EMC Risk Management and Design Compliance for Medical Devices

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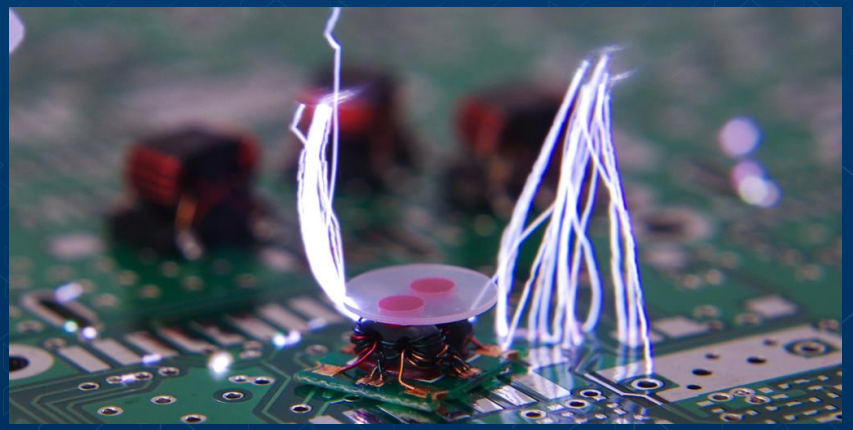
MN EMC Event – September 29, 2022

Agenda

- IEC 60601-1-2 EMC Collateral Standard
- Essential Performance & Risk Management
- “Performance” vs. “Essential Performance”
- Monitoring During Immunity Testing
- Design for EMC
- Testing

IEC 60601-1-2 EMC Collateral Standard

- **IEC/EN 60601-1-2:2014 (Ed 4.0)**
  - Effective September 2018
  - New "Environments" Introduced (Professional, Home, Special)
  - Higher ESD Voltages (± 8 kV contact, ± 15 kV air)
  - Address Magnetic Fields (3 A/m to 30 A/m)
  - Increased Radiated Immunity Range (up to 2.7 GHz)



- **IEC/EN 60601-1-2:2014+AMD1 (Ed 4.1)**
  - Effective December 2020
  - Outlines a new method for magnetic field threats (i.e. – RFID)
  - Updates to Risk Management Guidance (Annex F)

Essential Performance and Risk Management

IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2)

Essential Performance (Definition 3.27)

*"Performance of a clinical function, other than that related to BASIC SAFETY, where **loss** or **degradation** beyond the limits specified by the MANUFACTURER results in an **unacceptable risk**.*

NOTE: It is the manufacturer's responsibility to define this in their risk documentation. The key being to clearly document methods/results based on guidance from 60601-1 and any particular or collateral standards.

Example of Clinical Functions that are defined as Essential Performance:

BSC Rezūm System – Benign Prostatic Hyperplasia Treatment

- ***Visualize*** intraurethral anatomy and treatment procedure
- ***Placement***, ***positioning*** and ***removal*** of the device
- Needle ***Deployment***/***Retraction***
- Vapor ***Initiation***/***treatment***

Essential Performance and Risk Management

New Table F.1 in IEC 60601-1-2:2014+AMD1:2020 (Ed 4.1) clarifies where RM needs to be applied within IEC 60601-1-2:

Two Examples:

- The message of Table F.1 for Subclause 4.1:
  - We need to be thinking ahead in the analysis of ***reasonably foreseeable*** EM disturbances! (i.e. – 5G and Wireless Charging → ***iPhone 12!***)
    - ISO 14708 does check for static magnetic field disturbances, but is that in scope for your capital equipment?

- The message of Table F.1 for Subclause 4.2:
  - Non-MEE needs to be evaluated as to its contribution to the MEE BASIC SAFETY and ESSENTIAL PERFORMANCE.

Key Take-Away:

- Table F.1 Subclause guidance needs to be included in the application of risk management for your MEE.

