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ELECTROMAGNETIC COMPATIBILITY & FUNCTIONAL SAFETY

Annex C - Healthcare

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Annex C

EMC and Functional Safety in the Healthcare Industry

Abstract

The Medical Devices Directive (MDD), and the related Active Implantable Devices Directive, have recently been introduced in the EU. These cover the safety of medical devices that may come into contact with patients, and include requirements for manufacturers of such products to take EMC-related functional safety into account, as well as EMC in general.

A number of EMC-related safety incidents have been investigated and verified, principally by the USA's Food and Drug Administration (FDA), and these have caused considerable concern among healthcare professionals especially in the USA and Canada, where healthcare employs large numbers of electronic devices, products, and systems.

An EMC harmonised standard exists under the MDD, but this may not be adequate for controlling EMC-related functional safety, so the approach described in section 4 of this guidance document should be followed.

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C1. Introduction

The issue of product safety is of particular concern in the Healthcare Industry due to the fact that many of their products are used on or in the body. This has resulted in very stringent regulations concerning the approval and supply of these products as evidenced for example in the European Union by the Medical Devices directive. As far as the effects of EMC are concerned, we must consider the effects on Electro-medical devices and the directive does include requirements for both electromagnetic emissions and immunity for these products in terms of health and safety risks.

The problems have been compounded by the changes in technology utilised in healthcare products. There is an ever-increasing use of electronics and microprocessors in medical devices of all kinds, from relatively simple ones like electrical nerve stimulators to the more recent advances in imaging such as magnetic resonance imaging (MRI). In the medical industry there is also a tendency toward more automation in devices to monitor patients, administer therapy and help perform diagnosis. Micro-miniaturisation has revolutionised the medical device industry with smaller devices requiring less power that can perform more functions but unfortunately with lower operating voltages and currents comes lower thresholds of susceptibility.

At the same time, there is a proliferation of new communications technology with, cellular telephones, wireless LANs and computer links, to name but a few. With these advances we see increasing problems due to the interactions between the products emitting the EM energy and sensitive medical devices. Even the medical products themselves can emit EM energy, which can react with other devices or products.

Much of the reporting and investigation of EMC problems with medical equipment has been carried out in the USA under the auspices of the FDA. In a paper given in June 1992, Jeffrey Silberberg of the FDA brought together a whole collection of reported incidents of the effects of electromagnetic disturbance on electronic medical devices. He reports two case studies of an apnoea monitor and one of an anaesthesia gas monitor.

In the case of the apnoea monitor failing to register cessation of breathing, it was found that most commercial monitors in the USA were susceptible to relatively low field strengths of the order of 1V/m when irradiated with radio frequency signals such that they would register detection of respiration when exposed.

In the case of the anaesthesia gas monitor, an investigation showed interference from local RF-surgery equipment (a notorious source of emitted disturbances) disrupting the communications link between the monitor and a central mass spectrometer causing a failure of the monitor to display gas concentrations in the operating room.

Other examples are:

- A pacemaker failed during an ambulance ride while the two-way radio was in use.
- A man in a powered wheelchair was seriously injured when his chair rode off a cliff at high speed, shown later to be due to radio interference with its control systems. He was several miles from a radio tower and three blocks from a busy road, where mobile radios were likely in use. The interference was later thought to have come from a nearby police car transmitter.
- A pulse oximeter machine displayed a pulse rate and oxygen level on a dead body when a telemetry receiver that was part of the system was placed too close to the body.
- A foetal heartbeat detector picked up local radio and CB broadcasts instead of the baby's heartbeat.

In addition to these cases some 60 other problems were reported affecting products such as heart pacemakers, infant monitors, video recorders, infusion pumps, cardiac monitors and defibrillators. These problems were caused by power supply transients, radiated fields from other local equipment, magnetic fields and ESD; in fact the whole range of EMI sources. Deaths unfortunately did occur as a result of some of these incidents.

Silberberg concluded that the susceptibility of many of these devices and equipment, combined with the ever increasing electromagnetic "pollution" from intentional and spurious emitters, underscores the need for applying EMC Design techniques, standards and testing to electronic medical devices.

