IEC 60601-1-2, 4th Edition

Darryl P. Ray

Principal Consultant
Darryl Ray EMC Consulting, LLC
Carlsbad, CA, USA

darryl.ray@dray-emc.com
+1-925-487-0072
www.dray-emc.com

IEC 60601-1-2

Edition 4.0 2014-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Published February 25, 2014

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

Hierarchy of Standards

Medical Electrical Equipment Standards

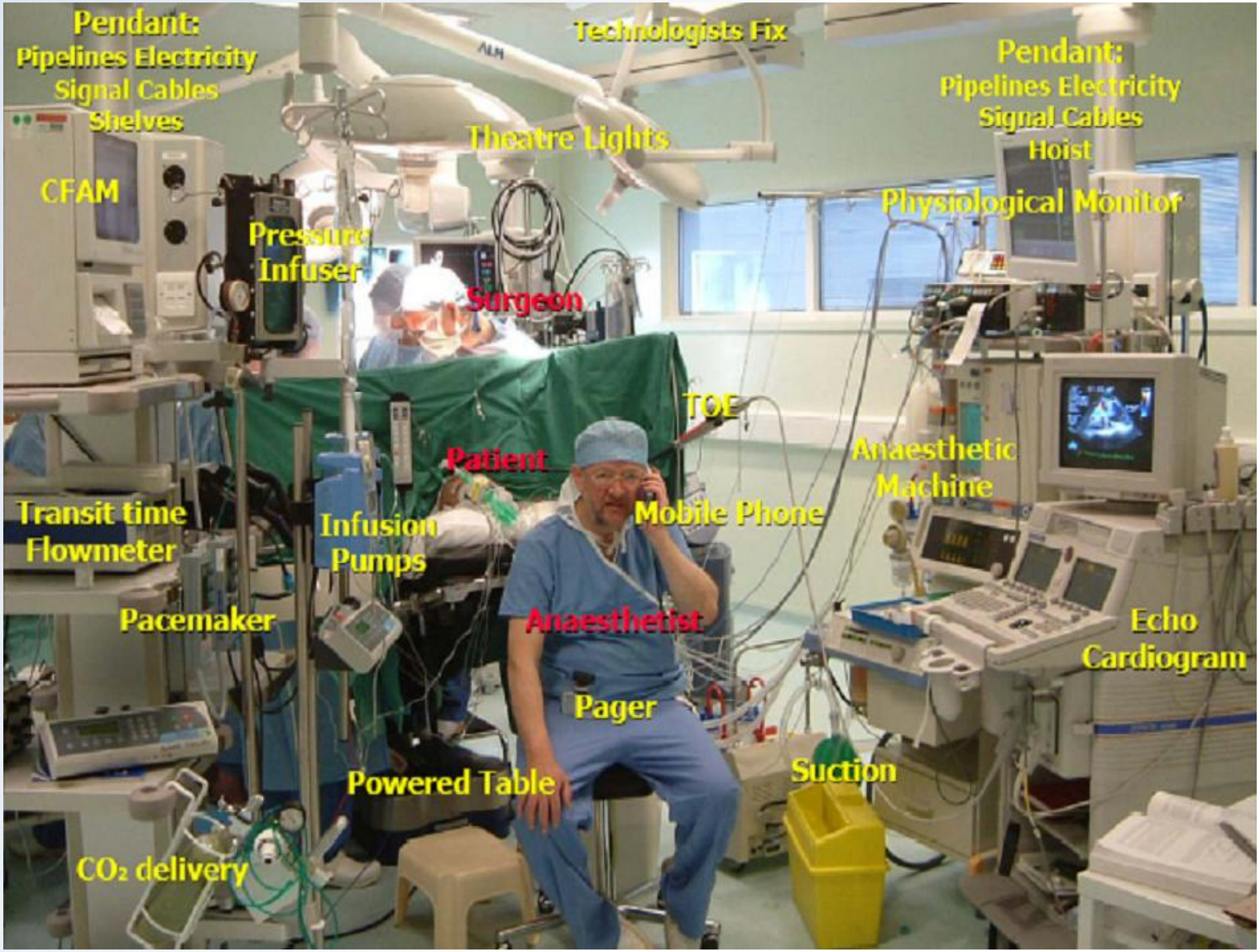
Precedence

- Particular - Product Specific (Vert.) IEC 80601-2-X
- Collateral - Parallel (Horizontal) IEC 60601-1-X
- General Safety Standard IEC 60601-1
- Basic Standards (e.g. 61000-4-x)

