New as of: 10.2014

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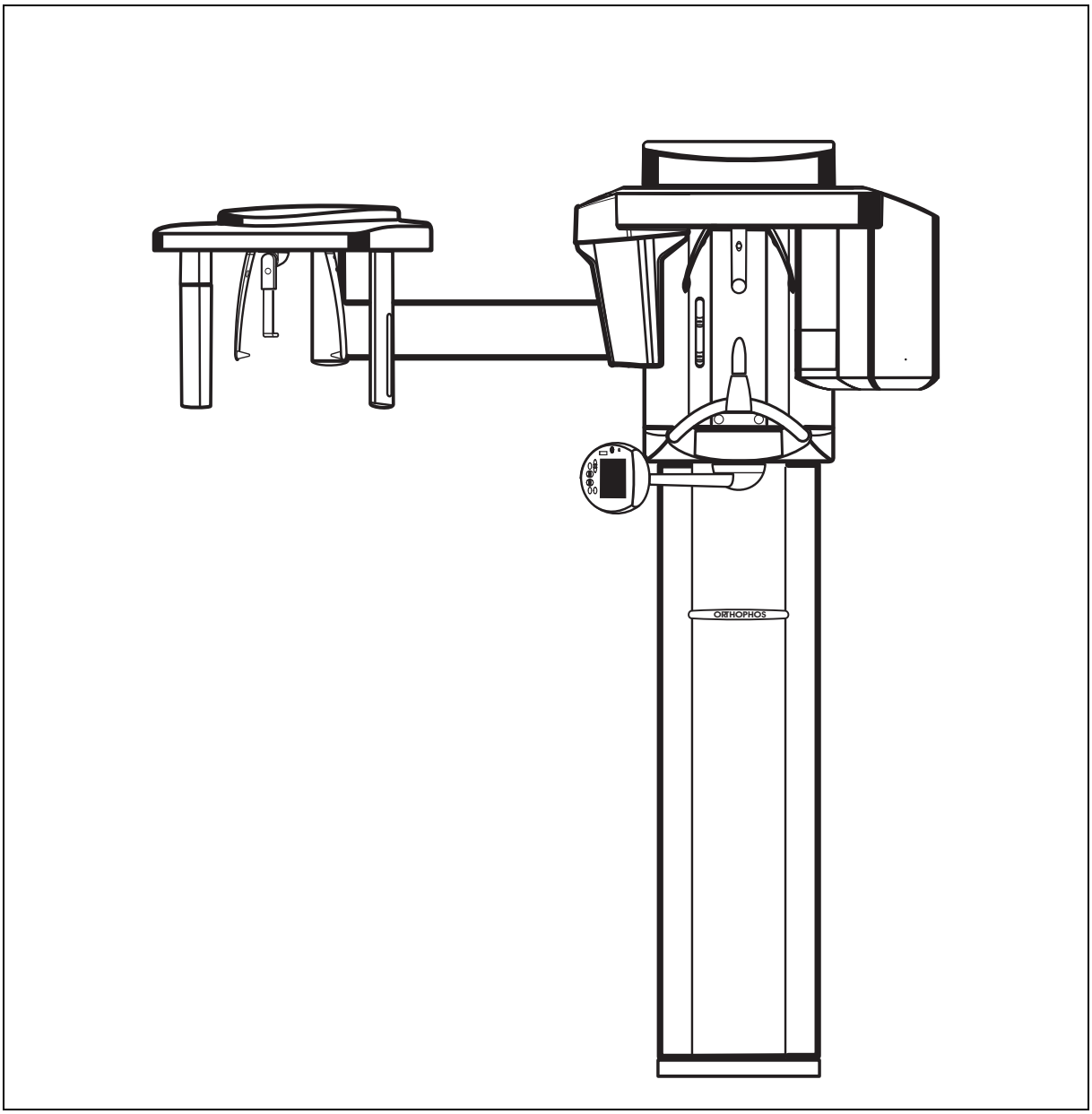
The Dental Company

ORTHOPHOS XG 3D / Ceph
ORTHOPHOS XG 3D^{ready}/ Ceph

Installation Requirements

English



General information

About this document

This document describes the installation requirements for the ORTHOPHOS XG 3D / Ceph and ORTHOPHOS XG 3D^{ready}/ Ceph X-Ray unit.

Their subsequent installation is described in the Installation Instructions, ORTHOPHOS XG 3D / Ceph REF 63 03 452 and ORTHOPHOS XG 3D^{ready}/ Ceph REF 59 87 651.

New as of: 10.2014

Changes since the last version 07.2012:

Chapter or section, page	
1.4 IT hardware	12
3.5 Technical data	36

List of Contents

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1 Installation requirements checklist

ORTHOPHOS XG 3D/3D^{ready}

1.1 Purpose of this checklist

We recommend checking the local conditions 4 weeks prior to the date of installation. This will help ensure a smooth workflow when the ORTHOPHOS XG 3D/3D^{ready} unit is actually installed. The most important points to be observed are specified in the checklist contained in this document.

1.2 Executing persons/companies

List of local executing persons/companies:	
Dealer:	
Date of installation inspection :	
Present/company:	
Present/company:	
Present/company:	

Installation site / Practice/ clinic	
Last name, first name:	
Street:	
City/State/Postal (ZIP) code:	
Phone:	
E-mail:	@
Special field of system owner:	

1.2 List of executing persons/companies

List of contact persons on-site:				
Function	**First name / Last name:**	**Phone:**	**Cell phone**	**E-mail**
Service engineer				
IT specialist				
Dental specialist				
Administrator				
Expert				
Clinic technician				
Prof.				
Dentist				

Scheduled day/date of installation:	
Time:	
Possible postponement to day/date:	
Time:	

1.3 Structural prerequisites

Transport path:		
• Clarify and/or walk along unit transport path from delivery location to installation site, measuring doorways and passageways (Dimensions/ weight, see 3.5) Transport path OK?	❑ yes	❑ no
• Elevator available?	❑ yes	❑ no
• Provide appropriate transport personnel!	❑ yes	❑ no

- Person responsible:
- Remarks/Tasks:

1.3 Structural prerequisites

Transport path:		
• Transport path: Unit location: Building number: Room name/number:		
• Is the room large enough? (see 3.1)	❑ yes	❑ no
• Is a radiation protection plan available?	❑ yes	❑ no
• Measured room height at least 2100 mm (82 3/4“)? • Maximum unit height without floor stand 2249 mm (88 1/2“) • Maximum unit height with floor stand 2279 mm (89 1/4“)	❑ yes	❑ no
• Floor heating installed? • If so, use 2nd wall bracket	❑ yes	❑ no
• Carpeting at system site? If so, remove carpeting underneath system.	❑ yes	❑ no
• Info available on wall material? Perform test drilling if necessary!!	❑ yes	❑ no
• Required extraction forces (wall plugs see 2.2) ensured?	❑ yes	❑ no
ATTENTION ***If the condition of the wall is not sufficient, a floor stand can be used. The upper wall fastening for immobilizing the unit is absolutely essential when installing it on the floor stand!***		
• Installation on the wall with or without floor stand? (see 2.3)?	❑ with	❑ without
• Intermediate storage possibilities available for styrofoam parts? The unit should be brought to the installation site with the styrofoam parts, one of the installation aids should also be present. They must be temporarily stored until they are shipped.	❑ yes	❑ no
• Remarks/Tasks:		

1.3 Structural prerequisites

Electrical connection of the ORTHOPHOS XG		
• Fuse protection of hard-wired unit connection 3x2.5mm^2 (14 AWG) 230/ B25A, 3x1.5mm^2 (16AWG) B 16A/20A may be connected only to ORTHOPHOS XG 3D/3D^{ready}.	❑ yes	❑ no
• Internal line impedance checked? (max. 0,8 Ohm)	❑ yes	❑ no
• 2. Protective ground wire installed? If no 2nd protective ground wire is installed, one must be retrofitted!	❑ yes	❑ no
• Are other large electrical devices installed nearby (e.g. air conditioning units, fan motors)? If so, what kind of devices (EMC influences)?	❑ yes	❑ no
• Distance from ORTHOPHOS XG 3D/3D^{ready}?	_____m	
• Remarks/Tasks:		

Type of remote control installation		
• Select the type of remote control required (see 2.2):		
– In the room	❑ yes	❑ no
– Outside without coiled cable	❑ yes	❑ no
– Outside with coiled cable	❑ yes	❑ no
• Conduit available?	❑ yes	❑ no
• Diameter Conduit? (Diameter mind. 10 mm (3/8“))	_____mm	
• Distance Conduit? (Distance max. 13 m (512“))	_____m	
• Remarks/Tasks:		

1.4 IT hardware

Minimum requirements for RCU/visualization-PC (not included in the scope of supply)

	Minimum requirements:	Recommendation:	Minimum	Recommendation
Operating system:	Windows 7 Professional (64-Bit)	Windows 7 Ultimate 64bit	❑	❑
Processor:	DualCore ab 2 GHz	Quadcore ab 2 GHz	❑	❑
Hard disk:	Min. 500 GB free storage space	Min. 1 TB free storage space	❑	❑
RAM:	4 GB	4 GB	❑	❑
Drives:	CD/DVD ROM	CD/DVD ROM	❑	❑
Graphics system:	external, > 512MB, min. resolution 1280x1024 16.7 mil. colors (TrueColor) Shader Model 3 for Advanced Rendering in GALILEOS Implant	external, > 512MB, min. resolution 1280x1024 16.7 mil. colors (TrueColor) Shader Model 3 for Advanced Rendering in GALILEOS Implant	❑	❑
Screen:	Suitable for diagnostics	Suitable for diagnostics	❑	❑
Network Card:	Network RJ45, 100MBit/s	Network RJ45, 1GBit/s	❑	❑

