Effective EMC & Wireless Co-Existence Test Plans for Medical Devices

MN EMC Event 2023

Speaker: Tom Brumbaugh

Date: September 21st, 2023

Add value.
Inspire trust.

The 6 P's

← Especially Important with Medical Devices!

Agenda

Current Landscape

An all too common story...

Before Testing

- Manufacturer does not have an EMC Test Plan Prepared
- Test Lab advises the need for performance criteria, modes of operation, etc.
- Manufacturer hastily puts a document together that lacks key information.

During Testing

- Test Lab performs testing with minimal knowledge of overall Basic Safety and Essential Performance characteristics from Manufacturer.
- Test Lab monitors device to best ability and documents the configurations tested and monitoring method.

Regulatory Submission

- Regulatory Body (FDA, Notified Body, etc.) Questions the:
  - Worst-Case Configuration/Mode Choice
  - Performance Criteria
  - Essential Performance / Intended Use
  - Monitoring Conditions

  ...AND...
  - Where was your Test Plan?

Ramifications

- Additional Testing and Re-Testing
- New Failures Observed
- Re-Design and Major Timeline Delay.

Current Landscape

Reasons for Change

- Regulatory Bodies are enforcing and requiring test plans more than ever (even though they have been required per standard for many years).
- A clear test plan provides the foundation for making an effective argument about the safety and performance of your medical device.
- Arguing about test strategy, conditions, and rationale is very difficult to do in the middle of a TD review by a regulatory agency.
- Thoroughly documenting a test plan can significantly aid future work on the same device (device changes) or even support testing of a similar device in the future.
- **Most Importantly:** Verification of device reliability and performance in its intended EM environment reduces the chance that an unforeseen issue occurs in the field.
  - Reduces risk of a costly design change or recall.

Current Landscape

Best Practice

Draft an effective test plan early in the Design Validation phase of the device.

Determine pre-testing/screening based on risks identified during test plan creation

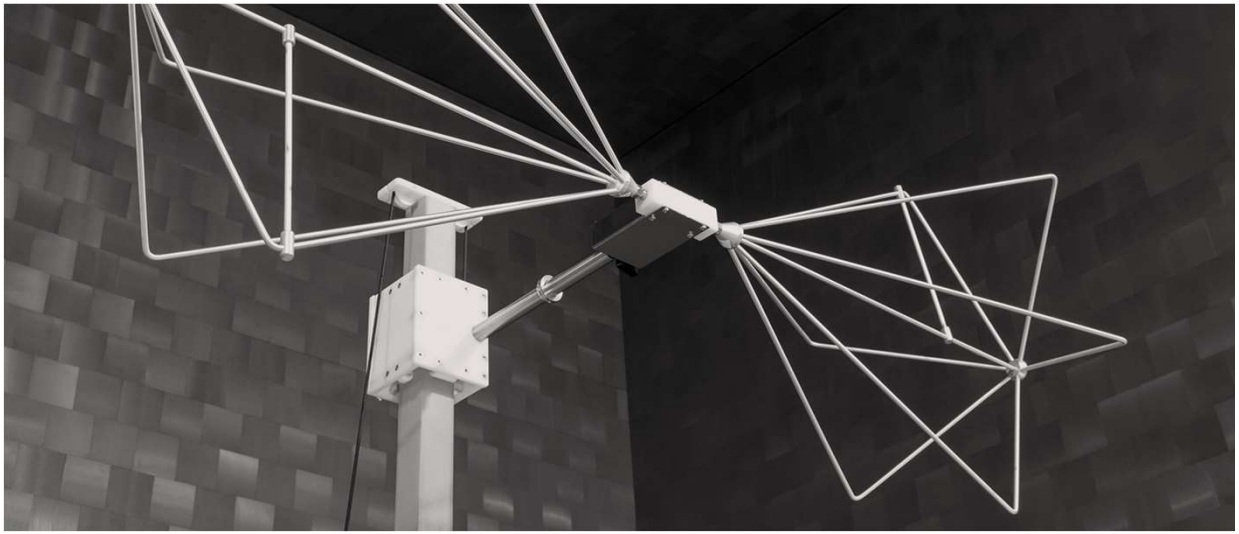
As final device is developed, make small modifications to test plan as needed.

Test Plan & Report combo adequately addresses all EMC considerations for regulatory submission.

Current Landscape

Most Common Question to Test Labs

“I understand that I need to make a *test plan*, but where do I start and what should be in it?”



