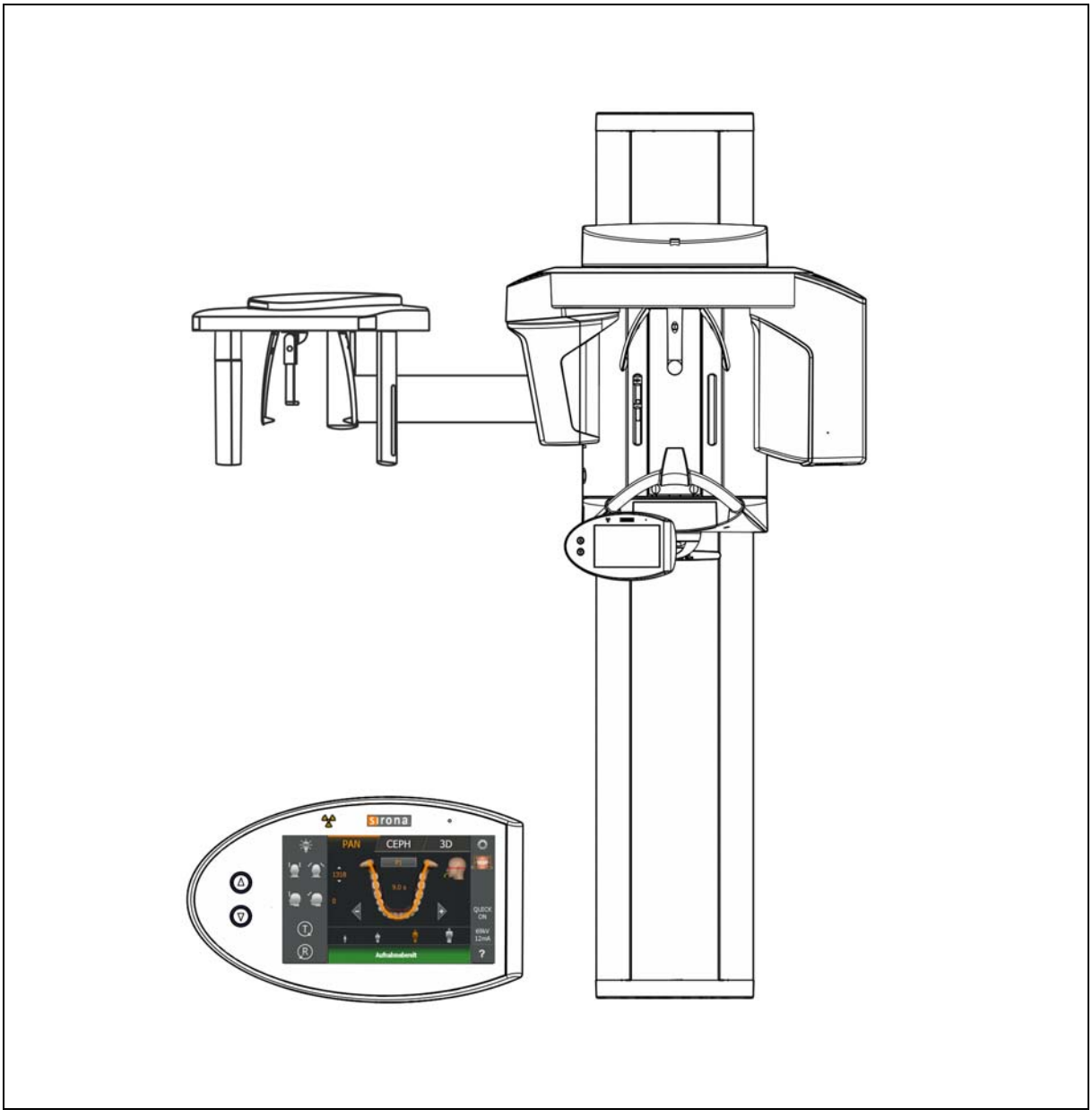
New as of: 03.2016

sirona
The Dental Company

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

Installation Requirements

English



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1 General data

1.1 Notes on the installation prerequisites

This document describes the installation conditions for the X-ray units
ORTHOPHOS SL 2D,
ORTHOPHOS SL 2D Ceph,
ORTHOPHOS SL 3D,
ORTHOPHOS SL 3D Ceph

Subsequent installation is described in the
ORTHOPHOS SL Installation Instructions (REF 64 95 142).

1.2 Structure of the document

1.2.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in the present operating instructions. Such information is highlighted as follows:

⚠ 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.

IMPORTANT

Application instructions and other important information.

Tip: Information on making work easier.

1.2.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Requests you to do something.
See "Formats and symbols used [→ 6]"	Identifies a reference to another text passage and specifies its page number.
• List	Designates a list.
"Command / menu item"	Indicates commands, menu items or quotations.

2 Safety instructions

2.1 Product safety

⚠ CAUTION

Risk to product safety

For reasons of product safety, this product may be operated only with original Sirona accessories or third-party accessories expressly approved by Sirona.

The user assumes the risk of using non-approved accessories.

Recommendation If any equipment not approved by Sirona is connected, it should comply with the applicable standards:

- IEC 60950 for information technology equipment (e.g. PC)

- IEC 60601-1 for medical electrical equipment.

In case of doubt, contact the manufacturer of the system components.

2.2 Combination with other units

Putting together or altering a medical electrical system by combining with other devices in accordance with IEC 60601-1 (safety requirements for medical electrical systems) is subject to the obligation to ensure compliance with the requirements of this provision for patient safety, the operator and the environment.

2.3 Shielding of room

When using the ORTHOPHOS SL X-ray unit, proper shielding of the room and operator position is essential.

It is the installer's responsibility to ensure that all local radiation regulations and safety measures are met.

2.4 Radiotelephones

Mobile RF communications equipment can affect electro-medical equipment. Therefore, the use of mobile wireless phones in medical office or hospital environments must be prohibited.

2.5 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 operating properly.

2.6 Electrical installation

The electrical installation must be made in compliance with DIN VDE 0100-710.

3 Checklist of installation prerequisites

3.1 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.**
An installed and executable version of the SIDEXIS 4 X-ray software must be installed as a prerequisite to operating the ORTHOPHOS SL unit. **DANGER! It cannot be used with the SIDEXIS XG version.**

3.2 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:		
Postal code / city:		
Phone:		
E-mail:		@
Special field of system owner:		

List of contact persons on-site:				
Function	**First name/Last name:**	**Phone**	**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	

3.3 Construction requirements

Transport paths	☑	
• Clarify and/or walk along unit transport path from delivery location to installation site, measuring doorways and passageways (For dimensions/weight, see Weight and packaging [→ 42]) Transport path OK?	☐ Yes	☐ No
• Elevator available and large enough for transporting the unit?	☐ Yes	☐ No
• Appropriate transport personnel provided.	☐ Yes	☐ No
• Person responsible:		
• Remarks/Tasks:		

Installation site	☑	
• Installation location: Unit location: Building number: Room name/number:		
• Is the room large enough? (see Dimensions 1:20 ORTHOPHOS SL [→ 34])	☐ Yes	☐ No
• Radiation protection plan available?	☐ Yes	☐ No
ATTENTION! **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.** • 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")	☐ Yes	☐ No
• Underfloor heating available? If yes, use 2 wall brackets.	☐ Yes	☐ No
• Is there carpet at the unit's installation location? If yes, remove carpet from under the unit.	☐ Yes	☐ No
• Information about the characteristics/material of the wall available? If possible perform test drilling!	☐ Yes	☐ No
• Required extraction forces ensured? (for wall plugs, see Installation options [→ 23])	☐ 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 Mounting options [→ 25])?	☐ with	☐ without
• 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.	☐ Yes	☐ No
• Remarks/Tasks:		

Electrical connection:	☑	
• Fusing of the unit termination 3x2.5mm^2 (14 AWG) 230/ B25A, for 3x1.5mm^2 (16AWG) B16A/B20A only the ORTHOPHOS SL may be connected.	☐ Yes	☐ No
• Checked internal line resistance? (Max. 0.8 ohms)	☐ Yes	☐ No
• Connection option available for second protective ground wire? If no connection option is available, one must be retrofitted!	☐ Yes	☐ No
• Other large electrical units (e.g. air conditioning systems, fan motors) in the vicinity? If yes, which (EMC influences)?	☐ Yes	☐ No
• Clearance of the large electrical units to ORTHOPHOS SL?	_____m	
• Remarks/Tasks:		

