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





- 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





- •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)



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



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.



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.





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.



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.



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.



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.



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))



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)





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



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.



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 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.



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



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.



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 TESTS



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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



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



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





Electrical Fast Transients (EFT) (36.202.4)

PER IEC 61000-4-4

- •AC and DC power lines: $\pm 0.5 \text{ kV}$, $\pm 1 \text{ kV}$ and $\pm 2 \text{ kV}$
- •I/O lines greater than 3 meters: \pm 0.25 kV, \pm 0.5 kV and \pm 1.0kV

•All patient coupled cables exempt from <u>direct</u> test test at <u>minimum and maximum rated input voltages</u> and any one of equipment's nominal power frequencies





Surges (36.202.5)

PER IEC 61000-4-5

- •AC power lines:
 - Line to Ground: $\pm 0.5 \text{ kV}$, $\pm 1 \text{ kV}$ and $\pm 2 \text{ kV}$
 - \blacktriangleright Line to Line: ± 0.5 kV and ± 1 kV
- •All other cables exempt from <u>direct</u> 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





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



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

Conducto	d PEL Volt		55011) 10	50kHz- 200		Required	Required	1	1	1	
Conducted RFI Voltage per (EN55011), 150kHz- 30MHz					Required	Required					
Radiated Emissions per (EN55011), 30MHz- 1000MHz and Harmonic Current Emissions per EN 61000-3-2 Voltage Fluctuations, Flicker Emissions per EN 61000-3-3						Required		toolo No	t may dead is	- 1002	
					Not Required	Required	Additional	tests. NO	t required i	n 1993	
TESTS (IN	MUNITY)		a light from								
Electrosta	tic Discha	rge (ESD) pe	er IEC 610	000-4-2		Required	Required	Contact m	ode level i	ncreases fo	or 2001
	and the second se	ode (1993): 2		Construction of the second second				From 3kV	THE ROUGH CONTRACTOR		
the second second second		ode (2001): 2		the second second second second second				- TOTT ON T			
and the second se		1993): 2, 4 a	and the second second second second			and second concernance					
		2001): 2, 4 a									
									- sepalmalmalma		
Radiated RF per IEC 61000-4-3						Required	Required	Frequency	Range ch	nanged and	voltage
		3): 26-1000M	ЛНz							specific fo	
Voltage lev		3 V/M for eq		nd/or syste	ems		-				
		Patient coup	oled equip	ment shall	be specified						
Frequency	range (200	1): 80MHz to	2.5GHz						NO STREET		
Voltage lev		3 V/M for eq		nd/or syste	ems		nononononononon	-	Colorador Colorador		
		not patient of	coupled/life	e support	No. 2012 State	ene electronication de la de			also also		
		10 V/M for	equipment	t that is life	support			service and a service of the			
Electrical	Fast Trans	sient/Burst/F	ET/B) pe	r IEC 6100	0-4-4	Required	Required	Test level	increases	for mains a	ind
Test level (Islent/Burst(EFT/B) per IEC 61000-4-4				riequireu	requireu	I/O lines			1
					d 2kV at mains				naina. Tes	t must be	performed
		to control of the control of the	NO-COLUD-CO-ACT-CO-	southing with an entry				and the second se		rated input	
Test level (2001): Equipment 0.5, 1, and 2kV at mains					The Automation	of the min			landgeo		
Interconnecting lines >3m, 0.25, 0.5 and 1kV											
	100										
Power Frequency Magnetic Fields per IEC 61000-4-8					Not required	Required	Additional	tests. No	t required i	n 1993	
Test level ((2001):	3 A/M at 50	and 60Hz							1.00	



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				
	Service and the	40%(60% dip)	for 5 cycles	and the second		S. S					
		70%(30% dip)				S. Carlos					
		<5%(95% dip) for 5 seconds									
										Contraction of the	
and some some states and	and the second se	IEC 61000-4-6	Constant Constants	and the second second	Not required	Required					
Frequency	Range:	150kHz to 80M	1Hz				See standard for product requirements				
Test level (2001):		3Vrms for non life support equipment					ing the second second		and the second		
		3Vrms for life support equipment and			a Casta a Casta				100000		
		10Vrms in the	ISM frequency ban	ls		and the second					
		up to 80MHz									
Surges per IEC 61000-4-5					Required	Required	No differences, test levels are identical				
Test level (1	(1993):	0.5 and 1kV in Differential mode			i segura da		For autoranging, Test must be performed				
		0.5, 1 and 2kV in common mode				Second Rest	at the min	and max n	ated input w	oltages	
Test level ((2001):	0.5 and 1kV in	Differential mode				and and the				
	a second to a	0.5, 1 and 2kV	in common mode								





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





- 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)





Annex EEE •Informative •Example of electromagnetic environments

Annex FFF •Normative •Normative references



THANK YOU.....