C2. The EM environment for medical devices

With the increasing use of sensitive electronics in devices, and the proliferation of sources of EM energy, there is heightened concern about electromagnetic interference in many devices. The results of interference may be only a transient "blip" on a monitor, or it could be as serious as preventing an alarm from sounding or inappropriate device operation, or incorrect operation leading to patient injury or death. Other areas of major concern are with automatic drug delivery systems, which may give harmful doses (or doses which were too low) when subjected to interference.

The FDA maintains that while the numbers of reports with possible links to EMI have been steady, these numbers are generally not indicative of the actual occurrence of incidents. Indeed, in investigating possible EMI-related problems it is often the case that the EM energy, which caused the event, has dissipated (e.g. the EM energy source was shut off or removed from the area).

The very nature of this range of devices does not lend itself to "generic" approaches. For example, an apnoea monitor is very different from a powered wheelchair, in form, function, and configuration but the various environments in which the devices operate can be defined and likely interference sources quantified.

The EM environment that envelops the devices can vary widely. The hospital environment is where most devices will be used although they will be found in clinics and surgeries and in the home. The International Electro-technical Commission (IEC) has published a standard, EN61000-2-5, which classifies the EM environment into eight areas and defines the typical EM environment in each area. This can be a useful guide when choosing appropriate immunity levels.

C3. European legislation on medical devices

All these directives are aimed at providing a high level of safety for users, patients and other third parties and so are driven primarily by safety considerations.

The Medical Devices Directive was adopted in June 1993. The intention was for Member States to adopt and publish the laws, regulations and administration provisions necessary to comply with this directive not later than 31 December 1993. The provisions were applied with effect from 1 July 1994.

There are two other directives relating to devices and equipment used for medical purposes. These are:

1) The Active Implantable Medical Devices Directive 90/385/EEC.
2) The In Vitro Diagnostic Devices Directive 98/79/EC.

All three of these groups of devices can have electrical or electronic systems or components either incorporated into them or connected to them as part of their operating function and so are in some degree likely to cause or be affected by electromagnetic disturbance. The results of these effects are potentially far more serious in the case of the Medical and Active Implantable Devices as they are attached to or inserted into the human body and any malfunction could have serious health and safety consequences.

C4. Scope of the Medical Devices Directive

The directive applies to any instrument, apparatus, appliance, material or other article including software, whether used alone or in combination intended to be used solely or principally for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

which does not achieve its principal intended action by pharmacological, immunological or metabolic means.

It specifically excludes, active implantable devices and in-vitro diagnostic devices covered by their own directives.

It will include any electronic apparatus such as Information Technology equipment, which is solely or principally used for medical purposes. The question as to whether a product is a medical device is in some cases a complex one. Products which are used in connection with healthcare may not necessarily be classed as a medical device under the directive.

For example, any product used in connection with pregnancy is not a medical device, presumably because pregnancy is not considered an illness or incapacity although it can lead to health risks. Again computers used to store records in a hospital or surgery are not medical devices even though corruption of their files could lead to a patient health risk. The directive goes into great detail on the definition and classification of devices and the Medical Devices Agency in the UK will help in this regard. The have a software tool and a guide to classification

C5. EMC Requirements of the Medical Devices Directive

In order to address the issue of EMC and functional safety for these products, we must first examine the EMC requirements enshrined in the legislation. Annex 1 to the Directive lists the "essential requirements" which must be met. These are split into general requirements and requirements regarding design and construction.

The general requirements are basically that the device should be safe and remain safe during use in its normal operating environment and under normal conditions of use for the lifetime of the device. In addition the device must achieve the functional performance intended by the manufacturer.

The requirements regarding design and construction cover all aspects of the device including chemical and physical properties, infection and microbial contamination, constructional and environmental properties; protection against radiation, electrical safety provisions and manufacturer supplied information.

The requirements for EMC are stated in Annex 1 clauses 9.2 and 12.5 as follows:

Clause 9.2

Devices must be designed and manufactured in such a way as to minimise as far as possible

- "risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,
- the risks of interference with other devices normally required for the investigations or for the treatment given."

