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IEC 60601-1-2
EDITION 4

NEW REQUIREMENTS FOR MEDICAL EMC

Products & Retail White Paper

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INTRODUCTION

In recent years, society has become more and more reliant on electronic devices, be they smartphones for communication or medical equipment performing vital functions for people's health. The US Centers for Disease Control and Prevention (CDC) reported that in 2013, 4.9 million individuals were receiving home healthcare[1]. In addition, The Pew Research Center reported that as of 2017, 95% of American adults own a cell phone, 77% of which own a smart phone. Furthermore, approximately 20% own an e-reader and nearly 50% own a tablet computer[2].

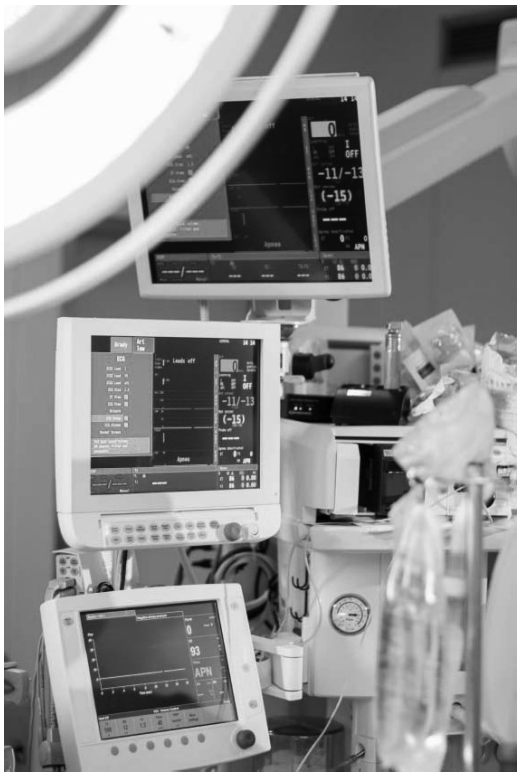
The prevalence of electronic devices in the world today emphasizes the need for medical electrical (ME) equipment and systems to achieve essential performance and maintain basic safety without electromagnetic interference (EMI) from other electronic equipment. A ventilator malfunctioning, a defibrillator activating unexpectedly, or an alarm failing to sound are all examples of issues that can arise with EMI and result in potential harm to a patient.

Faced with this reality, it is imperative that developers and manufacturers of ME equipment and systems consider electromagnetic compatibility (EMC) in the design of their products to ensure that they operate with essential performance and basic safety in all environments.

The International Electrotechnical Commission (IEC) standard 60601-1-2:2014 applies to "the basic safety and essential performance of medical electrical (ME) equipment and ME systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by ME equipment and ME systems." The US Food and Drug Administration (FDA), Health Canada, and the European Union (EU) have established December 31, 2018 as the deadline for compliance with this standard.

To offer guidance on the changes within the 4th edition standard, this white paper provides detailed information on the changes to the standard, the risk management file (RMF), test planning, and testing requirements, as well as a roadmap for its implementation in markets throughout the world.

4TH EDITION VS. 3RD EDITION



IEC 60601-1-2 is a collateral standard to IEC 60601-1, which is the general standard for basic safety and essential performance of ME equipment and systems. The 60601-1-2 standard applies specifically to EMC. The changes in the 4th edition of the standard include: new environments of intended use, new requirements of risk management and test planning, and more stringent testing for emissions and immunity.

Because it is no longer feasible to expect devices with transmitters to be excluded from certain environments, the 4th edition establishes new environments of intended use where ME equipment and systems could be used and EMI could impact performance. The updated standard requires developers to think about the kinds of EMI that could occur not only in a professional healthcare facility, but also in the home, in an automobile, on a plane, or any other locations where ME equipment and systems could come into contact with other electronic devices.

As has been the case in previous editions of IEC 60601-1-2, compliance with the 4th edition requires demonstrating basic safety and essential performance related to EMC. When developing devices, the important criteria to assess, particularly with regard to EMC, is the basic functions of the device, the device's essential performance, and how to determine that the device is performing correctly and maintaining basic safety relative to EMC. Establishing these criteria early in the development process is crucial to ensuring that ME equipment and systems are compliant with the 4th edition.

