Introduction to Medical EMC

Darryl P. Ray

Principal Consultant

Darryl Ray EMC Consulting, LLC

darryl.ray@dray-emc.com

925-487-0072

www.dray-emc.com

Scope

This presentation focuses on:

Medical Electrical Devices

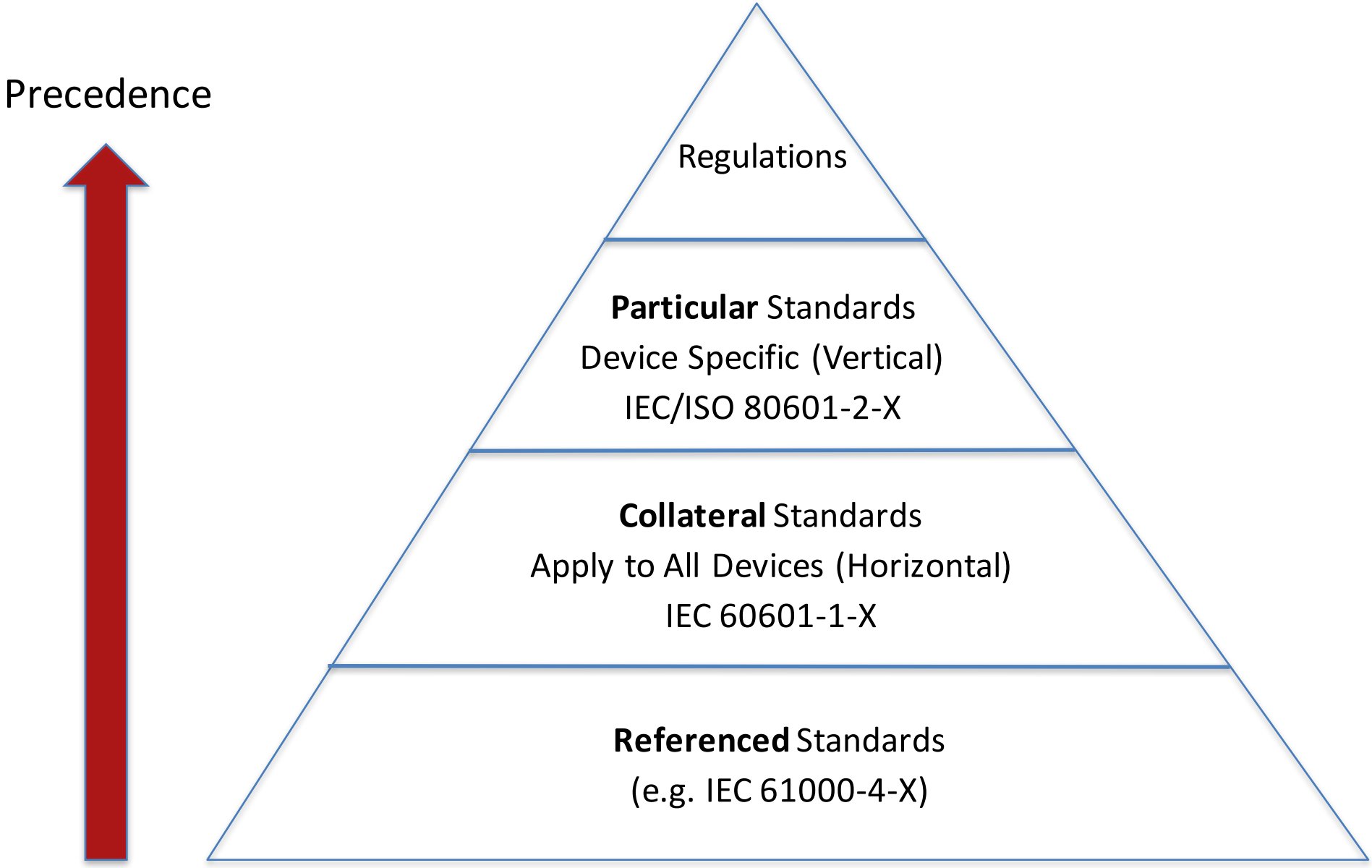
and

Medical Electrical Systems only

IEC 60601/80601 Series of Standards

- Safety standards
  - Patient
  - Operator
  - Environment
- Essential Performance covered
- Over 80 standards & growing
- 80601 = Joint IEC/ISO standard

Medical Device Requirements Hierarchy



Requirements

General Standard

Applies to all equipment

Particular standards

80+ standards

Amends the general requirements for specific types of equipment and take precedence!

60601-2-1	60601-2-2	60601-2-3	60601-2-4
Particular requirements	Particular requirements	Particular requirements	Particular requirements
Medical accelerators	HF surgical equipment	Short-wave therapy equipment	Defibrillator/ monitors

ISO Particular Standard Example – IEC 60601-2-54:2009

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

NOTE The third edition of IEC 60601-1-2 has been slightly modified to resolve the deficiencies of the second edition with respect to imaging equipment.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows.

Addition:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The accuracy of the test instruments used to assess the immunity of the ME EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the ME EQUIPMENT.

Medical EMC Requirements

- Requirements are generally per IEC 60601-1-2
- EN 60601-1-2 is equivalent
- Particular standards (IEC 80601-2-X) may modify immunity levels and acceptance criteria
- IEC 60601-1-2 4th edition published February 2014

What is Essential Performance (EP)?

- Deals with Safety Related Performance

  device can be susceptible but must stay safe

- Defined By:
  - IEC/ISO 80601-2-X (if applicable)
  - IEC 60601-1 Edition 3.1 (see cl 3.27 & 4.3)
  - Manufacture may broaden the scope – Using risk analysis
- Some devices have no Essential Performance
- Relevance: Immunity acceptance criteria is linked to EP

What is Essential Performance?

