

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
**Electromagnetic Compatibility (EMC) of Medical Devices –
Guidance for Industry and Food and Drug Administration Staff
(For In Vitro Diagnostic (IVD) Submissions)**

February 2, 2023

Electromagnetic Compatibility (EMC) of Medical Devices - Guidance for Industry and Food and Drug Administration Staff

For In Vitro Diagnostic (IVD) Submissions

Seth J. Seidman

EMC Program Advisor

Division of Biomedical Physics

Office of Science and Engineering Laboratories

Alberto Buenaventura

Scientific Reviewer

Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics (OHT7)

**Center for Devices and Radiological Health
U.S. Food and Drug Administration**

Final Guidance

- **Electromagnetic Compatibility (EMC) of Medical Devices, issued on June 6, 2022**
 - www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices

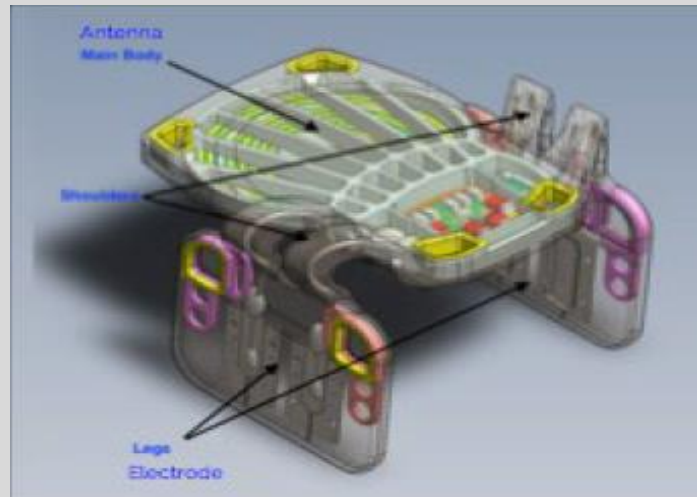
Learning Objectives

- Describe the purpose and scope of the final guidance
- Describe the recommended EMC information for premarket submissions, specifically for IVDs
- Describe an example of how to apply EMC recommendations for an IVD submission

Purpose and Scope

Scope of Final Guidance

- Applies to medical devices, including IVD products, and accessories that:
 - are electrically powered; or
 - have functions or sensors that are implemented using electrical or electronic circuitry.



Implementation Dates

- **August 5, 2022 for all device types, except IVDs**
 - FDA implemented this guidance 60 days after issuance for device types within the scope of this guidance, excluding IVDs
- **June 6, 2023 for IVDs**
 - FDA recognizes and anticipates that the Agency and industry might need up to 1 year to perform activities to operationalize the policies within the guidance for IVDs

Summary of Changes from 2016 EMC Guidance

- Added more substance and clarity, including for IVDs
- Organized to follow eSTAR/SMART
- Specified gaps in recognized standards
 - IEC 60601-1-2 is a safety standard and has no performance/effectiveness requirements
 - Recommendation for testing in both mains and battery modes of operation
 - Recommendations for common electromagnetic (EM) emitters not addressed in standards

EMC Information for Premarket Submissions

EMC-Related Device Characteristics and Intended Use Environments



- Device overview
 - Functions/modes, cables, accessories
- Description of the power supply
 - Mains-powered (i.e., AC) or internally powered (e.g., battery)
- Intended use environments
 - Professional healthcare facility environment
 - Home healthcare environment
 - Special environment
- Wireless technology used

Appendix A – Examples of Typical Medical Device Locations within Intended Use Environments



Professional Healthcare Facility Environment	Home Healthcare Environment	Special Environment
<ul style="list-style-type: none"> • Physician offices • Outpatient facilities • Dental offices • Clinics • Nursing homes • Hospital facilities including emergency rooms, patient rooms, intensive care, surgery rooms, etc., (except areas with high-powered medical equipment) • Limited care facilities • Surgical centers • Birthing centers • Laboratories 	<ul style="list-style-type: none"> • Personal residences • Dormitories • Independent living retirement homes • Restaurants and cafes • Shops, stores, markets • Cars, buses, trains, boats, ambulances • Office buildings • Schools • Churches • Libraries • Theaters and stadiums • Outdoor environments (e.g., streets, sidewalks, parks) 	<ul style="list-style-type: none"> • Medical treatment areas with high-powered medical equipment - (e.g., high-frequency surgical equipment, short-wave therapy equipment, inside the RF shielded room of an MRI system) • Military areas (e.g., submarines, radar installations, weapons control systems) • Heavy industrial areas (e.g., power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries) • Aircraft environments (e.g., planes, helicopters)