Agenda

01 Current Landscape

02 Elements of an Effective EMC Test Plan

02a Commonly Missed Considerations

03 Radio Functionality

04 Wireless Co-Existence Key Takeaways

Elements of an Effective EMC Test Plan

Table of Contents

1. Administrative Data
2. Description of the Equipment Under Test
3. Operation Mode and Configuration of EUT
4. Performance Criteria and Methods of Observation
5. Requirements for Testing Proximity Magnetic Fields in the Frequency Range 9 kHz to 13.56 MHz
6. Electrostatic Discharges – Test Points
7. Compliance Summary (Risk Management, Identification, Marking and Documents)
8. Revision History

Elements of an Effective EMC Test Plan

Administrative Data

Indicate any additional standards such as:
- Particular Standards (More on that later…)
- Guidance Documents (IEC TR 60601-4-2)
- Other Family Standards (ISO 14708-X, IEC 61010, RTCA DO-160G etc.)

Indicating and Documenting where and when samples were manufactured helps to provide traceability for both the Manufacturer and Test Lab.

Test Plan

Applicant's name	
Applicant's address	
Trade Mark	
Model/Type Reference	
Test Item Description	
Test Standards	IEC 60601-1-2:2014+A1:2020

1 Administrative Data

General Information (For Report)	
Order Number (your number)	
Applicant (incl. address and contact person:)	
Manufacturer (when different to applicant)	
Name and address of factory(ies) Includes more than one factory location: A declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory.	

Elements of an Effective EMC Test Plan

Description of the EUT

2 Description of the Equipment Under Test

Equipment Characteristics	
Test Item Description:	
Model/Type Reference * Brand Name Electrical Ratings:	
Classification of Installation and Use:	transportable: ☐ portable: ☐ stationary: ☐ mobile: ☐ fixed: ☐ permanently installed: ☐ hand-held: ☐ body-worn: ☐
ME Equipment or ME System will be Tested as:	Table-top equipment: ☐ floor-standing equipment: ☐ Combination of table-top and floor-standing equipment: ☐
Descripton of any Patient-Coupled Cable Terminations to be Used:	
General Product Information:	
Software and Hardware Version:	
Protection Class	
Clock Frequencies	
Dimensions (W x H x D)	
Version of EUT:	Prototype: ☐ Production Version: ☐
Unit(s) Tested (include serial numbers): Number of sample to be tested: (The number of samples for each EMC test)	
Intended Use	
Intended Healthcare Environment (Please select all that apply) :	☐ Test levels for "Professional healthcare facility environment" ☐ Test levels for "Home healthcare enviroment" ☐ Special Environments ☐ In The Presence of Common Electromagnetic Emitters (e.g. WPT, 5G, Wi-Fi, EAS, Diathermy, etc.)

Examples of Terminations:

- Artificial Hand –
  - For Conducted Emissions, EFT and Conducted Immunity.
- Physiological Simulation
- NOTE: Conductive or capacitive connection to ground NOT allowed.

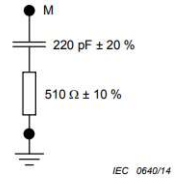


Figure 1 – RC element of the artificial hand

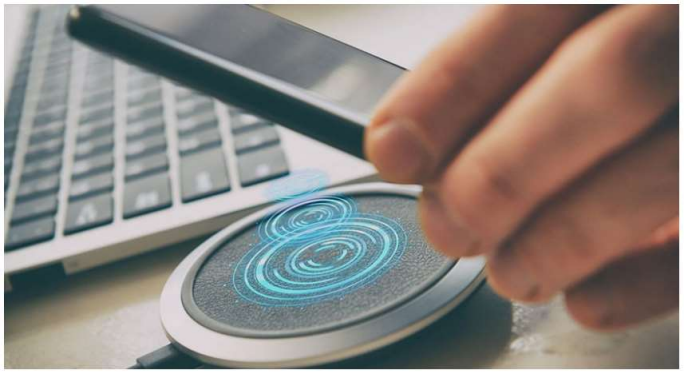
More on this in a later slide

During Risk Analysis and Intended Environment definition, manufacturers should consider possible EM emitters.

See Next Slide

Commonly Missed Considerations

5G, WPT (and Wi-Fi 6E) Risks



- FDA EMC Guidance Document (June 6, 2022) contains new statements about constantly evolving risks from transmitters.
- No current official or recognized standards that cover these considerations.
- For “low risk” medical devices:
  - Labelling to mention that EMI from expected emitters should be expected.
- For “high risk” medical devices (death or serious injuries):
  - Adhoc Testing Needed
  - Based on test results, labelling to address any mitigations or warnings needed.

Feel free to reach out about Test Protocol suggestion based on TUV SUD expert panel.

