Medical Locations & Healthcare Electrics

Part 1

Richard Knight
C Eng, MCIBSE, FIHEEM
Village Hotels, Coryton, Cardiff
Monday 6th March 2017

And now me in 2015!

Medical Locations

Safety issues and review of guidance and developments

Guidance and history

• HSR 25 Memorandum of guidance on the Electricity at Work Regs 1989:2015
Third ed, first published 1989

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

• MEIGaN first published 2005, with annex and updated in 2007 to take account of the changes in procedures undertaken in X-ray rooms and other similar locations.

Why MEIGaN?

• The IEC 60364 document makes certain performance requirements, but does not define well how to deliver it in the field

• MEIGaN, requires additional performance tests that are easier to measure in the field e.g. Touch voltages and when to measure them

• It also defines better the practical installation measures to improve chance of passing the tests e.g. ERB design
Guidance and history

The IEE then the IET

• GN7 :1998
• GN7 :2003
• GN7 :2004 reprinted 2006 incorporating amendments to imprints verso
• GN7 :2009
• BS 7671:2008 AMD 1: 2011
• GN7 :2012
• BS 7671:2008 Corrigendum June 2013
• BS 7671:2008 AMD 3: 2015
• GN7 :2015

Why IEE/IET?

• The IEC 60364 document makes certain performance requirements, but does not define well how to deliver it in the field
• GN7 and then BS 7671 are intended to put into a UK context the requirements of IEC 60364
• The variants of GN7 and BS 7671 (8 of them) are intended to cover IEC 60364-7-710:2002 (now HD:March 2012)

EaWR 1989 guidance on regulation 3

A person who may cause danger to others by their actions

In the healthcare setting this might be with withdrawal of power from an ICU (similar has occurred with medical gasses)
Or for example a PFI on an existing site sharing electrical infrastructure (often exasperated by poor understanding of risk and of the system)

Absolute/reasonably practicable

• 'reasonably practicable'. Where qualifying terms are absent the requirement in the regulation is said to be absolute.
• By definition if the clause is “absolute” the requirement must be met regardless of cost or any other consideration

“Reasonably practicable”

Cause 58 gives some guidance

The greater the degree of risk, the less weight that can be given to the cost of measures needed to prevent that risk.
**EaWR 1989 guidance on regulation 8**

**Earthing or other suitable precautions**

Precautions are to be taken by earthing or by preventing contact with exposed conductive parts

this being achieved by earthing, double insulation, safe voltages.....

This regulation is "absolute"

---

**EaWR 1989 guidance on regulation 8**

**Earthing or other suitable precautions**

(a) double insulation;
(b) **earthing**;
(c) connection to a common voltage reference point on the system;
(d) **equipotential bonding**; (e.g. ERB)
(e) use of safe voltages;
(f) earth-free non-conducting environments;
(g) current/energy limitation; and
(h) **separated or isolated systems** (e.g. IPS)

---

**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.**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Current (mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can’t let go (Child)</td>
<td>5</td>
</tr>
<tr>
<td>Can’t let go (Adult)</td>
<td>10</td>
</tr>
<tr>
<td>Suffocation</td>
<td>35</td>
</tr>
<tr>
<td>Ventricular fibrillation</td>
<td>100</td>
</tr>
<tr>
<td>Perception</td>
<td>~1</td>
</tr>
</tbody>
</table>

---

**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.

---

**In a medical location we must also consider the possibility of Micro-Shock.**

- 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.
**Micro-shock**

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.

The excitation wave passes from the atria through the Atrioventricular 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.

---

**Probability of inducing ventricular fibrillation**

![Graph showing probability of inducing ventricular fibrillation](image)

*Published by: Association for the Advancement of Medical Instrumentation ANSVAAMI ES1-1993*

---

**Micro-shock**

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.

---

**Micro-shock**

Mechanical stimulation of the heart carries some small risk of triggering ventricular fibrillation.

The risk remains at about 0.2% for currents below 10 µA, but increases sharply above this point.

At 50 µA the probability will have risen to about 1%.