Type of remote control installation:	☑	
• Type of remote control required (see Installation options [→ 23]):		
– In the room	☐ Yes	☐ No
– Outside without coiled cable	☐ Yes	☐ No
– Outside with coiled cable	☐ Yes	☐ No
• Ductwork available?	☐ Yes	☐ No
• Diameter of the ductwork? (Min. diameter 10mm (3/8"))	_____mm	
• Removal? (Length of the special control cable supplied 15m (590 1/2"))	_____m	
• Remarks/Tasks:		

3.4 IT Hardware

Requirements on workstation PCs when using a separate RCU

	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) • Windows 10 **IMPORTANT:** An Internet connection is required from Windows 8.			☐
Processor	≥ 2.3 GHz DualCore with SSE3 support	≥ 2.3 GHz QuadCore with SSE3 support	≥ 2.3 GHz QuadCore with SSE3 support	☐
Main memory	≥ 4 GB	≥ 8 GB	≥ 8 GB (16 GB recommended)	☐
Hard disk	≥ 500 GB free hard disk space			☐
Graphics card	DirectX 9.0c graphics card (512 MB RAM dedicated or Intel Onboard graphics)	DirectX 10 graphics card (1GB RAM dedicated or Intel Onboard graphics) with WDDM driver 1.0 or higher	DirectX 10 graphics card (1GB RAM dedicated or Intel Onboard graphics) with WDDM driver 1.0 or higher	☐
Graphics settings	Minimum 1280x1024 pixels Recommended 1600x1200 pixels			☐
Drive	• DVD ROM • DVD RAM (to use Wrap & Go)			☐
Screen	Suitable for diagnosis applications			☐
Software	• Acrobat Reader 8.0, contained on DVD (required for the PDF test report function)			☐

Requirements on RCU hardware

	Requirements	Fulfilled
Operating system:	• Windows 7 Professional/Ultimate (64 bit) • Windows 8.1 Professional (64 bit) • Windows 10 **IMPORTANT:** An Internet connection is required from Windows 8.	☐
Processor	≥ 2.3 GHz QuadCore with SSE3 support, only intel ≥ i73xx	☐
Main memory	≥ 16 GB	☐
Hard disk	≥ 2 TB of free hard disk space	☐
Graphics card	Only for combined use as workstation on one PC, see above.	☐
Drive	• DVD ROM • DVD RAM (to use Wrap & Go)	☐

Workstations/RCU	☑	
• Is a diagnostic monitor available? At least one diagnostic monitor must be available in the practice.	☐ Yes	☐ No
• 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.	_____workstations	
• Plan/determine location of RCU (room)		
• Is a switch available?	☐ Yes ☐ 1 GBit	☐ No
• Remarks/Tasks:		

SQL/Fileserver	☑	
• Are SIDEXIS databases already installed?	☐ Yes	☐ No
• If yes, which version of the SIDEXIS database? (Patients.paf, Pdata.mdb, SQL-Express or SQL)	_____	
• Is migration necessary?	☐ Yes	☐ No
• SQL server available? 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 address	_____ . _____ . _____ . _____	
– Processor performance (clock frequency)	_____	
– Available RAM?	_____ GB	
– Available hard disk storage?	_____ GB	
• Number of exposures planned. (Approx. 1GB per volume exposure are currently stored in the database! 3D: Approx. 100 - 650 MB database; 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	_____GB	
– Depending on this, is a backup system available?	☐ Yes	☐ No
– Is a backup system planned?	☐ Yes	☐ No

SQL/Fileserver	☑	
ATTENTION! Network Attached Storage (NAS) units The use of LINUX based Network Attached Storage (NAS) units for PDATA can cause problems.		
• Remarks/Tasks:		

3.5 Network

Network	☑	
• The entire network must be equipped with 1 GBit Ethernet! –Cat 5e/Cat 6 □ 1 GBit/sec	□ Yes	□ No
• Network connection for ORTHOPHOS SL available?	□ Yes	□ No
• Network connection available at all workstations?	□ Yes	□ No
• Network connection for RCU available?	□ Yes	□ No
IMPORTANT! **It is advisable to locate a workstation PC near the ORTHOPHOS SL 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 present?	□ Yes	□ No
• Network installation company?		
• Remarks/Tasks:		

3.6 Data processing

IP addresses/Firewall	☑	
• TCP/IP address range _____ . _____ . _____ . _____ - _____ . _____ . _____ . _____		
• Subnet mask	_____ . _____ . _____ . _____	
• Are addresses already defined/present?	☐ Yes	☐ No
• Is there a DCHP server (dynamic TCP/IP address assignment)?	☐ Yes	☐ No
ATTENTION! **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?	☐ Yes	☐ No
• Is a firewall installed? – Software or hardware firewall?	☐ Yes ☐ SW ☐ HW	☐ No
• Remarks/Tasks:		

IP addresses/Firewall	☑	
• The following ports must be open for configuration and operation!		
• ORTHOPHOS SL	12835 12836 12837 12838 12839 12935 12936 12937 12938 443	
• RCU	52837	
• 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:		

DICOM	☑	
• Is a DICOM installation already present? – Which version? – Configuration?	☐ Yes _____ _____	☐ No
• Is a DICOM connection required?	☐ Yes	☐ No
• If yes, what is required? – SIDICOM WLS or QR Which functionalities should be supported? In this case, the DICOM questionnaire must be completed! – DICOM Removable Media (included in delivery)	☐ Yes ☐ Yes	☐ No ☐ No
• Remarks/Tasks:		

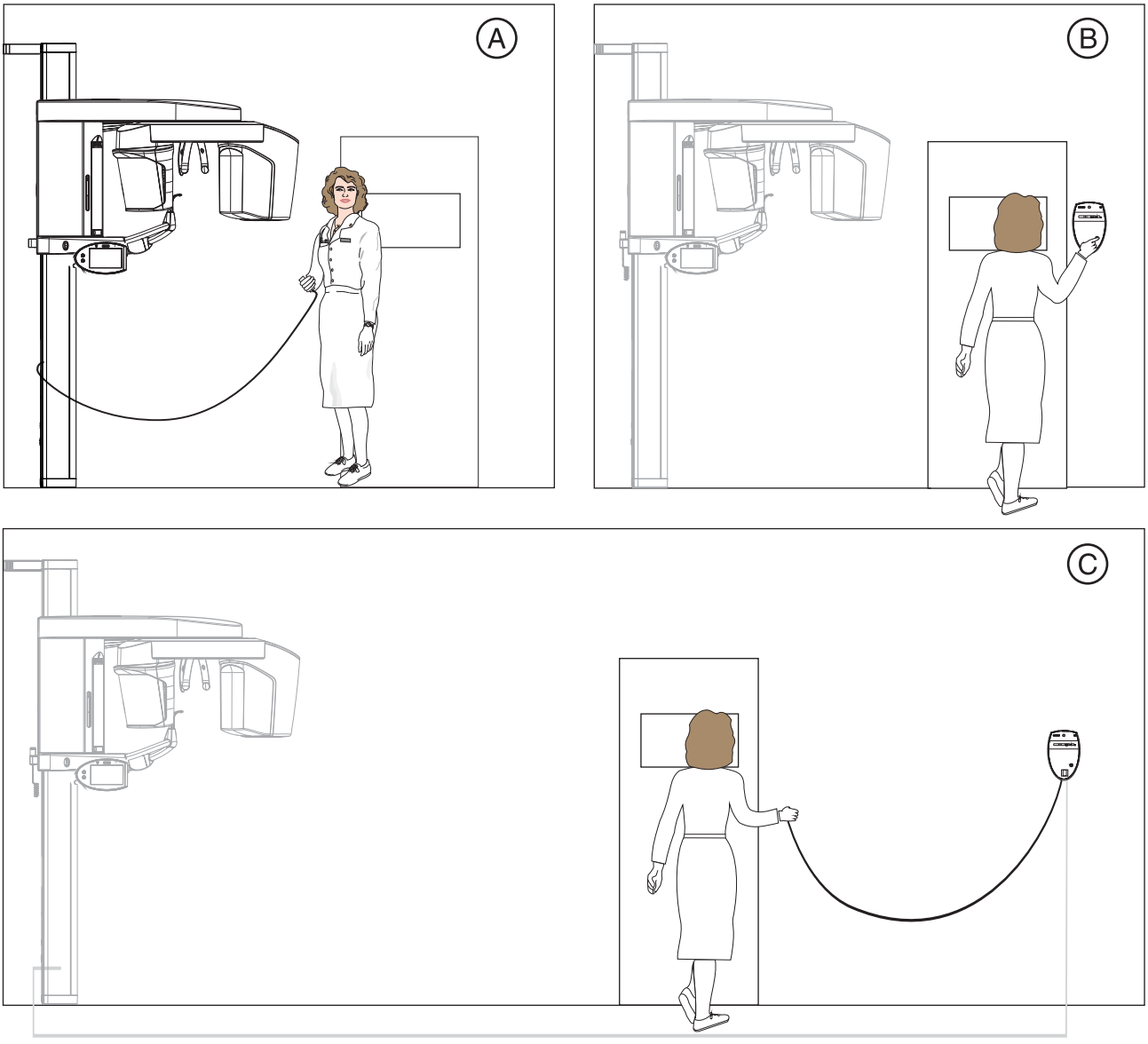
3.7 List of measures

What	Who	When

Inspection of installation requirements performed on:			
from:	Depot:	Name:	Signature:
	Customer:	Name:	Signature:

4 Preparations

4.1 Installation options



A	**Standard installation** Unit *without remote control with release button on the coiled cable* in the treatment room.
B	**Installation version 1** Unit *with remote control* outside the X-ray room *without release button on the coiled cable*. Length of the special control cable supplied 15m (590 1/2").
C	**Installation version 2** Unit *with remote control* outside the X-ray room *with release button on the coiled cable*.

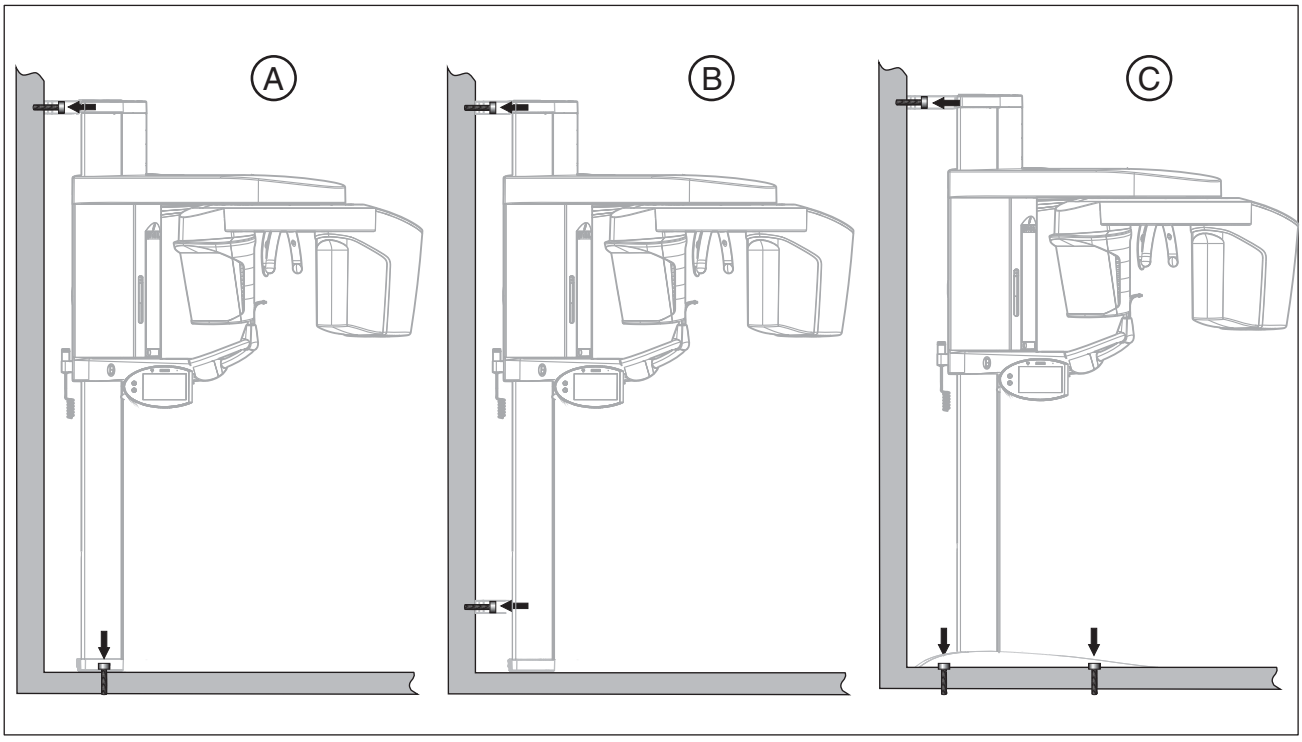
⚠ CAUTION

Wall plugs!

Each wall plug used to attach the unit must withstand an extraction force of 700 N.

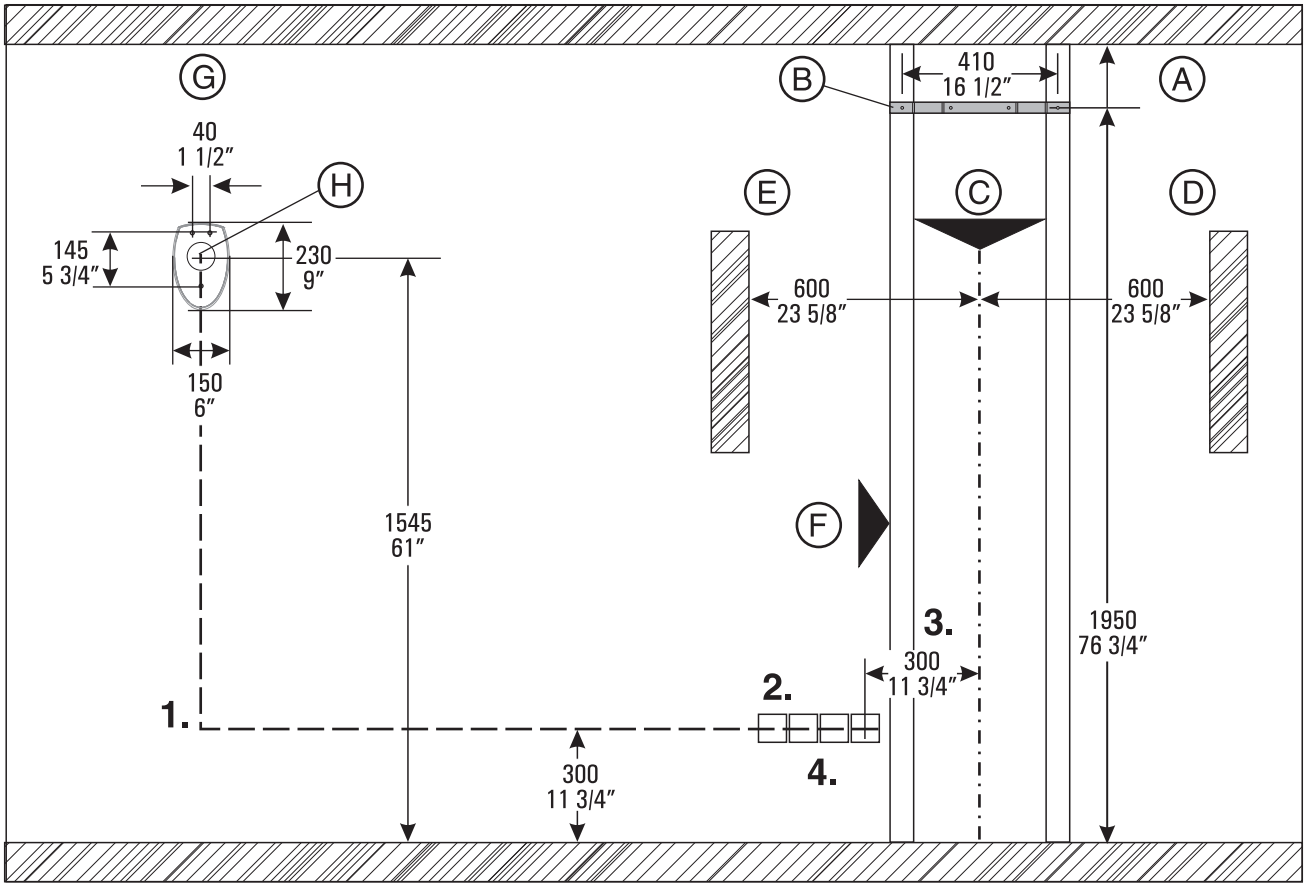
- Depending on the given wall construction, buy the corresponding special wall plugs from a specialized dealer or make an anchor plate.
- With remote control: When using a door contact: Run shielded 2-wire cable (0.22mm ^{2} / 24 AWG) to remote control.
  When using X-ray warning lamp is used: Run a 3-wire cable (1.5mm^2) (16AWG) to the warning lamp.
  DANGER!
  A maximum load of 50 W is permissible and no additional circuit may be connected.