- Remarks/Tasks:

1.4 IT hardware

Treatment centers/RCU		
• Is a diagnostic monitor available? At least one diagnostic monitor must be available in the practice.	❑ yes	❑ no
• Number of treatment centers planned (viewing PCs) It is advisable to locate a treatment center PC (viewing PC) near the ORTHOPHOS XG 3D/3D^{ready} for the purpose of readying the unit for exposure.	_____piece	
• Plan/determine location of RCU (room)		
• Is a switch installed?	❑ yes ❑ 100MBit ❑ 1GBit	❑ no
• Remarks/Tasks:		

1.4 IT hardware

SQL/Fileserver		
• Are SIDEXIS databases already installed?	❑ yes	❑ no
• f so, which version of the SIDEXIS database? (Patients.paf, Pdata.mdb, SQL-Express or SQL)		
• Is migration necessary?	❑ yes	❑ no
• SQL Server installed? Microsoft SQL Express is included in the scope of supply!	❑ yes	❑ no
– SQL Server version	_____	
– SQL Server name	_____	
• File server installed (separate server for image database only)?	❑ yes	❑ no
– Windows release with full access	❑ yes	❑ no
– Operating system/version	_____	
– Name of computer	_____	
– IP adress	____ . ____ . ____ . ____	
– Processor speed (clock frequency)	_____	
– Available RAM?	_____GB	
– Available hard disk storage?	_____GB	
• Estimated number of exposures (approx.) / Approx. 500 MB per volume are currently stored in the database!	_____	
– Per month?	_____	
– Month x 12 = per year	_____	
– Approx. required storage space	_____GB	
– Depending on this, is a backup system available?	❑ yes	❑ no
– Is a backup system planned?	❑ yes	❑ no

⚠ ***ATTENTION***

Network Attached Storage (NAS) units .
The use of LINUX based Network Attached Storage (NAS) units for PDATA can cause problems. Adjustment problems with these units have occurred in the past.

• Remarks/Tasks:

1.5 Network

Network			
• The entire network should be configured with 1GBit Ethernet!			
– Cat 5	❑ 100Mbit/sec	❑ yes	❑ no
– Cat 5e/Cat 6	❑ 1 Gbit/sec	❑ yes	❑ no
• Network connection installed for ORTHOPHOS XG 3D/3D^{ready}?		❑ yes	❑ no
• "Network connection installed on all treatment centers?		❑ yes	❑ no
• "Network connection installed for RCU?		❑ yes	❑ no
NOTE ***It is advisable to locate a treatment center PC near the ORTHOPHOS XG 3D/3D^{ready} for the purpose of readying the unit for exposure.***			
• Network configuration plan available?		❑ yes	❑ no
• "Have the network jacks been certified?		❑ yes	❑ no
• "Network certificate available?		❑ yes	❑ no
• "Network installation company?			
• Remarks/Tasks:			

1.6 Data processing

IP addresses/Firewall		
• TCP/IP address range	____ . ____ . ____ . ____ - ____ . ____ . ____ . ____	
• Subnet mask	____ . ____ . ____ . ____	
• Are addresses already defined/present?	❑ yes	❑ no
• Is there a DHCP server (dynamic TCP/IP address assignment)?	❑ yes	❑ no
ATTENTION ***A static address is required for the ORTHOPHOS XG 3D/3D^{ready}! It must not lie in the dynamic address range!***		
• ORTHOPHOS XG 3D/3D^{ready}:	____ . ____ . ____ . ____	
• RCU:	____ . ____ . ____ . ____	
• Viewing PCs:	____ . ____ . ____ . ____ - ____ . ____ . ____ . ____	
• Standard gateway:	____ . ____ . ____ . ____	
• "Antivirus software installed?	❑ yes Name:	❑ no
• Is a firewall installed?	❑ yes	❑ no
– Software or hardware firewall?	❑ SW ❑ HW	

The following ports must be open for the SIDEXIS and for unit configuration!

– SQL- Express Port Number=	1433
– SIDEXIS TCP Port=	11837
– XAB_UDP_Port=	11838
– PC_UDP_Port=	11839
– XG_TCP_STATUS_PORT=	12835
– XG_TCP_SERVICE_PORT=	12836
– XG_TCP_MAIN_PORT=	12837
– XG_PAN_UDP_PORT=	12838
– XG_PC_UDP_PORT=	12839

• Remarks/Tasks:

1.6 Data processing

Practice administration programs		
• "Are connections to the practice administration programs, etc. installed?	❑ yes	❑ no
– If so, which system - manufacturer + name?		
• Remarks/Tasks:		

DICOM		
• Is a DICOM installation already present?	❑ yes	❑ no
– Which version?	_____	
– Configuration?	_____	
• Is a DICOM connection required?	❑ yes	❑ no
• If so, which of the following are required?		
– SIDICOM V2.2 Which functionalities should be supported? In this case, the DICOM questionnaire must be completed!	❑ yes	❑ no
– DICOM Query & Retrieve	❑ yes	❑ no
– DICOM Print	❑ yes	❑ no
– DICOM Removeable Media (ist im Lieferumfang vorhanden)	❑ yes	❑ no
• Remarks/Tasks:		

1.7 Action list

What	Who	When

Inspection performed on:			
by:	Depot:	Name:	Signature:
	Customer:	Name:	Signature:

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2 Preparations

ORTHOPHOS XG

2.1 Safety

Warning and safety information

To prevent personal injury and material damage, please observe the warning and safety information provided in the present operating instructions.

The content, appearance and use of warning and safety information in Sirona documents are based on the ANSI Z535 standard.

The following warnings may be used in this document:

DANGER

An imminent danger that could result in serious bodily injury or death.

WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

CAUTION

A possibly dangerous situation that could result in slight bodily injury.

NOTICE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

Instructions for use

The following application information may be used in this document:

NOTE

Application instructions and other important information.

Tip: Information on making work easier.

WARNING

For reasons of product safety, only original Sirona accessories approved for this product, or accessories from third parties approved by Sirona, may be used. The user is responsible for dangers resulting from the use of non-approved accessories.
If any devices not approved by Sirona are connected, they must comply with the applicable standards, e.g.:
• IEC 60950 for information technology equipment and
• IEC IEC 60601-1 for medical electrical equipment
In case of doubt, contact the manufacturer of the system components.

CAUTION

Any person who assembles or modifies a medical electrical system complying with the standard IEC 60 601-1-1 (safety requirements for medical electrical equipment) by combining it with other equipment (e.g. when connecting a PC) is responsible for ensuring that the requirements of this regulation are met to their full extent for the safety of the patients, the operators and the environment.

WARNING

Proper shielding of room and operator position is essential.

Since these requirements vary from state to state it is the assembler's / installer's responsibility that all local radiation safety requirements are met.

CAUTION

Störung elektromedizinischer Geräte durch Funktelefone: Zur Gewährleistung der Betriebsbereitschaft elektromedizinischer Geräte ist der Betrieb mobiler Funktelefone im Praxis- oder Klinikbereich zu untersagen.Interference of electromedical devices caused by radio telephones: To ensure the operational readiness of electromedical devices, the use of mobile radio telephones in the practice or hospital area is prohibited.

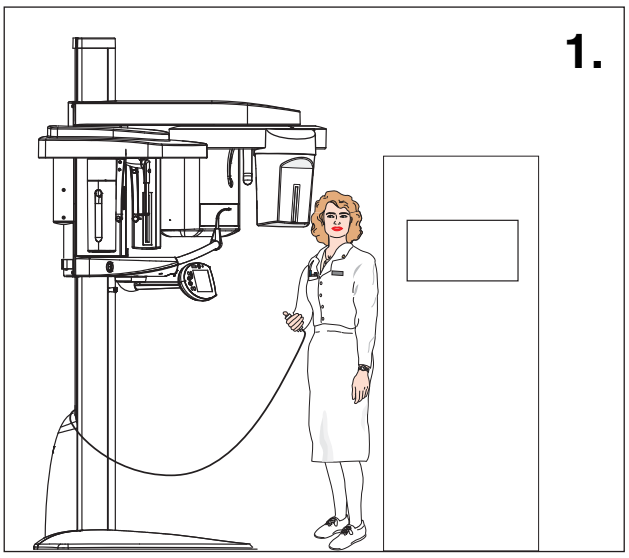
CAUTION

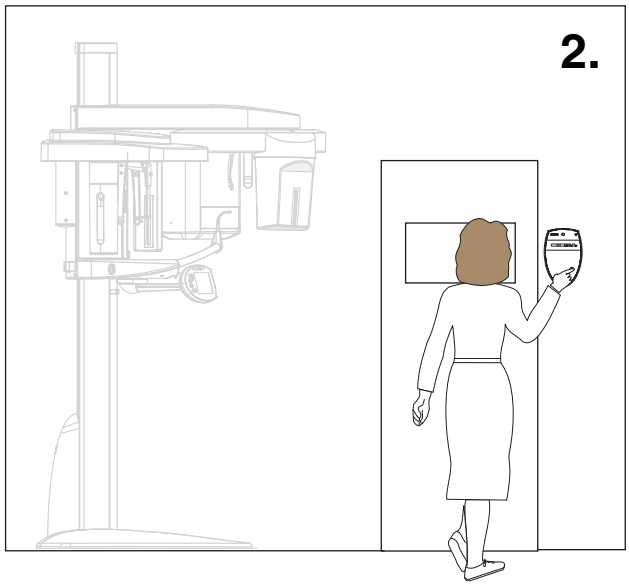
Electromagnetic compatibility: *The unit should not be operated in the immediate vicinity of other devices. If this proves to be unavoidable, the unit should be monitored to ensure that it is used properly.*

