IEC60601-1 3rd Ed
Medical System Requirements: Rational and Implementation

Presented by Michael Brun
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AGENDA

9:00-10:00
Overview of regulatory requirements for electricity in hospitals: Codes, Standards and other requirements.

10:00-11:00

11:00-11:15 – Coffee break

10:15-12:00 Risk Management and Medical Systems
Performance limits vs essential performance (safety and EMC aspects) Applied parts vs Patient connection – Risk based approach Equivalent safety - Alternative Risk Control measures or test methods

12:00-13:00 – Home Use and Beauty care medical devices
Installation environment and equipment classification Alarms and Useability issues Market access overview
Electricity in Hospitals

- Core business of a hospital is the welfare of its patients
- Requires a huge variety of electrical ME
- Electricity is therefore a vital utility, as any malfunction or interruption can lead to disastrous consequences.

This combination - being absolutely vital but far from the primary concern of the organization - is a risk in itself.

Electricity related regulations come to mitigate this risk
Specific electricity risks related to healthcare

Basic Safety

▶ Leakage currents leaking from various devices may be individually safe but combined with others can add up and exceed the safe level.

▶ Weak or sensitive patients have weakened or non-existing reflexes, reduced skin resistance, or catheters/electrodes introduced on or into the body.

▶ Risk of microshock – current through cardiac muscle may become hazardous if it exceeds 10uA

Essential Performance

▶ Continuity: Many medical treatments cannot be interrupted without risk for patient.

▶ Data integrity: Accurate medical data is essential and are often gathered by long-term or invasive patient examination.
ME in Hospitals: Stakeholders

- FDA is under DoHHS/ Ministry of Health
- Fire Administration is under DoHS / Ministry of Interior
- OSHA is under DoL/ Ministry of Economy
- AHJ - Authorities Having Jurisdiction
US Department of Health and Human Services (DHHS) has designated CMS to administer the standards compliance aspects of Medicare and Medicaid (Federal insurance programs).

The Social Security Act (the Act) mandates the establishment of minimum health and safety standards that must be met by providers and suppliers participating in the Medicare and Medicaid programs.

Providers, in Medicare terminology, include patient care institutions such as hospitals, critical access hospitals (CAHs), hospices, nursing homes, and home health agencies (HHAs).

Suppliers are agencies for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics, and ambulatory surgery centers (ASCs). The Act designates those providers and suppliers that are subject to Federal health care quality standards.
NFPA is a global nonprofit organization devoted to eliminating death, injury, property and economic loss due to fire, electrical and related hazards.

- Support for the development, adoption and enforcement of about 300 codes and standards
- Research and data analysis
- Technical training and certification
- Public education

UL established in 1894

NFPA established in 1896
NFPA vs UL

- NFPA 70: National Electrical Code
- NFPA 99: Health Care Facilities Code
- NFPA 110: Emergency and Standby Power Systems

Requirement for electrical products to be Listed and Labeled, but also specify environment where ME is used

- UL 60601-1: Medical Electrical Equipment
- UL 60950-1: Information Technology Equipment
- UL 2200: Stationary Engine Generator Assemblies
In your RMF, you need to decide if you need UPS to survive 10 sec mains outage. Particular standard (e.g. for ECG) may require to survive 30 sec outage.
Wet Procedure Locations

New to the 2012 Edition of NFPA 99

- 6.3.2.2.8.4* Operating rooms shall be considered to be a wet procedure location, unless a risk assessment conducted by the health care governing body determines otherwise.

- A.6.3.2.2.8.4 In conducting a risk assessment, the health care governing body should consult with all relevant parties, including, but not limited to, clinicians, biomedical engineering staff, and facility safety engineering staff.

Equipment for Operating Rooms shall have IP rated, or marketed “for dry locations only”
Codes & Standards

Code: A standard that is an extensive compilation of provisions covering broad subject matter or that is suitable for adoption into law independently of other codes and standards (Regulations, 3.3.6.1)

- National Electric Code (NEC)

Requirements address general electrical construction and installation criteria for facilities, material, equipment, and appliances. Examples: NFPA 70 (USA); BS 7671 (UK); IEC 60364 (international)
APPLICATION OF CODE

► AN EXISTING SYSTEM NOT IN COMPLIANCE SHALL BE PERMITTED to be continued in use, unless the AHJ determines that such use is a DISTINCT hazard to life.

► Alterations, renovations and modernization meet new code (latest and greatest).

► Electrical products must be evaluated and certified not only for risks to life and property, but also for potential conformity to the installation and use provisions of the Code.

https://www.nema.org/Standards/ComplimentaryDocuments/nec-iec60364.pdf
Health Care Facilities Code

Establishes criteria for health care facilities based on risk to the patients, staff, or visitors to minimize the hazards of electricity and fire.

Requirements address installation, inspection, testing, maintenance, performance, and safe practices in health care facilities

Examples: NFPA 99 (USA) and IEC 60364-7-710 (international)
Some Major Codes that Influence Design

- State Operations Manual
  CMS - Center for Medicare and Medicaid Services
- Life Safety Code (LSC)
  NFPA - National Fire Protection Association
- Building Codes
  International Code Council, Florida Building Code
- ADAAG - ADA Accessibility Guidelines
  ADA - Americans with Disabilities Act
- Food Code & Infection Control Guidelines
  Food and Drug Administration & Center for Disease Control
  U.S. Department of Health and Human Services
- State & Local Health Department Regulations
- Guidelines for Design & Construction of Health Care Facilities

Codes Enforced by Authorities Having Jurisdiction (AHJ)
Authorities Having Jurisdiction

- Building Official
- Fire Inspector
- State Licensing Surveyor
- Federal Certification Surveyor
- Design and Building Professionals
- Insurance Carrier
- Certifying Agencies
Synchronization issues

CODE CREEP...NFPA 99 has now become the Health Care Design Manual for all things Electrical including number of receptacles in patient care areas, and nurse call requirements...This is confusing and contradictory to state and national design codes.

- Several Categorical LSC Waivers Permitted: The Centers for Medicare & Medicaid Services (CMS) has identified several areas of the 2000 edition of the LSC and 1999 edition of NFPA 99 that may result in unreasonable hardship on a large number of certified providers/suppliers and for which there are alternative approaches that provide an equal level of protection.