“Performance” vs. “Essential Performance”

IEC TR 60601-4-2:2016

MEDICAL ELECTRICAL EQUIPMENT – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

- FDA recognized since September 2018
- Should consider as part of design and design validation
- Can aid in mitigating post-launch EMC performance surprises
- Can effectively be done ***concurrently*** with IEC 60601-1-2 testing
  - Note – may have different acceptance criteria

Monitoring of Basic Safety and Essential Performance During Immunity Testing

During Immunity Testing:

If Basic Safety and Essential Performance do not continue to be provided, the ME EQUIPMENT or ME SYSTEM has **failed** the test.

IEC 60601-1-2:2014 Clause 8.1 (Also in Annex F Table F.1 of Ed4.1)

The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria.

These PASS/FAIL criteria and this monitoring specification need to be included in the test plan and included in the test report and the RISK MANAGEMENT FILE.

Design for EMC

- **Design for EMC needs to consider 2 parts:**
  - Controlling EM disturbances ***into*** environment of use
  - Protecting ***from*** EM disturbances within the environment of use
    - Radiated and conducted emissions
    - Mains disturbances
    - ESD

- **Design to maintain the characteristics that provide EMC over the Expected Service Life:**
  - Evaluate the design through risk management (create risk control measures)
    - Enclosure design
    - Protection of ports
    - Cabling and interconnects
    - Circuit boards
    - Fault tolerance
    - Software/firmware

Test Plan

IEC60601-1-2 Ed 4.1 Clause 6.2 Test Plan

- ***Prior to the start of formal testing***, a detailed test plan shall be provided to the test laboratory

- Deviations from the test plan shall be documented in the test report
  - See ***Annex G*** for guidance on the recommended content of a test plan

#	Test Plan	Test Strategy
1	A test plan is derived from Software Requirement Specification (SRS), describing in detail the scope of testing and the different activities performed in testing.	A test strategy is a high-level document describing the way testing is carried out.
2	A test plan is project level.	A test stategy organization level
3	It describes the whole testing activities in detail - the techniques used, schedule, resources etc.	It describes the high-level test design techniques to be used, environment specifications etc.
4	It is prepared by test lead or test manager.	It is generally prepared by the project manager.
5	Components:The major components of Test Plan include – Test Plan ID, test environment, features to be tested, entry/exit criteria, status, type of testing, brief introduction etc	The major components of Test Strategy include – Scope, Objective, business issues, risks, testing approach, testing deliverables, defect tracking, training, automation etc.
6	A Test Plan usually exists individually.	Test strategy is divided into multiple test plans that are taken care further independently.

Reminder!

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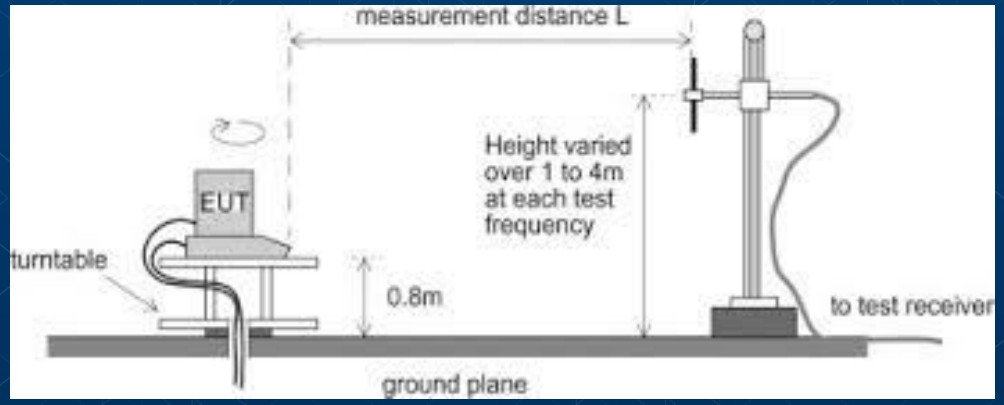
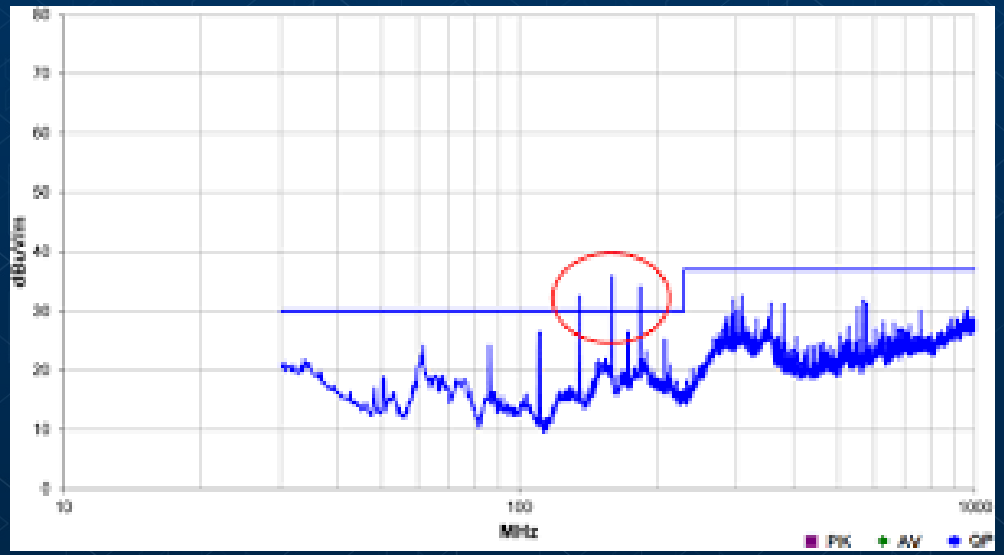
Factoring in EMC from the very beginning will result in ***fewer*** redesigns, ***shorter*** test durations, and ***more*** money saved!

