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Battery Powered Medical Equipment

Part II -- EM Disturbance Requirements

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Introduction

This article summarizes required Electromagnetic (EM) Disturbance testing, as well as special test considerations which may apply to battery powered devices. We've highlighted issues that aren't unique to battery powered medical equipment, but are commonly encountered, especially for Hand-Held and Body-Worn equipment.

Unless otherwise indicated, clause references are to the collateral Electromagnetic Disturbances standard, IEC 60601-1-2:2014 (edition 4.0). Where a term is defined within the safety standards, and used within this article, the term is written with first letter capitalization, (e.g. Essential Performance, Home Healthcare Environment).

1. Test Plan

The table below summarizes applicable requirements and tests for Medical Electrical Equipment (MEE) per IEC 60601-1-2, depending on what Ports the equipment has. When considering battery powered medical equipment (Internally Powered), even when there are no Mains connection (input ac power Port), and no dc connection (Input dc power Port), there's considerable EM Disturbances testing. All equipment has an Enclosure, and many will have an Applied Part (Patient Coupling Port), and SIP/SIP Port (data).

Clause and Test	Enclosure Port, 8.9, Table 4	Input ac power Port, 8.9, Table 5	Input dc power Port, 8.9, Table 6	Patient coupling Port, 8.9, Table 7	SIP/SOP Port, 8.9, Table 8
6.2. Test Plan including description of BS and EP, how monitor, and pass/fail criteria	X	X	X	X	X

7.1. Emissions, CISPR 11, and if home health care and for use in aircraft, ISO 7137	X				
7.2.1. Harmonic distortion, IEC 61000-3-2, only if Public Mains Networks (e.g. home healthcare)		X			
7.2.2. Voltage fluctuation, IEC 61000-3-3, only if Public Mains Networks (e.g. home healthcare)		X			
Electrostatic discharge (ESD), IEC 61000-4-2	X			X	X
Radiated RF EM fields, IEC 61000-4-3	X				
Proximity fields from RF wireless communications equipment, IEC 61000-4-3	X				
Electrical fast transients / bursts, IEC 61000-4-4		X	X		X
Surges, line to line, IEC 61000-4-5		X	X		
Surges, line to ground,IEC 61000-4-5		X	X		X
Conducted disturbances induced by RF fields, IEC 61000-4-6		X	X	X	X
Rated power frequency magnetic fields, IEC 61000-4-8	X				
Voltage dips, IEC 61000-4-11		X			
Voltage interruptions, IEC 61000-4-11		X			
Electrical transient conduction along supply lines, ISO 7637-2			X		

5.1. Markings, and 5.1. Accompanying Docs	X				

Other factors that can affect testing are:

- The environment (e.g. professional healthcare facility, home healthcare, or special);
- The mains network can be a public type (e.g. home), or private type (e.g. hospital);
- The product might include an intentional radio transmitter, (HF surgical, or wireless data device); and/or
- The product might be Handheld or Body-worn.

2. Electrostatic discharge (ESD) testing

ESD testing may prove to be a challenge if there is no connection to earth. False failures can occur as the ESD charge may build up to very high levels.

- Per IEC 60601-1-2, the rate of discharge can be reduced to allow the EUT to bleed off an ESD charge buildup. Obviously, the test time will significantly increase but this is preferred to experiencing a false failure forcing an unnecessary redesign.
- IEC 61000-4-2:2016 addresses this issue. The equipment under test (EUT) should be discharged by the use of a carbon brush attached to the local ground plane.

3. Artificial Hand for Hand-Held and Body-Worn Devices

Many battery powered products are Hand-Held or Body-Worn. For Hand-Held devices (hand supported during use, e.g. glucose meter), ensure the use of the Artificial Hand requirements are complied with, as listed in IEC 60601-1-2, clauses 4.3.2 and 7.1.10. The Artificial Hand provides a capacitively coupled path to earth.

Body-Worn devices (worn on body during use, e.g. body-worn insulin pump) are not specifically mentioned, but it stands to reason that they would be handled the same as Hand-Held devices.