NFPA99 and NFPA101 are codes, and AHJ can implement them in full, or grant exemptions (waivers) on temporary or permanent basis.
Emergency Generators and Standby Power Systems

- Permits a waiver to allow for a reduction in the annual diesel-powered generator exercising requirement from two (2) continuous hours to one hour and 30 minutes (1-1/2 continuous hours), but only if the provider is in compliance with all other applicable 1999 NFPA 110 operational inspection and testing provisions, as well as with section 8.4.2.3 of the 2010 NFPA 110.

Requirement for annual test of generator under full load. This waiver is related to hospital installation, has no effect on ME.
Power Strips or Extension Cords

- CMS Pub. 100-07 August 17, 2007
- Not to be used to take the place of adequate wiring
- Properly secured and not be placed overhead, under carpets or rugs, or anywhere that the cord can cause trips, falls, or overheat.
- Connected to only one device to prevent overloading of the circuit and have proper grounding
- May be used for a computer, monitor, and printer. Power strips are not designed to be used with medical devices in patient care areas

Not to be used instead of installation wiring (meaning only for temporary use), not to be used with medical devices, properly secured
Minimum Number of Receptacles

6.3.2.2.6.2 of NFPA99

- General Care Areas – 8 receptacles
- Critical Care Areas – 14 receptacles
- Operating Rooms – 36 receptacles
3.67 * one or more socket-outlets intended to be connected to, or integral with, flexible cables or, cords or ME EQUIPMENT for providing SUPPLY MAINS or equivalent voltage

NOTE: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

SO WHAT MSO IS GOOD FOR?

The Centers for Medicare and Medicaid Services (CMS) released a categorical waiver allowing the use of power strips in new and existing healthcare facility patient care rooms, if the provider/supplier is in compliance with Life Safety Code (NFPA 101) electrical system and equipment provisions.
LSC requirements for Medical-Grade MSO

- **UL Standards**: For patient-care-related electrical equipment, power strips must meet UL 1363A or UL 60601-1 standards as Special Purpose Relocatable Power Taps (SPRPT).

- **Mounting**: Power strips must be permanently mounted to *electrical equipment*.

- **Unused Outlets**: After leakage currents have been tested, the power strip’s unused outlets must be secured.

- **Protective Features**: Power strips must contain protective features, including internal ground fault circuit interruption (GFCI) and over-current protection.

- **Non-Medical Usage**: Non-medical devices, such as personal electronic equipment, cannot be plugged into a power strip in the patient care vicinity; however, they may be used outside of the patient care vicinity for non-medical use.

- **Maintenance**: The electrical equipment that uses the power strip must be inspected within a regular maintenance program for electrical/mechanical integrity (e.g. the casing, power cords, safety covers, and circuit breakers, etc.).
DO YOU KNOW IF YOUR POWER STRIPS ARE UP TO CODE?
YOUR REGULATORY AUTHORITY WILL!

Implement a power strip compliance plan before you are cited for code violations!

The governing bodies that monitor electrical power inside healthcare facilities base their regulations on Article 517 of NFPA 70 and NFPA 99. Tripp Lite Healthcare Power Outlet Strips are designed and manufactured in accordance with Article 517 and certified to meet UL standards to ensure regulatory code compliance, avoid hazardous conditions and provide a safe environment for patients, staff and visitors. Use this simple guide to make sure you are up to code in every part of your facility.
Regulatory Compliance Guide For Healthcare

- Power Strip and Surge Suppressor solutions for the entire facility
- Meet regulatory code requirements
PATIENT CARE AREAS

With an increase in medical devices, do you need additional outlets located within a 6 ft. radius around a patient?

If so, your solution must meet UL 60601-1, the standard for shock prevention required for all devices that potentially come in contact with patients and staff.

Tripp Lite Solutions:
PS-415-HGULTRA—Power Strip
SPS415HGULTRA—Surge Suppressor

- Patented shock prevention technology
- With or without surge protection
- Hospital-grade plug and outlets

In a patient room, the Patient Care Area typically extends 6 ft. beyond the perimeter of the bed and 7 1/2 ft. above the floor.

Can stand-alone medical product connected with plug to wall ac outlet be provided with surge protection (ac to ground)?
QUESTION TO NRTL: Can you please advise if you require permanently connected PROTECTIVE EARTHING for PLUGGABLE EQUIPMENT TYPE A with MOVs between primary to ground?

ANSWER: For products with a VDR between primary and earth, if pluggable equipment A is used, there must be a separate permanently connected earth in addition to any earthing in the appliance coupler.

Rational:

8.5.1.3 of 60601-1 MEANS OF OPERATOR PROTECTION (MOOP) Solid insulation forming a MEANS OF OPERATOR PROTECTION shall:
– comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6; or – comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.
CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF OPERATOR PROTECTION shall:
– comply with the limits specified in Table 13 to Table 16 (inclusive); or – comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.
PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION shall either:
– comply with the requirements of 8.6; or – comply with the requirements and tests of IEC 60950-1 for protective earthing.

1.5.9.4 of 60950-1 Bridging of basic insulation by a VDR It is permitted to bridge BASIC INSULATION by a VDR complying with the requirements of Annex Q, with or without a GDT in series, provided that one side of the VDR circuit is earthed in accordance with 2.6.1 a). Equipment with such a VDR bridging BASIC INSULATION shall be one of the following:
– PLUGGABLE EQUIPMENT TYPE B; or
– PERMANENTLY CONNECTED EQUIPMENT; or
– equipment that has provision for a permanently connected PROTECTIVE EARTHING CONDUCTOR and is provided with instructions for the installation of that conductor.
Special Purpose Relocatable Power Taps (SPRPT)

- Question for NFPA: Background: Some manufacturers advertise multiple outlet connections of two or more power receptacles conforming to UL 60601-1, UL 60950-1 and UL 1363A. Their product information states this product, Easily accommodates surface mounting.

Question 1: Does the term permanently attached to the equipment assembly mean the multiple outlet connection must be an integral part of the cart as part of the UL Classification and attached only by the manufacturer of the rack, table, pedestal or cart?
Question 2: Does 10.2.3.6 (1) permit a 3rd party, such as a hospital engineer, to permanently attach the multiple outlet connection, with mechanical attachments such as screws, to the rack, table, pedestal, or cart?