Clause 12.5

- “The devices must be designed and manufactured in such a way as to minimise the risk of creating electromagnetic fields which could impair the operation of other devices or equipment in the vicinity."

It can be seen that while clause 9.2 talks about “risks”(presumably health and safety risks), associated with environmental conditions including “electrical influences”, clause 12.5 is concerned with “risks” of creating EM fields which will impair the operation of devices i.e. not necessarily impair them in a way which might effect health or safety but merely impair them.

It should also be noted that in line with other "New Approach" directives there is no mention of any standards in the requirements. Conforming to a standard is not mandatory. However, standards need to be used in the conformity assessment procedures, which must be followed in order for the manufacturer to affix the CE marking and place the device on the market. In all cases the documentation makes reference to any Standards applied in full or in part and any other solutions adopted to meet the essential requirements.

As far as assessing the EMC characteristics of the device then harmonised standards are a sensible and practical tool to use. However, beware the trap of using standards which inadequately represent the electromagnetic environment in which the device must safely and satisfactorily function, or in the context of this document do not relate to any requirement for degrading to a safe condition during exposure to interference. The suitability of the intended harmonised standard EN60601-1-2 is discussed later.

C6. EMC Standards for Medical Devices

The governing standard is EN 60601 Part 1 (1990) Medical Electrical Equipment – General Requirements for Safety. This is identical to IEC 601-1:1988. The collateral standard for EMC, EN60601-1-2, covers both emissions and immunity and is based on existing IEC standards prepared by SC62A, TC65 (Industrial Process Measurement and Control), TC77 (EMC between electrical equipment, including networks) and CISPR (International Special Committee on Interference). **The standard is currently under revision and this Annex reflects the requirements proposed in the draft second edition.**

The Standard states that for certain types of medical devices the requirements are to be supplemented or modified by the special requirements of a particular standard. Where these particular standards exist, the collateral standard should not be used alone. Special care is required in applying the collateral standard to devices for which no particular standards exist (another caveat!).

The scope of the Standard includes Medical Electrical Equipment, Medical Electrical Systems, Information Technology equipment used in medical electrical applications and all other equipment forming part of medical electrical systems.

It should stressed here that in general the law and in particular the Medical Devices Directive does not require compliance with a standard. The obligation is on the supplier to demonstrate that the device complies with the essential requirements of the directive. The standard may be used to show this and there is a presumption of compliance conferred on the device if it complies with a published harmonised standard. However this presumption only applies until proven to the contrary.

This means that compliance with a standard may not be enough in its own right to demonstrate that a device complies with the directive. The manufacturer must be able to show that the requirements of the standard were reviewed for suitability in the light of the EMC and safety risk assessment carried out and modified if suspected as inadequate. This is unlikely to happen very often but the review must be done in order to be able to show due diligence in the event of a challenge.

C6.1 Emissions requirements

Devices shall comply with the relevant requirements of CISPR 11. The current publication is at Second Edition 1990. CISPR 11 contains limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment.

ISM equipment is classified into classes and groups.

Group 1	All ISM equipment in which there is internally generated and used, conductively coupled RF energy necessary for the internal functioning of the equipment.
Group 2	All ISM equipment in which RF energy is internally generated an/or used in the form of electromagnetic radiation for the treatment of material and spark erosion equipment.
Class A	Equipment is suitable for use in other than domestic establishments and those connected to the domestic power supply
Class B	Equipment is suitable for use in domestic establishments.

There are different limits for the two classes. Limits are specified for terminal disturbance voltage and for radiated emissions. CISPR 11 is specific in that although Class A equipment can be measured in situ, Class B must be assessed on a test site. The collateral Standard relaxes this,

allowing compliance for a specific model to be demonstrated by a type test of one unit on a typical user site. In addition type testing of a sub system or system on a test site or in situ under normal operating conditions may be used to demonstrate compliance. An additional allowance is for ITE certified to CISPR 22 to be included in systems without further verification. Class A ITE may only be included in Class A systems, while Class B ITE can be included in both Class A and B.