4.2 Mounting options



A	**Standard version** *Wall-mounted installation with 1 wall holder* (short) and floor fastening if both wall and floor installation are possible on-site.
B	**Option 1: with second wall holder** *Wall-mounted installation with 2 wall holders* (short) (and no floor fastening) if only wall installation is possible on-site.
C	**Option 2: with floor stand and wall holder** *Installation using a floor stand and 1 wall holder* (long) if it is possible to mount the unit on the wall and on the floor on-site and x-rays are often taken while the patient is seated on a chair → better positioning of seated patient.

4.3 On-site installation: Schematic diagram



A	Minimum room height 2100 mm
B	Mounting bracket
C	Unit center of column
D	Minimum clearance Ceph left
E	Minimum clearance Ceph right
F	USA/Canada: Wooden beam
G	Remote control
H	Cable bushing

⚠ 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.

NOTICE

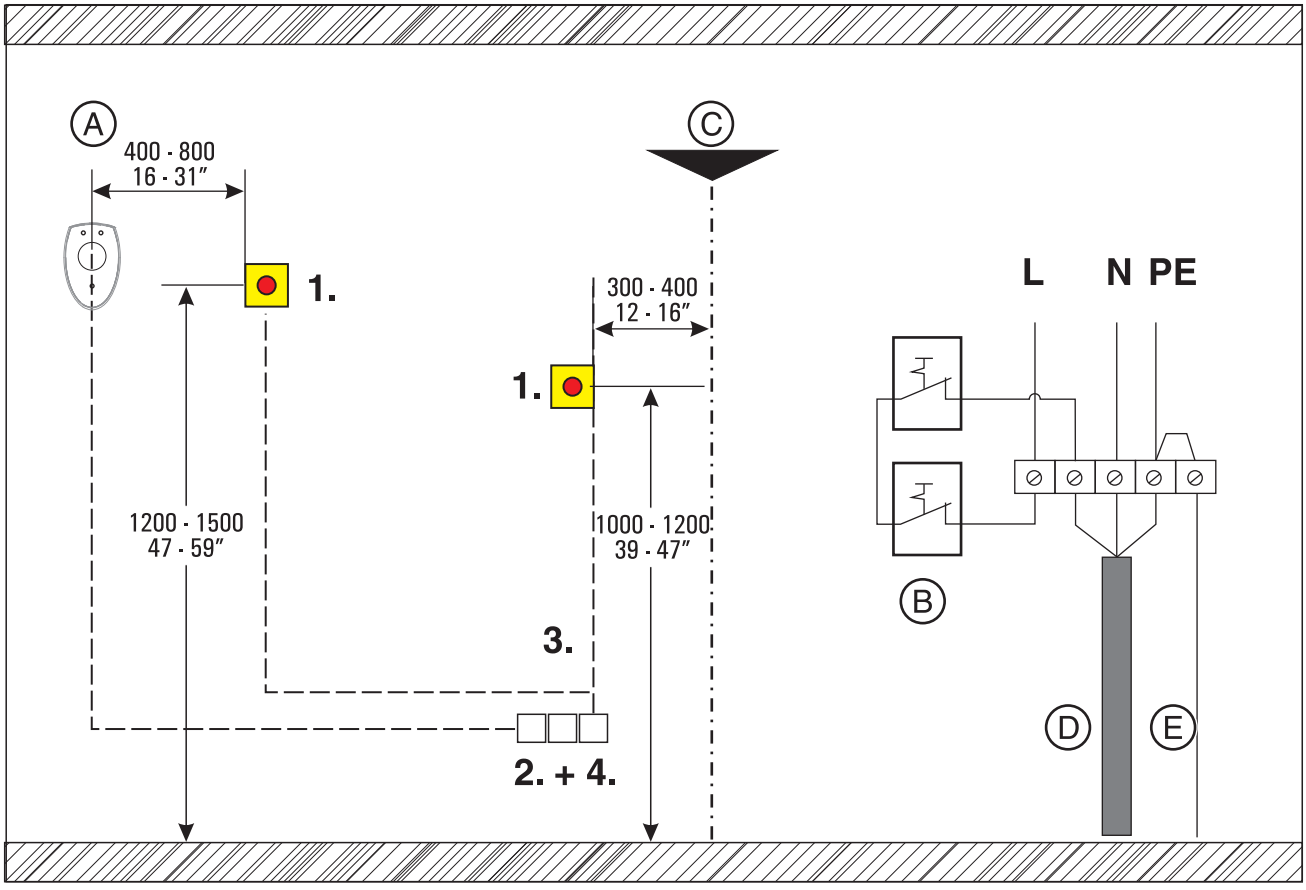
Only the control cable supplied may be used. It is installed during installation of the unit.

1. **Conduit for remote control**
   If the shielded control cable (supplied, length 15m (590 1/2")) is flush-mounted, a conduit **must** be used! ∅ int. min. 10mm, **maximum permissible length 13m (512")!**
2. **Distributor box for remote control.**
   A **distributor box with strain relief option must** be provided near/ behind the unit column.
3. **Distributor box with power cable and terminal strip Recommendation:**
   A 3-wire power cable (N, L, PE, at least 3x2.5 mm^2 or 3x4 mm^2 (14 AWG or 12 AWG)) must be connected to the central distributor of the building installation. Circuit breaker LS B25A.
   – For a building installation with 3 x 1.5 mm^2/ 3 x 2.5mm^2 (16 AWG / 14 AWG) and a circuit breaker LS B16A/B20A, only the ORTHOPHOS SL or devices which do not create a hazard for the patient when the circuit breaker is tripped and no data processing systems whatsoever may be connected.
4. Install **distributor box** for second protective ground wire.

⚠ WARNING

Install connection option for second protective ground wire. Second protective ground wire is prefabricated with 5 - 2.5 DIN 46234 cable lug. The cable lug can be removed when the cable is connected to a terminal.

4.4 Emergency stop switch (if legally required)



A	Remote control
B	Emergency stop switch; **ATTENTION** In Japan, the emergency stop switch is a legal requirement For Canada, see section Emergency Stop for Canada [→ 33]
C	Unit center of column
D	Power cable
E	Second protective ground wire

