

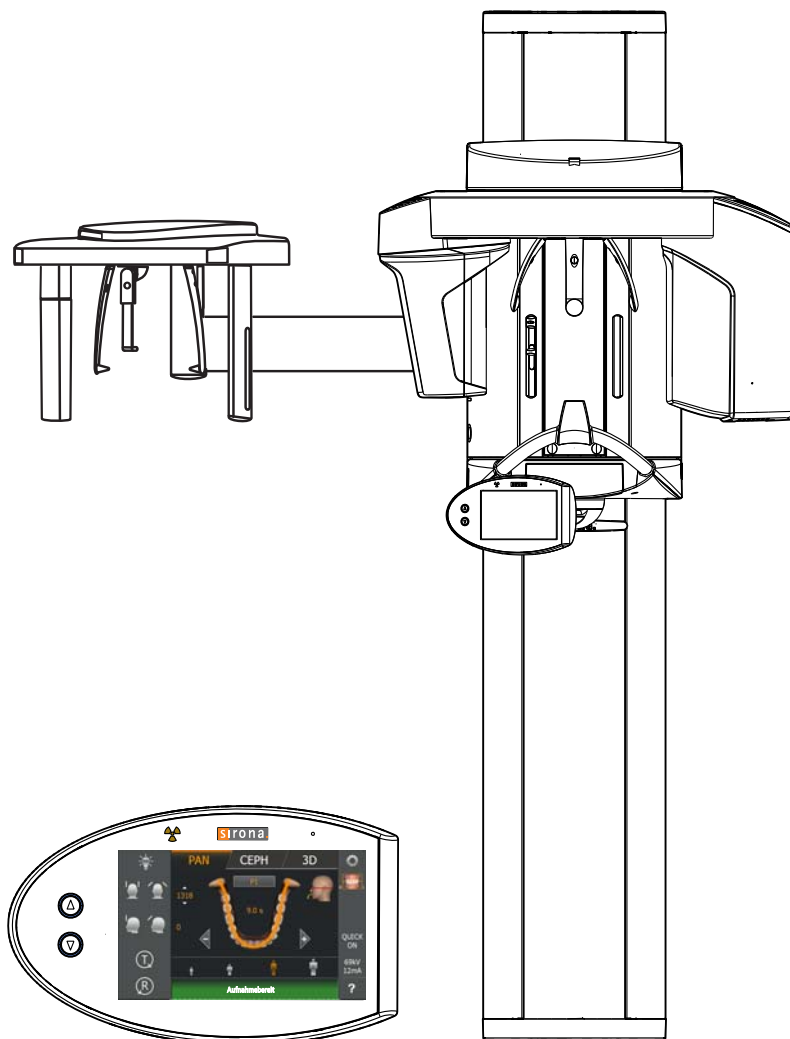
New as of:

05.2015

ORTHOPHOS SL 2D / ORTHOPHOS SL 2D Ceph ORTHOPHOS SL 3D / ORTHOPHOS SL 3D Ceph

Installation Requirements

English



General information

About this document

This document describes the installation requirements for the X-Ray unit:

ORTHOPHOS SL 2D,
ORTHOPHOS SL 2D Ceph,
ORTHOPHOS SL 3D,
ORTHOPHOS SL 3D Ceph

Their subsequent installation is described in the Installation Instruction, ORTHOPHOS SL REF 64 95 142.

New as of:

05.2015

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1 Checklist of installation prerequisites

ORTHOPHOS SL

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1.1 Purpose of the checklist

We recommend performing an inspection of the circumstances on location 4 weeks prior to installation. This can help ensure a smooth procedure on the day that the ORTHOPHOS SL device is actually installed. The checklist of this document contains the most important items to take into consideration.

1.2 Persons or companies performing inspection

List of the persons/companies performing inspection on location:	
Specialized dealers:	
Date of the 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 Persons or companies performing inspection

List of contact persons on-site:				
Function	First name/Last name:	Telephone	Cell phone	E-mail
Service engineer				
IT specialist				
Specialist advisors				
Administrator				
Expert				
Clinic engineer				
Professor				
Dentist				
Day/date of planned installation:				
Time:				
Installation postponement to day/date (if applicable):				
Time:				

1.3 Construction requirements

Transport paths:		
<ul style="list-style-type: none"> Clarify and/or walk along unit transport path from delivery location to installation site, measuring doorways and passageways (For dimensions/weight, see 3.5) Transport path OK? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Elevator available and large enough for transporting the unit? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Appropriate transport personnel provided 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Person responsible: 		
<ul style="list-style-type: none"> Remarks/Tasks: 		

1.3 Construction requirements

Installation location:		
<ul style="list-style-type: none"> Installation location: Unit location: Building number: Room name/number: 		
<ul style="list-style-type: none"> Is the room large enough? (see 3.1) 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Radiation protection plan available? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>⚠ CAUTION <i>If the room height is less than 2.27 m (89 3/8") or 2.30 m (90 1/2") for installation with the floor stand, the maximum travel must be limited.</i></p>		
<ul style="list-style-type: none"> Room height measures 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") 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Underfloor heating available? If yes use 2 wall brackets. 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Is there carpet at the unit's installation location? If yes, remove carpet from under the unit. 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Information about the characteristics/material of the wall available? If possible perform test drilling! 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Required extraction forces (wall plugs see 2.2) ensured? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>⚠ CAUTION <i>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!</i></p>		
<ul style="list-style-type: none"> Installation on the wall with or without floor stand (see 2.3)? 	<input type="checkbox"/> with	<input type="checkbox"/> without
<ul style="list-style-type: none"> Temporary storage facilities for the styrofoam parts available? The unit should be brought to the installation location with the styrofoam parts; one of the installation aids should also be available. These should be temporarily stored until collection. 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Remarks/Tasks: 		

1.3 Construction requirements

Electrical connection ORTHOPHOS SL		
• Fusing the unit termination 3x2.5mm ² (14 AWG) 230/ B25A, for 3x1,5mm ² (16 AWG) B 16 A/20 A only the ORTHOPHOS SL may be connected.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Internal line impedance checked? (max. 0.8 Ohm)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Connection possibility available for second protective ground wire? If no connection possibility is available, one must be retrofitted!	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Other large electrical units (e. g. air conditioning systems, fan motors) available in the vicinity? If yes, which (EMC influences)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Clearance of the large electrical units to ORTHOPHOS SL?	_____m	
• Remarks/Tasks:		

Type of remote control installation		
• Type of remote control required (see 2.2):		
– In the room	<input type="checkbox"/> Yes	<input type="checkbox"/> No
– Outside without coiled cable	<input type="checkbox"/> Yes	<input type="checkbox"/> No
– Outside with coiled cable	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Ductwork available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Diameter of the ductwork? (Diameter at least 10 mm (3/8"))	_____mm	
• Removal? (Length of the special control cable supplied 15 m (590 1/2"))	_____m	
• Remarks/Tasks:		

1.4 IT Hardware

Workstation PC requirements when using a separate RCU (not included in scope of supply)				
	Requirements for 2D Workstation:	Requirements for 3D Workstation:	Requirements for 2D/3D Workstation with panorama editor:	Fulfilled
Operating system:	Windows 7 Professional/Ultimate (64 bit) Windows 8.1 Professional (64 bit) An Internet connection is required from Windows 8.			<input type="checkbox"/>
Processor:	≥ 2,3 GHz DualCore with SSE3 support	≥ 2.3 GHz QuadCore with SSE3 support	≥ 2.3 GHz QuadCore with SSE3 support	<input type="checkbox"/>
Main memory:	≥ 4 GB	≥ 8 GB	≥ 8 GB (16 GB recommended)	<input type="checkbox"/>
Hard disk:	≥ 500 GB free hard disk space			<input type="checkbox"/>
Graphic card:	DirectX 9.0c graphics card, (512 MB RAM decidedly)	DirectX 10 graphics card, (1GB RAM decidedly) with WDDM 1.0 or higher driver	DirectX 10 graphics card, (1GB RAM decidedly) with WDDM 1.0 or higher driver	<input type="checkbox"/>
Graphics settings:	Minimum resolution 1280x1024 pixels, 1600x1200 pixels recommended			<input type="checkbox"/>
Drives:	DVD ROM DVD RAM (to use Wrap & Go)			<input type="checkbox"/>
Screen:	Suitable for diagnosis applications			<input type="checkbox"/>
Software:	Acrobat Reader 8.0, contained on DVD (required for the PDF test report function)			<input type="checkbox"/>
<ul style="list-style-type: none"> • Remarks/Tasks: 				

