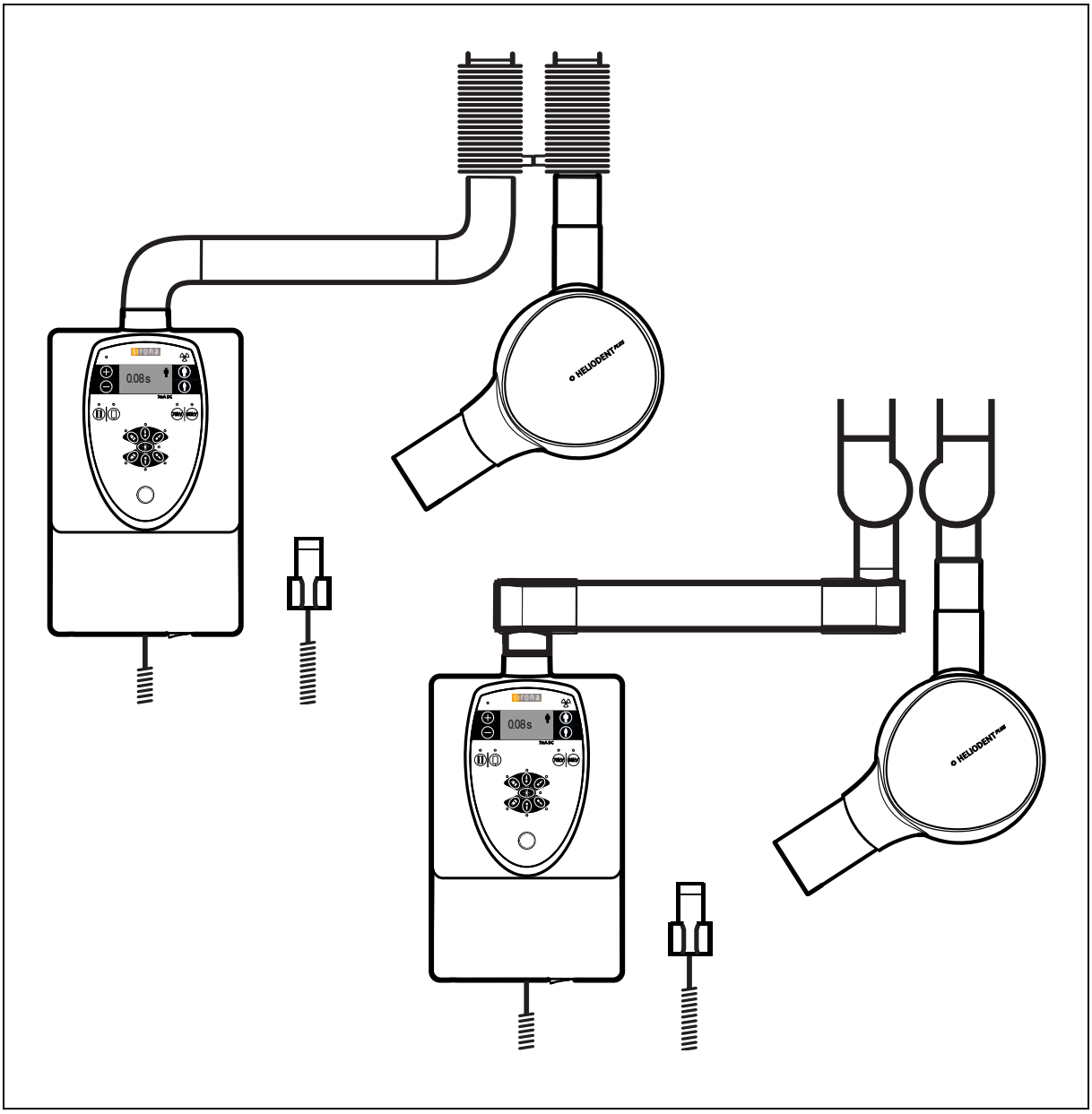
New as of: 07.2016

sirona
The Dental Company

# HELIODENT PLUS

## Installation Requirements

**English**



# Table of contents

# 1 Structure of the document

## 1.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these 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 Formats and symbols used

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

| | |
|---|---|
| ✓ Prerequisite<br>**1.** First action step<br>**2.** Second action step<br>or<br>➢ Alternative action<br>↳ Result<br>➢ Individual action step | Prompts you to do something. |
| See "Formats and symbols used [→ 4]" | 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 Shielding of room

When using the HELIODENT Plus X-ray tube assembly, 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.

## 2.2 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.

## 2.3 Modifications and extensions of the system

Modifications to this unit which might affect the safety of the system owner, patients or other persons are prohibited by law.

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.

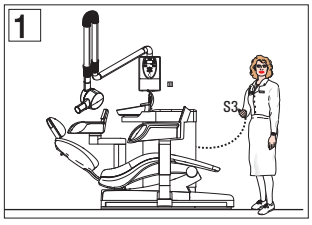
# 3 Prior to installation

## 3.1 Installation options

### Designations for release buttons and door contact

- Manual release **S3**
  - Coiled cable
- Release key on the control membrane **S4**
  - Directly connected to control board DX4
- Remote control release key **S9**
  - Integrated in remote control housing
- Door contact (safety circuit) **S7**

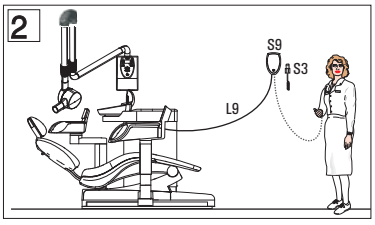
### Installation option 1




Release in the treatment room **without** remote control

- Release
  - Manual release **S3**

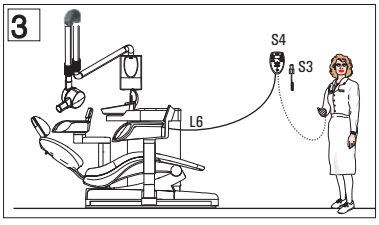
### Installation option 2




Release in the treatment room **with** remote control

- Release
  - Manual release **S3**
    **or**
  - Remote control release key **S9**

### Installation option 3



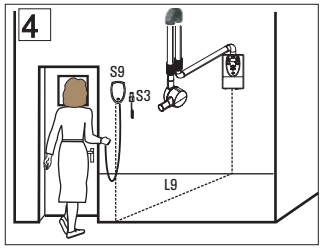

Release in the treatment room **with**Remote Timer

- Release
  - Manual release **S3**
    **or**
  - Release key on the control membrane **S4**

**NOTICE**

Length of cable supplied for Remote Timer approx. 10 meters (393") (must not be extended).

Conduit int. dia. at least 12 mm (1/2").




### Installation option 4

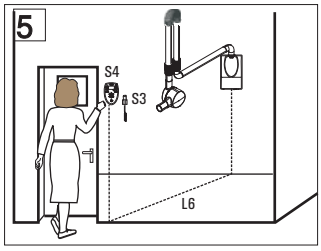
Release outside of the X-ray room **with** remote control

- Release
  - Manual release **S3**
    **or**
  - Remote control release key **S9**

**NOTICE**

**Installation prerequisites**

Use of the remote control is permissible only if the yellow X-Ray LED is visible to the operating personnel during radiation release.




### Installation option 5

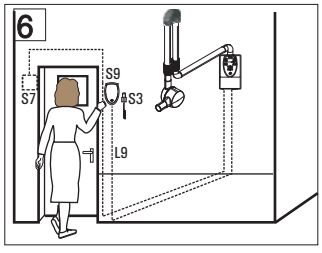
Release outside of the X-ray room **with**Remote Timer

- Release
  - Manual release **S3**
    **or**
  - Release key on the control membrane **S4**

**NOTICE**

Length of cable supplied for Remote Timer approx. 10 meters (393") (must not be extended).

Conduit int. dia. at least 12 mm (1/2").




### Installation option 6

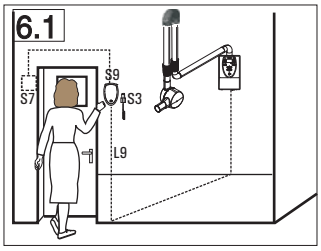
Release outside of the X-ray room **with** remote control, door contact safety circuit

- Door contact
  - Door contact **S7** wired to the wall adapter
- Release
  - Manual release **S3**
    **or**
  - Remote control release key **S9**

**NOTICE**

**Installation requirement**

Use of the remote control is permissible only if the yellow X-Ray LED is visible to the operating personnel during radiation release.




### Installation option 6.1

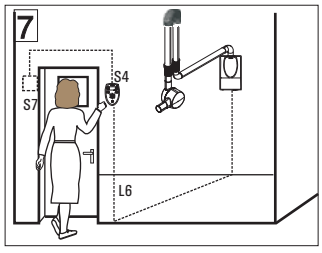
Release outside of the X-ray room **with** remote control, door contact safety circuit

- Door contact
  - Door contact **S7** wired to the remote control housing
- Release
  - Manual release **S3**
    **or**
  - Remote control release key **S9**

**NOTICE**

**Installation requirement**

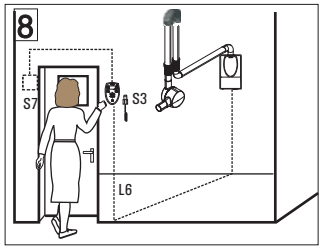
Use of the remote control is permissible only if the yellow X-Ray LED is visible to the operating personnel during radiation release.




### Installation option 7

Release outside of the X-ray room **with** Remote Timer, door contact safety circuit

- Door contact
  - Door contact **S7**
- Release
  - Release key on the control membrane **S4**




### Installation option 8

Release outside of the X-ray room **with** Remote Timer, door contact safety circuit

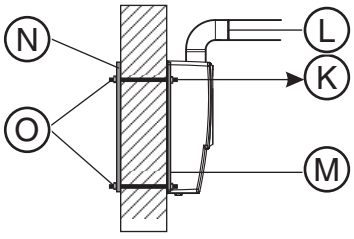
- Door contact
  - Door contact **S7** wired to Remote Timer
- Release
  - Manual release **S3**

## 3.2 On-site installation

**⚠ CAUTION**

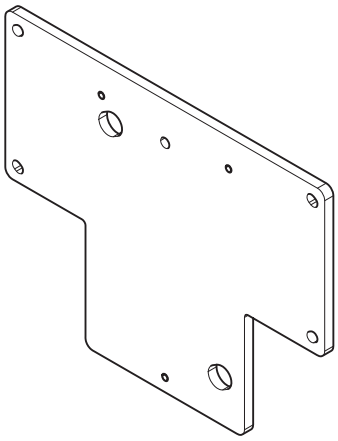
**Observe wall properties**

In installation situations, the technician is responsible for the assessment of wall properties and selecting the method of attaching the unit to the wall.




| | |
|---|---|
| **K** | Tensile force per screw<br>3600 N (800 lbf) if **L** ≤ 700 mm (27 1/2“)<br>4200 N (950 lbf) if **L** ≤ 950 mm (37 3/8“) |
| **L** | Length of support arm |
| **M** | Mounting plate (supplied) |
| **N** | Anchor plate |
| **O** | Threaded bolt M8 |

- The permissible tensile force of the selected attachment must at least equal the tensile force listed above.
- Matching wood screws for wooden beams are included in delivery.
- For all other wall structures, special wall anchors must be purchased from a selected dealer. The wall anchors and screws should be identical for every attachment point.
- Alternatively, an anchor plate can be used as a counter bearing. In this case, M8 threaded rods of the appropriate length for the wall (thickness of the wall + 2 x mounting plate thickness + attachment material) are required.



### Re-use installation sites of old units

It is possible to conceal the installation site of an old unit when installing a HELIODENT PLUS.

- For the replacement of vertically mounted old units (e.g. HELIODENT DS, HELIODENT MD, Planmeca Intra[1]) an adapter plate is available for this purpose, REF 62 42 254.
- The drill holes of some vertically mounted units (e.g. Progeny Previa [1], Gendex 765DC [1]) coincide with the dimensions of the drill holes of the Heliodent PLUS. No adapter plate is required.

**NOTICE**

Regardless of their prior use, the existing drill holes and wall plugs must comply with the installation regulations and must be checked by the person performing installation.

**NOTICE**

The different connection areas of the old units make it necessary to relocate the existing electrical connections (e.g. concealed installation) on-site.

**⚠ CAUTION**

The on-site electrical installation must be performed according to the valid regulations for medical electrical equipment (DIN VDE 0100-710).