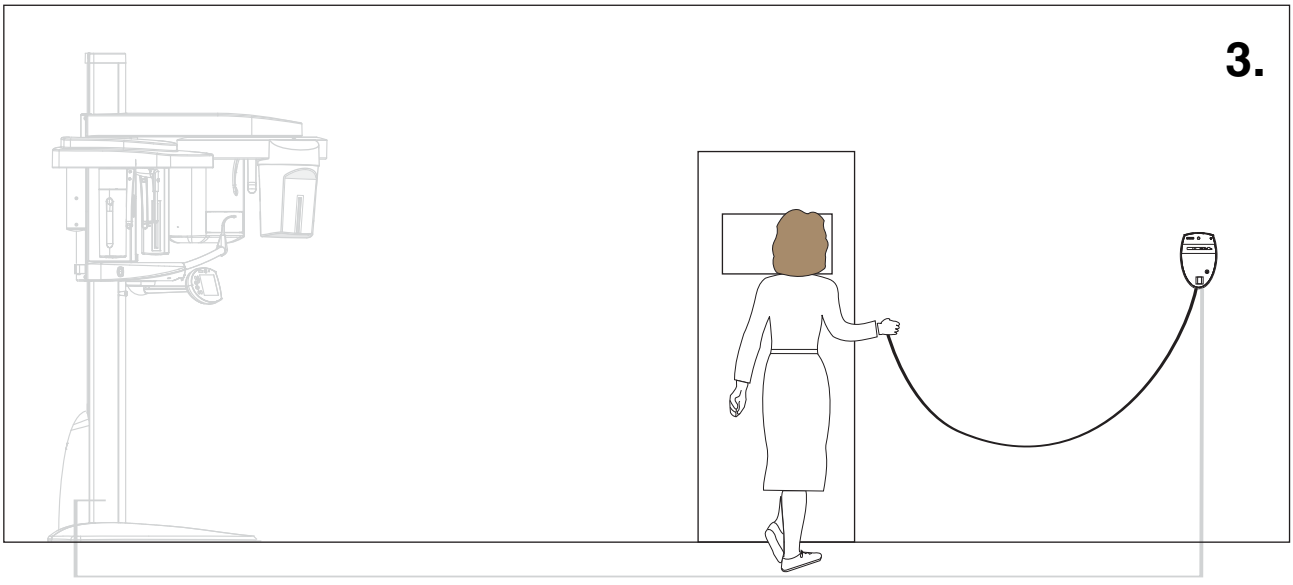
CAUTION

The electrical installation must comply with local code requirements for electromedical systems, IEC 364-7-710.

2.2 Possibilities of Installation







1. ORTHOPHOS XG 3D/3D^{ready}® **without** remote control with release button on coiled cable in the treatment room.
2. ORTHOPHOS XG 3D/3D^{ready} **with** remote control[1] utside of X-ray room, **without** release button on coiled cable.
   Length of special control cable supplied: approx. 15m (590 1/2“).
3. ORTHOPHOS XG 3D/3D^{ready} **with** remote control[1] outside of X-ray room, **with** release button on coiled cable.

CAUTION

Wall plugs!
Every wall anchor for fixing the unit must be able to resist a withdrawal force of 700N.

- Depending on the construction of the wall, suitable special wall plugs must be obtained or an anchor plate made.

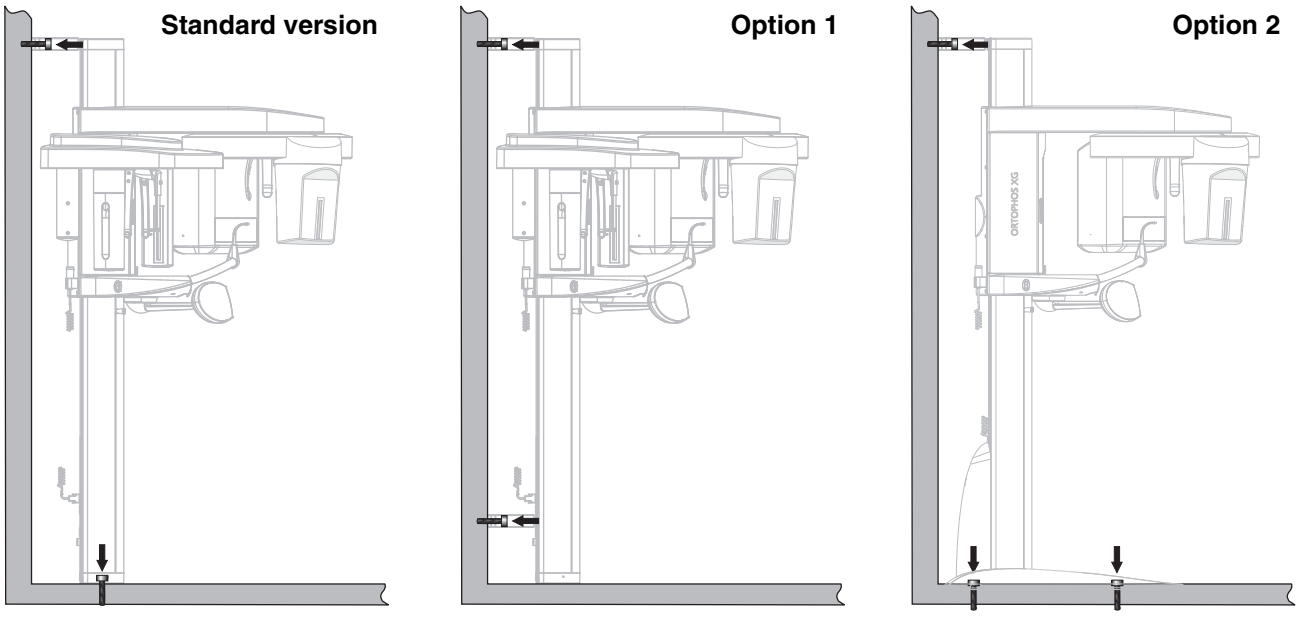
1 With use of a door contact: run shielded 2-core cable (24 AWG / 0.22 mm^2) to the remote control.
When an X-ray warning lamp is used: run a 3-wire cable 1.5 mm^2 (16 AWG),to the warning lamp.
CAUTION
A maximum load of 50 W is permissible and no additional circuit may be connected.

2.3 Mounting options

1. **Standard version**

2. **Option 1**

3. **Option 2**



Standard version

1. **Wall-mounted installation with 1 wall holder and floor fastening** if both wall and floor installation are possible on-site.

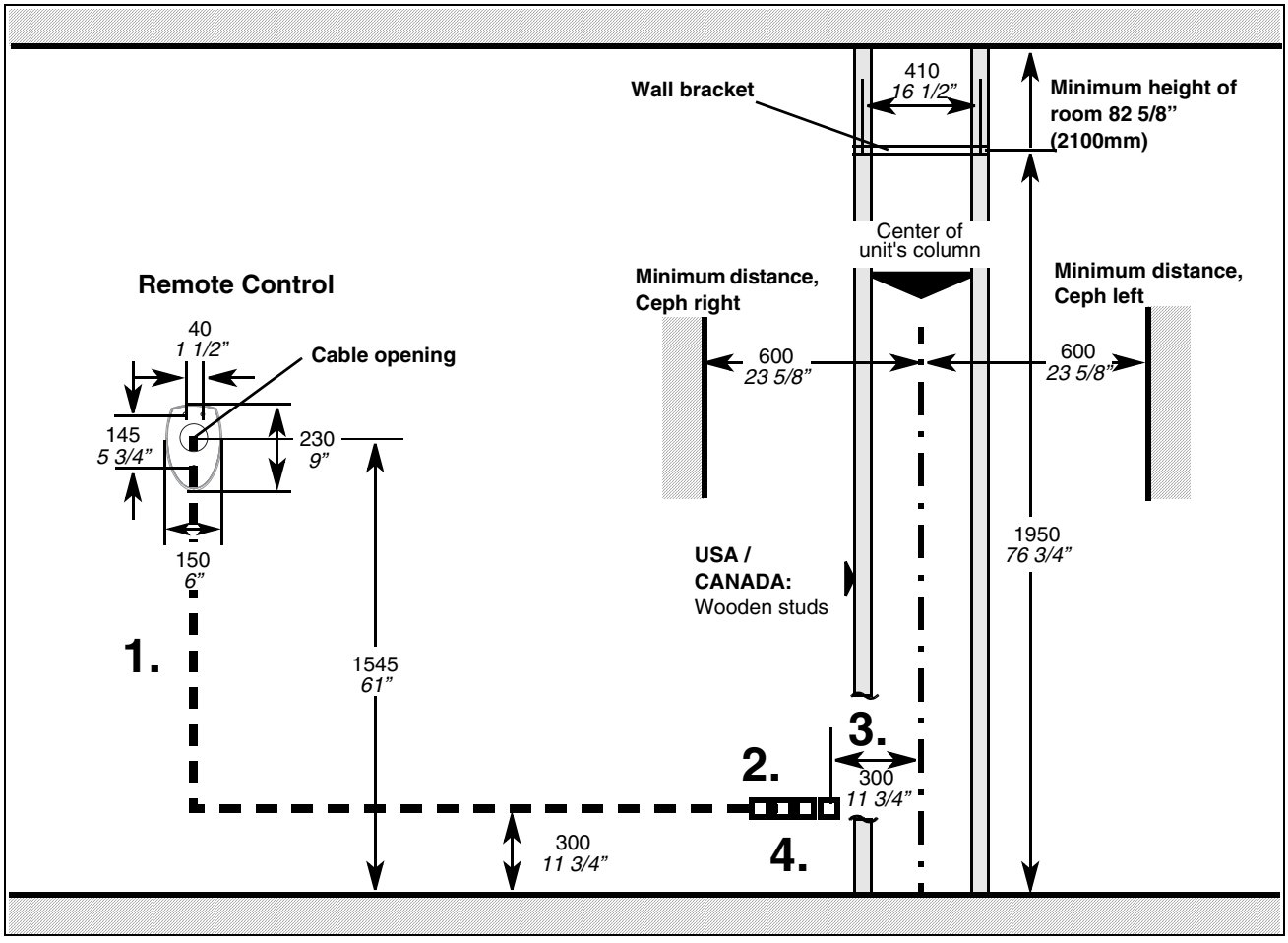
Option 1: with second wall holder

2. **Wall-mounted installation with 2 wall holders** (and no floor fastening) if only wall installation is possible on-site.

