GE Healthcare

Pre-installation Manual and Checklist for Aria (Chorale)

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LU46005EN Revision 1 (March 2021)

Contents

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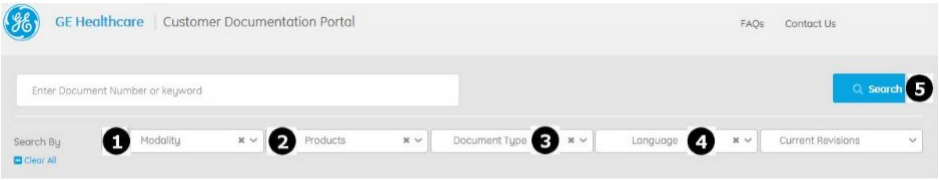
The latest revision of the Pre-installation Manual and Checklist can be accessed at the following website: https://www.gehealthcare.com/documentationlibrary.

1. Scroll down and click ***VISIT THE SITE*** button under ***Customer Documentation Portal*** section.
2. Select Modality [1] ***Bone Mineral Densitometry (XR)***.
3. Select Product [2] ***XR (BMD) Aria DXA*** for Aria (Chorale) products.
4. Select Document Type [3] ***Preinstallation Document***.
5. Select your language [4]. Not all languages are available. Leave blank to see available languages.
6. Click the ***Search*** button [5]. The result will be the Pre-installation Manual and Checklist.



Overview

This Pre-installation Manual contains equipment specifications and is a global customer requirements document that customers use for the design, planning, and construction of a site in preparation for the delivery, installation, service and clinical operation of GE Healthcare equipment.

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Physical Specifications

Component	Version	Specifications
Scanner table	Full Size Table	Dimensions: approximately 200 cm x 80 cm x 130 cm (L x W x H) Weight: less than 275 kg Maximum patient weight supported: 159 kg (350 lb)

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Operational Environment Specifications

Adhere to these specifications during scanner operation.

Ambient Space (Interior Subcomponents)

For scanner operation and servicing, do not block the area around the scanner table. For minimum clearances, see Space Requirements (31).

Ambient Space (Ventilation)

Do not block the cooling vents on the computer and scanner table. Make sure there is at least 15 cm between the console table and the wall for cable clearance and computer plugs.

Dust, Fumes, and Debris

Install the system in a clean, ventilated area. Dust and other airborne debris can cause the drive heads and other sensitive mechanical components to malfunction. Do not smoke in the scanner room.

Humidity

Make sure the humidity for the scanner area is 20%-80%, non-condensing.

Power Consumption

For all scanner types, a dedicated 15A 100-127 VAC ±10% or 10A 200-240 VAC ±10% circuit (single duplex outlet) with isolated ground (THD<5%) is recommended. The outlet should be located behind the host PC. See Declarations of Immunity and Emissions table (25) for power quality guidance.

- The scanner draws approximately 40 watts when idle and 250 watts during a patient scan (76kV / 1mA).
- The host PC (typical PC with a monitor) draws approximately 110 watts when powered on.

Distortion

Sinusoidal waveform, less than 5% THD.

Heat Output

- The scanner outputs approximately 150 BTU per hour when idle and 900 BTU per hour when actively scanning.
- The host PC (typical PC with a monitor) draws approximately 400 BTU per hour when powered on.

Static Electricity

Install and operate the system in a static-free area. Adhere to minimum humidity requirements to prevent malfunctions caused by static electricity.

Temperature

Make sure the temperature during system operation is 65°F-81°F (18°C-27°C).

NOTE If the scanner is turned off for more than an hour, or if there is a power failure, you must turn the system on and let it warm for one hour. After one hour, complete a Quality Assurance procedure.

Elevation

Lunar scanners are not for use above 3000 m.

Seismic Requirements

Seismic requirements are determined and specified by the hospital design professional of record and may require approval by the specific state or country agency. Seismic attachment hardware shown on seismic calculations may differ from hardware supplied with system. Any additional hardware that is required will be the responsibility of the institution and/or their contractor. Contact your local GE Project Manager of Installations or Installation Representative to obtain seismic calculations.