- Cable for remote control or Remote Timer: Conduit ⌀ int. min. 12mm (1/2"), requires an excess length of at least 0.25 m (10") at both ends.
- Power cable 3x1.5 $mm^2$ (AWG 16); required excess length for concealed installation: 0.25m (10").

**⚠ CAUTION**

Do not install the cables for Remote Timer and power cables in the same conduit.

**NOTICE**

The Heliodent Plus wall model is suitable for fixed installation only.

**⚠ DANGER**

**Perilous shock hazard!**

**Fixed connection!**
Installing a mains plug instead of the specified fixed connection infringes international medical regulatory actions and is prohibited. In case of error, this puts patients, users, and other parties seriously at risk.

1. The product names mentioned may be copyrighted by their respective owners.

**⚠ CAUTION**

**Observe the permissible nominal voltage range!**

The unit can be connected to 120 V (1-phase connection) or to 200 - 240 V (1- or 2-phase connection),
for all other voltages a pre-transformer is required. As a ceiling model or device model,
the HELIODENT$^{PLUS}$ must
**only be connected to 200 - 240 V** (1 or 2-phase connection).

**For the USA only**

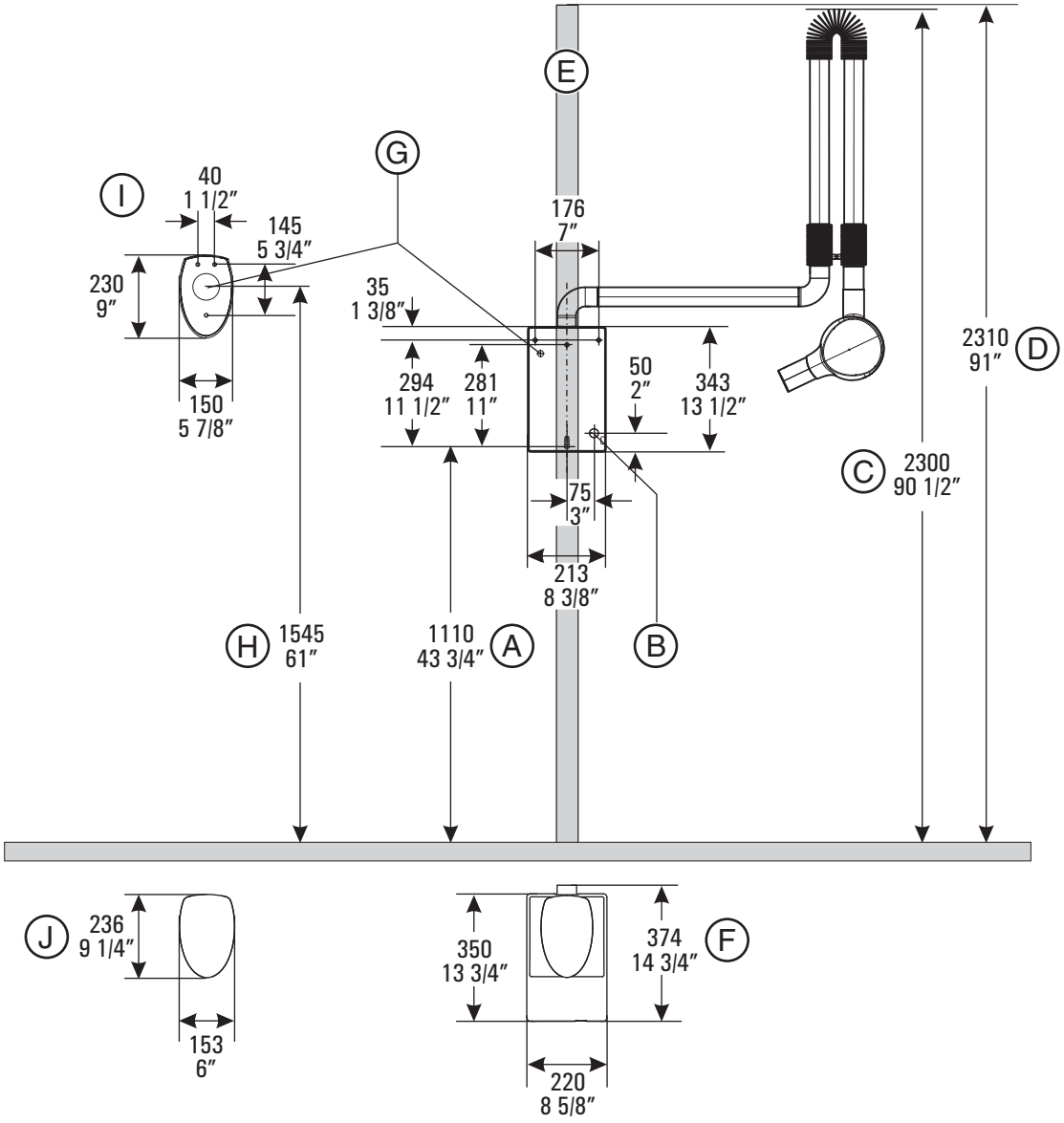
**Power supply:**

A separate three wire grounded circuit connected directly to the central distribution panel with an over-current protection rated for 20 amperes should be used.

# 4 Dimensions, technical data

## 4.1 Dimensions with round support arm

### 4.1.1 Dimensions of front view with all options



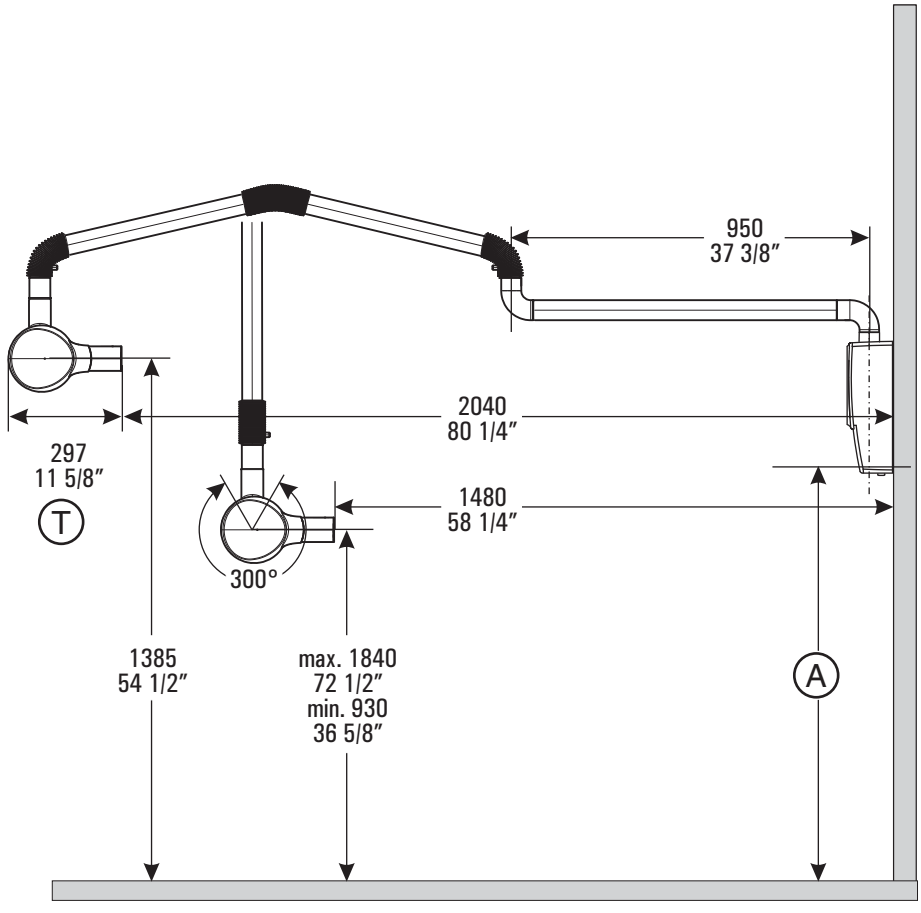

| | |
|---|---|
| **A** | Recommended installation height for the wall module |
| **B** | Cable bushing for network cable |
| **C** | Unit height |
| **D** | Ceiling height |
| **E** | Wooden beam |
| **F** | Wall module cover |
| **G** | Cable bushing for remote control or Remote Timer |

| | |
|---|---|
| H | Recommended installation height of remote control or Remote Timer |
| I | Remote control or Remote Timer |
| J | Cover for remote control or Remote Timer |

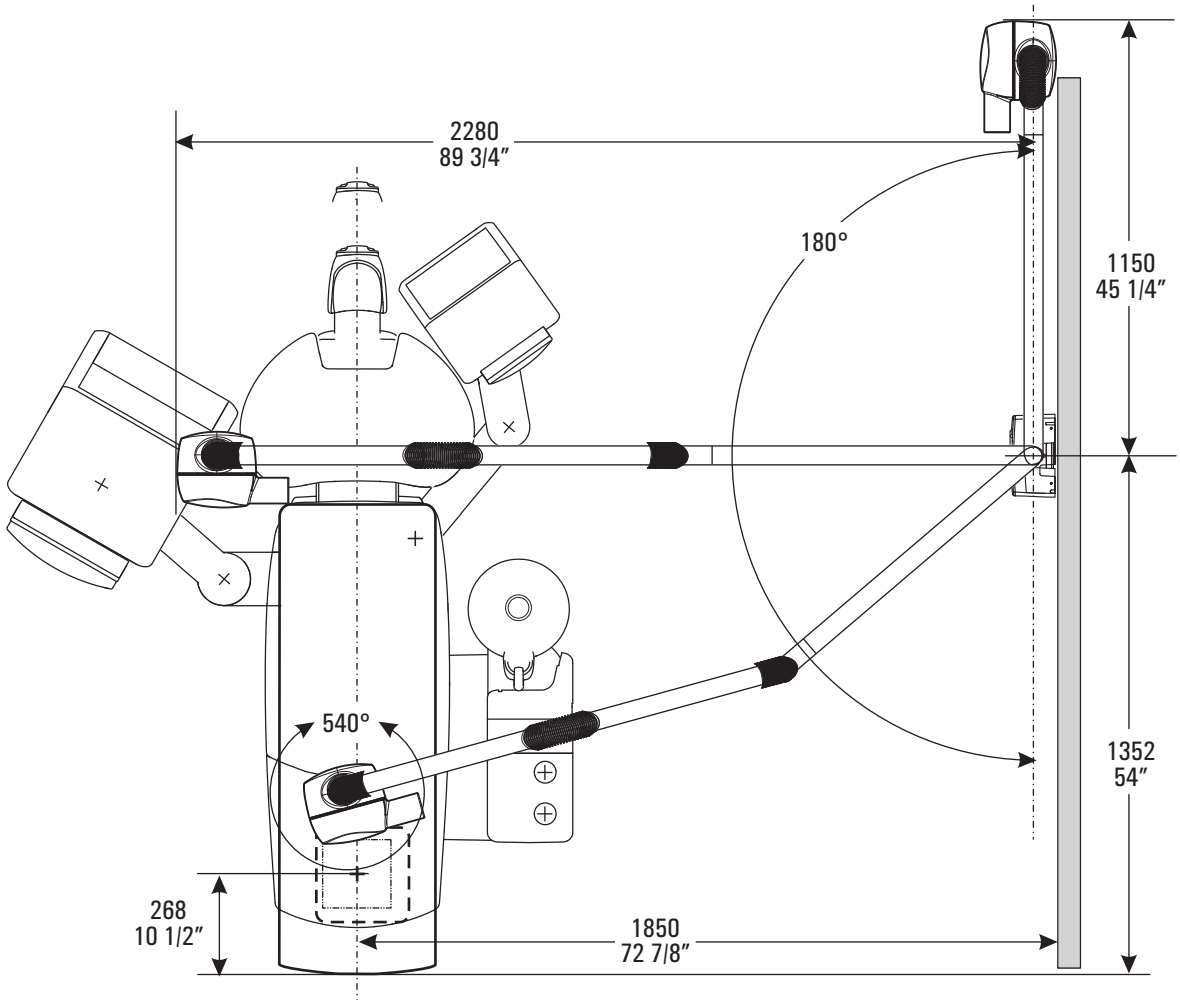
### 4.1.2 Dimensions for 950 mm (37 3/8") support arm