**Answer from NFPA Staff:**

Section 10.2.3.6(1) of NFPA 99 (2012 and 2015) intentionally uses the term "permanently attached" as opposed to "integral". This allows for attachment to be made on site and after the fact rather than only by the manufacturer. This interpretation therefore allows for a 3rd party, possibly the hospital engineer to "permanently attach” the device by a variety of different means.

**DOES AHCA ACCEPT THIS?**

**NOT NECESSARILY**

American Health Care Association run another certification program. For participants of this program AHCA is AHJ

**BUT REAL PROBLEM IS … THIS MSO DOES NOT WORK WITH IPS!**
MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT)

Electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT.

IEC 60364-7-710
Art. 710.2.3

Electrical equipment, provided with not more than one connection to a particular supply mains and intended to diagnose, treat or monitor the patient under medical supervision and which makes physical or electrical contact with the patient, and/or transfers energy to or from the patient, and/or detects such energy transfer to or from the patient. The equipment includes those accessories defined by the manufacturer as being necessary to enable normal use of the equipment.
MEDICAL ELECTRICAL SYSTEM (ME SYSTEM)

Combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MSO.

YOU CAN BECOME A MANUFACTURER OF ME SYSTEM JUST BY… SPECIFYING USE OF EXTERNAL PRINTER
An ME SYSTEM shall provide:

– within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with IEC60601-1 standard; and

– outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.
How code can affect your product

- If product is within the PATIENT ENVIRONMENT, level of safety equivalent to ME EQUIPMENT complying with IEC60601-1 standard. Example – smart shelves with RF ID

- If product is intended for OR – it may need IP rating.

- Type of AP may be affected by medical location group Art. 710.2.5-7

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**IEC 60364-7-710**

Art. 710.2.1

A part of the medical electrical equipment which in normal use
- necessarily comes into physical contact with the patient for the equipment to perform its function, or
- can be brought into contact with the patient, or
- needs to be touched by the patient

The applied part can be an electrode external or internal to the body or a surface of the device that, for functional reasons, must be brought into contact with the patient. As regards the type of applied part, medical electrical equipment are divided into devices with parts applied of type CF, BF and B, classified in order of decreasing safety.

<table>
<thead>
<tr>
<th>Part applied</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF</td>
<td><img src="heart.png" alt="Heart" /></td>
<td>Devices whose applied part is earth insulated (F = floating) and can be placed in direct contact with the heart since their applied part is insulated</td>
</tr>
<tr>
<td>BF</td>
<td><img src="person.png" alt="Person" /></td>
<td>Devices whose applied part is earth insulated (F = floating), but which provide a lesser degree of protection than CF devices. They are therefore not suitable for direct cardiac application</td>
</tr>
<tr>
<td>B</td>
<td><img src="person.png" alt="Person" /></td>
<td>Devices whose applied part is not earth insulated. They are therefore less safe as regards earth leakage</td>
</tr>
</tbody>
</table>
Group 0, 1 and 2 medical locations

- group 0 rooms:
  medical location where no applied parts are intended to be used.

  *No medical grade requirements*

- group 1 rooms:
  medical location where applied parts are intended to be used externally or invasively to any part of the body, except for the cardiac zone.

  *Medical Grade requirements, critical services (such as lighting) should switch to an alternative power supply*

- group 2 rooms:
  medical location where applied parts are intended to be used in applications such as intracardiac procedures, operating theatres and vital treatment rooms

  *Medical Grade requirements, no power interruption is allowed, equipotential bonding.*

  *IT system is used to protect from earth faults.*

  *UPS may be used as tertiary power source.*
Know your medical location!

Is it a room intended for medical use, in other words, intended for diagnostic, therapeutic, surgical, patient monitoring or rehabilitation (including aesthetic treatments)?

- **YES**
  - Other type of rooms: for example ordinary

- **NO**
  - Is at least one medical electrical equipment with applied parts used?
    - **NO**
      - Group 0
    - **YES**
      - Are intracardiac interventions or other surgical operations with hazard of microshock performed?
        - **NO**
          - Group 1
        - **YES**
          - Are operation preparation, surgical plaster, post-operative waking-up activities carried out and is general anaesthesia practiced?
            - **YES**
              - Group 2
Equipotential bonding is the connection of all conductive parts of the electrical system and conductive parts extraneous to the electrical system with each other, and subsequently connecting this bonding network to the earthing network.

Equipotential bonding avoids the situation that two metal parts could hold a different electrical potential, entailing the risk of electrocution if they were to be touched simultaneously.

The general standard on electrical safety in buildings prescribes equipotential bonding for all rooms with a bath or shower.
Standard IEC 60364-7-710 requires the equipotential bonding of all conductive parts extraneous to the electrical system that are entering the same building.

Extraneous conductive parts include metal pipes, metal window frames, and iron components of reinforced concrete.

IEC 60364-7-710 further requires supplementary equipotential bonding for all Group 1 and Group 2 locations.

These rooms must be equipped with their own equipotential bonding bus bar to which all electrical devices and all extraneous conductive parts are connected.
For group 2 medical locations, the resistance presented by the conductor and by the connections between an equipotential bonding bus bar and an extraneous conductive part must not be greater than 0.2 Ω.

Also Class II medical devices must be connected to the local equipotential bus bar!
IT system is to be used for final circuits supplying medical electrical equipment intended for

- life support systems
- surgical applications
- electrical equipment used in the patient environment.
I, Isolated; T, Terre
isolated from earth, usually by means of an isolating transformer.
8.11.5 * Mains fuses and OVER-CURRENT RELEASES
A fuse or OVER-CURRENT RELEASE shall be provided in each supply lead for CLASS I ME EQUIPMENT, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT.

Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow.

NOTE: If fuses complying with IEC 60127 are used, and the prospective short-circuit current exceeds 35 A or 10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1 500 A).