CISPR 11 allows for unrestricted radiation levels allocated by the ITU in certain frequency bands, in recognition of the fact that for some equipment, high levels of radiated emissions are unavoidable as part of their function. For example, licensed radio transmitters incorporated in medical equipment are excluded from the emission requirements in the defined exclusion band. Of particular note is that limits for radiology and RF surgical diathermy equipment are still under consideration. Equipment operating in the close vicinity of such apparatus should expect exposure to very high intensity wideband disturbance.

For equipment used inside shielded enclosures such as x-ray locations, the Standard also allows for increases in field strength levels equivalent to the shielding effectiveness of the enclosure, when measured on a test site. This would really require measurements and checks on the actual enclosure intended to be used, as shielding effectiveness can vary enormously depending on the construction of the enclosure and the method used

Medical equipment not containing any electronics generating frequencies over 9 kHz, may be tested according to CISPR 14. This does not apply to systems, which need to meet CISPR 11. Lighting equipment used in medical applications may be tested to CISPR 15.

Low Frequency Emissions	For harmonic distortion and voltage fluctuations, the standard proposes using IEC 1000-3-2 and IEC 1000-3-3 for equipment rated up to 16Amps per phase and connected to the public mains network.
Magnetic Field Emissions Below 9KHz	These are under consideration by CE77 and SC62A WG13.

C6.2 Immunity requirements

The Standard defines limits and references test methods for

- Electrostatic discharge (ESD)
- Radiated RF fields
- Conducted RF
- Fast burst transients (FTB)
- Surges
- Power frequency magnetic field
- Voltage dips, variations and interruptions

This is not an exhaustive list of possible EM phenomena, and should be regarded as a typical list covering the principal disturbances in typical environments. Again it must be emphasised that the manufacturer of the device is responsible for identifying all the possible electromagnetic threats.

Although the limits and test methods used to evaluate immunity against these phenomena are based on the IEC 61000 series of standards as generally used for compliance with the EMC directive, there the similarity ends. This standard defines its own approach to what test levels should be applied and what approach is taken with devices, which fail at the specified levels.

Firstly, in each case, compliance with the immunity requirements shall be checked by verifying that under the specified test conditions, the equipment maintains "**Clinical Utility"**. This is defined as a

minimum level of performance in the presence of a disturbance in which an equipment and/or system is fully functional but may exhibit some degradation in performance outside of the manufacturers specifications, provided it is clinically acceptable. In other word the failure criteria is relaxed compared with the EMC Directive which requires equipment to continue to function but we can assume that “clinically acceptable” implies “safe” and therefore the failure criteria is one of allowing degradation to a safe condition.

As an indication to the user, the manufacturer has to fill in Table 5 in the standard and supply it in a “warning section” to the accompanying documentation. It includes the general IMMUNITY test levels and descriptions of a general electromagnetic environment. For equipment and /or Systems, which comply with the immunity levels specified, the tables 5 and 6 are included verbatim. For equipment and/or systems for which immunity compliance test levels are lower than the specified test levels, when justified, the test in Table 5 can be adjusted. The third column of the table is filled in with the IMMUNITY compliance test level and the fourth column with statements defined in the standard.

For example for equipment where the radiated immunity field strengths specified cannot be met at the specified distance calculated according to the formula in table 6, the protection distance in column 4 is increased in direct proportion to the reduced immunity level. In the case of ESD, where the device could not meet the specified levels, the manufacturer must describe what actions the user must take to control the electrostatic environment to levels compatible with the immunity levels of the device. This may not be feasible.

In addition to tables 5 and 6, the manufacturer must list, in the ACCOMPANYING DOCUMENTS, all accessories, transducers, and cables that the manufacture certifies allows the equipment and/or system to be in compliance with the immunity requirements. References may be generic (e.g. shielded serial cable) or specific (e.g. by manufacturer and model or part number)). If EMC performance cannot be effected by accessories, transducers and cables no list is required. If there are restrictions on the use of accessories, the warning must be provided in the ACCOMPANYING DOCUMENTS.

