C-SCAN DEDICATED MRI

DEDICATED MRI ARTOSCAN C

MR

Service Manual

Planning Guide

English

Doc.Gen.: July/2008

Replaces: Ver.B

8300096030 VER.C DGT

Document revision level
The document corresponds to the version/revision level effective at the time of system delivery. Revisions to hard copy documentation are not automatically distributed.
Please contact your local ESAOTE office to order current revision levels.
This document has been written referring to the ESAOTE document code 980 0005 009 ST Rev.H.

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Part 1 Introduction

General

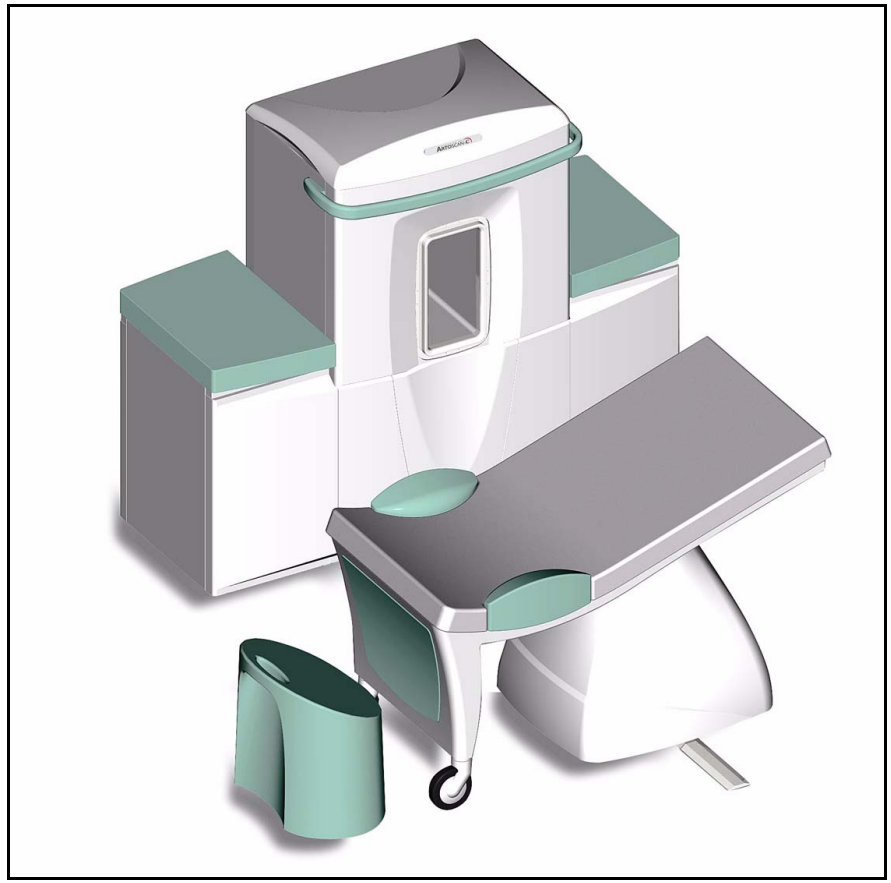
This planning guide provides a description of the items to be considered when planning the installation of the system in order to assure its safe operation.

Like other MR systems, the system is sensitive to RF interference even if the close architecture shields magnetic field fluctuations better than an open architecture system.

Up to a certain limit, the system's EFI unit can compensate for these fluctuations.

To ensure that the external RF noise and the magnetic field fluctuation do not exceed the specified limits, site survey measurement has to be performed (see also RF and Magnetic Field Interference and Annex 2, Preliminary Site Survey). Refer to Annex 1 for an overview of actions to be taken while planning a system installation.

Fig. 1: System Layout



System Components

⚠WARNING **Different system configurations are not allowed.**

System component modifications are not allowed.

Any modification of system configuration and/or system component will immediately cause the loosing of all the approvals, the loosing of the warranty and may cause safety and effectiveness issues.

- Magnet unit, including a horizontal magnetic field type permanent magnet and the system electronic modules
- Electronic Units (placed laterally to the Magnet Unit)
- Patient seat with rail
- Operating Console (computer unit, monitor, keyboard and mouse)

Fig. 2: Operating Table with LCD Monitor

Safety Notes

The magnet installed in the scan room is always under field and attracts magnetic material. The apparatus and instruments to be carried into the pavilion should be non-magnetic. Gurneys, stretchers or other large metallic objects, which may possibly be attracted to the magnet, can be dangerous. It could be useful to differentiate these objects from the standard furnishings through the use of color-coding.

Items must not be brought into the pavilion unless they are made of non-magnetic material.

In general, people must be prohibited from entering the scan room. Local regulations require that warning signs be posted with respect to possible malfunctioning of instruments or pacemakers due to the fringe magnetic field. Preventive measures must be taken with regard to this.

A warning sign calling the attention of the hospital workers and patients entering the scan room must be posted (refer also to next figure). Carrying a watch, credit card, etc., into the pavilion may cause them to malfunction.

Generally the attraction exerted on a magnetic material is felt in a magnetic field of 100 gauss or more. The area reached by the fringe magnetic field may be seen from the distribution in the reference data furnished.

Fig. 3: Warning Sign

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Part 2 Planning

Room Specifications

Room Size

Only one room is required to install the system.

The minimum space required, for the installation of the system without operator console, is 2.8 m x 3.2 m.

Tab. 1: Minimum Space Requirements

Minimum Space Requirements
2.8 m x 3.2 m

Floor Load

The floor must be as strong as sufficiently withstanding the weight of the magnetic subsystem and of the other parts of the equipment for a total weight of about 1500 Kg., including two people: the operator and the patient. If the floor load is greater than 350 Kg/sq.mt., the unit may be installed without any particular requirement, paying attention not to overload the above specified area with a further charge.

