GE HealthCare

SIGNA™ Voyager

User Manual

SIGNA_LX1 (30.1)

CE 0197

5932863-1EN
Revision 1
US English

Revision history

Table 1 Revision history

Revision	Date	Change
1	2023/01	Initial release

Strong Magnetic Field

Important

The magnet produces a strong magnetic field. The MR magnet is always on even when the system is not acquiring scan data. For details, Security zone on page 149.

Figure 1 Security zone warning sign

Applicable regulations and standards

Medical Device Regulation

This product conforms with the requirements of the Medical Device Regulation 2017/745 when they bear the following CE Mark of conformity:

CE 0197

The year of CE marking is 2016.

Магнітно-резонансна томографічна система SIGNA Voyager	
UA.TR.116	Знак відповідності технічним регламентам
	GE HEALTHCARE (TIANJIN) COMPANY LIMITED **NO. 266 JINGSAN ROAD, TIANJIN AIRPORT ECONOMIC AREA, TIANJIN, 300308, P.R. CHINA** ДЖИІ ХЕАЛСКЕА (ТЯНДЖІН) КОМПАНІ ЛІМІТЕД НО. 266 ДЖІНГСАН РОАД, ТЯНДЖІН ЕІРПОРТ ЕКОНОМІК ЕРІА, ТЯНДЖІН, 300308, КИТАЙСЬКА НАРОДНА РЕСПУБЛІКА
Уповноважений представник в Україні: ТОВ «ДЖИІ ХЕЛСКЕР УКРАЇНА.» 02000, Україна, місто Київ, проспект Павла Тичини, будинок 1В, офіс 408 Тел.: +38 (044) 390 06 08	
Дата останнього перегляду інструкції із застосування є датою останньої редакції та вказана у інструкції із застосування.	

Regulatory Markings-UDI Label

Every medical device has a unique marking for identification. The UDI marking appears on the device labeling.

The following figures are only examples of a UDI marking. The device may have a linear barcode, or a DataMatrix code, or only alphanumeric identifiers with no barcode. Also the identifiers vary per product.

Figure 2 Example of a UDI linear barcode

Figure 3 Example of a UDI DataMatrix code

Manufacturer

GE HEALTHCARE (TIANJIN) COMPANY LIMITED

NO.266 JINGSAN ROAD, TIANJIN AIRPORT ECONOMIC AREA,

TIANJIN, P.R.CHINA 300308

Manufacturing Site 1

GE HEALTHCARE (TIANJIN) COMPANY LIMITED

NO.266 JINGSAN ROAD, TIANJIN AIRPORT ECONOMIC AREA,

TIANJIN, P.R.CHINA 300308

Manufacturing Site 2

GE Healthcare Manufacturing LLC

3001 West Radio Drive

Florence, SC 29501 USA

For the specific manufacturing site for your system, please refer to the rating plate attached on your system cabinet.

EU Authorized Representative

EC REP

GE Medical Systems SCS

283, rue de la Minière

78530 Buc

FRANCE

Telephone: +33 1 30 70 40 40

Legal notices

GE and the GE Monogram are trademarks of General Electric Company.

ASSET, VIBRANT, ReportCARD, INSITE and ILinq are trademarks of General Electric Company.

DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

All other trademarks are the property of their respective owners.

Turkey importer details

GE Medical Systems Türkiye Ltd. Şti.

Esentepe Mah. Harman Sok. No: 8

34394 Şişli-İstanbul Türkiye

Authorized representative of the manufacturer to receive claims in the Republic of Belarus

Language	Address
English	GE Healthcare LLC. room 30, 14 floor, premises I, 10, Presnenskaya Naberezhnaya, inner city territory Presnensky municipal district, Moscow, 123112, Russian Federation Tel. service department: 8 800 333 6967 Tel. Office: +7 495 739 6931, Fax: +7 495 739 6932, 88003336967@ge.com, http://www.gehealthcare.ru/
Russian	ООО «ДжиИ Хэлскеа» 123112 Российская Федерация, Москва, вн.тер.г. муниципальный округ Пресненский, Пресненская набережная, д. 10, помещение I, этаж 14, ком.30. Тел. сервисной службы: 8 800 333 6967 Тел. офиса: + 7 495 739 6931, Факс + 7 495 739 6932 88003336967@ge.com https://www.gehealthcare.ru/