4th Edition Motivation

- Create safety standard w/ respect to EM disturbances
- Drawbacks with the 3rd edition
  - Basic Safety and Essential Performance aspects – not adequately addressed
  - Test levels in the 3rd edition are 13+ years old *(new EM environments unaccounted for, e.g. cell phones)*
  - Mobile device usage restrictions are now generally ignored
  - Devices in the same intended use location meet different immunity levels

The Real World!



Initial Considerations

- Four use environments initially defined
- Many EM environments considered
  - Magnetic Immunity – DC to 30 MHz
  - Power-line harmonics immunity
  - Radiated Immunity to 50 V/m
  - ESD to 25 kV
  - Surge to 4 kV
  - Amateur Radio
- Radiated Emissions above 1 GHz
- New test methods for close field proximity & vehicle power surges
- Both Safety with Performance Included – IEC 61XXX proposed

4th Edition Philosophy

- Requirements based on the intended use environment
  (not the device type)
- Immunity levels based on the *reasonably foreseeable maximum*
- Susceptibility from mobile transmitters must be addressed

4th Edition Philosophy (cont.)

- Use Risk Management to tailor requirements
- Immunity requirements defined by port (like CISPR24)
- Improve user friendliness of standard
  - Use of tables
  - Numerous annexes with supplemental information

Basic Safety & Essential Performance

From IEC 60601-1:2005 + A1:2012

3.10 Basic Safety

freedom from unacceptable risk directly caused by physical hazards when me equipment is used under normal condition and single fault condition

3.27 Essential Performance

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

Essential Performance

- Deals with Safety performance;
  (Freedom From unacceptable risk)
- Defined By:
  - IEC 60601-1 Edition 3.1
  - IEC/ISO 80601-2-X
  - Manufactures may define using Risk Analysis
- Relevance: Immunity acceptance criteria is linked to Essential Performance and Basic Safety

Essential Performance - Example

From IEC/ISO 80601-2-72 (Draft)

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or generation of an ALARM CONDITION	[a]
absence of a detected PATIENT breath	201.12.4.110
expired volume	201.12.4.103
high AIRWAY PRESSURE	201.12.4.106
hypoventilation	201.12.4.109
INTERNAL ELECTRICAL POWER SOURCE nears depletion	211.8.4.101
obstruction	201.12.4.107
oxygen levels	201.12.4.101

[a] Subclause 202.6.2.1.10 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this standard.

