EMC for Medical Products

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EMC for Medical Products

- Medical device directive:93/42/EEC
  - Medical devices: General
  - European standard: EN60601-1-2:2001

    Medical Electrical Equipment - Part 1-2:

    General Requirements for Safety -

    Collateral Standard:

    Electromagnetic Compatibility - Requirements and Tests

EMC for Medical Products

European standard: EN60601-1-2:2001

- This European Standard was approved on November 11, 2001
- This standard is located in the:
  - General Medical Device directive (93/42/EEC)

Published in the directive on August 1, 2002

Supercedes The EN60601-1-2:1993 on November 1, 2004

Until November 1, 2004, a manufacturer has the choice of testing to either the 1993 or 2001 version.

On November 1, 2004, manufacturers must comply with the 2004 version

What's New

- Recognizes responsibility between:
  - Manufacturer
  - Customer
  - User
- Manufacturers responsibility to:
  - design and manufacture to meet the requirements and
  - to disclose information to the customer or user
- Technical Face Lift

IEC 60601-1-2: 2001 Organization

- Scope and Object
- Terminology and definitions
- Markings (6.1.201)
- Accompanying documents:(6.8.201)
- Emissions (36.201)
- Immunity (36.202)
- Annexes

Markings on the Outside of equipment or equipment parts (6.1.201)

- Equipment with RF transmitters or equipment using RF energy for diagnosis or treatment (6.1.201.1)
- Connector ESD testing exemption used (6.1.201.2)
- Equipment specified for use in shielded enclosure (6.1.201.3)

Markings on the Outside of equipment or equipment parts

Equipment with RF transmitters or equipment using RF energy for diagnosis or treatment (6.1.201.1)

Marking on the outside of equipment or equipment parts that include RF transmitters or that apply electromagnetic energy for diagnosis or treatment

Equipment and systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with the following symbol

Markings on the Outside of equipment or equipment parts

Examples of equipment that use RF energy are:

- Systems for Magnetic resonance imaging (MRI)
- Therapy equipment:

  Diathermy equipment:

  High frequency electromagnetic waves to produce local heat in body tissues.

Markings on the Outside of equipment or equipment parts

Connector ESD testing exemption (6.1.201.2)

- Marking on the outside of equipment or equipment parts for which the connector testing exemption is used
- For equipment and systems for which connector testing exemption is used, the following symbol for ESD sensitivity shall be applied adjacent to each connector for which the testing exemption is used.

Markings on the Outside of equipment or equipment parts

Equipment specified for use in shielded enclosure (6.1.201.3)

- Marking on the outside of equipment and systems that are specified for use only in a shielded location

- Equipment and Systems specified for use only in a shielded location shall be labeled with a warning that they should be used only in the specified type of shielded location.
  - Due to Lower immunity test levels.

Accompanying Documents (6.8.201)

Instructions for Use (6.8.2.201)

- **All Equipment**
  - Statement that medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the information provided in the accompany documents.
  - A Statement that portable and mobile RF communications equipment can affect medical electrical equipment.

Accompanying Documents (6.8.201)

Instructions for Use (6.8.2.201) Continued

- Equipment where connector **ESD test exemption** used
  - A Reproduction of warning symbol.
  - ESD precautions must used.
  - A Specification of ESD precautionary procedures.
  - Training in ESD precautionary procedures for staff.

Accompanying Documents (6.8.201)

Technical Description (6.8.3.201)

For **all** Equipment and systems, the accompanying documents shall include the following information (6.8.3.201(a)) :

- A list of Cables and max. lengths, transducers and other accessories that could affect compliance.
- A warning that the use of accessories, transducers and cables other than those specified, may result in increased **emissions** or decreased **immunity** of the equipment.

Accompanying Documents (6.8.201)

Technical Description (6.8.3.201) Continued

For Equipment and systems specified:

That intentionally receive RF energy (6.8.3.201(e))

- That include RF transmitters (6.8.3.201(f))
- A list of Cables, transducers and other accessories that could affect compliance (6.8.3.201(g))
- Large, permanently installed equipment (6.8.3.201(h))
- Equipment found by risk analysis to have no essential performance criteria and were not tested for immunity (6.8.3.201(i))

Accompanying Documents (6.8.201)

Equipment	Table Description	Use Table	Use Flowchart
All Equipment	Emissions	Table 201	CISPR 11 – Figure 201 CISPR 14 and 15 – Figure 202
All Equipment	Immunity (ESD, EFT, Surge, Dips, Magnetic Immunity)	Table 202	Figure 203
Life-Supporting	Conducted and Radiated Immunity	Table 203	Figure 204
Not Life-Supporting	Conducted and Radiated Immunity	Table 204	Figure 205
Life-Supporting	Separation Distances to Mobile and Portable RF Communication Equipment	Table 205	Figure 204
Not Life-Supporting	Separation Distances to Mobile and Portable RF Communication Equipment	Table 206	Figure 205
Life-Supporting in Shielded Location	Conducted and Radiated Immunity	Table 207	None
Not Life-Supporting in Shielded Location	Conducted and Radiated Immunity	Table 208	None