Option 2: with floor stand and wall holder

3. Installation using a **floor stand** and 1 wall holder, if it is possible to mount the unit on the wall.

2.4 Principle of On-site Installation



1. **Conduit for remote control**
   For concealed installation of the shielded control cable (included in delivery), a conduit **must** be used.
   ∅ int. min. 10mm (1/2"), **max. length admissible 13 m (512"/43 feet)**!

NOTICE

Only the provided control cable may be used. This cable will be installed during installation of the unit. No other cable is permissible.

2. **Distributor box for remote control**
   A distributor box **with strain relief capability must** be provided next/behind to the unit column.

DANGER

Fixed connection!
The installation of a power plug instead of the prescribed fixed (hard-wired) connection violates international medical regulations and is prohibited.
In case of a fault, you would thus endanger the life and limb of the patient, the operator or other persons.

3. **Distributor box with power cable and terminal strip**
   Recommendation: A separate three wire (N, L, PE, at least 3 x 2,5 mm^2 or 3 x 4 mm^2 (14 AWG or 12 AWG)) power cable connected directly to the central distribution panel with an overcurrent circuit breaker B rated for 25 A should be used.

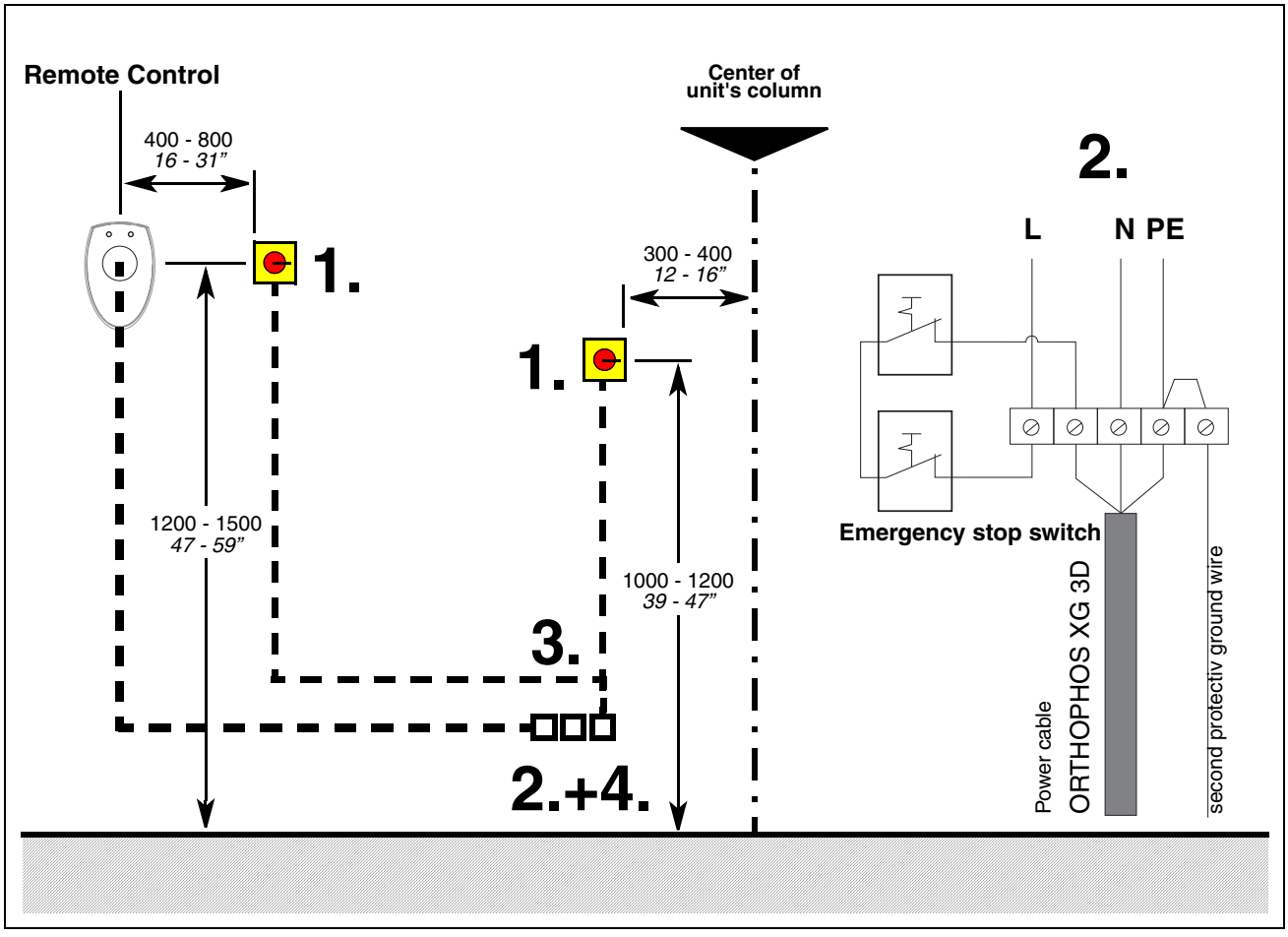
- For an on-site installation with 3 x 1,5 mm^2 / 3 x 2,5 mm^2 (16 AWG / 14 AWG) and an overcurrent circuit breaker B rated for 16 A/20 A), it is permissible to connect only the ORTHOPHOS XG 3D/3D^{ready} or other such units that cause no danger to the patients or to the computer systems in case the automatic circuit breaker is activated.

4. Install the installation socket for the second protective ground wire.

WARNING

Install the connection possibility for the second protective ground wire. Second protective ground wire is preassembled with a 5 - 2.5 DIN 46234 cable lug. For connection to a terminal the cable lug can be removed.

