IEC 60601-1-2

Edition 4.0 2020-09

INTERNATIONAL STANDARD

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AMENDMENT 1

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

IEC 60601-1-2:2014-02/AMD1:2020-09(en)

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01; 33.100.10; 33.100.20

ISBN 978-2-8322-8630-2

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FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/1390/FDIS	62A/1405/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION TO AMENDMENT 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fifth edition of IEC 60601-1-2, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 15 items were presented to the National Committees present. All 15 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

1.3.1 IEC 60601-1

Replace, in the second existing paragraph, the first two existing dashes with the following new dashes:

– "the general standard" designates IEC 60601-1 alone, including any amendments;

– "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;

2 Normative references

Replace the existing references to IEC 60601-1 (including footnote 1), IEC 60601-1-8 (including footnote 2), IEC 60601-1-11, IEC 60601-1-12 (including footnote 3), IEC 61000-4-5, IEC 61000-4-11, CISPR 11 (including footnote 6), CISPR 14-1, CISPR 16-1-2 (including footnote 7), CISPR 32 and ISO 14971 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
Amendment 1:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
Amendment 1:2020

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*
Amendment 1:2017

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – Voltage dips, short interruptions and voltage variations immunity tests*
Amendment 1:2017

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
Amendment 1:2016
Amendment 2:2019

CISPR 14-1:2016, *Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission*

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*
Amendment 1:2017

CISPR 32:2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements*

ISO 14971:2019, *Medical devices - Application of risk management to medical devices*

Delete the existing normative reference to ISO 7137.

Add the following normative reference to the existing list:

IEC 61000-4-39:2017, *Electromagnetic compatibility (EMC) – Part 4-39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test*

3 Terms and definitions

Replace the existing first paragraph with the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 +A1:2012+A2:2020, IEC 60601-1-8:2006+A1:2012+A2:2020, IEC 60601-1-11:2015+A1:2020, IEC 60601-1-12:2014+A1:2020, IEC 60601-2-2:2009, IEC 60601-2-3:2012 and the following definitions apply.

3.20
SPECIAL ENVIRONMENT

Replace, in the definition, the words "Table 2 through Table 9" *with* "Table 2 through Table 9 and Table 11".

Table 1 – Power input voltages and frequencies during the tests

Replace the existing header and first row of Table 1 (1 of 2) with the following new header and first row:

Test	Power input voltage	Power frequency
Conducted DISTURBANCES (conducted EMISSIONS) CISPR 11	Minimum and maximum RATED voltage [c) d)]	Any one frequency [b)]

Replace the existing Table 1 (2 of 2) with the following new table:

Table 1 *(2 of 2)*

Test	Power input voltage	Power frequency
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage [a]	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the power frequency of the ME EQUIPMENT or ME SYSTEM shall be the same. [b]
Voltage dips IMMUNITY IEC 61000-4-11	Minimum and maximum RATED voltage [c] [d]	Any one frequency [b]
Voltage short interruptions and voltage variations IMMUNITY IEC 61000-4-11	Any one voltage [a]	Any one frequency [b]
Proximity magnetic fields IEC 61000-4-39	Any one voltage [a]	Any one frequency [b]

[a] The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

[b] The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.

[c] If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.

[d] ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

7.1.12 PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Replace the existing title of the subclause with the following new title:

7.1.12 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Table 2 – EMISSION limits per environment

Replace, in the third column of the first row of the existing Table 2, "CISPR 11 [c), d)]" *with* "CISPR 11 [c)]".

Replace, in the existing Table 2, table footnote [c] *with the following new footnote:*

[c] Standards applicable to modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

Delete, in the existing Table 2, table footnote [d].

8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

8.1 * General

Replace, in the existing first paragraph following Table 3, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11" *in four places.*

Replace, in the existing first paragraph following NOTE 3, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

Replace, in the existing first paragraph following NOTE 4, "Table 4 through Table 9 for the HOME HEALTHCARE ENVIRONMENT" *with* "Table 4 through Table 9 for the HOME HEALTHCARE ENVIRONMENT, and 8.11".

Replace, in the existing second paragraph following NOTE 4, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

Replace, in the existing sixth paragraph following NOTE 4, "Table 1 and Table 4 through Table 9" *with* "Table 1".

Replace, in the existing last paragraph of the subclause, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11, as applicable".

8.6 PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Replace the existing title of the subclause with the following new title:

8.6 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Replace, in the existing first paragraph following the NOTE, "8.9 and 8.10" *with* "8.9, 8.10 and 8.11".

8.9 * IMMUNITY TEST LEVELS

Replace, in the existing first paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

Delete the existing NOTE.

Replace, in the existing second paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11" *in two places.*

Figure 3 – Examples of environments of INTENDED USE

Replace the existing title of Figure 3 with the following new title:

Figure 3 – Examples of locations within EM ENVIRONMENTS

Table 4 – * ENCLOSURE PORT

Replace, in the existing Table 4, the fourth row with the following new rows:

RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	See 8.11.

Replace, in the existing Table 4, table footnote [e] with the following new footnote:

[e] Void.

Delete, in the existing Table 4, table footnote [g].

Table 5 – * Input a.c. power PORT

Replace, in the first column of the first row of the existing Table 5 (1 of 2), "Electrical fast transients / bursts [a) l) o)]" *with* "Electrical fast transients / bursts [l) o)]".

Replace, in the first column of the second row of the existing Table 5 (1 of 2), "Surges [a) b) j) o)] Line-to-line" *with* "Surges [b) j) o)] Line-to-line".

Replace, in the first column of the third row of the existing Table 5 (1 of 2), "Surges [a) b) j) k) o)] Line-to-ground" *with* "Surges [b) j) k) o)] Line-to-ground".

Replace, in the first column of the sixth row of the existing Table 5 (1 of 2), "Voltage interruptions [f) i) o) r)]" *with* "Voltage interruptions [f) i) o)]".

