



## EXPLODING THE MYTHS OF MEDICAL LOCATIONS

We look at some of the common myths and misunderstandings surrounding touch voltages and the use of medical IT in group 2 locations.

By Paul Harris

ELECTRICAL installations in medical locations are the subject of numerous myths and misunderstandings within the electrical industry. In particular, there are widespread misunderstandings surrounding the use of medical IT systems – commonly known as Medical IPS (Medical Isolated Power Supply) systems. Along with these common confusions, this article will examine three other important myth-attracting areas within medical locations: isolated pin earthing systems (known as MEIGaN or ‘clean’ earthing), touch voltages and the use of the human body model.

All of these misunderstandings can be attributed to the misapplication and misunderstanding of installation and equipment standards. With the passage of time, international standards for medical equipment and medical electrical installations have been

developed and refined. These new standards have not been used in the UK to the level that they should, partly due to the availability of other guidance such as HTM 2007, which later became HTM 06-01, along with TRS 89, which was later developed into MEIGaN. The MEIGaN documentation was adopted virtually verbatim by equipment manufacturers and suppliers, and is embedded in the NHS psyche.

### Medical IT systems

The ‘medical IT system’ refers to the specialist items of equipment, isolation transformers, insulation monitoring devices and alarms, which collectively provide isolated power supplies. One common misunderstanding among engineers and other stakeholders regarding the medical IT system is that the isolation/separation from

earth provides a totally ‘shock free’ supply, and that this meets the  $10\mu\text{A}$  discussed in Guidance Note 7 or the touch voltages contained in MEIGaN.

The primary purpose of the Medical IT system is to provide a robust electrical supply that will not fail on first fault to earth – that is L1 or L2 on the connected medical equipment shorting to earth. A secondary function is to reduce the risk from electric shock if either L1 or L2 is touched. This principle is similar to the shaver socket in bathrooms. However, the arrangement is more sophisticated than the shaver socket as the medical IT system arrangement does not use electrical separation as the sole means of protection against electric shock.

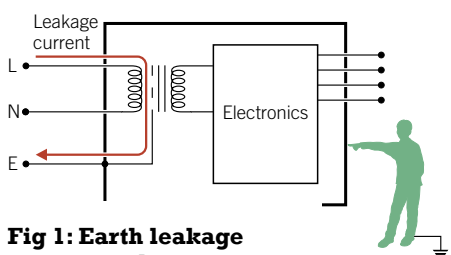
In the event of a supply conductor being touched or shorted to earth, the medical IT system current is limited to a



**Misunderstanding over electrical installations has become embedded in the industry psyche**

safe value. This current is formed from the isolation transformer leakage (0.5mA maximum) and any current leakages picked up through cable capacitive coupling between the transformer and socket outlets; this is one reason why the interconnection cables between the IT system and socket outlets should not be too long.

This enhanced level of protection against electric shock is completely lost



**Fig 1: Earth leakage current path**

once a single fault to earth has occurred.

Use of an IT system has one other useful characteristic: it reduces the total earth leakage current of all the devices supplied by the IT system to that of the IT system itself (normally <math><0.5\text{mA}</math>). For example, if 10 items are connected to the IT supply and each has an earth leakage current of 0.5mA, then we would expect the total earth current to be 5mA. In fact it will be only be a maximum of 0.5mA – the value from the IT system transformer (plus the leakage created by capacitive coupling of the interconnecting wires). Again, this leakage reduction is lost when a single fault to earth occurs on either the L1 or L2 supply lines.

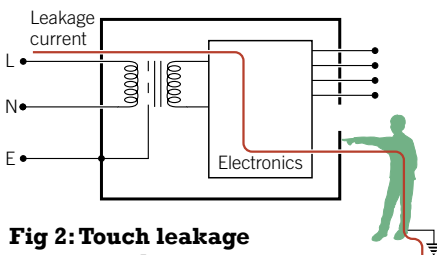
Previous articles in *Wiring Matters* (issues 45 and 46) have shown that the national wiring standard BS7671: 2008 (2011), including the upcoming 2013 corrigendum, provides the UK with an electrical standard for medical locations. Because BS7671, along with the corrigendum, is based on internationally agreed standards, as opposed to UK-specific standards such as MEIGaN, it contains few of the MEIGaN or similar stipulated procedures for earthing, or requirements for testing earth leakage or touch voltage.