2.5 Emergency Stop (if required by law)

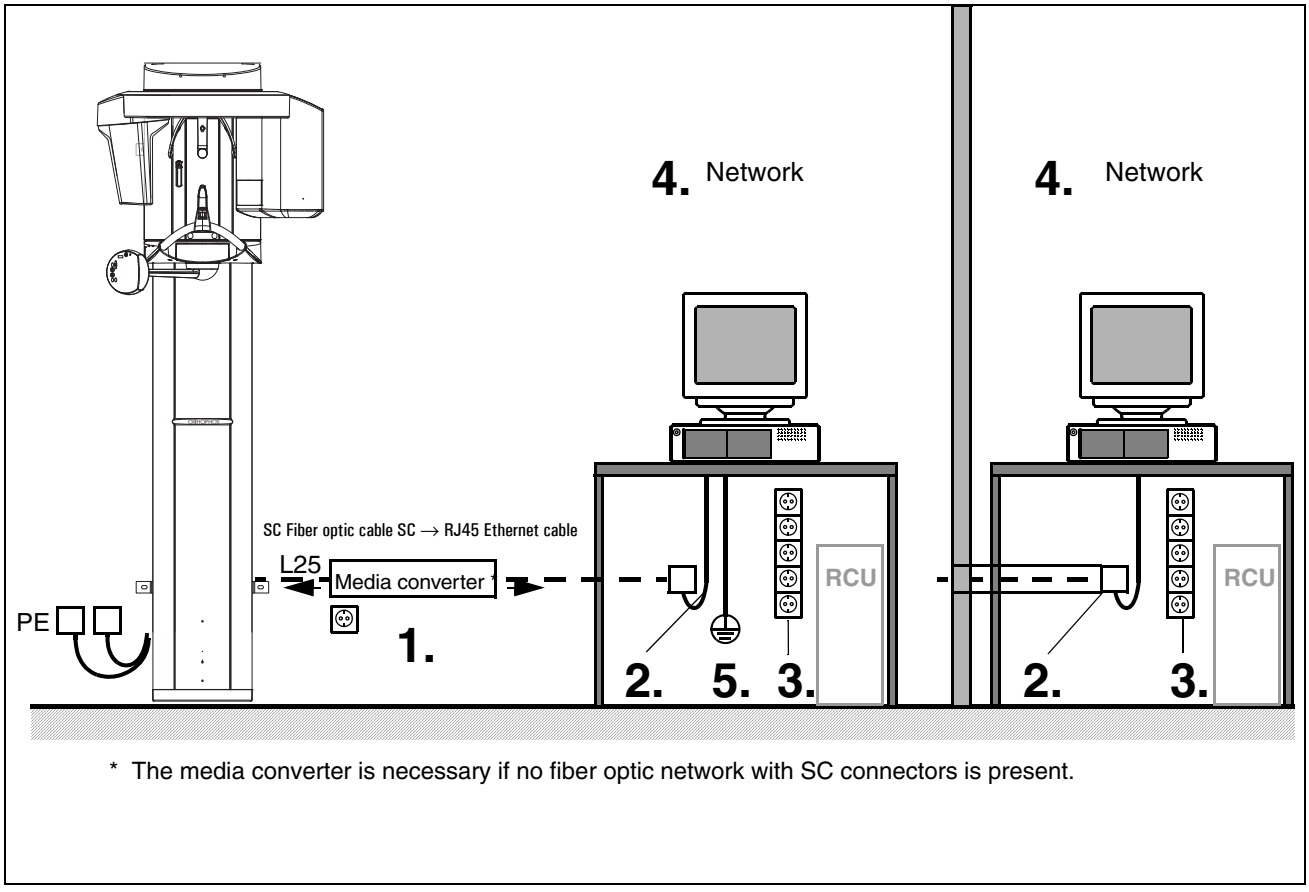


1. Install the emergency stop switches in the power cable. Mount the switches so that they are easy to reach but cannot be activated by mistake.
2. **Distributor box with power cable and terminal strip**
   Recommendation: A separate three wire (N, L, PE, at least 3 x 2,5 mm^2 or 3 x 4 mm^2 (14 AWG or 12 AWG)) power cable connected directly to the central distribution panel with an overcurrent circuit breaker B rated for 25 A should be used.
3. The cables to the emergency stop switches must have at least the same diameter as the power cable.
   - For an on-site installation with 3 x 1,5 mm^2 / 3 x 2,5 mm^2 (16 AWG / 14 AWG) and an overcurrent circuit breaker B rated for 16 A/20 A), it is permissible to connect only the ORTHOPHOS XG 3D/3D^{ready} or other such units that cause no danger to the patients or to the computer systems in case the automatic circuit breaker is activated.
4. Install the installation socket for the second protective ground wire.

CAUTION

Install the connection possibility for the second protective ground wire. Second protective ground wire is preassembled with a 5 - 2.5 DIN 46234 cable lug. For connection to a terminal the cable lug can be removed.

2.6 On-site Installation for PC/Networks



* The media converter is necessary if no fiber optic network with SC connectors is present.

1. Length of patch cable supplied with media converter: 5 m (197“).
Reserve room for the media converter either behind the column or near the PC. An **electric outlet** is required for the media converter.

2. For concealed installation of the Ethernet cable, an installation conduit **must** be used, internal diameter: min. 21 mm (7/8“) (provide a sufficient bending radius for a 4 cm (1 1/2“) long plug).
Provide for strain relief!

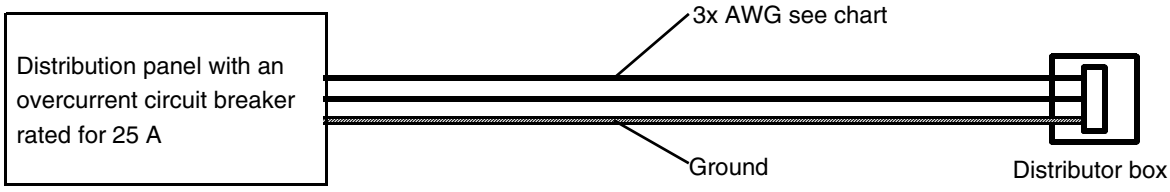
- **Recommendation:** To rule out interference, do **not** run the cable together with other cables.

3. For RCU-Server, visualization PC, Monitors, switch etc. (not included in the scope of supply) at least five wall installed **safety outlets** are required.

4. **Network:** 1 Gbit Ethernet recommended.
Communication interface: RJ45 for LAN cable.

5. For PCs connected to an x-ray unit and standing in the same room an **additional protective ground wire** ⏚ is required at IEC 60601-1-1 (4 mm^2 with cable lug 4 – 6 DIN 46234 CU).

2.7 For USA and Canada



Minimum wire size	Wire run distance in feet 25	50	75	100	125
No.12 AWG					
No.10 AWG					
No.8 AWG					

Wire Size for Power Line

- The unit is designed to operate on a **nominal** 200 - 240 VAC line.
  Permitted line voltage variation ±10% .
  On request, the local Electrical Utility Company will perform a voltage regulation test to verify the line quality.
- The distributor box should be installed in the position as shown on page 23.
- To assure proper line quality, a separate three-core **grounded** power cable connected directly to the central distribution panel with an overcurrent circuit breaker rated for 25 A must be used.
  For an on-site installation with 14 AWG (3 x 2,5 mm^2) and an overcurrent circuit breaker rated for 20 A, it is permissible to connect only the ORTHOPHOS XG 3D/ $3D^{ready}$ or other such units that cause no danger to the patients or to the computer systems in case the automatic circuit breaker is activated.
- The line voltage drop in the power supply circuit from the central distribution panel to the distributor box depends on length and size of wire.
  Measure the distance from the central distribution panel to the distributor box and select the correct wire size, see chart.

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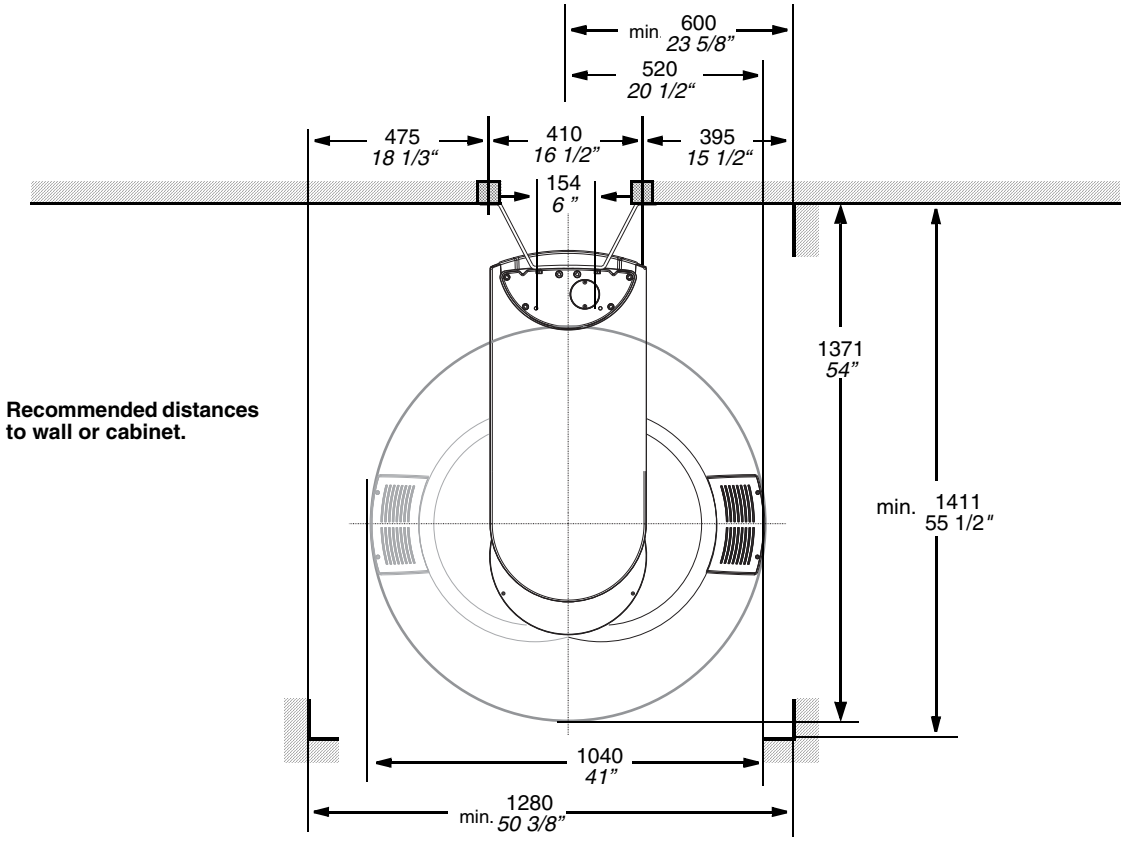
3 Dimensions, technical data