1.4 IT Hardware

RCU hardware requirements (not included in scope of supply)		
	Requirements	Fulfilled
Operating system:	Windows 7 Professional/Ultimate (64 bit) Windows 8.1 Professional (64 bit) An Internet connection is required from Windows 8.	<input type="checkbox"/>
Processor:	≥ 2.3 GHz QuadCore with SSE3 support, only intel ≥ i73xx	<input type="checkbox"/>
Main memory:	≥ 16 GB	<input type="checkbox"/>
Hard disk:	≥ 2 TB free hard disk space	<input type="checkbox"/>
Graphics system:	Combined requirements when using both RCU and workstation on one PC.	<input type="checkbox"/>
Drives:	DVD ROM DVD RAM (to use Wrap & Go)	<input type="checkbox"/>
<ul style="list-style-type: none"> Remarks/Tasks: 		

1.4 IT Hardware

Workstations/RCU		
<ul style="list-style-type: none"> Is a diagnostic monitor available? At least 1 diagnostic monitor must be available in the practice! 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> Number of planned workstations It is advisable to locate a workstation PC near the ORTHOPHOS SL for the purpose of readying the unit for exposure. 	_____ units	
<ul style="list-style-type: none"> Plan/determine location of RCU (room) 		
<ul style="list-style-type: none"> Is a switch available? 	<input type="checkbox"/> Yes <input type="checkbox"/> 1GBit	<input type="checkbox"/> No
<ul style="list-style-type: none"> Remarks/Tasks: 		


1.4 IT Hardware

SQL/Fileserver		
• Are SIDEXIS databases already installed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• If yes, which version of the SIDEXIS database? (Patients.paf, Pdata.mdb, SQL-Express or SQL)		
• Is migration necessary?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• SQL server available? Microsoft SQL-Express is included in the scope of supply! – SQL-Server version – SQL-Server name	<input type="checkbox"/> Yes _____ _____	<input type="checkbox"/> No
• File server installed (separate server for image database only)? – Windows release with full access – Operating system/version – Name of computer – IP address – Processor performance (clock frequency) – Available RAM? – Available hard disk storage?	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No _____ _____ _____._____._____._____ _____ _____ _____GB _____GB
• Number of expected exposures / Approx. 1GB per volume are currently stored in the database! 3D: Database approx. 100 MB - 650MB; Data container 500 MB - 2300 MB 2D: Database approx. 1000 MB; Data container 1700 MB – Per month? – Volume per month x 12 = volume per year – Approx. memory required – Depending on this, is a backup system available? – Is a backup system planned?	_____ _____ _____ _____GB <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No
⚠ CAUTION Network Attached Storage (NAS) units The use of LINUX based Network Attached Storage (NAS) units for PDATA can cause problems.		
• Remarks/Tasks:		

1.5 Network

Network				
<ul style="list-style-type: none"> • The entire network must be equipped with 1 GBit Ethernet! <ul style="list-style-type: none"> – Cat 5e/Cat 6 <input type="checkbox"/> 1 Gbit/sec 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<ul style="list-style-type: none"> • Network connection for ORTHOPHOS SL available? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<ul style="list-style-type: none"> • Network connection available at all workstations? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<ul style="list-style-type: none"> • Network connection for RCU available? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<div style="border: 1px solid black; padding: 5px;"> <p>i NOTICE <i>It is advisable to locate a workstation PC near the ORTHOPHOS SL for the purpose of readying the unit for exposure.</i></p> </div>				
<ul style="list-style-type: none"> • Network configuration plan available? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<ul style="list-style-type: none"> • Have the network jacks been certified? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<ul style="list-style-type: none"> • Network certificate available? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<ul style="list-style-type: none"> • Network installation company? 				
<ul style="list-style-type: none"> • Remarks/Tasks: 				

1.6 Data processing

IP addresses/Firewall		
• TCP/IP address range	_____ . _____ . _____ . _____ - _____ . _____ . _____ . _____	
• Subnet mask	_____ . _____ . _____ . _____	
• Are addresses already defined/present?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
• Is there a DHCP server (dynamic TCP/IP address assignment)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
 CAUTION A static address is required for the ORTHOPHOS SL and the RCU! It must not lie in the dynamic address range!		
• ORTHOPHOS SL:	_____ . _____ . _____ . _____	
• RCU:	_____ . _____ . _____ . _____	
• Workstation PCs:	_____ . _____ . _____ . _____ - _____ . _____ . _____ . _____	
• Standard gateway:	_____ . _____ . _____ . _____	
• Antivirus software available?	<input type="checkbox"/> Yes Name:	<input type="checkbox"/> No
• Is a firewall installed? – Software or hardware firewall?	<input type="checkbox"/> Yes <input type="checkbox"/> SW <input type="checkbox"/> HW	<input type="checkbox"/> No
• Remarks/Tasks:		

1.6 Data processing

IP addresses/Firewall

The following ports must be open for configuration and operation!

<ul style="list-style-type: none"> - ORTHOPHOS SL 	12835 12836 12837 12838 12839 12935 12936 12937 12938 443
<ul style="list-style-type: none"> - RCU 	52837
<ul style="list-style-type: none"> - SIDEXIS 4 Server 	42916 42927 42928

• Remarks/Tasks:

Practice administration programs

• Are connections to the practice administration programs, etc. installed?

Yes

No

– If yes, which system (manufacturer + name)?

• Remarks/Tasks:

1.6 Data processing

DICOM		
<ul style="list-style-type: none"> • Is a DICOM installation already present? <ul style="list-style-type: none"> – Which version? – Configuration? 	<input type="checkbox"/> Yes _____ _____	<input type="checkbox"/> No
<ul style="list-style-type: none"> • Is a DICOM connection required? 	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<ul style="list-style-type: none"> • If yes, what is required? <ul style="list-style-type: none"> – SIDICOM WLS or QR Which functionalities should be supported? In this case, the DICOM questionnaire must be completed! – DICOM Removable Media (included in delivery) 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No
<ul style="list-style-type: none"> • Remarks/Tasks: 		

2 Preparations

ORTHOPHOS SL

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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 (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