From IEC 60601-1: 2005 +A1: 2012

3.27

*** ESSENTIAL PERFORMANCE**

~~performance necessary to achieve freedom from unacceptable RISK~~
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 ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

Essential Performance - Example

From IEC 60601-2-37:2015

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.102 lists the potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT and the subclauses in which the requirements are found.

Table 201.102 – Distributed essential performance requirements

Requirement	Subclause
Free from noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.	202.6.2.1.10
Free from the display of incorrect numerical values associated with the diagnosis to be performed [a].	202.6.2.1.10
Free from the display of incorrect safety-related indications.[a]	201.12.4.2 202.6.2.1.10
Free from the production of unintended or excessive ultrasound output.	201.10.101 202.6.2.1.10
Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.	202.6.2.1.10
Free from the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.	202.6.2.1.10
[a] "incorrect" in the sense that the displayed value differs from what is calculated (having been altered during data transfer), or the calculation itself is not correct.	

More on Essential Performance

- EMC Susceptibility does not always equal failure!
- Essential Performance can not be "complied with"

  (*must be maintained*)
- The Risk Management File should relate to the definition of EP

  (entries must state unacceptable risk)
- Many test labs do not understand EP

IEC 60601-1-2

Edition 4.0 2014-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Appareils électromédicaux –
Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE CODE PRIX XD

3rd Edition has been withdrawn

Motivation

- Aim was to create a safety standard with respect to EM disturbances
- Drawbacks with the 3rd Edition;
  - Basic Safety and Essential Performance aspects have not been adequately addressed
  - Test Levels in the current standard are nearly 20 years old *(New EM environments unaccounted for, e.g. cell phones)*
  - Mobile device usage restrictions are now generally ignored
  - Devices in the same use location meet different immunity Levels

The Real World!