TESTING (ELECTROMAGNETIC COMPATIBILITY)

Emissions (36.201)

Protection of Radio Equipment - Tests (36.201.1(b))

- Electromagnetic Radiation Disturbance (Radiated Emissions)
  - CISPR 11 (Class A/B, Group 1/2)
  - 30MHz to 1000MHz

- Mains Terminal Disturbance Voltage (Conducted Emissions)
  - CISPR 11
  - 0.15MHz to 30MHz

Emissions (36.201)

Class A Equipment - Suitable for use in all establishments other than domestic and those connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Class B Equipment - Suitable for use in domestic establishments and establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Emissions (36.201)

Group 1 ISM - Equipment in which there is intentionally generated or used conductively coupled RF energy that is necessary for the internal functioning of the equipment itself. Otherwise, Un-intentional transmitter

Group 2 ISM - Equipment in which RF energy is intentionally generated or used in the form of electromagnetic radiation for the treatment of material and spark erosion equipment.

Emissions (36.201)

EMISSIONS OTHER THAN CISPR 11

- CISPR 14-1* – Simple Medical Electrical Equipment
  - No Clocks above 9kHz
- CISPR 15* – Lighting Equipment (Illumination of X-rays)
- CISPR 22 – ITE connected to medical equipment

*Limited to "Stand Alone" equipment and not applicable to Systems or sub-systems.

Emissions (36.201)

Protection of Public Mains Network (36.201.3.1)

- Harmonic Distortion (36.201.3.1)
  - Input current up to and including 16A
  - IEC 61000-3-2

- Voltage Fluctuation and Flicker (36.201.3.2)
  - Input current up to and including 16A
  - IEC 61000-3-3

Immunity (36.202)

The standard allows the immunity levels to be lowered, provided there is sufficient justification based on physical, technological or physiological limitations. In this case the manufacturer is required to:

- specify characteristics of the use environment and how this environment is established.
- disclose levels where system meets performance.

Immunity (36.202)

Compliance Criteria (36.202.1(j))

- The following degradations associated with essential performance and safety shall not be allowed:
  - component failures
  - changes in programmable parameters
  - reset to factory defaults
  - change of operating mode
  - data corruption of any kind
  - false alarms
  - cessation or interruption of any intended operation, even if accompanied by an alarm
- Applies to all functions of the product

Immunity (36.202)

IMMUNITY TESTS

Immunity (36.202)

Electrostatic Discharge (ESD) (36.202.2)

PER IEC 61000-4-2

- Air Discharge Mode: ± 2 kV, ± 4 kV and ± 8 kV
- Contact Discharge Mode: ± 2 kV, ± 4 kV and ± 6 kV
- horizontal and vertical coupling planes

•connectors labeled per 36.202.2(b)(4) are exempt from testing
•test at any one of equipment's nominal input voltages and frequencies

Immunity (36.202)

Radiated RF Electromagnetic Fields (36.202.3)
PER IEC 61000-4-3

- Frequency range 80MHz to 2.5GHz
- AM modulated, 80% at

  Control, monitor or measure a physiological parameters
  The Modulation frequency is 2Hz
  - All other - Modulation frequency 1000Hz

Immunity (36.202)

Radiated RF Electromagnetic Fields (36.202.3) (Continued)

- one percent steps
- minimum dwell time
  - 3 seconds for 2Hz modulation
  - 1 second for 1kHz modulation
  - never less than slowest responding function time

- Test at any one of equipment's nominal input voltages and frequencies

Immunity (36.202)

Electrical Fast Transients (EFT) (36.202.4)

PER IEC 61000-4-4

- AC and DC power lines: ±0.5 kV, ± 1 kV and ± 2 kV
- I/O lines greater than 3 meters: ± 0.25 kV, ± 0.5 kV and ± 1.0kV
- All patient coupled cables exempt from direct test

test at minimum and maximum rated input voltages and any one of equipment's nominal power frequencies

Immunity (36.202)

Surges (36.202.5)

PER IEC 61000-4-5

- AC power lines:
  - Line to Ground: ±0.5 kV, ± 1 kV and ± 2 kV
  - Line to Line: ±0.5 kV and ± 1 kV
- All other cables exempt from direct test
- Five surges at each polarity (positive and negative)
- Phase Angles: 0 or 180, 90 and 270 degrees

test at minimum and maximum rated input voltages and any one of equipment's nominal power frequencies

Immunity (36.202)

Conducted Disturbances (36.202.6)

PER IEC 61000-4-6

150kHz to 80MHz

- AM modulated, 80% at
  - Control, monitor or measure a physiological parameters The Modulation frequency is 2Hz
  - All other - Modulation frequency 1kHz
- test at any one of equipment's nominal input voltages and frequencies

Immunity (36.202)