Replace, in the existing Table 5 (1 of 2), table footnote [a)] with the following new footnote:

[a)] Void.

Replace, in the existing Table 5 (2 of 2), table footnote [r)] with the following new footnote:

[r)] For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1.

Table 8 – Signal input/output parts PORT

Replace the existing title of Table 8 with the following new title:

Table 8 – SIP/SOP PORT

Replace, in the first column of the fourth row of the existing Table 8, "Conducted disturbances induced by RF fields [b) d) g)]" *with* "Conducted disturbances induced by RF fields [d) g) j) k)]".

Add, in the existing Table 8, the following table footnotes:

[j)] See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

[k)] SIP/SOPS whose maximum cable length is less than 1 m are excluded.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Replace the existing Table 9 with the following new table:

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Add, after the existing Subclause 8.10, the following new subclause:

8.11 * IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz shall be evaluated according to steps a) through d) below. MANUFACTURERS may proceed directly to step d). The result of the evaluation for each applicable step shall be documented in the test report or RISK MANAGEMENT FILE, as applicable. See also Figure A.3.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

a) ME EQUIPMENT and ME SYSTEMS that do not contain magnetically sensitive components or circuitry within the ENCLOSURE or as part of an attached ACCESSORY need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

b) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in Table 11 is ensured by the ENCLOSURE or by the physical design of an attached ACCESSORY during INTENDED USE need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

c) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, then the tests of Table 11 need not be performed; otherwise,

d) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry not meeting the separation distance criteria in b) or the RISK acceptability criteria in c) shall be tested for IMMUNITY to magnetic fields as specified in Table 11 using the test methods specified in IEC 61000-4-39. The magnetic field shall be applied only to those surfaces of the ENCLOSURE or attached ACCESSORIES that are accessible during INTENDED USE. The test windows to be used with IEC 61000-4-39 may be selected to illuminate only the area of the magnetically sensitive components or circuitry. The location of application of the magnetic field should be specified in the test plan and shall be documented in the test report.

Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

9 * Test report

Add, in the existing Table 10 (2 of 2), before the last row:

38	The locations of application of proximity magnetic fields.	If the testing according to 8.11 step d) is performed.

A.1 Safety and performance

Replace, in the existing NOTE, the reference "IEC/TS 61000-1-2 in the 2008 edition [8]" *with* "IEC/TS 61000-1-2:2008".

A.3 Rationale for particular clauses and subclauses

Subclause 4.2 – Non-ME EQUIPMENT used in an ME SYSTEM

Add, immediately following the existing third paragraph, the following new text:

For example:

EMISSIONS:

If non-ME EQUIPMENT is used in an ME SYSTEM, the non-ME EQUIPMENT should fulfil the same EMISSIONS requirements as the ME SYSTEM, proven by the applicable product standards of the non-ME EQUIPMENT.

IMMUNITY:

Consider if failure or degradation of the non-ME EQUIPMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

– If failure or degradation of the non-ME EQUIPMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, apply to the non-ME EQUIPMENT the same IMMUNITY TEST LEVELS specified for the ME SYSTEM, based on the environments of INTENDED USE.

– If failure or degradation of the non-ME EQUIPMENT does not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, compliance with the product standard of the non-ME EQUIPMENT is sufficient.

Subclause 4.3.3 – Power input voltages and frequencies

Add, immediately following the existing last paragraph, the following new text:

Table 1, table footnote [c)], provides the MANUFACTURER with an allowance to perform testing at any one RATED input voltage when the difference between the maximum and minimum RATED input voltage is less than 25 % of the highest RATED input voltage. Table A.2 provides several examples of the calculation and associated conclusion for testing at a single RATED input voltage.

Table A.2 – Example calculations for applying the allowance to test at a single RATED power input voltage

Min. V	Max. V	Max. – Min. V	25 % of Max. V	(Max. – Min.) < 25 % of Max.?	Testing at one voltage allowed?
100	120	20	30	Yes	Yes
100	127	27	31,75	Yes	Yes
100	240	140	60	No	No
200	240	40	60	Yes	Yes
380	480	100	120	Yes	Yes

Subclause 5.2.2.1 a) – Compliance for each EMISSIONS and IMMUNITY standard

Replace, in the existing paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11" *in two places.*

Subclause 7.1.7 – ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices

Add, immediately following the existing last paragraph, the following new rationale:

Subclause 7.1.12 – PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

This subclause offers three methods for EMISSION testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS:

– on a test site as a system;

– on a test site on a subsystem basis;

– in situ as a system at the premises of a RESPONSIBLE ORGANIZATION.

For some ME SYSTEMS, testing on a test site or on a subsystem basis is deemed to be very difficult. ME SYSTEMS (e.g. large X-ray equipment and particle therapy systems) requiring ceiling installation, or equipment that needs to be placed in different locations such as examination rooms, technical rooms and control rooms, cannot be installed in today's test sites due to the size or installation requirements. Note that "large" in this context is defined in this collateral standard to mean ME EQUIPMENT or ME SYSTEMS that cannot fit within a 2 m x 2 m x 2,5 m volume in any orientation (see 3.12 and 3.13).

Testing on a subsystem basis requires the simulation of physical behaviour of the replaced system, which is also deemed to be technically very difficult and sometimes impossible without a representative configuration. Such a test would likely not fulfil the "worst case" or "modes that maximize EMISSIONS" approach of CISPR 11/IEC 60601-1-2 without several re-configurations and extensive test time.

In situ testing – testing at the place of installation – as a system, at a RESPONSIBLE ORGANIZATION (i.e. a hospital or individual clinic) often requires a certification/approval before shipment to the facility. The ME SYSTEM might be in use and might not present the maximum configuration. Furthermore, it might not be possible to be tested in the modes that maximize EMISSIONS as required by this subclause because the available configuration for such testing is limited to what the customer/RESPONSIBLE ORGANIZATION has installed.