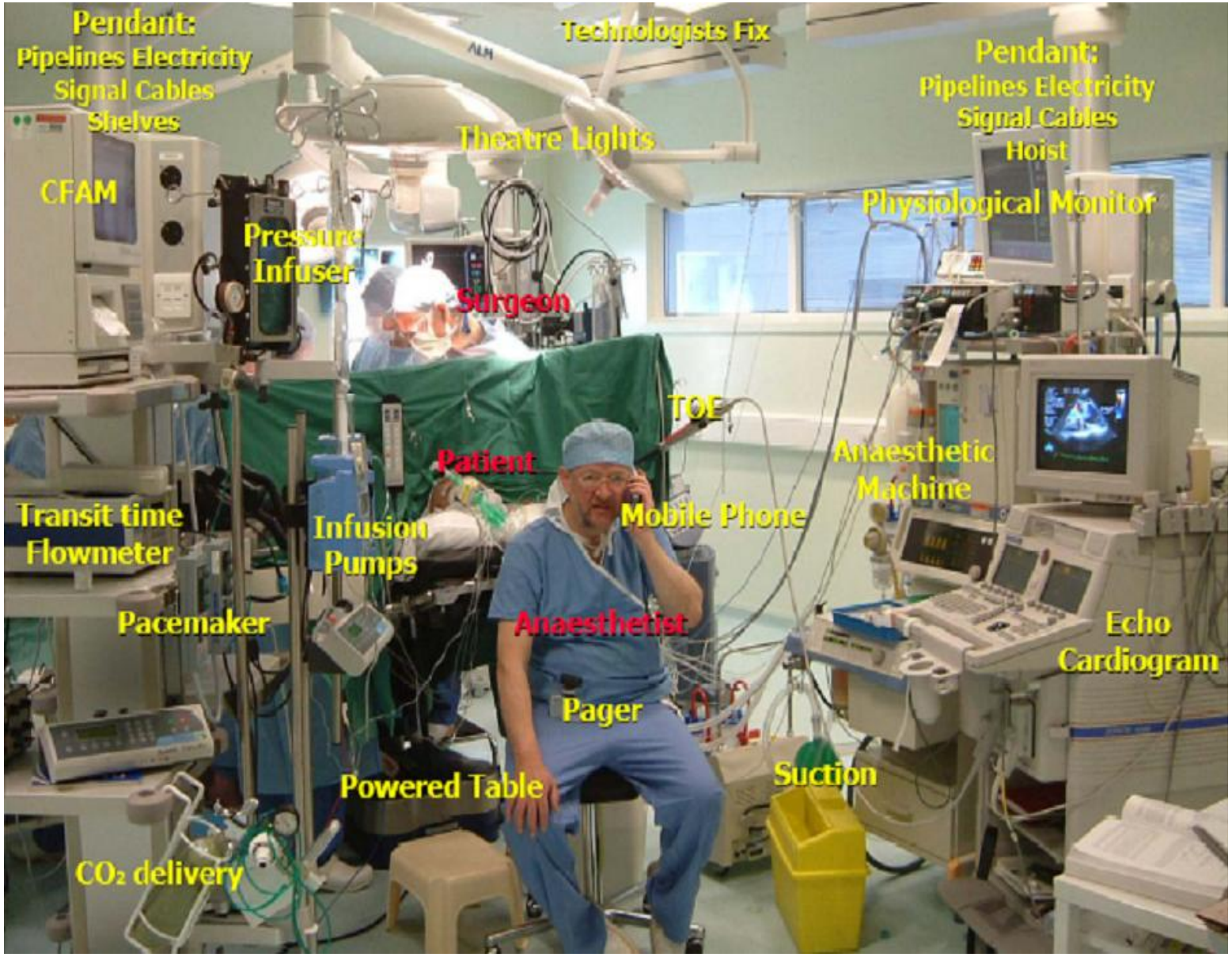


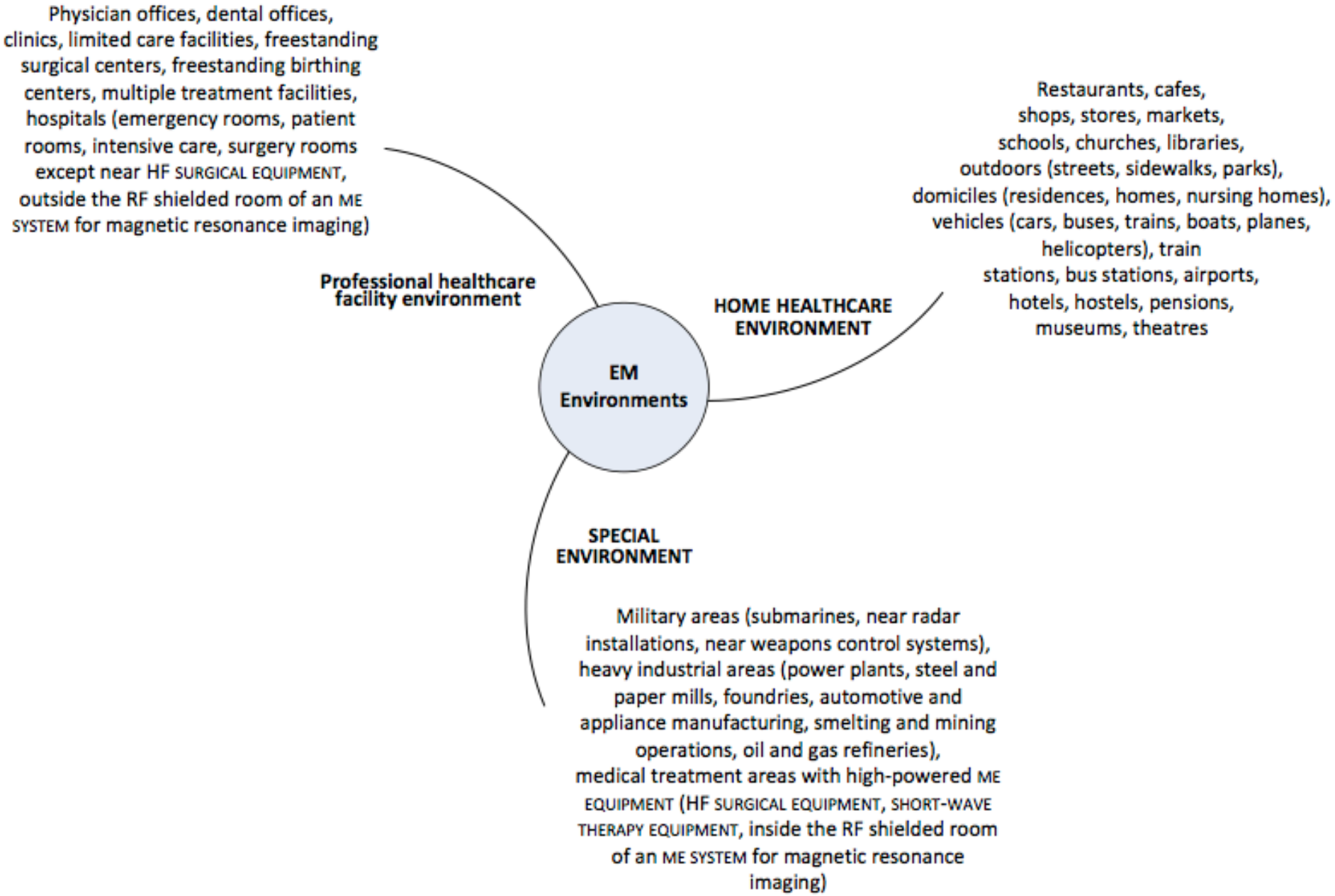
Photo courtesy of Dr. David H T Scott, Department of Anesthetics, The Royal Infirmary of Edinburgh, United Kingdom

4th Edition – General

Immunity requirements now based on three user environments

- Professional Healthcare
  (hospital & small clinic)
- Home Healthcare
  (most locations outside the hospital/small clinic)
- Special
  (determined on a case-by-case basis)