**Side view**

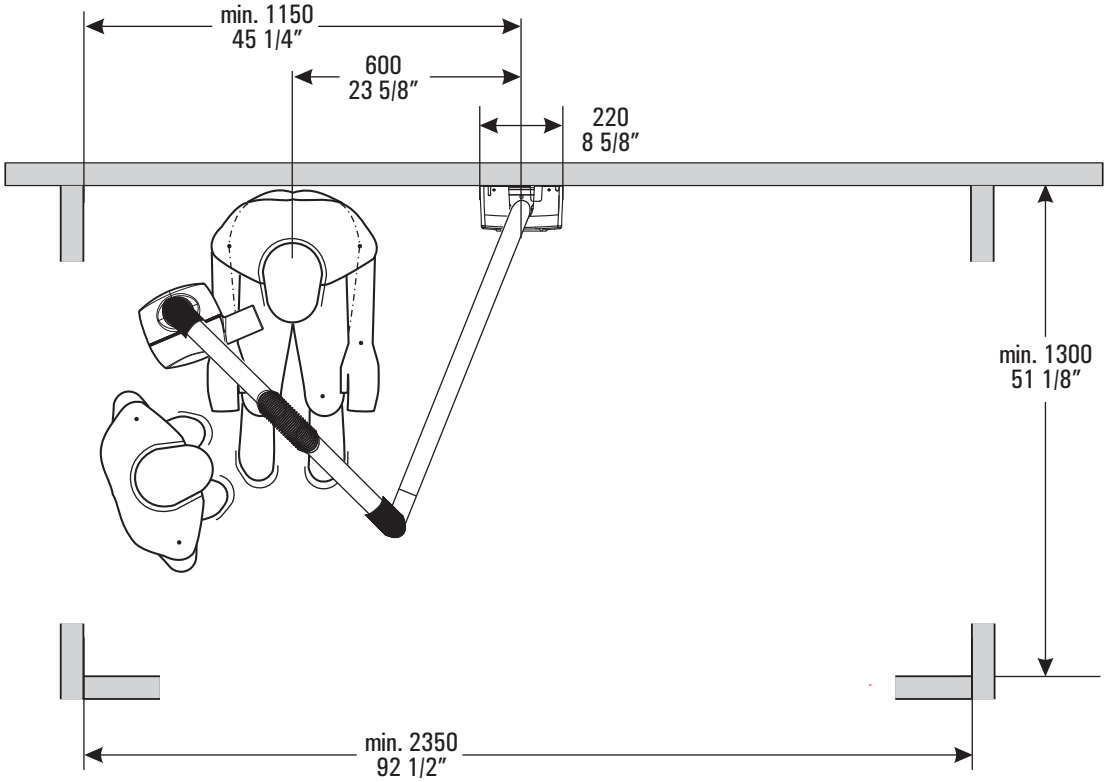
| | |
|---|---|
| A | Recommended installation height: 1110 mm (43 3/4") |
| T | X-ray tube assembly with standard tube, 200 mm (8") SSD |

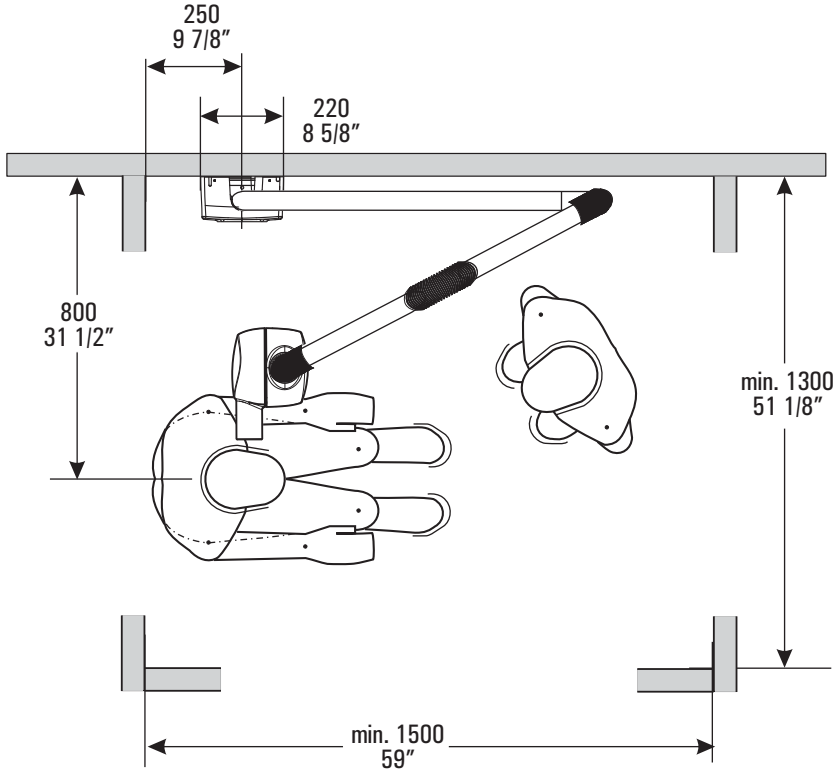


**Top view**



**Minimum dimensions for X-ray rooms with 950 mm (37 3/8") support arm**

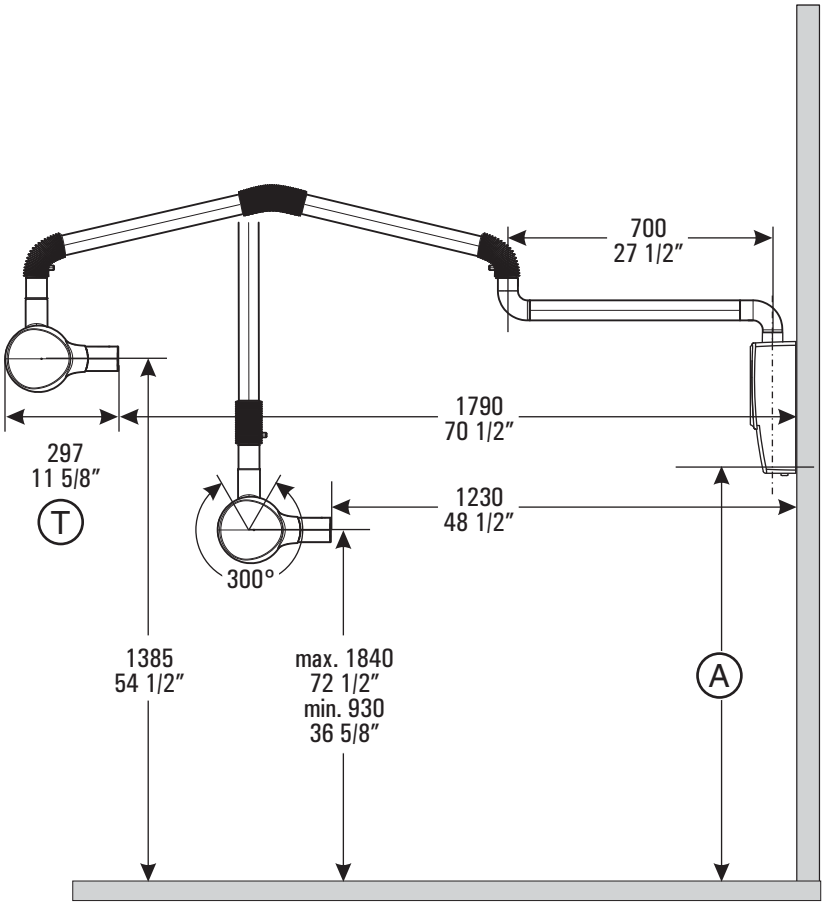


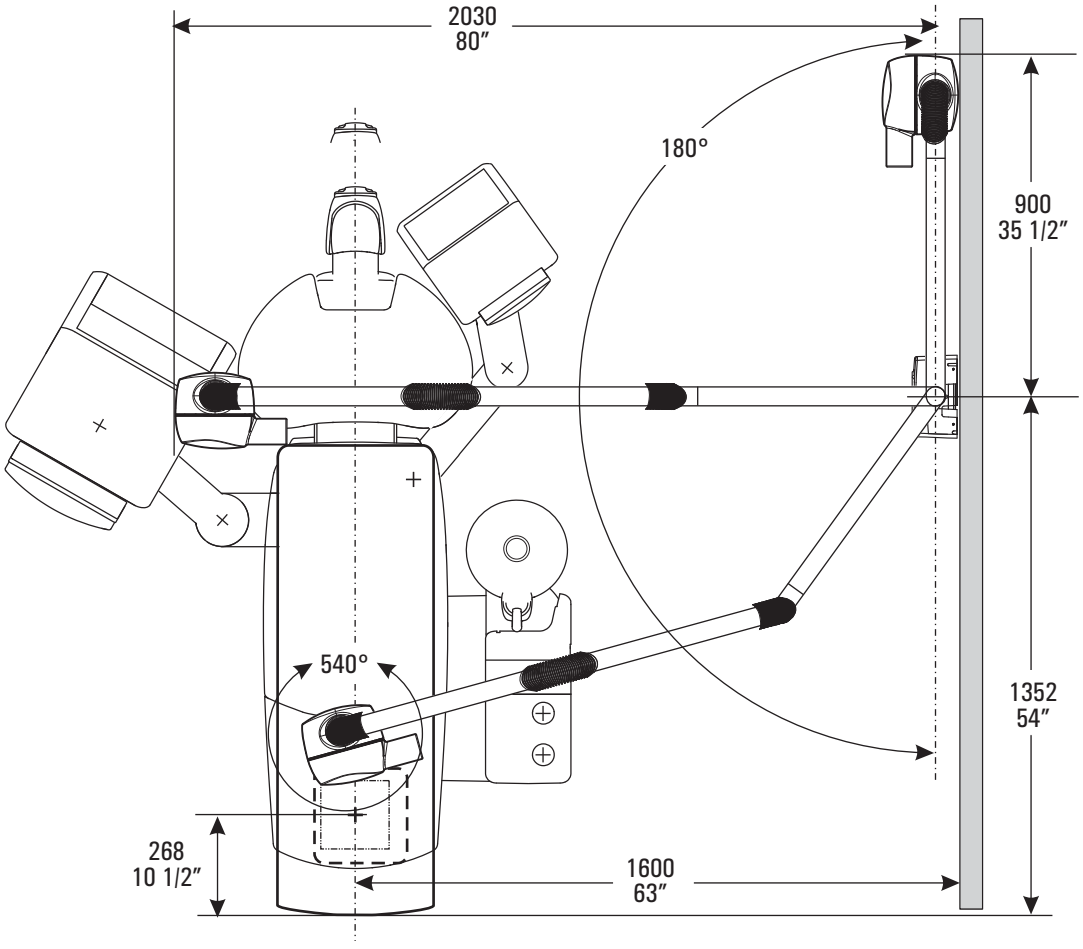
### 4.1.3 Dimensions for 700 mm (27 1/2") support arm

**Side view**

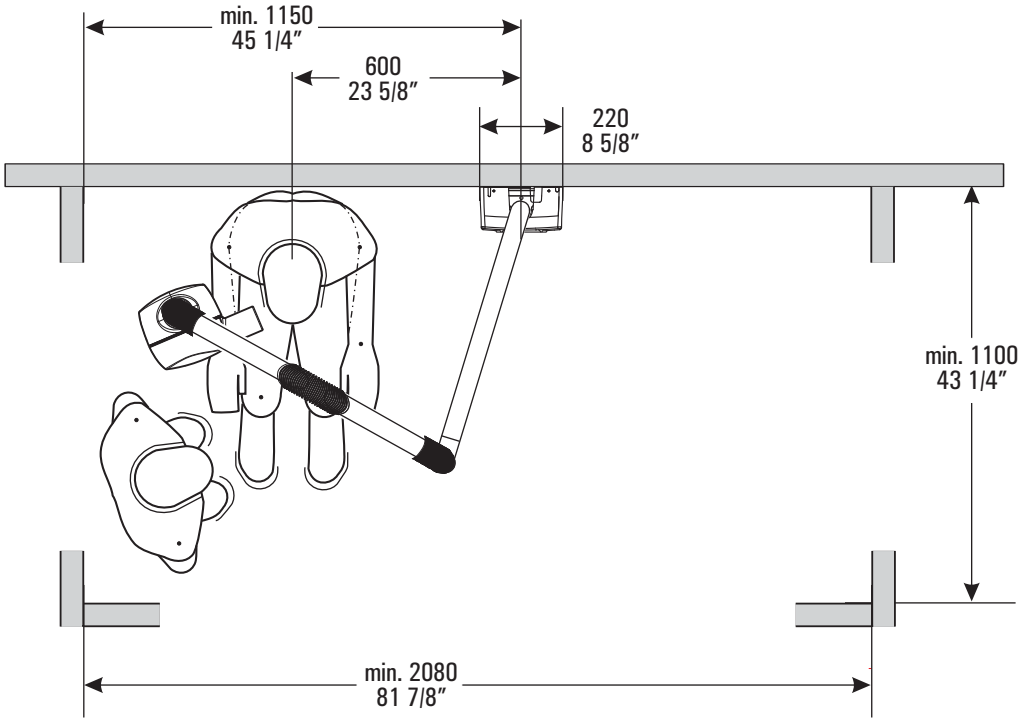
| | |
|---|---|
| A | Recommended installation height: 1110 mm (43 3/4") |
| T | X-ray tube assembly with standard tube, 200 mm (8") SSD |