Elements of an Effective EMC Test Plan

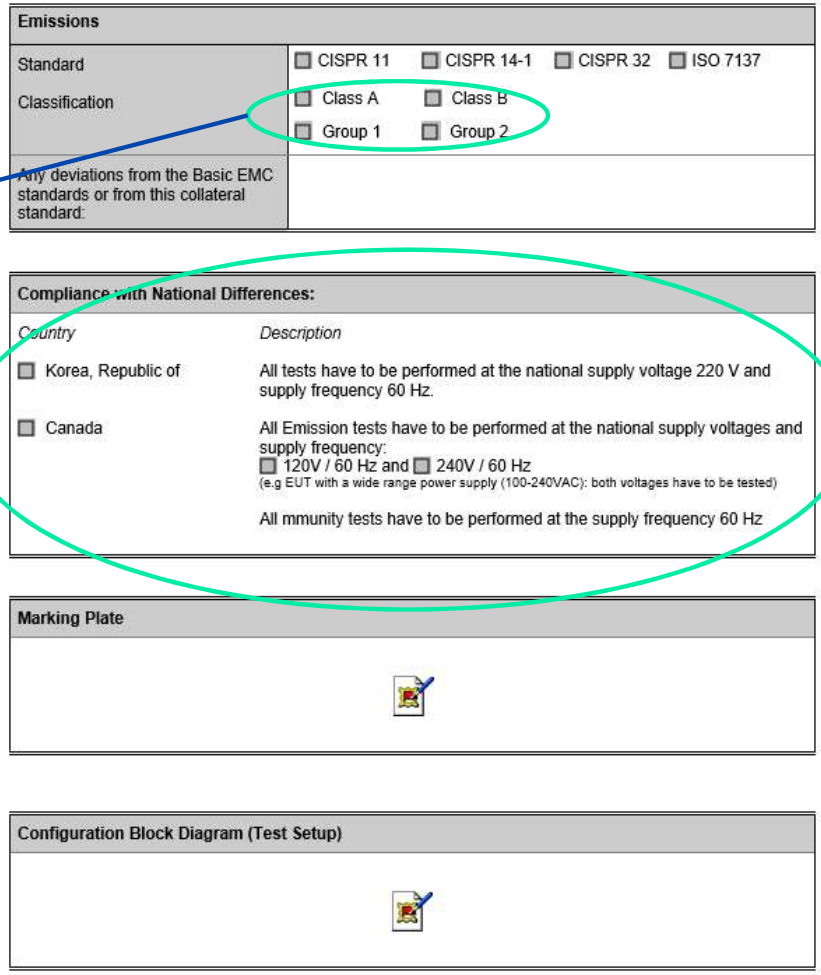
Description of the EUT

Group 2 is commonly misunderstood!

Any medical equipment that applies RF Energy to Patients (non-communication function), including:

- HF Surgical Equipment
- MRI
- Diathermy

1. **Compile and internally align on an intended market list for the next 3-5 years.**
2. **Pay particular attention to known testing condition requirements for those countries (especially for CB Scheme!)**



Emissions	
Standard	☐ CISPR 11 ☐ CISPR 14-1 ☐ CISPR 32 ☐ ISO 7137
Classification	☐ Class A ☐ Class B ☐ Group 1 ☐ Group 2
Any deviations from the Basic EMC standards or from this collateral standard:	

Compliance with National Differences:	
Country	*Description*
☐ Korea, Republic of	All tests have to be performed at the national supply voltage 220 V and supply frequency 60 Hz.
☐ Canada	All Emission tests have to be performed at the national supply voltages and supply frequency: ☐ 120V / 60 Hz and ☐ 240V / 60 Hz (e.g EUT with a wide range power supply (100-240VAC): both voltages have to be tested) All mmunity tests have to be performed at the supply frequency 60 Hz

Marking Plate

Configuration Block Diagram (Test Setup)

Elements of an Effective EMC Test Plan

Operation Mode and Configuration of EUT

3 Operation Mode and Configuration of EUT

EUT Operation Mode(s)	
For Immunity:	
For Emissions:	

EUT Configuration	
For Immunity:	
For Emissions:	
Supplementary Information (include any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests).	

Potential Equalization Conductor Used
Yes ☐ No ☐
Note: If yes, include information on connection to the terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR used during testing.

Testing of permanently installed large ME equipment or large ME system:
This exemption from the testing requirements of IEC 61000-4-3 is only used for permanently installed large ME Equipment and large ME Systems that are constructed in such a way that simulated operation of subsystems is not feasible.
According to IEC 60601-1-2:2014 chapter 8.6.

Yes ☐ No ☐

If Yes, include the following information:

Frequencies tested	
Power levels of RF test sources	
Modulation of RF test sources	
Test distance used	
Other relevant information related to test	

Difference between MODES and CONFIGURATIONS:

Modes: What is the device doing?

