Medical Electrical Installation Guidance Notes.

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MEIGaN: The history.

MEIGaN was published to replace TRS 89: (Technical Requirements for the supply and installation of Equipment for Diagnostic Imaging and Radiotherapy (1989))

The first version was published in 2005. The decision to update and enlarge the guidance was made in order to take account of the changes in procedures undertaken in X-ray rooms and other similar locations. V2.0 was published in 2007.
What is the difference between an imaging location and any other type of electrical installation?

A conventional X-ray unit can have three modes of operation.
1. Standby mode.
2. Fluoroscopy mode.
3. Radiography mode.

In Standby mode the unit would draw about 5 kW.
In Fluoroscopy mode the unit would draw about 25 kW.
In Radiographic mode the unit could draw up to 160kW!

The duration of the 160kW load would be one halfcycle.
For some types of examination a burst of exposures may be required at a rate of up to 25 exposures per second for a total of 10 seconds.

In order to accommodate the difference in output required to produce correctly exposed images there are three variables that can be set.
- kV across the tube.
- Tube current.
- Exposure.

kV.
mA.
Time.
The current waveform of a typical high power X-ray unit would look like this:
Such high current pulses would distort the voltage waveform.
There is no voltage stabiliser capable of correcting the input voltage, but modern X-ray units are able to compensate for the variations, providing the characteristics of the mains supply are known.

When the exposures are set, the X-ray unit will predict the effect that this will have on the final output, and alter the internal settings accordingly.
The X-ray equipment manufacturer will specify the maximum mains resistance needed to ensure the correct operation of the equipment. Other parameters such as voltage waveform profile, sag, spikes, and surges, harmonic distortion, etc. will also be specified.

More complex installations such as Angiography systems will call for tighter control of these parameters. Where this is required, the mains supply should be monitored for at least a week including a weekend, and the results made available to the equipment suppliers before an order is placed.

The type of fuse or circuit-breaker will also be specified. The specification must be closely followed. (Most X-ray manufacturers prefer a fuse to a circuit-breaker.)
Single and three phase Mains Resistance.

For a three phase X-ray unit, the mains resistance at the consumer unit in the room should be measured between phases.

For a single phase unit, the mains resistance is measured between phase and neutral.

For a high power three phase unit the mains resistance is likely to be in the order of 0.1Ω.
For a low power single phase unit the mains resistance is likely to be in the order of 0.5Ω.
There are not many instruments available that are capable of measuring the mains resistance of a three phase supply.

In order to give accurate and consistent readings the meter must draw a high current, (~25A)
What Size Cable.

In order to meet the mains resistance requirements the CSA of the mains cable must be greater than the current carrying capacity would suggest.

The longer the cable run the greater would be the CSA of the cable.
What Size Cable.

A three phase installation should be supplied by a five core cable, each conductor being of the same CSA.

Where an existing four core SWA cable is already installed, an additional earth conductor of the same CSA as the phase conductors should be run in parallel with the existing cable.
The earth conductor should terminate on the ERB, ensuring the lowest possible resistance in the earth path.
The other requirements of a Medical Electrical Installation.

Protection against an electric shock is normally based on a hand to hand or hand to foot shock. Current is assumed to be limited by skin resistance. The type of shock experienced is classified as a MACRO Shock.

Classification of Macro-Shock.

- Can’t let go (Child): 5 ma
- Can’t let go (Adult): 10 ma
- Suffocation: 35 ma
- Ventricular fibrillation: 100 ma
- Perception: ~ 1 ma
In a medical location we must also consider the possibility of Micro-Shock.

A Micro-Shock is a shock below the threshold of perception, and is therefore not felt as a shock. (~1mA)

All patients undergoing procedures which involve placing a conductor in the central circulatory system which is accessible outside of the patient are at risk. Such procedures are increasingly used in treatment and diagnosis.

The conductor could be an endoscope used in Key-Hole Surgery, a pacing lead, or most common of all, a catheter, a plastic tube filled with saline.
The diagram shows the potential gradient across the heart for a hand to hand shock, and for a hand to catheter shock.

A Micro-Shock applied to the heart can trigger Ventricular Fibrillation, in which the upper and lower chambers of the heart loose synchronisation.
The drawing shows the structure of the heart and the electrical activity during one cycle.

The pumping action is initiated by a nerve impulse at a point called the Sinus Node(1).

This impulse spreads out, causing the contraction of both atria(2), and gives rise to the P wave.

The atria contract pumping the blood into the ventricles.
Micro-shock

The excitation wave passes from the atria through the Atrio-ventricular node and the “Bundle of His” nerve pathway (3) to the ventricles.

As soon as the excitation reaches the ventricles, their activity, shown by the QRS complex, begins. The ventricles contract forcing blood out into the aorta and pulmonary arteries.

This is followed by the re-polarisation of the ventricles, shown as the T wave. This is the most vulnerable point in the cardiac cycle.
The ECG and Blood pressure curve below shows that when ventricular fibrillation occurs, the synchronised contractions of the atria and ventricles become disorganised, so that pumping action no longer takes place. This causes the blood pressure to drop, and the blood stops circulating.