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

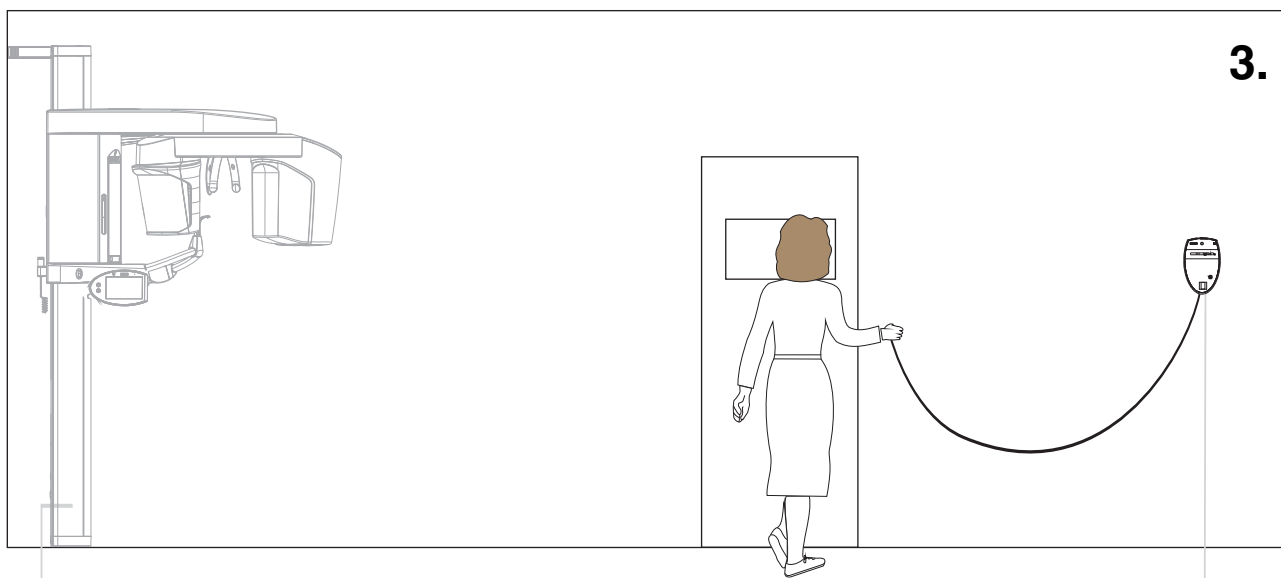
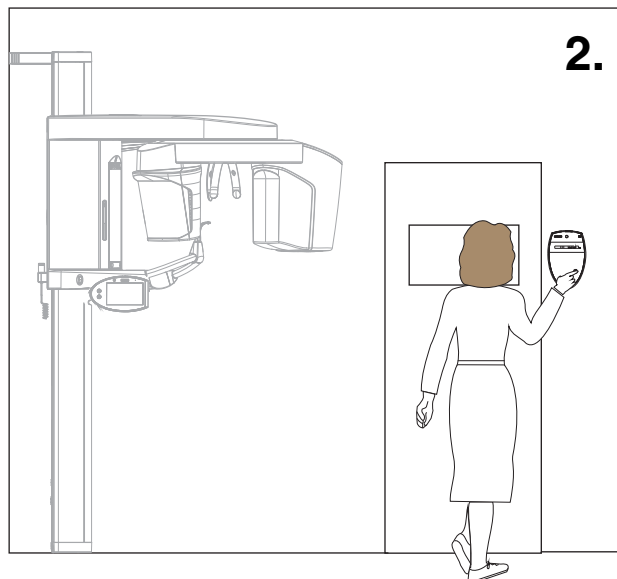
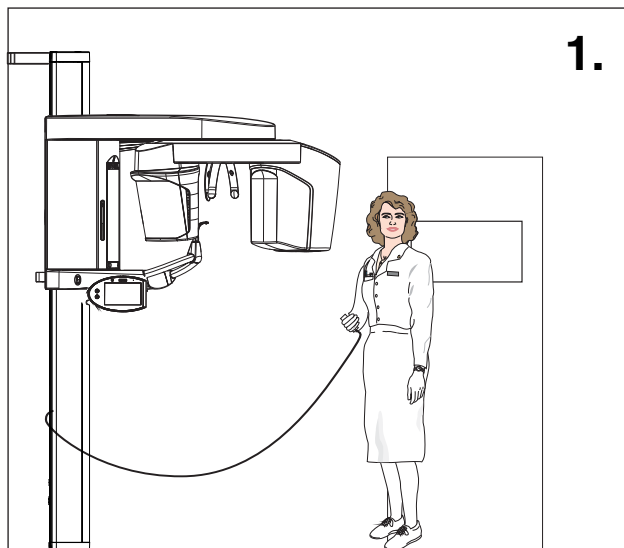
Electromagnetic compatibility: The unit should not be operated in the immediate vicinity of other devices. If this proves to be unavoidable, the unit should be monitored to ensure that it is used properly.



CAUTION

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

2.2 Possibilities of Installation



1. ORTHOPHOS SL **without** remote control with release button on coiled cable in the treatment room.
2. ORTHOPHOS SL **with** remote control¹ outside of X-ray room, **without** release button on coiled cable.
Length of special control cable supplied: approx. 15m (590 1/2").
3. ORTHOPHOS SL **with** remote control¹ 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.

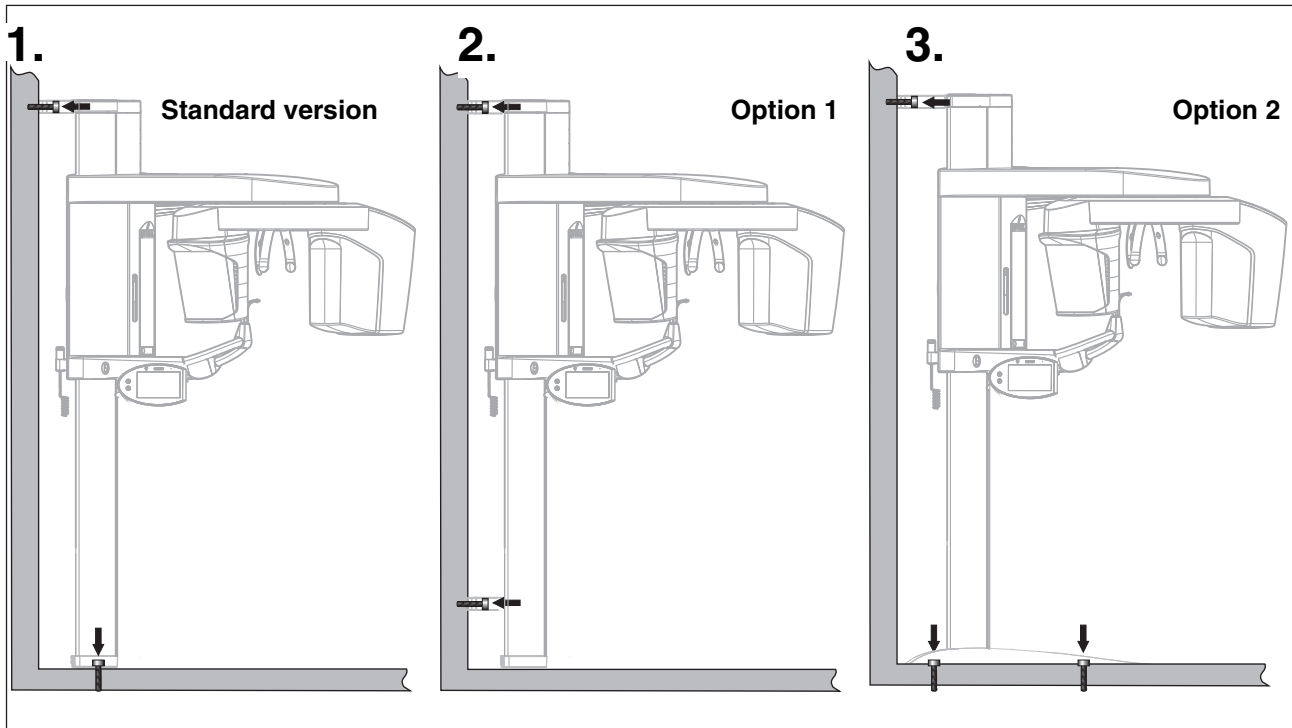
- Depending on the construction of the wall, suitable special wall plugs must be obtained or an anchor plate made.

¹ With use of a door contact: run shielded 2-core cable (24 AWG / 0.22 mm²) to the remote control.
 When an X-ray warning lamp is used: run a 3-wire cable 1.5 mm² (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