Basic Safety & Essential Performance

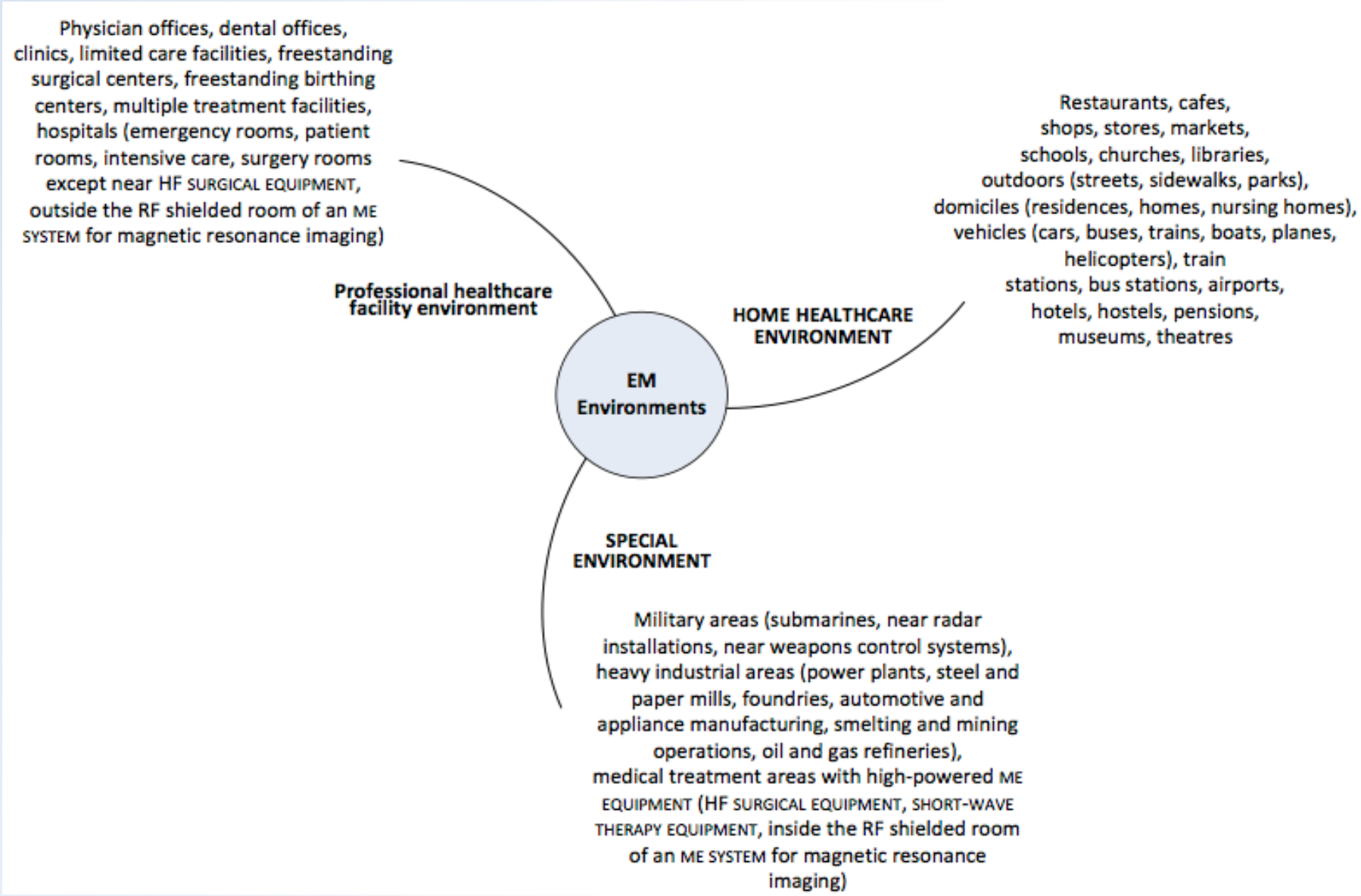
- Some devices do not have specified Essential Performance
- All devices must comply with Basic Safety

The Environment

Requirements now based on three use 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 Environment Examples



Intended & Normal Use Definitions

From IEC 60601-1, Edition 3.1

3.44 Intended Use
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

3.71 Normal Use
operation, including routine inspection and adjustments by any operator and stand-by according to the instructions for use

Intended & Normal Use Definitions

From IEC 60601-1, Edition 3.1

NOTE Intended use should not be confused with normal use. While both included the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, transport, etc. as well

Intended & Normal Use Definitions

Summary

- INTENDED USE – Medical purpose use only
- NORMAL USE – Intended use plus maintenance, standby mode, transport, etc.