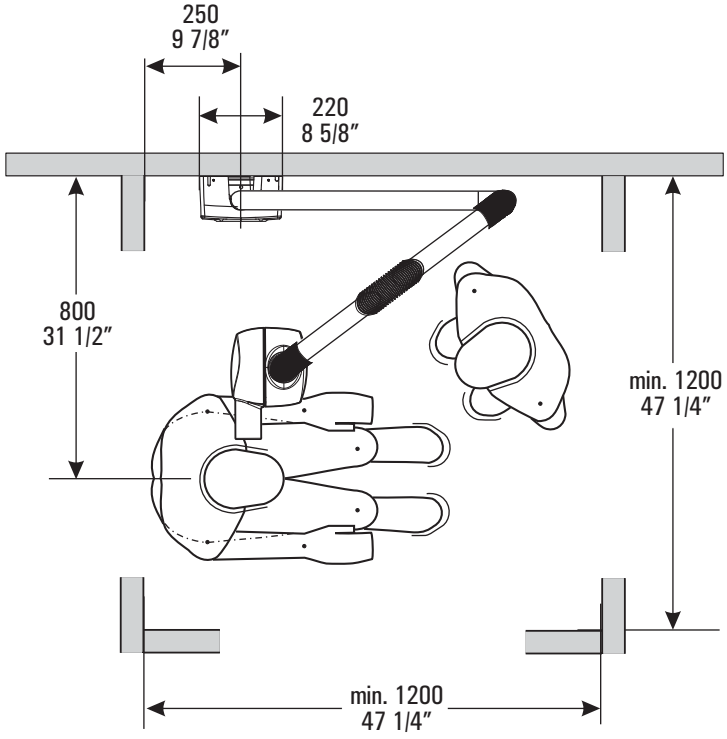


## Top view



**Minimum dimensions for X-ray rooms with 700 mm (27 1/2") support arm**

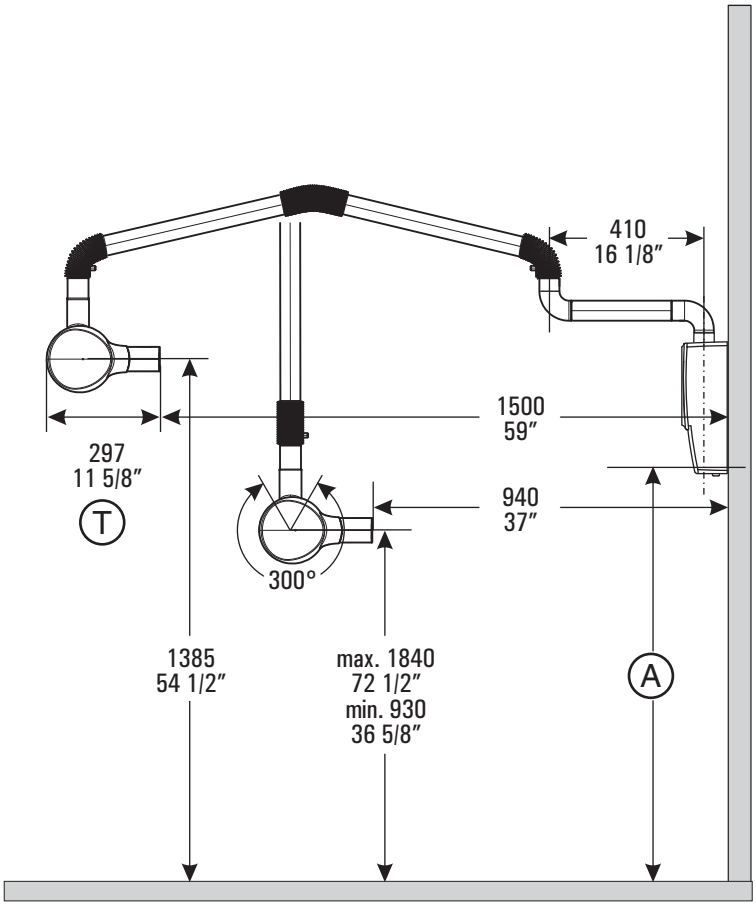


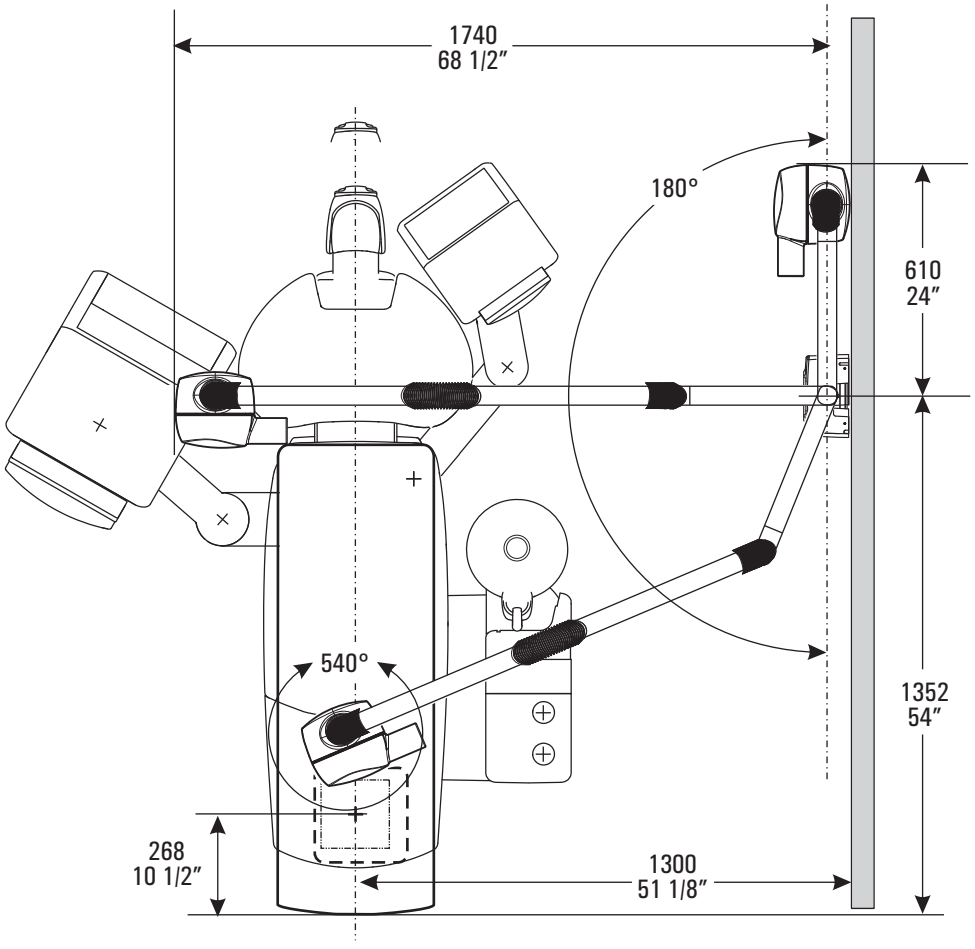
### 4.1.4 Dimensions for 410 mm (16 1/8") support arm

**Side view**

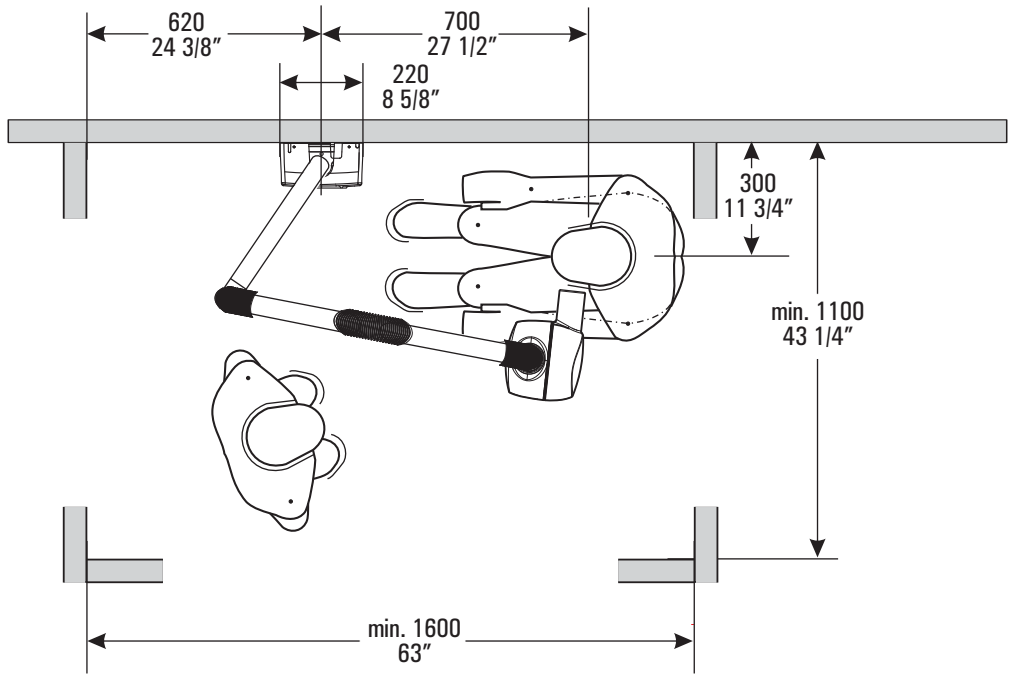
| | |
|---|---|
| A | Recommended installation height: 1110 mm (43 3/4") |
| T | X-ray tube assembly with standard tube, 200 mm (8") SSD |

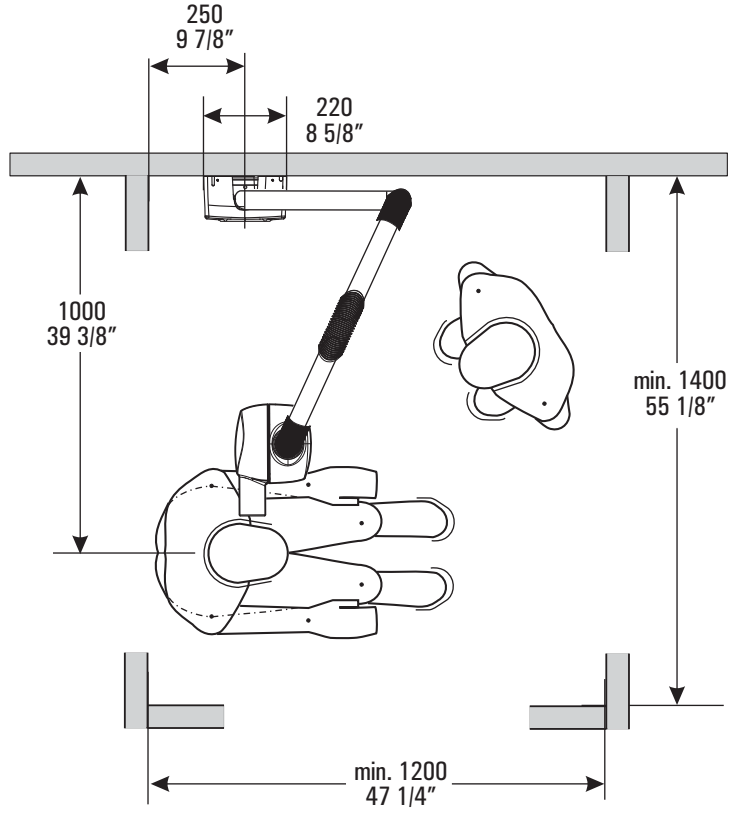


**Top view**



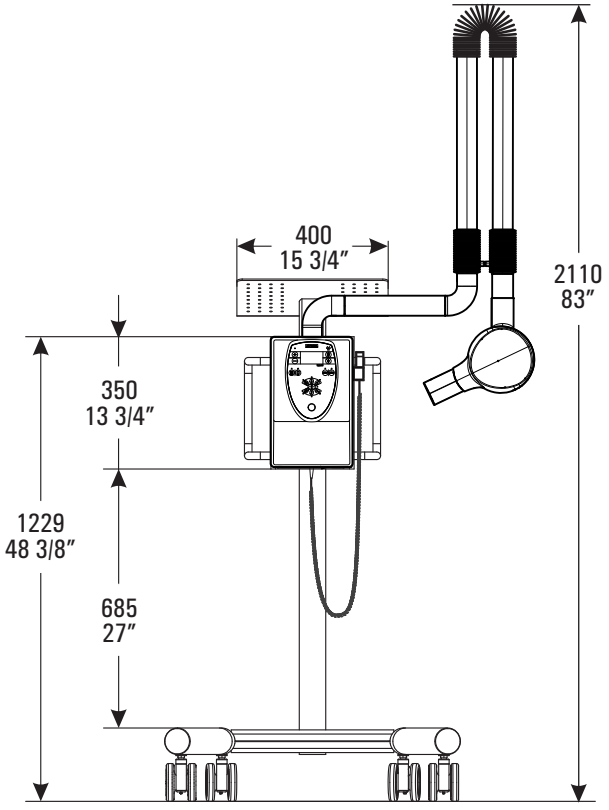
**Minimum dimensions for X-ray rooms with 410 mm (16 1/8") support arm**