Configurations: How is the device set up?

Notes:

- Modes should be chosen such that the ***failure or malfunction*** would most likely result in an ***unacceptable risk*** or loss of ***intended use***.
- Consolidation of modes to reduce amount of testing is acceptable as long as it does not significantly effect the test being performed.

In-Situ Testing should be strongly considered for permanently installed or Large systems!

Elements of an Effective EMC Test Plan

Operation Mode and Configuration of EUT

<u>Important to populate and exercise all ports of a medical device that can be used</u>

➔ Represents “worst-case” configuration from a potential risk perspective.

➔ E.g. HDMI Displays, USB Connections, etc. should be connected to a representative setup and active during testing.

Dwell Time for Immunity Testing shall be based on the time required for the device to be exercised and adequately respond to the test signal!

Power Interface for Immunity:

Mode No.:	Voltage (V):	Current (A):	Power (W):	Frequency (DC/AC - Hz):	Phases (No.)	Comments

Power Interface for Emissions:

Mode No.:	Voltage (V):	Current (A):	Power (W):	Frequency (DC/AC - Hz):	Phases (No.)	Comments

SIP/SOP and Input/Output Ports:

Port No.	Name:	Type*	Cable shielded (Y/N)	Cable length used / maximum	Comments:

*Note

AC = AC power port | DC = DC power port | Batt = Battery

N/E = Non-Electrical | SIP/SOP = Signal Input/Output | PC = Patient-Coupled Cable

EUT and Supporting Equipment used During Testing:

Use*:	Product Type:	Manufacturer:	Model:	Serial no. or ID:	Comments:

*Note

EUT = Equipment Under Test | AE = Accessories / Associated Equipment | SIM = Simulator (Not Subjected to Test)

Dwell time during testing

Test	Dwell time (sec.)
Radiated, radio-frequency, electromagnetic field IEC 61000-4-3:2006 + A1:2007 + A2:2010	
Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013	

Elements of an Effective EMC Test Plan

Performance Criteria and Methods of Observation

More on Separate Slide

4 Performance Criteria and Methods of Observation

Description of Basic Safety and Essential Performance

Description of Intended Use and Performance (per IEC TR 60601-4-2)

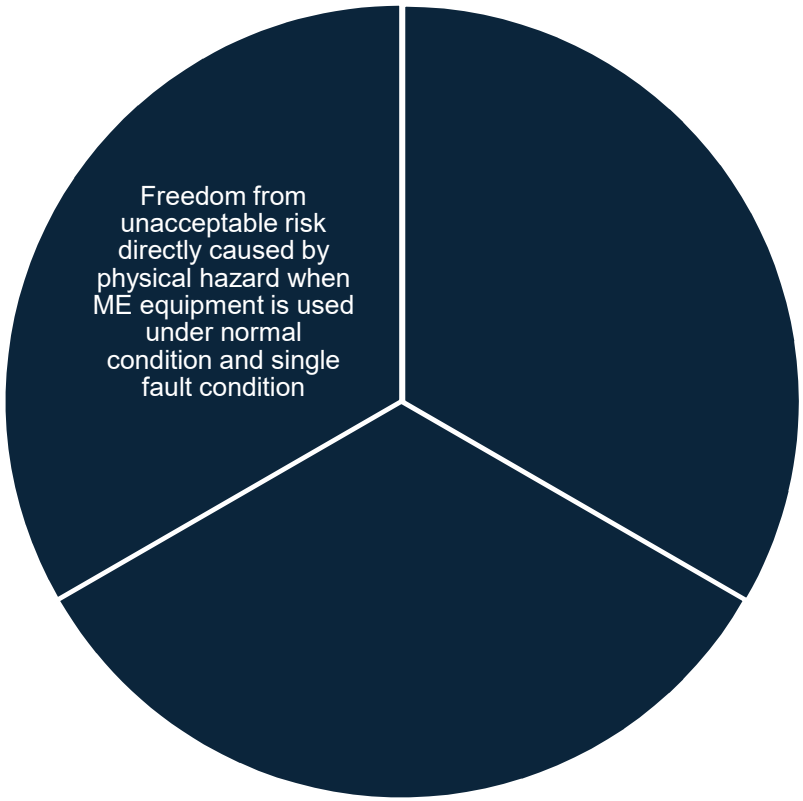
Details of how the Intended Use/Performance, Basic Safety and Essential Performance are monitored during each test

Immunity Pass/Fail Criteria:		
Product Function related to Basic Safety and Essential performance	Pass/Fail Criteria description	Part 2 reference (if applicable)
Note: Specific, detailed immunity pass/fail criteria, shall be based on applicable part two standards or risk management, for immunity with regard to EM disturbances. These pass/fail criteria shall be included in the risk management file.		