Moreover, BASIC SAFETY and ESSENTIAL PERFORMANCE needs to be verified according to the MANUFACTURER's specification and requires specific operating modes and auxiliary equipment that might not be available or authorized in situ.

At the MANUFACTURER's premises, the equipment used to provide input to, and monitoring of, the equipment under test (EUT) is likely to be fully available and testing in representative configurations is usually possible. Testing at the MANUFACTURER's premises could fulfil the operational mode requirements of this subclause.

Furthermore, at the MANUFACTURER's premises, all necessary components, service support and knowledge of maintenance is in place, as well as protection requirements (e.g. to protect the environment and personnel).

Comparing the limitations as described in this subclause against the advantages of testing at the MANUFACTURER's premises, the latter could be considered equal to in situ testing. In such cases, good EMC practice regarding the measurement distance and positions should be achievable, and for EMISSION testing at the MANUFACTURER's premises, a measurement distance of at least 3 m should be maintained. Additionally, a rationale to explain why testing the ME EQUIPMENT or ME SYSTEM on the MANUFACTURER's premises is justified should be provided in the test plan and documented in the test report. The measurement locations, including distance to the EUT, should be documented in the test report.

Subclause 8.5 – Subsystems

Add, immediately following the existing paragraph, the following new rationale:

Subclause 8.6 – PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

This subclause offers three methods for IMMUNITY testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS:

– on a test site as a system;

– on a test site on a subsystem basis;

– in situ as a system at the premises of a RESPONSIBLE ORGANIZATION.

For certain ME SYSTEMS, testing on a test site or on a subsystem basis is deemed to be very difficult. ME SYSTEMS (e.g. large X-ray equipment and particle therapy systems) requiring ceiling installation or of equipment that needs to be placed in different locations such as examination rooms, technical rooms and control rooms, cannot be installed in today's test sites due to the size or installation requirements. Note that "large" in this context is defined in this collateral standard to mean ME EQUIPMENT and ME SYSTEMS that cannot fit within a 2 m × 2 m × 2,5 m volume in any orientation (see 3.12 and 3.13).

Testing on a subsystem basis requires the simulation of physical behaviour of the replaced system, which is also deemed to be technically very difficult and sometimes impossible without a representative configuration.

In situ testing – testing at the place of installation – as a system at a RESPONSIBLE ORGANIZATION (i.e. a hospital or individual clinic) often requires a certification/approval before shipment to the facility.

The ME SYSTEM might be in use and might not present the maximum configuration. To operate the device in the modes and settings that are most likely to result in an unacceptable RISK might not be allowed by the RESPONSIBLE ORGANIZATION due to the potential for damage to the ME SYSTEM.

Moreover, BASIC SAFETY and ESSENTIAL PERFORMANCE needs to be verified according to the MANUFACTURER's specification and requires specific operating modes and auxiliary equipment that might not be available or authorized in situ.

At the MANUFACTURER's premises, the equipment used to provide input to, and monitoring of, the EUT is likely to be fully available and testing in representative configurations is usually possible. Testing at the MANUFACTURER's premises could fulfil the operational mode requirements of this subclause.

Furthermore, at the MANUFACTURER's premises, all necessary components, service support and knowledge of maintenance is in place, as well as protection requirements (e.g. to protect the environment and personnel).

Comparing the limitations as described in this subclause against the advantages of testing at the MANUFACTURER's premises, the latter could be considered equal to in situ testing. In such cases, good EMC practice regarding the measurement needs to be maintained, and if the applicable basic EMC standards allow in situ testing, the requirements in the basic EMC standards will take precedence. Additionally, a rationale to explain why testing the ME EQUIPMENT or ME SYSTEM on the MANUFACTURER's premises is justified should be provided in the test plan and documented in the test report.

Subclause 8.9 – IMMUNITY TEST LEVELS

b) Environments

Replace, in the existing second paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

c) IMMUNITY TEST LEVEL determination

Replace, in the existing second paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

Subclause 8.10 – IMMUNITY to proximity fields from RF wireless communications equipment

Delete the existing fourth and fifth paragraphs.

Replace the existing second-to-last paragraph with the following new paragraph:

The IMMUNITY TEST LEVELS specified in Table 9 were calculated using the maximum power shown in Table A.3, an assumed separation distance of 0,3 m, and the following equation:

Add, following the existing last paragraph, the following table and text:

Table A.3 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency MHz	Band [a] MHz	Service [a]	Maximum power W	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	1,8	27
450	430 to 470	GMRS 460, FRS 460	2	28
710	704 to 787	LTE Band 13, 17	0,2	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	2	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	2	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	0,2	9
5 500				
5 785				

[a] For some services, only the uplink frequencies are included.

Subclause 8.11 – IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

This requirement was added due to concerns about the RISKS associated with fields radiated by a wide variety of sources in both the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT. ME EQUIPMENT can contain electronic components and circuitry that are sensitive to radiated magnetic fields from these sources.

The procedure for determining the applicability of the proximity magnetic fields IMMUNITY test and the testing required are shown in Figure A.3. In general, this subclause applies to all ME EQUIPMENT and ME SYSTEMS. However, due to the fact that the sources of magnetic fields considered for this subclause are proximity sources, appropriate exemptions from testing are specified. Even if this test is not performed, there are requirements for documentation of the choices/decisions made. It should be noted that MANUFACTURERS are permitted to bypass these exemptions and conduct the tests if they so choose.

Exemptions

The first of three exemptions (see 8.11 a)) is where the ME EQUIPMENT or ME SYSTEM does not contain (i.e. within the ENCLOSURE or as part of an attached ACCESSORY) magnetically sensitive components or circuitry.

For the purposes of this subclause, magnetically sensitive components are those components that are either designed to sense magnetic fields or are likely to be influenced as a result of the fields specified in this subclause while in close proximity to the sources. Examples include but are not limited to coils, signal transformers, and hall-effect sensors.