Herein, we will examine each of these changes more closely and provide detailed information on 4th edition requirements for EMC testing of ME equipment and systems.

ENVIRONMENTS OF INTENDED USE

The first major change within the 4th edition is the elimination of the life-supporting equipment category for ME equipment and systems. In the past, equipment and systems were classified as either life-supporting or non-life-supporting, with the 3rd edition defining life-supporting ME equipment and systems as:

"Including at least one function that is intended to actively keep alive or resuscitate patients and the failure of which to comply with the requirements of 6.2.1.10 is likely to lead to serious injury or death of a patient."

This definition often created uncertainty of what truly was and was not life-supporting, leading the IEC to eliminate the category altogether. Furthermore, in previous versions of the standard, equipment and systems had been classified only in professional healthcare facility environments, since ME equipment and systems were used primarily in those locations. The elimination of the life-supporting category and the regular use of ME equipment and systems outside of professional healthcare facilities led the IEC to establish environments of intended use for ME equipment and systems, divided into three categories:

- The professional healthcare environment includes hospitals, physicians' offices, surgical centers, and limited care facilities, where equipment and systems are administered by healthcare professionals.

- The home healthcare environment includes locations such as homes, schools, churches, restaurants, hotels, cars, and airplanes, where equipment and systems are less likely to be administered by healthcare professionals.

- Special environments include military areas, oil and gas refineries, automotive and appliance manufacturing facilities, or heavy industrial areas.

Given that the home healthcare and special environments are so wide-ranging, there may be some overlap between the two. For each of these environments, it is important to bear in mind the level of control for the equipment allowed within them. The professional healthcare environment for instance allows some level of control as to other devices allowed within it, whereas in the home healthcare and special environments there is less control over the types of devices being used in proximity to ME equipment or systems. This should be taken into consideration when designing products used in those environments and when identifying the environments where equipment is intended to be used, which is required to be included in the RMF.

RISK MANAGEMENT FILE (RMF)

The RMF is perhaps the most important document in the entire process, since it demonstrates that the manufacturer understands the device, its functions, essential performance, and basic safety as it relates to EMC, as well as what is necessary for compliance with IEC 60601-1-2.

One of the most significant changes in the 4th edition is the requirements placed on the RMF. Although the 2nd and 3rd editions of the standard implied that risk analysis and risk management were measures that should be taken prior to testing, they did not offer any specific instruction as to what information was required. As a result, RMFs fell short in many cases with regard to assessing EMC.

It is critical that manufacturers know the functions and essential performance of their devices, and include that information in the RMF. The 4th edition places greater emphasis on making certain that all of the required risk analysis, risk management, and test planning information are included in the RMF and submitted prior to testing.

Requirements placed on the RMF include:

- Specific and detailed immunity pass/fail criteria for basic safety and essential performance related to EMC.
- Determination as to how the device will be monitored to demonstrate compliance with established pass/fail criteria.
- Immunity pass/fail criteria that specify acceptable degradations that do not result in unacceptable risk.
- Documentation and justification for any cause for increased or decreased testing levels.
- Justification for the environment category chosen for the device, as well as a determination of whether the device is life-supporting.

A thorough, well done RMF will demonstrate an understanding of the functions and basic safety of the equipment or system, and serve as a major step to ensuring compliance with the 4th edition.

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INFORMATION TO USER

The 4th edition requires that instructions for use include the intended environment, exclusions for that environment, and a description of the essential performance and user expectations during loss of performance. There must also be a safe distance warning and a Class A device warning on such equipment. The technical description must include compliance for each EMC test, all deviations, and all necessary instructions for maintaining basic safety and essential performance for the expected service life of the device.

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TEST PLAN

In addition to new risk management requirements, the 4th edition also requires that a test plan based on the RMF be developed and submitted to the test laboratory prior to testing. The test plan is the materialization of the assessments made and criteria established during the risk analysis and risk management process. The RMF should be reflected within the test plan and include intended use, intended environments, test levels, and immunity pass/fail criteria, among other information.