Radiated Emissions

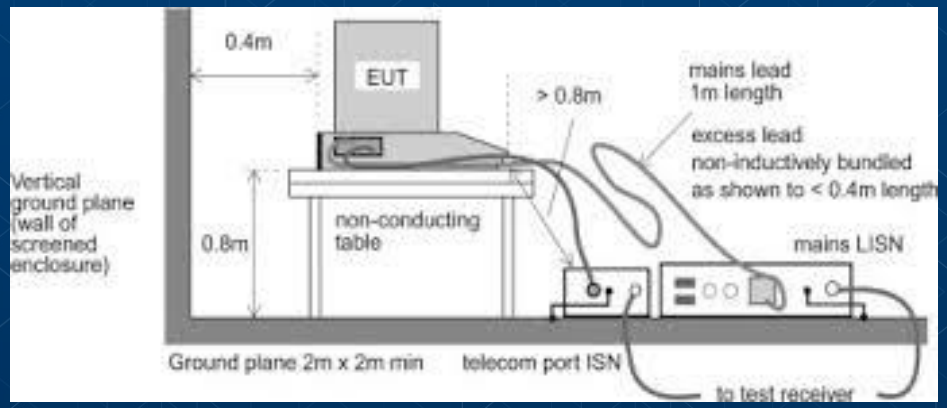
- Equipment Under Test (EUT) is setup on a turntable in a ***worst-case*** configuration(s) and operating mode(s) within a semi-anechoic chamber.
- A receive antenna "listens" at a specified distance while turntable spins 360°.
- Frequency spectrum is swept from ***30 MHz to 1 GHz***, with any peaks over the limit needing to be fixed.
  - Initial scan only takes ~ 10 minutes!
  - Final scan (quasi-peak measurements) takes ~ 30 minutes
- Most common issues are cables (***catheters!***), power supplies, and PCB oscillators (clocks).
- Most common fixes are ferrites, power filters, copper tape, and EM gasketing.