Magnetically sensitive circuitry includes but is not limited to those circuits where voltages induced into wiring or the interconnect structure might alter the intended function of the circuit. Examples of such circuits are:

– an analogue signal processing circuit whose passband is within the frequency range specified in this subclause and where the area enclosed by any interconnecting pathways is such that the induced voltage can interfere with signals of interest.
– digital circuits where the induced voltage in an interconnect pathway approaches the logic threshold of the devices.
– an external pacemaker system, where the leads attached to temporarily implanted heart wires form a loop whose area is sufficient to result in an induced voltage comparable to the ECG signals being sensed from the heart.

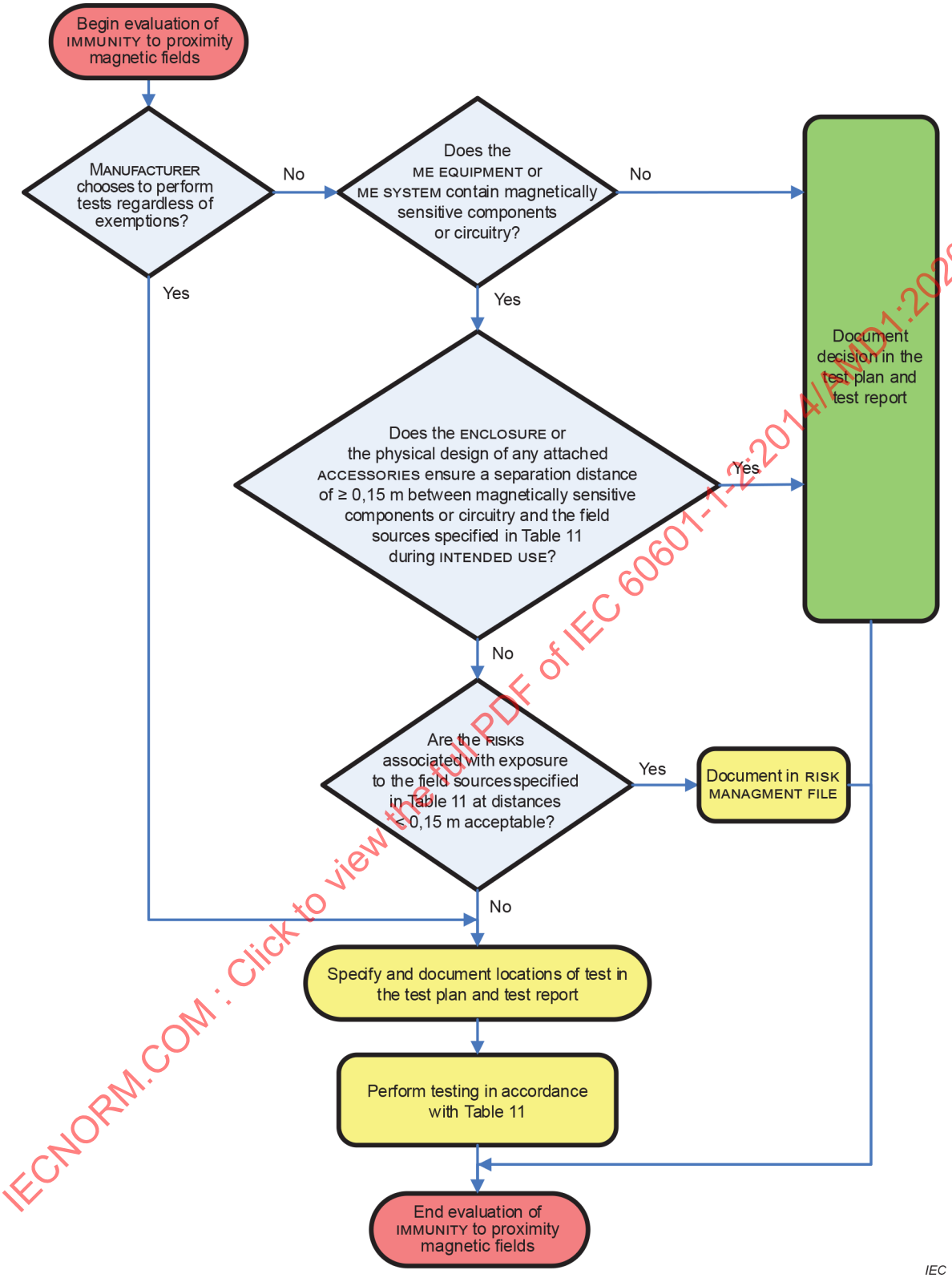

Figure A.3 – Steps for evaluation of IMMUNITY to proximity magnetic fields

The second exemption (see 8.11 b)) specified by this subclause is allowed when the ME EQUIPMENT or ME SYSTEM or an attached ACCESSORY does contain magnetically sensitive components or circuitry but these components or circuits are mounted behind the surface of the equipment ENCLOSURE (or the ENCLOSURE or other physical barrier associated with an attached ACCESSORY) such that during INTENDED USE a minimum separation distance from the sources of proximity magnetic fields specified in Table 11 is ensured. For the purposes of this collateral standard, this minimum separation distance is considered to be a “proximity threshold”, and a value of 0,15 m was assigned to it. To establish the “proximity threshold”, SC 62A considered the types of proximity magnetic field DISTURBANCE sources expected:

– induction cooking appliances and ovens operating at frequencies up to 30 kHz;
– RFID readers operating at both 134,2 kHz and 13,56 MHz;
– electronic article surveillance (EAS) systems;
– sponge detection systems;
– equipment used for position detection (e.g. in catheter labs);
– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.

These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of this collateral standard. All of these sources (with the exception of wireless charging for electric vehicles) generally use coils that are small in diameter. RFID readers operating at 134,2 kHz use coils with a radius of about 0,06 m, and those operating at 13,56 MHz use coils with a radius of about 0,02 m.