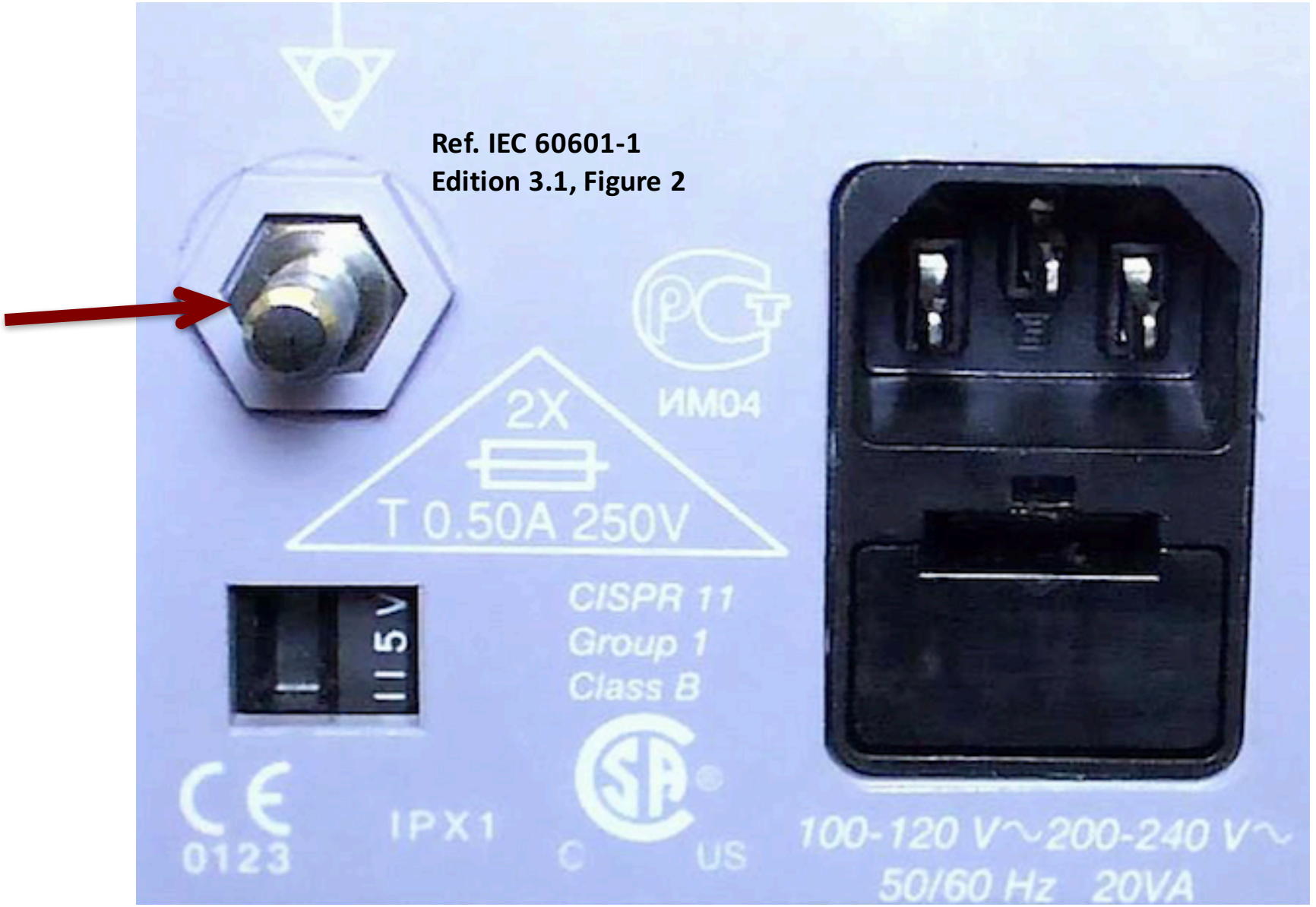
Intended Use Locations Examples



4th Edition – General

- AC input voltage requirements clarified
  - Streamlined to one voltage/frequency
    (exception: Voltage Dips & Interrupts)
  - Regulators may require testing using national voltages
  - Testing of I/O ports (SIP/SOPS) clarified
- The Potential Equalization Conductor Terminal (if applicable) must be connected during testing

Potential Equalization Conductor Terminal



4th Edition – Emissions

- Must comply with CISPR11, IEC 6100-3-2/3
- Standby mode should be considered
- Requirements of CISPR 14-1 limited to switching devices and motors
- Requirements of CISPR 15 eliminated
- ITE equipment must meet CISPR 32
  (not CISPR 22)
- X-Ray generators allowed 20 dB relaxation
  (intermittent mode)

4th Edition – Immunity

- Immunity pass/fail criteria is based on Essential Performance and Basic Safety only
- Specific failure attributes from 3rd edition are no longer specified
- Immunity test levels are based on use location *(not the device type)*

4th Edition – Immunity

- Higher immunity test levels in some instances
- Standby mode should be considered
- ESD
  - Increased ESD test levels
  - Modified ESD test method on connectors

4th Edition – Immunity

- Transmitter Exclusion Band eliminated
  (Radiated Immunity Only)
- Testing on DC input port conditionally required
  (Permanent Cables >3m)
- Provision added to address test samples damaged during testing
- Two new immunity tests added
  - Close Field Proximity
  - 12 VDC Surge

4th Edition – Immunity

- Conducted immunity levels increased in some cases
- Modified Voltage Dips & Interrupts testing
- Magnetic Immunity test levels significantly increased
- Artificial Hand testing requirements clarified

Comparison of Immunity Levels

Phenomenon	IEC 60601-1-2: 3rd Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
ESD	8 kV Air Discharge (max.) 6 kV Contact Discharge	**15 kV** Air Discharge (max.) **8 kV** Contact Discharge	
EFT/Burst	2 kV - AC Mains 1 kV - I/O Ports 5 kHz or 100 kHz PRR	2 kV AC Mains 1 kV I/O Ports **100 kHz PRR**	
Surges (AC Mains)	2 kV	2 kV	
Bold = Changes From the 3rd edition			

Comparison of Immunity Test Levels (cont.)

Phenomenon	IEC 60601-1-2: 3rd Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Magnetic Immunity (50/60 Hz)	3 A/M	**30 A/M**	
Conducted Immunity	3 V (0.15- 80 MHz) 10V ISM Bands *(Life Support)*	3 V (0.15 - 80 MHz) **6 V (ISM Bands)**	3 V (0.15 - 80 MHz) **6 V (ISM + Amateur)**
Voltage Dips & Interrupts	• U_T < 5%, 0.5 periods • U_T = 40 %, 5 periods • U_T = 70%, 25 periods • U_T < 5%, 5 seconds	• U_T = 0%, 0.5 cycle *(0, **45, 90, 135, 180, 225, 270 and 315°**)* • **U_T = 0 %; 1 cycle** U_T = 70%; 25/30 cycles *(@ 0 degrees)* • U_T = 0%; 250/300 cycle	
Bold = Changes From the 3rd edition			

Comparison of Immunity Test Levels (cont.)