Standard version

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

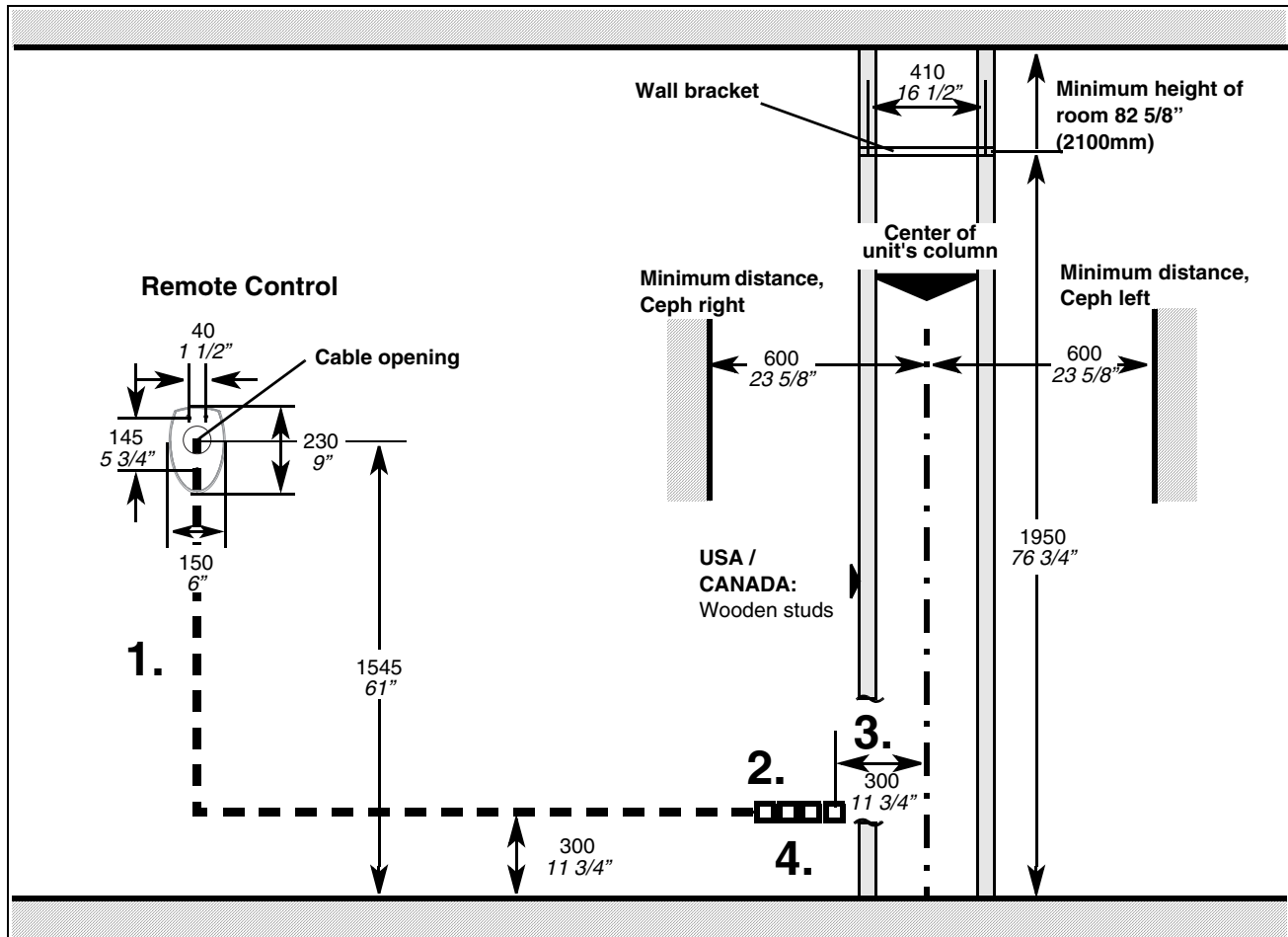
Option 1: with second wall holder

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, length 15 m (590 1/2")), 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 mm² or 3 x 4 mm² (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 mm² / 3 x 2,5 mm² (16 AWG / 14 AWG) and an overcurrent circuit breaker B rated for 16 A/20 A, it is permissible to connect only the ORTHOPHOS SL or other such units that cause no danger to the patients or to the computer systems in case the automatic circuit breaker is activated.

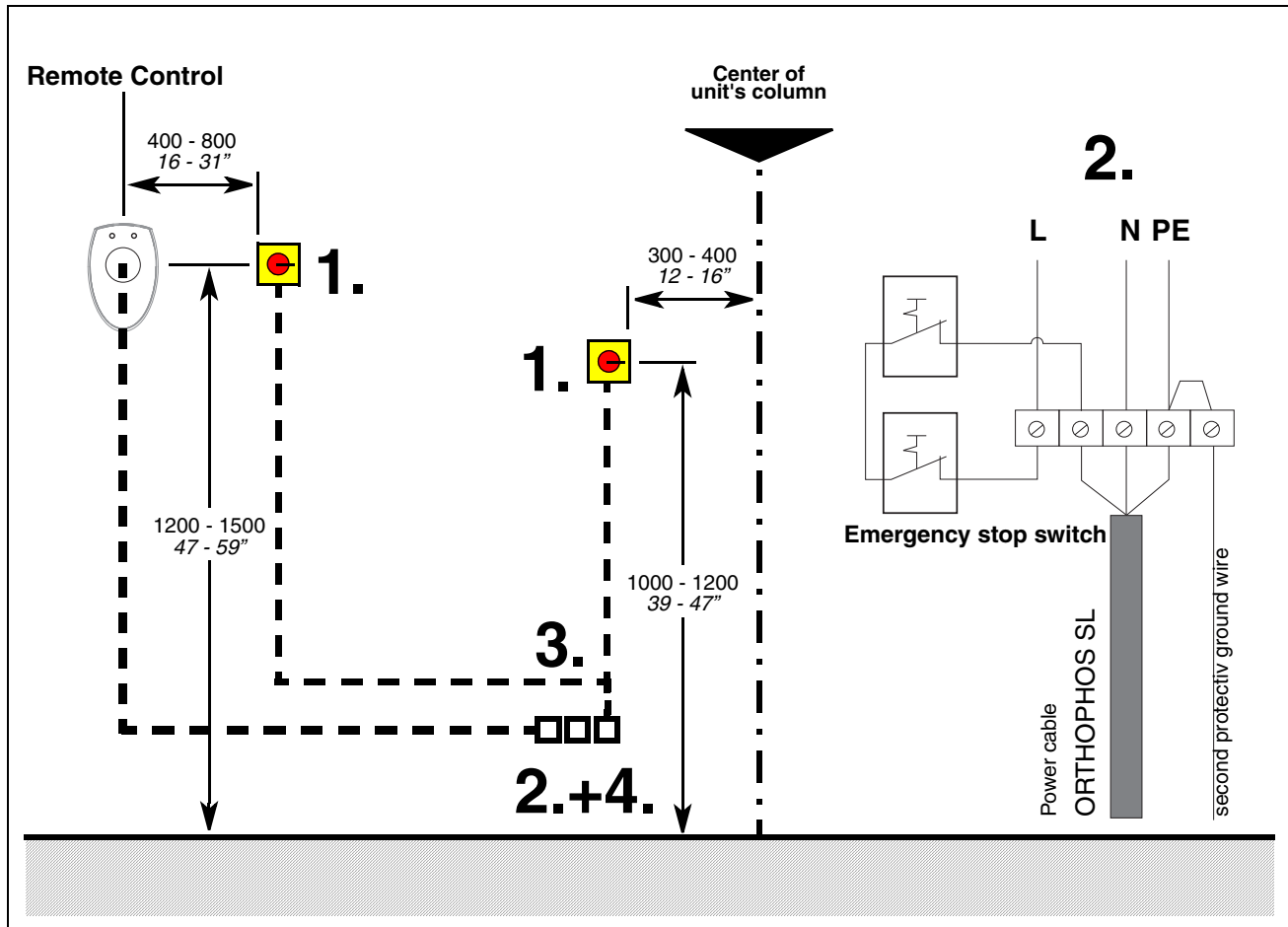
- Install the installation socket for the second protective ground wire.



WARNING

Install the connection possibility for the second protective ground wire. Second protective ground wire is pre-assembled 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 $3 \times 2,5 \text{ mm}^2$ or $3 \times 4 \text{ mm}^2$ (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.

