GE HealthCare

International Electrotechnical Commission (IEC) Electromagnetic Compatibility (EMC)

Preinstallation Requirements for MR Systems

5850261-1EN
Revision 2

Language Policy

DOC0371395 - Global Language Procedure

ПРЕДУПРЕЖДЕНИЕ (BG)	Това ръководство е налично само на китайски (ZH-CN), английски, френски, немски, японски, корейски, полски, португалски (PT-BR), руски, испански и виетнамски. Ако доставчикът на услуги на даден клиент изисква език, който е различен от тези езици, отговорност на клиента е да предостави преводачески услуги.
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HOIATUS (ET)	See juhend on saadaval ainult hiina (ZH-CN), inglise, prantsuse, saksa, itaalia, jaapani, korea, poola, portugali (PT-BR), vene, hispaania ja vietnami keeles. Kui kliendi teenusepakkujal on vaja juhendit mõnes muus keeles, on tõlketeenuste osutamine kliendi kohustus.
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Contents

1 Purpose

1.1 Who Should Read This Manual

The following personnel must be aware of the contents of this manual:

Icon	Personnel
	Architect

1.2 Introduction

This document details the IEC EMC requirements for all new production systems. This information was previously located in the system Preinstallation Manual and Operator Manual. Since there are common elements to IEC requirements for the different systems and magnets, this manual has been created, and the IEC requirements have been removed from the individual system Preinstallation and Operator Manuals.

2 Requirements

2.1 IEC EMC Compliance

⚠ WARNING

If the system is being installed in China, refer to 2.2 EMC Compliance (for Systems Produced for China Only) on page 10. For all other countries, refer to this section.

A Magnetic Resonance diagnostic device (MRI) uses non-ionizing radiation to produce high-quality images of the inside of the human body and is intended to be used in a hospital or clinical setting.

Per IEC 60601-1-2, Medical Electrical Equipment requires special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in the following tables. The tables below provide details about the level of compliance and provide information about potential interactions between devices.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Transducers and cables specified by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components must be used to maintain EMC compliance. If needed, refer to applicable system Field Replaceable Units (FRU) Manual.

WARNING

Other equipment may interfere with the MR System, even if that other equipment complies with CISPR EMISSION requirements.

WARNING

The MR System should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the MR System should be observed in order to verify normal operation in the configuration in which it will be used.

WARNING

The MR System should be used only in a shielded location named as the Magnet Room.

Magnetic shielded room requirements are defined in the Preinstallation Manual for the system being installed.

RF shielded room requirements for all systems are defined in 5850260-1EN.

WARNING

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by GE or replacement parts for internal components, may result in increased emissions or decreased immunity of the MR System.

WARNING

The MR System operates with a highly sensitive RF receiving front end to be able to capture the signal of an object scanned. The Magnet Room part of the MR System installation provides the RF isolation to reduce the interference from electrical devices outside the shielded location. It is possible that any device that functions with active electronic circuitry may potentially interfere with the operation of the MR System if such device is introduced inside the Magnet Room even though the device does not have an intentional RF Transmitter. Extreme EMC measures must be taken into account in the design and manufacturing of an electrical device if such device is intended to operate inside the Magnet Room.

Devices that may potentially interfere with the MR System if introduced inside the Magnet Room are those containing active electronics. Some examples include: Switching Mode Power Supply (SMPS), microprocessor, Digital Signal Processors, analog to digital converters, LCD displays, keypad controllers, motors, battery operated devices.

The MR System has no essential performance, however, the MR System will maintain its critical functions by continuing to acquire, display, and store scanning images safely.

The MR System is designed and tested to the following standards:

Table 2-1 Guidance And Manufacturer's Declaration – Electromagnetic Emissions

The MR System is intended for use in a typical health care electromagnetic environment specified below. The customer or the user of the MR System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 2	The MR System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The MR System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2-2 Guidance And Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact	± 8 kV contact
	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF IEC 61000-4-3	3 V/m[b] 80 MHz to 2.7 GHz	3 V/m[b] 80 MHz to 2.7 GHz
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines

Table 2-2 Guidance And Manufacturer's Declaration – Electromagnetic Immunity (Table continued)

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test level**	**Compliance Level**
	± 1 kV for input/output lines	± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV Line to line	± 0.5 kV, ± 1 kV Line to line
	± 0.5 kV, ± 1 kV, ± 2 kV Line to ground	± 0.5 kV, ± 1 kV, ± 2 kV Line to ground
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz at ISM bands[a]	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz at ISM bands[a]
Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	U_T = 0%, 250/300 cycles	U_T = 0%, 250/300 cycles
Voltage dips IEC 61000-4-11	U_T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 315 degrees) U_T = 0%, 1 cycle U_T = 70%, 25/30 cycles (0 degrees)	Not applicable
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields IEC 61000-4-39[c]	65 A/m 134.2 kHz	65 A/m 134.2 kHz
	7.5 A/m 13.56 MHz	7.5 A/m 13.56 MHz

U_T is the AC mains voltage prior to application of the test level.

a: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b: For additional information, see Table 2-3 Guidance And Manufacturer's Declaration – Electromagnetic Proximity field Immunity on page 9.

c: Applicable to systems compliant to IEC 60601-1-2:2020 [Ed 4.1].