In case of doubt regarding the floor load, we suggest to provide a reinforcement that may be chosen in those described as follows:

- Modular reinforcement Kevlar plate of about a 9 sq. mt. (100 square feet) surface and appropriate thickness; the equipment must be placed in the middle of the plate
- Floor reinforcement through a beams steel work in order to distribute the load on the load-bearing structures of the building; this reinforcement may be included in the concrete of the floor or may be fixed, when possible, thus supporting the floor from the bottom
- Steel work plate (whose thickness is about 10 cm.) distributing the unit load on a surface of at least 9 sq. mt. (100 square feet); this plate is simply put on the floor and therefore it must be covered with an overpass floor. The equipment must be centered with respect to the plate

Anyway, in the case of a 200 Kg/sq.mt floor load, keep attention to install the unit only if you are sure that the floor span is greater than 4.5 mt (15 feet), assuring that the 4.5 x 4.5 sq. mt (15 x 15 sq. feet) area, around the unit itself, will never be overloaded. If these

conditions cannot be assured, consider using reinforcement as described above.

Tab. 2: Floor Load Requirements

Floor Load Requirements
>350 Kg/sq.mt.

Total Floor Load

The floor must be able to support the weight of the magnet unit (1150 kg), Patient Seat (60 kg), Operating Console (30 kg) and three people (250 kg). Therefore, the floor may have to be reinforced to sustain a total load of 1500 kg.

Tab. 3: Floor Load Requirements

Total Floor Load Requirements
1500 kg

Examples of Room Configurations

Fig. 4: Example of installation (without operator console)

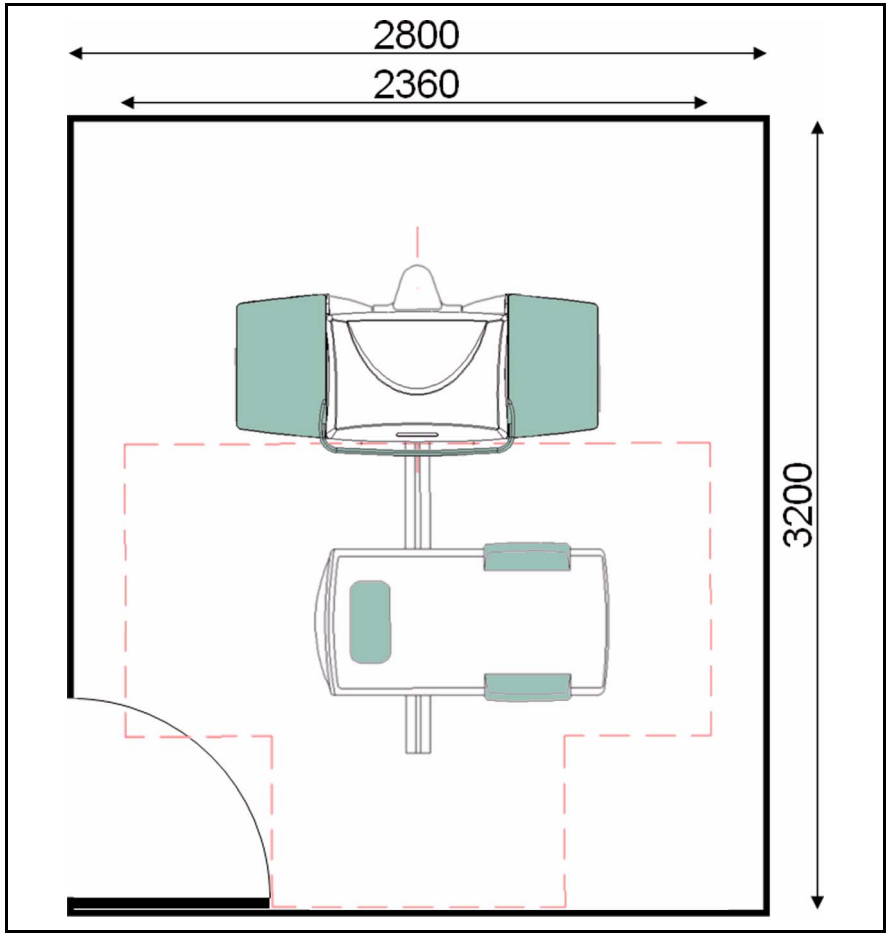
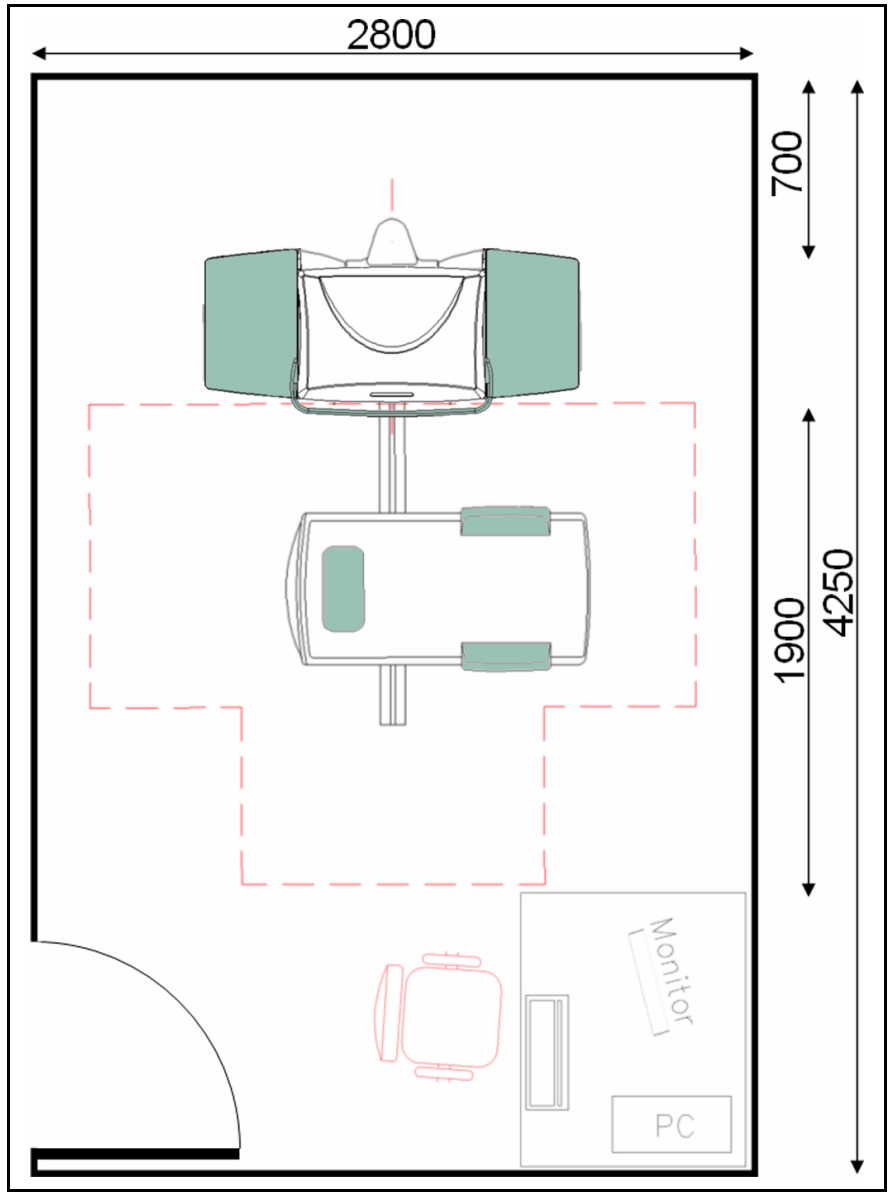