The magnetic field along the axis of a “thin” coil relative to the maximum field at its centre is approximated by:

$$\frac{B(x)}{B(0)} = \frac{1}{(1+a^2)^{1,5}}$$

where

$a = \frac{x}{r}$;

x is the distance from the centre of the coil along the coil axis;

r is the radius of the coil.

Figure A.4 illustrates the field decay characteristics of coils having radii up to 0,06 m.

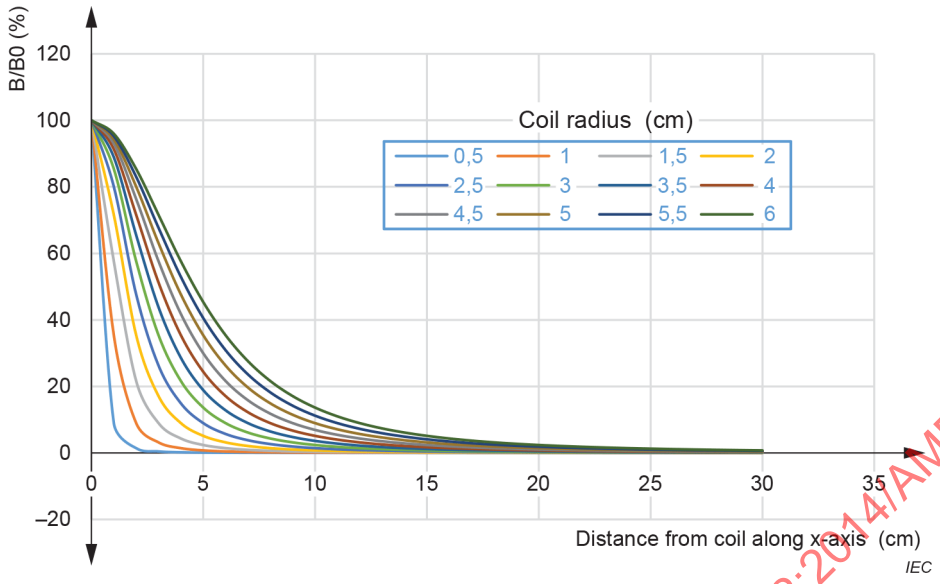

Figure A.4 – Magnetic field roll-off characteristics along the x-axis for a thin planar coil and various coil radii

This shows that at a distance of 0,15 m, the magnetic field for all coil radii up to 0,06 m has decayed to 5 % or less of the maximum field. In order to assess the impact of these reductions in field amplitude upon a receiving circuit, analysis of the field characteristics and coupling coefficients between two coils according to [50] was undertaken. The induced voltage in a single-turn coil of the same radius as the transmit coil was then estimated using Faraday's law and the coupling coefficients. The results of this analysis are shown in Figure A.5 and Figure A.6. It can be seen from these results that at a separation distance of 0,15 m, the induced voltage from an RFID reader operating at 134,2 kHz in a loop of wire with diameter of 0,12 m is approximately 45 mV peak-to-peak. Similarly, a 13,56 MHz RFID reader will induce approximately 300 µV peak-to-peak in a loop of diameter 0,04 m. The low levels determined by these calculations provide adequate justification for a "proximity threshold" of 0,15 m.

The coil sizes associated with wireless electric vehicle charging, while larger than analysed above, are not of concern because these systems employ protection mechanisms that prohibit approach closer than distances of the order of 1 m.

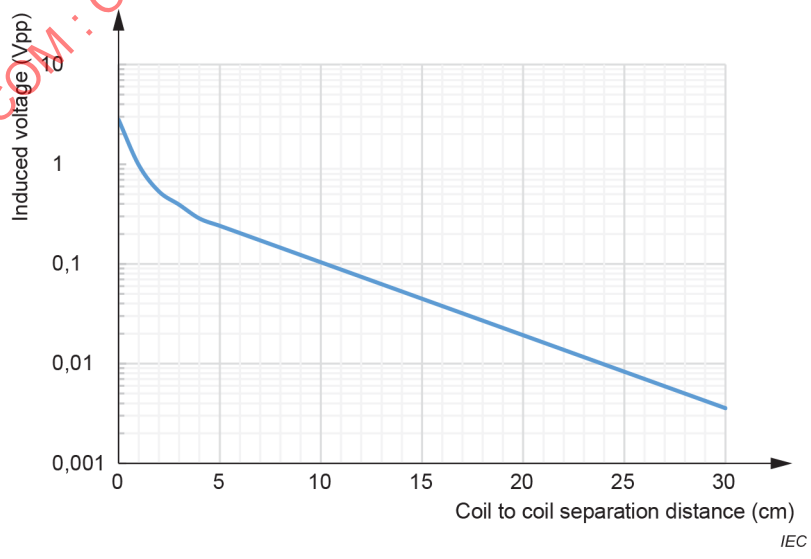

Figure A.5 – Voltage induced in a 1-turn, 6 cm radius coil by a 6 cm radiating coil operating at 134,2 kHz and H_0 of 82,65 A/m (r.m.s.)

