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

Darryl P. Ray

Principal Consultant

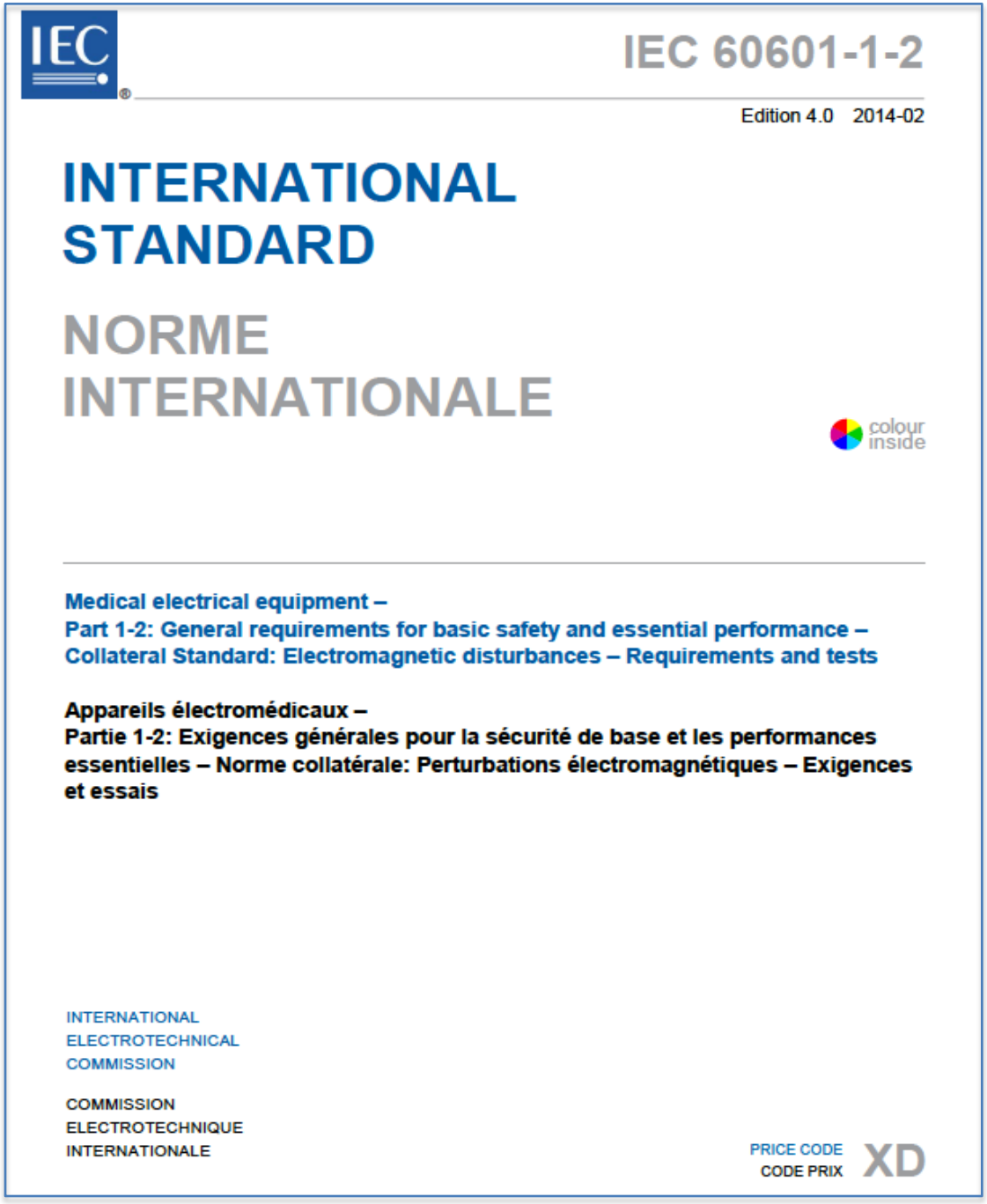
Darryl Ray EMC Consulting, LLC

Carlsbad, CA

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

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

Relevance to Power

- IEC 60601-1-2 is for Medical Equipment and Medical Systems Only
- This standard does not apply to sub-systems
- Many of the EMC tests are related to the power ports

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

From IEC 60601-1:2005 + A1:2012

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

Basic Safety

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

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)

Immunity Testing

- 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 Testing

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

Immunity Testing

- 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

References to Other Standards

Standard	References
IEC 60601-1-2, 3rd Edition	Undated
IEC 60601-1-2, 4th Edition	Dated

Undated Reference = The current version in publication, no grandfathering

Comparison of Emissions Limits

Phenomenon	IEC 60601-1-2: 3rd Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
power Conducted & Radiated Emissions	CISPR 11, Edition 6.1	CISPR 11, Edition **5.1** *(sample size implications)*	
power Harmonics	IEC 61000-3-2 Class A	IEC 61000-3-2 Class A	
power Flicker	IEC 61000-3-3	IEC 61000-3-2	
Bold = Changes From the 3rd edition			

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	
power 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**	
power 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**	
power 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)**
power 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			

power

3rd Edition vs. 4th Edition

Does compliance to the 4th Edition

=

compliance to the 3rd Edition?

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

United States	European Union	Other Regions
Legacy Devices; Never* New Submittals; April, 2017	Dec 31, 2018**	Varies With; The Country*** Part 2 Standards

Notes:

* Per FDA predicate scheme *(substantial equivalence*)

** Dates published in the OJ are pending

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

The End – Thank You!

Questions?