### Understanding the context

An understanding of the origins of other medical locations myths requires some background information on medical equipment and the BS EN 60601-1 standard.

The various leakage currents associated with medical electrical equipment are defined by the paths the currents take. There are three such leakage currents to consider.

**Earth leakage current** (Fig 1) is the current that normally flows in the earth conductor of an earthed piece of class I equipment (see panel 'The Three Classes'). No insulation is perfect, and there is always a certain amount of leakage, even if this is just a nominal level. The safety of the equipment can be checked by earth leakage testing on class I appliances.



**Fig 2: Touch leakage current path**

The level of the earth leakage current depends on three factors: the voltage applied to the conductor, the resistance between the conductor and earth and the capacitive coupling between the conductor and earth.

From Fig 1 it is evident that, in the event of the loss of the protective earth, then all the current will flow through the person touching the conductive parts of the appliance.

**Touch current** (Fig 2) which is the same as enclosure leakage current in earlier versions of BSEN 60601, can be defined as the current that flows from the enclosure or parts thereof, excluding patient connections, to earth through a conductor other than the protective earth conductor.

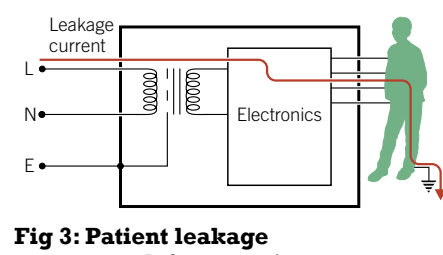
**Patient leakage current** (Fig 3) is the current that flows through a patient connected to the particular applied part(s). Current can flow from the applied part(s) via the patient to earth as indicated in Fig 3. Alternatively, in the case of F type applied parts, patient leakage current can flow from an external source via the patient and the applied parts to earth, as indicated in Fig 4.

**Patient auxiliary current** (Fig 5) is defined as the current that normally flows between parts of the applied part through the patient, which is not intended to produce a physiological effect.

### A flawed approach

There has been a flaw in previous approaches to medical locations design. It is well documented that within medical locations special measures are needed because patients will be undergoing procedures that weaken the body's natural defence against electric shock. This weakness can result from their condition, the drugs they are receiving or the simple fact that the protective membrane of the skin is breached. Many procedures within medical locations will involve the puncturing or cutting of the skin, resulting in a greatly increased susceptibility to electric shock.

The flaw in the design process has been to assume that the installation

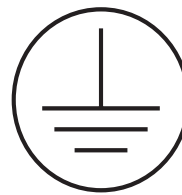


**Fig 3: Patient leakage current path from equipment**

**FACT BOX**  
**THE THREE CLASSES**



**Earth**

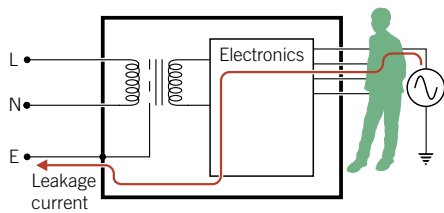


**Protective Earth**

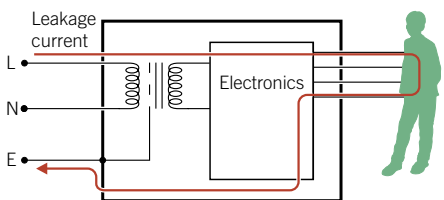


**Equipotential**

**Symbols seen on earthed equipment**



**Fig 4: Patient leakage current path to equipment (F-Type parts only)**



**Fig 5: Patient auxiliary current path**

is the applied part or the medical device itself. The process of treating a room or an installation of a medical location in this way is flawed as there are strict requirements and product standards for medical devices, which could not possibly apply to an installation.

To protect the patient, all electrical equipment and accessories used within the defined patient environment must comply with the medical device directive (93/42/EEC). This is normally achieved by conforming to the appropriate product standard, which in this case is the IEC 60601 series of standards.

These standards lay down the requirements for safety of the equipment and, in particular, the allowable currents that can flow into the patient in normal and fault conditions. The current limit depends on how the equipment is connected or applied to the body of the patient. These medical equipment interfaces to the body are defined in IEC 60601-1 (which is followed through nationally in BSEN 60601-1) into three types of connections, called applied parts:

- **B Body applied part**
- **BF Body floating applied part**
- **CF Cardiac floating applied part.**

B-type applied parts may or may not connect to earth, but they must ensure that the patient leakage current remains within the allowable limits. These parts are not intended to transfer energy either to or from the patient.