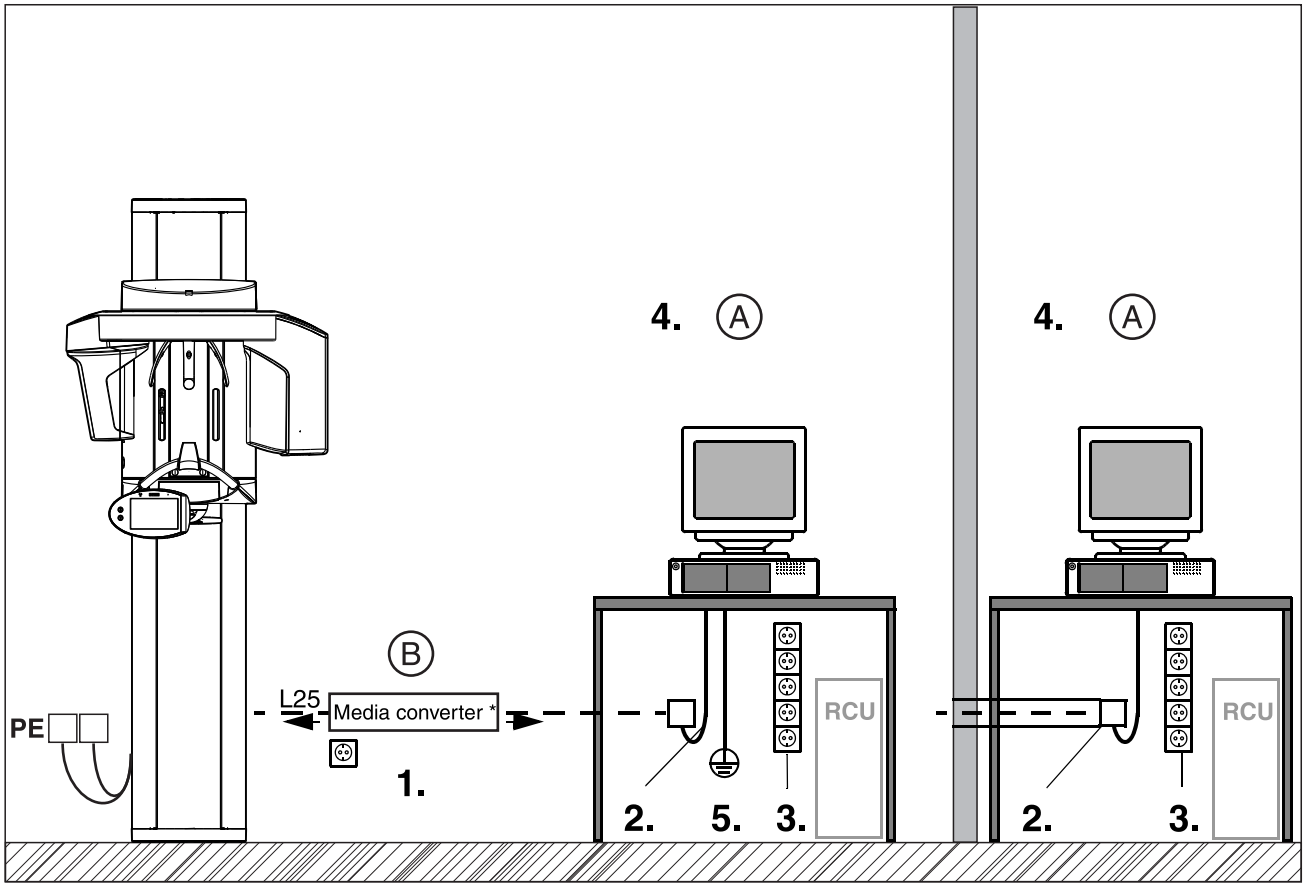
1. Install emergency stop switch in the power cable. Attach switch so that it is easily accessible, but cannot be switched accidentally.
2. **Distributor box with power cable and terminal strip**
   Recommendation: A 3-wire power cable (N, L, PE, at least 3x2.5 mm^2 or 3x4 mm^2 (14 AWG or 12 AWG)) must be connected to the central distributor of the building installation.
   Circuit breaker LS B25A.

3. The cable to the emergency stop switch must have at least the same diameter as the power cable.
   - For a building installation with 3 x 1.5 mm^2/ 3 x 2.5mm^2 (16 AWG / 14 AWG) and a circuit breaker LS B16A/B20A, only the ORTHOPHOS SL or devices which do not create a hazard for the patient when the circuit breaker is tripped and no data processing systems whatsoever may be connected.
4. Install **distributor box** for second protective ground wire.

⚠ WARNING

Install connection option for second protective ground wire. Second protective ground wire is prefabricated with 5 - 2.5 DIN 46234 cable lug. The cable lug can be removed when the cable is connected to a terminal.

4.5 On-site installation for PC/networks

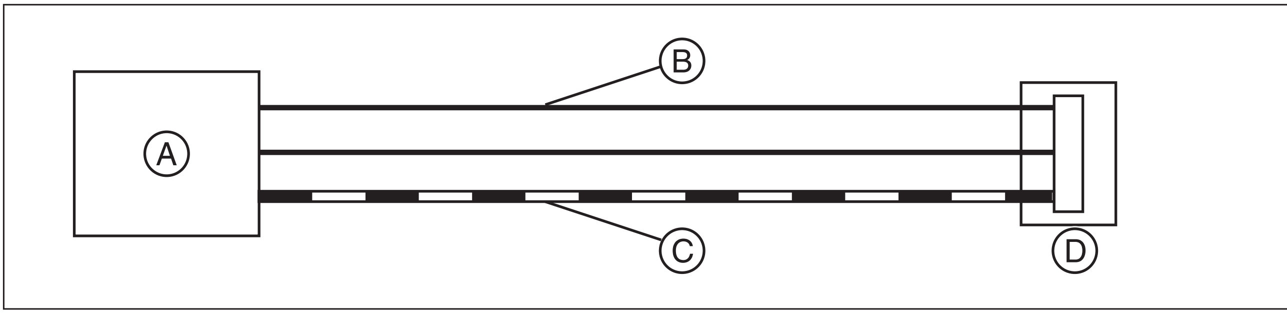


A	Network
B	Fiber-optic cable SC → Ethernet cable RJ45 * The media converted is required if there is no fiber-optic cable with SC connector available.

1. Length of the patch cable supplied with the media converter: 5m (197")
   Space available for media converter either behind the column are at the PC. A **power socket** is required for the media converter.
2. If the Ethernet cable is flush-mounted, a conduit **must** be used ∅ int. min. 21mm (7/8") (sufficient bending radius for 4cm (1 1/2") connector).
   Strain relief provided!
   - **Recommendation:** To avoid malfunctions, do **not** lay the cable with other cables.
3. At least five permanently installed **Schuko plugs** are required for RCU server, workstation PC, monitors, switches etc. (not included in scope of supply).
4. Network: 1 GBit Ethernet recommended.
   Communication connection: RJ45 for LAN cable.

5. For PCs which are connected to an X-ray unit and are in the same room as the unit, an **additional protective ground wire** is required (4 mm^2 with cable lug 4 - 6 DIN 46234 CU) in accordance with IEC 60601-1.

4.6 For USA and Canada



A	Distribution panel with an overcurrent circuit breaker rated for 25 A
B	3x AWG see chart
C	Ground
D	Distributor box

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 Principle of On-site Installation [→ 26].
- 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 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.

4.6.1 Emergency Stop for Canada

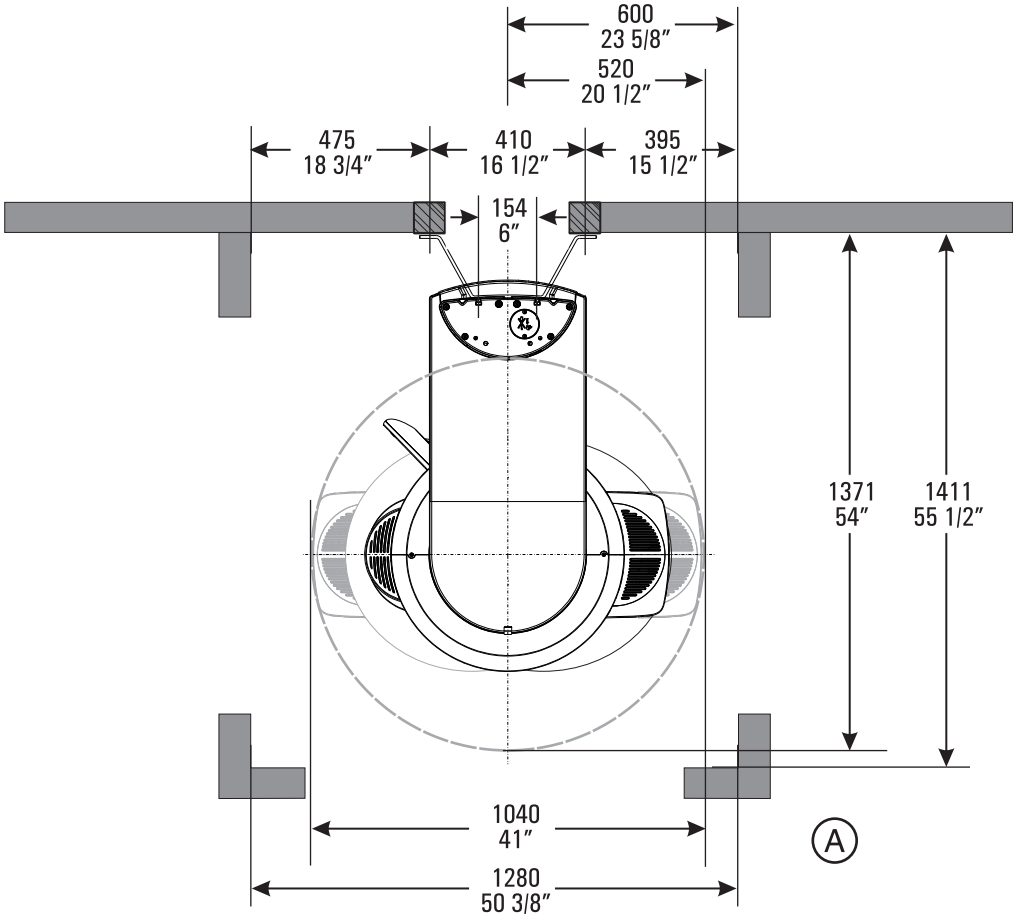
⚠ CAUTION

An emergency stop switch is required for Canada.