Table 2-3 Guidance And Manufacturer's Declaration – Electromagnetic Proximity field Immunity

The MR System is intended for use in a typical health care electromagnetic environment specified below. The customer or the user of the MR System should assure that it is used in such an environment.							
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**IEC 60601 Test Level**	**Compliance Level**
385	380 ~ 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27 V/m	27 V/m
450	430 ~ 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28 V/m	28 V/m
710	704 ~ 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9 V/m	9 V/m
745							

Table 2-3 Guidance And Manufacturer's Declaration – Electromagnetic Proximity field Immunity (Table continued)

The MR System is intended for use in a typical health care electromagnetic environment specified below. The customer or the user of the MR System should assure that it is used in such an environment.							
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**IEC 60601 Test Level**	**Compliance Level**
780							
810	800 ~ 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28 V/m	28 V/m
870							
930							
1720	1700 ~ 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28 V/m	28 V/m
1845							
1970							
2450	2400 ~ 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28 V/m	28 V/m
5240	5100 ~ 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9 V/m	9 V/m
5500							
5785							

NOTE

The distance values represent the recommended separation distance between interfering equipment and components of the MR System.

2.2 EMC Compliance (for Systems Produced for China Only)

A Magnetic Resonance diagnostic device (MRI) uses non-ionizing radiation to produce high-quality images of the inside of the human body and is intended to be used in a hospital or clinical setting.

Per YY 9706.102-2021, Medical Electrical Equipment requires special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in the following tables. The tables below provide details about the level of compliance and provide information about potential interactions between devices.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

WARNING

The MR System may be interfered with by other equipment, even if that other equipment complies with GB 4824 EMISSION requirements.

WARNING

The MR System should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the MR System should be observed in order to verify normal operation in the configuration in which it will be used.

WARNING

The MR System should be used only in a shielded location named as the Magnet Room.

Magnetic shielded room requirements are defined in the Preinstallation Manual for the system being installed.

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WARNING

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by GE or replacement parts for internal components, may result in increased emissions or decreased immunity of the MR System.

WARNING

The MR System operates with a highly sensitive RF receiving front end to be able to capture the signal of an object scanned. The Magnet Room part of the MR System installation provides the RF isolation to reduce the interference from electrical devices outside the shielded location. It is possible that any device that functions with active electronic circuitry may potentially interfere with the operation of the MR System if such device is introduced inside the Magnet Room even though the device does not have an intentional RF Transmitter. Extreme EMC measures must be taken into account in the design and manufacturing of an electrical device if such device is intended to operate inside the Magnet Room.

Devices that may potentially interfere with the MR System if introduced inside the Magnet Room are those containing active electronics. Some examples include: Switching Mode Power Supply (SMPS), microprocessor, Digital Signal Processors, analog to digital converters, LCD displays, keypad controllers, motors, battery operated devices.

Adhering to the recommendations provided herein for the interaction of the MR System with other electrical devices within the electromagnetic environment may not eliminate all the disturbances.

The MR System has no essential performance, however, the MR System will maintain its critical functions by continuing to acquire, display, and store scanning images safely.

The MR System complies with emissions limits (Group 2, Class A) Medical devices as stated in YY 0505-2012.

Table 2-4 Guidance And Manufacturer's Declaration – Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions GB 4824	Group 2	The system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions GB 4824	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions GB 17625.1	Not Applicable	
Voltage fluctuations/flicker emissions GB 17625.2	Not Applicable	

Table 2-5 Guidance And Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) GB/T 17626.2	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	± 8 kV air	± 8 kV air	
Electrical fast transient / burst GB /T 17626.4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	± 1 kV for input/ output lines	± 1 kV for input/ output lines	
Surge GB /T 17626.5	± 0.5 kV, ± 1 kV line(s) to line(s)	± 0.5 kV, ± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV, ± 2 kV common mode	
Conducted RF GB /T 17626.6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the MR System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHZ - 800MHZ $d=2.3\sqrt{P}$ 800MHZ – 2.5GHZ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur

Table 2-5 Guidance And Manufacturer's Declaration – Electromagnetic Immunity (Table continued)

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Radiated RF GB /T 17626.3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	in the vicinity of equipment marked with the following symbol: 
Power Frequency (50/60Hz) magnetic field GB/T 17626.8	3 A/m 50Hz	3 A/m 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines GB /T 17626.11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MR System requires continued operation during power mains interruptions, it is recommended that the MR System be powered from an uninterruptible power supply or a battery.
	<5 % U_T (>95 % dip in U_T) for 5 sec.	<5 % U_T (>95 % dip in U_T) for 5 sec.	

U_T is the AC mains voltage prior to application of the test level.

NOTE

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular or cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MR System issued exceeds the applicable RF compliance level above, the MR System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MR System.

b: For frequencies greater than the 150 kHz to 80 MHz range, field strengths should be less than 3 V/m.

Table 2-6 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MR System

The MR System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MR System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MR System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter stated in meters**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23

Table 2-6 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MR System (Table continued)

The MR System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MR System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MR System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter stated in meters**		
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE** 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Revision History

Rev	Date	Description
Rev 2	October 2023	**Section 2.1:** Removed sentence "Full declaration is stored on-site in the Operator Manual delivered with the system." **Table 2-2:** Added row for Proximity magnetic fields IEC 61000-4-39 and Note c **Section 2.2:** Removed "IEC" from chapter title; Replaced YY 0505-2012 with YY 9706.102-2021
Rev 1	July 2020	Initial Release of 5850261-1EN based on DOC2348773 Rev. 2

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