The tables below illustrate Annex G of the IEC 60601-1-2 4th edition standard, which includes all of the information required in an EMC test plan and additional details on certain requirements.

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EMC TEST PLAN REQUIREMENTS

No.	Item	Additional Detail
1	Name and address of the test facility	
2	Description of the ME EQUIPMENT or ME SYSTEM	Describe all devices, racks, modules, boards, cables, etc. belonging to the ME EQUIPMENT or ME SYSTEM
3	Description of the BASIC SAFETY and ESSENTIAL PERFORMANCE including a description of how the BASIC SAFETY and ESSENTIAL PERFORMANCE will be monitored against the pass/fail criteria during each test	
4	Identification of the ME EQUIPMENT or ME SYSTEM	Include device name and model number
5	ME EQUIPMENT or ME SYSTEM software/firmware version of the sample to be tested	
6	Number of samples to be tested	The number of samples for each EMC test
7	INTENDED USE and intended environments	
8	Applicable standards and test methods	A list of the standards (with dates) and EMISSIONS limits or IMMUNITY TEST LEVELS
9	Deviations from the basic EMC standards or from this collateral standard	Include any instructions needed
10	Applicability/tests that will not be performed	The decision and justification not to perform a measurement or test shall be documented
11	If the procedure specified by Annex E or an equivalent procedure is used: a justification for any SPECIAL ENVIRONMENTS identified or adjustments made; the adjusted reasonably foreseeable maximum EM DISTURBANCE levels; the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit; and details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS	
12	IMMUNITY TEST LEVELS for each IMMUNITY test and EMISSIONS compliance class and group	
13	IMMUNITY pass/fail criteria	Specific IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as per the RISK ANALYSIS (see Annex I)

EMC TEST PLAN REQUIREMENTS		
No.	**Item**	**Additional Detail**
14	ME EQUIPMENT or ME SYSTEM configurations, settings, and operating modes	List by test
15	Test setup electrical and physical diagrams	Show how the ME EQUIPMENT or ME SYSTEM hardware will be configured and connected to the test systems, how cables will be routed and bundled, and disposition of excess cable
16	ME EQUIPMENT or ME SYSTEM power input voltages and frequencies	List by test
17	Earthing configuration	Describe how the ME EQUIPMENT or ME SYSTEM connects to protective earth
18	Whether the ME EQUIPMENT or ME SYSTEM will be tested as table-top or floor-standing equipment, or a combination of the two.	
19	Testing of PERMANENTLY INSTALED LARGE ME EQUIPMENT or LARGE ME SYSTEM	If on-site testing is required, diagram the equipment or system in the location in which it will be installed and describe how testing will be performed.
20	Exercising of signal input/output parts (SIPS/SOPS)	Describe how each SIP/SOP PORT is to be exercised
21	For floor-standing ME EQUIPMENT or ME SYSTEMS, the height of the support	
22	Description of any PATIENT-COUPLED cable terminations to be used	
23	Simulators, accessories, and auxiliary equipment	Describe simulators, ACCESSORIES, and auxiliary equipment used, including PATIENT physiological and subsystem simulation
24	Documentation of any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests	
25	ALARM LIMIT settings	If applicable, provide rationale for the settings chosen
26	Planned electrostatic discharge (ESD) test points	If possible, include a drawing or annotated photo showing the ESD test points
27	Dwell time for each IMMUNITY test requiring a dwell time	

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TEST AC VOLTAGE & POWER FREQUENCY

The table below provides a comparison between the 3rd and 4th edition standards with regard to test AC voltage and power frequency. It should be noted that regulators in countries such as Brazil, Japan, and Korea supersede the established standard for this testing by setting their own voltage and power frequency test requirements.