Fig. 5: Example of installation



RF & Magnetic Field Interference

The surroundings of any MR-site must be examined very carefully. In the case of System sites, it is imperative to check for external magnetic and RF interference (EMI and EFI) at an early stage of the project. This check is called a “site survey” and consists of a set of measurements that must be performed by a site survey specialist. These results are then compared to the corresponding specifications (refer also to table 5 and to table 6).

The first step is to complete the Preliminary Site Survey Report (refer to Annex 2) during the sales phase of the project, and to return it to your site survey specialist. This information is needed in order to estimate installation costs, the costs associated with the measurement, and to determine whether or not the system can be installed at that particular location. However, the final decision on the suitability of the site depends on the results of site measurements, and not on the Preliminary Site Survey Report.

Both RF noise and magnetic field fluctuations are determined during the site survey using specially designed measuring equipment called SMD (Site Measurement Device).

RF Noise

The external RF noise must be no more than 40 dB mV/m for the linear coils and no more than 30 dB mV/m for the DPA coils.

Tab. 4: Maximum RF Noise

Maximum Acceptable RF Noise
40 dB µV/m (linear coils)
30 dB µV/m (DPA coils)*

*The DPA RF threshold can be increased to 40 dB µV/m by adding a copper plate under the patient’s seat as described in the related service information.

Magnetic Field Fluctuation

The need for EFI compensation and the shielding method must be determined according to the quasi-static (DC, < 5 Hz) and slow-changing magnetic field fluctuation (AC, 16-20 Hz; AC, 50-60 Hz). All the values below refer to peak/peak fluctuation in the proposed position of the magnet center.

The DC and AC values, measured by SMD, to be considered are the peak/peak variations. A very important parameter to take into consideration is the time stability of AC disturbance. The more stable the level of the disturbance, the simpler a good compensation will be.

Tab. 5: Maximum Values without EFI

Maximum Values without EFI	
DC (< 5 Hz)	100 nT pkpk (1 mG)
AC (16.7 Hz)	60 nT pkpk (0.6 mG)
AC (50-60 Hz)	150 nT pkpk (1.5 mG)

Tab. 6: Maximum Values with EFI

Maximum Values with EFI	
DC (< 5 Hz)	3000 nT pkpk (30 mG)
AC (16.7 Hz)	1500 nT pkpk (15 mG)
AC (50-60 Hz)	2000 nT pkpk (20 mG)

In order to keep these values valid, no more than one source must be present within the limit shown in the Maximum Values without EFI table.

Environment

To achieve optimum performance from the installed system, it is important to provide patients and operators with a comfortable environment, as well as to meet the temperature, humidity and other environmental conditions that each system component requires.

Tab. 7: Environmental Requirements

Environmental Requirements	
Temperature range	20 - 26 °C
Temperature stability	3 °C/h
Humidity range	45 - 80%
Pressure	700 - 1060 hPa

Power and Grounding

Due to the sensitivity of the system to RF interference, great care should be taken when providing the power supply and when grounding the system.

To safely operate the installed system, dedicated power supplies must be provided for the MRI system and the air-conditioner, as well as any lighting equipment and convenience outlets.

A switch box should be provided on the wall of the room, with separate switches for each of the above power supplies to allow system maintenance and service. Simultaneous use of the power supply for the system with air-conditioning, lighting and other electrical equipment is not allowed.

The power requirements are listed in the following table.

Tab. 8: Power Requirements

Power Requirements	
Power requirements	AC 100/110/220/230/240 V ± 10%
Frequency	50/60 Hz ± 10%
Power (during quick magnet heating)	0.9 kVA
Power (during normal work)	0.6 kVA
Power (stand by)	0.15 kVA

Power supply cable

The power supply cable, provided with the system, is a three-wire (phase: brown, neutral: blue and earth: yellow-green), 10 m long, shielded cable with a 1.5 mm2 section. See the next table for the characteristics of the power supply cable.

Tab. 9: Power Supply Cable Features

Power Supply Cable Features	
Section	1.5 mm^2
Length	10 m

System Grounding

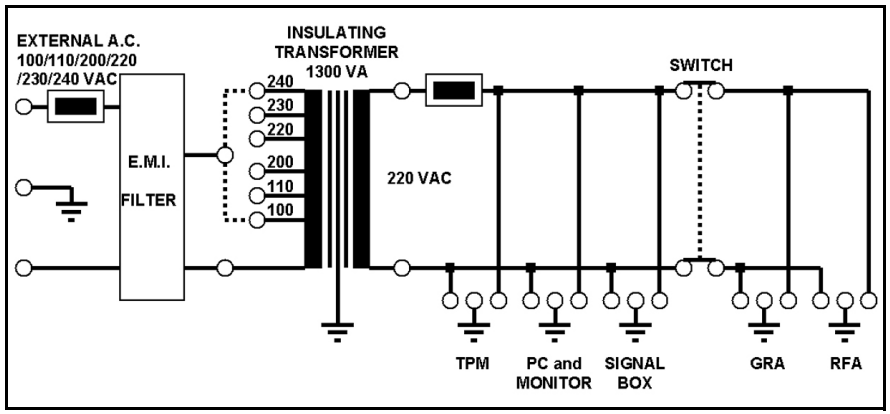
The grounding conductor must be insulated and must not be electrically connected to surrounding structures.