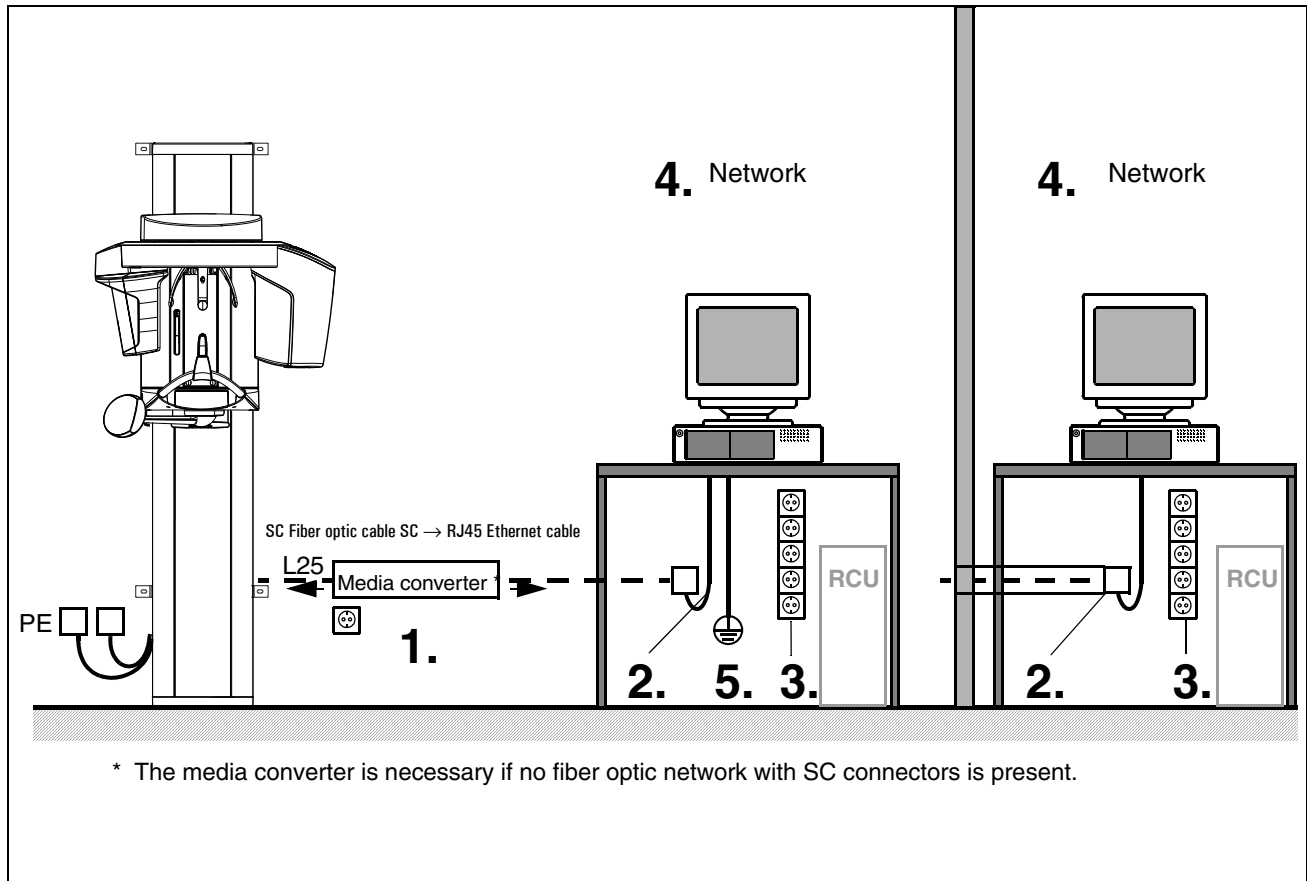
- For an on-site installation with $3 \times 1,5 \text{ mm}^2$ / $3 \times 2,5 \text{ mm}^2$ (16 AWG / 14 AWG) and an overcurrent circuit breaker B rated for 16 A/20 A, it is permissible to connect only the ORTHOPHOS SL or other such units that cause no danger to the patients or to the computer systems 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



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, workstation 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 (4 mm² 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	Shaded				
No. 10 AWG	Shaded	Shaded			
No. 8 AWG	Shaded	Shaded	Shaded	Shaded	Shaded

Wire Size for Power Line

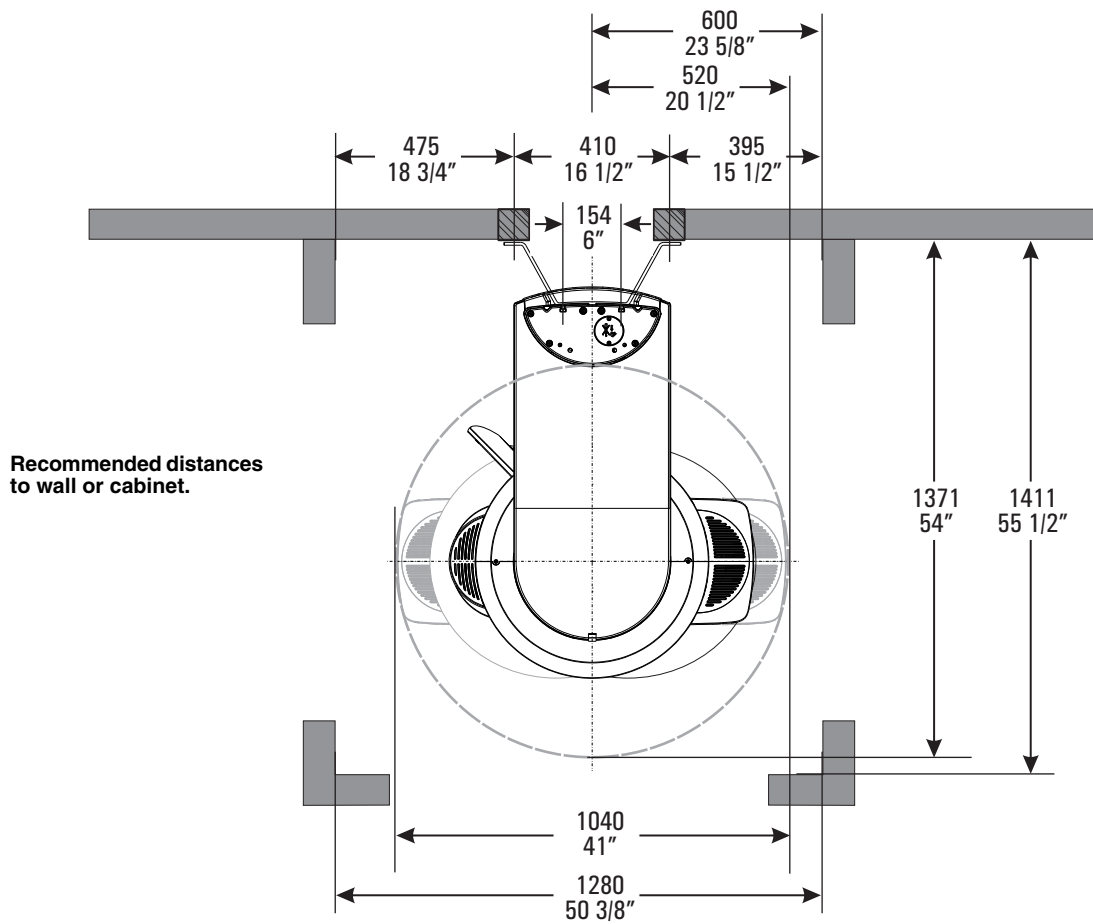
- The unit is designed to operate on a **nominal** 200 - 240 VAC line.
 Permitted line voltage variation $\pm 10\%$.
 On request, the local Electrical Utility Company will perform a voltage regulation test to verify the line quality.
- The distributor box should be installed in the position as shown on page 25.
- 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 mm²) and an overcurrent circuit breaker rated for 20 A, it is permissible to connect only the ORTHOPHOS SL 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.