C6.3 Comments on the immunity criteria

The standard as currently proposed will allow significant responsibility for compliance to be passed on to the user. Were lower test levels than those in the standard are used, justifications based on physical, physiological, technological and or economical limitations must be given and stated in the table. This approach is worrying, as it suggests, for example, that “we couldn’t afford it “ would be a valid justification for supplying a device which had no intrinsic immunity and relying on the user to ensure that the device functions within the failure criteria.

There exists the possibility of a legal challenge to this approach along the lines discussed earlier, as it could be argued in some cases, that although the standard allows a relaxation of immunity levels, the essential requirement of the directive to “remove or minimise as far as is possible, risks connected with reasonably foreseeable environmental conditions”, has not been met and the defence of due diligence would be considerably weakened.

Because some of these products can present severe safety risks if not designed manufactured and installed or used correctly, the idea of passing on responsibility for safe EMC compliance to the user is ill advised and can leave the manufacturer open to product liability claims and civil action for damages.

C6.4 Levels and limits

The following limits and levels are those that would be applied when the harmonised standard is used. It is worth re-emphasising again that although the use of the standard confers a presumption of

compliance with the essential requirements, it does not relieve the manufacturer from the legal obligation to ensure the device operates properly and safely in its intended environment. So, for example if a manufacturer knows and intends that a device will be used in close proximity to powerful emitters, where the field strengths can reach say 100V/m but only tests to 3 or 10V/m and there is a functional safety problem causing injury during use, then it will not be a strong defence to rely on use of the standard.

C6.4.1 Electrostatic discharge

Equipment shall comply with IEC 61000-4-2. A level of 6KV contact discharge to conductive accessible parts shall apply. A level of 8kV air discharge shall apply to non-conductive accessible parts.

These levels are generally representative of the hospital environment but be careful of areas where humidity and temperature may be unusually low, i.e. < 50% RH and 5°C as this can lead to higher levels of ESD potential.

C6.4.2 Radiated RF Fields

Equipment shall comply with IEC 61000-4-3. A MINIMUM level of 3V/m shall be applied over the frequency range of 80MHz to 3GHz with the amplitude modulated by a 2Hz tone for equipment intended to control monitor or measure a physiological parameter and by a 1KHz tone for all other equipment. For life supporting equipment the level is 10V/m above 800MHz. Receivers are exempt in their exclusion band.

There are allowable reductions in the field strengths for equipment used only in shielded locations. For equipment used in x-ray shielded rooms, the level will be 1V/m (when tested on a test site with shielding). For equipment used in other types of shielded enclosure, the level of 3V/m can be reduced in proportion to the screening effectiveness. This of course raises the question as to whether you can or have measured it correctly and whether the shielding level is permanently maintained and whether or not there are other sources of high intensity fields inside the enclosure with the equipment in question.

Large permanently installed equipment is tested on an installed or open site using the ambient RF sources, cell phones, walkie -talkies etc. likely to be found in its environment.

Patient coupled equipment is tested with the patient connection in the test environment and with a patient simulator.

These test levels may be too low for some operational environments. For example, the level of 10V/m is equivalent to a cellphone at a distance of between 0.5 and 1.4 metres, (depending on signal strength and reflections from nearby metal surfaces). Diathermic knives and other RF surgical equipment may well produce fields in their vicinity that are well above 10V/m.

The test frequencies may be inadequate to represent the real environment, for example cellphones operating at 1.8GHz and microwave ovens and communications devices operating at 2.45GHz (or higher) are becoming commonplace and easily exceed the 1GHz upper frequency limit of the test standard.

C6.4.3 Fast burst transients

The test methods in IEC 61000-4-4 shall apply. The level shall be +/- 2kV at the ac or dc power supply input lines. For long interconnecting cables over 3 metres, a level of +/- 1kV shall be applied with the exception of patient coupled cables, which are connected but not subjected to the test. The PRF is 5kHz for all lines tested.

These levels are generally representative of the intended environment, but may be exceeded on rare occasions, often associated with the electro-mechanical switching of inductive loads such as motors.

