Medical Electrical Installations.

Guidance for Healthcare Staff Involved in Commissioning of New or Refurbished Clinical Areas where Medical Devices with applied parts will be used (including non-electrical).

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.
This document simplifies the complex language used in 7671 and streamlines the risk assessment of a medical location which can be an area or a room (see BS7671). It also aims to additionally explain, 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. Such additional checks are over and above those that the installing electrician is obliged to undertake and help to achieve the highest standards in order to reduce risks to the patient and business.

1 Determine the use of the location

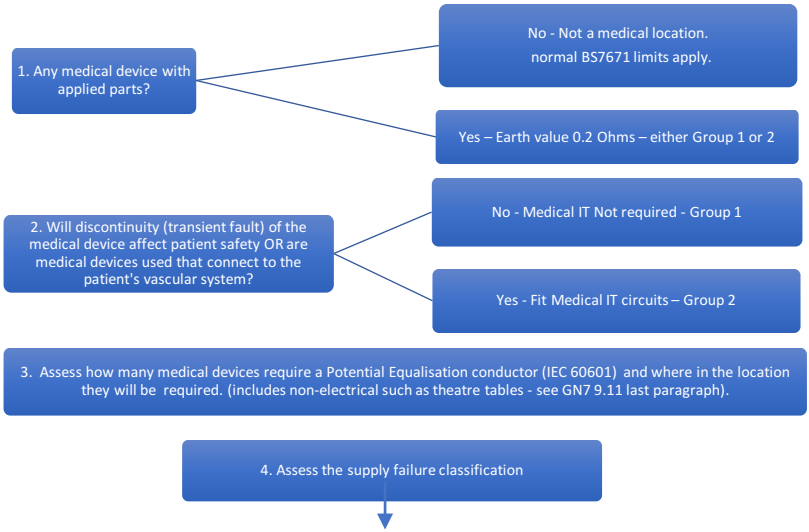
Estates or the responsible organisation should engage clinical staff to ascertain if and what medical devices will be used in that location. This governance process is described in the Department of Health and Social Care guidance - HTM 06-01 and suggests the formation of an electrical safety group (ESG). In the case of independent healthcare providers, the clinical staff still need to follow a similar process.

The process includes finding out if medical devices have an applied part and, if disconnection or failure of the mains supply will put the patient at risk. The clinical staff should also state if device(s) will be directly connected to the patient's vascular system or inserted into a cavity. The type of applied part is listed in a field on the medical device CE or UKCA label but the applied part type doesn't matter for deciding if it is a medical location or not. Record the outcome of this decision process along with the room drawings – as described in HTM 06-01 para 16.36. The ESG should also decide where the supplementary equipotential bonding connection points should be located by **listing the devices that require a PE conductor.**

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

Since the introduction of BS7671 (2018), of which fully applies from January 2019, the process is much simpler, because the earth resistance value is now the same for groups 1 and 2 medial locations.

Decision flow chart for the medical location group. Clinical Staff to answer the device questions



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.

2 Contracts and Duty of Care.

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. Medical Locations supply a template questionnaire and spreadsheet as part of the training.

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 a risk assessment for derogations.

3 What clinical users should also discuss with Estates

Determine how many socket-outlets of each type are required. Consider installing a cleaner's socket-outlet, on a unique circuit, using a unique identifier such as a grey single-gang socket-outlet (to prevent the IT tripping). Ensure Supplementary Equipotential Bonding Connection Points (SEBCP) are near to the Medical IT sockets and TN-S for mobile x-ray c-arms.

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 or the patient zone. Refer to HTM 06-01.

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

Check that the supplier quotes their 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 tube mA! Ensure that somebody checks the adequacy of the local existing earth cable for refurbished rooms if a new earth isn't being installed.

Make sure that the Medical IT socket-outlets and SEBCP's are fitted near to the patient area and include some TN-S (all the same phase) for resilience.

Testing:

- Regular annual medical location earth testing is required by HTM 06-01. Include RCD and medical IT trip tests!
- Consider testing/inspection of a new installation or produce a test protocol that the device installer fills in.
- Always test the trailer supply and earth connections every time a mobile scanner etc is brought onto site. Consider a brass plate with loop values.

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

4.11 – 4.30 Assessment process.
13.18 The Equipotential Bonding Busbar (EBB) - consider the number of busbars because medical radiological equipment often 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 requirements.

16.36 Record the decision for the medical location Group
17.74 – 17.77 Testing.

5 Differences between Medical Location Groups.

Note – do not read across the table – just vertically.

Group 1. Medical devices with **Applied Parts** are used.	**Group 2.** Medical Devices with **Applied Parts are used, patient risk with mains discontinuity or a medical device is used that is connected to the vascular system.** As Group 1 plus:
EBB required within the location or nearby vicinity.	SEBCP points - At least four or 25% of the number of the total Medical IT socket-outlets.
Consider fitting one SEBCP per location.	RCD use for devices > 5kVA.
Earth resistance to EBB is 0.2 Ohms (0.1 Ohm design target is suggested).	Wiring system exclusively within location trunking.
RCD (A/B) or RCBO required for TN-S socket-outlets. Dual circuits preferred.	Fit dual circuit Medical IT socket-outlets within location.
25V AC touch limit.	
No Arc Fault Detection Devices. Fit RCD for TT supply.	