5 Dimensions, technical data

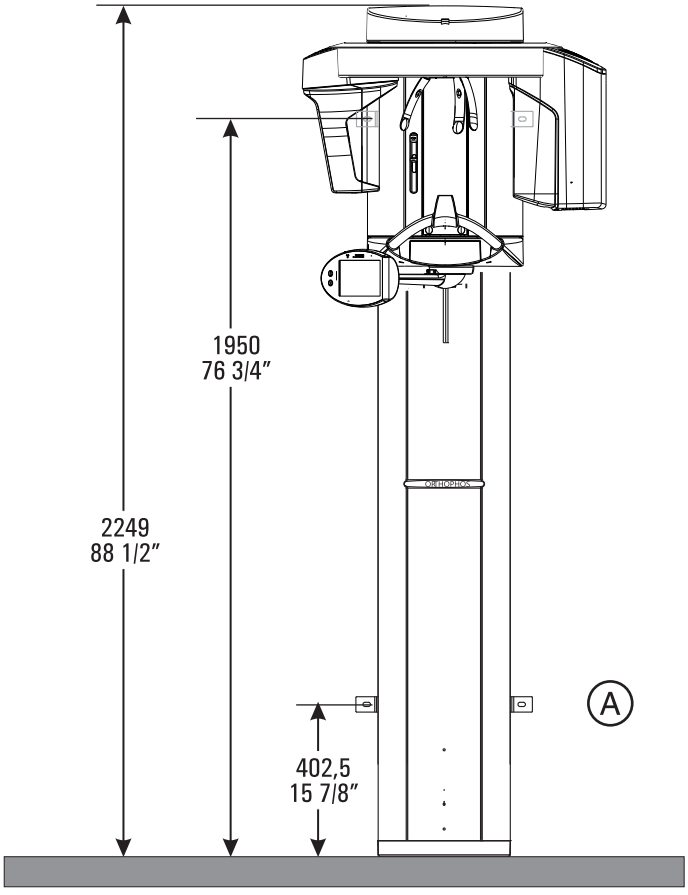
5.1 Dimensions 1:20 ORTHOPHOS SL

5.1.1 Top view



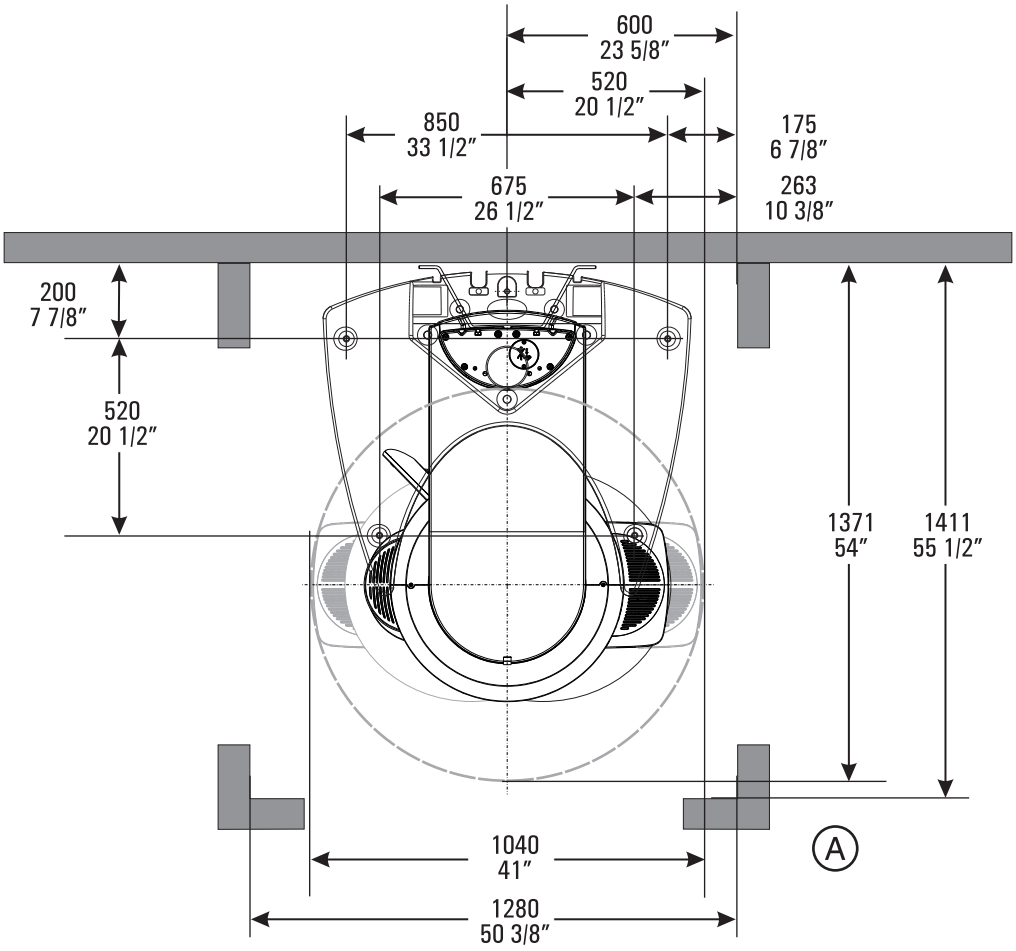
A	Recommended distances from cabinet or wall

5.1.2 Front view



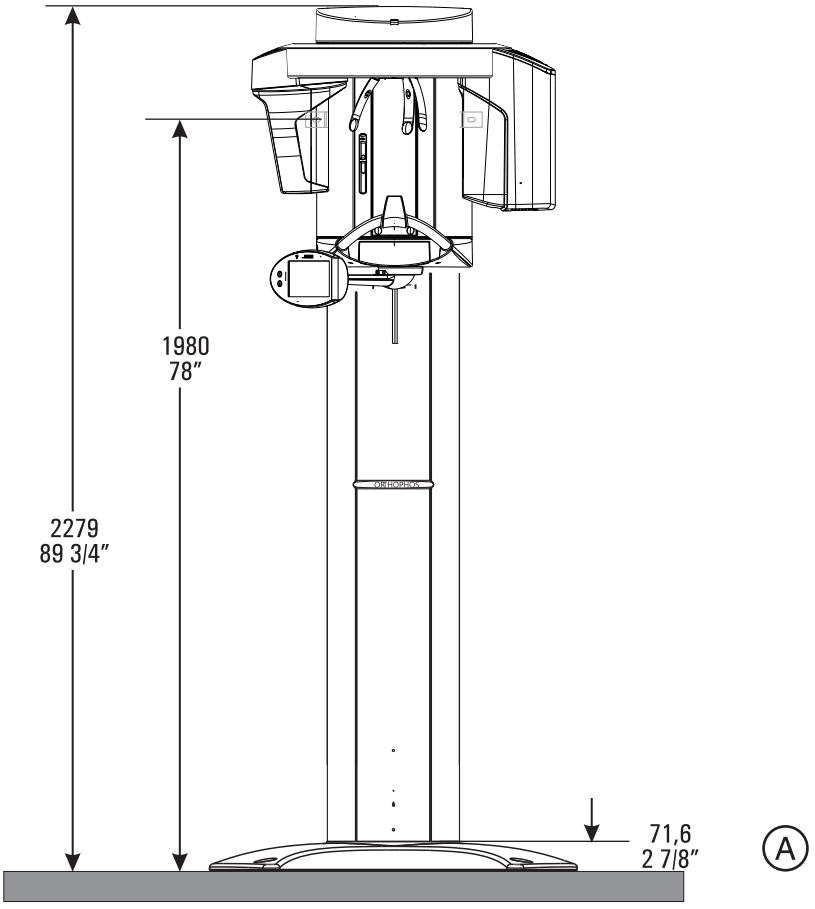
A	Alternative fastening if it is not possible to screw the unit onto the floor. Order bracket separately.