3 Dimensions, technical data

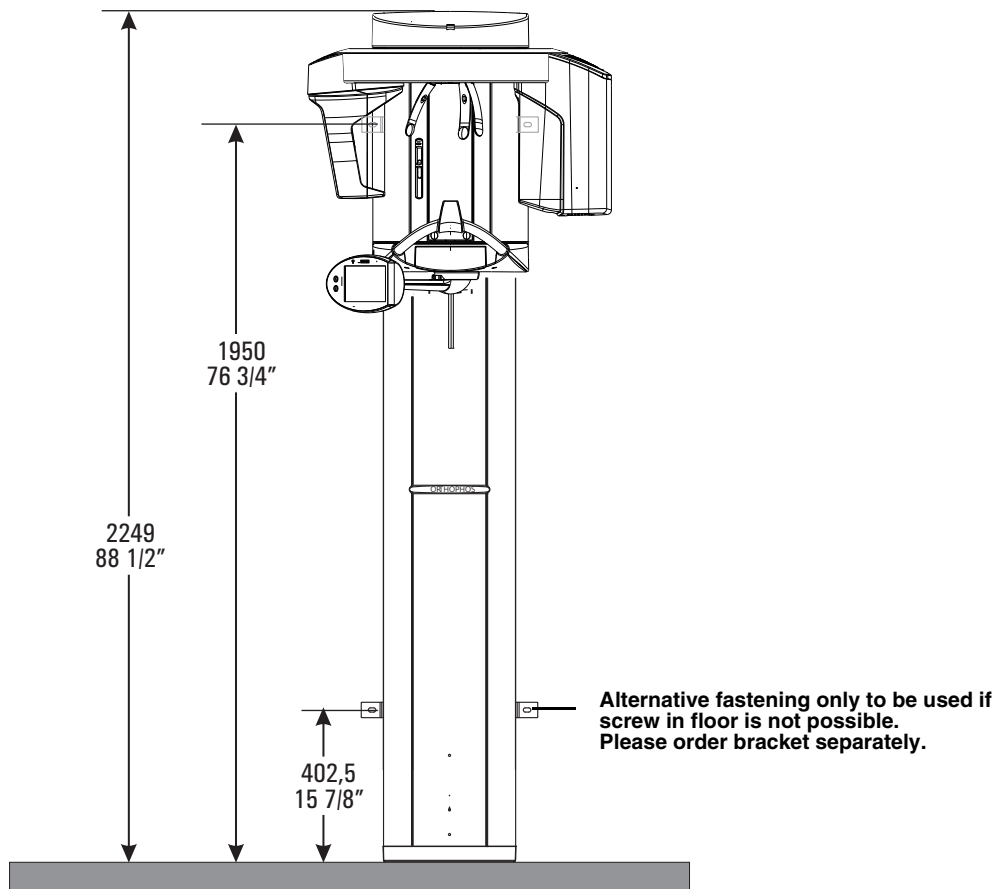
ORTHOPHOS SL

3.1	Dimensions of the ORTHOPHOS SL 1:20	30
3.2	Dimensions of the ORTHOPHOS SL 1:20 on Floor stand	32
3.3	Dimensions of the ORTHOPHOS SL Ceph 1:20 Ceph left	34
3.4	Dimensions of the ORTHOPHOS SL Ceph 1:20 Ceph right	36
3.5	Technical data	38