4. Metallized plastic parts

The shielding provided by metallized plastic enclosure parts, can facilitate EM Disturbances compliance. If plastic enclosure parts employ a metallized coating, where the metallized coating could flake and pose an unacceptable Risk (e.g. electrical shock or fire), there's a US/AMMI and Canadian/CSA deviation to the general MEE safety standard, IEC 60601-1-2:2005 + C1:2006 + C2:2007 + A1:2012 + C1-A1:2014 (consolidated edition 3.1), clause 4.8 that requires the plastic and metalized coating combination to comply with UL 746C or its CSA equivalent.

5. Maintaining Essential Performance versus medical purpose

5.1. General

An EM Disturbances Test Plan must include a description of Basic Safety (BS) and Essential Performance (EP), how to monitor during testing, and pass/fail criteria. If there are some aspects of the intended medical purpose that aren't considered EP, (required for acceptable

Risk), then your Test Plan may want to include the lower Immunity Test Levels specified in IEC TR 60601-4-2:2016, with the criteria that the intended medical purpose remains functional.

5.2. Maintaining Essential Performance for Safety

For some medical equipment, the Risk can be acceptable for loss or degradation of its medical purpose (e.g. therapy levels or diagnostic information). The loss or degradation may be obvious to the Operator, (which might include an equipment indication or Alarm); and when a delay in medical purpose is not appropriate, appropriate measures can be taken to maintain acceptable Risk, or a delay in medical purpose doesn't result in an unacceptable Risk. As the Risk is considered acceptable, these aspects of the medical purpose are not considered Essential Performance, and not required by IEC 60601-1-2 to be maintained during Immunity Testing. IEC 60601-1-2 is a Safety standard. Its Immunity Test Levels are intended to represent EM Disturbances that have a probability similar to Single Fault Conditions. The intention is acceptable Risk must be maintained during and after these EM Disturbances. For additional discussion about how to define Essential Performance for your medical equipment, see our article on EP.

5.3. Maintaining medical purpose functionality to allow for the practice of medicine

A medical device manufacturer may want to maintain the medical purpose of the medical device when subjected to worst case Normal Use EM Disturbances for customer satisfaction and product quality considerations. Regulators, such as the US FDA, can require this. IEC TR 60601-4-2:2016 specifies worst case Normal Use EM Disturbance Immunity Test Levels, and suggests that medical equipment's intended medical purpose remain functional when subjected to these EM Disturbance levels. The specified Immunity Test Levels are less than those specified in the EM Disturbances safety standard, IEC 60601-1-2. When conducting IEC 60601-1-2 testing, and where you find the medical purpose is not maintained during Safety Immunity Test Levels, it may be cost effective to check that the medical purpose remains functional during lower Normal Use Immunity Test Levels. The US FDA may look for compliance with IEC TR 60601-4-2:2016. The standard is in the FDA Recognized Consensus Standard Database, recognition no 19-19.

6. Safety

Battery powered products have a wide range of hazards associated with safety Risks, including electrical, thermal, chemical, and bad Usability. For an overview of Safety requirements for battery powered medical products, see our Part I article at this link.

Conclusion

Battery powered Medical Electrical Equipment (MEE) will have substantial EM DIsturbance testing, even if there's no Mains or DC connection. A Test Plan must include a description of Basic Safety (BS) and Essential Performance (EP), how to monitor during testing, and pass/fail criteria.

Even when the battery powered product doesn't have a path to earth, which can facilitate EM Disturbance immunity compliance, if the product contacts the Patient or Operator, an Artificial Hand provides a filtered path to earth. During ESD testing, some bleeding to earth is allowed between tests. Metallized plastic parts can facilitate EM Disturbance compliance, but must be from a supplier who's had the adhesion related testing in UL 746C.

If while using the Immunity Test Levels specified in IEC 60601-1-2 there will be situations where some aspects of the medical purpose are not maintained, which are not part of Essential Performance, your Test Plan may want to include the lower Immunity Test Levels specified in IEC TR 60601-4-2:2016, with the criteria that the intended medical purpose remains functional.

Feedback is welcome, fobrien@obcompman.com.

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OBCM Training Workshops

O'Brien Compliance Management offers public training workshops for IEC 60601. There's typically 1 on the west coast, the east coast, and in Europe.

These are intensive 5 day training seminars with instruction and work-group exercises to help participants apply the requirements to their medical electrical equipment designs. For more information and to register see here, www.obcompman.com/training.