TEST AC VOLTAGE AND POWER FREQUENCY

Test	3rd Edition	4th Edition
AC Emissions, CISPR 11	Nominal	Any
Radiated Emissions, CISPR 11	Nominal	Any
Harmonics, IEC 61000-3-2	230V/50Hz (sometimes 100V/50Hz and 100V 60Hz) or rated voltage	Rated single voltage or 230V for single-phase; 400V for 3-phase, 50 or 60 Hz
Voltage Fluctuation and Flicker, IEC 61000-3-3	230V/50Hz or rated voltage	Rated single voltage or 230V for single-phase; 400V for 3-phase, 50 or 60 Hz
Electrostatic Discharge, IEC 61000-4-2	Any	Any
Radiated RF Immunity, IEC 61000-4-3	Any	Any
Electrical Fast Transients/Bursts, IEC 61000-4-4	Lowest and highest rated voltage, any frequency	Any
Surge, IEC 61000-4-5	Lowest and highest rated voltage, any frequency	Any
Conducted RF Immunity, IEC 61000-4-6	Any	Any
Power Frequency Magnetics, IEC 61000-4-8	Any voltage, 50 and 60hz	Any voltage, either 50 or 60 Hz
Voltage Dips, Dropouts, and Interruptions, IEC 61000-4-11	Min and max rated voltage, minimum power frequency	If rated voltage range is <25% of lowest rated voltage, any one voltage. Otherwise, lowest and highest rated voltage.

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KEY EMISSIONS TESTING REQUIREMENTS

The 4th edition contains noteworthy changes in terms of new requirements for emissions testing of both professional medical devices and home healthcare devices. Manufacturers and developers should familiarize themselves with these changes prior to 4th edition testing to ensure compliance with the updated standard. It should be noted that the operating modes required for emissions testing are based on the modes that have been determined to maximize emissions, and that active and standby modes should be considered.

Professional Medical Devices

Emissions testing requirements for professional medical equipment state that radiated and conducted radio frequency (RF) emissions must continue to be tested to CISPR 11. However, the 4th edition requires that simple electrical components such as drills, motors, or switches be tested to CISPR 14, and that multimedia equipment test to CISPR 32.

In addition, the 4th edition no longer requires lighting equipment to be tested to CISPR 15. It has also removed the requirement for radiated and conducted RF emissions tests on Type A medical professional devices to be tested to CISPR 11. Professional medical equipment can now meet Class A *or* Class B.

Home Healthcare Devices

Similar to the requirements for professional medical devices, home healthcare devices must conduct radiated and RF emissions testing to CISPR 11. This type of equipment also requires additional testing based on applicable standards for the particular environments where they may be used.

For example, devices that could be used in an aircraft would need to be tested to standards such as ISO 7137, RTCA DO-160, or EUROCAE ED-14. If equipment is intended for use in a vehicle, it must be tested to the CISPR 25 or ISO 7637 automotive EMC standards. It should be noted that any wireless ME equipment or systems must comply with applicable standards for such products, in addition to the ME equipment and systems standards.

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IMMUNITY
TESTING REQUIREMENTS

Immunity testing requirements constitute the most significant change between the 3rd and 4th editions, particularly in terms of radiated RF immunity. The operating modes and settings required for immunity testing are those that are most likely to result in unacceptable risk, as determined by risk analysis, experience, engineering analysis, or pretesting. As with emissions testing, both active and standby modes should be considered for immunity testing.

The sections below provide a side-by-side comparison of the differences between the 3rd and 4th edition for each type of immunity testing, as well as descriptions of the test procedures.

Electrostatic Discharge

For electrostatic discharge testing, the discharges are applied to the patient coupling port, with no connection to an artificial hand or patient simulation. Afterwards, the device is checked for compliance with established pass/fail criteria. On input/output (I/O) ports, contact discharges are applied to the connector shell. For insulated connector shells, air discharges are applied only to the shell and any pins that can be contacted or touched.

ELECTROSTATIC DISCHARGE, IEC 61000-4-2

Test	3rd Edition	4th Edition
Contact Discharges	± 2, 4, 6 kV	± 2, 4, 8 kV
Air Discharges	± 2, 4, 8 kV	±2, 4, 8, 15 kV

Radiated RF Immunity

When testing for radiated RF immunity, consideration must be given to the proximity fields from RF wireless communications equipment, and to special environments. Basic safety and essential performance must be maintained throughout testing; however, the exclusion band for RF receivers applies. The dwell time for testing is based on the settling time of the test system and the adequate time for the device under test to be exercised and affected.