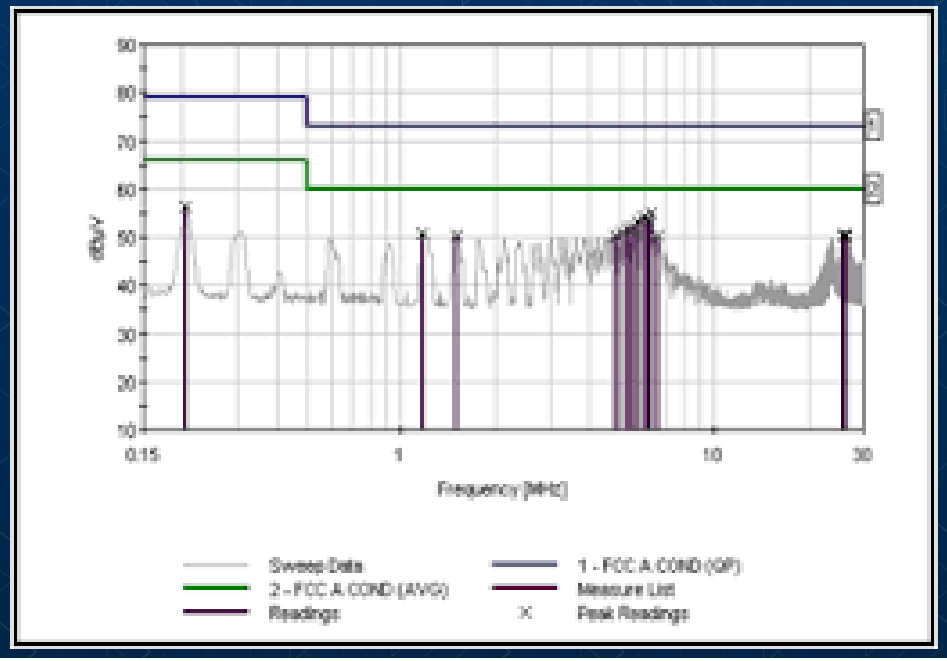




Conducted Emissions

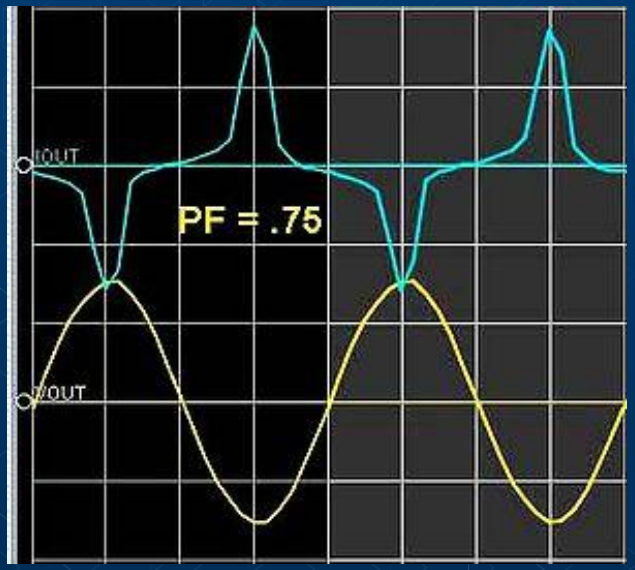
- Same EUT setup as Radiated Emissions, but not inside semi-anechoic chamber as measurements are being made directly on the AC power cable.
- Frequency spectrum is swept from ***150 kHz to 30 MHz***, with any peaks over the limit needing to be fixed.
  - Each scan (Line & Neutral) only takes about 5 minutes each!
- Most common issues are power supplies and PCB oscillators (clocks).
  - Cables are not measured for conducted emissions (except Ethernet if testing to EN 301 489 for the RED).
- Most common fixes are ferrites and power filters.
  - Copper tape and gasketing only fix radiated problems.

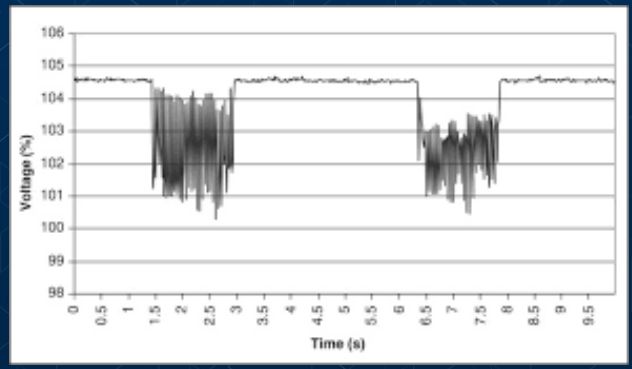




Flicker & Harmonics (Emissions)