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Storage and Transport Environment Specifications

Adhere to these specifications for scanner storage and transportation.

Humidity

0% to 95% non-condensing.

Atmospheric pressure

500 to 1060 hPa.

Temperature

-30° to 65° C.

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Input Power

The scanner has a rated input of 100-240 VAC. Voltage may fluctuate ±10% from the rated input without a loss of scanner performance. The input power must meet IEEE 519-1992 for power quality and total harmonic distortion (THD <5%).

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Electrical Safety

WARNING

Do not plug the scanner into any outlet strip. Always plug the scanner directly into the supply mains.

WARNING

Do not plug additional outlet strips or extension cords into power source connected to scanner.

WARNING

To avoid risk of electric shock, this equipment must be connected only to a supply mains with protective earth. Scanner power cord must be connected directly to the wall outlet or to a redundantly grounded UPS. Never power the scanner via an outlet strip.

Peripheral Configurations

WARNING

The correct connection of the computer and all peripherals is necessary to maintain electrical safety. The signal cable of the scanner is intended only for connection to an approved computer. Call GE Support or your GE distributor before adding peripherals.

WARNING

Operator shall not touch patient and computer or peripherals simultaneously.

WARNING

Failure to use outlet strips properly can cause medical electrical system leakage currents in excess of 100 microamperes. For more information on medical electrical systems, refer to IEC 60601-1.

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IEC and UL/CSA Certification

To maintain electrical safety, all computer equipment and accessories connected to the scanner must meet all requirements for safety. European countries require CE mark certification. Other countries should follow their local requirements for computer equipment and accessories certification. Declarations of conformity to the required standards should meet or exceed the requirements of EN 60950, Safety of Information Technology Equipment and EN 55024 Information Technology Equipment - Immunity Characteristics.

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Electromagnetic Interference

Although the scanner meets safety standards regarding electromagnetic interference (EN60601-1-2), you may still experience a loss of performance under extreme electromagnetic conditions. Maximize the distance between the scanner and other equipment. Use a dedicated power line to avoid interference to and from the scanner. Scanners should be separated from MR equipment, so the field is <1 Gauss.

9 Electromagnetic Compatibility (EMC) Performance

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC (Electromagnetic Compatibility) indicates the capability of equipment to curb electromagnetic influence from other equipment and at the same time not affect other equipment with similar electromagnetic radiation from itself. Proper installation following the service manual is required in order to achieve the full EMC performance of the product. In case of issues related to EMC, please call your service personnel.

EMC Environment and Guidance

Recommended Separation Distance

The bone densitometers are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between RF communications equipment (transmitters) and the bone densitometer as recommended below, according to the maximum output power of the communications equipment.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the X-ray Bone Densitometer

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.8
1.0	1.2	1.2	2.4
10	3.7	3.7	7.4

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
100	12	12	23

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: Use of transmitters above 2.7 GHz is not recommended.

10 Declarations of Immunity and Emissions

Declaration of Electromagnetic Emissions

The bone densitometers are intended for use in the electromagnetic environment specified below. The user of the bone densitometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CISPR 11	Group 1	The bone densitometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The bone densitometer is suitable for use in all establishments, other than domestic. The bone densitometer is not suitable for establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Caution:** This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

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.

Declaration of Electromagnetic Immunity

The bone densitometers are intended for use in the electromagnetic environment specified below. The user of the bone densitometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in UT) for 1 cycle 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	<5 % *U*T (>95 % dip in UT) for 1 cycle 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	If the user of the bone densitometer requires continued operation during power mains interruptions, it is recommended that the bone densitometer be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radio frequency (RF):			RF communications equipment should be used no closer to any part of the bone densitometer (including cables) than the recommended separation distance. The recommended separation distance is calculated 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, and *d* is the recommended separation distance in meters (m):

Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	$d = 1.2 \sqrt{P}$ (150 kHz to 80 MHz)
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	$d = 1.2 \sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3 \sqrt{P}$ (800 MHz to 2.7 GHz)
Note 1: *U*T is the A.C. mains voltage prior to application of the test level. Note 2: At 80 MHz and 800 MHz, the higher frequency range applies. Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

This equipment is suitable for use in industrial areas and hospitals (except for near active HF surgical equipment and the RF shielded room of an MRI, where electromagnetic disturbances are high). Loss of performance (inaccurate bone density results) due to electromagnetic disturbances may be indicated by artifacts within scan images or failure of quality assurance tests. If such indicators are encountered, increase the distance between RF generating equipment and the bone densitometer.