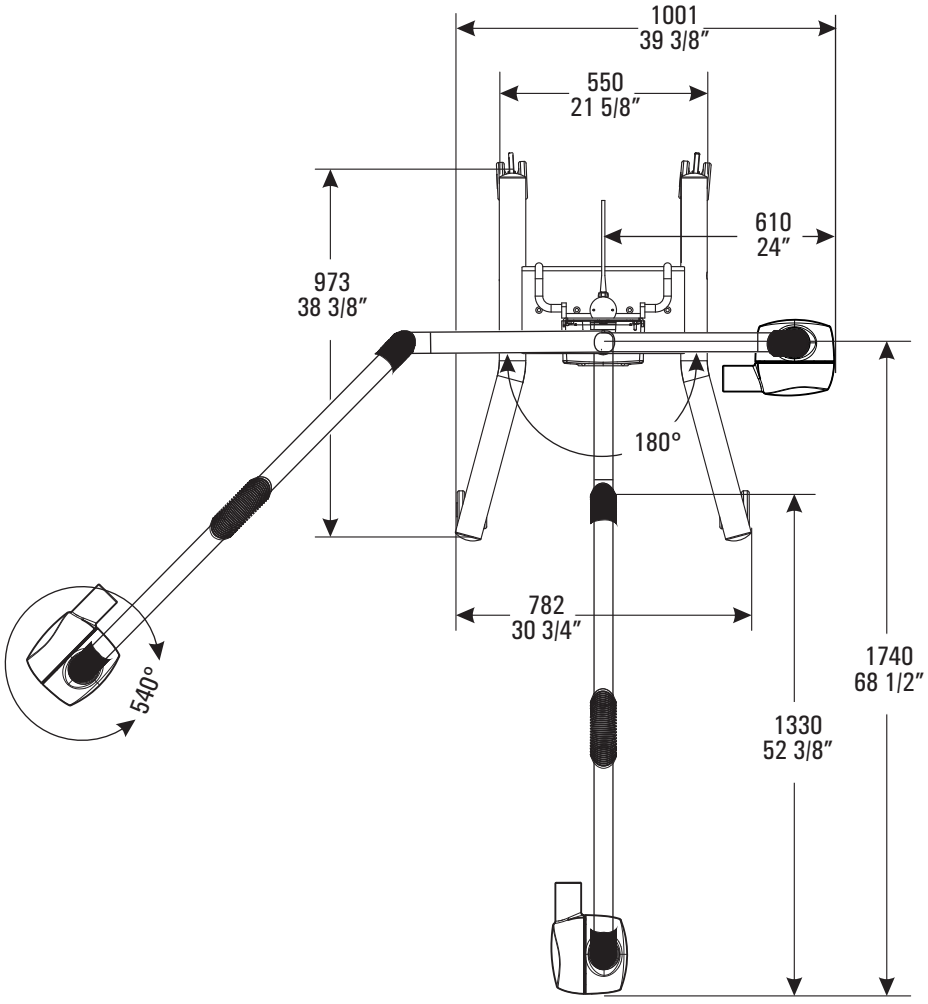



### 4.1.5 Dimensions mobile stand

**Front view**

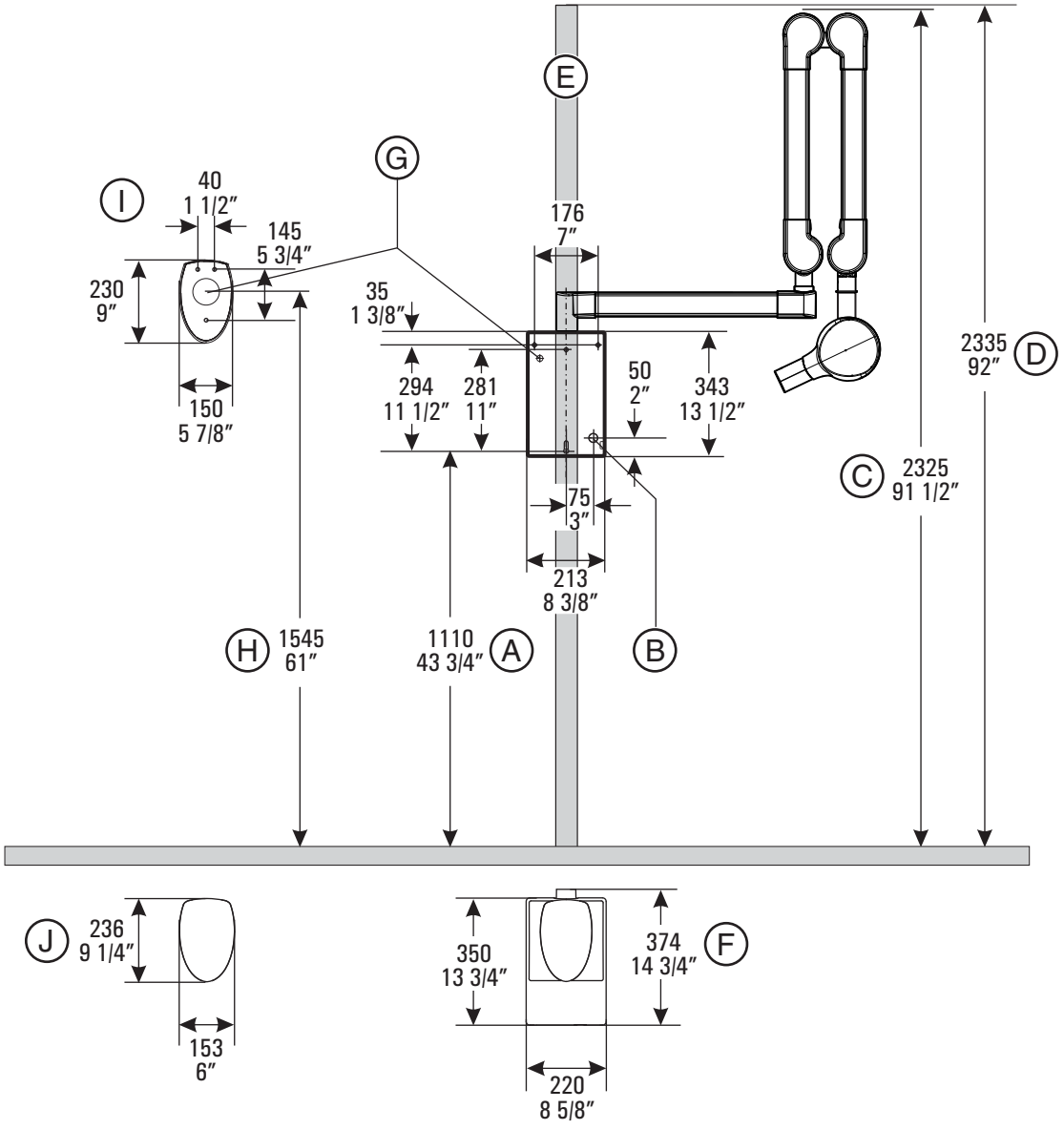


## Top view


1001
39 3/8″
550
21 5/8″
610
24″
973
38 3/8″
180°
782
30 3/4″
540°
1740
68 1/2″
1330
52 3/8″

# 4.2 Dimensions with angular support arm

## 4.2.1 Dimensions of front view with all options



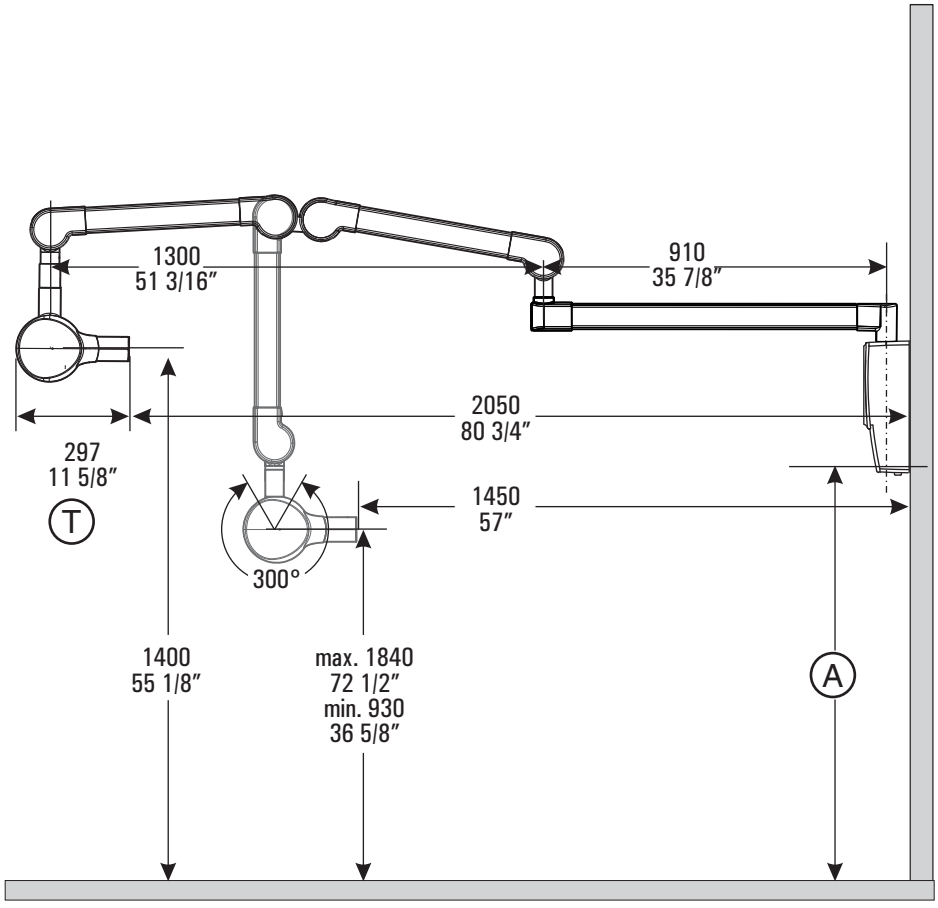

| | |
|---|---|
| **A** | Recommended installation height for the wall module |
| **B** | Cable bushing for network cable |
| **C** | Unit height |
| **D** | Ceiling height |
| **E** | Wooden beam |
| **F** | Wall module cover |
| **G** | Cable bushing for remote control or Remote Timer |
| **H** | Recommended installation height of remote control or Remote Timer |

| | |
|---|---|
| I | Remote control or Remote Timer |
| J | Cover for remote control or Remote Timer |