Power Distribution

System Power Distribution Scheme

The main power distribution diagram is shown in the next figure.

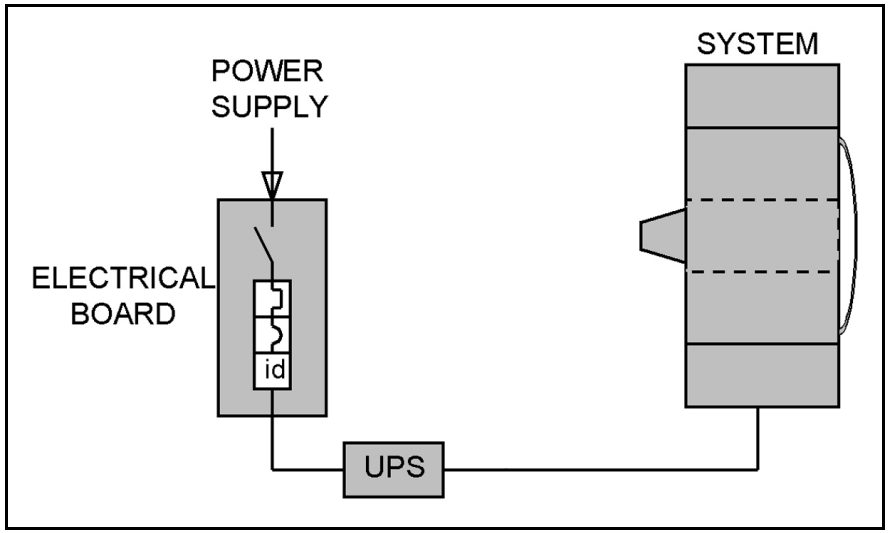
Fig. 6: System Power Distribution Scheme



Room Power Distribution Scheme

The room's power distribution scheme is shown in the following picture. All the parts that the electrical circuits need are displayed in this scheme.

Fig. 7: Room Power Distribution Scheme



Un-interruptible Power Supply (UPS)

Line voltage stabilizers or UPS systems are required in countries with unreliable power supplies. As the magnet needs to be permanently heated to keep its temperature, you are highly recommended to use UPS in case the main power supply is not reliable.

One type of UPS has been tested and released for use with the system: ONEAC, model ON1300I-SN.

Air-conditioning

Air-conditioning should be provided according to the environmental conditions of the room. (Refer to Tab. Environmental Requirements). No air-conditioning duct openings must be installed above the magnet or central control console.

⚠WARNING To prevent magnetic field drifts, the magnet must not be exposed to direct airflow from any of the air duct openings

Because the system has a small magnetic fringe field, standard air-conditioner items (galvanized sheet iron) may be used for the air-conditioning duct and accessories in the scan room.

The air-conditioner for the scan room must operate constantly. The temperature of the scan room must be maintained within a range from 20 °C to 26 °C and with a stability of at least 3 °C/h, even when the MRI system is not in operation. Otherwise, the system cannot be operated.

Connections

Maximum System Cable Lengths

The cable ducts for the System wiring is not part of the delivery.

Tab. 10: Maximum Distance PC Unit - Electronic Unit

Maximum Distance PC Unit - Electronic Unit
18 m (real cable length 20 m)

Modem, Network and Camera

Modem

The system includes an analog modem for Remote Diagnostics purposes. A direct analog phone line should be provided close to the console to connect the modem. The length of the modem cable is 2.15 m.

Tab. 11: Length of Modem Cable

Length of Modem Cable
2.15 m

Network

The system includes an internal network card for LAN connection. An appropriate outlet should be provided to connect to the LAN. The network connection cable is not provided with the system.

NOTICE	The network connection cable is not provided with the system

Camera

The system can be connected to laser cameras in two different ways: analog (BNC cable) and digital (cable or optical link)

The printer board inside the PC provides both connections.

Please contact the customer to establish the type of camera connection.

NOTICE	The Camera cable (either analog or digital) is not provided with the system, it must be provided by the camera company/manufacturer

Digital Connection

The maximum length of cable for digital connection of the camera is 40 m.

You must provide the correct location for the camera when it is connected in this way.

The cable is not supplied with the system. Please contact the camera manufacturer for the required cable details.

Tab. 12: Maximum Cable Length for Digital Connection

Maximum Cable Length for Digital Connection
40 m

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Part 3 Technical Data

Heat Dissipation

The system (without the laser camera or any other equipment) produces a maximum heat of 400W.

Tab. 13: Heat Dissipation of System Components

Heat Dissipation of System Components	
Magnet unit and console	400 W

Acoustic Noise

The system generates a noise of 58dB (A) measured in the operator position; in other words, in front of the monitor.