- Voltage Dips, Short Interruptions and Voltage Variations
  - Life-Supporting Equipment and other rated <1KVA
    - Must meet essential requirements and remain safe per 36.202.1(j)
  - Non-Life-Supporting Equipment and other >1KVA
    - <16A - Equipment must remain safe and auto reset
    - >16A – Exempt

test at minimum and maximum rated input voltages and minimum rated power frequency

Immunity (36.202)

Voltage Dips, Short Interruptions and Voltage Variations

PER IEC 61000-4-11

Voltage test level %Ut	Voltage dip %Ut	Duration
< 5	> 95	0.5 periods
40	60	5 periods
70	30	25 periods
< 5	> 95	5 seconds

Immunity (36.202)

- Power Frequency Magnetic Fields (36.202.8.1)

PER IEC 61000-4-8

  - Test at 3A/m
  - Test at 50Hz and 60Hz
- test at any one of equipment's nominal input voltages

Testing Differences

INTERNATIONAL STANDARD EN 60601-1-2:2001 (Directive 93/42/EEC)

Medical Electrical Equipment EMC Requirements

TESTS (EMISSIONS)	1993	2001	Major Differences
Conducted RFI Voltage per (EN55011), 150kHz- 30MHz	**Required**	**Required**	
Radiated Emissions per (EN55011), 30MHz- 1000MHz and	**Required**	**Required**	
Harmonic Current Emissions per EN 61000-3-2	Not Required	**Required**	Additional tests. Not required in 1993
Voltage Fluctuations, Flicker Emissions per EN 61000-3-3	Not Required	**Required**	Additional tests. Not required in 1993
TESTS (IMMUNITY)			
Electrostatic Discharge (ESD) per IEC 61000-4-2	**Required**	**Required**	Contact mode level increases for 2001
Contact Discharge Mode (1993): 2 and 3kV			From 3kV to 6kV
Contact Discharge Mode (2001): 2, 4 and 6kV			
Air Discharge Mode (1993): 2, 4 and 8kV			
Air Discharge Mode (2001): 2, 4 and 8kV			
Radiated RF per IEC 61000-4-3	**Required**	**Required**	Frequency Range changed and voltage
Frequency range (1993): 26-1000MHz			Level is now product specific for 2001
Voltage levels: 3 V/M for equipment and/or systems			
Patient coupled equipment shall be specified			
Frequency range (2001): 80MHz to 2.5GHz			
Voltage levels: 3 V/M for equipment and/or systems			
not patient coupled/life support			
10 V/M for equipment that is life support			
Electrical Fast Transient/Burst(EFT/B) per IEC 61000-4-4	**Required**	**Required**	Test level increases for mains and
Test level (1993): Plug connected 0.5 and 1kV at mains			I/O lines
Permanent connected 0.5, 1, and 2kV at mains			For autoranging, Test must be performed
Interconnecting lines >3m, 0.25 and 0.5kV			at the min and max rated input voltages
Test level (2001): Equipment 0.5, 1, and 2kV at mains			
Interconnecting lines >3m, 0.25, 0.5 and 1kV			
Power Frequency Magnetic Fields per IEC 61000-4-8	Not required	**Required**	Additional tests. Not required in 1993
Test level (2001): 3 A/M at 50 and 60Hz			

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TESTS (IMMUNITY)			1993	2001	Major Differences
Voltage Dips and Interruptions per IEC 61000-4-11			Not required	**Required**	Additional tests. Not required in 1993
Test level (2001):	<5%(95%dip) for 0.5 cycles				See standard for product requirements
	40%(60% dip) for 5 cycles				
	70%(30% dip) for 25 cycles				
	<5%(95% dip) for 5 seconds				
Conducted RF per IEC 61000-4-6			Not required	**Required**	Additional tests. Not required in 1993
Frequency Range:	150kHz to 80MHz				See standard for product requirements
Test level (2001):	3Vrms for non life support equipment				
	3Vrms for life support equipment and				
	10Vrms in the ISM frequency bands				
	up to 80MHz				
Surges per IEC 61000-4-5			**Required**	**Required**	No differences, test levels are identical
Test level (1993):	0.5 and 1kV in Differential mode				For autoranging, Test must be performed
	0.5, 1 and 2kV in common mode				at the min and max rated input voltages
Test level (2001):	0.5 and 1kV in Differential mode				
	0.5, 1 and 2kV in common mode				

ANNEXES

Annex AAA

- **Informative**
  - **Provides general guidance and rationale for requirements**
  - **Correlated to specific sub-clause in standard**

Annex BBB

- **Informative**
  - **Provides general guidance and rationale for completion of Tables 201 through 208**

ANNEXES

Annex CCC

•Informative

- **➢Guidance in classification according to CISPR 11**
- **➢Example provided**

Annex DDD

•Informative

- **➢Guidance in the application of IEC 60601-1-2 to Particular Standards**
  - **•Contains recommendations for standards committees writing EMC requirements for Particular Standards (IEC 60601-2-X)**

ANNEXES

Annex EEE

- **Informative**
- **Example of electromagnetic environments**

Annex FFF

- **Normative**
- **Normative references**

THANK YOU……

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