<table>
<thead>
<tr>
<th>Medical insulating transformers order codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Insulating transformer 3 kVA</td>
</tr>
<tr>
<td>Insulating transformer 5 kVA</td>
</tr>
<tr>
<td>Insulating transformer 7.5 kVA</td>
</tr>
<tr>
<td>Insulating transformer 10 kVA</td>
</tr>
</tbody>
</table>
Updates in Ed. 3.1

16.3 * Power supply

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard (see 4.10.1, 5.5 f) and 7.9.2.3). See also Figure F.5.

If an ME SYSTEM:

– is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and

– the ME SYSTEM can draw large transient currents when being switching on or off or when operating,

the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied.

If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.

Compliance is checked by inspection.

16.9.2.2 * PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ.
Conclusion

- ME environment is heavily regulated. Some regulations may affect ME design.
- Approval to 60601-1 does not always mean that product or component can be used in any medical application.

Example: Tripplite said their MSO of UL60601-1 type does not work with IPS. So it may be a big problem to use it in Group 2 Medical Location.

- Protective Earthing and Protective bonding issues should be always considered on product and system level.
a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

EXAMPLE 1  Subclause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)
EXAMPLE 2  Subclause 9.4.2.1, Instability in transport position

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

This requirement is related to RM, and is applicable to both BS and EP!

Example1: Section 8.5.2.1 requires MOPP between BF type AP to chassis to have

- 4.0mm creepage,
- 2.5mm clearance,
- 1500Vac dielectric.

Anything less that than does not mitigate the risk of electric shock to patient.
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities
CF vs BF

NIBP, SpO2, and Quick Temp vital signs parameters measurements

SpO2, NIBP: BF Defibrillation type; TEMP: CF type.

- 4.0mm creepage,
- 4.0mm clearance,
- 1500Vac dielectric.
202.6.2.101  * Electrosurgery interference

If the ME EQUIPMENT is intended to be used in an electrosurgery environment, a means shall be provided for protection against malfunction caused by electrosurgery. Perform the test below, using any PATIENT CABLES, LEAD WIRES, ACCESSORIES or settings recommended by the MANUFACTURER, applies.

When the ME EQUIPMENT is used together with HF SURGICAL ME EQUIPMENT it shall return to previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL ME EQUIPMENT, without loss of any stored data.

Example 2: For ECG, data integrity is EP. Loosing data during exposure to HF surgery is acceptable, but not more that for exposure duration and 10 sec after.

Anything less that than does not mitigate the risk of wrong heart activity diagnostic/display.
During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.

The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.

202.6.2.101 * Electrosurgery interference

If the ME EQUIPMENT is intended to be used in an electrosurgery environment, a means shall be provided for protection against malfunction caused by electrosurgery. Perform the test below, using any PATIENT CABLES, LEAD WIRES, ACCESSORIES or settings recommended by the MANUFACTURER, applies.

When the ME EQUIPMENT is used together with HF SURGICAL ME EQUIPMENT it shall return to previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL ME EQUIPMENT, without loss of any stored data.

What about EFT?
201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.101 identifies essential performance requirements for electrocardiographs and the subclauses in which they are found.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Subclause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defibrillation protection</td>
<td>201.8.5.5.1</td>
</tr>
<tr>
<td>ESSENTIAL PERFORMANCE of ME EQUIPMENT</td>
<td>201.12.1.101</td>
</tr>
<tr>
<td>FILTERS (including line frequency interference FILTERS)</td>
<td>201.12.4.105.3</td>
</tr>
<tr>
<td>Electrostatic discharge</td>
<td>202.6.2.2.1</td>
</tr>
<tr>
<td>Electric fast transients and bursts</td>
<td>202.6.2.4.1</td>
</tr>
<tr>
<td>Conducted disturbances</td>
<td>202.6.2.6.1</td>
</tr>
<tr>
<td>Electrosurgery interference</td>
<td>202.6.2.101</td>
</tr>
</tbody>
</table>

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT are found in the subclauses listed in Table 201.101

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Subclause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defibrillator protection</td>
<td>201.8.5.5.1</td>
</tr>
<tr>
<td>Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT</td>
<td>201.11.8</td>
</tr>
<tr>
<td>Protection against depletion of battery</td>
<td>201.11.8.101</td>
</tr>
<tr>
<td>ESSENTIAL PERFORMANCE of ME EQUIPMENT</td>
<td>201.12.1.101</td>
</tr>
<tr>
<td>Electrosurgery interference</td>
<td>202.6.2.101</td>
</tr>
<tr>
<td>Time to alarm for heart rate ALARM CONDITIONS</td>
<td>208.6.6.2.103</td>
</tr>
<tr>
<td>TECHNICAL ALARM CONDITIONS indicating inoperable ME EQUIPMENT</td>
<td>208.6.6.2.104</td>
</tr>
</tbody>
</table>
4.5 Equivalent safety for ME EQUIPMENT or ME SYSTEMS

* Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard.

* Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.

Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard.

NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided.

* Compliance is checked by inspection of the RISK MANAGEMENT FILE.
**16.5 * Separation Devices**

When functional connection between ME equipment and other items of equipment of an ME system or other systems can cause the allowable values of leakage current to be exceeded, then safety measures incorporating a separation device shall be applied.

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**Table I.1 (continued)**

<table>
<thead>
<tr>
<th>Situation No.</th>
<th>Medically used room</th>
<th>Non-medically used room</th>
<th>Examples of possible causes for exceeding leakage current limits</th>
<th>Practical means of compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inside the patient environment</td>
<td>Outside the patient environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3c Item A is ME equipment and item B is ME equipment or non-ME equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>a) Potential difference between protective earth connections of A and B</td>
<td>Additional protective earth connection for (A), or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>b) Due to high touch current of B</td>
<td>Separation device, or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>See rationale for 16.5.</td>
<td>Do not use metal connector housing in the patient environment</td>
</tr>
</tbody>
</table>
Protection against electrical HAZARDS

The fundamental principle for protection against electric shock:

- the voltage or current between any accessible surface and any other accessible surface or earth is low enough not to present a HAZARD;

- in all relevant circumstances, including
  - NORMAL CONDITION, and
  - SINGLE FAULT CONDITION
In order for the fundamental principle to be satisfied:

- a) parts that are “live” (as defined in 2nd Ed) or “hazardous live” or “hazardous voltage” (as defined in some other standards, such as IEC 60950 and IEC 61010-1) have to be inaccessible, and

- b) ACCESSIBLE PARTS including APPLIED PARTS have to be not “live”/“hazardous live.”