Once the location group is decided, assess the business and patient risk for supply FAILURE, to determine if a UPS is required (Classification within BS7671).

6 Supply Discontinuity and Failure.

Medical IT socket-outlets are fitted to reduce the risk of DISCONTINUITY. 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 Ensuring Medical Device Safety.

The sole aim of a Supplementary Equipotential Bonding Connection Point (SEBCP) is to connect a removable earth cable to the Medical Device which has a connection point for the extra earth cable (known in IEC 60601 as the potential equalisation (PE) cable). If the medical device instructions advise the use of PE cables, then make sure they are used.

Use SEBCPs where required and make sure the PE cables are kept nearby or with the medical device. Battery powered devices don't need a PE 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. 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 terminal EBB - this is because the patient table is an applied part (IEC 60601 sub-clause 3.8 applied parts). Consider fitting a permanent SEB cable to either of the above to back-up the flexible mains cable earth and use flexible protective conduit.

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 SEBCP points?

Does it comply with BS7671 710.415.2.1? 1 SEBCP per Group 1 Location or for Group 2 Locations - at least four SEBCPs or 25% of the number of Medical IT (1 SEBCP for two double-gang socket-outlets).

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

Are TN-S and Medical IT circuits clearly labelled (at least 2 for each) 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) – the EBB was previously called the Earth Reference 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 bar/stud/terminal EBB).

Medical Radiological Equipment:

- 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. Replace all EPOs when equipment is replaced.
- Is the main x-ray isolator clearly labelled eg "Main X-ray Isolator"? Can the isolator handle be locked off?
- Do the supply cables connect to the isolator supply terminals and not the load terminals? Check the cable colours/markings are correct.
- Are fuses/trips/RCD/RCBO the correct rating?
- DEXA or Intra-oral dental – Fused spur and single EBB fitted?

MRI Suites.

Undertake testing before the magnet is switched on. Annual SEB/socket-outlet resistance tests can be undertaken using the resistance meter outside of the room with long leads. (HTM 06-01 17.74/75)

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). Locally

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 supplier of medical radiological equipment is not responsible for the room wiring – this is why the hospital needs to consider testing 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. 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 in the location from conductive fittings, socket-outlet earth pins and SEB connection points to the EBB should be less than 0.2 Ohms. BS EN 7671 710.415.2.2. This also applies to earth connection points on medical devices - not its casing.

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.

As part of the annual check requirement in HTM06-01, check the earth resistance values and use the test button on RCD trips.

D. Checking for two TN-S phases in a Medical Location (only within the Patient Zone).

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.

E. Records and Test Forms (for Hospital Staff)

To reduce red tape – create a form with a “pass” or “fail” but use a text box to give any failure details.

9 Definitions

Applied Part – as defined in IEC 60601 - part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function (ME Medical Equipment).

Equipotential Bonding Busbar (EBB) – *one or a number of copper busbars, insulated from extraneous earth, that act as a central connection point for all protective and supplementary equipotential conductors connected radially. The EBB also acts as the measurement reference point in the medical location and it should be located near or within the medical location so that it is not difficult to measure the earth resistance.*

Electrical Safety Group *- Consultation group run by the healthcare provider. This is described in detail within HTM 06-01.*

Gross Shock *– This describes the classic risks of electric shock caused by electrical power and is minimised by the usual safety standards for electricity.*

Medical Location: location *(area or room), where medical devices with applied parts are used*, intended for purposes of diagnosis, treatment including cosmetic treatment, monitoring and care of patients. Note – see patient definition below. *(A cosmetic laser may be a*

medical device and have an applied part).

Group 0 Medical Location. *Group 0 is essentially any part of the Healthcare establishment other than a medical location – in summary – not applicable.*

Group 1 Medical Location - where supply discontinuity* to the medical device with **does not** represent a threat to the safety of the patient and Medical Devices with applied parts are intended to be used.

Group 2 Medical Location - where supply discontinuity to the medical device can cause danger to life **or** where medical devices with are intended to be used that *connect to the patient's circulatory system.*

Medical Device. *Refer to the definition in the Medical Device Regulations - note: this description refers to a medical device rather than medical equipment (BS7671) because regulations are of a higher order than guidance.*

Micro-shock – *the generic term used to describe the risk of human heart fibrillation caused by small 50Hz AC currents passing through heart muscle. The risks are stochastic (calculated) and are often referred to as risk percentages. Radial earth conductors to the EBB with a low resistance, minimises the risk of micro-shock.*

Patient - Living being (person or animal) undergoing a

medical or surgical or dental procedure. A person undergoing surgical treatment for cosmetic purposes may also be regarded as a patient.

Potential Equalising Conductor (PEC) IEC 60601 *– a cable supplied with a medical device that should be used in order to equalise any potential differences in the medical location. It is connected to the device metal casing and a Supplementary Equipotential Bonding Connection Point.*

Single fault condition. IEC 60601. condition of me equipment in which a single means for reducing a risk is defective or a single abnormal condition is present.

Supply Discontinuity. Loss of mains *supply due to an RCD or circuit breaker tripping.*

Supply Failure. *Mains network supply loss.*

Supplementary Equipotential Bonding Connection Point (SEBCP) (BS7671). *Wall or panel-mounted connection point for medical device potential equalisation (PE) conductors.*

About the document editor.

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

The medical locations 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 to ensure patient safety. The one-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.

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