Electromagnetic Immunity Test Signals for Proximity Fields from 5G FR1 Wireless Communication Equipment

User Manual

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User Manual

1. Introduction / Scope

The purpose of this document is to describe and provide instructions for a test method for evaluating medical device immunity to proximity fields from 5G FR1 wireless communication equipment. This method can be applied to medical devices, including in vitro diagnostic products, and accessories that are electrically powered or that contain electrical or electronic circuitry.

This RST does not establish minimum acceptable performance for a device under test (DUT), nor does it provide immunity test pass/fail criteria. The user may specify their own acceptance criteria based on testing needs for the DUT. The user may consider referring to applicable FDA-recognized consensus standards such as IEC 60601-1-2:2014/AMD1:2020 or ISO 14708-1:2014 for more information [1].

2. Immunity Test Method for 5G FR1 Proximity Fields

2.1 Test Modulation

A set of representative test modulations were developed based on a data analysis of 5G FR1 signals [2]. These are summarized in Table 1 below:

Table 1 - Representative test signals for 5G FR1 emissions.

Signal Type	Duty Cycle (DC)	Pulse Repetition Rate (PRR)
5G NR FR1-FDD	(20 ± 2) %	1 kHz, 2 kHz, 4 kHz ± 10 Hz
5G NR FR1-TDD	(20 ± 2) %	1 kHz, 2 kHz, 4 kHz ± 10 Hz

2.2 Exposure Method

The developed test signals are intended to be used with various exposure methods based on the user's testing needs for a given DUT. This may include EMC test methods described by consensus standards, including FDA-recognized standards such as IEC 60601-1-2:2014/AMD1:2020 [1], IEC 61000-4-3:2020 [3], or ISO 14708-1:2014 [4] and its particular standards depending on the DUT[1,2].

[1] FDA recognizes consensus standards IEC 60601-1-2:2014/AMD1:2020, ISO 14708-1:2014, and some associated particular standards, including ISO 14708-2:2019, ISO 14708-3:2017, ISO 14708-5:2020, ISO 14708-6:2019, and ISO 14708-7:2019. It should be noted that FDA does not recognize ISO 14708-4:2022.

[2] Although IEC 61000-4-3:2020 is not recognized by FDA, an earlier version of the standard (IEC 61000-4-3 Ed. 3.2 b:2010) is a normative reference in IEC 60601-1-2:2014/AMD1:2020.

2.3 Immunity Test Level

The user may choose an immunity test level based on their DUT's intended user environment. One illustrative example approach is to choose an immunity test level, E [V/m], as:

$$E = \frac{6}{d}\sqrt{P}$$

where *P* is the maximum power in W and *d* is a user-specified minimum separation distance in m. For example, per ETSI TS 38.101-1 V17.7.0 (2022-10), 5G FR1 user equipment is limited to 23 dBm output power, with a tolerance of +2/-3 dBm [5], so an example immunity test level could be calculated as 11.3 V/m for an output power of 25 dBm and a separation distance of 30 cm.

NOTE: This example is illustrative only and does not represent FDA recommendations.

2.4 Carrier Frequency

Some representative FR1 frequency bands for 5G wireless communication equipment operating in the US include n2, n5, n12, n25, n29, n41, n48, n66, n70, n71, and n77 [5]. A test frequency centered in each band along with the modulation from Table 1 may provide representative test signals for assessing DUT immunity to 5G FR1 emissions.

2.5 Test Signals

Table 2 – Representative test frequencies corresponding to frequency bands for 5G operating in the US

Test frequency (MHz)	Band (MHz)	NR Operating Bands	Duplexing
658	617 to 698	n71	FDD
723	699 to 746	n12, n29	FDD
859	824 to 894	n5	FDD
1738	1695 to 2200	n2, n25, n66, n70	FDD
1923			
2098			
2593	2496 to 2690	n41	TDD
3600	3300 to 4200	n48, n77	TDD
3900			

References:

[1] IEC 60601-1-2:2014/AMD1:2020, “Amendment 1 - 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.

[2] S. Mosleh, J. B. Coder, J. M. Ladbury, M. O. Al Kalaa, J. L. Silberberg, Y. Ardeshirpour, J. W. Guag, Y. Liu, and S. J. Seidman, "A metrology-driven approach to distilling live wireless signals into immunity test signals," IEEE Access, vol. 13, pp. 28711-28732, 2025, doi: 10.1109/ACCESS.2025.3540754.

[3] IEC 61000-4-3:2020, “Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test”. https://webstore.iec.ch/en/publication/59849.

[4] ISO 14708-1:2014, “Implants for surgery — Active implantable medical devices Part 1: General requirements for safety, marking and for information to be provided by the manufacturer”. https://www.iso.org/standard/52804.html.

[5] ETSI TS 138 101-1 V17.7.0 (2022-10), “5G; NR; User Equipment (UE) radio transmission and reception; Part 1: Range 1 Standalone (3GPP TS 38.101-1 version 17.7.0 Release 17)”. https://www.etsi.org/deliver/etsi_ts/138100_138199/13810101/17.07.00_60/ts_13810101v170700p.pdf