Phenomenon	IEC 60601-1-2: 3rd Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Radiated Immunity	3 V/m - Not Life Support 10 V/m - Life Support 80 MHz – 2.5 GHz 80%@2 Hz (or 1 kHz) AM Modulation	**3 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation	**10 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation
Proximity Field from Wireless Transmitters **(New Test)**	N/A	**9 V/m to 28 V/m** 15 specific frequencies	
Bold = Changes From the 3rd edition			

Close Field Proximity Test Levels

Test Frequency (MHz)	Test Level (Volts/meter)	Modulation (@ 50% duty cycle)	Communication Service (*partial list*)
385	27	18 Hz	TETRA 400
450	28	FM *(5 kHz deviation)*	GMRS/FRS
710, 745, 780	9	217 Hz	LTE
810, 870, 930	28	18 Hz	GSM 800
1720, 1845, 1970	28	217 Hz	GSM 1800
2450	28	217 Hz	RFID
5240, 5500, 5785	9	217 Hz	WLAN

Based on 0.3 m Separation Distance

Comparison of Immunity Levels (cont.)

Phenomenon	IEC 60601-1-2: 3rd Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Electrical Transients - *Vehicle* *12 V Powered* (**New Test**)	N/A	N/A	**ISO 7637-2 Pulses – 600 V max.**
Bold = Changes From the 3rd edition			

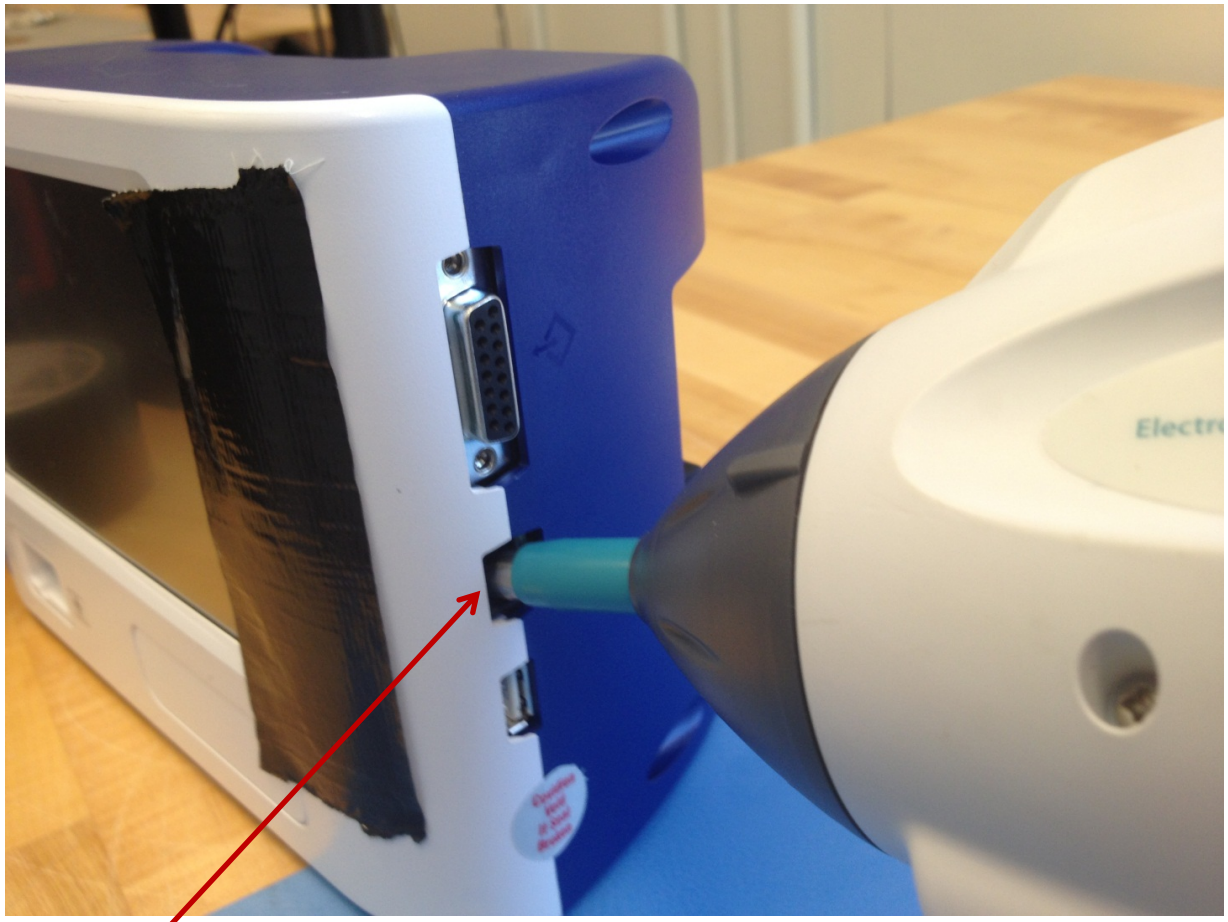
ESD Testing on Connectors

Connector Shell	Discharge Requirements	Connector Usage
Metallic	Contact Discharge to Shell Only	INTENDED USE
Non Metallic	• Air Discharge to Shell • Air Discharge to Pins *(if Reachable by Test Finger)*	INTENDED & NORMAL USE

Intended Use – Clinical Use Only

Normal Use – Intended Use Plus Maintenance, Standby Mode, etc.