These two requirements are in principle equivalent, but safety standards state both of them and also provide specific assessment methods for each.
For Medical Grade products, these requirements in turn imply that:

- **ACCESSIBLE PARTS** including APPLIED PARTS have to be separated from live parts, and
  - Two separate MEANS OF PROTECTION are necessary—one to provide separation in NORMAL CONDITION and a second to maintain BASIC SAFETY in SINGLE FAULT CONDITION

- **LEAKAGE CURRENTS** (and possibly also voltages and energies) have to be below acceptable limits.
  - Also in SINGLE FAULT CONDITION; for ME systems - only those defined in the standard
3rd ED: No “Live” circuits

Example: Electrical circuit with patient connection insulated by BASIC insulation and can source a current of 200 μA. Is it “live” or not?

ASSESSMENT

- It is separated from all ACCESSIBLE PARTS, including PATIENT CONNECTIONS in NORMAL CONDITION.

- The same part can be connected to other ACCESSIBLE PARTS and PATIENT CONNECTIONS in SINGLE FAULT CONDITION, but 200 μA is permissible; except that

- The separation from PATIENT CONNECTIONS of TYPE CF APPLIED PARTS has to remain effective in SINGLE FAULT CONDITION, because a current of 200 μA from these is not permissible.
Example: Robot in Patient Environment

If there is some insulation at both points A and B, then no part of the SECONDARY CIRCUIT is “live” according to the definition in the 2nd Ed, so standard specifies no requirements for that insulation, which can therefore be minimal. The approach adopted in 3rd Ed is intended to overcome this problem.

Controller Unit

Robot in PE

ME EQUIPMENT

Metal APPLIED PART

Figure A.10—Floating circuit
The APPLIED PART has a metal enclosure that is not protectively earthed. If there is a direct connection at point A, then the other end of the secondary circuit is “live,” and we need double insulation or reinforced insulation at point B.

If, instead, there is a direct connection at point B, the 2\textsuperscript{nd} Ed requires DOUBLE INSULATION or REINFORCED INSULATION at point A (20.2 B-e).
“...The total impedance of the protective earth path for a SYSTEM may be up to 0.4 0.2 ohm. Compliance is checked by current of 25 A or 1.5 times the highest RATED current of the relevant circuit(s), whichever is greater..”
The 3rd ED specifies:

- that NORMAL CONDITION (NC) includes short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE, or impedance which does not comply with specified MOP requirements for the relevant WORKING VOLTAGE, and open circuit of any earth connection which does not comply with the requirements for PROTECTIVE EARTH CONNECTIONS; and

- that SINGLE FAULT CONDITIONS (SFC) include short circuit of any insulation, AIR CLEARANCE, or CREEPAGE DISTANCE which does comply with specified MOP requirements for the relevant WORKING VOLTAGE, short circuit of any relevant component, and open circuit of any earth connection which does comply with the requirements for PROTECTIVE EARTH CONNECTIONS.
**RISK: Electric Shock**

**Control Measures: 2 Means of Protection per IEC60601-1**

**Construction:**
1) Insulation (clearance, creepage comply with 1MOPP)
2) Grounding (dedicated terminal, green/yellow wire)

**Testing:**
1) Leakage (NC/SFC) and Dielectric Strength
2) Ground Continuity – FAIL (0.3ohm, exceed max. 0.2 ohm)

**Alternate Test Methods:**
Connect Equipotential Bonding during ground continuity test
Conclusion

- It is always better to comply with standard requirements, both on product and system level.
- When technology does not allow to comply with certain clause of standard, alternate risk control measures can be considered.
- Acceptance of alternate risk control measures depends on regulatory authorities.
Title: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

The home healthcare environment includes:

- the dwelling place in which a patient lives;
- other places where patients are present both indoors and outdoors, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present.
3.63
MEDICAL ELECTRICAL EQUIPMENT

Equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and
b) intended by its MANUFACTURER to be used:

1) in the diagnosis, treatment, or monitoring of a PATIENT; or
2) for compensation or alleviation of disease, injury or disability

We suggest you begin by using the Cleansing Brush once daily.
Remove makeup before use. Apply cleanser to moistened skin or brush head.
Massage in circular motion for 15 seconds on cheeks using white bristles. No need to apply pressure.
Massage in up-and-down motion for 15 seconds combined on T-Zone using green bristles.
International Approvals for Home Healthcare

Manufacturers of healthcare equipment intended for use in homes may be required to comply with

Europe: EN60335-1 with particular standards
N. America: UL60601-1 or UL1431
ROW: IEC60335-1 or IEC 60601-1

IEC 60601-1-11 is harmonized and accepted in most countries, but some devices may still be subject to the requirements of other standards.

Example: UL1431 “Personal Hygiene and Health Care Appliances” covers household electric products for hygiene or other healthcare applications rated at 250 V or less. Products covered under this standard include massage units, nebulizers, breast pumps, toothbrushes and contact lens disinfectors.

Europe: EN60601-1 (3rd Ed) with EN60601-1-11 (1st Ed)
N. America: ES60601-1 (3.1) with IEC60601-1-11 (2), or UL1431
ROW: IEC60335-1 with -2-23 (xx), or IEC 60601-1 2nd Ed
Home Healthcare Environment

Any environment that is NOT a professional healthcare facility (where OPERATORS with medical training are continually available).

NO PROTECTIVE EARTH connection only floating type applied parts permitted, unless the equipment is permanently installed by an electrician.

Equipment intended for the home healthcare environment must be Class B with respect to emissions.

The usability evaluation is required.

ENCLOSURES must be at least IP21 (light rain proof).

TRANSIT-OPERABLE, HANDHELD, and BODY-WORN equipment must be at least IP22.

Do not seal battery compartments!
Can be same person. For most operations not related to treatment (like battery charging), MOOP insulation level is required and touch leakage (vs patient leakage).