WARNING

Use of the bone densitometer adjacent to or stacked with other equipment should be avoided. Use of accessories and cables other than those provided by GE Healthcare could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part (including cables) of the bone densitometer. Failure to do so could result in improper operation.

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X-Ray Shielding Requirements

Install a **Caution: X-Radiation** sign in the area or room where the system is operated. Because of low leakage levels of radiation from the x-ray tube assembly, additional shielding in the walls, floor, or ceiling is not necessary. However, call your state or local health and radiation safety departments for shielding requirements.

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Space Requirements

For safety reasons, the scanner and patient should be visible to the operator during the exam. Consult local regulations on radiation safety.

Standard Room Configuration

The computer, peripherals, and all other equipment must be located more than 1.5 m from the scanner. If an outlet strip is used to power the computer, it must be mounted off the floor so that it does not touch other equipment.

A modem and/or network connection can be made at any time if you are using the standard room configuration.

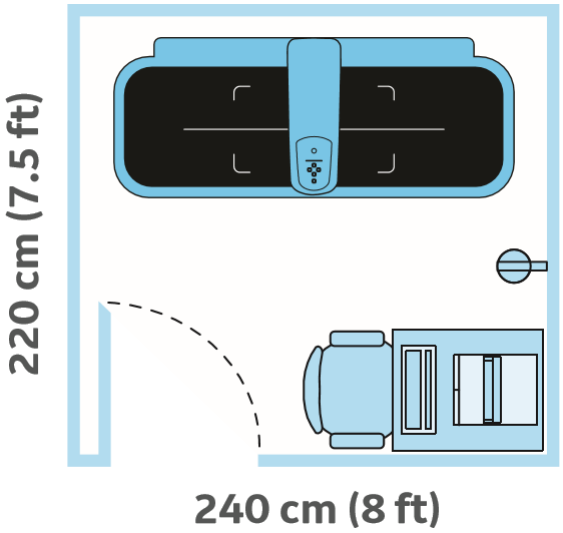
Small Room Configuration

You must power the computer and peripherals with an isolating transformer if the room is too small to maintain at least 1.5 m of separation between the scanner and all other equipment.

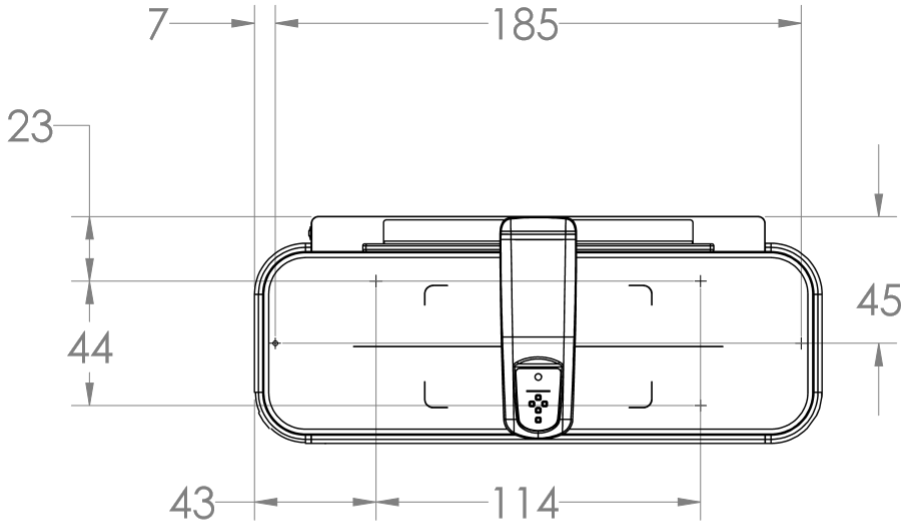
The isolation transformer supplied by GE Healthcare has a maximum output of 400/500VA. Because the transformer includes a multiple socket outlet, only the computer and peripherals shall be powered by the isolation transformer. The scanner shall be powered directly from the supply mains.