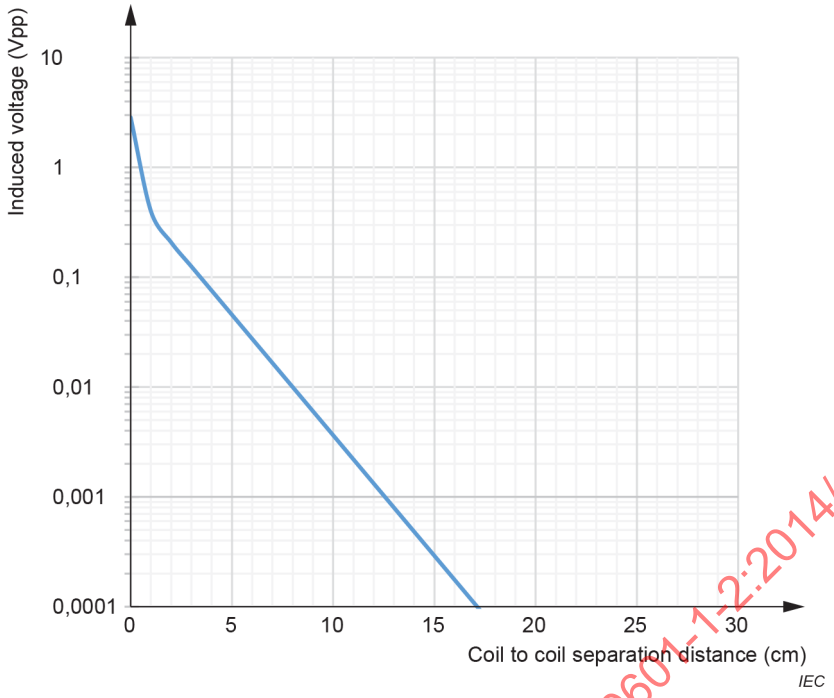

Figure A.6 – Voltage induced in a 1-turn, 2 cm radius coil by a 2 cm radiating coil operating at 13,56 MHz and H_0 of 7,5 A/m (r.m.s.)

Where neither of the exemptions specified in a) or b) are applicable, 8.11 introduces an option (see 8.11 c)) for the MANUFACTURER to perform a RISK ANALYSIS when it is known that exposure of magnetically sensitive components or circuitry with separation distances less than 0,15 m during INTENDED USE might be possible. Where the RISKS are determined to be acceptable, following documentation of the assessment in the RISK MANAGEMENT FILE, further testing for IMMUNITY to proximity magnetic fields at the frequencies specified is not necessary. If the RISKS are found to be unacceptable, or if the MANUFACTURER chooses to perform testing regardless of the exemptions or RISK ANALYSIS option, then testing proceeds according to 8.11 d).

Test levels, frequencies, and modulations

The test specifications are not intended to cover every frequency and application used in every country. The concept of testing at just a few frequencies as opposed to sweeping over a range of frequencies is predicated on the assumption that the inductive coupling into the ME EQUIPMENT within the scope of this subclause is non-resonant. Under this assumption, it only becomes necessary to test using the highest known frequency of the known emitter types. SC 62A intentionally limited the scope of frequencies for this subclause to align with the minimum test frequency of IEC 61000-4-39. For this reason, emitters operating below 9 kHz are not considered.

In the frequency range 9 kHz to 150 kHz, SC 62A considered the RISKS primarily from induction cooking appliances and the emerging sources of wireless power transfer used to charge electric vehicles. There are many operating frequencies for induction cooking appliances, but SC 62A chose the single, highest known operating frequency (30 kHz) to simplify the testing. The test level for this frequency was chosen based upon reference [45]. This test is applicable to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT, as exposure to the noted sources is not expected in the professional healthcare facility environment.

With respect to electric vehicle charging, SC 62A considered emerging standards for these systems from the Society of Automotive Engineers (SAE) and the IEC. The operating frequencies range from approximately 50 kHz to over 100 kHz and the magnetic fields are CW. The field strengths outside of the vehicles are not expected to exceed 12 A/m. This exposure level is less than that expected from pulsed magnetic sources such as electronic article surveillance (EAS) and RFID systems. Therefore, until further information becomes available, no emitter-specific test for electric vehicle charging at frequencies below 100 kHz is specified. Instead, the test at 134,2 kHz is used as a surrogate test for disturbances associated with electric vehicle charging.

SC 62A recognizes that other forms of wireless power transfer have recently been deployed or are in development (e.g. for charging of portable electronic devices (PEDs)). However, the HAZARDS associated with the potential DISTURBANCES due to this type of equipment have not yet been evaluated at the time of publication.

The HAZARDS associated with exposure to EAS and RFID equipment at 134,2 kHz and 13,56 MHz are addressed in 8.11. The IMMUNITY TEST LEVELS specified for these technologies were based upon reference [44]. For RFID equipment operating at 134,2 kHz, the test level in [44] was established by measurement of magnetic field EMISSIONS from RFID readers at a distance of 0,025 m. The analysis of induced voltage in Figure A.5 uses a field strength of 82,6 A/m as the maximum, which is the 65 A/m IMMUNITY TEST LEVEL specified in Table 11, extrapolated to a distance of 0 m. For similar equipment operating at 13,56 MHz, the test level was measured in contact with the equipment (no separation). These test levels are considered adequate to cover any other known sources in the frequency range 134 kHz to 13,56 MHz.

All test levels specified in this subclause are based on equipment standards or other source-based references. Levels associated with human exposure standards such as those published by ICNIRP or IEEE are not used because they were not developed with regard to IMMUNITY of ME EQUIPMENT or ME SYSTEMS.

The modulation type and rates shown in Table 11 for 134,2 kHz and 13,56 MHz were chosen as surrogates for the multiplicity of actual modulations associated with commercial RFID equipment. The test modulations are considered to be an adequate challenge to the ME EQUIPMENT within the scope of the tests, while at the same time avoiding the need for complex signal generation equipment.

Annex F – RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES

Replace the existing annex with the following new annex:

Annex F
(informative)

Guidance on the application of RISK MANAGEMENT with regard to ELECTROMAGNETIC DISTURBANCES in this collateral standard

Annex F provides specific guidance for those subclauses of this collateral standard that involve aspects of RISK MANAGEMENT. In general, this collateral standard requires the MANUFACTURER to analyse, evaluate and apply RISK CONTROLS as part of an effort to achieve BASIC SAFETY and ESSENTIAL PERFORMANCE. The tests in this collateral standard are only one form of RISK EVALUATION.

The users of this collateral standard are reminded that particular standards IEC 60601-2-xx and ISO/IEC 80601-2-xx can include RISK MANAGEMENT requirements that could supersede (replace) those provided in this collateral standard.