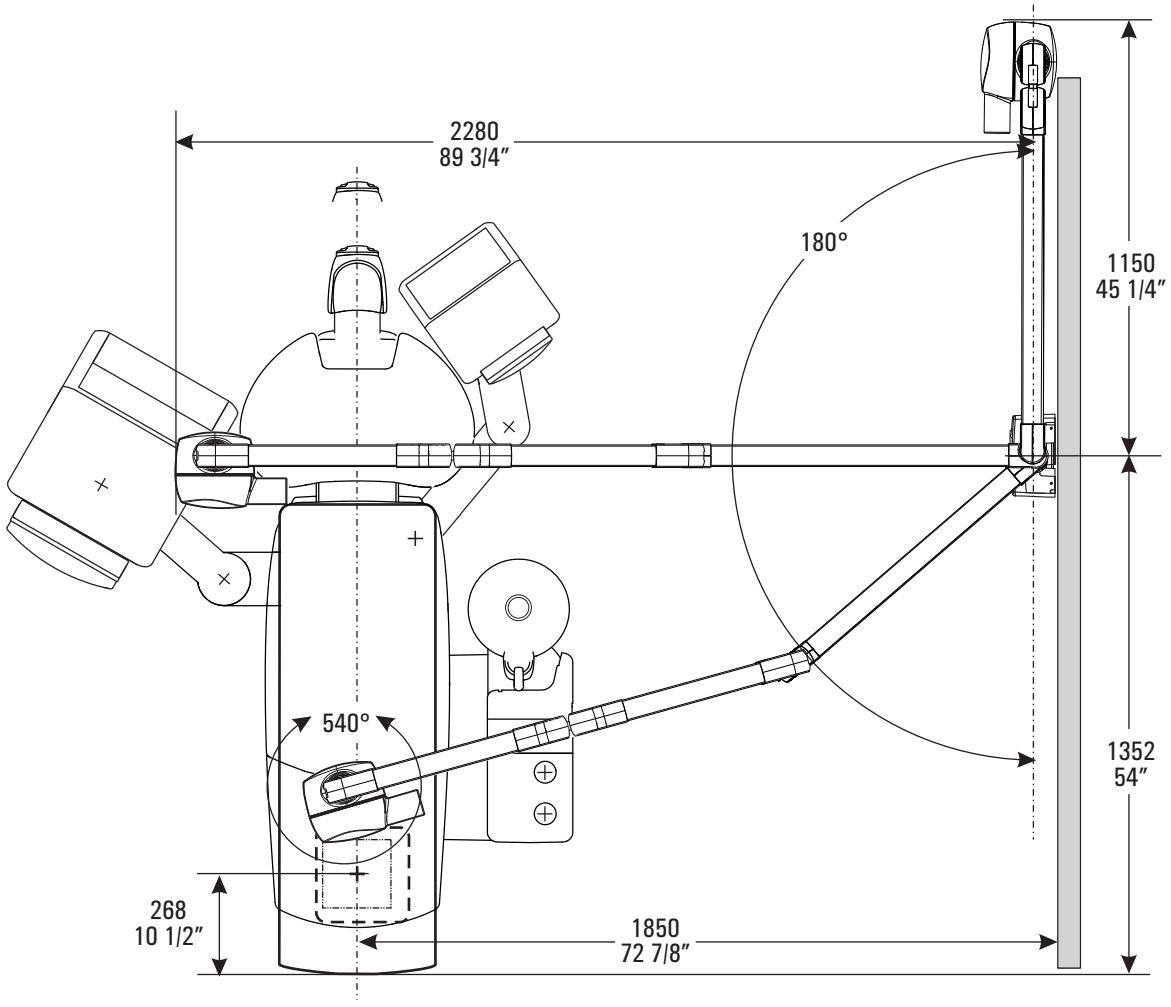
### 4.2.2 Dimensions for 910 mm (35 7/8") support arm

**Side view**

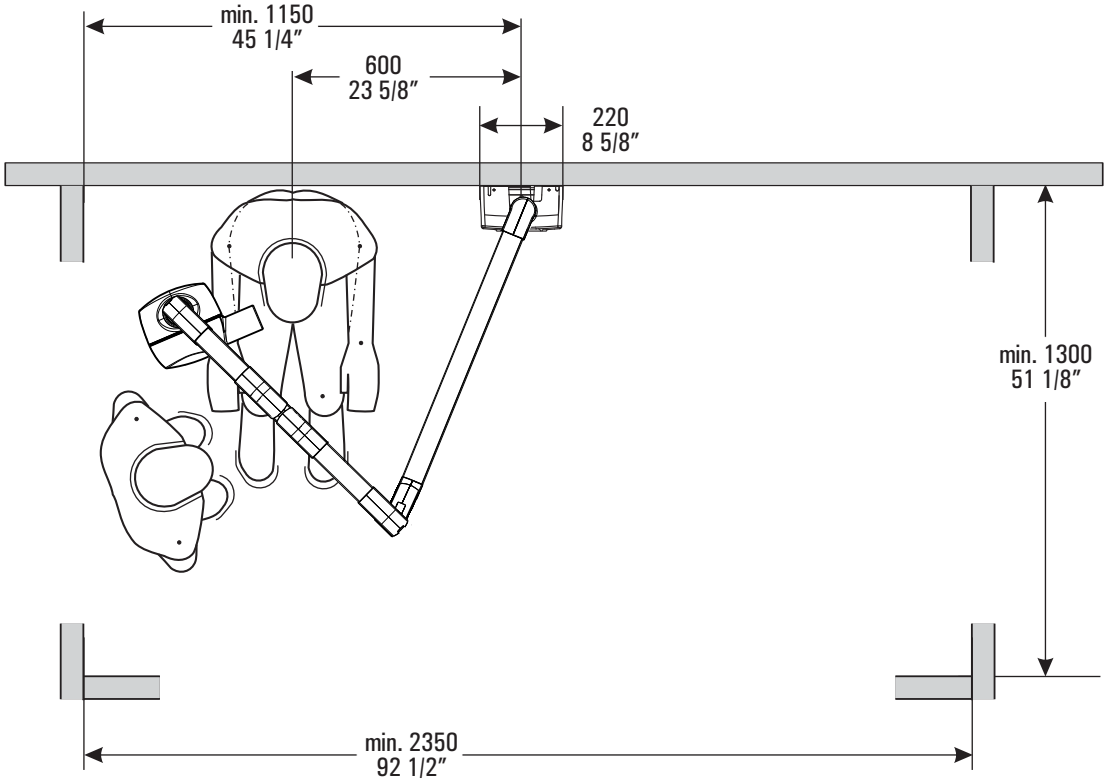
| | |
|---|---|
| A | Recommended installation height: 1110 mm (43 3/4") |
| T | X-ray tube assembly with standard tube, 200 mm (8") SSD |

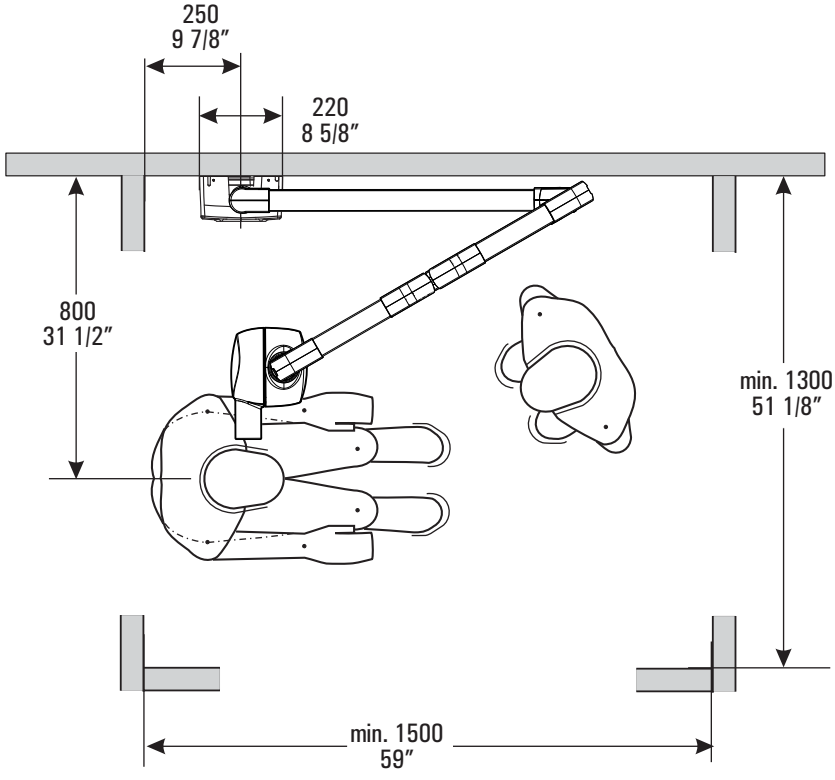


**Top view**



**Minimum dimensions for X-ray rooms with 910 mm (35 7/8") support arm**

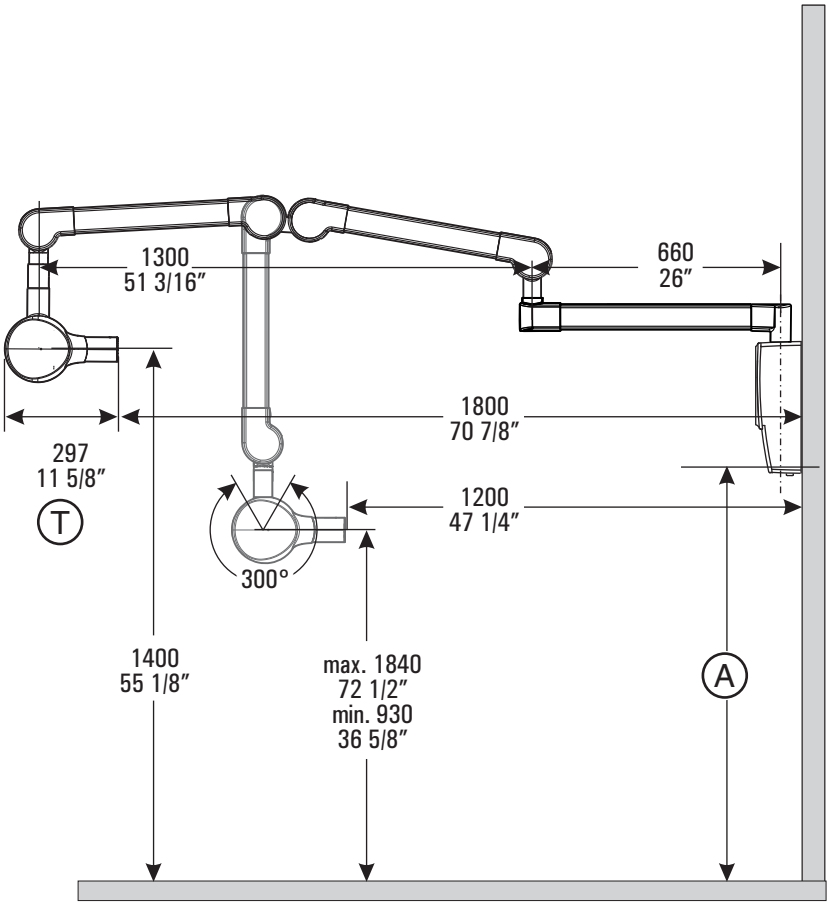


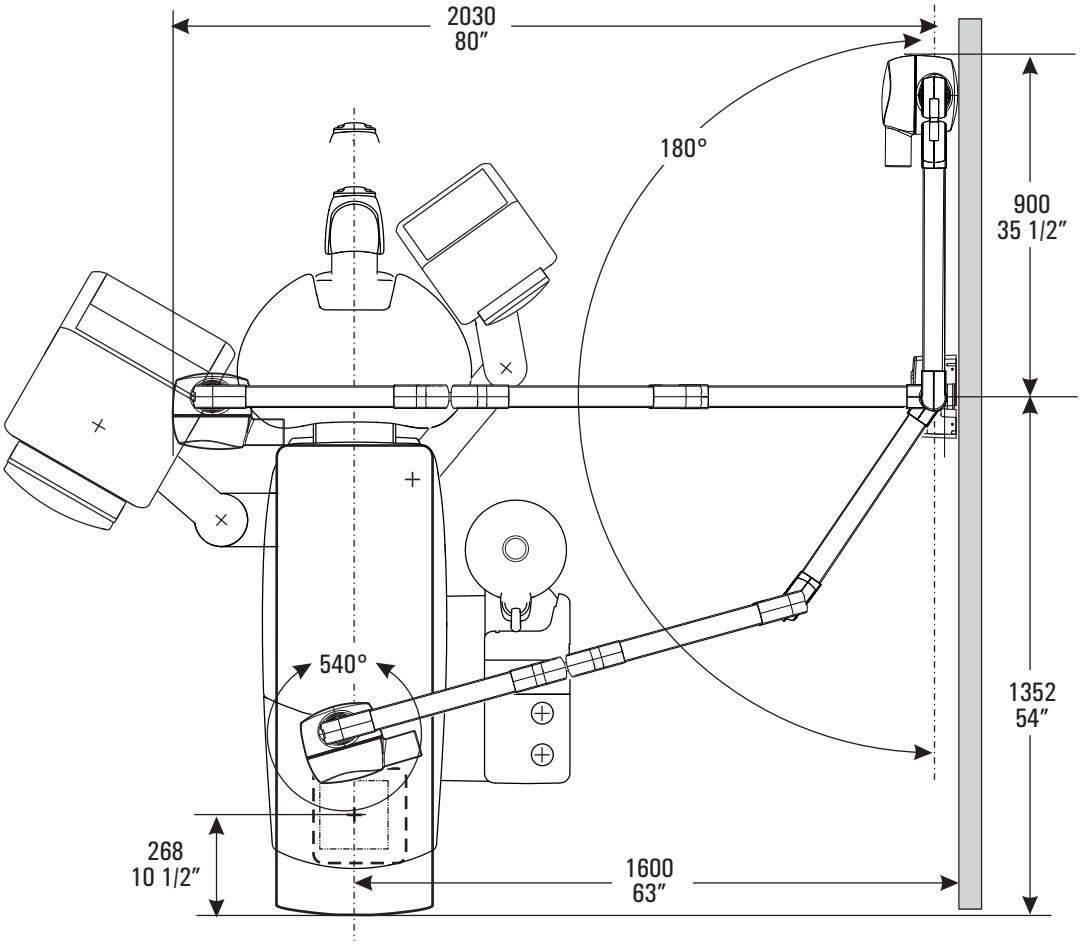
### 4.2.3 Dimensions for 660 mm (26") support arm