A modem and/or network connection can only be made in the small room configuration if all exposed metal surfaces of the computer and peripherals are out of the patient environment.

Minimum Room Dimensions



Foot Glide locations



Aria glide location
All dimensions in centimeters

Minimum PC Requirements

The computer provided with the DXA system must be used to operate the scanner. The customer may supply the computer for Auxiliary Workstations providing it meets the minimum requirements listed in this section.

Item	Requirement	
Intel	Processor	Intel Core i3
	Keyboard/Mouse	USB
RAM		8 GB
Video		SVGA (1024x768, 24/32-bit color)
Hard Drive		1 TB 1 GB must be available for enCORE
Network Interface (InSite Connectivity)		10/100 Mbit Ethernet
Optical Drive		DVD-R
Archive		500 GB USB hard drive
Monitor		20" SVGA (minimum resolution 1024x768, 32-bit color)
Optional Printer		Hewlett-Packard 8210 or equivalent
Additional Software		Windows 10 Enterprise, Adobe Reader DC

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Training Information

GE Healthcare or its authorized distributors provide individual, hands-on training as part of the installation procedure for your system. (GE distributors provide training for systems installed outside the United States.) An Applications Specialist provides information on software and hardware operations, and reviews the warnings and cautions in the manuals.

IMPORTANT

Only trained technologists should operate the system. New technologists should receive training prior to unsupervised operation of the system. Additional training sessions are available on request for a nominal fee. For more information, contact the GE Customer Service Department at 888-281-4947, or your local GE representative.

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Pre-installation Checklist

Facility Name: **Phone:**

	Contact Name	Phone	eMail
Customer Contact			
Sales Territory Manager			
Network/IT Administrator			
DICOM PACS Admin			
HL7 Administrator			
Patient Worklist Admin			
Other			

Customer Responsibilities:

To prepare for the installation of your new equipment, please complete and return the following form. Full completion of this form will minimize disruption to your practice and ensure a quick, efficient installation. Please complete this form in full to confirm your installation date. Please contact your Sales Territory Manager directly if you have any questions.

Regulatory:

Government health departments can require medical facilities to register diagnostic x-ray equipment. Many municipal and state health agencies require medical health facilities to employ certified radiologic technologists to operate diagnostic x-ray devices. Contact your local regulatory authorities or GE representative for registration guidelines and regulation compliance.

Please send completed form to your sales representative

#	General/Site information	Yes	No
1	Is this area accessible to an 18 wheel semi-truck?	☐	☐
2	Is there a trade-in (replacement of existing equipment)?	☐	☐
3	If yes, is the new equipment going into the room of the existing equipment?	☐	☐
4	Is there a room move with this install?	☐	☐
5	Office hours _____ - _____ Do you allow after hours work be performed?	☐	☐

#	Room information	Yes	No
1	Is room ready for installation - all construction/finished flooring/ceiling/walls/painting/lighting completed? If no, date will be ready: _____ / _____ / _____	☐	☐
2	Room dimensions are _____ ft x _____ ft, or _____ m x _____ m Does room meet minimum room size specifications above?	☐	☐
3	Minimum doorway width required is 32 inches (81 cm). If doorway width is narrower than 32 inches (81 cm), please specify door width: _____ inches or _____ cm	☐	☐
4	What floor will the equipment be on? Floor number _____ Is there an elevator? If yes, minimum required elevator dimensions are 3 ft x 3 ft x 8.3 ft (0.91 m x 0.91 m x 2.53 m).	☐	☐