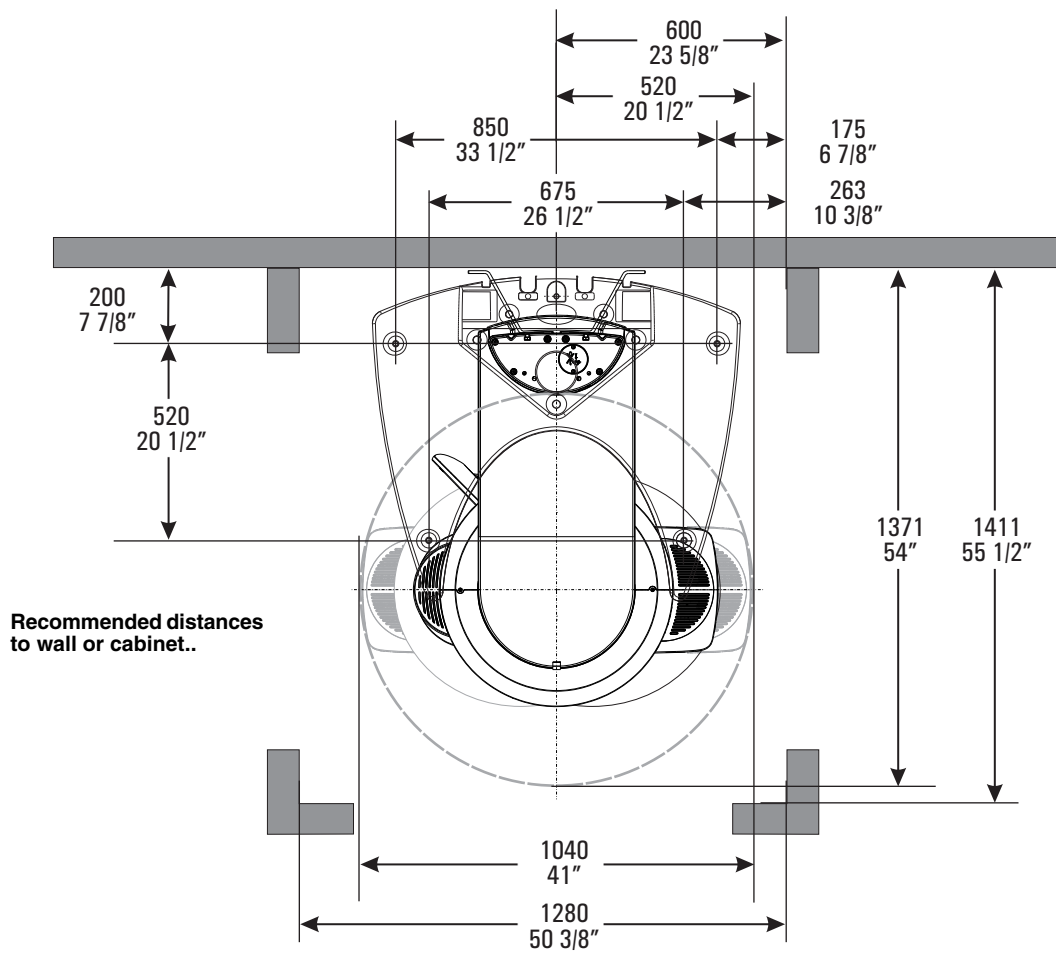
3.1 Dimensions of the ORTHOPHOS SL 1:20



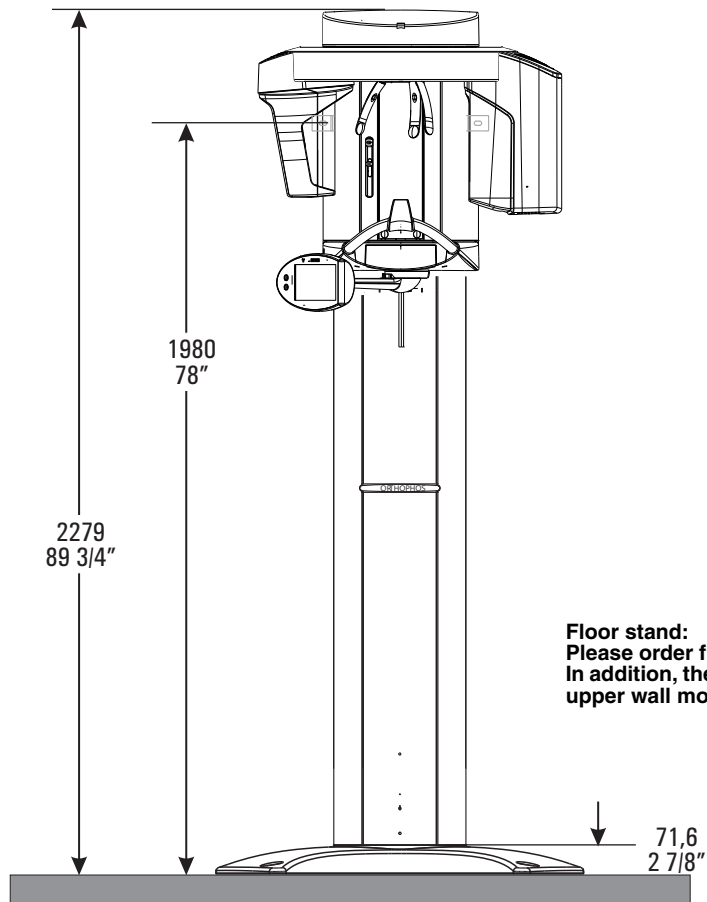
Dimensions of the ORTHOPHOS SL 1:20



3.2 Dimensions of the ORTHOPHOS SL 1:20 on Floor stand

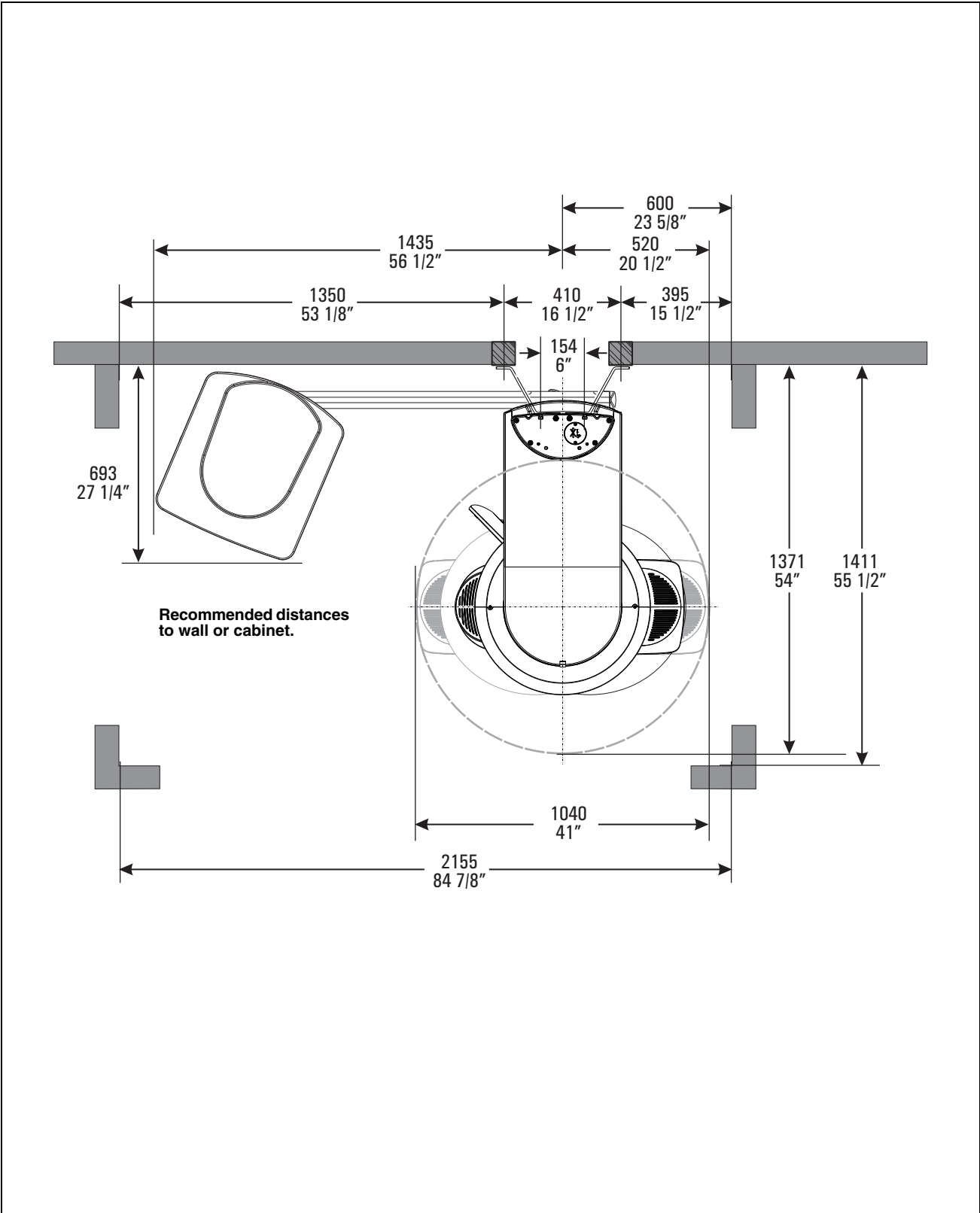


Dimensions of the ORTHOPHOS SL 1:20 on Floor stand

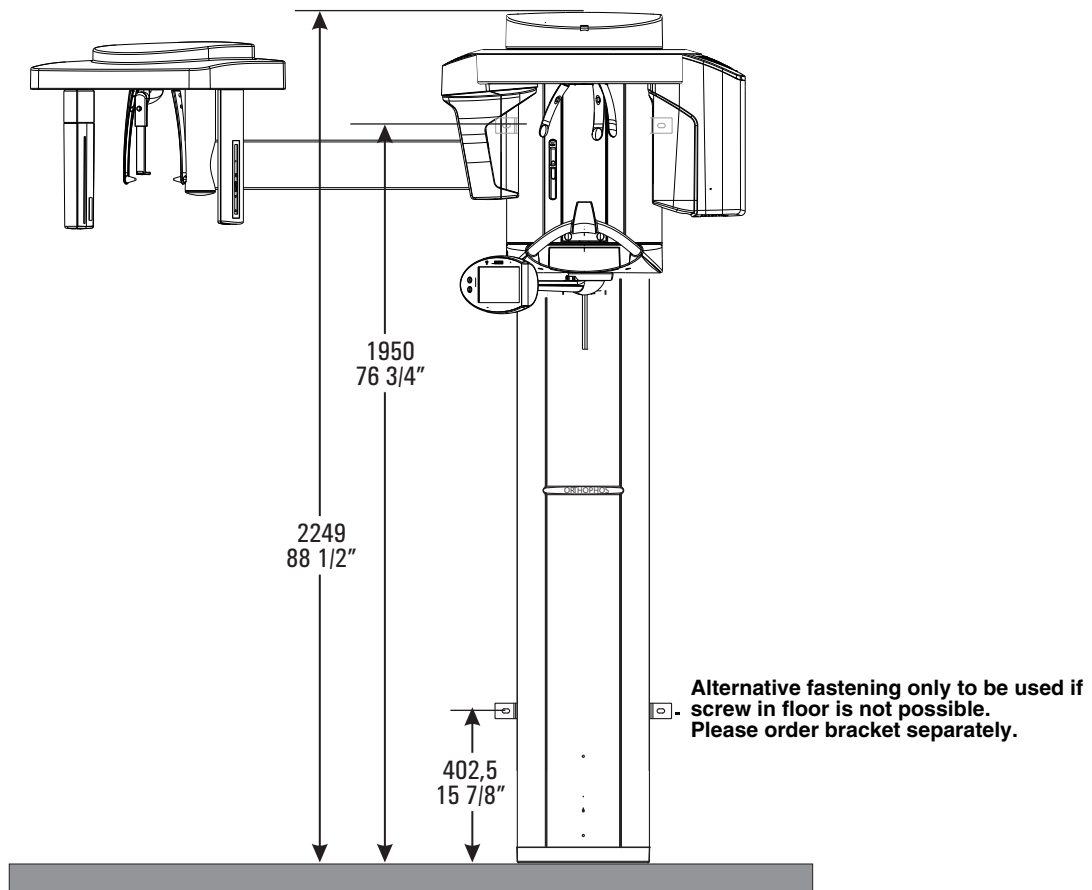


Floor stand:
Please order floor stand separately.
In addition, the unit must always be fixed with the upper wall mount.

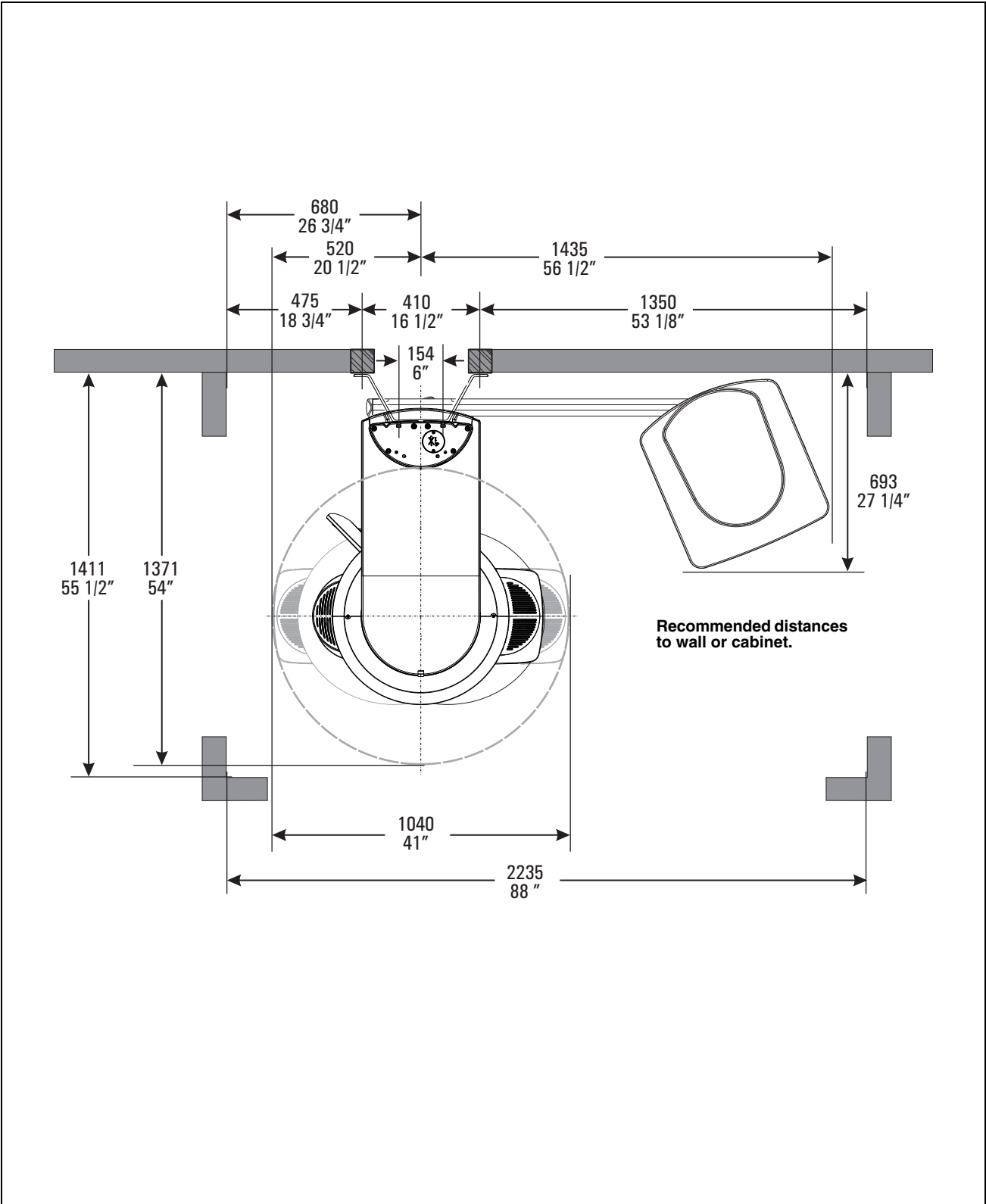
3.3 Dimensions of the ORTHOPHOS SL Ceph 1:20 Ceph left