The result is that the brain becomes starved of oxygen and begins to shut down.

Unless this situation can be quickly reversed death will ensue.
Mechanical stimulation of the heart carries some small risk of triggering ventricular fibrillation. The risk remains at about 0.2% for currents below 10\(\mu\)A, but increases sharply above this point. At 50 \(\mu\)A the probability will have risen to about 1%.
How can we ensure that there are no significant differences in potential between various earthed surfaces?

Providing a correctly designed Earth Reference Bar is installed, there should be no difficulty in achieving a potential difference of less that 10 mV between the various earthed surfaces.

This will ensure that a current of less than $10\,\mu\text{A}$ will flow into the heart.
The Earth Reference Bar.

The only way of preventing micro-shock is to ensure that all earthed surfaces are at the same potential.

In practical terms this means that every medical location where interventional procedures take place should have an Earth Reference Bar.

An Earth Reference Bar is defined as: One or more copper connection bars installed in an enclosure, and forming part of the protective earth system in a room and designated as a reference or datum for the purpose of defining and measuring resistance values.
The Earth Reference Bar.

The copper connecting bars should have a CSA sufficient to carry the peak short circuit current in the event of a short circuit from phase to earth. The bars should be housed in a lockable enclosure mounted in an accessible position and labelled Earth Reference Bar or ERB.

In order to facilitate fault finding, earths should be grouped together as shown in the diagram. There should be sufficient bolts available for each earth conductor to be individually connected. Brass bolts, washers, and nuts should be used.
The photograph below shows an example of an inadequate ERB.
Earthing.

All equipotential bonding and protective earths should be returned to the ERB, together with the earths from all the mains sockets. The maximum resistance measured from the ERB to the earth connection of all installed devices, and the resistance from the ERB to the earth pin of all the mains sockets should be less than 100 milliohms. All accessible conductive surfaces should be earthed to the ERB. A touch voltage check should be made to ensure that there are no touch voltages greater than 10 millivolts present in locations where interventional procedures will take place.
Phase.

All of the mains sockets in the location should be on the same phase. It would seem that this is unnecessary advice since all of the sockets in a given location are always connected to the same phase. Experience shows this not to be the case!
IPS/UPS systems

Most Angiographic room will include an IPS/UPS system, the purpose of which is to increase supply resilience.
The maximum rating of an IPS system is 10kVA. Where there is the possibility of the need for more output than this, two IPS systems must be installed, but both can be supplied from the same UPS. It is common practice where there are more than one IPSs supplying a theatre suite, to split the load in each theatre between two IPS units, so that should one fail, critical items of equipment can be transferred to sockets that are still live. Sockets that are supplied by the IPS should be blue in colour, engraved “Medical Devices Only” in white.

They can be either fitted with a double pole switch or unswitched.

Sufficient, conveniently located sockets should be installed to ensure that extension mains leads are not needed.
Mains supplies to Transportable Diagnostic or Treatment Rooms.

It is often necessary to provide mains supplies to Transportable rooms. Some are self-contained, having a generator built in, or possibly towed behind the vehicle, but in most cases, the mains supply is provided by the hospital where the unit is to be sited.

The example shown here is a mobile chest screening unit.

It is built with an internal generator, but is more usually run from the local mains supply.
MEIGaN says:-

The source of the external mains supply supplying the transportable room shall be TN-S, terminated in a BS EN 60309 compliant switched socket-outlet, which shall be housed in a suitable weather protective, lockable enclosure (minimum IP44). The mains impedance to the socket-outlet shall be measured, and the value recorded. A label shall be fixed to the enclosure giving the mains impedance and current rating of the supply. Any Power Consumption meters shall also be housed in an appropriate enclosure.
The characteristics of the mains supply will be determined by the type of room that will be using the supply.

There are many different types of transportable room, ranging from mobile Mammography units to mobile Angiography units.

There are Mammography units that require only a single phase supply, and which will run on a supply having a mains resistance of 0.5 Ohms.

A full scale Angiography unit will require a three phase supply having a mains resistance of about 0.1 Ohms.
Connecting the transportable room.

A Flexible, Double Insulated cable must be used. For a three phase supply, a five core cable must be used, a single phase supply will need a three core cable. The supply lead and connector rating shall be of sufficient size to prevent significant voltage-drop with instantaneous loads (e.g. X-ray exposure) along with other constant loads. The transportable room is to be earthed by means of the earth conductor in the mains cable. Earth rods, or plates should not be used.
Connecting the transportable room.

For added security, a supplementary earth wire, made up of a high flexibility 10mm² double insulated cable should be connected between the vehicle and the mains socket outlet before the mains cable is plugged in.
Getting more information.

The latest version of the MEIGaN document, together with other papers relating to Electrical Safety can be downloaded from the MHRA web site.

http://www.mhra.gov.uk/SearchHelp/Search/Searchresults/index.htm?within=Yes&keywords=MEIGaN
Conclusion and final thoughts