5.1.3 Top view with floor stand



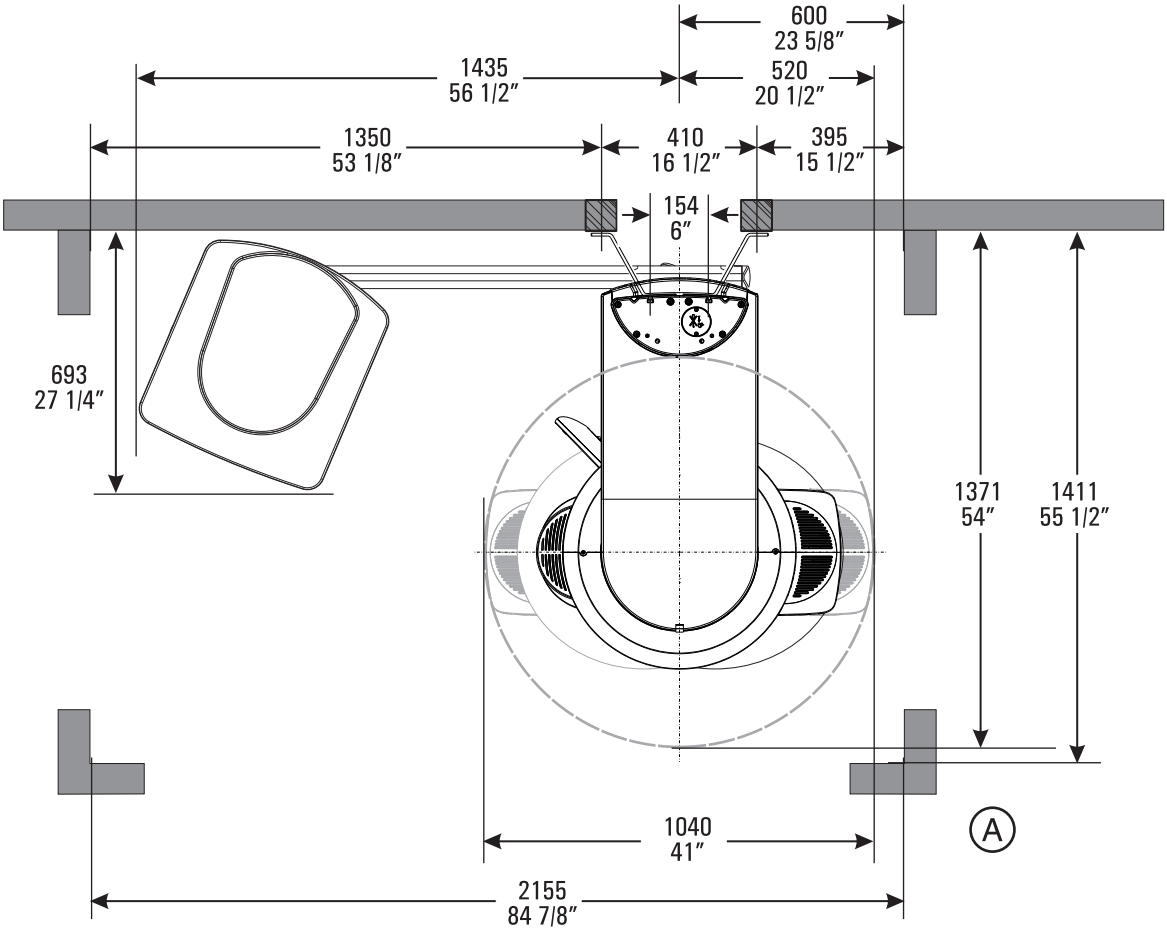
A	Recommended distances from cabinet or wall

5.1.4 Front view with floor stand



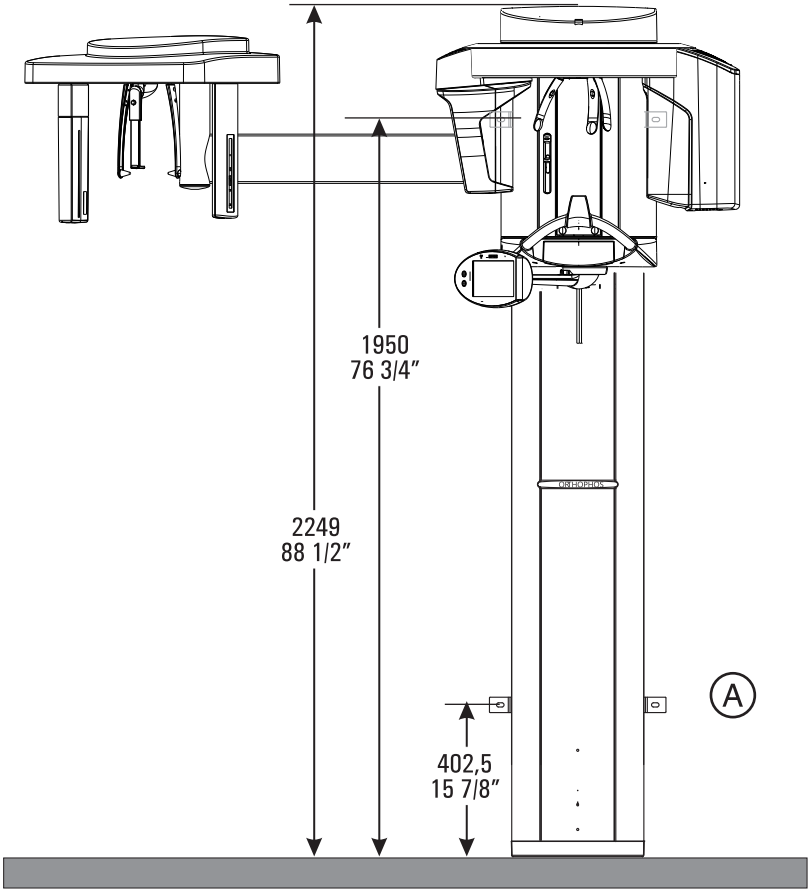
A	Floor stand: Order floor stand separately. The unit must also always be secured to the top wall holder.

5.1.5 Top view with Ceph left



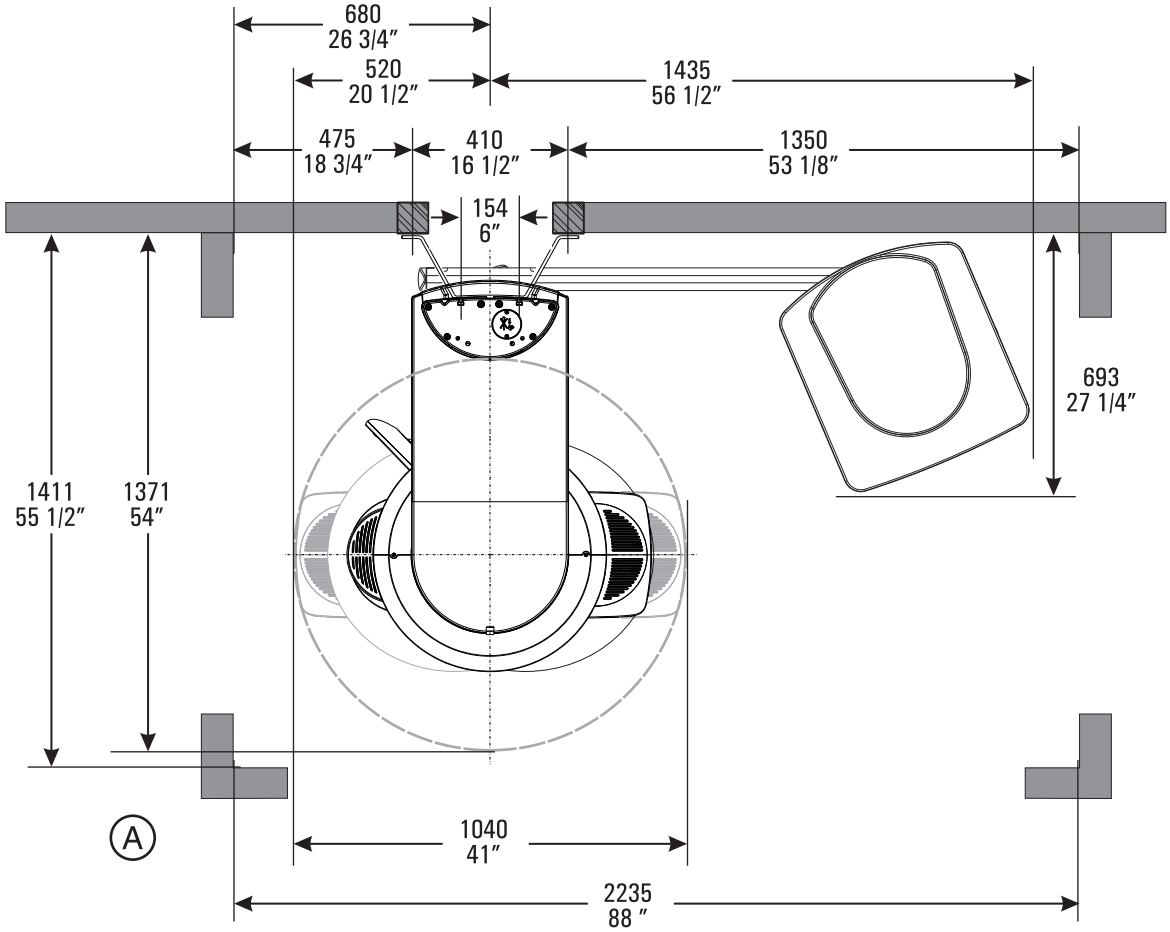
A	Recommended distances from cabinet or wall