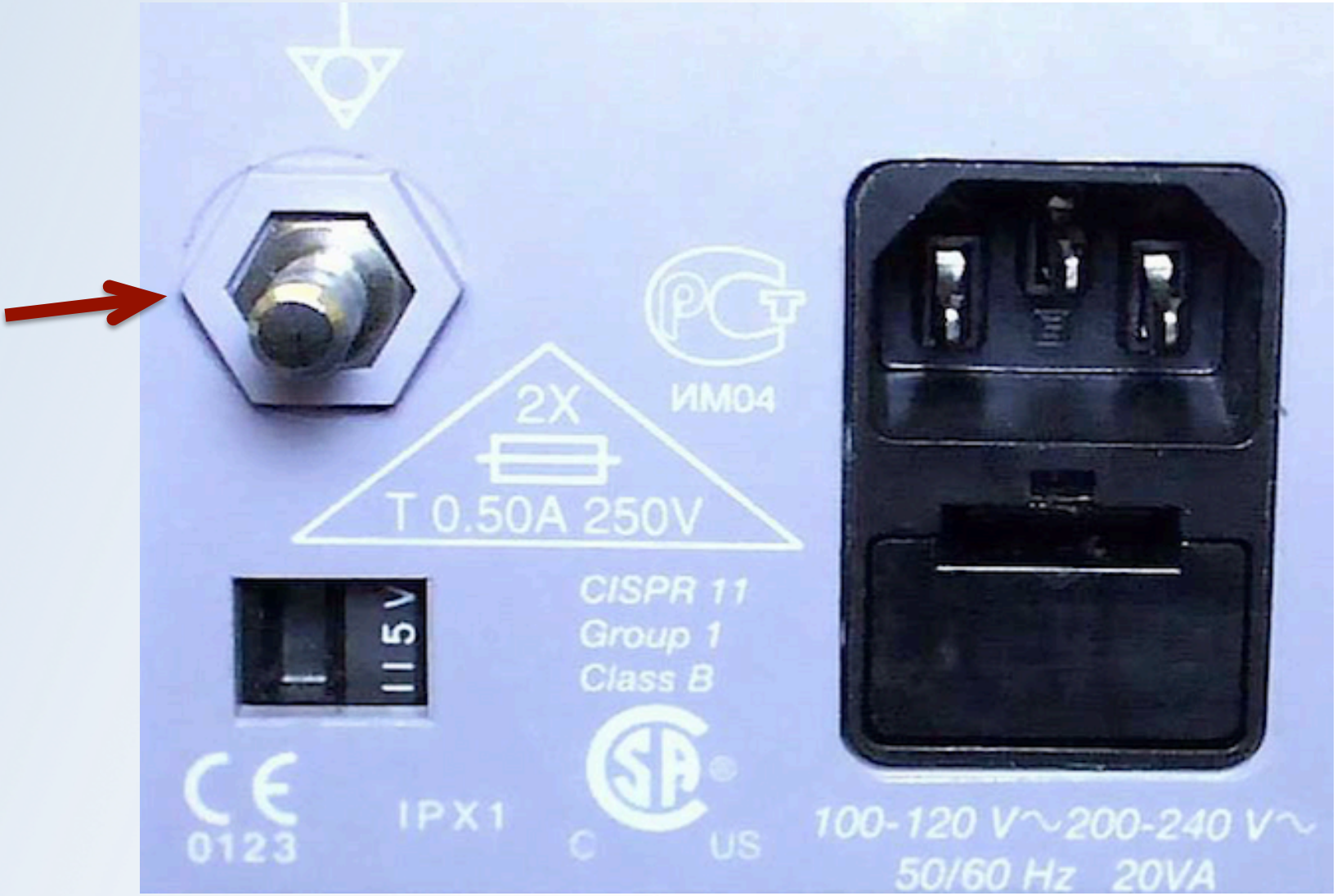
General Test Considerations

- AC input voltage requirements defined
  - Streamlined to one voltage/frequency
    (exception: Voltage Dips & Interrupts)
  - Regulators however may insist on national voltages
  - Testing of I/O ports (SIP/SOPS) – Intended use

General Test Considerations

- The Standby Mode should be considered
- The Potential Equalization Conductor must be connected during testing – if applicable
- Use of the Artificial Hand

Potential Equalization Conductor



Artificial Hand

See CISPR 16-1-2 for additional details

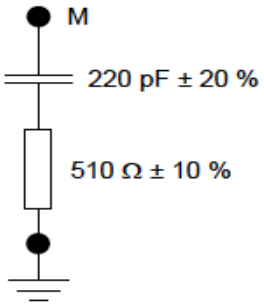


Figure 1 – RC element of the artificial hand

Connection of the AH may impact the test results

Required per Clauses;

4.3.2	General Test Conditions
7.1.9	Patient Physiological Simulation
7.1.10	Artificial Hand
8.2	Patient Physiological Simulation
8.4	Handheld Equipment
Table 7	Patient Coupling Port