RADIATED RF IMMUNITY, IEC 61000-4-3

Test	3rd Edition	4th Edition
Enclosure	3V/m, life support: 10 V/m 80% AM at 1 kHz or 2hz 80 MHz-2500 MHz	3V/m, home: 10V/m 80% AM at 1 kHz or risk frequency 80 MHz-2700 MHz

Electrical Fast Transients/Bursts

Electrical fast transient/burst testing requires that the artificial hand be attached to all patient-coupled parts, consistent with intended use. It should be noted that any I/O cables shorter than 3m in length are exempt. Although the test level for this test has not changed, the 100 kHz pulse repetition frequency (PRF) was considered more realistic than 5 kHz PRF, bringing about the change to the standard.

ELECTRICAL FAST TRANSIENTS/BURSTS, IEC 61000-4-4

Test	3rd Edition	4th Edition
AC Mains or DC Input	± 2 kV, 5 kHz PRF	± 2 kV, 100 kHz PRF
I/O Ports	± 1 kV, 5 kHz PRF	±1 kV, 100 kHz PRF

Surges

The major change in testing surges is the removal of one of the exemptions for the zero crossing phase angles. Rather than testing to either 0^o or 180^o, the 4th edition requires testing to all four phase angles – 0^o, 90^o, 180^o, and 270^o.

SURGES, IEC 61000-4-5

Test	3rd Edition	4th Edition
AC Mains, Line to Ground	± 0.5, 1, 2 kV	± 0.5, 1, 2 kV
AC Mains, Line to Line	± 0.5, 1 kV	±0.5, 1 kV
DC Input (>3m), Line to Ground	No test	± 0.5, 1, 2 kV
Dc Input (>3m), Line to Line	No test	±0.5, 1 kV
I/O, Line to Ground	No test	±2 kV (outdoor lines only)

Power Frequency Magnetics

Power frequency magnetics testing does not present significant changes, unless the device contains many magnetically sensitive components. This test assumes a minimum distance of 15 cm from the magnetic source. If your device does not contain magnetically sensitive components, you are allowed to waive this test.

POWER FREQUENCY MAGNETICS, IEC 61000-4-8

Test	3rd Edition	4th Edition
Enclosure	3 A/m, 50 and 60 Hz	30 A/m, 50 or 60 Hz

Conducted RF Immunity

The changes to conducted RF immunity testing are similar to those in radiated RF immunity tests. All devices receive a 6V dwell time in the ISM bands, and home healthcare devices receive a 6V RMS dwell in amateur bands. It should be noted that while the standard states that DC ports, I/O ports, and patient-coupled cables shorter than 3m are exempt from testing, the FDA does not accept the 3m exclusion for this particular test. The standard also states that any patient tubes intentionally filled with a conductive liquid are patient-coupled cables and must be tested.

CONDUCTED RF IMMUNITY, IEC 61000-4-6

Test	3rd Edition	4th Edition
AC Mains	3V, life support: 10V ISM 1 kHz or 2 Hz 80% AM 150 kHz – 80 MHz	3V with 6V ISM, home: 6V amateur 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz
DC & I/O & Patient Couples	3V, life support: 10V ISM 1 kHz or 2 Hz 80% AM 150 kHz – 80 MHz	3V with 6V ISM, home: 6V amateur 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz

Voltage Dips, Dropouts, and Interruptions

A notable change for voltage dip, dropout, and interruption testing is the new requirement that the 100% drop for ½ periods be conducted not only for zero crossings, but for every potential part of the sign wave. It also requires that the five second, 100% dropout apply to all phases when testing a multiphase device. The 4th edition also requires that if a manufacturer does not sell an AC to DC converter with a device, they must specify a converter prior to testing and find a converter for testing that meets the established specifications.