5.1.6 Front view with Ceph left



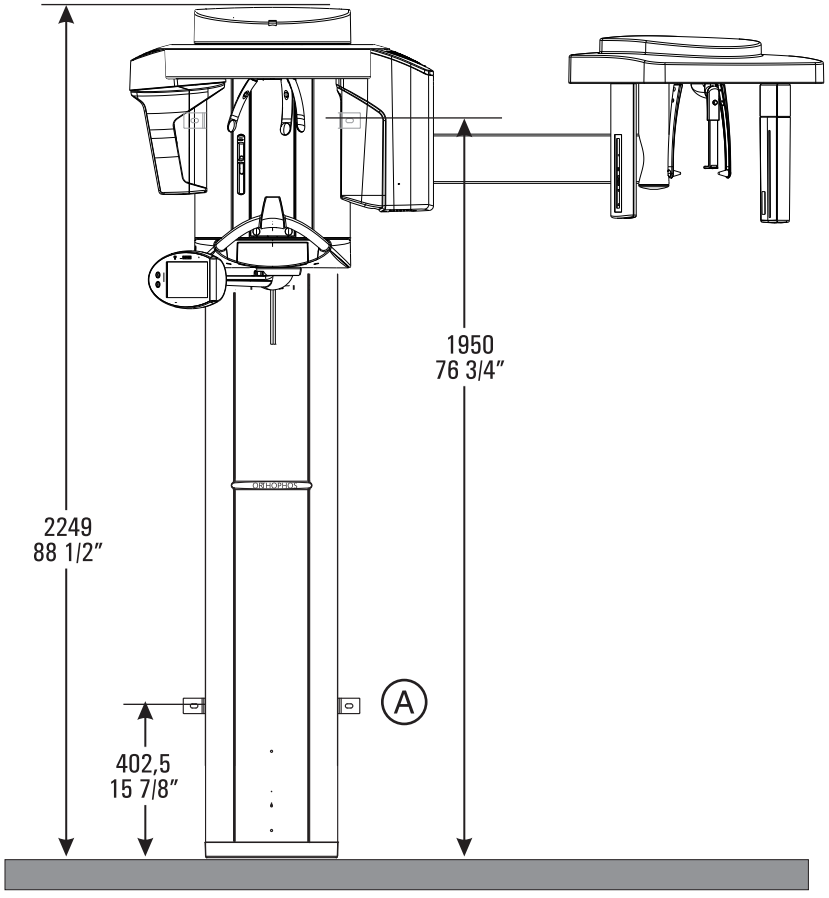
A	Alternative fastening if it is not possible to screw the unit onto the floor. Order bracket separately.

5.1.7 Top view with Ceph right



A	Recommended distances from cabinet or wall

5.1.8 Front view with Ceph right



A	Alternative fastening if it is not possible to screw the unit onto the floor. Order bracket separately.

5.2 Technical data

5.2.1 Unit data

Model designation:	ORTHOPHOS SL
Nominal voltage:	200 – 240 V
Permissible fluctuation:	± 10%
Permissible drop under load:	10%
Rated current:	max. 12 A
Nominal frequency:	50 Hz / 60 Hz
Mains resistance:	max. 0.8 ohms
Main building fuse/circuit breaker:	LS B25A slow-blow; for single connection: B16A/B20A slow-blow
Power consumption:	max. 2.0 kW

5.2.2 Operating and transport conditions

Transport and storage temperature:	-10 °C – +70 °C (14 °F – 158 °F)
Air humidity:	10 % – 95 %
Admissible operating temperature:	+18 °C - +31 °C (64 °F – 88 °F)
Operating altitude:	≤ 3,000 m above sea level

5.2.3 Weight and packaging

Weight (with packaging / without packaging):

ORTHOPHOS SL	188 kg / 110 kg 415 lb / 243 lb
Cephalometer	40 kg / 33 kg 95 lb / 49 lb
Floor stand	50 kg / 31 kg 110 lb / 68 lb

Dimensions of the packaging:

ORTHOPHOS SL	199 cm x 69 cm x 122 cm 78 3/8" x 27 1/8" x 48"
Cephalometer	175 cm x 78 cm x 73 cm 68 7/8" x 30 3/4" x 28 3/4"
Floor stand	114 cm x 105 cm x 22 cm 56 3/4" x 41 3/8" x 8 5/8"

5.2.4 Certification and registration

ORTHOPHOS SL complies with:

- IEC 60601-1
- IEC 60601-1-3
- IEC 60601-2-63

Original language: German

CE 0123

This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices (MDD).

6 Electromagnetic compatibility

NOTICE

The ORTHOPHOS SL 2D / ORTHOPHOS SL 3D meets electromagnetic compatibility requirements (EMC) in accordance with IEC 60601-1-2.
The ORTHOPHOS SL 2D / ORTHOPHOS SL 3D is referred to going forward as the "UNIT".
Observing the following information ensures safe operation with regard to EMC aspects.

6.1 Accessories

Designation of the interface cables	REF
PC as peripheral device	-
Remote control L17/ L117XG, 15m (590 1/2")	6094697
Cable L25 OP-XG, 5m (197")	5922765
Media converter	6470194
LAN cable CAT, 3mm (118“)	5168963
Second protective ground wire, 1.5mm^2 (16 AWG)	6141563
Power cable	8920605

The **UNIT** may only be operated with accessories and spare parts approved by Sirona. Unapproved accessories and spare parts may lead to an increased emission or to a reduced immunity to interference.

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 operating properly.

6.2 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
RF emissions according to **CISPR 11**	Group 1	The **UNIT** 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 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**	coincides	

6.3 Interference immunity

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.

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) according to **IEC 61000-4-2**	± 6 KV contact discharge ± 8 KV air discharge	± 6 KV contact discharge ± 8 KV air discharge	Floors should be made of wood or concrete or finished with ceramic tiling. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst according to **IEC 61000-4-4**	± 1 kV for input and output lines ± 2 kV for power supply lines	± 1 kV for input and output lines ± 2 kV for power supply lines	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge voltages according to **IEC 61000-4-5**	± 1 kV differential mode ± 2 kV common mode voltage	± 1 kV differential mode ± 2 kV common mode voltage	The quality of the line power supply should be that of a typical commercial 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 line power supply should be that of a typical commercial 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC supply voltage prior to application of the test level.			
			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:

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF disturbance **IEC 61000-4-6**	3 V_{eff} 150 kHz to 80 MHz[1]	3 V_{eff}	$d = [1,2] \sqrt{P}$
Radiated RF interference **IEC 61000-4-3**	3 V/m 80 MHz - 800 MHz[1] 3 V/m 800 MHz - 2.5 GHz[1]	3 V_{eff} 3 V_{eff}	$d = [1,2] \sqrt{P}$ at 80 MHz - 800 MHz $d = [2,3] \sqrt{P}$ at 800 MHz - 2.5 GHz with P as the power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as recommended safety distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2] should be less than the compliance level[3] in each frequency range. Interference is possible in the vicinity of equipment bearing the following graphic symbol. 

1. The higher frequency range applies at 80 MHz and 800 MHz.
2. The field strengths of fixed transmitters, such as base stations of radiotelephones and mobile agricultural radio broadcast services, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. A site survey is recommended to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location in which the **UNIT** is used exceeds the applicable RF compliance level above, the **UNIT** should be observed to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the **UNIT**.
3. Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

6.4 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 RF interference is checked. The customer or the user of the **UNIT** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **UNIT** - depending on the maximum output power of the communication device, as shown below.

Power rating of the transmitter [W]	Working clearance according to transmission frequency [m]		
	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz - 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

The recommended safety distance d in meters (m) can be determined for transmitters, whose maximum power rating is not specified in the above table, using the equation that belongs to the corresponding column, wherein P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1

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

Note 2

These guidelines may not apply 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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