Assessment of Medical Device Risks

- Provide a summary description of the risks associated with malfunction, disruption, or degradation of the performance of the subject medical device due to EM disturbances
- This summary should categorize the severity of each harm into one of the following three levels:
 - Deaths and Serious Injuries
 - Non-Serious Adverse Events
 - No Reported or Potential Harm

Consensus Standards

- Recommend use of appropriate FDA-recognized consensus standards, when applicable
- If a standard is not FDA-recognized, provide justification regarding how the EMC testing performed adequately addresses EMC
- If no consensus standard exists for a certain medical device type:
 - Recommend specific EMC testing be performed based on foreseeable EM disturbances in the intended use environments

Standards for IVDs

- IEC 61326-1:2012 and IEC 61326-2-6:2012 are in the FDA Non-Recognized Standards Database
 - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm
- FDA partially recognizes IEC 61326-1:2020 and IEC 61326-2-6:2020
 - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard_identification_no=42834
 - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard_identification_no=42841
- The Supplementary Information Sheets (SIS) for the 2020 versions of IEC 61326 clarify that the immunity requirements from these standards are not FDA recognized

Partially Recognized Standards

- For IVDs, FDA currently recommends:
 - Using the recognized parts or test methods from the partially recognized IEC 61326 standards; and
 - Using acceptance criteria specific to the device's functions and intended use using test levels specified by IEC 60601-1-2
- If the next editions of IEC 61326 become fully recognized by FDA, then FDA will recommend their use

Essential Performance (EP) and Immunity

Pass/Fail Criteria



- IVDs should use acceptance criteria specific to the device's functions and intended use
- EP is most easily understood by considering whether its absence or degradation would result in an unacceptable risk, which may be accomplished by utilizing acceptance criteria from IEC 60601-1-2. (i.e., essential performance)
- Pass/Fail criteria can be different for transient vs. continuous phenomena
- IEC 60601-1-2 is limited to safety
 - Does not necessarily test that the device is effective or performs as intended
 - Use IEC 60601-4-2 to assess the immunity of the performance associated with the intended use

Medical Device Configuration and Functions Tested



- Test the device as a system
 - The device should be tested as a system with all medical device accessories, components, and subsystems connected and functioning as intended.
 - If non-medical equipment is used in a medical system and could affect the ability of the medical device to meet the immunity pass/fail criteria, the non-medical equipment should also be tested as part of the medical device system.

Medical Device Configuration and Functions Tested Continued



- Configure in the device's intended use
 - Medical device and test or ancillary equipment should be configured in the modes and with settings considered to be representative of the medical device's intended use.
 - For example, a medical device that can operate in battery power mode and in mains power mode should be tested in both modes. Additionally, batteries with embedded electronic circuitry (i.e., smart batteries) that are intended to be handled by the user should be removed from the medical device and tested separately for immunity to electrostatic discharge due to the potential of electrostatic discharge damaging the circuitry of the battery.
- Wireless technology should be “on” and communicating

Common Electromagnetic (EM) Emitters

- Common EM emitters not adequately addressed by FDA-recognized consensus standards are:
 - Radiofrequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment
- When to Test:
 - “Deaths and Serious Injuries” or “Non-Serious Adverse Events”
- When labeling is generally an acceptable mitigation:
 - “No Reported or Potential Harm”

Labeling

- Recommended separation distances and appropriate environments of use for which the device is suitable
- The performance of the device that was determined to be essential performance
- Compliance for each emissions and immunity standard
- Any deviations or allowances used
- Specifications required in any standards to which the device claims conformity