Authorized representative of the manufacturer in Russian Federation

Language	Address
English	GE Healthcare LLC room 30, 14 floor, premises I, 10, Presnenskaya Naberezhnaya, inner city territory Presnensky municipal district, Moscow, 123112 , Russian Federation Tel. service department: 8 800 333 6967 Tel. Office: +7 495 739 6931, Fax: +7 495 739 6932, 88003336967@ge.com, https://www.gehealthcare.ru/
Russian	ООО «ДжиИ Хэлскеа» 123112 Российская Федерация, Москва, вн.тер.г. муниципальный округ Пресненский, Пресненская набережная, д. 10, помещение I, этаж 14, ком.30. Тел. сервисной службы: 8 800 333 6967 Тел. офиса: + 7 495 739 6931, Факс + 7 495 739 6932 88003336967@ge.com https://www.gehealthcare.ru/

Authorized representative in Kazakhstan

Table 2 Kazakh authorized representative details

Language	Address
English	General Electric Kazakhstan LLP 26/41, Zenkova Street, Medeu District, Almaty, 050010, Kazakhstan T +7 727 3560020
Kazakh	«Дженерал Электрик Қазақстан» ЖШС Қазақстан, Алматы қаласы, Медеу ауданы, көшесі ЗЕНКОВ, үй 26/41, пошталық индексі 050010 T +7 727 3560020
Russian	ТОО «Дженерал Электрик Казахстан» Казахстан, город Алматы, Медеуский район, улица Зенкова, дом 26/41, почтовый индекс 050010 T +7 727 3560020

Radio frequency energy

This equipment generates, uses, and can radiate radio frequency energy. The equipment may cause radio frequency interference with other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, the:

GE MR Systems

comply with emissions limits for (Group 2, Class A) Medical Devices as stated in IEC 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measures:

- reorient or relocated the affected devices;
- increase the separation between equipment and the affected device;
- power the equipment from a source different from that of the affected device; and/or
- consult the point of purchase or service representative for further suggestions.

The manufacturer is not responsible for any interference caused by using interconnect cables that are not recommended or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

Do not use devices that transmit RF Signals (cellular phones, transceivers, or radio controlled products) in the vicinity of this equipment as they may cause performance outside the published specifications. Keep the power to these types of devices turned off when near this equipment.

The medical staff in charge of this equipment is required to instruct technicians, patients, and other people who may be around this equipment to fully comply with the above requirement.

Immunity/Emissions Exceptions: Note the exceptions from the EMC test results. Check with the business EMC engineer for this information.

In accordance with the international safety standard IEC 60601-1, this system is:

- a Class I device

⚠ WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- acceptable for Continuous Operation
- having ordinary protection against ingress of water (IPX0)
- type B and BF applied parts
- is not for use in the presence of flammable anesthetics.

Equipment disposal

A WEEE passport report is available from a GE representative upon request.

⚠ CAUTION

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

⚠ CAUTION

Federal law restricts the sale, distribution, and use of this device to or on the order of a physician.

Indications for use

The SIGNA™ Voyager system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the SIGNA™ Voyager system reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

⚠ WARNING

Read the *full prescribing information* on the contrast media label before use of contrast media. Use contrast media only in accordance with Indications and Usage as described in full prescribing information.