NOTE 1 This collateral standard does not address how to incorporate into the design of a product RISK CONTROLS for RISKS arising from ELECTROMAGNETIC DISTURBANCES. Reference [8] provides guidance on this topic. In addition, SC 62A is developing a technical report in the IEC 60601-4-x series on RISK CONTROL with regard to ELECTROMAGNETIC DISTURBANCES.

Table F.1 lists the subclauses in this collateral standard that include RISK MANAGEMENT as part of normative requirements. Guidance is provided for these subclauses when applying RISK MANAGEMENT activities while considering the RISKS related to ELECTROMAGNETIC DISTURBANCES.

A view of the relationship between this collateral standard and ISO 14971:2019 in the form of a flowchart is provided in Figure F.1. Another useful example of the relationship between the PROCESS described in ISO 14971 and HAZARDS/HAZARDOUS SITUATIONS identified in IEC 60601-1 is provided in Figure E.1 of ISO/TR 24971:2020 [48].

NOTE 2 Subclause 3.108 of IEC 60601-1:2005+A1:2012+A2:2020 specifies the contents of the RISK MANAGEMENT FILE.

Table F.1 – Specific guidance for subclauses of this collateral standard that reference RISK MANAGEMENT *(1 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in the RISK MANAGEMENT PROCESS. NOTE 1 Annex F provides additional guidance on taking ELECTROMAGNETIC DISTURBANCES into account in the RISK MANAGEMENT PROCESS. NOTE 2 This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the design and realization of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities. *Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.*	This RISK MANAGEMENT PROCESS is intended to identify whether the normative requirements specified in this collateral standard address the RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES in the environments where the ME EQUIPMENT or ME SYSTEM is intended to be used. An example of reasonably foreseeable ELECTROMAGNETIC DISTURBANCES not covered by this collateral standard is EMISSIONS from 5G mobile phones. This equipment might affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of ME EQUIPMENT or ME SYSTEMS.

Table F.1 *(2 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
4.2 Non-ME EQUIPMENT used in an ME SYSTEM In addition to 16.1 of the general standard: – 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. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard.*	The RISK MANAGEMENT FILE needs to show the results of RISK ANALYSIS that leads to a determination of whether the non-ME EQUIPMENT is involved in any way with the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. If the non-ME EQUIPMENT is not tested in accordance with this collateral standard, there needs to be OBJECTIVE EVIDENCE (i.e. an EMC test report) showing that the non-ME EQUIPMENT meets its applicable requirements. For example, ITE used in conjunction with the ME SYSTEM needs to conform with CISPR 32 and CISPR 35 [49].
4.3 General test conditions **4.3.1 Configurations** ME EQUIPMENT and ME SYSTEMS shall be tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. (other text omitted) *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The RISK MANAGEMENT FILE needs to show how the configurations to be tested were determined (i.e. experience, engineering analysis, or pretesting). Where the ME EQUIPMENT or ME SYSTEM has only one configuration, there should be a comment in the RISK MANAGEMENT FILE stating this. An example is an ultrasound system designed to work with several families of probes. The MANUFACTURER could select one probe from each family of probes as individual configurations for test. In this case, the RISK MANAGEMENT FILE would include justification for why the selected probe was representative of all other probes in a given family.
5.2 ACCOMPANYING DOCUMENTS **5.2.1 Instructions for use** **5.2.1.1 General** In addition to the requirements of 7.9.2 of the general standard, the instructions for use shall include the following: a) a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF SHIELDED ROOM of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.	If there are excluded environments as determined by RISK ANALYSIS, they need to be stated in both the instructions for use and the RISK MANAGEMENT FILE. For example, a statement in instructions for use could exclude the use of the ME EQUIPMENT or ME SYSTEM in the presence of active HF SURGICAL EQUIPMENT.

Table F.1 *(3 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS **8.1 General** (other text omitted) **Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal** If any equipment is damaged, it can continue to be used for the IMMUNITY test for this specific phenomenon, as long as it can be proven (e.g. by RISK MANAGEMENT, engineering analysis, experience, redundancy) that the ability of the ME EQUIPMENT or ME SYSTEM to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE can still be determined while using the damaged equipment. (other text omitted) Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE. IMMUNITY pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable RISK. (other text omitted)	RISK MANAGEMENT is applied generally in this subclause in three areas: 1) As one of several optional means to determine whether or not equipment that is being tested and subsequently damaged can continue to be used for testing. 2) Determination of pass/fail criteria when the criteria have not been provided in an applicable part two standard. 3) Provision of feedback to the RISK MANAGEMENT PROCESS concerning any effects that might be observed during testing. When RISK MANAGEMENT is used to determine any of the pass/fail criteria, the RISK MANAGEMENT FILE needs to document that this was done. If justified, Annex E is used to determine the IMMUNITY TEST LEVELS. Also see 4.1 of this table. Upon completion of testing, the effects observed need to be evaluated to determine if there is a clinical impact that could lead to unacceptable RISK. Depending on the outcome of the review, additional RISK mitigations might be required for the ME EQUIPMENT or ME SYSTEM.
Following the tests, any effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES should be considered in the on-going RISK MANAGEMENT PROCESS. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report for inclusion of the pass/fail criteria and by application of the tests specified in Table 4 through Table 9 and 8.11, as applicable. If the ME EQUIPMENT or ME SYSTEM meets its specified IMMUNITY pass/fail criteria before, during and after these tests and the compliance tests of the individual subclauses of this clause are met, then compliance with Clause 8 is verified.*	