All F-type applied parts are isolated from other parts of the equipment, including earth. The allowable leakage limits are stricter for CF than BF parts. Table 1 shows the maximum permitted

**Class I** equipment has a protective earth, although not all equipment having an earth connection is necessarily Class I.

The earth conductor may be for functional purposes only, such as screening. Likewise, equipment finishes can cause confusion – a case that appears to be plastic does not necessarily indicate that the equipment is not Class I.

BS 7671 defines Class I equipment as: “Equipment in which protection against electric shock does not rely on basic insulation only, but which includes means of connection of exposed-conductive-parts, to a protective conductor in the fixed wiring of the installations (see BS61140).”

There is no agreed symbol in use to indicate that equipment is Class I. It is not mandatory to state on the equipment itself that it is Class I but the symbols shown above may be seen on medical electrical equipment adjacent to terminals.

Unlike other Class I equipment, medical electrical equipment should have fuses in both live and neutral conductors at the equipment end of the mains supply lead.

**Class II** equipment employs either double insulation or reinforced insulation as the method of protection against electric shock. In double insulated equipment the first layer of insulation affords the basic protection. If the basic protection fails then a supplementary, second layer, of insulation, preventing contact with live parts, provides protection.

BS7671 defines Class II equipment as: “Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as supplementary insulation are provided, there being no provision for the connection of exposed metalwork of equipment to a protective conductor, and no reliance upon precautions to be taken in the fixed wiring of the installation (see BS61140).”

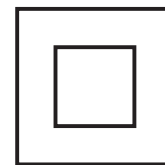
Basic insulation is usually afforded by physical separation of live conductors from the equipment enclosure. This makes the basic insulation air. Supplementary insulation is provided

by the enclosure material.

Reinforced insulation is defined in BS 7671 as: “Single insulation applied to live parts, which provides a degree of protection against electric shock equivalent to double insulation under the conditions specified in the relevant standard. The term ‘single insulation’ does not imply that the insulation must be one homogenous piece. It may comprise of two or more layers which cannot be tested singly as supplementary or basic insulation.”

Class II medical electrical equipment should be fused at the equipment end of the supply lead in either phase conductor, or in both conductors if the equipment has a functional earth.

The symbol for Class II equipment is two concentric squares illustrating double insulation as shown below.



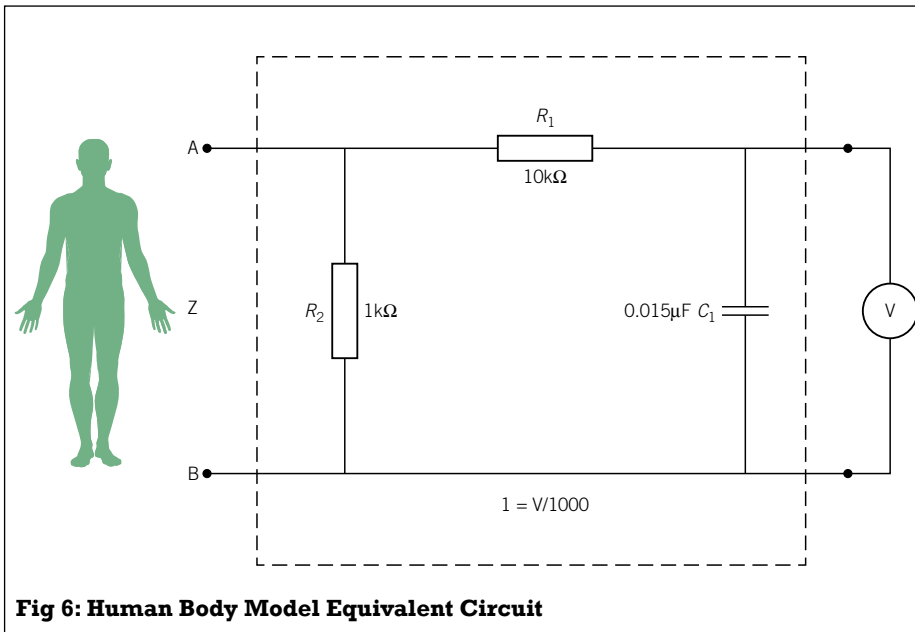
**Symbol for Class II equipment**

**Class III** equipment is defined by BS7671 as: “Equipment in which protection against electric shock relies on supply at SELV and in which voltages higher than those are not generated (see BS61140).”