Commonly Missed Considerations

Basic Safety / Essential Performance / Intended Use

Basic Safety



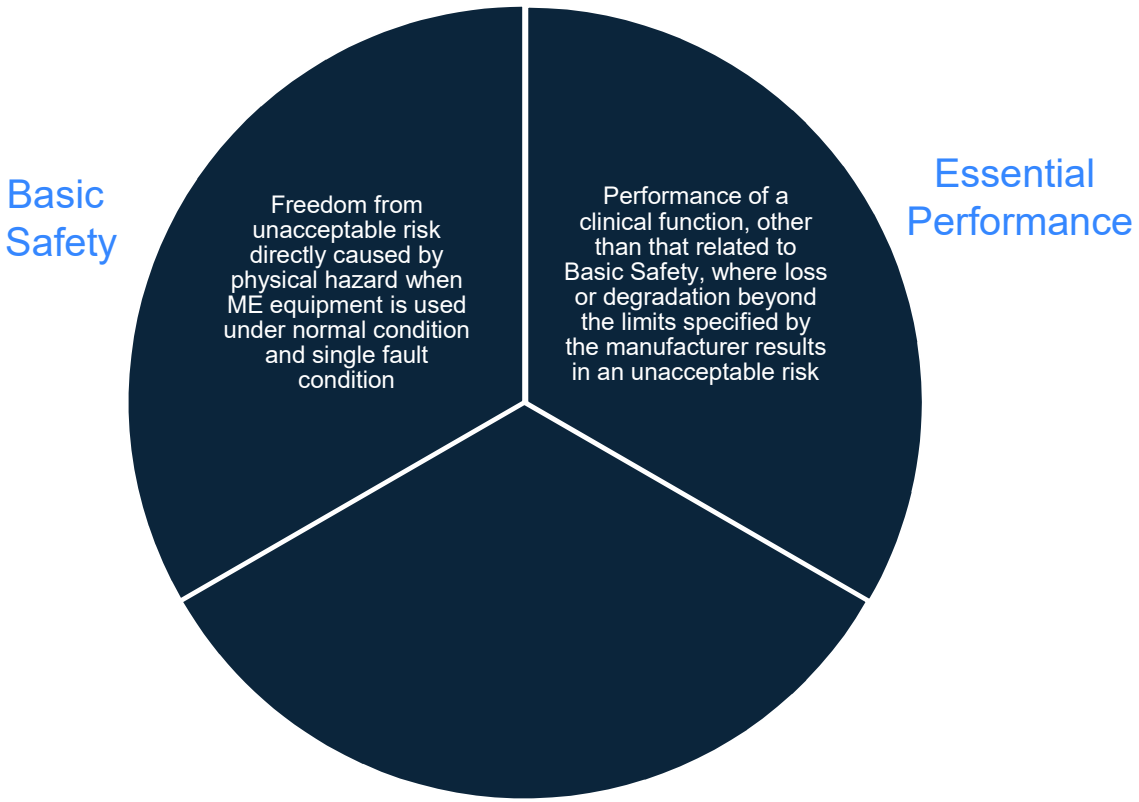
Examples for a *Cryo-Ablation* Device:

Basic Safety:

➔ In the event of performance degradation or loss, the device fails safely and does not produce a hazardous situation.

Commonly Missed Considerations

Basic Safety / Essential Performance / Intended Use



Examples for a *Cryo-Ablation* Device:

Basic Safety:

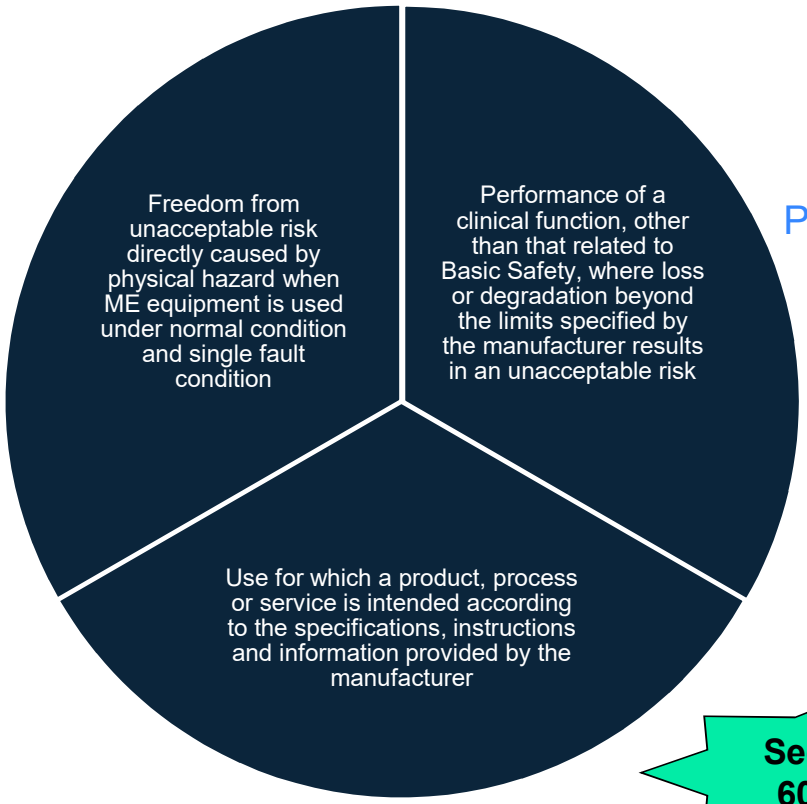
➔ In the event of performance degradation or loss, the device fails safely and does not produce a hazardous situation.

Essential Performance:

➔ If the Cryo-Balloon deflates, the console triggers a system notice AND does not re-inflate without user intervention.

Commonly Missed Considerations

Basic Safety / Essential Performance / Intended Use



See IEC TR 60601-4-2

Examples for a *Cryo-Ablation* Device:

Basic Safety:

➔ In the event of performance degradation or loss, the device fails safely and does not produce a hazardous situation.

Essential Performance:

➔ If the Cryo-Balloon deflates, the console triggers a system notice AND does not re-inflate without user intervention.

Intended Use:

➔ During Cryo-Ablation, the temperature is monitored in order to reach sufficient tissue necrosis.

Elements of an Effective EMC Test Plan

Performance Criteria and Methods of Observation

4 Performance Criteria and Methods of Observation

Description of Basic Safety and Essential Performance

Description of Intended Use and Performance (per IEC TR 60601-4-2)

Details of how the Intended Use/Performance, Basic Safety and Essential Performance are monitored during each test

Immunity Pass/Fail Criteria:		
Product Function related to Basic Safety and Essential performance	Pass/Fail Criteria description	Part 2 reference (if applicable)
Note: Specific, detailed immunity pass/fail criteria, shall be based on applicable part two standards or risk management, for immunity with regard to EM disturbances. These pass/fail criteria shall be included in the risk management file.		

More on Separate Slide

Monitoring Methods are preferably:

1. Automated (not manually observed)
2. Possibly set up outside a chamber
3. Specific and measurable output to compare to pass/fail criteria.

Elements of an Effective EMC Test Plan

Performance Criteria and Methods of Observation

4 Performance Criteria and Methods of Observation

Description of Basic Safety and Essential Performance

Description of Intended Use and Performance (per IEC TR 60601-4-2)

Details of how the Intended Use/Performance, Basic Safety and Essential Performance are monitored during each test

Immunity Pass/Fail Criteria:		
Product Function related to Basic Safety and Essential performance	Pass/Fail Criteria description	Part 2 reference (if applicable)
Note: Specific, detailed immunity pass/fail criteria, shall be based on applicable part two standards or risk management, for immunity with regard to EM disturbances. These pass/fail criteria shall be included in the risk management file.		

More on Separate Slide

Monitoring Methods are preferably:

1. Automated (not manually observed)
2. Possibly set up outside a chamber
3. Specific and measurable output to compare to pass/fail criteria.

Applicable Part 2 Standards MUST be considered!

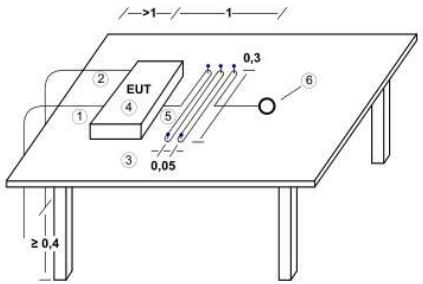
See Next Slide

Commonly Missed Considerations
Particular Standards

- IEC 60601-2-XX and 80601-2-XX Standards.
  - EMC Requirements often Presented in **Clause 202**.