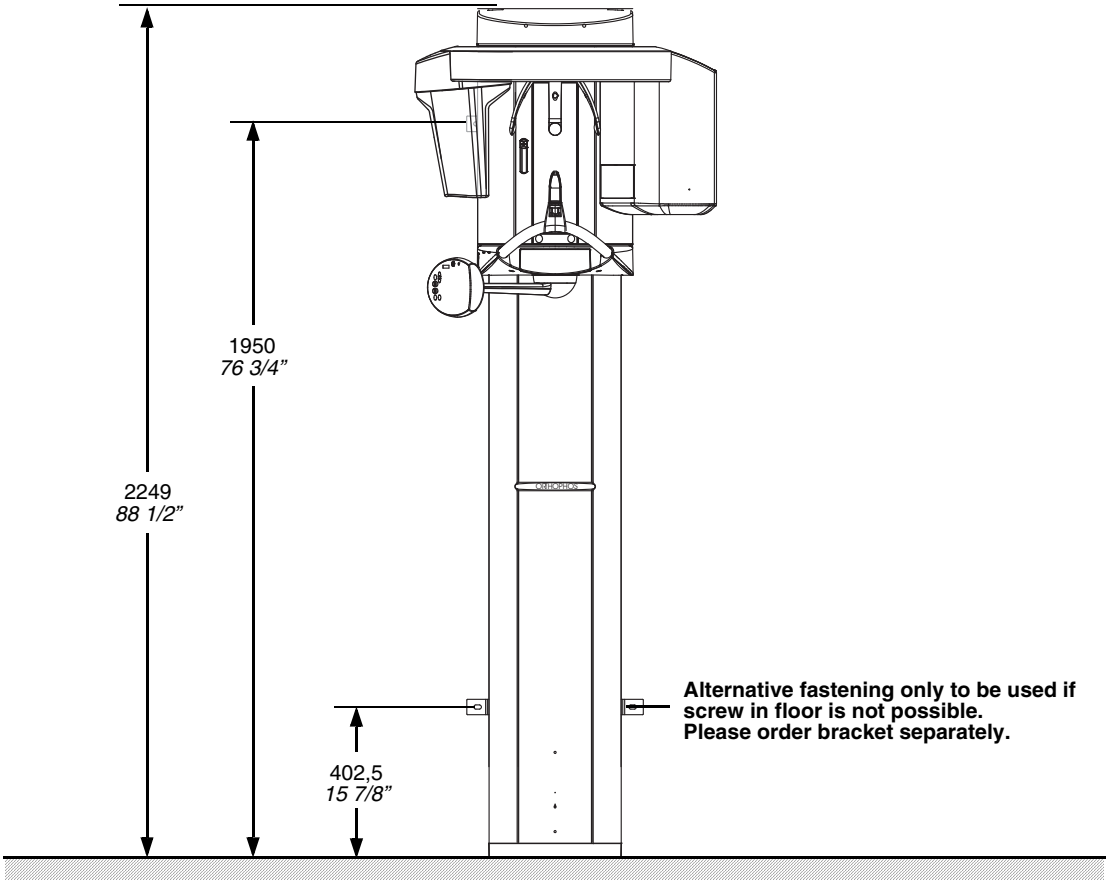
ORTHOPHOS XG 3D/3D^{ready}

3.1 Dimensions of the ORTHOPHOS XG 3D / 3D^{ready} 1:20

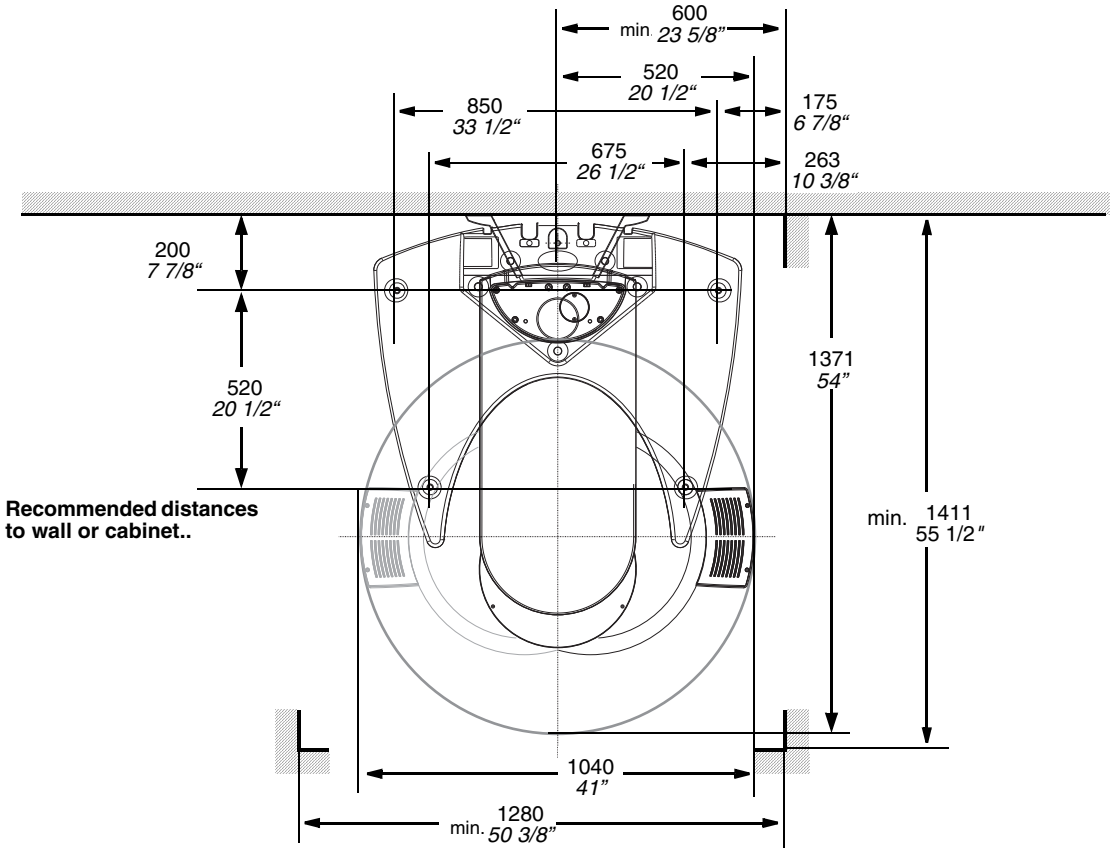


Recommended distances to wall or cabinet.

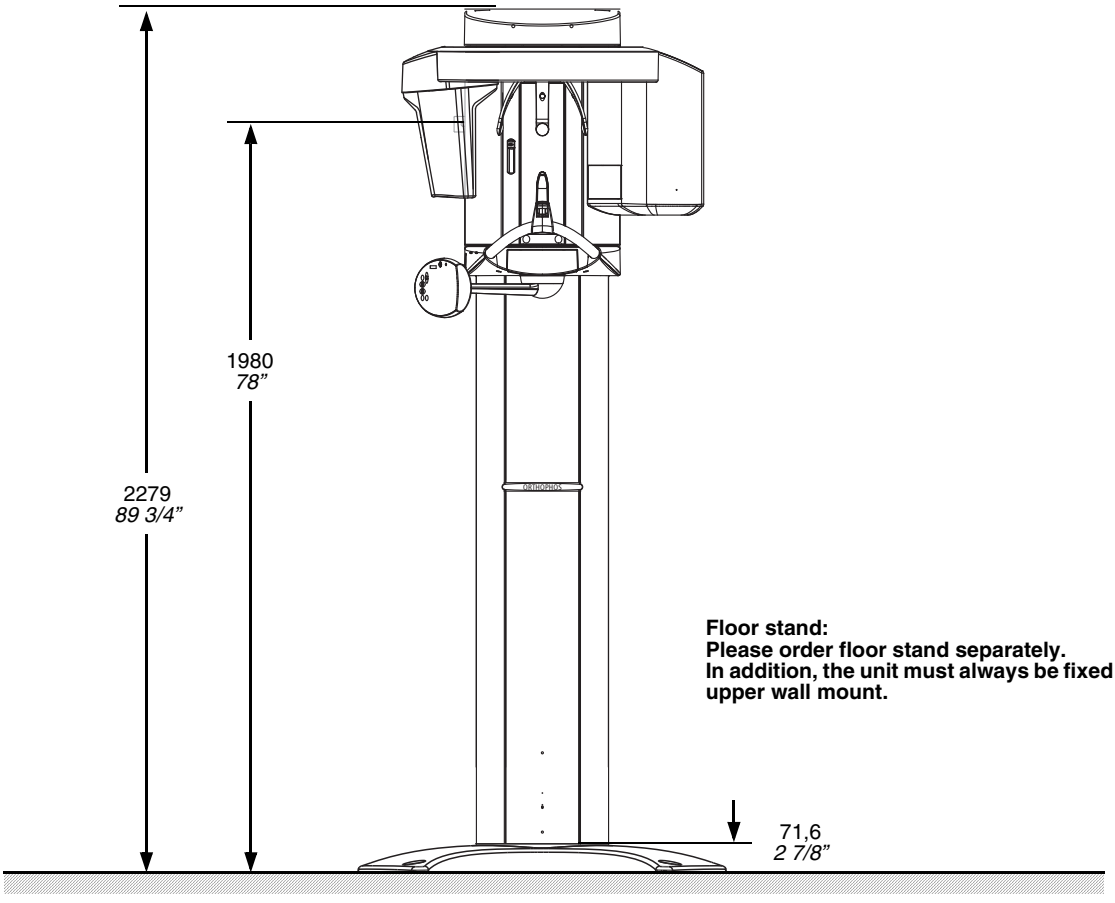
Dimensions of the ORTHOPHOS XG 3D / 3D^{ready} 1:20