4th Edition – ESD Testing Example



RJ45 Ethernet Connector
(Non-Metallic)

EMC Risk Management – Tabular Summary

Clause	Requirement
4.1	Verify that RM entries are present in the RMF
4.2	Non ME Equipment used with Medical Electrical Systems
4.3.1	Verify test configuration
8.1	Effects observed during immunity testing shall be analyzed
8.1	Pass/Fail Criteria and method of monitoring shall be listed in the RMF
8.1	Assess the EM environment and add additional EMC tests as necessary
8.1	Will at least (1) of each type of port be connected during testing?
8.1	Are any special environments defined that justify non-standard test levels?
8.1	Will the ME intended use include types of transportation (sea, air, vehicle) or used near RFID or anti-theft devices?
8.1	Will the ME be used in the emergency medical services environment?

EMC Risk Management – Tabular Summary

Clause	Requirement
8.1	Is the dwell time for based on the time required for the ME to be exercised and adequately respond to the test signal?
8.5	Assessment of subsystem testing
8.7	Selection of operating modes
8.8	Use of Non ME equipment
8.9	Are modified immunity test levels and modulations used?
8.10	Take into consideration current communication services
Table 3	Equipment that is damaged during immunity testing
Table 4	Modified immunity levels may be used
Table 9	Consider reduced distance to mobile communication devices

4th Edition – Risk Management

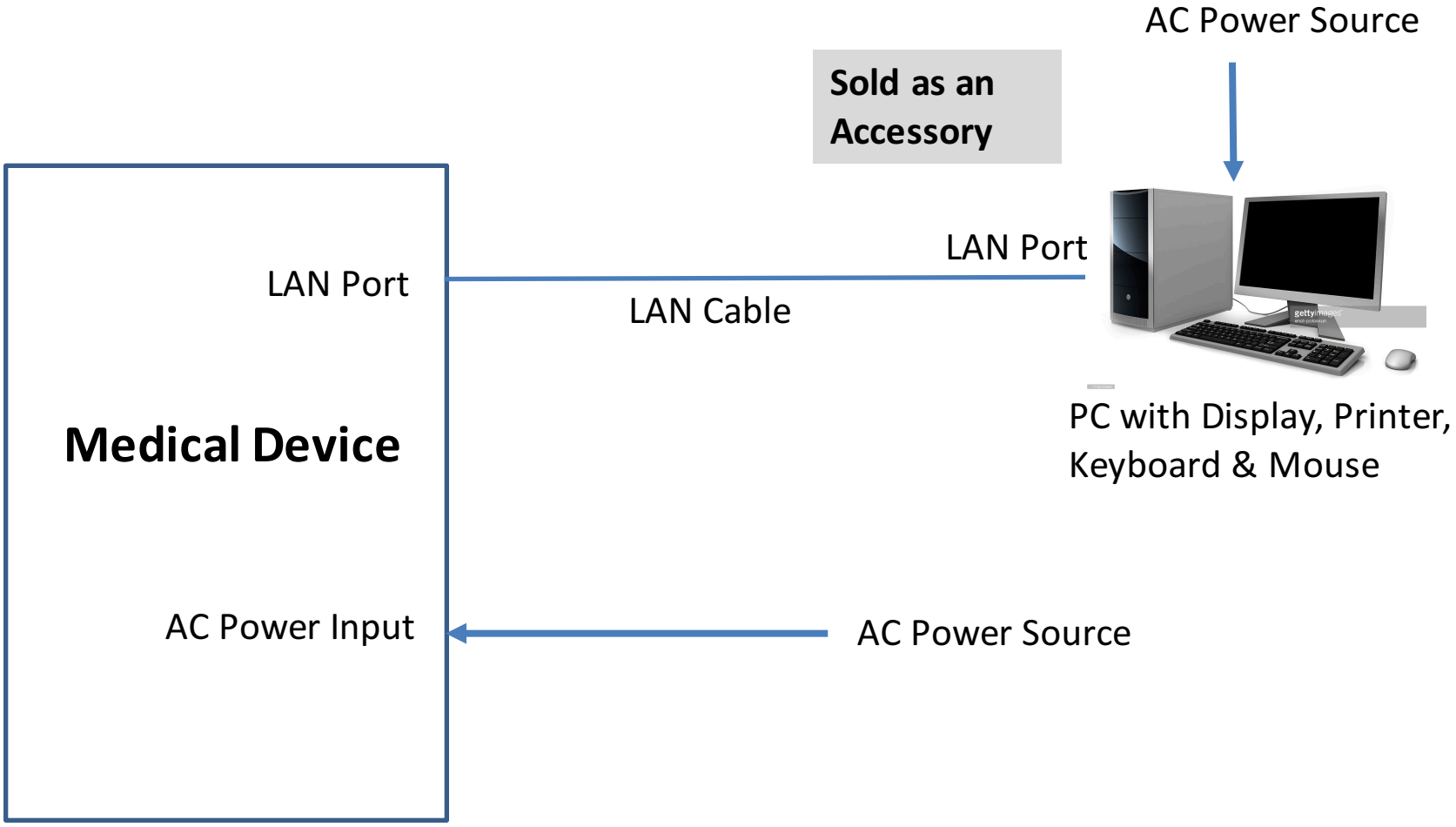
Table F.1 – Examples of EM phenomena that should be considered in a RISK ANALYSIS

EM Phenomenon	Consider in a RISK ANALYSIS
Conducted low frequency phenomena	Harmonics, interharmonics Signalling voltages Voltage fluctuations Voltage dips and interruptions Voltage unbalance Power frequency variations Induced low frequency voltages d.c. in a.c. networks
Radiated low frequency field phenomena	Magnetic fields [a)] Electric fields
Conducted HIGH FREQUENCY phenomena	Directly coupled or induced continuous voltages or currents Unidirectional transients [b)] Oscillatory transients [b)]
Radiated HIGH FREQUENCY field phenomena	Magnetic fields Electric fields Electromagnetic fields – continuous waves – transients [c)]
ELECTROSTATIC DISCHARGE phenomena (ESD)	Human and machine

Integration with Non Medical Equipment 4th Edition

- Must not compromise the system Essential Performance and Basic Safety
- Non-medical equipment must comply with applicable standards
- ITE (multimedia) must comply with CISPR 32 *(not CISPR 22)*

What's the EUT?