Table F.1 *(4 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8.5 Subsystems Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed. Any simulator used instead of actual equipment shall properly represent the electrical and, if necessary, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types. *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The citation of RISK MANAGEMENT in this subclause means that the MANUFACTURER'S knowledge of how the ME SYSTEM operates can be used to determine if normal operating conditions can be simulated. Note that normal operating conditions are, for the purposes of this subclause, defined as at least the simulation of representative electrical, mechanical, RF signals, impedances and cables and their configurations. See Annex A for further explanation regarding this subclause. The decision to perform subsystem-level testing should be documented in the RISK MANAGEMENT FILE.
8.7 Operating modes During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL PERFORMANCE shall be tested in the modes and settings (e.g. gain) that are most likely to result in an unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. If the ME EQUIPMENT or ME SYSTEM is not RATED for continuous duty, a duty cycle may be selected that is appropriate for the ME EQUIPMENT or ME SYSTEM under test. The standby mode should be considered for inclusion in IMMUNITY testing, particularly for ME EQUIPMENT and ME SYSTEMS that are in standby mode for long periods of time in the presence of PATIENTS or OPERATORS. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report.*	For ME EQUIPMENT and ME SYSTEMS that have multiple modes of operation or operational settings, the MANUFACTURER needs to first determine the specific set of modes and settings that will be used during testing. The choice of these modes and settings is made by identifying which are most likely to result in an unacceptable RISK (loss of BASIC SAFETY or ESSENTIAL PERFORMANCE) as a result of the applied ELECTROMAGNETIC DISTURBANCE. RISK ANALYSIS is one option to make the choice, but regardless, the choices made and rationale for them should be documented in the RISK MANAGEMENT FILE.
8.8 Non-ME EQUIPMENT Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The citation of RISK MANAGEMENT in this subclause means that the MANUFACTURER's knowledge of how the ME SYSTEM operates can be used to determine if testing of the non-ME EQUIPMENT is required according to 4.2.

Table F.1 *(5 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8.9 IMMUNITY TEST LEVELS (other text omitted) When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11, the MANUFACTURER shall take this into consideration in the RISK MANAGEMENT PROCESS. Annex E may be used to determine IMMUNITY TEST LEVELS for environments or phenomena not specified in Table 4 through Table 9 and 8.11 and, when justified, to adjust the specified IMMUNITY TEST LEVELS based on e.g. mitigations or conditions of INTENDED USE. If this determination or adjustment is made, the following information should be documented in the test plan, as specified in Table G.1, and shall be documented in the RISK MANAGEMENT FILE and in the test report, as specified in Table 10: a) justification for any SPECIAL ENVIRONMENTS identified or adjustments made; b) the adjusted reasonably foreseeable maximum EM DISTURBANCE levels; c) the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit; d) details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS. If mitigations are used to justify lower IMMUNITY TEST LEVELS, the RISK MANAGEMENT FILE shall include documentation explaining how it can be reasonably expected that the mitigations will continue to be effective over the EXPECTED SERVICE LIFE in all locations in which the ME EQUIPMENT or ME SYSTEM is expected to be used. In all cases, the IMMUNITY TEST LEVELS used should be documented in the test plan (see Annex G) and shall be documented in the test report (see Clause 9). *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	When the environment of INTENDED USE is known to alter the reasonably foreseeable EM DISTURBANCE levels specified in this collateral standard, this knowledge needs to be incorporated into the RISK MANAGEMENT PROCESS. Specifically, this information might affect the determination of IMMUNITY TEST LEVELS, which might be increased or decreased, according to Annex E. The MANUFACTURER needs to ensure that all choices and justifications for them are documented in the RISK MANAGEMENT FILE. Most importantly, it needs to explain how any mitigations applied or assumed can be reasonably expected to remain effective over the EXPECTED SERVICE LIFE, and in all locations of INTENDED USE, for the ME EQUIPMENT or ME SYSTEM. For example, if the MANUFACTURER assumes that the ME EQUIPMENT or ME SYSTEM will be used in a controlled humidity environment where the reasonably foreseeable ESD DISTURBANCE level (and the corresponding IMMUNITY TEST LEVEL) are reduced, then the RISK MANAGEMENT FILE needs to explain why the controlled humidity environment can be expected to be maintained and the ME EQUIPMENT or ME SYSTEM will only be used in that environment over its EXPECTED SERVICE LIFE.
Table 4 – ENCLOSURE PORT Table footnotes: c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Table 4, table footnote c), provides the option to perform the radiated RF swept test using modulations other than those given in the table. The alternative modulation frequencies would be determined by a RISK ANALYSIS. For example, if the MANUFACTURER knows that their ME EQUIPMENT or ME SYSTEM is particularly sensitive to a specific modulation frequency or range of frequencies, they might choose to use these instead of or in addition to those specified in Table 4 as they could be the highest RISK modulations.

Table F.1 *(6 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
Table 5 – Input a.c. power PORT *(1 of 2)* Table footnotes: e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 6 – Input d.c. power PORT Table footnotes: e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 7 – PATIENT coupling PORT Table footnotes: a), fourth indent Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 8 – SIP/SOP PORT Table footnotes: c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
8.10 IMMUNITY to proximity fields from RF wireless communications equipment (other text omitted) The frequencies and services listed in Table 9 are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 9. (other text omitted) The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance.	For this subclause, RISK MANAGEMENT is used in two ways: 1) To identify communications services that might be encountered in the environment of INTENDED USE and that are not listed in Table 9. The RISK ANALYSIS needs to consider whether these services present a RISK, and if so, they should be documented in the RISK MANAGEMENT FILE and incorporated into the test plan. An example of this would be services for 5G mobile phones. 2) To identify whether the environment(s) of INTENDED USE for the ME EQUIPMENT or ME SYSTEM will routinely allow for exposure to RF wireless communications equipment at separation distances less than 0,3 m. The RISK ANALYSIS would determine a different reasonably foreseeable minimum separation distance and adjust the IMMUNITY TEST LEVELS (higher) to account for this scenario.
8.11 IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz (other text omitted) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, the tests of Table 11 need not be performed.	For this subclause, if the exemptions of 8.11 a) and b) do not apply, then a RISK ANALYSIS can be performed to determine if this test is necessary.