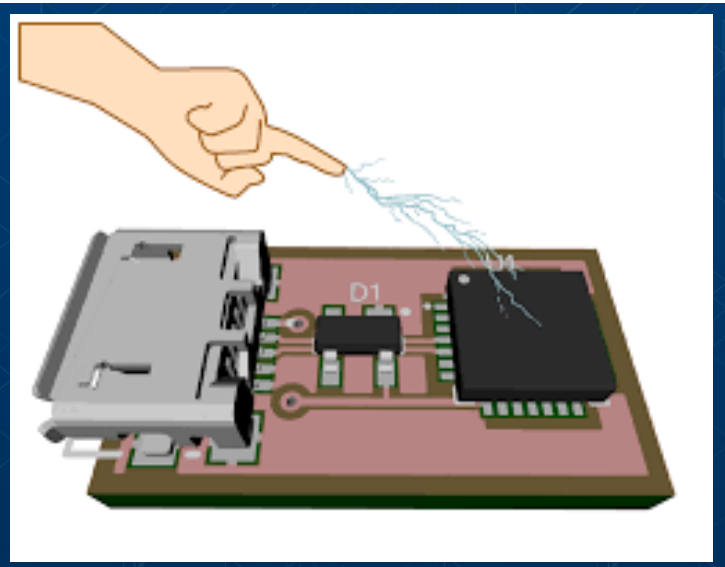
- Same EUT setup as Radiated & Conducted Emissions, but not inside semi-anechoic chamber as measurements are being made directly on the AC power cable.
- Measured limits for conducted harmonic and flicker emissions.
  - Both tests completed in less than 20 minutes
- Unlikely to fail these tests unless your EUT is sourcing large amounts of current periodically.
  - e.g. - heaters, heated blankets, etc.
- Generally, only a new power supply can fix any issues.





Electrostatic Discharge (Immunity)

- Same worst-case setup as emissions tests; EUT must remain ***safe before and after*** transient discharges.
  - ± 8 kV contact
  - ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
- **Highly recommend an ESD Test Plan!**
  - Defines which ESD test points along the Enclosure, Patient-Coupled and/or SIP/SOP ports are to be discharged too and why. (may provide diagrams or photos)
  - Include whether cables are populated, not-populated, and any other special instructions.
  - Usually included within the EMC protocol itself and may include PASS/FAIL criterion
- Note: 60601-1-2 is only concerned with "*normal, intended use*" – but you should also consider what happens during ***installation*** and ***maintenance*** if a discharge happens!
  - This can happen during internal DVT if you have an ESD gun!
- Most fixes unfortunately require electrical and mechanical redesigns.
  - ***Test early and often!!!***



Radiated Immunity & Proximity Fields

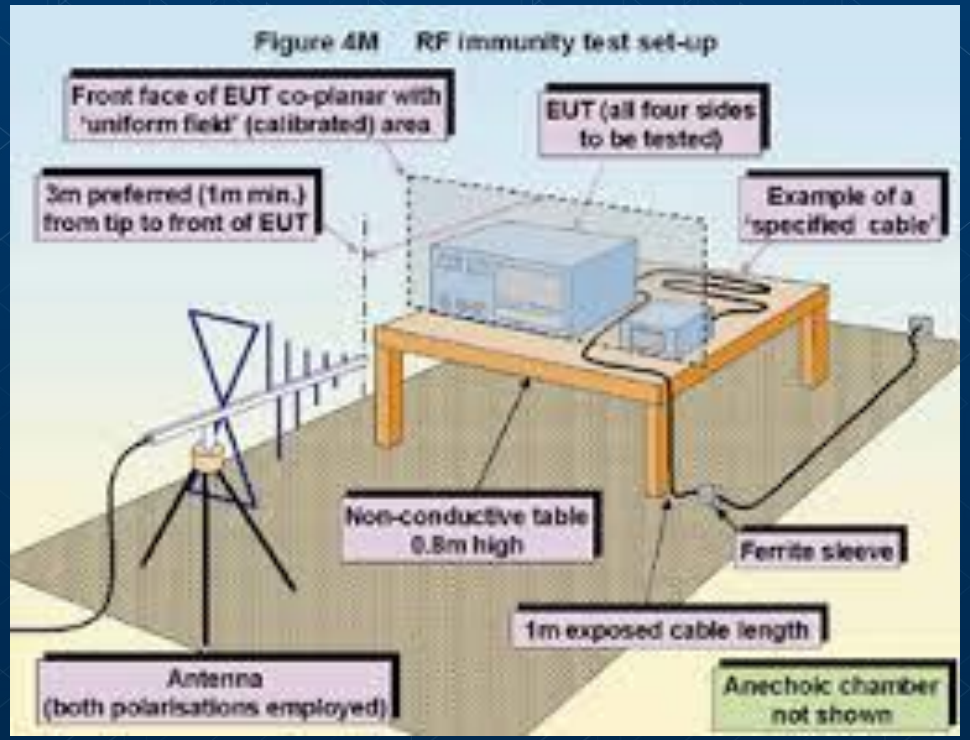
- Slightly different setup during this test to make sure the entire EUT is within the "uniform field" (edge of table).
  - Equipment is manually rotated to make sure all sides are tested.