3.2 Dimensions of the ORTHOPHOS XG 3D / 3D^{ready} 1:20 on Floor stand

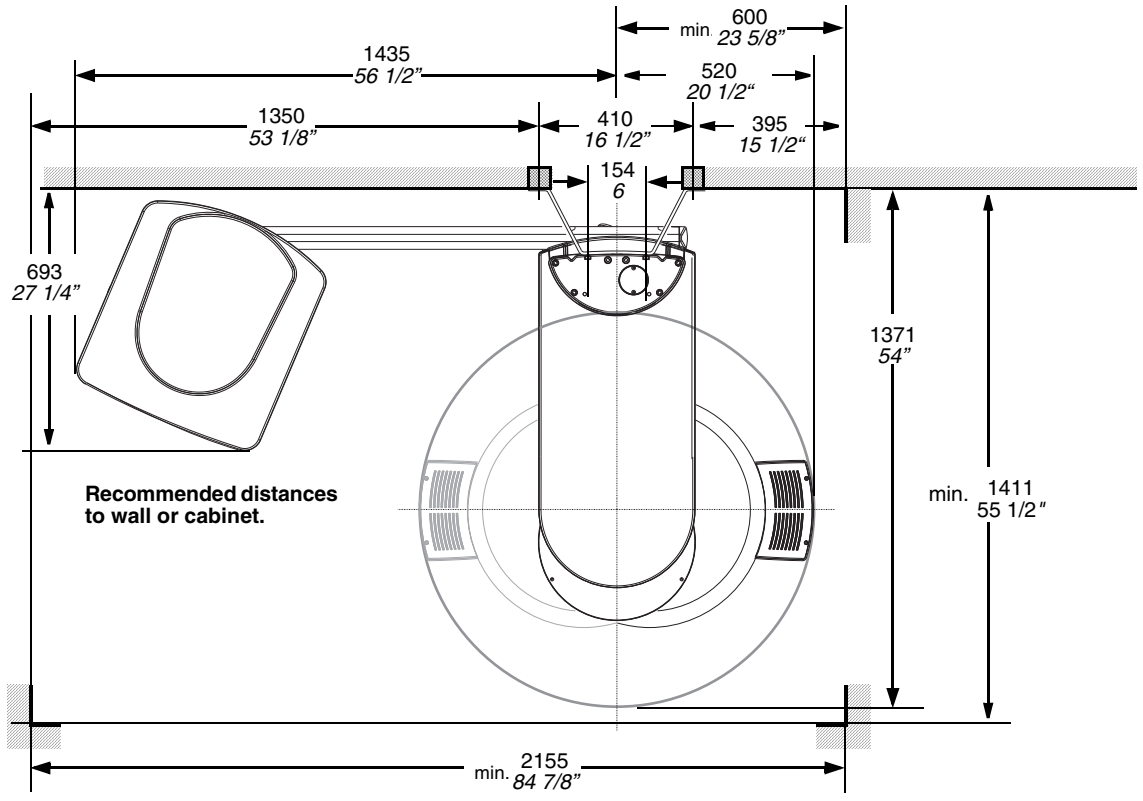


Dimensions of the ORTHOPHOS XG 3D / 3D^{ready} 1:20 on Floor stand

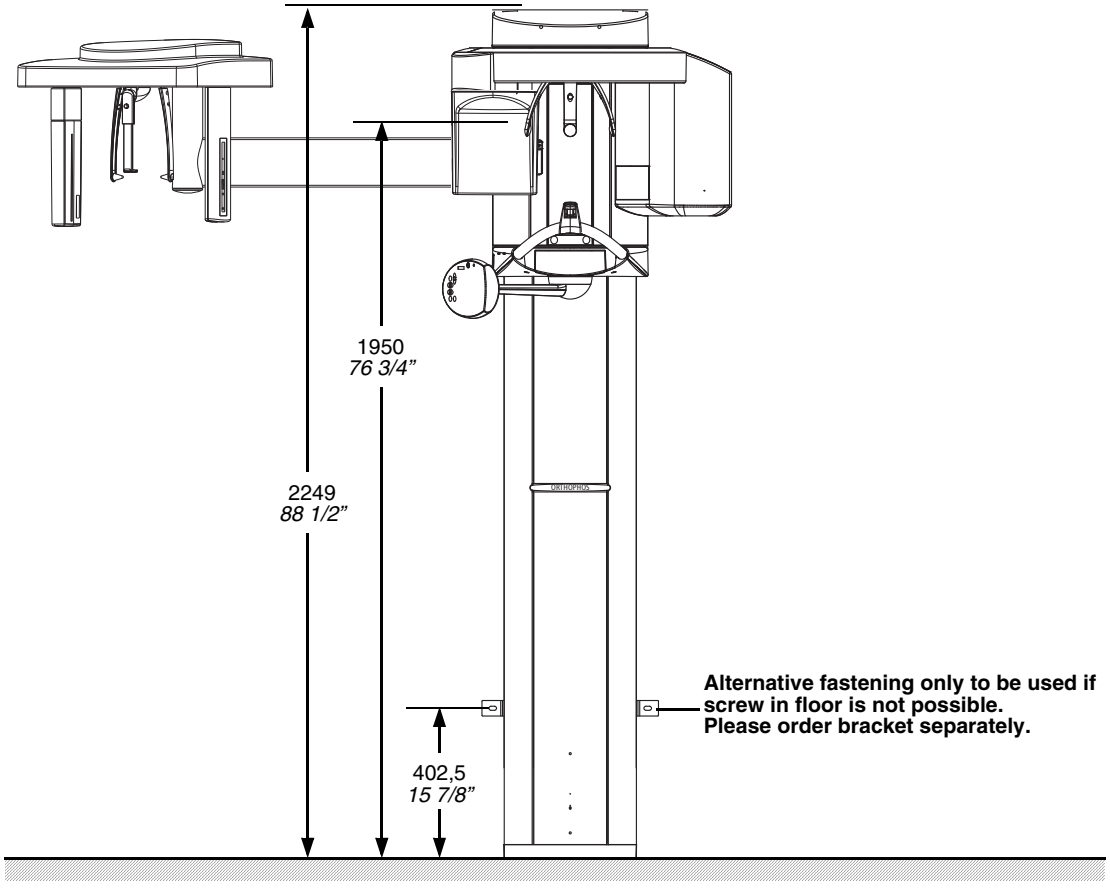


Floor stand:
Please order floor stand separately.
In addition, the unit must always be fixed with the upper wall mount.

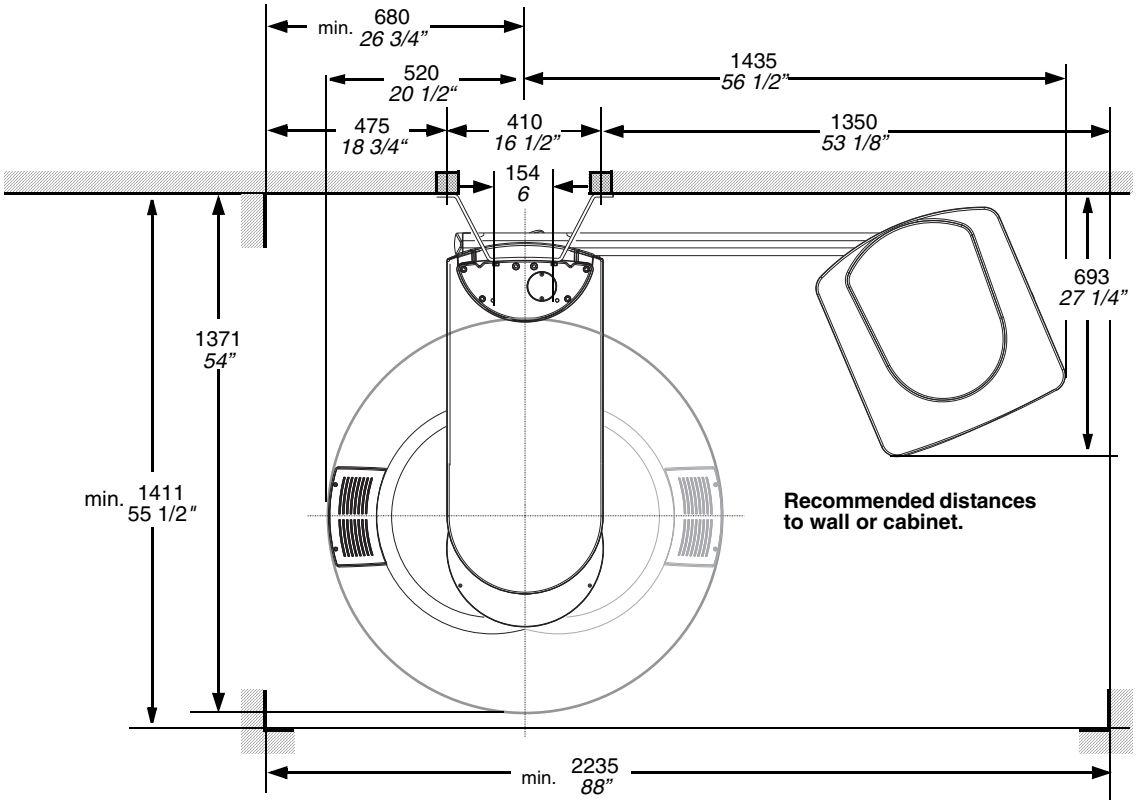
3.3 Dimensions of the ORTHOPHOS XG 3D / 3D[ready] / Ceph 1:20 Ceph left



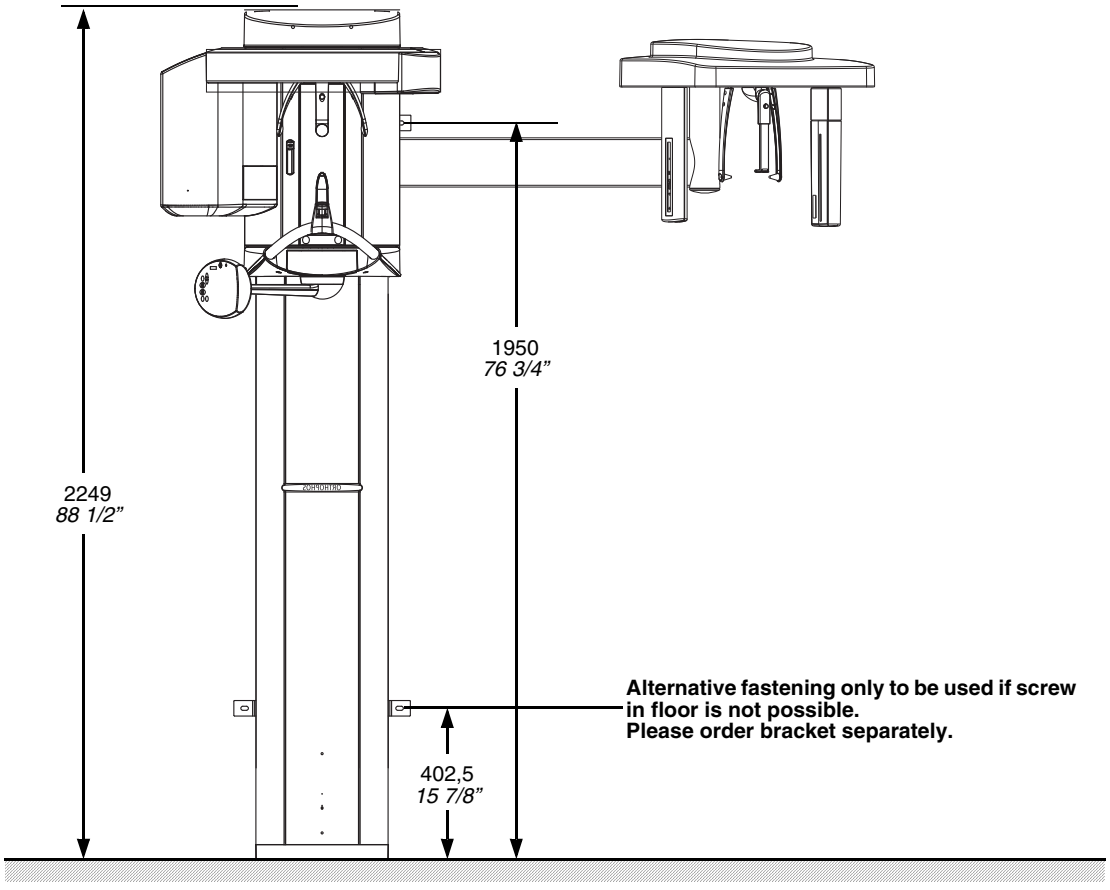
Dimensions of the ORTHOPHOS XG 3D / 3D[ready] / Ceph 1:20
Ceph left