C6.4.4 Surges

Test methods in IEC 61000-4-5 shall apply. Equipment shall meet an immunity level at the mains supply of 1kV in differential mode and 2kV in common mode. Signal lines are not tested.

These levels are generally representative of the intended environment, but figures for the UK's power distribution indicate that urban premises can expect around 3 surges of 6kV or above each year. Rural premises (especially those fed by overhead cables) can expect a great many more high-level surges.

C6.4.5 Voltage fluctuations, dips and interruptions

For equipment rated at less than 1kW, clinical utility must be maintained when subjected to voltage reductions of up to 70% of nominal supply voltage for 25 periods. For equipment more than 1kW, temporary loss of clinical utility is allowed provided the equipment remains safe, suffers no damage and is re-settable with operator intervention. These criteria also apply for conditions of zero volts for up to 5 seconds.

(Annex B concludes that voltage dips and interruptions are the power-related EM disturbances least well controlled by standards, and are responsible for a great deal of concern. Modern kidney machines controlled by microprocessors have been known to be reset or even permanently damaged by the dips caused by switching to emergency power generation, whilst older models were unaffected).

C6.4.6 Conducted RF

The test is carried out according to IEC 61000-4-6.Clinical utility is to be maintained at a test level of 3Vrms with a modulation frequency of 2Hz or 1kHz depending on intended use of equipment as defined for radiated immunity. Patient connected cables shall be tested using BCI methods.

Generally only a problem when long cables are used. These levels are generally representative of the intended environment, but in certain conditions (e.g. proximity of CB radio or radio amateur transmitters, especially vehicle-mobile types) can be significantly exceeded.

C6.4.7 Power frequency magnetic fields

The test is to be carried out generally according to IEC 61000-4-8 but only the continuous field test is performed at all rated frequencies and for both 50Hz and 60Hz for dc powered equipment used in areas where both mains frequencies are used.

The test level specified is believed to be representative of normal environments, but may be significantly exceeded in close proximity to power cables, motors, or transformers, or during earth-faults when high currents flow for a second or two until fuses open. MRI scanners expose nearby equipment to intense DC magnetic fields, not covered at all by this test.

C6.5 Comments on the suitability of the standard

The emission levels are in line with other equipment intended for the ISM environment and may cause interference problems if the equipment is used in the home close to other equipment.

The immunity failure criterion using the concept of clinical utility is suitable, but the ability to pass on responsibility for compliance with expected levels to the user is worrying, as discussed earlier.

Immunity levels for radiated immunity may be too low, and frequency ranges inadequate, for use in certain hospital environments, particularly in theatre or treatment rooms where high field strengths can be found, e.g. surgery (diathermic knives and cauterisation, defibrillation, etc.), physiotherapy (diathermic tissue heaters), X-ray, MRI scanners (high levels of DC magnetic fields), etc.

It is essential for manufacturers to carry out an assessment of the EMC environment in which the device is intended to be used in order to identify the likely threats and levels of these threats. The safety risk resulting from these threats must be removed or reduced to a minimum.

C6.6 Design Requirements

Examination of these standards will show that they are primarily test standards and give little assistance to the designer, unlike the standards used in the product safety field which are predominantly design and build standards. The phenomena of concern are those of radiated and conducted emissions and a range of immunity threats. These are:

- ESD
- Radiated fields
- Conducted RF and transients

The standards will indicate the levels of these threats likely to be found in various environments and the test methods, which can be employed to simulate their effect. For example the radiated emissions standards will typically define a limit in terms of the EM field strength in dBμV/m measured at a distance of 10 metres from the equipment under test. This limit cannot be directly correlated back to the design of the equipment in terms of say the layout of the circuits or design of the enclosure, although these features will have a major impact on the levels of fields emitted.

The design approach must be one of identifying the EM environment, employing good EMC design practices early on in the development of the equipment, all supported by confirmatory testing.

Note however that (as described in sections 3 and 4 of the Core of this guidance document) because EM disturbances are statistical in nature, testing cannot be used as proof of functional safety. Where functional safety is implicated a risk analysis is also required, and the EM disturbance levels applied (and the consequent design approaches and techniques) will be greater, the greater is the consequence of error or mis-operation.