Testing with Non Medical Devices Attached

Clause 4.2

- non-ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment;

- non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard.

Is Non Medical Equipment Required to be Tested?

For Immunity testing, use Risk Analysis to determine if EP/BS could be compromised:

- If yes – testing is required
- If no – testing is not required
- If unknown – testing is required

6 Documentation of the tests

6 Documentation of the tests

6.1 General

The documentation of the tests shall contain all the information necessary to facilitate adequate planning (test plan) and execution (test report) of the tests so that they can be readily reproduced.

Compliance is checked by inspection of the test report.

The test plan contents are informative

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.

6.3 Test report

The test report shall meet the requirements of Clause 9.

4th Edition – Documentation

Documentation

- Labeling requirements modified & partially streamlined – EMC tables deleted
- EMC test plan required, recommended content
- EMC test report required, minimum content defined
- Risk Management – numerous EMC considerations required

4th Edition – Documentation

- CISPR 11 Class A emissions warning statement
  (text differs from CISPR 11)
- Labeling requirements modified
  (EMC tables deleted - but may still be used if desired)
- EMC test plan required - recommended content

4th Edition - Documentation

- EMC test report required - minimum content specified
- Referenced standards - dated references specified
- CISPR 11 Edition 5.1 specified, Edition 6.1 published
- Risk management process – numerous EMC considerations required

5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents

- No Longer Required;
  - Emissions compliance table
  - Immunity compliance table
  - Immunity (transients) compliance table
  - Separation distance table

- No Longer Allowed;
  - I/O Port ESD exemption & marking

9 * Test report

9 * Test report

abbreviated

The test report shall include the items listed in Table 10. Additional information may be added to the test report as necessary.

Table 10 – * Minimum test report contents *(1 of 2)*

No.	Item	Additional detail
1	Name and location of the test facility	
2	Names and functions or equivalent identification of the persons authorizing the test report	
3	Description of the ME EQUIPMENT or ME SYSTEM	Include the device name, model number and MANUFACTURER.
4	Description of the BASIC SAFETY AND ESSENTIAL PERFORMANCE including a description how the BASIC SAFETY AND ESSENTIAL PERFORMANCE were monitored during each test	
5	ME EQUIPMENT or ME SYSTEM software / firmware version	
6	Prototype or production version of the ME EQUIPMENT or ME SYSTEM	Additionally, the relationship of the model tested to production models may be described.

IEC 60601-1-2, 4th Edition - Labelling

B.2 ACCOMPANYING DOCUMENTS, instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2 and Table C.5 of the general standard. Additional requirements for information to be included in the instructions for use are found in the subclauses of this collateral standard listed in Table B.2.

Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use

Description	Clause or subclause
Environments for which the ME EQUIPMENT or ME SYSTEM is suitable: statement of	5.2.1.1 a)
Performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES	5.2.1.1 b)
Use of ME EQUIPMENT or ME SYSTEM adjacent to or stacked with other equipment: warning of	5.2.1.1 c)
Cables, transducers and other ACCESSORIES that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 and Clause 8: list of	5.2.1.1 d)
Use of ACCESSORIES, transducers and cables other than those specified or provided by the MANUFACTURER: warning about	5.2.1.1 e)
Minimum separation from RF communication equipment: warning of	5.2.1.1 f)
CISPR 11 class A ME EQUIPMENT and ME SYSTEMS used in a residential area, warning about	5.2.1.2

Declaring Compliance to IEC 60601-1-2

Item	Edition 3	Edition 4
Test plan		X *(suggested content)*
All applicable tests must pass	X	X
Test report	X	X *(specified content)*
Labelling compliance	X	X
Risk Management File *(addressing EMC)*		X

4th edition versus 3rd Edition

Does Compliance to the 4th Edition constitute compliance to 3rd Edition?

Answer: **No Way !**

When Do We Have to Comply with the 4th Edition?

United States	European Union Canada	Other Regions
Legacy Devices: Never* New Submittals: January 1, 2019	January 1, 2019	Varies by: The Country** Part 2 Standards

Notes

* Per FDA substantial equivalence (predicate) scheme

** Some countries do not presently accept the 4th Edition

What Does All This Mean?

- Legacy Products - To Comply with the 4th Edition (*minimum*):
  - Retesting is Required;
    - w/ Potential Equalization Conductor attached *(if applicable)*
    - Emissions in Standby Mode
    - Modified Immunity Pass/Fail criteria
    - Modified Immunity Test Requirements per clause 8
    - New Tests – Close Field Proximity & Vehicle Surge
  - Labeling Modifications
  - Risk Management – Additions to the file
- New Designs – recommend 4th Edition – but consider international requirements

IEC TR 60601-4-2

Edition 1.0 2016-05

TECHNICAL REPORT

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

IEC TR 60601-4-2:2016

- Initial plan – Included in 60601-1-2:2016 - Annex J
- Deleted at the last minute
- Separate stand alone document
- IEC version only – No corresponding EN planned
- Regulatory Requirement?