Tab. 14: Acoustic Noise

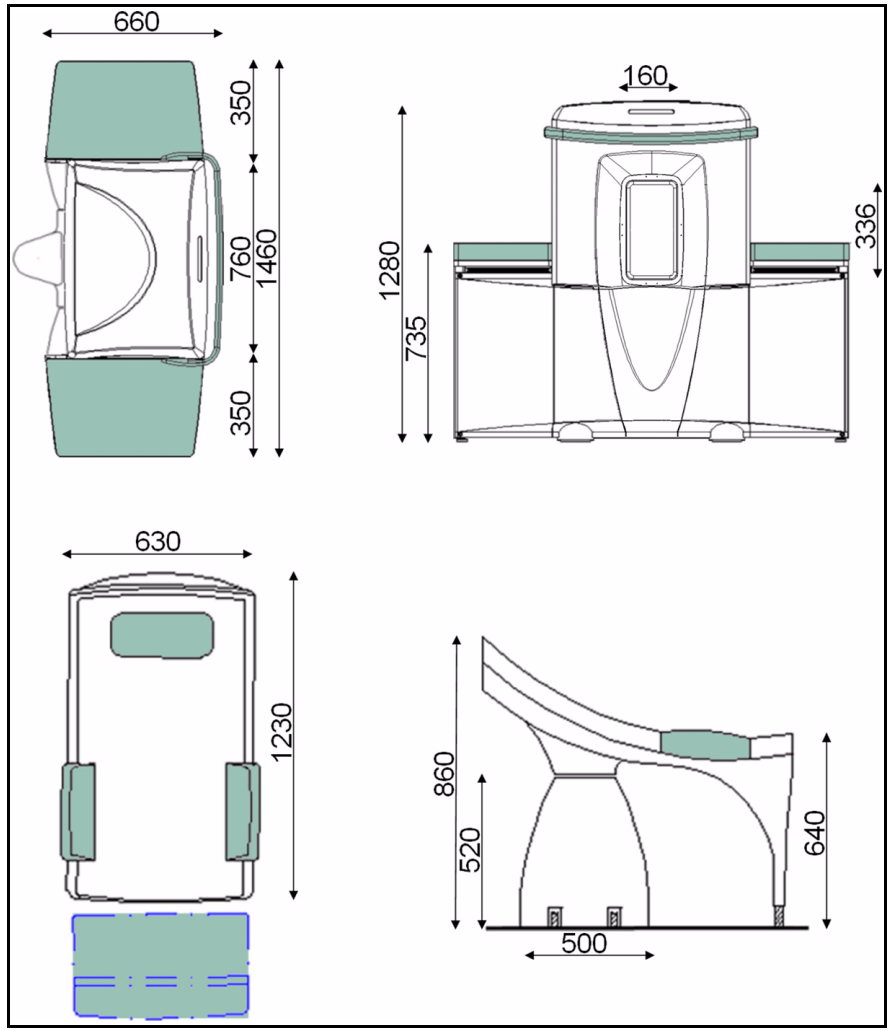
Acoustic Noise
58dB (A)

System Component Dimensions

Tab. 15: Dimension and Weight of System Components

Dimension and Weight of System Components				
Part	Dimensions [mm]			Weight
	Width	Depth	Height	
Magnet and Electronic Units	1460	660	1280	1150 kg
Patient Seat	630	1230	860	60 kg
PC Unit	260	440	430	14,5 kg

Fig. 8: System Dimensions



Magnet Fringe Field

Tab. 16: Fringe Field Distribution

Fringe Field		Distance from the Magnetic Center in Direction of		
Gauss	**mTesla**	**X axis (m)**	**Y axis (m)**	**Z axis (m)**
30	3	n.a.	0.45	0.55
10	1	0.5	0.65	0.7
5	0.5	0.75	0.8	0.9
1	0.1	1	1.1	1.3