#	Room information	Yes	No
5	What are your elevator dimensions? (Length x Width x Height) _____ ft x _____ ft x _____ ft, or _____ m x _____ m x _____ m	☐	☐
6	What is the width of your hallway? _____ ft or _____ m		
7	Please provide the dimensions of, or describe, any narrow sections/turns less than 4 feet (1.21 meters) on the path to the room.		
8	**POWER:** Is there a 240 VAC / 10 Amp or 120 VAC / 20 Amp dedicated duplex outlet (isolated ground) installed and available at the location of the workstation (within 4 ft/1.21 m) - not behind scan table?	☐	☐
9	**Isolation Transformer:** Will the PC workstation mount 5 ft/1.5 m or closer to the scanner to require a small room kit during install?	☐	☐
10	**Ethernet Jack:** Ethernet jack available at the location of the workstation?	☐	☐

Please draw room layout in grid provided

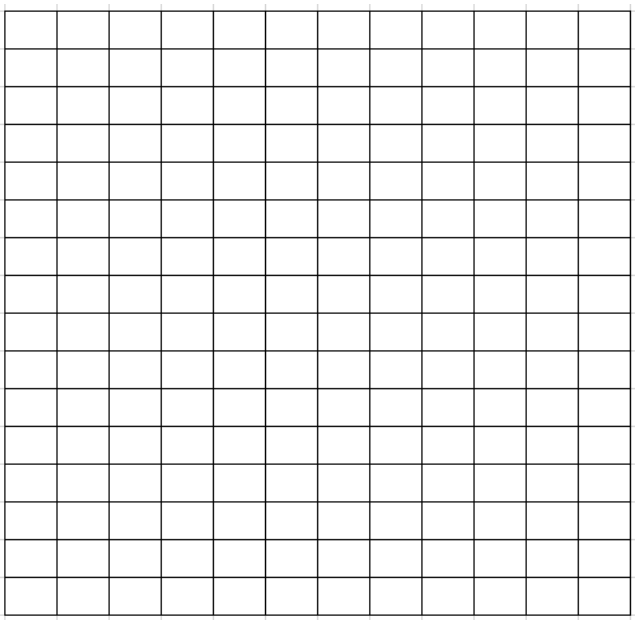
Check appropriate legend for drawing

☐ 1 square = 1 foot

☐ 1 square = .25 meters

Refer to specific guidelines below:

1. Show location and width of all doors, walls, sinks, cabinets and all other fixed furniture.
2. Show location of electrical outlets and internet connections.
3. Show desired location of scanner and computer console.



Room measurement comments (optional):

#	Network Connectivity	Yes	No
1	Is there connectivity required? If yes, continue below.	☐	☐
2	Is there a network jack installed in the room?	☐	☐
3	Is DICOM Storage required? If yes, PACS vendor name: _____ IP: _____ Port: _____	☐	☐
4	Is HL7 storage required? If yes, HL7 vendor name: _____ IP: _____ Port: _____	☐	☐
5	Is patient worklist functionality required? If yes, format is: ☐ DICOM ☐ HL7	☐	☐
6	Is Insite connection allowed? If no, skip to #9.	☐	☐
7	Provide Hospital Network Proxy if applicable: IP: _____ Port: _____ Name: _____ Password: _____		
8	Provide admin account on domain. Name: _____ Password: _____		
9	Is multi-user database access (MUDBA) required? If no, skip to #11. My database will reside on: ☐ LUNAR Workstation ☐ My network SQL Server IP address: _____	☐	☐
10	List versions of enCORE software on all systems to be connected to MUDBA: _____		
11	Quality of Databases to transfer (if required): _____ Quantity of patients in each Database: _____		
12	Hologic database import required? If yes, is the database: ☐ SQL Server ☐ Microsoft Access (Patscan.mdb)	☐	☐

#	Network Connectivity	Yes	No
13	Will there be any remote workstations? If yes, what quantity? _____	☐	☐
14	Is a telephone in the room available to assist the scanner operator when contacting customer support? (Recommended)	☐	☐

Please send completed form to your sales representative

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