IEC 60950-1 (ITE) power supplies and PC/accessories can be used to provide MOOP, but

- No protective ground is allowed, only Class II units
- What about leakage? ITE allows 0.5mA for Class II, MED is 0.1mA
- What about EMC? ITE device or its components were not tested with immunity test levels of MD.
- Insulation coordination, including altitude
Component selection

Introduction of concept “component approval” can create a gap between your expectations for coverage of component assessment, and actual testing performed.

Components covered under UL Component Recognition Mark program are considered incomplete and are intended to be installed into another device, system or end-product.

UL approved medical grade power supplies are UL Recognized, not Listed
VI. User Considerations

The users of home use devices are different from the health care professionals who typically operate medical devices in a professional health care facility. Home users can have a large range of physical, sensory, and cognitive capabilities and disabilities, and emotional differences that should be considered in your home use device design. If the home use device is not designed for ease of use and understanding, you increase the likelihood of misuse and non-use of the device. Home use devices should be designed to prevent reasonably-foreseeable misuse. You should consider that children or adults might interact with the device in inappropriate ways.

Usability is part of any ME approval. We will test

- Safety related functions
- Frequently used functions
Usability issues: Alarms

8. Alarm Systems

Alarm systems are of particular concern for home use devices because noise and other distractions inside and outside the home can interfere with the users’ ability to be made aware of an alarm signal. For example, users can have hearing impairments, including the inability to hear specific frequencies. Device alarm systems with high or medium-priority alarm signals should be designed to be perceived in environments typically found in the home. If the alarm system incorporates wired or wireless connections to other locations, the entire device system should be designed and tested to mitigate risks from loss or degradation of these connections.

Alarm signals may not apply to all devices. If the need for an alarm applies to your device, FDA recommends that you provide alarm signals in at least two of the three following modes: visual, auditory, tactile. This alarm signal could be localized to the area where the device is being operated or in another location, which is known as a distributed alarm.

- Example: insulin pumps are body-worn, may need vibration in addition to visual alarms
8.5  Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE

8.5.1  * Indication of state

If the INTERNAL ELECTRICAL POWER SOURCE is essential to maintain BASIC SAFETY or to maintain ESSENTIAL PERFORMANCE or control the RISKS associated with the loss of ESSENTIAL PERFORMANCE, the ME EQUIPMENT shall be equipped with a means for the OPERATOR to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.

The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated as:

- a number of PROCEDURES remaining;
- the remaining operating time;
- the percentage of the remaining operating time or energy; or
- a "fuel" gauge.

The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated continuously or by OPERATOR action.
7.9.2.13 Maintenance

The instructions for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.

C. Calibration

Home use devices should be designed without the need for calibration, but if that is not possible, the device should be designed to require minimal calibration by the user. Calibration instructions should be step-by-step and preferably provide the user with any feedback necessary to complete the calibration process. This could also include an indication on the device that states that it is calibrated, when it was last calibrated, and when the next calibration is needed.
Thank You!
Electromagnetic compatibility (EMC) requirements for Medical Devices
Based on 4th Edition of IEC 60601-1-2

Presented by: Mr. Michael Nikishin,
Hermon Laboratories
EMC & Radio Group Manager
IEC 60601-X-XX Standards structure

Collateral standards define the requirements for certain aspects of safety and performance.
Particular standards define the requirements for specific products and technologies.

Some particular standards provide additional setup requirements and/or test limits for EMC.
This collateral standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of medical equipment and systems

Immunity

- in the presence of ELECTROMAGNETIC (EM) DISTURBANCES and

Emissions

- to ELECTROMAGNETIC DISTURBANCES emitted by ME EQUIPMENT and ME SYSTEMS

BASIC SAFETY with regard to ELECTROMAGNETIC DISTURBANCES is applicable to all medical equipment and systems
RISK MANAGEMENT PROCESS

- Risks resulting from reasonably foreseeable EM disturbances shall be taken into account in the RISK MANAGEMENT PROCESS.

- The MANUFACTURER has to perform a number of activities with regard to EM disturbances during the design and realization of their product, and to document them in the RISK MANAGEMENT FILE.

- EMC test laboratories cannot be expected to perform or document these activities.

- Further information is provided in Annex F - RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM disturbances.


Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.
<table>
<thead>
<tr>
<th>Test name</th>
<th>Test conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emissions</strong></td>
<td></td>
</tr>
<tr>
<td>Radiated emissions</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Conducted emissions</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Harmonic distortion</td>
<td>At 230(L-N) / 400(L-L) VAC under 50 or 60 Hz</td>
</tr>
<tr>
<td>Voltage fluctuations and flicker</td>
<td>At 230(L-N) / 400(L-L) VAC under 50 Hz</td>
</tr>
<tr>
<td><strong>Immunity</strong></td>
<td></td>
</tr>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Radiated RF EM fields (RF)</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Electrical fast transients and bursts (EFT/B)</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Surges</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Conducted RF EM fields (CI)</td>
<td>At any nominal power voltage/frequency (one is enough)</td>
</tr>
<tr>
<td>Magnetic fields</td>
<td>At any power voltage, 50 or 60 Hz (one is enough, however power frequencies shall be the same as applied field)</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and variations</td>
<td>At the minimum and maximum rated voltages, if the rated voltage range is less than 25% may be tested at any power voltage within the range at any power frequency</td>
</tr>
</tbody>
</table>

* National deviations shall be addressed for required power voltages
Immunity - Environments of intended use

**Home healthcare environment**
Restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), vehicles (cars, buses, trains, boats, planes, helicopters), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres

**Professional healthcare facilities**
Physician offices, dental offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals (except medical treatment areas with high-powered RF equipment)

**Special environment**
Military areas
Heavy industrial areas
Medical treatment areas with high-power (HF surgery, short wave therapy, MRI)

**EM ENVIRONMENT**
Special Environments

- SPECIAL ENVIRONMENT is EM ENVIRONMENT with EM characteristics different from those specified in IEC 60601-1-2 Ed.4 for the professional healthcare facility and the home healthcare.

- These environments are not unusual, but the EM ENVIRONMENTS differ significantly from those defined in the standard or are not well-characterized.