n.a.: inside the Magnet Structure

Fig. 9: 1 Gauss Fringe Field Line in the X-Y Plane

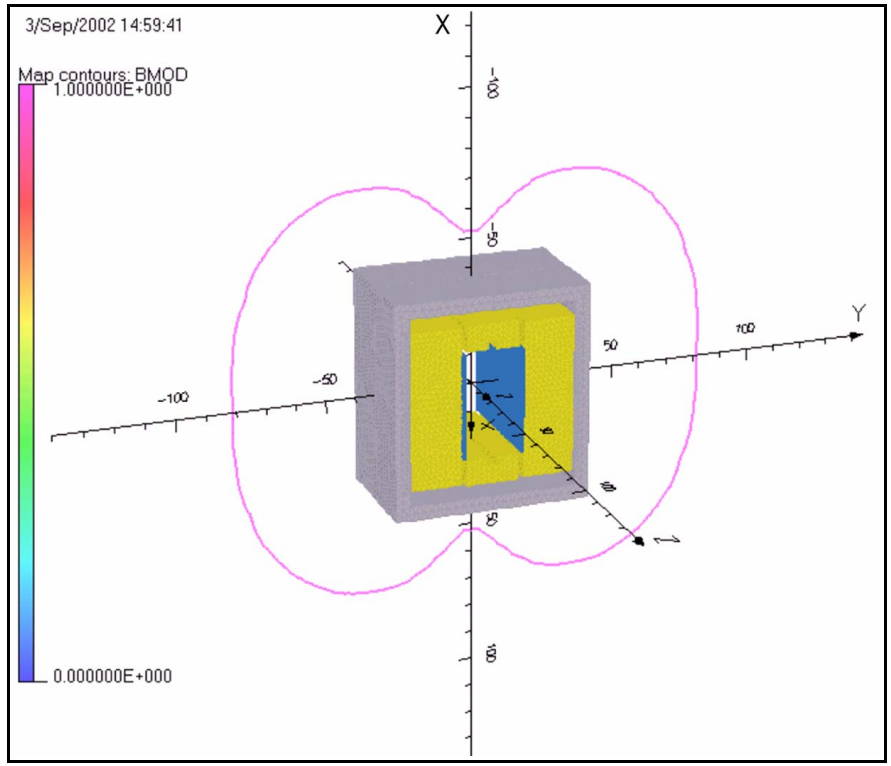


Fig. 10: 1 Gauss Fringe Field Line in the X-Z Plane

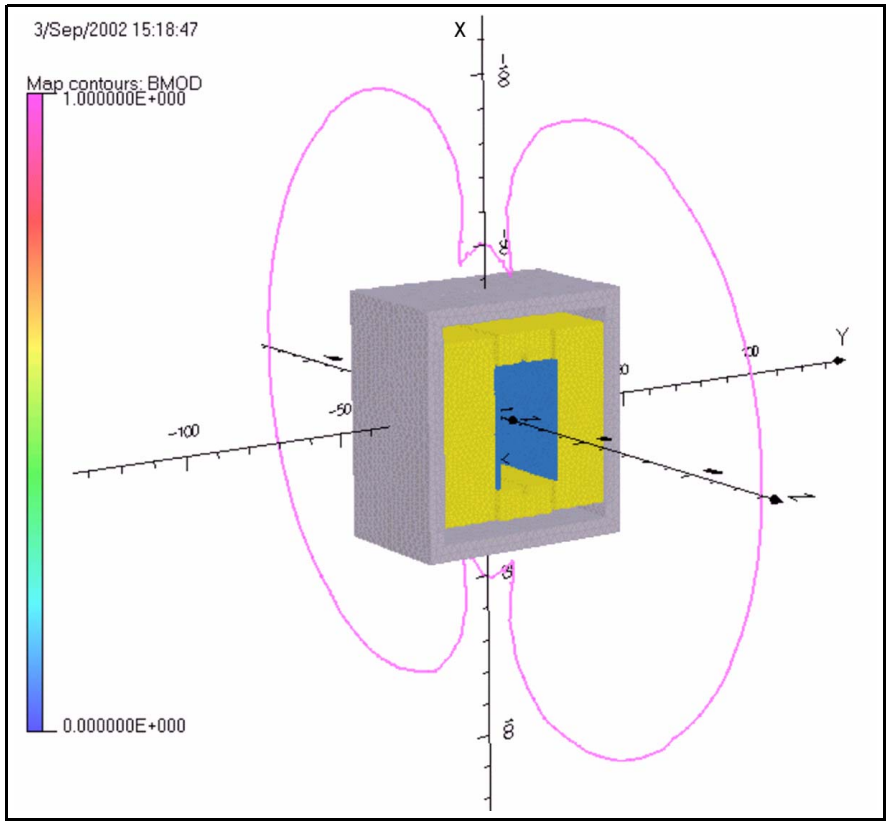
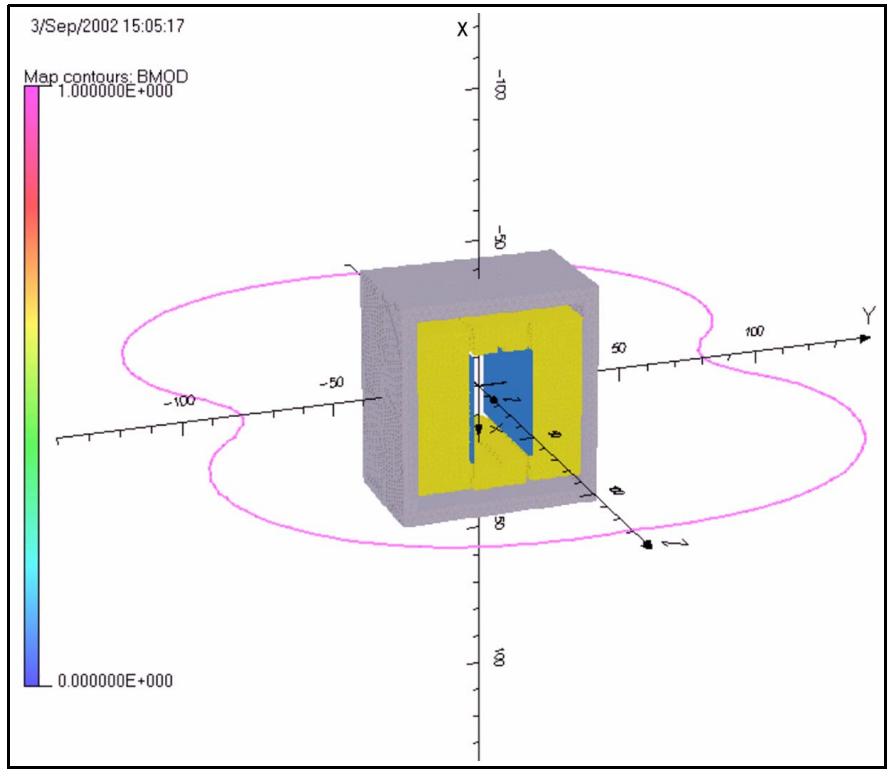


Fig. 11: 1 Gauss Fringe Field Line in the Y-Z Plane



Part 4 Transport & Storage

Transport & Storage Conditions

⚠WARNING SAVE PEOPLE TRANSPORTING: DO NOT FORGET THAT YOU ARE GOING TO MOVE GOODS POTENTIALLY DANGEROUS (e.g.: THE MAGNET FRINGE FIELD). YOU MUST DEFINE AND DELIMIT A ROUTE USED BY AUTHORIZED PEOPLE ONLY. SIGNS INDICATING THAT A PERMANENT MAGNET WILL BE MOVED MUST BE USED ALONG THE ROUTE AS WELL

⚠WARNING SAVE PEOPLE STORING: DO NOT FORGET THAT YOU ARE GOING TO STORE GOODS POTENTIALLY DANGEROUS (e.g.: THE MAGNET FRINGE FIELD). YOU MUST DEFINE AND DELIMIT AN AREA USED BY AUTHORIZED PEOPLE ONLY. SIGNS INDICATING THAT A PERMANENT MAGNET WILL BE STORED MUST BE USED ALONG THE AREA AS WELL

⚠WARNING The following specifications are suitable for not more than 15 weeks. Other this period the system creates must be stored in a place with the same temperature, humidity and pressure specifications of the final installation room (refer to the Planning chapter of this manual for more info)!!!

Temperature

When transporting and storing the magnet unit, never exceed the temperature range specified in the following table. Otherwise, the magnet will be damaged.

Tab. 17: Temperature Range during Transportation and Storage of the Magnet

Temperature Range During Transportation and Storage	
Minimum temperature	0 °C
Maximum temperature	50 °C

Humidity

When transporting and storing the magnet unit, never exceed the humidity range specified in the following table. Otherwise, the magnet will be damaged.

Tab. 18: Humidity Range during Transportation and Storage of the Magnet

Humidity Range During Transportation and Storage	
Humidity range	30 ÷ 85%

Pressure

When transporting and storing the magnet unit, never exceed the pressure range specified in the following table. Otherwise, the magnet will be damaged.

Tab. 19: Pressure Range during Transportation and Storage of the Magnet

Pressure Range During Transportation and Storage	
Minimum pressure	500 hPa
Maximum pressure	1060 hPa

Maximum Tilt

If you have to use a ramp when transporting and storing the magnet unit, never exceed a maximum tilt of 10%. Otherwise, the magnet will be damaged.