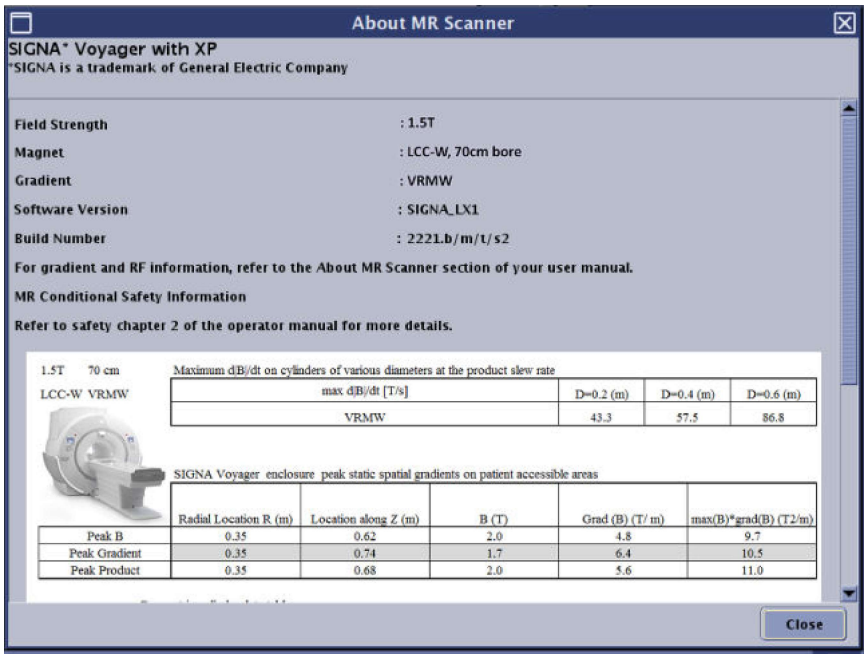
About MR Scanner

About this task

- Specific energy limit exams are limited to 14,400 joules (4 W/kg for one hour (3600 s). After a suitable rest period (perhaps 2 hours) patient scanning may be resumed. A physician may override the specific energy limit for medical reasons.
- B1rms is the root mean square value of the radio frequency (RF) magnetic field for a given protocol. It is useful to determine how aggressive a protocol may be is terms of RF intensity.
- The About MR Scanner screen displays with safety information that may be useful for determining if MR Conditional requirements are met for certain implants and other devices. Available information includes:
  - magnetic field strength (B0)
  - maximum spatial gradient (rate of change with distance) of the static magnetic field
  - nominal frequency range per nuclei
  - maximum gradient output on cylinders with diameters of 0.2 m, 0.4 m, and bore diameter minus 0.1 m (for transverse magnets the “bore diameter” is the magnet gap).

For more details about technical specifications, see Technical specifications on page 15.

Figure 4 Example of an About MR Scanner screen



Use these steps to view the About MR Scanner screen, which provides details about your MR scanner. The contents of the screen varies based on your MR system.

Step-by-step instructions

1. In the header area of the screen, click the **Tools** icon  .
2. From the Tools menu, click **About MR Scanner**.
3. Click and drag the slider to view all the contents on the screen.

   NOTE

   The top portion of the screen provides system details, such as filed strength, gradient, and software build.
4. To close the screen, from the About MR Scanner screen, click **Close**.

Peak static spatial gradients on patient accessible areas

To determine your system configuration (magnet and gradient type) view About MR Scanner on page 9 .

Enclosure

Figure 5 SIGNA™ Voyager classic enclosure for IPM magnet

Figure 6 SIGNA™ Voyager modern enclosure for IPM magnet

Figure 7 SIGNA™ Voyager enclosure for LCCW magnet

LCCW magnet

Table 3 SIGNA™ Voyager enclosure peak static spatial gradients on patient accessible areas for LCCW magnet

Patient bore type	Parameter	Radial Location R(m)	Location along Z(m)	B(T)	Grad(B) (T/m)	max(B)* grad(B) (T^2/m)
70 VRMW	Peak B	0.35	0.62	2.0	4.8	9.7
	Peak Gradient	0.35	0.74	1.7	6.4	10.5
	Peak Product	0.35	0.68	2.0	5.6	11.0

IPM magnet

Table 4 SIGNA™ Voyager enclosure peak static spatial gradients on patient accessible areas for IPM magnet

Patient bore type	Parameter	Radial Location R(m)	Location along Z(m)	B(T)	Grad(B) (T/m)	max(B)* grad(B) (T^2/m)
70 VRMW	Peak B	0.35	0.62	2.0	3.7	7.2
	Peak Gradient	0.35	0.78	1.5	5.7	8.8
	Peak Product	0.35	0.74	1.7	5.3	9.2

Magnetic field plots

Static magnetic field plots for siting (rule of thumb - assumes no ferromagnetic materials) may be found at:

https://www.gehealthcare.com/support/site-planning

Coordinate system for field and gradient where Z is in the B0 direction, R is the radius, and the origin is isocenter.

The following figures represent the contour map for the static magnetic field (B0) from the MR system at positions accessible to the MR worker.

Figure 8 Contour map of the static magnetic field (B0) for an 1.5T LCCW magnet. View from above magnet with a 25 cm grid overlaid