VOLTAGE DIPS, DROPOUTS, AND INTERRUPTIONS, IEC 61000-4-11

Test	3rd Edition	4th Edition
Voltage Dips (<16A)	90% dip, 0.5 seconds 0^o and 180^o 60% dip, 5 periods 30% dip, 25 periods	100% drop, 0.5 periods, 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, 315^o 100% dip, 1 period 30% dip, 25/30 periods
Voltage Interruptions (all input current)	>95% drop, 5 seconds	100% drop, 5 seconds

Radiated RF Immunity: RF Wireless Communications Equipment

The table below contains radio devices for manufacturers to consider when testing radiated RF immunity. This is an incomplete list and manufacturers should determine what their devices could be exposed to in realistic usage.

RADIATED RF IMMUNITY, IEC 61000-4-3 RF WIRELESS COMMUNICATIONS EQUIPMENT						
Test (MHz)	Band (MHz)	Service	Modulation	Max Power (W)	Distance (M)	Test Level (V/m)
385	380-390	TETRA 400	Pulse 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	Pulse 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9

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LEGACY PRODUCTS VS. NEW PRODUCT LAUNCHES

The 4th edition will mean different things to legacy products than to new products, and there are steps that manufacturers can take to help guide their decision making process. Conducting pre-test screening of legacy equipment or systems provides the opportunity for assessment of those products and their probability of compliance.

Some manufacturers who have conducted pre-test screening on legacy products have determined that for certain products, compliance with the 4th edition would be cost prohibitive. This has led them to no longer manufacture certain legacy products and move forward with new devices.

GLOBAL IMPLEMENTATION ROADMAP

In January 2014, the final draft of IEC 60601-1-2 Ed 4:2014 was voted on and accepted by a majority of national committees, with the IEC release of the standard following in February 2014. As previously mentioned, the FDA, Health Canada, and the EU have established December 31, 2018 as the deadline for compliance with the 4th edition.

In *Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff*[3], the FDA explicitly recommends testing to the 4th edition **now**; calling attention to the fact that EMI in the home healthcare environment could exceed the default test levels required in the 3rd edition of the standard. The FDA does not currently require legacy products to undergo testing to the 4th edition unless changes are made to the product that would affect compliance.

In the EU, any products manufactured after December 31, 2018 will have to meet the 4th edition standard. ME equipment and systems could, however, still meet the 3rd edition standard if they are manufactured prior to the date of withdrawal for the 3rd edition and imported into the EU. The Asia-Pacific market is currently still accepting the 3rd edition standard for EMC testing.

Under the CB scheme, all versions of the standard including the 4th edition are currently operative, however only certain versions of the standard are being accepted by specific CB Scheme members. Austria, Belgium, France, Germany, Hungary, Singapore, Spain, Sweden, Switzerland, and the US have notified bodies who are accepting the 4th edition.

Although some markets are still accepting the 3rd edition, it is advisable to test now to the 4th edition given that, in time, it will become the standard for EMC testing of ME equipment and systems in all markets throughout the world.

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CONCLUSION

With the compliance deadline for the 4th edition fast approaching, and already being accepted by the FDA, it is crucial for developers and manufacturers of ME equipment and systems to understand these new requirements and what they mean for their products.

Intertek's extensive experience and expertise in EMC testing makes us well-equipped to partner with you in the development of your ME equipment and systems. Intertek's team of talented engineers will guide you through the development process, from the review of your RMF and creation of your test plan, through the testing process and to the launch of the product, all while ensuring that EMC testing is conducted in the fastest and most efficient manner possible.

This process will begin with an Intertek review of your RMF, followed by a working meeting with an Intertek Senior Engineer to develop your test plan. At the end of that meeting, both you and the engineer will sign off on the test plan, putting you on the path to an effective EMC test of your device.

Involving Intertek early in the process will improve your speed to market and ensure that you have taken the correct measures to ensure that your device will be compliant with the IEC 60601-1-2 4th edition standard.

CITATIONS

[1] US Centers for Disease Control and Prevention, 2013
[2] Pew Research Center, 2017
[3] US Food and Drug Administration, 2014

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