In practice such equipment is either battery operated or supplied by a SELV transformer.

If battery-operated equipment is capable of being operated when connected to the mains (for example, for battery charging) then it must be safety tested as either Class I or Class II equipment. Similarly, equipment powered from a SELV transformer should be tested in conjunction with the transformer as Class I or Class II equipment as appropriate.

All medical electrical equipment that is capable of mains connection must be classified as class I or class II. Medical electrical equipment having no mains connection is simply referred to as ‘internally powered’.



if they are taken out of context, causing installations to be declared unsafe.

### Worrying voltage readings

For example, using a DVM to take a measurement on a class II double insulated device will inevitably result in a voltage measurement up to half the mains voltage. As can be seen in Fig 7, a totally innocent scenario can create a reading which is beyond the touch voltage described in BS7671. However, correct application of the human body model will not only filter out any high-frequency interference it will also add a current component to the DVM values which assuming is only capacitive coupling or similar, will fall to a negligible value as can be seen in Fig 8.

leakage currents that could flow in the patient for these applied parts.

As can be seen from Table 1 the values for B and BF are the same (excluding the F-type mains on applied parts values, which are not indicated in the table). Two other points are worth noting: the B & BF normal leakage limit is also the limit for touch leakage and the fault condition values generally correspond to the equipment or earth leakage limits. Touch leakage is defined as current flowing through an external path, other than the protective earth conductor, from any accessible parts, excluding patient connections, to earth or another part of the equipment.

### Application of the human body model

One very important point to note is the method by which these leakage currents are measured using a human body model as shown in Fig 6.

In a normal environment the average equivalent resistance for a human being is about 2000Ω (2kΩ), but the average for a patient undergoing a medical procedure is deemed to be half this value, i.e. about 1kΩ. This is reflected in Fig 6, where R2 is 1kΩ, corresponding to the human body in a medical location.

A filter made up of R1 and C1 reflects the fact that the cells in a human body do not respond to electrical stimulus at higher frequencies (much above 100kHz) and therefore do not present a risk of electric shock (only a burns risk).

A key point is that if 100μA is flowing in R2 a voltage of 100mV will be read on the voltmeter, 10μA flowing will result in a reading of 10mV and so on. The touch voltages quoted in many references to medical locations have been derived from the 60601-1 leakage current limits for medical equipment. However, Guidance Note 7

and MEIGaN look at the initial voltage measurement without the use of the correct human body model (referred to as an IEC filter in MEIGaN).

### Making the wrong measurements

It is quite easy to be confused by all of the documentation and values quoted. If you forget to apply the impact of the human body model (IEC Filter) on measurements taken, then you will lead yourself on to a route plagued with confusion and worrying readings. The problem arises because the commonly-used digital voltage meter (DVM) is characterised by a very high input impedance (10MΩ to 100MΩ) and, as such, provides no load to the circuit, leading to stray voltages being measured around the medical location. Many of these values will be of concern

### Induced voltages

It also possible to measure seemingly high voltages on any conductive part that is isolated from earth, arising from the close proximity of strong fields from nearby AC or even RF (radio frequency) sources. These detected voltages will be significantly reduced (corrected) if the human body model is applied with a 1kΩ resistor in circuit. This will have the effect of filtering out high-frequency interference and passing current through a 1kΩ resistance. A similar effect (a reduction in the voltage measured by a DVM) will occur if the low-frequency current is measured used a sensitive ammeter in conjunction with a DVM, as the current flow through the ammeter will normally cause the voltage reading to collapse. ➤

Symbol	Applied part type	Definition/description	Normal Condition (NC)	Fault (SFC)
	Type B Applied Part	<b>TYPE B APPLIED PART</b> APPLIED PART complying with the specified requirements of the standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT	100μA	500μA
	Type BF Applied Part	<b>TYPE BF APPLIED PART</b> F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS	100μA	500μA
	Type CF Applied Part	<b>TYPE CF APPLIED PART</b> F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS	10μA	50μA

Table 1: Applied Parts symbols and current leakage

### What type of applied part is an electrical Installation?

There are many guidance documents both past and present that describe values of 10mV or 50mV in group 2 medical locations. These documents are in fact describing the leakage requirements of CF applied parts (10mV normal and 50mV SFC- (single fault condition)).