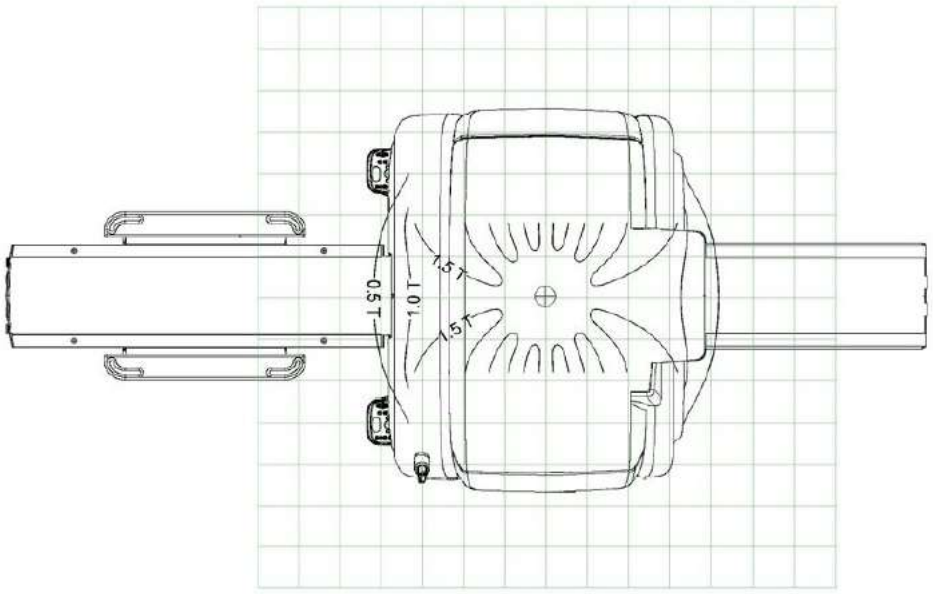
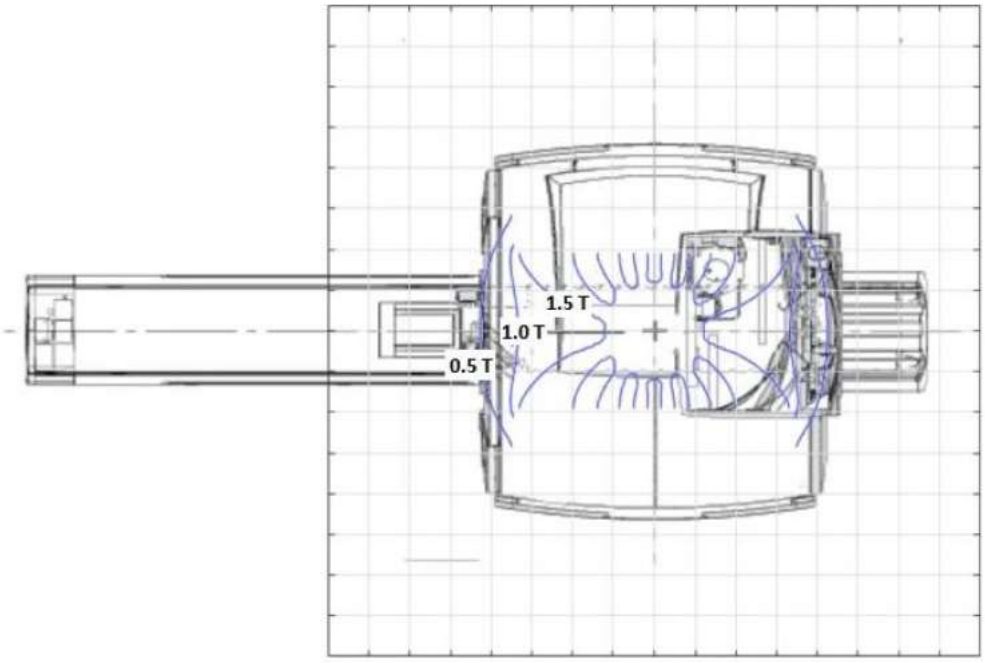


Figure 9 Contour map of the static magnetic field (B0) for an 1.5T IPM magnet. View from above magnet with a 25 cm grid overlaid



Static spatial gradients on concentric cylinders

The static magnetic field might cause forces or torques on some devices near the magnet. The following table shows the maximum magnetic field (B0), the spatial rate of change of the magnetic field (grad(B0)), and the product of the magnetic fields and its rate of change (B0*grad(B0)) for

infinitely long cylinders concentric with the patient bore. This information may be of use in evaluating risk assuming patients are confined to the cylinder bounds. Note that higher values of these parameters exist on the magnet bore covers (see above).

For example, for the SIGNA Voyager system LCCW magnet, use below table to find the peak static gradient field in the 70 cm bore is 6.4 Tesla/m. The peak spatial gradient in the patient bore is located on the 70 cm cylinder surface at z = 0.735 m from isocenter. The user then evaluates the risk from the device manufacturer's MR Conditional Labeling, from the characteristics of the scanner, and from other information such as patient history.