Hypothetical IVD Example

Hypothetical Example

- An IVD manufacturer of a handheld portable blood analyzer is changing the microcontroller unit (MCU) of their FDA-cleared device (chip component)
- To continue offering products to their customers, the manufacturer switched to a different integrated circuit supplier
 - This modification may have a significant impact on the overall safety and effectiveness of the IVD as well as on the device's performance and risk profile
 - The modification could also cause compatibility issues between the IVD and its parts and/or accessories
- EMC testing is recommended to determine that the IVD is safe and performs as intended

Manufacturer's Response

- Manufacturer used the FDA partially recognized standard IEC 61326-1:2020 in their EMC test report
- However, Clause 6 Immunity Requirements from IEC 61326-1:2020 is not recognized by FDA per the SIS for IEC 61326-1:2020
- EMC Report would be found deficient due to the use of the unrecognized immunity requirements (performance criteria - A,B,C) from IEC 61326-1:2020

Standard	Description	Severity Applied	Performance Criteria allowed under IEC 61326-1:2020
IEC 6100-4-8	Magnetic Field Immunity	50 Hz / 60 Hz, 30 A/m	A
IEC 61000-4-11	Voltage Dips of AC lines	0% during ½ cycle	B
IEC 61000-4-11	Voltage Dips of AC lines	0% during 1 cycle &	B
	Voltage Dips of AC lines	70% during 25/35 cycle	C

Recommended Approach

- EMC test levels from IEC 60601-1-2:2020 recognized by FDA and recommended in the final EMC guidance document
- Test Methods from partially recognized IEC 61326-1:2020 and IEC 61326-2-6:2020, but with an acceptance criteria specific to the device's function and intended use; and test levels specified by IEC 60601-1-2
- Device specific pass/fail criteria that are (1) quantitative, (2) specific to the medical device and functions, and (3) observable.
 - These criteria should be determined based on the medical device's functions, modes, indications for use, intended use, and EP (if applicable)

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	

Additional Considerations

- Follow the recommendations in the final EMC guidance document if submitting an IVD submission after June 6, 2023
- EMC testing of an IVD (when applicable) should include:
 - A detailed description of the medical device undergoing testing, including the configuration, functions, modes, and settings that were tested
 - Testing for both mains and battery modes of operation
 - Common EM emitters not addressed in standards

Other Relevant Guidance



Recommendations in this EMC guidance apply to any new submission. EMC guidance recommendations should be considered in conjunction with other applicable guidances.

- To determine whether a new 510k is required for a modification that may or may not affect EMC, refer also to FDA Guidance “Deciding When to Submit a 510(k) for a Change to an Existing Device” (www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device), issued October 25, 2017.
- To determine whether a modification to one’s own device that may or may not affect EMC is appropriate for review as a Special 510(k), refer also to FDA Guidance “The Special 510k Program” (www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program), issued September 13, 2019.
- For additional information on reagent changes to an already FDA cleared instrument or assay, refer also to “Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices” (www.fda.gov/regulatory-information/search-fda-guidance-documents/replacement-reagent-and-instrument-family-policy-in-vitro-diagnostic-devices), issued August 17, 2022.

Summary

- Guidance implementation date for IVDs is June 6, 2023
- Clarification of EMC expectations for IVDs
 - IEC 61326-1:2020 and IEC 61326-2-6:2020 are partially recognized and the immunity requirements from these standards are not FDA recognized
 - Use IEC 61326 for test methods and IEC 60601-1-2 for test levels
- Specifies gaps in recognized standards
 - IEC 60601-1-2 is a safety standard and has no performance/effectiveness requirements
 - Test in both mains and battery modes of operation
 - Expectations for common EM emitters not addressed in standards
- Standards that are fully or partially recognized may be used to evaluate the EMC of an IVD device



Additional Panelist

Yasaman Ardeshirpour

EMC Program Advisor


Division of Biomedical Physics

Office of Science and Engineering Laboratories

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Let's Take Your Questions

- **To Ask a Question:**
 1. Raise your hand in Zoom 
 2. Moderator will announce your name and invite you to ask your question
 3. Unmute yourself when prompted in Zoom to ask your question
- **When Asking a Question:**
 - Ask one question only
 - Keep question short
 - No questions about specific submissions
- **After Question is Answered:**
 - Mute yourself and lower your hand
 - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**

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How to Study and Market Your Device - (Updated module 12/15/22) <i>510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification</i>	▼
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