- Additional or Modified requirements for EMC Testing, often in the forms of (e.g. IEC 60601-2-34 for IBP):

Different Test Setups



IEC 996/11

Key

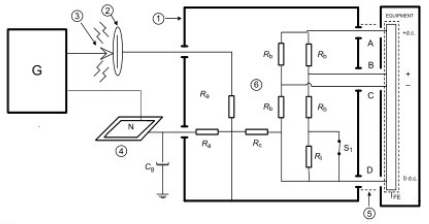
1 Mains cable (if applicable)
2 Signal output cable as applicable
3 Table made of insulating material
4 ME EQUIPMENT under test
5 Signal input cable as applicable connecting the TRANSDUCER with EUT
6 TRANSDUCER

Figure 202.101 – Test layout for conducted and radiated emission and radiated immunity test
(see 202.6.1)

Specific Monitoring and Essential Performance

ME EQUIPMENT shall not change the operating state, lose or change any stored data, generate errors in control software that cause an unintended change in output, or cause errors in blood pressure readings that are outside of the MANUFACTURER'S specifications. The ME EQUIPMENT shall comply with the requirements of 6.2.1.10 of IEC 60601-1-2:2007 and the accuracy requirements of 201.12.1.101.2 except for subclauses 202.6.2.2.1 and 202.6.2.101 in this particular standard. These criteria do not apply during ESD testing.

Additional Tests



IEC 997/11

Key

1 Metal box
2 Metal plate
3 ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
4 Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT
5 Connecting cable; 2 m cable length between ME EQUIPMENT and metal box; screen around connecting cable
6 Coupling network
G HF SURGICAL EQUIPMENT
R_a 220 Ω, 200 W (low-inductive, simulates PATIENT impedance)
R_b 500 Ω (simulates TRANSDUCER bridge)
R_c 50 kΩ (simulates CATHETER impedance)
R_t selected for 100 mmHg
C_g 47 nF (to minimise the influence of different types of HF SURGERY EQUIPMENT designs)
S_1 Switch

NOTE The test report should identify the HF SURGICAL EQUIPMENT that was used.

Figure 202.102 – Test circuit for high-frequency surgery interference measurement, when the isolation of the APPLIED PART is in the monitor
(see 202.6.2.101)

Elements of an Effective EMC Test Plan

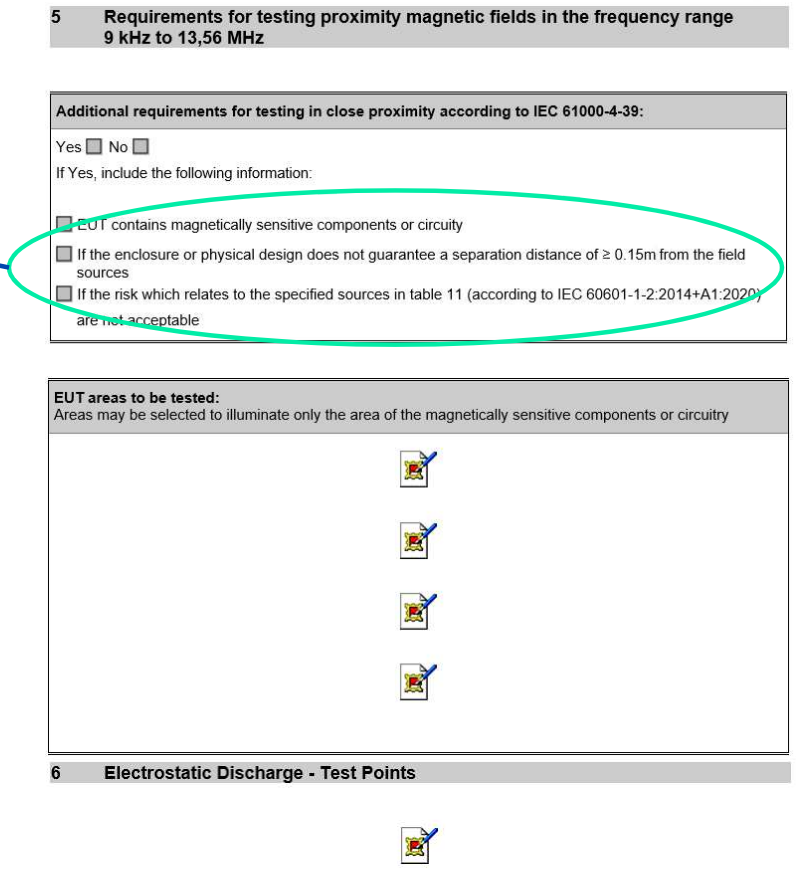
Testing and Identification of Test Points

- **See Subclause 8.11 in IEC 60601-1-2:2014/AMD1:2020 for flowchart to determine applicability of IEC 61000-4-39**
- **When in doubt, it's safe to perform this testing since it's not destructive and is a very short test**

List of Testing in IEC 60601-1-2:

- CISPR 11 (Radiated and Conducted Emissions
- IEC 61000-4-2 (ESD)*
- IEC 61000-4-3 + Table 9 (Radiated Immunity)
- IEC 61000-4-4 (EFT)
- IEC 61000-4-5 (Surge)
- IEC 61000-4-6 (Conducted Immunity)
- IEC 61000-4-8 (Power Freq. Magnetic Fields)
- IEC 61000-4-11 (Voltage Dips and Interruptions)
- IEC 61000-4-39 (Proximity Magnetic Fields)*

*Require Test Points to be identified, as shown to right.