- First find that the maximum peak gradient on the magnet covers (from the above table) is 6.4 Tesla/m (640 gauss/cm). This peak occurs at a radius of 0.35 m of axis and a z location 0.74 m from isocenter (typically on the magnet covers). Some risk managers consider this information adequate for determining risk from static spatial gradients.
- Some risk managers may limit the patient to regions contained by cylinders concentric with the patient bore. They may use the table below to find that the maximum spatial gradient in the bore is 6.4 Tesla/m (640 Gauss/cm). The peak spatial gradient in the patient bore is located on the 70 cm cylinder surface at z = 0.74 m from isocenter. The user then evaluates the risk from the device manufacturer's MR Conditional Labeling, from the characteristics of the scanner, and from other information such as patient history. In this case the peak static gradient is same as the maximum value on the magnet cover.

For example, for the SIGNA Voyager system IPM magnet, use below table to find the peak static gradient field in the 70 cm bore is 5.7 Tesla/m. The peak spatial gradient in the patient bore is located on the 70 cm cylinder surface at z = 0.784 m from isocenter. The user then evaluates the risk from the device manufacturer's MR Conditional Labeling, from the characteristics of the scanner, and from other information such as patient history.

- First find that the maximum peak gradient on the magnet covers (from the above table) is 5.7 Tesla/m (570 gauss/cm). This peak occurs at a radius of 0.350 m of axis and a z location 0.78 m from isocenter (typically on the magnet covers). Some risk managers consider this information adequate for determining risk from static spatial gradients.
- Some risk managers may limit the patient to regions contained by cylinders concentric with the patient bore. They may use the table below to find that the maximum spatial gradient in the bore is 5.7 Tesla/m (570 Gauss/cm). The peak spatial gradient in the patient bore is located on the 70 cm cylinder surface at z = 0.78 m from isocenter. The user then evaluates the risk from the device manufacturer's MR Conditional Labeling, from the characteristics of the scanner, and from other information such as patient history. In this case the peak static gradient is same as the maximum value on the magnet cover.

Figure 10 Static spatial gradients at various radii

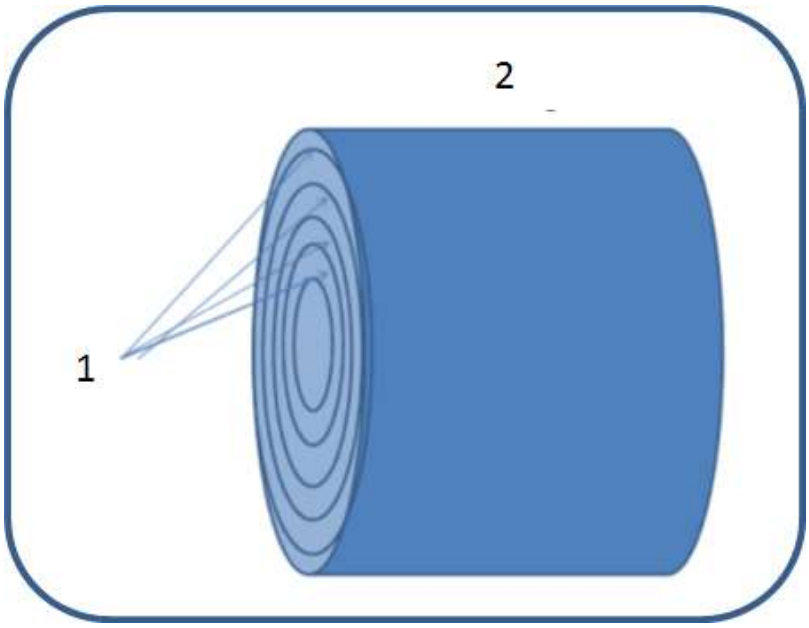


Table 5 Image legend

Number	Description
1	Concentric cylinders
2	Magnet

To determine your system configuration (magnet and gradient type) view the About MR scanner. To access About MR Scanner, seeAbout MR Scanner on page 9 .