C7. EMC and intrinsic safety design conflicts

There are several areas of EMC design where the measures used to achieve good EMC performance can conflict with the safe design of the equipment, giving rise to a direct threat. These concern intrinsic safety, rather than functional safety, and are now reviewed.

C7.1.1 Grounding

Grounding for EMC performance and for safety are two different issues and must not be confused. For good EMC performance it is important that a low impedance path to ground is provided for interfering currents. This is particularly important when dealing with fast transients and ESD.

Normally the grounding provided by the yellow and green safety protective earth will not be a low enough impedance at high frequencies due to the inductance, so a separate ground in the form of a braided or solid strap will be used to ground the equipment's metal structure. For large distributed systems, grounding may be done at several different points, some distance apart. As there may be appreciable impedance between these points and currents will be flowing in the ground, ground loop coupling may result.

Techniques exist for overcoming this problem and a common approach is to use multi-point grounding or to lift one or several of the grounding connections. **Under no circumstances should any safety earth connection to the chassis or enclosure be interfered with when addressing this issue.**

C7.1.2 Use of filters and transient suppression devices

Filters are used to deal with high levels of conducted interference either entering or leaving and equipment. They normally consist of a combination of capacitance across the line and inductance in the line which will reflect part of the spectrum of the EM energy and prevent its passage.

There is a major safety issue when choosing filters relating to the components used in their construction. A typical mains power filter will have several capacitors (the "Y" capacitors) connected to ground. This is essential for the filter to work. An ideal filter capacitor would have infinite impedance at mains frequency but this is not the case. Some current, known as the leakage current, does flow to ground and although comparatively small can be in the order of tens of milli-Amps. Normally in a safety Class I equipment with a protective earth, this would not be an issue as it would be shunted by the protective earth path, so anyone touching the metal enclosure would be safe.

But in the case where the protective earth is faulty and the enclosure is touched, the leakage current may have no alternative path to ground other than through the person touching the equipment. Currents as low as 40mA at mains frequency may be enough to cause cardiac fibrillation and death, so the leakage current may present a lethal threat. In medical equipment which may be in direct contact with the patient, it is even more important that these leakage currents are limited to very low levels, in the order of micro-Amps. Filters are available that fulfil these requirements and manufacturers will be able to tell you what is available.

Transient suppression devices are used to prevent the passage of potentially damaging or interfering transient voltages into the equipment caused by switching or lightning surges. The devices divert the energy of the transient to ground and fall into two general categories, those that do this by switching to a very low resistance, or "crowbar" devices and those which have a resistance that varies with voltage or current, so called "clamping" devices. Examples of a crowbar device are gas discharge tubes or thyristors, while Metal Oxide Varistors(MOVs) or Zener diodes are examples of clamping devices. Generally the switching types are slower but will carry higher currents than the clamping types and are more suitable for dealing with lightning surge transients with typical micro-second

rise times. The clamping types are better for dealing with the faster events such as fast burst transients which exhibit nano-second rise times. Classically a hybrid circuit is used to get the best of both worlds.

As these transients occur in common mode on the mains supply, then the devices may be connected across from live to ground in the power line. Fortunately the leakage currents of these devices are normally very low, in the order of micro-Amps, so they pose no direct safety problems in the way that filters might. However it is possible for MOVs to fail short circuit and to be completely destroyed by excessive overcurrent, leading to overheating damage and possibly fire, so provision must be made for adequate fusing to protect both the equipment and the device. This fuse must be fitted on the input or up-line side of the device.

C7.1.3 Summary of design issues

When designing electro-medical equipment to meet EMC requirements, the first place to start is early on with the electronic circuitry, as much effective work can be done here. Working outwards, the internal cable layout should be considered and any enclosure used to provide additional EMC protection should be carefully designed. Filters, ferrites and transient protection devices provide a high degree of control of conducted interference and proper high frequency grounding must be provided for.

In all cases the impact of introducing these measures on safety must be paramount.

Safety must come first.