- SPECIAL ENVIRONMENTS can also be justified for locations in the professional healthcare facility and/or in the home healthcare due to special conditions or mitigations:
  - HF SURGICAL EQUIPMENT
  - MRI system
  - Shielded location

- When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels it shall be considered in the RISK MANAGEMENT PROCESS.

- Annex E - Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS may be used to adjust the specified IMMUNITY TEST LEVELS based on mitigations or conditions of INTENDED USE.

- If determination or adjustment of test levels is made, the following information should be documented in the test plan, the RISK MANAGEMENT FILE and the test report:
  - justification for any SPECIAL ENVIRONMENTS identified or adjustments made
  - the adjusted reasonably foreseeable maximum EM DISTURBANCE levels
  - the resulting final IMMUNITY TEST LEVELS
  - details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS

- If mitigations are used to justify lower IMMUNITY TEST LEVELS, the RISK MANAGEMENT FILE shall include explanation that the mitigations will be effective over the EXPECTED SERVICE LIFE in all expected locations.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.
### Emission limits

<table>
<thead>
<tr>
<th>Reference standard</th>
<th>Port</th>
<th>Test level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test</strong></td>
<td><strong>Procedure</strong></td>
<td><strong>Group 1</strong></td>
</tr>
<tr>
<td>Radiated emissions</td>
<td>CISPR 11</td>
<td>Enclosure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducted emissions</td>
<td>CISPR 11</td>
<td>AC power</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Harmonics</td>
<td>IEC 61000-3-2</td>
<td>AC power</td>
</tr>
<tr>
<td>Voltage fluctuations and flickers</td>
<td>IEC 61000-3-3</td>
<td>AC power</td>
</tr>
</tbody>
</table>

- Medical equipment intended for use in aircrafts shall comply with ISO 7137 (RTCA DO-160C:1989)
- CISPR 25 and/or ISO 7637-2 might be applicable for other transportation modes
Separation into groups

- **Group 1 equipment**: contains all equipment in the scope of this standard which is not classified as group 2 equipment. Most types of ME EQUIPMENT and ME SYSTEMS generate or use RF energy only for their internal functioning and therefore belong to group 1.

- **Group 2 equipment**: contains equipment in which RF energy in the frequency range 9 kHz to 400 GHz is intentionally generated and applied, in the form of electromagnetic radiation, inductive and/or capacitive coupling, to patients.
Group 1 equipment - examples

EQUIPMENT intended to deliver energy to the PATIENT, but in a form that is other than RF electromagnetic

- **Medical imaging equipment**
  - diagnostic X-ray systems for radiography and fluoroscopy
  - computed tomography ME SYSTEMS
  - ME SYSTEMS for nuclear medicine
  - diagnostic ultrasound ME EQUIPMENT

- **Therapy ME EQUIPMENT and ME SYSTEMS**
  - therapeutic x-ray
  - dental ME EQUIPMENT
  - electron beam accelerators
  - ultrasound ME EQUIPMENT for therapy
  - ME EQUIPMENT for extracorporeal lithotripsy
  - infusion pumps
  - radiant warmers
  - infant incubators
  - ventilators
  - anaesthesia machines

- **Monitoring ME EQUIPMENT and ME SYSTEMS**
  - impedance plethysmography monitors
  - pulse oximeters

- **PATIENT monitors**
  - electro- and magneto-cardiography
  - electro- and magneto-encephalography
  - electro- and magneto-myography
Group 2 equipment - examples

- Only a few EQUIPMENT apply RF energy to PATIENTS and are therefore members of group 2.
  - MRI
  - Therapy EQUIPMENT
  - Diathermy EQUIPMENT (short wave, ultra-short wave, microwave therapy EQUIPMENT)
  - Hyperthermy EQUIPMENT
  - High frequency surgical EQUIPMENT (when active)
Class A and B equipment

**Class A:**
Only equipment/systems for use by healthcare professionals and that are not intended for sale to the general public are allowed to meet either the requirements for CISPR 11 class A or class B under the following conditions:

- intended to be connected to dedicated supply systems (separation transformers)
- rated input power > 20 kVA and intended to be powered by a dedicated power transformer and connected to it solely by a clearly identifiable power line path.

Instructions for use of class A medical equipment shall include the following note

**NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

**Class B:**
intended for use in domestic establishments and connected to the public mains network (e.g. home care equipment and equipment for doctors’ offices in residential areas)
Performance PASS/FAIL criteria

- The MANUFACTURER shall determine specific, detailed immunity pass/fail criteria, based on applicable part two standards or risk management, for BASIC SAFETY and ESSENTIAL PERFORMANCE.

- The MANUFACTURER shall also determine how the medical equipment will be monitored during the tests to check for compliance with the specific pass/fail criteria. This monitoring specification should be included in the test plan, the test report and the RISK MANAGEMENT FILE.

- For ME EQUIPMENT and ME SYSTEMS with multiple functions, the pass/fail criteria should be applied to each function, parameter and channel.

- IMMUNITY pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable RISK.

- For transient phenomena for which it might not be practical to assess performance during the application of the transient, assessing performance before and after the test is acceptable.

- ME EQUIPMENT and ME SYSTEMS shall meet the IMMUNITY pass/fail criteria during and after the tests.

- The effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES shall be documented.

