Electromagnetic Immunity Test Method for Evaluating Device Exposure to Consumer Inductive Wireless Power Transfer (WPT) Systems

User Manual v1.0

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1. Introduction / Scope

The purpose of this document is to provide instructions for using the described regulatory science tool (RST), which is an immunity test method for evaluating medical device exposure to consumer-grade inductive wireless power transfer (WPT) systems. This method may be applied to medical devices, including in-vitro products and accessories, that are electrically powered or that contain electrical or electronic circuitry.

2. Immunity Pass/Fail Criteria

This RST does not establish minimum acceptable performance for a medical device under test (DUT), nor does it provide specific immunity test pass/fail criteria. To apply this test method, the user may specify immunity pass/fail criteria based on the Device Under Test (DUT)'s operating environment and risk profile. It is recommended that prior to testing, all pass/fail criteria along with their associated device operating modes and the methods for monitoring the device performance during and after testing be documented. The user may consider referring to FDA-recognized EMC consensus standards [1] (e.g., IEC 60601-1-2:2020 [2]) for more information.

3. Test Method Protocol

3.1 Input Test Signal

WPT equipment emissions may use a broad range of modulations and field strengths, which makes identification of a single representative WPT test signal challenging. This RST includes example representative test signals based on measurements conducted on 13 commonly used consumer-grade WPT systems available on the market at the time of development [3]. While these emission characteristics may not fully characterize all possible consumer WPTs available now or that may emerge in the future, the test method is generalizable and may be readily adapted to use different test signals.

3.1.1 Carrier Frequency and Test Levels

Based on emission characterization data [3], most common emission frequencies of major consumer inductive WPT equipment on the market fall between either 110-190 kHz or 325-360 kHz. Table 1 shows the carrier frequency and magnetic test level for different separation distances from the measured WPT systems. 134 kHz was selected as a representative frequency for the lower frequency range to allow use of the same magnetic coil and its matching circuit described in clause 8.11 of IEC 60601-1-2:2020 [2]. 330 kHz was selected as a representative signal between 325-360 kHz.

Users may choose the test level for each frequency range based on the reasonable minimum separation distance expected between WPTs and a given medical device in its intended environment of use. The test levels in Table 1 may be interpolated using log-log linear interpolation [4], if a chosen separation distance falls between these measured values. Extrapolation may be performed using the log-log slope of magnetic field data for distances outside the range of separation distances in Table 1, but note that extrapolated values are beyond the scope of the measured data.

The first and third rows in Table 1 corresponds to WPT ping (communication) modes. For those signals, the carrier frequency signals are modulated based on the modulation envelope files in section 3.1.2 using an arbitrary waveform generator (AWG) and a signal generator.

4. *Table 1 – Carrier frequency and magnetic field A/m of CW signal before modulation*

Carrier frequency	Max magnetic field of the Carrier frequency before Modulation (RMS-A/m)			
	1 cm	2 cm	5 cm	15 cm
134 kHz (modulated)	594	380	86	12
134 kHz (CW)	498	312	58	7
330 kHz (modulated)	80	20	2	
330 kHz (CW)[1]	n/a	74	5	

n/a: not available

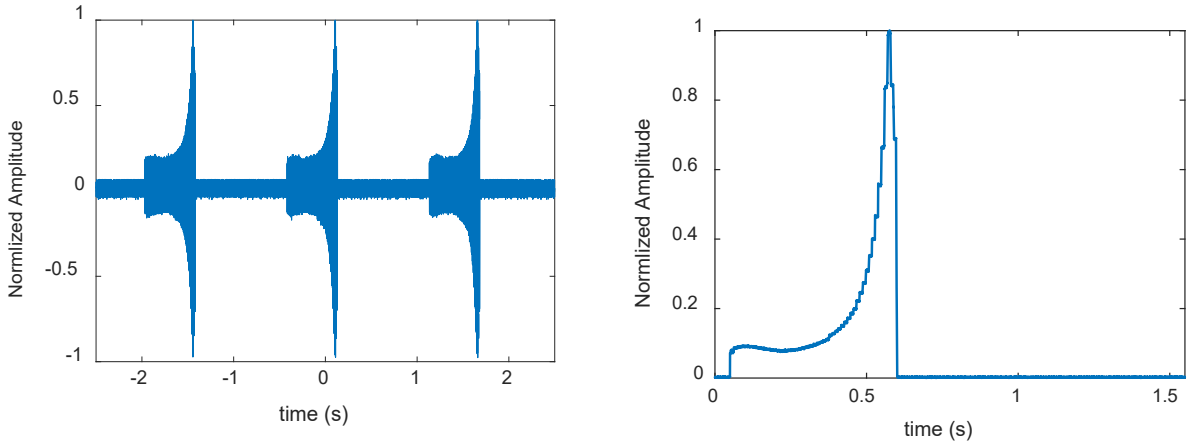
3.1.2 Modulation

Ten different WPT modulations (two modulation profiles for 330 kHz and eight for 134 kHz) [3] are provided in Excel sheet format in the following link (https://github.com/dbp-osel/Consumer-WPT-modulations).

These modulation profiles were based on the actual modulation envelopes captured from each charging coils on those WPTs. The modulation envelope for each frequency provided in the Excel files, may be uploaded to an arbitrary waveform generator to modulate the carrier signals in Table 1.