1.5T LCCW magnet

Table 6 Concentric cylinder data table 1

Field magnet	Item	On patient Z axis		On 20 cm Diameter Cylinder surface		On 30cm Diameter Cylinder surface		On 40cm Diameter Cylinder surface	
		Peak	R,Z (m,)	Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)
1.5T LCCW	Bo (T)	1.5	(0,0.23)	1.5	(0.1,0.374)	1.5	(0.15,0.465)	1.5	(0.2,0.525)
	Gradient (T/m)	2.7	(0,0.84)	2.8	(0.1,0.836)	3.0	(0.15,0.81)	3.3	(0.2,0.805)
	BxG (T2/m)	2.8	(0,0.77)	3	(0.1,0.763)	3.3	(0.15, 0.775)	3.8	(0.2,0.745)

Table 7 Concentric cylinder data table 2

Field Magnet	Item	On patient Z axis		On 50cm Diameter Cylinder surface		On 55 cm Diameter Cylinder surface		On 60cm Diameter Cylinder surface		On 70cm Diameter Cylinder surface	
		Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)
1.5T LCCW	Bo (T)	1.5	(0,0.23)	1.6	(0.25,0.57)	1.6	(0.275,0.59)	1.7	(0.3,0.6)	2.0	(0.35,0.62)
	Gradient (T/m)	2.7	(0,0.84)	3.7	(0.25,0.83)	4.1	(0.275,0.79)	4.6	(0.3,0.75)	6.4	(0.35,0.735)
	BxG (T2/m)	2.8	(0,0.77)	4.7	(0.25,0.75)	5.5	(0.275,0.74)	6.5	(0.3,0.72)	11.0	(0.35,0.69)

1.5T IPM magnet

Table 8 Concentric cylinder data table 1

Field magnet	Item	On patient Z axis		On 20 cm Diameter Cylinder surface		On 30cm Diameter Cylinder surface		On 40cm Diameter Cylinder surface	
		Peak	R,Z (m,)	Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)
1.5T IPM	Bo (T)	1.5	(0.000,0.000)	1.5	(0.100,0.000)	1.5	(0.150,0.000)	1.5	(0.200,0.000)
	Gradient (T/m)	2.6	(0.000,0.862)	2.8	(0.100,0.868)	3.0	(0.150,0.829)	3.2	(0.200,0.823)
	BxG (T2/m)	2.7	(0.000,0.777)	2.9	(0.100,0.780)	3.3	(0.150,0.737)	3.7	(0.200,0.774)

Table 9 Concentric cylinder data table 2

Field Magnet	Item	On patient Z axis		On 50cm Diameter Cylinder surface		On 55 cm Diameter Cylinder surface		On 60cm Diameter Cylinder surface		On 70cm Diameter Cylinder surface	
		Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)	Peak	R,Z (m,m)
1.5T IPM	Bo (T)	1.5	(0.000,0.000)	1.6	(0.250,0.573)	1.6	(0.275,0.584)	1.6	(0.300,0.604)	1.8	(0.350,0.624)
	Gradient (T/m)	2.6	(0.000,0.862)	3.7	(0.250,0.835)	4.1	(0.275,0.781)	4.5	(0.300,0.813)	5.7	(0.350,0.784)
	BxG (T2/m)	2.7	(0.000,0.777)	4.5	(0.250,0.740)	5.5	(0.275,0.738)	5.9	(0.300,0.765)	8.5	(0.350,0.736)

Technical specifications

This section provides technical system specifications.

- For details regarding spatial magnetic field compatibility, see Peak static spatial gradients on patient accessible areas on page 10.

- Static magnetic field plots for siting (rule of thumb - assumes no ferromagnetic materials) may be found at: https.//www.gehealthcare.com/support/site-planning.

Magnet

Component	Specification
Magnet Type	Super-Conducting
Static Field Strength	1.5T
Bore Dimension	163 cm x 70 cm x 70 cm
Cryogen Type	Liquid Helium
Boil Off Rate	Zero under normal operating conditions

Gradient

Component	Specification
Gradient type	Non resonant, actively shielded, rapidly switching

RF

Component	Specification
Transmit RF	
Types of RF transmit coils	Body Coil, Head Coil, and Extremity Coils
Amplifier peak RMS power	• 16kW for Body • 2kW for local transmit
Amplifier nominal center frequency	63.86MHz
Maximum transmit bandwidth	+/- 0.650 MHz
Receive RF	
Minimum/Maximum reception frequency	63.46MHz/64.26MHz
Nominal RF reception center frequency	63.86MHz
Receive Bandwidth	+/- 250 kHz

Patient comfort

Component	Specification
Patient space size	163 cm x 70 cm x 70 cm
Ventilation	In bore patient ventilation system
Communication	In bore 2 way intercom system
Lighting	Variable intensity LED lighting

Patient support

Component	Specification
The table is stationary. The patient table cradle is a Type BF applied part.	