Emissions

- Requirements of CISPR 14-1* & CISPR 15 eliminated
  *(*except for switching devices and motors)*
- ITE equipment must meet CISPR 32
  (not CISPR 22)
- X-Ray generators allowed 20dB relaxation
- New test: Patient cable common mode emissions (*informative*)

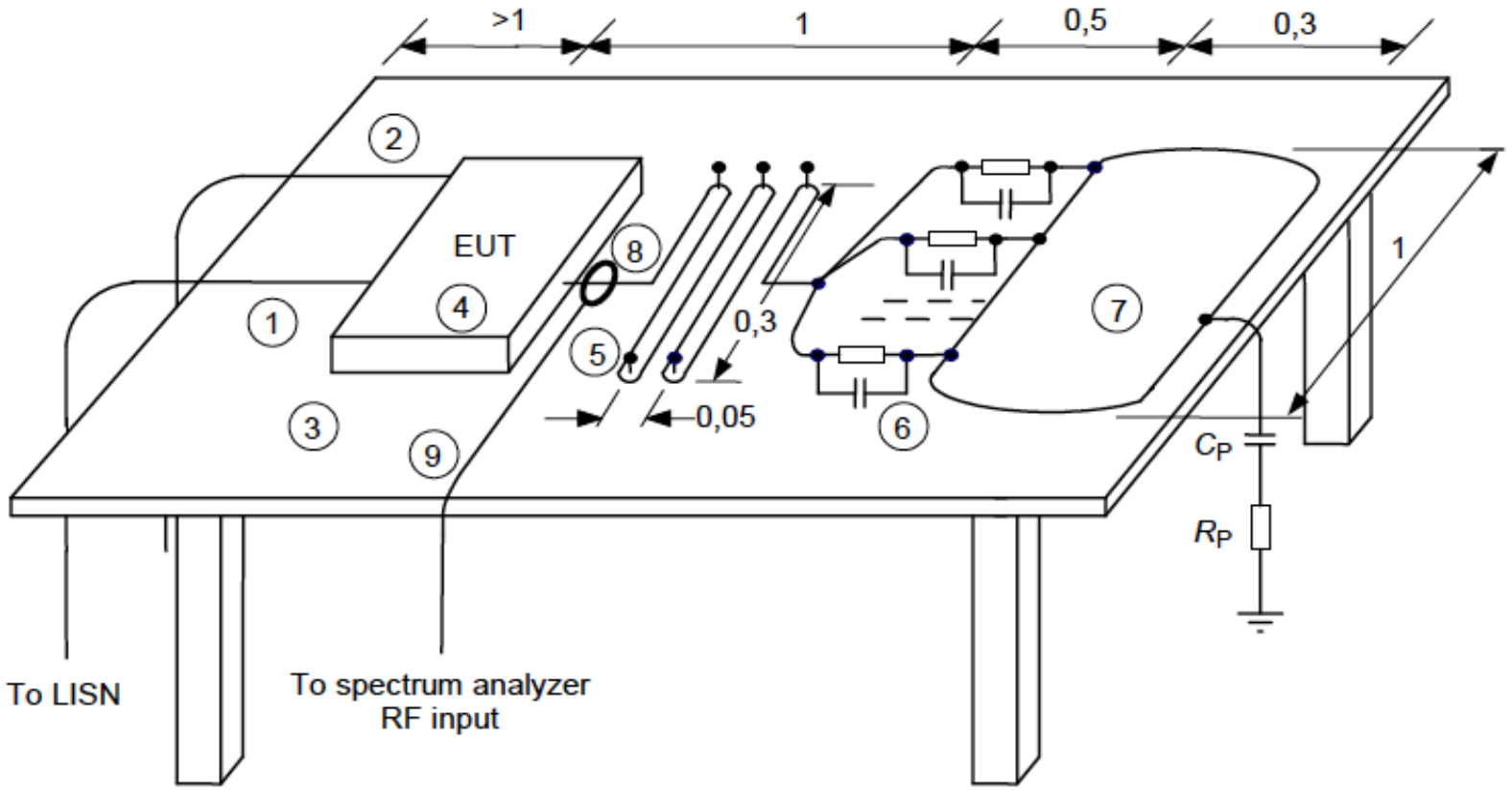
Patient Coupled Cables - Emissions

Table H.1 – PATIENT-COUPLED conducted EMISSIONS recommended limit

Frequency MHz	Peak current dBμA
1-30	24

Annex H
(informative)