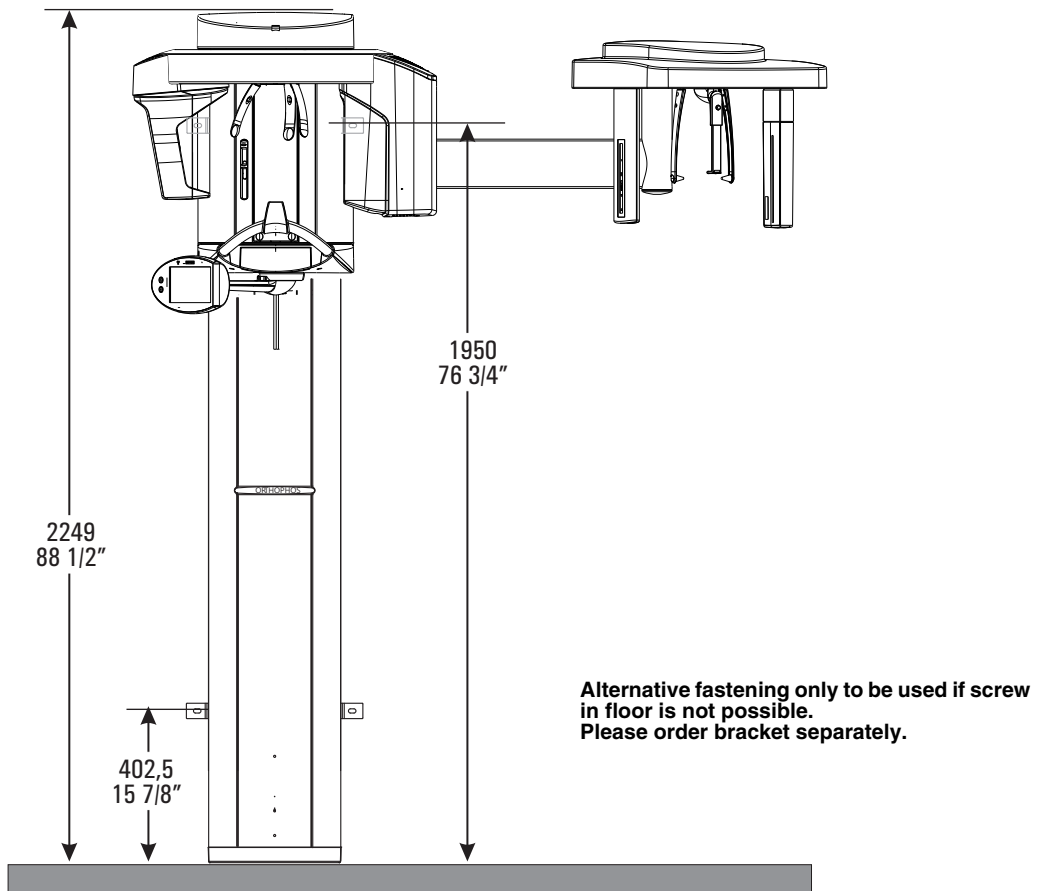
Dimensions of the ORTHOPHOS SL Ceph 1:20 Ceph left



3.4 Dimensions of the ORTHOPHOS SL Ceph 1:20 Ceph right



Dimensions of the ORTHOPHOS SL Ceph 1:20 Ceph right



3.5 Technical data

Dimensions packaging

ORTHOPHOS SL	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 (1 kg=2.2lbs)

ORTHOPHOS SL	188kg / 110kg	(415lb / 243lb)
Cephalometer	43kg / 22kg	(95lb / 49lb)
Floor stand	50kg / 31kg	(110lb / 68lb)

Power supply

Line voltage	200V- 240V, 50 / 60Hz
Tolerance of line voltage	±10%
Power line resistance	max. 0,8 Ω
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	2 kVA (permanent)
Maximal voltage breakdown with 10A ohmical load:	≤ 10%

Operating conditions

Ambient temperature:
+18 °C - +31 °C (64 °F – 88 °F)
Relative humidity: 10% – 95%
Operating altitude : ≤ 3,000m above sea level

Transport and storage conditions

ORTHOPHOS SL	Temperature: -10°C – +70°C (14°F – 158°F) Relative humidity: 10% – 95% without condensation
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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 SL X-ray unit complies with
IEC 60601-1
IEC 60601-1-3
IEC 60601-2-63



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 SL

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i NOTE

The ORTHOPHOS SL/ORTHOPHOS SL Ceph fulfills all requirements for electromagnetic compatibility (EMC) compliant with IEC 60601-1-2.
The ORTHOPHOS SL/ORTHOPHOS SL 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	REF
PC as peripheral device.	
Remote cable L117 XG, 15m (590 1/2")	6094697
Cable L25 OP-XG, 5m (197")	5922765
Media converter	6470194
LAN-cable Kat5, 3m (118")	5168963
2nd protective ground wire, 1.5mm ² (16 AWG)	6141563
Power cable	8920605

- 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 synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst according to IEC 61000-4-4	± 1 kV for input and output lines ± 2kV power cables	± 1 kV 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	± 1 kV push-pull voltage ± 2kV push-pull voltage	± 1 kV 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
<p>Conducted HF interference IEC 61000-4-6</p> <p>Radiated HF interference IEC 61000-4-3</p>	<p>$3V_{\text{eff}}$ 150 kHz to 80 MHz^a</p> <p>$3V/m$ 80MHz to 800MHz^a</p> <p>$3V/m$ 800MHz to 2.5GHz^a</p>	<p>$3V_{\text{eff}}$</p> <p>$3V_{\text{eff}}$</p> <p>$3V_{\text{eff}}$</p>	<p>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.</p> <p>Recommended working clearance:</p> $d = [1, 2] \sqrt{P}$ $d = [1, 2] \sqrt{P}$ at 80MHz to 800MHz $d = [2, 3] \sqrt{P}$ at 800MHz to 2.5GHz <p>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).</p> <p>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.</p> <p>Interference is possible in the vicinity of equipment bearing the following graphic symbol.</p> 

- a. The higher frequency range applies at 80MHz and 800MHz.
- 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 150kHz to 80MHz results in a field strength of less than 3V/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]		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d= [1, 2] \sqrt{P}$	$d= [1, 2] \sqrt{P}$	$d= [2, 3] \sqrt{P}$
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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