Elements of an Effective EMC Test Plan

Risk Management, Identification/Marking and Revision History

7 Compliance Summary (Risk Management, Identification, Marking and Documentation)

Documents as provided by the applicant	Risk Management:
	Manual:

Possible test case verdicts
- test case does not apply to the test object: N/A - test object does meet the requirement: P (Pass)
Note: If Pass, refer to the reference document (chapter and page)

IEC 60601-1-2			
Clause	*Requirement + Test*	*reference document (chapter and page)*	*Verdict*
4	GENERAL REQUIREMENTS		
4.1	RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES taken into account in the RISK MANAGEMENT PROCESS.	Risk Management:	

8 Revision History

Revision History			
Edition	*Date*	*Issued by*	*Modifications*
1			

Two Important Notes Here:

#1: Risk Management per ISO 14971 is very important to have at least "considered" prior to testing

-> Needed to help determine pass/fail criteria during testing.

NOTE: List of RM clauses to the left is NOT exhaustive – there are many more clauses that would take several slides to share.

#2: Revision History is required to satisfy the requirement that a Test Plan should be a *controlled* document with documented *revisions.* Test plans are frequently revised during testing.

Agenda

Radio Functionality

What Changes when Leveraging Wireless Functionality?

- Must consider method for monitoring “radio link” during Transient and Continuous Immunity Tests.
- Validate that radio in “receive only” mode does not unintentionally transmit when subjected to immunity test (primarily an EU RED requirement).
- Determine to what degree your radio functionality might alter your Essential Performance or Intended Use.

  -> May need additional Modes/Configurations and Monitoring methods to address accordingly.
- For FDA: Evaluate Wireless Co-Existence per ANSI c63.27

- NOTE: Additional Radio Integration or Modular Approval and Certification may be required depending on your radio path.

Agenda

01 Current Landscape

02 Elements of an Effective EMC Test Plan

02a Commonly Missed Considerations

03 Radio Functionality

04 Wireless Co-Existence Key Takeaways

Wireless Co-Existence Key Takeaways

Evaluating to ANSI/USEMCSC C63.27:2021

Co-Existence Goal: Device is able to perform a task in a given shared space where *other* wireless systems are also performing their own tasks.

Test Plan Should follow a similar pattern for EMC, but should also:

1. Define Intended EM Environment
2. Define Your Risk Tier per AAMI TIR 69.
   - **When in doubt – select a higher tier to evaluate to (can always be "relaxed" later)!**
3. Define Your KPI Thresholds (Key Performance Indicators)
4. Define FWP (Functional Wireless Performance)
5. Define Monitoring Method during Testing

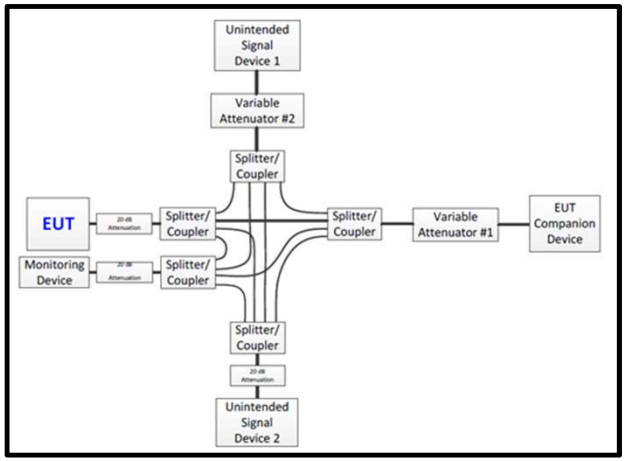
Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.



Final Note

For **all major testing disciplines**, the process of making a *test plan* is the same:

1. Define Requirements for Device.
2. Perform Hazard Analysis and Summarize Risks (Probability and Severity).
3. Plan a Test Strategy that will Evaluate the Effectiveness of your Risk Control Measures.

Thank You

Contact Information:

Tom Brumbaugh
Medical Device Testing & Certification

Email: Tom.Brumbaugh@tuvsud.com
Phone: +1 651-295-0940

Follow us on:

tuvsud.com
info@tuvsud.com