PATIENT-coupled cables EMISSIONS



Immunity

- Immunity pass/fail criteria is based on Essential Performance and Basic Safety only
- Specific failure attributes from 3rd edition eliminated
- Immunity levels are based on use location *(not the device type)*

Immunity

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

Immunity

- Transmitter Exclusion Band eliminated
  (Radiated Immunity Only)
- Testing on DC input port conditionally required
  (Permanent Cables >3m)
- Provision for test samples damaged during testing
- Two new immunity tests added

Immunity

- New test: Close Field Proximity
  - 15 specific test frequencies
  - 9 V/m to 28 V/m
  - Mostly pulse modulations
- New test:

  Surge for devices connected to 12V vehicle power

Immunity

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

Documentation Requirements

- CISPR 11 Class A emissions warning statement
  (text differs from CISPR 11)
- Labeling requirements modified
  (EMC tables deleted)
- EMC test plan required - recommended content

Documentation Requirements

- EMC test report required - minimum content defined
- Risk management process – numerous EMC considerations required
- Referenced standards - dated references specified

Risk Analysis – Requirements from the 4th Edition

- Operating Modes may be based on Risk Analysis
- Testing of Non Medical (*i.e disturbances shall be taken into account*)
- Following the testing, any effects observed during or after the application of the test disturbances should be considered
- The Risk Management process shall be used to determine whether subsystem testing is allowed

Risk Analysis – Requirements from 4th Edition

- The minimum separation distance (from Mobile Devices) should be considered in the Risk Management process
- Annex F, addresses Risk Management for Basic Safety and Essential Performance
- Reduced test levels must be justified in the Risk Management File

Risk Analysis – Requirements from 4th Edition

- Mitigations used to justify lower immunity test levels must be documented in the Risk Management process
- Other modulation frequencies can be identified by the Risk Management process
- The Risk Management process should take current communications services into account

Risk Management

Annex F

Some examples of faults and use/misuse that can affect the ability of an ME EQUIPMENT or ME SYSTEM to function as required in the presence of ELECTROMAGNETIC DISTURBANCES include:

- dry joints or short circuits;
- intermittent contacts in connectors;
- incorrect/out-of-tolerance electronic components;
- incorrect, loose or missing fasteners associated with shielding or radio-frequency bonding;
- damaged or missing conductive gaskets;
- failure of a surge protection device, for example by wear-out;
- shielding doors or covers left open;
- installation or modification using an incorrect type of cable.

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 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 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 - Non 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			

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 Volt Powered* (**New Test**)	N/A	N/A	**ISO 7637-2 Pulses - 600V max.**
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 0.3m Separation Distance

Close Field Proximity Test Methods

- Current method based on IEC 61000-4-3
- Proposed new method:
  - IEC 61000-4-39 (early draft stage)