3.4 Dimensions of the ORTHOPHOS XG 3D / 3D^{ready} / Ceph 1:20 Ceph right



Dimensions of the ORTHOPHOS XG 3D / 3D^{ready} / Ceph 1:20
Ceph right



3.5 Technical data

Dimensions packaging	
ORTHOPHOS XG 3D / 3D^{ready}	199cm x 69cm x 122cm (78 3/8“ x 27 1/8“ x 48“)
Cephalometer	175cm x 78cm x 73cm (68 7/8“ x 30 3/4“ x 28 3/4“)
Floor stand	114cm x 105cm x 22cm (56 3/4“ x 41 3/8“ x 8 5/8“)
Weight	including /without packaging (1kg=2.2lbs)
ORTHOPHOS XG 3D	183kg / 105kg (404lb / 232lb)
ORTHOPHOS XG 3D^{ready}	177kg / 99kg (390lb / 218lb)
Cephalometer	40kg / 33kg (88lb / 73lb)
Floor stand	50kg / 31kg (110lb / 68lb)
Power supply	
Line voltage	200V- 240V, 50 / 60Hz
Tolerance of line voltage	±10%
Power line resistance	max. 0,8W
Nominal current / Fuse	max. 12A / B 25A inert; with single connection: B 16A/20A inert
Power consumption	max. 2,0kW
Required transformer with 100V / 110V / 125V	
Output	230V
Power	2kVA (permanent)
Maximal voltage breakdown with 10A ohmical load:	≤ 10%
Operating conditions	
	Ambient temperature: 10°C – 40°C (50°F – 104°F) Relative humidity: 10% – 95%
Transport and storage conditions	
ORTHOPHOS XG 3D / 3D^{ready}	Temperature: -10°C – +70°C (14°F – 158°F) Relative humidity: 10% – 95% without condensation
Protection class	
	Class **I** equipment Type **B** equipment
Degree of protection against ingress of water	
	Ordinary equipment (not protected)
Mode of operation:	
	Continuous operation.
Tests / approvals	
	The ORTHOPHOS XG 3D / 3D^{ready} X-ray unit complies with **IEC 60601-1** **IEC 60601-1-3** **IEC 60601-2-63**
CE 0123	This product bears the CE marking in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

4 Electromagnetic compatibility

ORTHOPHOS XG 3D/3D^{ready}

NOTE

The ORTHOPHOS XG 3D / 3D^{ready} / Ceph fulfills all requirements for electromagnetic compatibility (EMC) compliant with IEC 60601-1-2.

*The ORTHOPHOS XG 3D / 3D^{ready} / Ceph is referred to as **"UNIT"** in the following.*

***Observance of the following information is necessary to ensure safe operation regarding EMC aspects**.*

4.1 Accessories

Designation of interface cables	Supplier
PC as peripheral device.	
Remote cable L17/ L117 XG, 15m (590 1/2“)	LEONI
Cable L25 OP-XG, 5m (197“)	EFB-Elektronik
Media converter	TTL-Network
LAN-cable Kat5, 3m (118“)	51 68 963 D3348
2nd protective ground wire, 1.5mm^2 (16 AWG)	58 72 648 D3285

- The **UNIT** may be operated only with accessories and spare parts approved by Sirona. Unapproved accessories and spare parts may lead to an increased emission of or a reduced immunity to interference.
- The **UNIT** should not be operated immediately adjacent to other devices. If this proves to be unavoidable, the **UNIT** should be monitored to check and make sure that it is used properly.

4.2 Electromagnetic emission

The **UNIT** is intended for operation in the electromagnetic environment specified below.

The customer or user of the **UNIT** should make sure that it is used in such an environment.

Emission measurement	Conformity	Electromagnetic environment guidelines
HF emission according to **CISPR 11**	Group 1	The **UNIT** uses HF energy only for its internal function. The HF emission is therefore very low, and it is improbable that nearby electronic devices might be disturbed.
HF emission according to **CISPR 11**	Class B	The **UNIT** is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to buildings used for residential purposes.
Harmonics according to **IEC 61000-3-2**	Class A	
Voltage fluctuations / Flicker according to **IEC 61000-3-3**	compliant	

4.3 Immunity to interference

The **UNIT** is intended for operation in the electromagnetic environment specified below.

The customer or user of the **UNIT** should make sure that it is used in such an environment.

Immunity interference tests	IEC 60601-1-2 test level	Conformance level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) according to **IEC 61000-4-2**	± 6kV contact discharge ± 8 kV air discharge	± 6kV contact discharge ± 8kV air discharge	Floors should be made of wood or concrete or covered with ceramic tiling. If the floor surface consists of synethetic material, the relative humidity must be at least 30%.
Electrical fast transient/ burst according to **IEC 61000-4-4**	± 1kV for input and output lines ± 2kV power cables	± 1kV for input and output lines ± 2kV power cables	The quality of the supply voltage should conform to the typical business or hospital environment.
Surge voltages according to **IEC 61000-4-5**	± 1kV push-pull voltage ± 2kV push-pull voltage	± 1kV push-pull voltage ± 2kV push-pull voltage	The quality of the supply voltage should conform to the typical business or hospital environment.
Voltage dips, short interruptions and variations of the power supply according to **IEC 61000-4-11**	<5% U_T for ½ period (>95% dip of U_T) 40% U_T for 5 periods (60% dip of U_T) 70% U_T for 25 periods (30% dip of U_T) <5% U_T for 5sec. (>95% dip of U_T)	<5% U_T for ½ period (>95% dip of U_T) 40% U_T for 5 periods (60% dip of U_T) 70% U_T for 25 periods (30% dip of U_T) <5% U_T for 5sec. (>95% dip of U_T)	The quality of the supply voltage should correspond to the typical business or hospital environment. If the user of the **UNIT** requires it to continue functioning following interruptions of the power supply, it is recommended to have the **UNIT** powered by an uninterruptible power supply or a battery.
Magnetic field of power frequencies (50/60 Hz) according to **IEC 61000-4-8**	3 A/m	3 A/m	The power frequency magnetic fields should correspond to the typical values found in the relevant business and hospital environment.
Remarks: U_T is the AC supply voltage prior to application of the test level.			

Immunity interference tests	IEC 60601-1-2 test level	Conformance level	Electromagnetic environment guidelines
			Portable and mobile radio equipment must not be used within the recommended working clearance from the **UNIT** and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended working clearance:
Conducted HF interference **IEC 61000-4-6**	3 V_{eff} 150 kHz to 80 MHz[a]	3 V_{eff}	$d = [1, 2]\sqrt{P}$
Radiated HF interference **IEC 61000-4-3**	3 V/m 80 MHz to 800 MHz[a] 3 V/m 800 MHz to 2.5 GHz[a]	3 V_{eff} 3 V_{eff}	$d = [1, 2]\sqrt{P}$ at 80 MHz to 800 MHz $d = [2, 3]\sqrt{P}$ at 800 MHz to 2.5 GHz where **P** is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and **d** is the recommended working clearance in meters (m). The field strength of stationary radio transmitters is based on a local investigation for all frequencies[b] less than the conformance level for all frequencies[c] . Interference is possible in the vicinity of equipment bearing the following graphic symbol. 

a. The higher frequency range applies at 80 MHz and 800 MHz.

*b. The field strength of stationary transmitters such as the base stations of radio telephones and land mobile services, amateur radio stations as well as AM and FM radio and television broadcasting stations cannot be accurately predetermined. An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF transmitters. If the field strength measured at the **UNIT** location exceeds the conformance level specified above, the **UNIT** must be observed with respect to its normal operation at each application site. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the **UNIT**.*

c. A frequency range of 150 kHz to 80 MHz results in a field strength of less than 3 V/m.

4.4 Working clearances

Recommended working clearances between portable and mobile HF communication devices and the UNIT

The **UNIT** is intended for operation in an electromagnetic environment, where radiated HF interference is checked. The customer or the user of the **UNIT** can help prevent electromagnetic interference by duly observing the minimum distances between portable and/or mobile HF communication devices (transmitters) and the **UNIT**. These values may vary according to the output power of the relevant communication device as specified above.

Nominal transmitter output [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [1, 2]\sqrt{P}$	$d = [1, 2]\sqrt{P}$	$d = [2, 3]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

Annotation 1
The higher frequency range applies at 80 MHz and 800 MHz.

Annotation 2
These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

We reserve the right to make any alterations which may be required due to technical improvements.

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