[1] Max RMS magnetic field values for 330 kHz CW signal in charging mode are not available (n/a) at 1 cm distance due to the receivers' thickness required to activate the WPTs' charging mode for that frequency. The magnetic field values for 330 kHz at 15 cm are omitted since they were smaller than 1 A/m.

The first column of each modulation Excel sheet represents the time in seconds, and the second column is the normalized amplitude of positive portion of the signals. Fig. 1 demonstrates an example of a WPT signal, and its envelope provided in the Excel file. Some AWG devices may require normalization of the signal envelope to [–1 1] rather than [0 1]; check the AWG manual and verify the output of your modulated signal to ensure that the signal is correct.



(a) (b)

Figure 1. Example (a) WPT signal (b) modulation envelope provided in Excel file.

3.2 Exposure Test Protocol

Step 1) Use a 6-cm radiating loop antenna (e.g., radiating loop antenna recommended in IEC 61000-4-39 standard [5]) to emulate WPT emissions described in this RST, as detailed in [6].

Step 2) Connect an arbitrary waveform generator (bandwidth > 1 MHz) and a signal generator (covering a frequency range of 100 – 500 kHz) to an amplifier capable of generating WPT signal modulation and intensity levels per section 3.1. Connect the radiating loop antenna to output of the amplifier using an appropriate matching circuit for each carrier frequency. Then configure the system to deliver the magnetic field in Table 1 at 5 cm above the center of the radiating antenna loop, as recommended in the 61000-4-39 standard [5]. If the specific field strength cannot be achieved at this distance, the separation distance may be reduced; however, the new distance should be documented along with a detailed spatial magnetic field distribution and its peak intensity at that distance, to support that it still represents the intensity level and spatial distribution of the magnetic field of consumer WPT systems.

Step 3) Use a calibrated H-field sensor to confirm the magnetic field characteristics (test level and modulation). Before applying the modulation, gradually increase the output power of the signal generator and amplifier until the magnetic field reaches the intended magnetic field intensity at 5 cm above the center of the radiating coil. Then confirm the modulation shape by H-field sensor, or a loop wire connected to a scope, after turning the modulation on.

Step 4) Configure the DUT properly, with all interfaces appropriately terminated and connected to a patient simulator as needed to replicate physiological conditions, ensuring accurate simulation of its normal operation. If the DUT is an implant with lead(s), choose an appropriate lead configuration and place within a tissue-equivalent interface or saline, for example as recommended in relevant particular standards [1] (e.g., ISO 14117:2019 [7], ISO 14708-3:2017 [8]).

Step 5) Power on the DUT and confirm it is functioning properly.

Step 6) The dwell time for each test should be determined based on the settling time of the test system, as well as the time needed for the DUT to operate in the relevant operating mode and response appropriately to the test signal for all defined immunity pass/fail criteria.

Step 7) Place the radiating loop antenna at 5 cm distance parallel to the surface of the DUT for a duration greater than or equal to the dwell time determined in step 6 for each test signal and location. If any part of the DUT was exposed to magnetic field strength below the specified test level, apply the windowing technique, as recommended in 61000-4-39 standard, by positioning the antenna successively over each surface of the DUT and its connectors to ensure that all areas are exposed to the radiated magnetic field.

Step 8) Monitor DUT performance and functionality as indicated in its specified pass/fail criteria throughout the dwell time for each position, frequency, and modulation of the coil.

Step 9) Record any performance degradation observed during and after each exposure test

Step 10) Repeat steps 7-9 for each remaining exposure condition, including different frequencies, modulations, and test levels, as applicable.

References:

[1] FDA Recognized Consensus Standards: Medical Devices, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[2] IEC 60601-1-2, 2020, “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”, https://webstore.iec.ch/en/publication/59644

[3] Y. Ardeshirpour, J.W. Guag, J.L. Silberberg, and S.J. Seidman, "Medical Device Electromagnetic Immunity Testing for Exposure to Consumer Wireless Power Transfer Systems - Part I: Emission Characteristics," in *IEEE Electromagnetic Compatibility Magazine*, vol. 15, no. 1, pp. 48-59, 1st Quarter 2026, https://doi.org/10.1109/MEMC.2026.11435322

[4] ANSI C63.30:2021, "American National Standard for Methods of Measurements of Radio-Frequency Emissions from Wireless Power Transfer Equipment," https://doi.org/10.1109/IEEESTD.2021.9491984

[5] IEC 61000-4-39:2017, “Electromagnetic compatibility (EMC) - Part 4-39: Testing and measurement techniques - Radiated fields in close proximity - Immunity test”, https://webstore.iec.ch/en/publication/30202

[6] Y. Ardeshirpour, J.W. Guag, J.L. Silberberg, and S.J. Seidman, "Medical Device Electromagnetic Immunity Testing Method for Exposure to Consumer Wireless Power Transfer Systems - Part II: Test Method, *IEEE Electromagnetic Compatibility Magazine*, vol. 15, no. 1, pp. 60-68, 1st Quarter 2026, https://doi.org/10.1109/MEMC.2026.11435344 .

[7] ISO 14117:2019, “Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices”, https://www.iso.org/standard/73915.html

[8] ISO 14708-3:2017, “Implants for surgery — Active implantable medical devices Part 3: Implantable neurostimulators”, https://www.iso.org/standard/60539.html