**Side view**

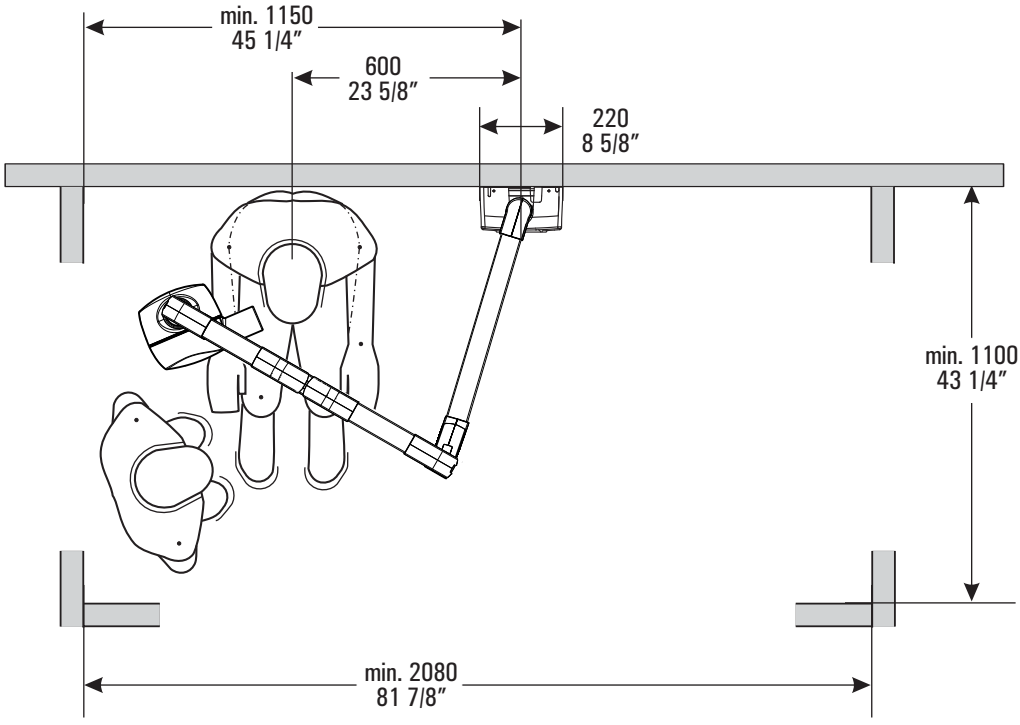
| | |
|---|---|
| A | Recommended installation height: 1110 mm (43 3/4") |
| T | X-ray tube assembly with standard tube, 200 mm (8") SSD |

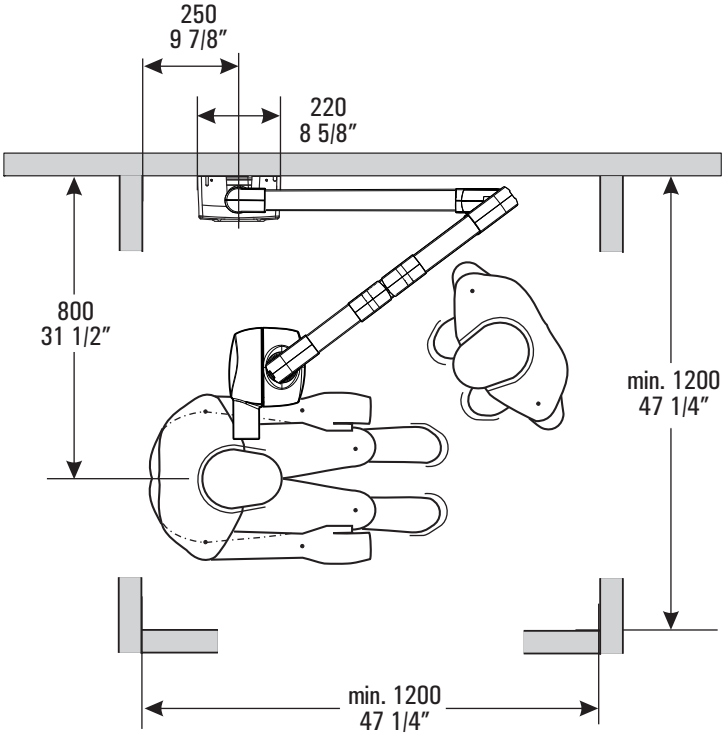


**Top view**



**Minimum dimensions for X-ray rooms with 660 mm (26") support arm**

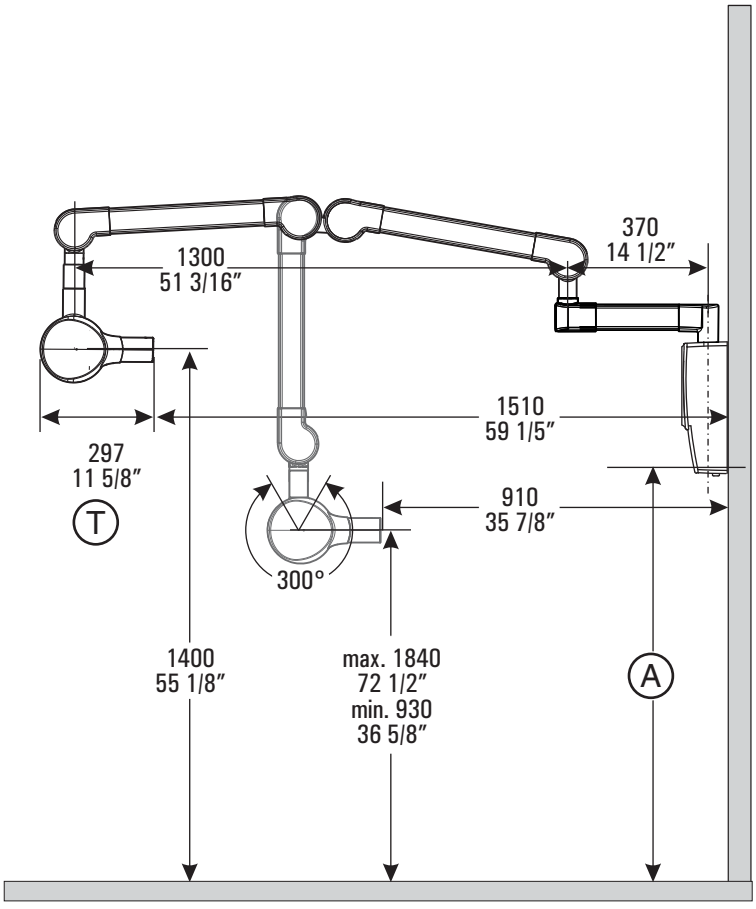


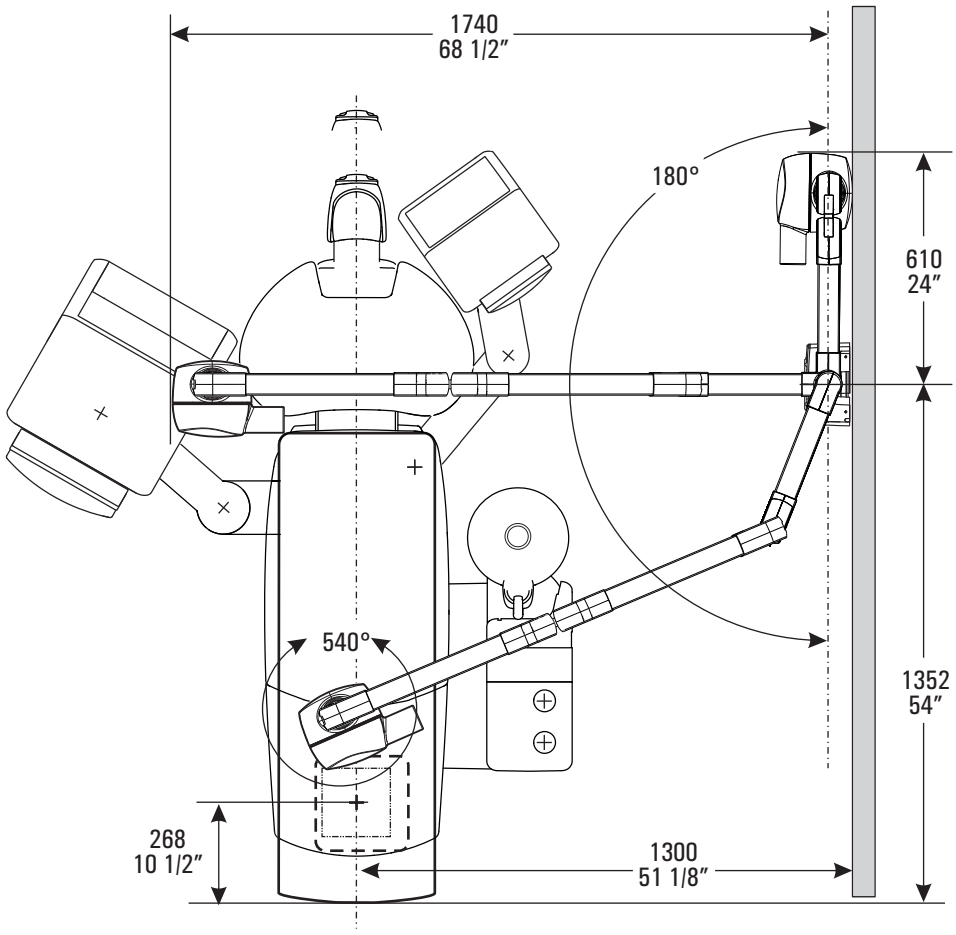
### 4.2.4 Dimensions for 370 mm (14 1/2") support arm

**Side view**

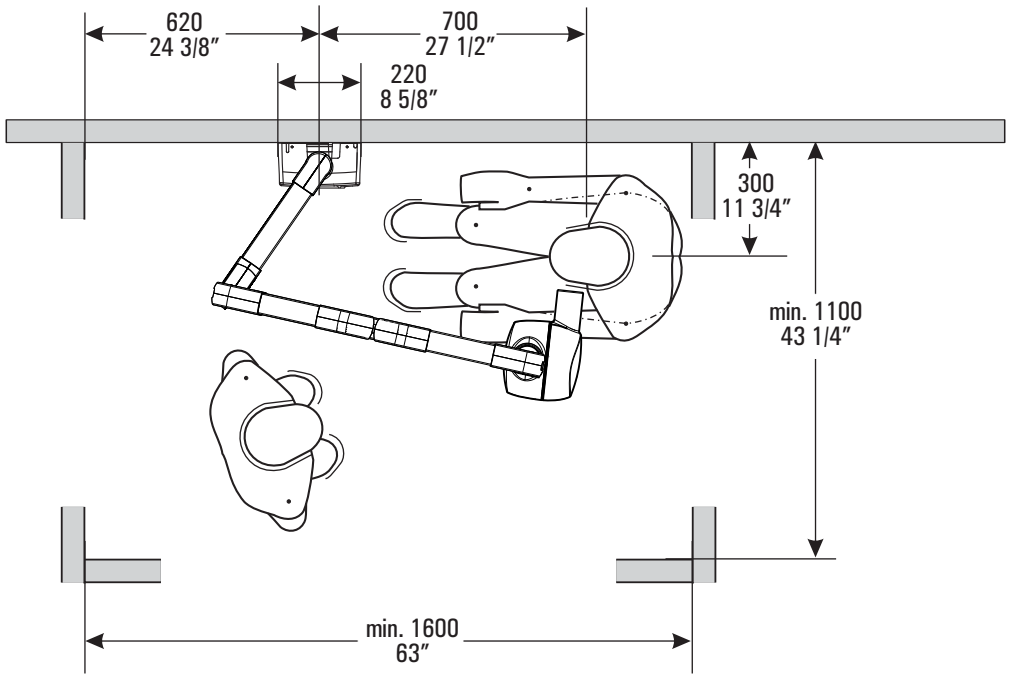
| | |
|---|---|
| A | Recommended installation height: 1110 mm (43 3/4") |
| T | X-ray tube assembly with standard tube, 200 mm (8") SSD |