- Guidance and examples for determining specific, detailed IMMUNITY pass/fail criteria are provided in Annex I.
<table>
<thead>
<tr>
<th>Test</th>
<th>Port</th>
<th>Test settings</th>
<th>Professional ENV</th>
<th>Home ENV</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD IEC 61000-4-2</td>
<td>Enclosure</td>
<td>Contact</td>
<td>8 kV</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Air</td>
<td>2, 4, 8, 15 kV</td>
<td></td>
</tr>
<tr>
<td>RI to RF fields IEC 61000-4-3</td>
<td>Enclosure</td>
<td>80-2700 MHz</td>
<td>3 V/m</td>
<td>10 V/m</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AM 80% 1 kHz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EFT IEC 61000-4-4</td>
<td>AC power</td>
<td>100 kHz</td>
<td>2.0 kV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DC power IN(≥3m)</td>
<td>5/50 ns</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient coupling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Signal(≥3m)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>AC power</td>
<td>Differential</td>
<td>0.5/1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DC power IN</td>
<td>0 Ω (2 Ω)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Common</td>
<td>10 Ω (12 Ω)</td>
<td>0.5/1.0/2.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Signal (Outdoor)</td>
<td>Common</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vehicular transients</td>
<td>DC power IN</td>
<td>ISO 7637-2</td>
<td>Not required</td>
<td>ISO 7637-2</td>
</tr>
<tr>
<td>CI to RF fields IEC 61000-4-6</td>
<td>AC power</td>
<td>0.15-80 MHz</td>
<td>3 V_{RMS}</td>
<td>6 V_{RMS}</td>
</tr>
<tr>
<td></td>
<td>DC power IN(≥3m)</td>
<td>AM 80% 1 kHz</td>
<td>(in ISM bands)</td>
<td>(in ISM &amp; amateur bands)</td>
</tr>
<tr>
<td></td>
<td>Patient coupling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Signal(≥3m)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnetic fields IEC 61000-4-8</td>
<td>Enclosure</td>
<td>50/60 Hz</td>
<td>30 A/m</td>
<td>30 A/m</td>
</tr>
<tr>
<td>Voltage dips and interruptions IEC 61000-4-11</td>
<td>AC power</td>
<td>0.5 cycle (10/8.33 ms) at 0-45-90-135-180-225-270-315° of power V</td>
<td>0% (0 V_{RMS})</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 cycle (20/16.67 ms)</td>
<td>0% (0 V_{RMS})</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>25/30 cycles (500 ms)</td>
<td>70% (161/70 V_{RMS})</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>250/300 cycles (5000 ms)</td>
<td>0% (0 V_{RMS})</td>
<td></td>
</tr>
</tbody>
</table>
### ISM and Amateur bands

- **ISM Bands – Both Professional and Home Healthcare ENV**
  
<table>
<thead>
<tr>
<th>Frequency Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.765-6.795 MHz</td>
</tr>
<tr>
<td>13.553-13.567 MHz</td>
</tr>
<tr>
<td>26.957-27.283 MHz</td>
</tr>
<tr>
<td>40.66-40.70 MHz</td>
</tr>
</tbody>
</table>

  - **150 kHz**
  - **ISM Bands**
  - **80 MHz**

- **Amateur radio bands – Home Healthcare ENV**

<table>
<thead>
<tr>
<th>Frequency Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8-2.0 MHz</td>
</tr>
<tr>
<td>3.5-4.0 MHz</td>
</tr>
<tr>
<td>5.3-5.04 MHz</td>
</tr>
<tr>
<td>7.0-7.3 MHz</td>
</tr>
<tr>
<td>10.1-10.15 MHz</td>
</tr>
<tr>
<td>14.0-14.2 MHz</td>
</tr>
<tr>
<td>18.07-18.17 MHz</td>
</tr>
<tr>
<td>21.0-21.4 MHz</td>
</tr>
<tr>
<td>24.89-24.99 MHz</td>
</tr>
<tr>
<td>28.0-29.7 MHz</td>
</tr>
<tr>
<td>50.0-54.0 MHz</td>
</tr>
</tbody>
</table>

  - **150 kHz**
  - **Amateur Bands**
  - **80 MHz**
## Immunity to wireless RF communications equipment

<table>
<thead>
<tr>
<th>Test frequency (MHz)</th>
<th>Band (MHz)</th>
<th>Service</th>
<th>Modulation</th>
<th>Max Power (W)</th>
<th>Distance (m)</th>
<th>Test level (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380-390</td>
<td>TETRA 400</td>
<td>PM 18Hz</td>
<td>1.8</td>
<td>0.3</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430-470</td>
<td>GMRS 460 FM ±5kHz, FRS460 1kHz SW</td>
<td>2.0</td>
<td>0.3</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>710</td>
<td>704-787</td>
<td>LTE 13/17 PM 217Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>745</td>
<td>704-787</td>
<td>LTE 13/17 PM 217Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>780</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>810</td>
<td>800-960</td>
<td>GSM800/900, TETRA 800, IDEN 820, CDMA850, LTE 5 PM 18Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>870</td>
<td>800-960</td>
<td>GSM800/900, TETRA 800, IDEN 820, CDMA850, LTE 5 PM 18Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
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<tr>
<td>930</td>
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<td></td>
</tr>
<tr>
<td>1720</td>
<td>1700-1990</td>
<td>GSM 1800, CDMA 1900, GSM 1900, DECT, UMTS, LTE 1/3/4/25 PM 217Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>1845</td>
<td>1700-1990</td>
<td>GSM 1800, CDMA 1900, GSM 1900, DECT, UMTS, LTE 1/3/4/25 PM 217Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
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<tr>
<td>1970</td>
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<tr>
<td>2450</td>
<td>2400-2570</td>
<td>Bluetooth, WLAN 802.11b/g/n, RFID 2450, LTE 7 PM 217Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
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<tr>
<td>25240</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>5240</td>
<td>5100-5800</td>
<td>WLAN 802.11a/n PM 217Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>5500</td>
<td>5100-5800</td>
<td>WLAN 802.11a/n PM 217Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>5785</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Summary of changes comparing to Ed.3

- Simplified power voltage and frequency conditions for the tests
- Performance during transients may be monitored before and after the test
- Allowance for degradations of performance that do not result in unacceptable RISK
- ESD – higher test levels ± 8 kV Contact and ±15 kV Air discharges added
- ESD – mitigation for sensitive connector removed
- RI – single test modulation AM80% 1 kHz is adopted or other modulation frequencies identified by the risk management process
- RI – expanded up to 2.7 GHz
- RI – proximity fields from RF wireless communication test added
- RI – no exclusion band for radio devices
- EFT test frequency changed from 5 kHz to 100 kHz
- Surge – requirements for DC power input and signal output ports added
- MF – immunity at 30 A/m level for magnetically sensitive equipment
- CI – shorter than 3 meters cables length exclusion added
- CI – higher level 6 V_{RMS} within ISM/Amateur bands required
- Voltage dips - test levels changed and phase variation added
- Vehicle transients per ISO 7637-2 for 12 VDC /24 VDC added
- Life support equipment category was eliminated
- Emissions and Immunity declarations omitted
Thank you, for your attention!

EXPERTS IN GLOBAL COMPLIANCE SOLUTIONS

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