Tab. 20: Maximum Tilt during Transportation and Storage of the Magnet

Maximum Tilt During Transportation and Storage	
Maximum tilt	10%

Crates Dimensions

Tab. 21: Crates Dimensions

Content	Total weight	Size (LxWxH) [mm]
Magnet unit	1100 kg	930 x 830 x 1630
PC Unit and Electronic Units	230 kg	1470 x 770 x 1480
Patient's Bed	172 kg	1390 x 770 x 1100
Covers	96 kg	1230 x 780 x 550
Monitor	30 kg	580 x 550 x 630

Magnet Platform Dimension

Tab. 22: Pallet Dimensions

Platform Size (LxWxH) [mm]
900 x 800 x 165

Fig. 12: Magnet and Platform

Installation Device

Tab. 23: Installation Device Dimensions

Carriage Device Dimensions & Weight
L 770 x W 1200 x H 870 mm 100 kg

Fig. 13: Carriage

Minimum Door Dimension

Depending on the way the magnet unit is transported, the minimum size for the doors must be at least 770 mm.

Tab. 24: Minimum Door Dimensions

Minimum Door Dimensions
800 mm

Part 5 Annex

Annex 1

Recommended Planning Actions

This is a list of recommended actions to be taken while planning a system installation:

1. Check the room size against the minimum space required for siting a system
2. Check whether the floor has to be reinforced to sustain the total load of a system
3. Make sure that the building vibration requirements are met
4. Check whether the fringe field of the magnet requires an external room shielding
5. Ensure that the minimum passage dimension required for carrying in the system as well as the minimum weight of the system components do not represent a problem for doors, floors, elevator, etc.
6. Fill in the Preliminary Site Survey Report and send it to your site survey specialist
7. Arrange for a site measurement with your site survey specialist.
8. Check whether the floor leveling requirements are met
9. Check whether the air-conditioning system fulfills the room temperature requirements
10. Check whether the power, grounding and lighting requirements are met
11. Make sure that modem, network and camera connections are available
12. Find out whether convenience outlets (emergency lamp, smoke sensor, medical tubing) are to be installed
13. Define the room layout (position of modular shielding pavilion, doors and console). Allow at least 0.2 m distance against the wall for the filter panel and remember that the console must be placed within a distance range of 6 m from the filter panel

Annex 2

Preliminary Site Survey

Preliminary Site Survey Report must be filled in during the sales phase of the project and then returned to your site survey specialist.

Situation Report

The Situation Report is a brief description of the location of the proposed site. Check the rooms surrounding the location with respect to all six directions and enter the results into the Tab: Distance check: - Where are...?

Sources of Interference

The Distance Check is a systematic analysis of existing sources of magnetic interference and the distance between these sources and the center of the magnet. Sources of magnetic interference may be associated with one or more of the following:

a) AC 50 Hz or 60 Hz: high current cables, etc.

b) AC 50 Hz or 60 Hz: transformers, motors, etc.

c) AC 16.6 Hz or 25 Hz: power cables used for trains

d) Moving iron objects: cars, trucks, elevators, patient beds, equipment, etc.

e) Switched DC: tram, subway, other MR-systems

f) RF noise: antennas, fans (even not magnetic), monitors, engines, transformers, ups, phone switch boards, medical systems, etc.

NOTICE	Fans can create AC noise even if they are not magnetic

In addition, place a check in the corresponding box to indicate the distance range for any sources of interference. The mark(s) in the column with the lowest class number will determine the preliminary site status:

– Class 1: Very critical site, installation probably impossible

– Class 2: Critical site, installation probably possible but additional shielding required

– Class 3: Normal site, installation possible but additional shielding may be required

– Class 4: Uncritical site, installation probably possible, additional shielding not required