- Frequency spectrum is swept from ***80 MHz to 2.7 GHz*** (up to 6 GHz for RED), stopping every 1% for the required "dwell" time.
  - The EUT must be able to "respond" or "report a problem" within the given dwell time at each frequency step
    - i.e. – the chosen dwell time must be long enough for the system to respond and usually is not less than 1 second.
  - EUT must remain safe during entire sweep (not before/after like ESD).
  - Test time is dependent on how long the dwell is and how many sides are to be tested (usually 2-4 hours).
  - Includes "Proximity Field" testing with higher amplitudes to mimic common interfering transmitters (i.e. – cell phones).

- Most common issues are cables (***catheters!***), mechanical openings (slots, gaps, air flow, etc.) leading to the energy getting "inside" and wreaking havoc.

- Most common fixes are ferrites, copper tape, and EM gasketing.

- Electric wheelchair and Rotablator stories (if time).



Low-Frequency Magnetic Field Immunity

- New test per Amendment 1!
- Previously covered by AIM 7351731 which the FDA was requesting back in ~2018, but only includes 3 test frequencies:

Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

- **Remember** – AIM 7351731 may still be applicable if your device will be around other RFID technology that is covered by the above table!

Conducted Immunity

- EUT is setup on a table with each cable laid out (not representative of clinical setup).
  - ALL patient cables are tested, regardless of length
  - SIP/SOP's < 1 meter *may* be excluded

- Each cable has noise injected capacitively with a current clamp (both ends if applicable).

- Frequency spectrum is swept from ***150 kHz to 80 MHz***, stopping every 1% for the required "dwell" time (same as Radiated Immunity).
  - EUT must remain safe during entire sweep (not before/after like ESD).
  - Test time is dependent on how long the dwell is and how many cables are to be tested (usually 2-4 hours).
  - Includes "ISM" and "Amateur Radio" spot checks at higher amplitudes (similar to Proximity Fields) depending on defined environment (i.e. – "Professional" vs. "Home").

- Most common issues are cables with sensitive signals and little or no shielding.

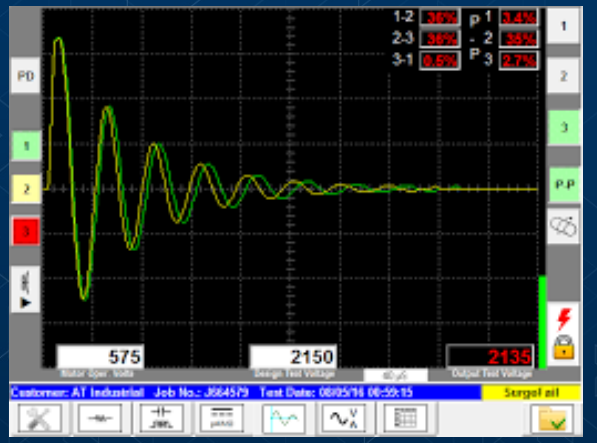
- Most common fixes are shielded cables and PCB filters (ferrites don't usually help CI issues).