---

**Probability of inducing ventricular fibrillation**

![Graph showing probability of inducing ventricular fibrillation](image)

*Published by: Association for the Advancement of Medical Instrumentation ANSVAAMI ES1-1993*

Some papers show the risk is higher...
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 10μA 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 conductor should terminate on the ERB, ensuring the lowest possible resistance in the earth path.

This installation was live when this photograph was taken.

Earth conductors should terminate at the ERB not on the isolator or bus bar.

The earth reference bar should be arranged as MEiGaN, this facilitates testing (GSD and section 11) also an easier but slightly less defined.
The photograph below shows an example of an inadequate ERB

Bolt and lug connections are important if these are not carried out correctly these often cause earth resistances (and touch voltages) to increase from what is a very low level.

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.

Earthing

• 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.

So what if both sockets were on the same phase in a group 2 location?

• If socket a is fed from UPS A circuit L1 and another socket is fed from UPS B circuit L1

• Are they really on the same phase?

• Only if the UPSs frequency is tied together by the UPS controls and interlinking cables what if the generator is supplying UPS A, and UPS B is in by pass? If not that will be a touch voltage over 25volts then!!

Phase

• All of the mains sockets in the location should be on the same phase.

• In most locations they should also be fed from an IPS

Supplementary Earth Points

Where:

In 2012 Renal group 1

IET BS 7671:2008 Corrigendum June 2013

Perhaps UPS A & B installations should not have a by pass!!
Supplementary Earth Points

Where:

IET GN 7:2015

How many:

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

vi Group 1: a minimum of one per patient location

vii Group 2: a minimum of four but not less than 25% of the number medical IT socket-outlet provided per medical location.

Supplementary Earth Points

How many are needed?

3 here

Supplementary Earth Points

How many are needed?

1 here

Supplementary Earth Points

How many are needed?

to many to count

lets see how many....

Supplementary Earth Points

How many are needed?

3 here
Supplementary Earth Points
How many are needed? and another here

Supplementary Earth Points
How many are needed? and another here

From a community hospital without a CCU
All from a fairly old stack system

Good socket and stud arrangement
In a cardiac theatre
Shame about the plastic socket

Look out for these, not allowed

Earth reference Bars

Earth reference Bars
So how are they to be identified?

514.13 Warning notices: earthing and bonding connections

States:.....

A durable label to BS 951 with the words "Safety Electrical Connection — Do Not Remove" shall be permanently fixed in a visible position at or near:

(i) the point of connection of every earthing conductor to an earth electrode, and

(ii) the point of connection of every bonding conductor to an extraneous-conductive-part, and

(iii) the main earth terminal, where separate from main switchgear.
Cabling

Equipotential Bonding points, labels

Testing

Test all metal surfaces

And the supplementary earth studs

Including the fixed medical equipment
Testing
That will be a bit high then!

Taps as well
Not all that seems is metal is metal except when it is glued together

Mad socket locations

IPS/UPS systems
Most Cat 4/5 (or group 2) rooms will include an IPS/UPS system, the purpose of which is to increase supply resilience.

IPS/UPS systems
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.

IPS/UPS systems
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.
IPS/UPS systems

• 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.

Spot the mistake, plastic sockets not allowed

Metal finished sockets

Metal finished sockets should be installed within a clinical risk Category 3 area and above in order to limit the effect of electromagnetic interference and the increased mechanical protection.

Note
BS 7671:2008 AMD 3:2015 Section 512 now makes reference to the EMC directive and includes requirements for the designer of the fixed installation.

Circuit protection (IET touch voltage)

Electrical medical locations, are defined in GN7 as a special location, like many special locations circuits

The designer should check that the touch voltage cannot exceed 25 V a.c...

What does this mean for typical circuits?

From HTM 06 01 Part A

• Socket-outlets in clinical risk category 4 and 5 (e.g. Group 2) areas and connected to the medical IT system (IPS circuits) will be connected in a radial format.
• The protective device for such circuits should be a 20 A MCB with a Type B characteristic.

What is this guy on!!

• Richard Knight
• Mobile +44 (0) 77 949 14 211
• Email millham.orchard@tiscali.co.uk

Thank you