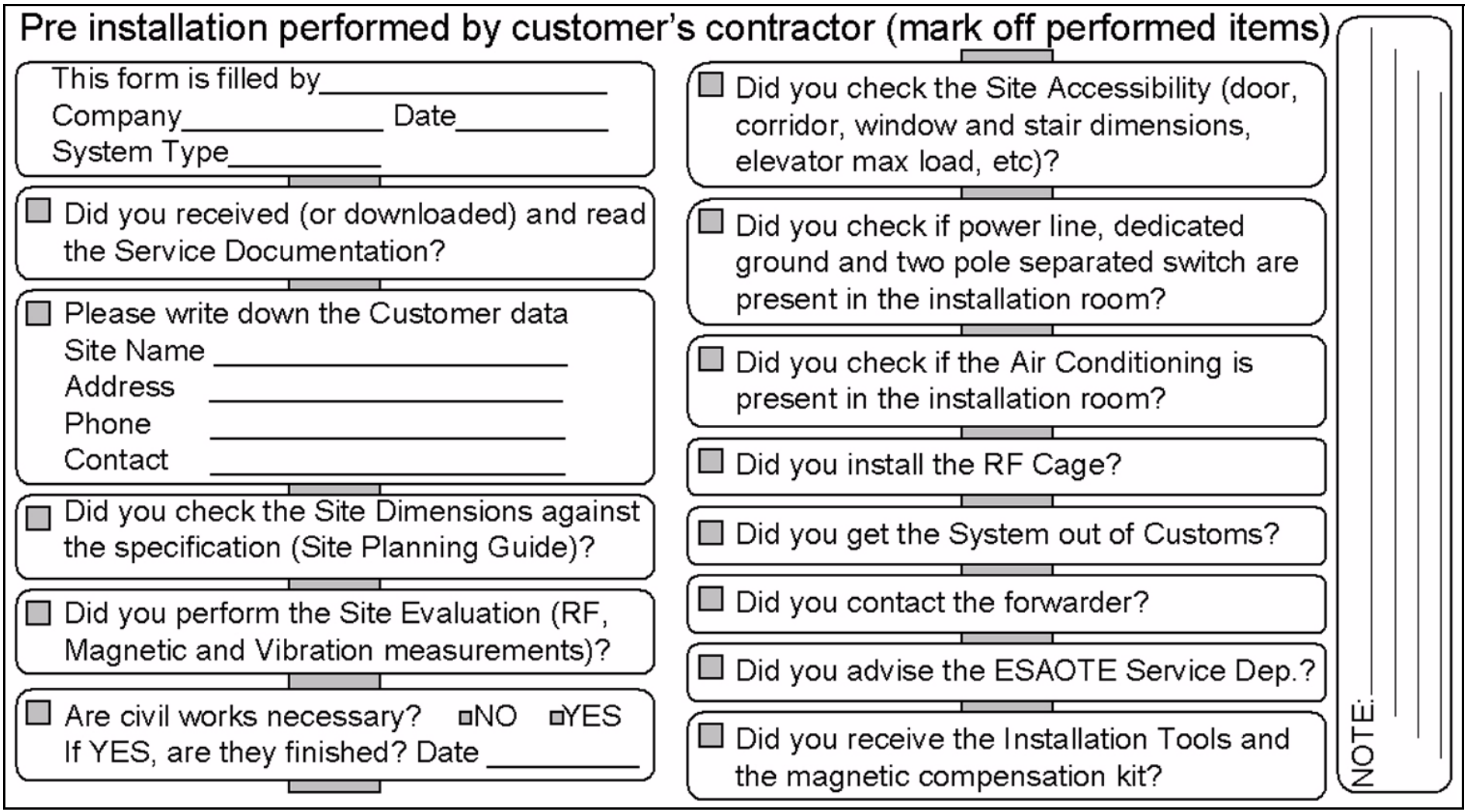
Remarks

Use the next section to enter any comments you consider important regarding installing the system at that location.

Checks and Actions

PLEASE COMPLETE THE FOLLOWING FORM MARKING OFF ALL THE PERFORMED ITEMS AND E-MAIL/FAX BACK TO ESAOTE.

Fig. 14: Check and Actions flowcharts



General Information

Tab. 25: General Information

Sales representative:			
Project manager:			
Sales status:	sold:	probable:	possible:
Customer name:			
City:			
Report issued by:			
Date and signature:			

Situation Report

Tab. 26: Situation Report - What is located where...?

Behind the magnet	+X	
In front of the magnet	-X	
Above the magnet	+Y	
Below the magnet	-Y	
Right of the magnet	+Z	
Left of the magnet	-Z	

Distance Check

Tab. 27: Distance check: - Where are...?

Sources of interference	Class 1		Class 2		Class 3		Class 4		X	Y	Z
a) AC 50 Hz or 60 Hz: High current cables	<1 m		1 to 5 m		5 to 10 m		>10 m				
b) AC 50 Hz or 60 Hz: Transformers	<4 m		4 to 7 m		7 to 10 m		>10 m				
c) AC 16.6 Hz or other train frequencies	<20 m		20 to 100 m		100 to 250 m		>250 m				
d) Moving iron (dynamic interference)											
– <50 kg: Wheel chair, etc.	<2 m		2 to 4 m		4 to 5 m		>5 m				
– 200 kg: Patient bed, etc.	<3 m		3 to 6 m		6 to 8 m		>8 m				
– 900 kg: Car, small elevator, etc.	<5 m		5 to 9 m		9 to 12 m		>12 m				
– >4500 kg: Truck, large elevator, etc.	<6 m		6 to 11 m		11 to 17 m		>17 m				
e) DC cables from tram or subway	<15 m		15 to 40 m		40 to 250 m		>250 m				
f) Iron plates in floor	<30 kg/m^2										

Comments

Tab. 28: Enter any additional comment here

Annex 3

Planning summary

Minimum Space Requirements
3 m x 3.2 m

Floor Load Requirements
>350 Kg/sq.mt.

Total Floor Load Requirements
>1500 kg

Maximum RF Noise
40 dB μV/m (linear coils)
30 dB μV/m (DPA coils)

Maximum Values without EFI	
DC (< 5 Hz)	100 nT pkpk (1 mG)
AC (16.7 Hz)	60 nT pkpk (0.6 mG)
AC (50-60 Hz)	150 nT pkpk (1.5 mG)

Maximum Values with EFI	
DC (< 5 Hz)	3000 nT pkpk (30 mG)
AC (16.7 Hz)	1500 nT pkpk (15 mG)
AC (50-60 Hz)	2000 nT pkpk (20 mG)

Environmental Requirements	
Temperature range	20 - 26 °C
Temperature stability	3 °C/h
Humidity range	45 - 80%
Pressure	700 - 1060 hPa

Power Requirements	
Power requirements	AC 100/110/220/230/240 V ± 10%
Frequency	50/60 Hz ± 10%
Power (during quick magnet hating)	0.9 kVA
Power (during normal work)	0.6 kVA
Power (stand by)	0.15 kVA

Power Supply Cable Features	
Section	1.5 mm^2
Length	10 m

Maximum Distance PC Unit - Electronic Unit
15 m (real cable length 17,5 m)

Modem

Length of Modem Cable
2.15 m

System Components

Dimension and Weight of System Components				
Part	Dimensions [mm]			Weight
	Width	Depth	Height	
Magnet and Electronic Units	1460	660	1280	1150 kg
Patient Seat	630	1230	860	60 kg
PC Unit	260	440	430	14,5 kg

Fringe Field

Fringe Field		Distance from the Magnetic Center in Direction of		
Gauss	**mTesla**	**X axis (m)**	**Y axis (m)**	**Z axis (m)**
30	3	n.a.	0.45	0.55
10	1	0.5	0.65	0.7
5	0.5	0.75	0.8	0.9
1	0.1	1	1.1	1.3

Heat Dissipation

Heat Dissipation of System Components	
Magnet unit and console	400 W

Acoustic Noise

Acoustic Noise
58dB (A)

Transport

Content	Total weight	Size (LxWxH) [mm]
Magnet unit	1100 kg	930 x 830 x 1630
PC Unit and Electronic Units	230 kg	1470 x 770 x 1480
Patient's Bed	172 kg	1390 x 770 x 1100
Covers	96 kg	1230 x 780 x 550
Monitor	30 kg	580 x 550 x 630

Platform Size (LxWxH) [mm]
900 x 800 x 165

Carriage Device Dimensions & Weight
L 770 x W 1200 x H 870 mm 100 kg

Minimum Door Dimension
800 mm

Maximum Tilt During Transportation and Storage	
Maximum tilt	10%

⚠WARNING The following specifications are suitable for not more than 15 weeks. Other this period the system creates must be stored in a place with the same temperature, humidity and pressure specifications of the final installation room (refer to the Planning chapter of this manual for more info)!!!

Temperature Range During Transportation and Storage	
Minimum temperature	0 °C
Maximum temperature	50 °C

Humidity Range During Transportation and Storage	
Humidity range	30 ÷ 80%

Pressure Range During Transportation and Storage	
Minimum pressure	500 hPa
Maximum pressure	1060 hPa

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