Non Patient Connected I/O Ports

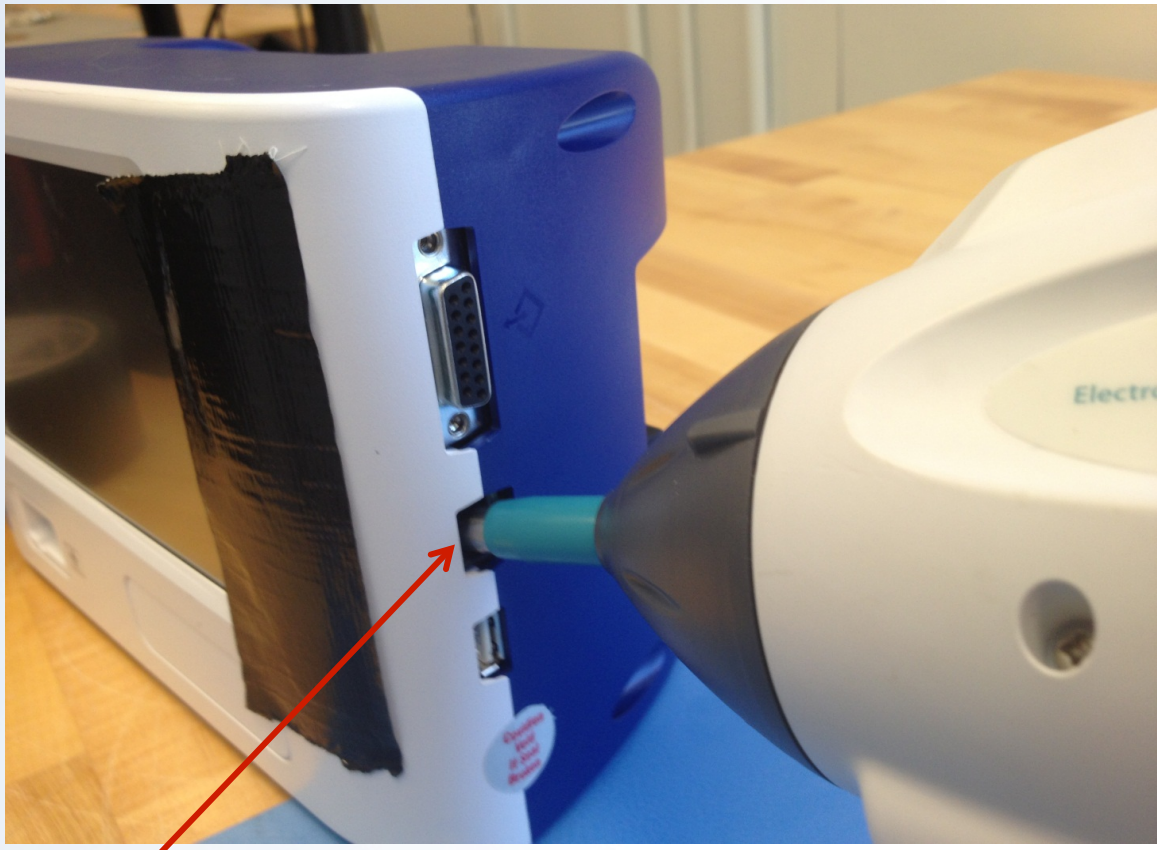
- Related to the use of the port
- Intended Use – no testing *(except ESD)*
- Normal Use – testing is required

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*	Intended Use & Normal Use

- *if Reachable by the IEC test finger*

ESD Testing on Connectors



RJ45 Ethernet Connector
(non metallic)

Integration with Non Medical Equipment

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

FDA Recognition

In Subclause 8.9, Table 8 on Page 39: The citation of Note b) under Conducted Disturbances induced by RF fields (4th Row) is not recognized.

* Please note the following corresponding titles, subtitles or provisions:

** Subclause 8.9: IMMUNITY TEST LEVELS

** Table 8: Signal input/output parts PORT

** Note b): SIP/SOPS whose maximum cable length is less than 3 m in length are excluded

** 4th Row: Conducted disturbances induced by RF fields

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

United States	European Union	Other Regions
Legacy Devices; Never* New Submittals; August, 2016	Late 2018 *(estimated)*	Varies With; The Country** Part 2 Standards

Notes

* Per FDA predicate scheme

** Some countries may not presently accept the 4th edition

Impact on Legacy Products

- Retesting
  - w/ Potential Equalization Conductor attached *(if applicable*)
  - Emissions & immunity testing in standby mode
  - Possible modified immunity pass/fail criteria
  - Modified immunity test requirements per clause 8
  - New Tests – Close Field Proximity & Surge (vehicles)
- Labeling modifications
- Update Risk Management file – may impact testing

EMC Performance Standard – IEC/TR 60601-4-2

- Don't confuse with "Essential Performance"
- Pass/Fail criteria may be more stringent than essential performance & basic safety
- Expected publication mid 2015 – assumes positive vote
- IEC/TR 60601-4-2 – regulatory connection TBD

The End

Thank You!