements of BS7671, IET Guidance Note 7 (Chapter 9) and Department of Health and Social Care Guidance HTM 06-01. ***This guidance assumes the testing engineer is fully trained and competent for this work including an understanding of, and access to, the required documentation.**

A. Visual Check for compliance with BS EN 7671 and HTM 06-01.

Has the medical location been grouped correctly? See previous flowchart.

Count the Medical IT sockets if fitted and are there sufficient Supplementary Earth Bonding (SEB) points?

Does it comply with BS7671 710.415.2.1? 1 SEB per Group 1 Location or for Group 2 Locations - at least four SEBs or 25% of the number of Medical IT. (1 SEB point for every 2 double Socket-outlets).

What type of SEB connector is used? Some pendants come with unique SEB connectors.

Are TN-S and Medical IT circuits clearly labelled so that clinical staff can differentiate between circuits eg A or B? This is so they know which circuit to transfer devices in the event of one circuit failing.

Look at the Equipotential Bonding Busbar (EBB) – was previously called the Earth Ref. Terminal. Is it neat, labelled or untidy? An untidy EBB with faults indicates the quality of the installer. Is the EBB location correct? Is the EBB door and frame earthed if the casing is metal?

Are EBB busbar(s):

- Mounted on insulating mountings?
- The correct fault current rating?
- Nuts tight?

- Removable links fitted? (not required with single stud/terminal EBB).

Medical Radiology Equipment rooms

- Look at the labels of Emergency Off switches. Check the function. Does it drop the room supply contactor (that is after the Main Isolator)? If not - it may be that motorised movements require an Emergency **Stop** which is part of the Medical Device.
- Is the main x-ray isolator labelled “Main X-ray Isolator”? Can the isolator handle be locked off?
- Do the supply wires connect to the isolator supply terminals and not the load terminals? Check the phase colours/markings are correct.

B. Testing TN-S (white) socket-outlets in a Medical Location.

Socket outlets - Use the socket-outlet tester on TNS socket-outlets. Ensure it can test for Earth Neutral reverse. **Do not use on Medical IT socket-outlets** (this is because there is no live and neutral – the voltage is floating and not relative to earth).

If any socket-outlets fail – alert electrical staff and prohibit the use of the sockets immediately.

Note – this tester cannot check for Earth Neutral Reverse.

Domiciliary Medical Device use.

This type of tester can also be used when Medical Devices are to be used in the patient's home. If a fault is identified, do not use the medical device until a qualified electrician has been consulted. This test can be easily introduced and safely undertaken by staff with no electrical skills.

C. Testing Bonding Resistance.

Mains socket-outlet access plug to facilitate safe connection of 4mm test leads.
This can be used for the earth to EBB resistance test and the live to live voltage test (for two phases).

Patient safety relies on the equipotential bonding in a medical location being a low resistance to minimise voltages even in no fault conditions. It is important to understand that the medical device supplier of x-ray equipment is not responsible for the room wiring – this is why the hospital needs to test it when first installed and then annually (as required by HTM 06-01).

This resistance measurement is ideally undertaken by using a meter that does not require test lead compensation (Kelvin Bridge). These meters provide an accurate measurement because the measuring current is higher (1A) than the required minimum of 0.2A as stated in BS EN 61557-16 paragraph 4.1.2 and, the measuring circuitry is of a higher specification than those used by most electricians. The most effective way to test earth resistance is with a high current (25A) meter but these are heavy and can damage medical device circuitry or burn metal surfaces. Using a meter

of at least 200mA short-circuit current, measure the resistance of all socket-outlet **earth** connections on both TNS and Medical IT socket-outlets to the EBB. Consider using a 13A mains socket-outlet access plug as depicted above. This enables 4mm test leads to be connected safely. Measure the resistance of the earth connection between other exposed metal work including the medical device and steel sinks to the EBB.

Any point from exposed metal or the medical device(s) to the EBB should be less than 0.2 Ohms. BS EN 7671 710.415.2.2.

More than 0.2 Ohms means non-compliance but would suggest that readings approaching 0.2 Ohms should be investigated further in interventional/theatre locations.

If the resistance readings are close to non-compliance, using a high resolution DVM with HF block, measure for any touch voltages present between metal parts in the patient area and the EBB. This may strengthen any case to change the earth conductor size to reduce the resistance. Touch voltages are unlikely but it is worth being aware of the possibility. There is no real case to undertake this measurement with resistance values under the 0.1 Ohm design target value – 0.2 Ohm being the maximum permitted.

D. Checking for two TN-S phases in a Medical Location.

Do not do this test on the blue Medical IT sockets.
This test is suggested to help minimise a foreseeable risk. It can be argued that Medical IT sockets eliminate this foreseeable risk to patients if they are sufficiently specified and only used for medical devices but not all locations have them.

The aim is to measure the TN-S live to live voltages between one reference socket-outlet and every other socket-outlet to find out if they are on the same phase or not.

Leave one adapter in one reference socket and compare against the other TN-S white sockets in the same room by moving the second socket-outlet access plug. Measure the VOLTAGE between the red live terminal on one to the other red live terminal.

Set the DVM to > 415 Volts AC. Do not use the current measurement selection or sockets on the DVM.

0V means only one phase in the medical location. No action required. A reading of 415V means two phases in the location – this should be remediated to reduce any risks to the patient.

About the document editor.

Ian Chell MSc FSRP

Ian operates a training and consultancy venture known as Medical Locations.

The training course covers all of the necessary elements with respect to the commissioning and testing of medical electrical installations.

There is a requirement for the installing electrician to test the installation, but the hospital is responsible for the wiring up to the medical device and should consider undertaking extra checks for compliance.

The two-day course includes testing methods as above, but the training can be tailored to meet local needs. Follow up shadowing during the testing of a new location can be included.

Testing and dispute resolution services are also available. Please refer to the website or contact Ian Chell on medical.locations@icloud.com