IEC TR 60601-4-2:2016

- This is a recommendation – the term “shall” is used sparingly
- Do not confuse with Essential Performance
- Intended as a companion to IEC 60601-1-2, 4th Ed.
- Immunity only – no emissions requirements
- Pass/Fail criteria may be more stringent than specified in IEC 60601-1-2, 4th Edition

IEC TR 60601-4-2:2016

- Pass/Fail criteria is based on “Performance”
- Essential Performance and Basic Safety is not relevant
- ESD Test Procedure for connectors is modified
- Warning symbol for ESD is allowed
  (not allowed in IEC 60601-1-2, 4th Edition)

IEC TR 60601-4-2:2016

Concurrent testing with safety testing of IEC 60601-1-2 is possible if:

- Same test setup
- Same modes of operation

IEC TR 60601-4-2:2016

Immunity Compliance

Difficulty = Test Levels x Failure Criteria

IEC TR 60601-4-2:2016

Performance Criteria

A) The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria during and after the following tests, without the need for OPERATOR intervention.

B) The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria after the following tests, without the need for operator intervention.

C) The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria after the following tests. Operator intervention is allowed.

Performance Criteria by Test

Test	Performance Criteria
ESD	B
Radiated Immunity	A
EFT/Burst	B
Surge	B
Conducted Immunity	A
Magnetic Immunity	A
Voltage Dips	B/C
Voltage Interrupts	C
Close Field Proximity	A
Surge – *(12 VDC Powered)*	B

Pass/Failure Criteria Comparison

EUT Response	IEC 60601-1-2 4TH Edition*	IEC TR 60601-4-2 1st Edition**
Shuts Off / Latch Up	Pass	Fail
Catastrophic Failure	Pass	Fail
False Alarms	Pass	Fail
Performance Anomalies	Depends on EP	Fail

* Assumes Essential Performance & Basic Safety is maintained

** Assumes performance degradation beyond manufactures specifications

Comparison of Immunity Test Levels

Phenomenon	IEC TR 60601-4-2: 1st Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
ESD	8 kV Air Discharge (max.) 4 kV Contact Discharge *Criteria B*	15 kV Air Discharge (max.) 8 kV Contact Discharge	
EFT/Burst	1 kV - AC Mains 500 V - I/O Ports 5 kHz or 100 kHz PRR *Criteria B*	2 kV AC Mains 1 kV I/O Ports 100 kHz PRR	
Surges (AC Mains)	2 kV *Criteria B*	2 kV	

Comparison of Immunity Test Levels (cont.)

Phenomenon	IEC 60601-4-2: 1st Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Magnetic Immunity (50/60 Hz)	3 A/M *Criteria B*	30 A/M	
Conducted Immunity	3 V (0.15 - 80 MHz) *Criteria A*	3 V (0.15 - 80 MHz) 6 V (ISM Bands)	3 V (0.15 - 80 MHz) 6 V (ISM + Amateur)
Voltage Dips & Interrupts	• *U_T = 0%, 0.5 cycle (0, & 180°)* • *U_T = 0 %; 1 cycle UT = 70%; 25/30 cycles (@ 0 degrees)* • *U_T = 0%; 250/300 cycle* • *Criteria B/C*	• U_T = 0%, 0.5 cycle *(0, 45, 90, 135, 180, 225, 270 and 315°)* • U_T = 0 %; 1 cycle U_T = 70%; 25/30 cycles *(@ 0 degrees)* • U_T = 0%; 250/300 cycle	

Comparison of Immunity Test Levels (cont.)

Phenomenon	IEC TR 60601-4-2: 1st Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Radiated Immunity	3 V/m 80 MHz – 2.7 GHz 80%@ 1 kHz AM Modulation *Criteria A*	3 V/m 80 MHz – 2.7 GHz 80%@ 1 kHz AM Modulation	10 V/m 80 MHz – 2.7 GHz 80%@ 1 kHz AM Modulation
Proximity Field from Wireless Transmitters	3 V/m to 9 V/m 15 specific frequencies *Criteria A*	9 V/m to 28 V/m 15 specific frequencies	

Comparison of Immunity Test Levels (cont.)

Phenomenon	IEC TR 60601-4-2: 1st Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Surges 12 VDC Powered	Per ISO 7637-2:2011, 5.6 *Criteria A*	N/A	Per ISO 7637-2:2011

Close Field Proximity Test Levels

Test Frequency (MHz)	Test Level (Volts/meter)	
	IEC TR 60601-4-2, 1st	IEC 60601-1-2, 4th
385	6	27
450	9	28
710, 745, 780	3	9
810, 870, 930	9	28
1720, 1845, 1970	9	28
2450	9	28
5240, 5500, 5785	6	9

IEC TR 60601-4-2 Summary

- Intended as a companion to IEC 60601-1-2
- Can be used to establish EMC performance requirements
- Based on performance not Essential Performance
- Pass/Fail criteria may be more stringent than IEC 60601-1-2
- ESD test procedure for connectors differs from IEC 60601-1-2

The End

Thank You!

Darryl P. Ray

- Darryl Ray is the founder and Principal Consultant for Darryl Ray EMC Consulting. He has more than 40 years EMC experience working in the medical device, ITE and defense industries.
- He received a Bachelors of Engineering Technology degree from Wayne State University in Detroit, Michigan.
- He has performed engineering design testing and troubleshooting on over 100 products.
- He has built 9 EMC labs including numerous anechoic chambers. He has authored several papers for past IEEE EMC symposiums.
- He is a Senior Member of the IEEE and former chair of the **IEEE Santa Clara Valley EMC chapter.**
- He is an active member of IEC TC62 SC 62A, Maintenance Team 23 pertaining to the development of IEC 60601-1-2. He is also a member of the US national committees for CISPR 11, 22, 24, 32 and 35.
- He is an iNarte Certified Master EMC Design Engineer.

Darryl P. Ray EMC Consulting, LLC

- EMC Design & Troubleshooting
- EMC Testing & Documentation
- Risk Analysis
- EMC Standards
- EMC Regulatory Engagement & Support
- Medical Device EMC Labeling
- Training
- EMC Lab Design, Construction Oversight and Setup