Reflecting on these details in the cold light of day we can see a piece of equipment that is intended to have connections that touch the heart would need to be classified as a CF applied part and be manufactured to meet the requirements of BSEN 60601-1.

It would also be tested to confirm its safety using IEC 62353. It is thus clear that only those items of equipment that conform to the 60601 series of standards can be tested to those stringent standards.

It is also clear that the electrical installation is not and can never be a BF or CF applied part, as it should never come into direct contact with the patient in that context.

The only part of an electrical installation that can ever come into contact with a patient is the earth (via a B type applied part such as a patient table).

### Electrical installations in medical locations

Much criticism is raised by industry stakeholders who have been familiar with the MEIGaN documents. This criticism is normally aimed at the lack of particular tests with respect to protective conductor currents in EBBs, which were formally known as ERBs in MEIGaN.

Certain tests such as partial dismantling of earthing systems are not called for by BS7671, as they can be dangerous and possibly in breach of the Electricity at Work Regulations 1989. Disconnection

of earthing systems for live testing purposes should only be carried by suitably qualified and trained personnel, and even then should be avoided if at all possible.

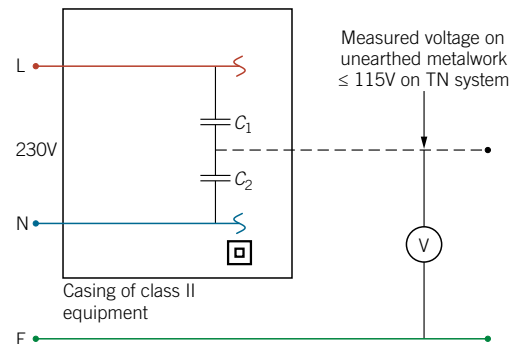
BS 7671 is the national wiring standard which contains requirements for general installations and additional requirements for installation testing is contained in Section 710. Any attempt to include specialist equipment testing would be outside the scope of BS7671.

### Medical appliance testing

The testing of the medical equipment is covered by the standard IEC 62353, and requires specialist test equipment and knowledge (including IEC or BS EN 60601). It is not appropriate or generally possible for non-specialists to perform such tests. This is reinforced by the specific exclusion of testing medical equipment within the IET code of practice on In-service inspection and testing of electrical equipment (4th edition).

Whether or not a designer chooses to use a 'clean earthing' approach or not, it is essential that he or she applies the principles of BS7671 and applies section 710 appropriately. 'Clean earthing' arrangements such as those described in MEIGaN are onerous and material/labour intensive and bring about limited or no added value to installations that are in accordance with BS7671. The correct use of EBBs and the other measures described in section 710 provides sufficient protection for the patient staff and visitor to a medical location.

This article has set out to demonstrate that the values discussed in MEIGaN and other guidance documents need to be considered for applied parts and medical devices in accordance with BSEN 60601 series of documents, and that the correct testing



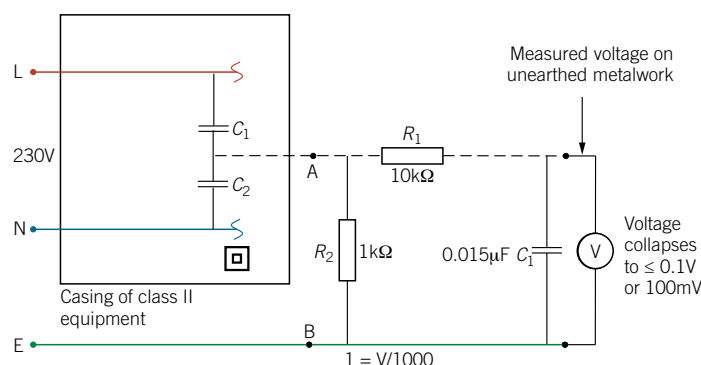
**Fig 7: Superimposed voltage from Class II equipment on unearthed metalwork**

techniques for installations is contained in Section 710 of BS7671.

Whilst the flow of leakage current through medical locations should not be ignored, it is important to remember the electrical installation should not be touching the heart or be inside the body cavity. It is medical equipment which is designed to touch or intrude into the body which is to be applied. This equipment is manufactured to comply with BS EN 60601 and is tested in accordance with IEC 62353. For this reason, when an electrical installation conforms to BS 7671:2008 (2011) and the requirements of section 710 are met, there should be no possibility of the touch leakage exceeding 100µA.

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**Fig 8: Voltage collapses as human body model is applied**