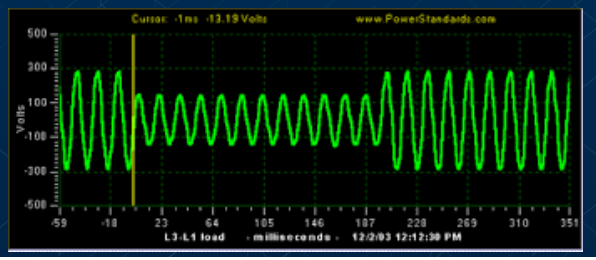
Magnetic Field Immunity

- EUT is setup with all or parts of contained within a “coil” which will generate a magnetic field.
- Both 50 Hz and 60 Hz frequencies should be tested (30 A/m).
  - EUT must remain safe ***during*** entire sweep (not before/after like ESD).
- Very rare to have issues during this test unless you have magnetically susceptible components.
  - Hall effect sensors, Reed switches, etc.
  - Or if your product generates its own magnetic field for navigation.

Electrical Fast Transients (EFT), Surge, and Voltage Dips & Interrupts (Immunity)

- These are all AC power tests, primarily focused on the power supply's ability to withstand power fluctuations.
  - EFT is also performed on any non-patient-coupled cables which are > 3 meters.
- Like ESD, the EUT must remain safe ***before and after*** transient pulses.
  - See EMC protocol for PASS/FAIL criterion
  - During VDI, the last drop out is 5 seconds – if your EUT does not have a battery backup it must shutdown and restart safely once power is restored.
- Test time is dependent on a multitude of factors:
  - EFT will depend on how many cables are to be tested (1-2 hours)
  - Surge is a minimum of 2 hours per voltage tested
  - VDI only takes ~ 15-30 minutes
- Generally, the only fixes for these tests are increased PCB filtering or finding a new power supply.





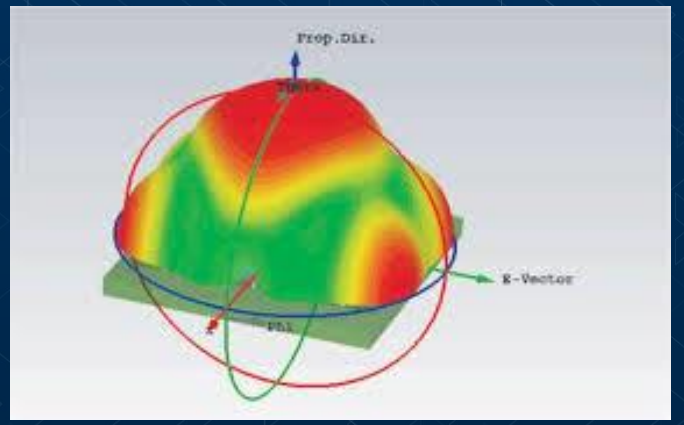
Testing Summary

- Depending on many variables, test time can vary from 1-2 days to weeks or even ***months***!
  - Size of EUT
  - Number of configurations
  - Operational Modes
  - Worst-case set-up conditions (i.e. – configuration, maximum power output, fastest operating speed, etc.)
  - Number of test voltages/frequencies (to address all geographies of sale)
  - Number of cables
  - Dwell time

- If failures happen and design fixes are needed, re-testing is ***almost always required!***

Other Related Testing

- **Wireless Radios (Intentional Radiators)**
  - Not covered by 60601-1-2!
  - Pre-Approved Geographies
  - Permissive Changes, Colocation, and Spurious Radiated Emissions Testing (FCC)
  - Radio Equipment Directive and Spurious Radiated Emissions Testing (EU)
  - Other geographies (Japan, South Korea, Taiwan, etc.)
  - Wireless Coexistence (FDA)
- **Implantables**
  - ISO 14708-X for surgical, AIMD's, infusion pumps, ventricular assist devices, etc.
- **Specific Absorption Rate (SAR)**
  - Usually only required for high power wireless transmitters used close to the body (i.e. – cell phones, wearables, etc.).
- **Over-the-Air (OTA) Antenna Testing**
  - Not a compliance test, but provides 3D mapping of antenna's performance.



Final Reminder!

Test ***early*** and ***often*** to save yourself from headaches later down the road!