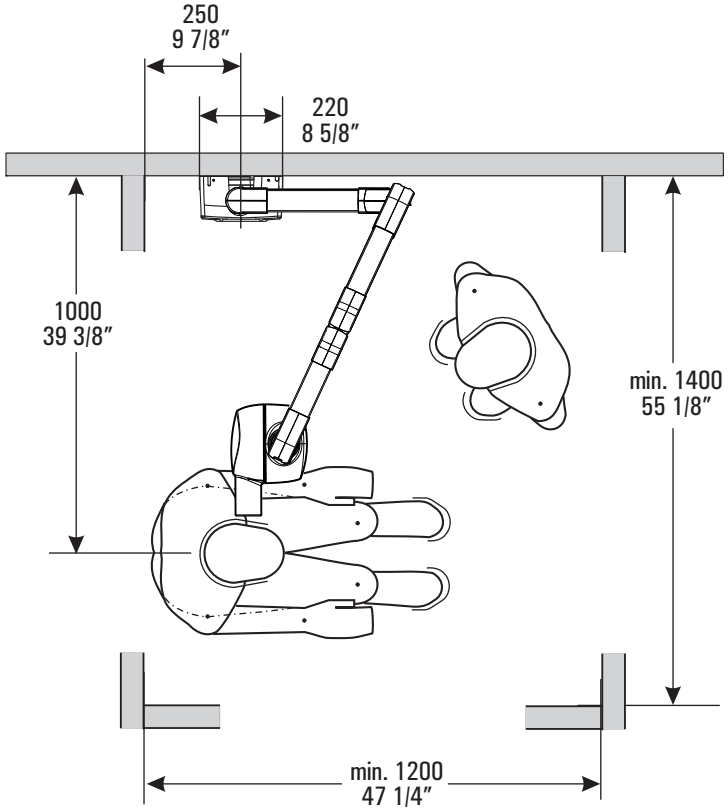


**Top view**



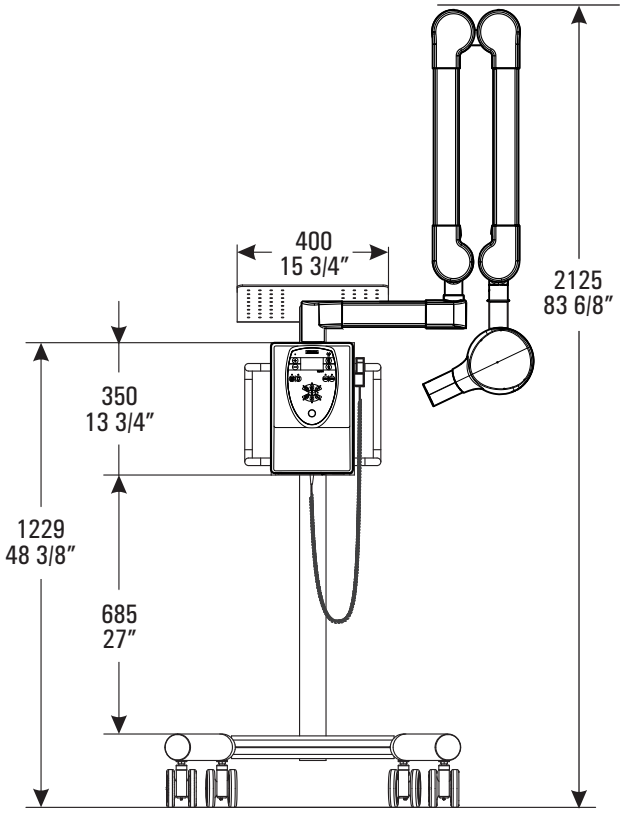
**Minimum dimensions for X-ray rooms with 370 mm (14 1/2") support arm**



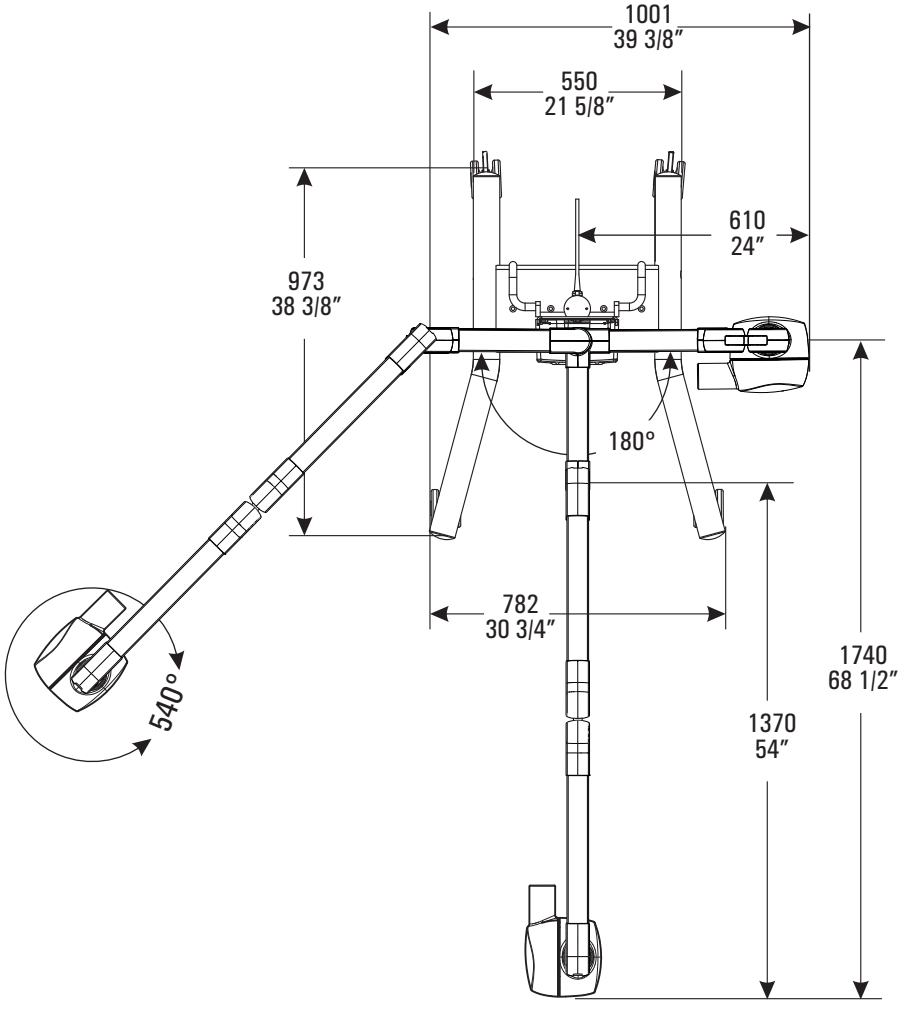



### 4.2.5 Dimensions mobile stand

**Front view**



## Top view


1001
39 3/8″
550
21 5/8″
610
24″
973
38 3/8″
180°
782
30 3/4″
540°
1740
68 1/2″
1370
54″

## 4.3 Technical data

| **Dimensions of the packaging** | |
|---|---|
| HELIODENT PLUS<br>Round support arm system | 87 cm x 91 cm x 29 cm<br>34 1/4" x 35 7/8" x 11 1/2" |
| Angular support arm system | 99 cm x 94 cm x 29 cm<br>39" x 37" x 11 1/2" |
| Mobile stand | 120 cm x 80 cm x 40 cm<br>47 1/4" x 31 1/2" x 15 3/4" |
| **Weight** | incl. / without packaging |
| HELIODENT PLUS<br>Round support arm system | 31 kg / 24 kg<br>68.34 lb / 53 lb |
| Angular support arm system | 37 kg / 30 kg<br>81.57 lb / 66.14 |
| Mobile stand | 128 kg / 105 kg<br>282.2 lb / 231.5 lb |
| **Power supply connection** | |
| Line voltage<br>wall model<br>ceiling model, unit model | <br>120 V, 200 V - 240 V, 50 / 60 Hz<br>200 V - 240 V, 50 / 60 Hz |
| Line voltage variation | ± 10% |
| Internal line resistance | At 120 V: 0.3 Ω<br>for 200 V - 240 V: 0.8 Ω |
| Nominal current | At 120 V: 10 A<br>for 200 V - 240 V: 6 A - 5 A |
| Fuse | 16 A slow blow |
| Power consumption | ≤ 1.2 kW |

| **Transport and operating conditions:** | |
|---|---|
| Transport and storage temperature: | -40°C – +70°C (-40°F – 158°F) |
| Air humidity: | 10% – 95% |
| Operating conditions as specified in IEC 60601-1: | Ambient temperature +10 °C – +40 °C (50 °F – 104 °F)<br>Relative humidity: 30% – 75% |
| Recommended operating temperature: | 18°C - 35°C (64°F - 95°F)<br>With room temperatures > 35°C (> 95°F) Sirona recommends the use of an air conditioning system. |
| Operating altitude: | ≤ 3000 m |

# 5 Electromagnetic compatibility

| NOTICE |
| --- |
| HELIODENT$^{Plus}$ complies with the requirements for electromagnetic compatibility (EMC) according to IEC 60601-1-2.<br><br>HELIODENT$^{Plus}$ is referred to in the following as "UNIT". Observance of the following information is necessary to ensure safe operation regarding EMC aspects. |

## 5.1 Accessories

| Designation of the interface cables | Order no. |
| --- | --- |
| LIYCY 2x0.25mm$^2$ (AWG 24) remote cable L9 for remote release, 10 m | 62 42 064 |
| LIYYC 8x0.22mm$^2$ (AWG 24) remote cable L6 for Remote Timer, 10 m | 62 42 056 |
| 3x1.5mm$^2$ NYM | Commercially available |

- 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 or to 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 ensure that it is operating properly.

## 5.2 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 | |

## 5.3 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.

| Interference immunity tests | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment - guidelines |
|---|---|---|---|
| Electrostatic discharge (ESD) according to **IEC 61000-4-2** | ± 8 kV contact discharge<br>± 15 kV air discharge | ± 8 kV contact discharge<br>± 15 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<br>± 2 kV for power supply lines | ± 1 kV for input and output lines<br>± 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 voltage<br>± 2 kV common mode voltage | ± 1 kV differential mode voltage<br>± 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** | Voltage dips:<br>0% $U_T$ with 1/2 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ with 1 period and<br>70% $U_T$ with 25 periods at 50 Hz and<br>30 periods at 60 Hz each at 0°<br>Short interruptions:<br>0% $U_T$ with 250 periods at 50 Hz and<br>300 periods at 60 Hz | | The quality of the line power supply should be that of a typical commercial or hospital environment.<br>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** | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| 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.<br>Recommended working clearance: |

| Interference immunity tests | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment - guidelines |
|---|---|---|---|
| Conducted RF interference<br>**IEC 61000-4-6** | 3 $V_{eff}$<br>150 kHz to 80 MHz[1] | 3 $V_{eff}$ | $d= [1.2] \sqrt{P}$ |
| Radiated RF interference<br>**IEC 61000-4-3** | 3 V/m<br>80 MHz to 800 MHz[1]<br>3 V/m<br>800 MHz to 2.7 GHz[1] | 3 $V_{eff}$<br>3 $V_{eff}$ | $d= [1.2] \sqrt{P}$<br>at 80 MHz to 800 MHz<br>$d= [2.3] \sqrt{P}$<br>at 800 MHz to 2.7 GHz<br>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).<br>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.<br>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 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

| Test frequency (MHz) | Frequency band(a) (MHz) | Radio service (a) | Modulation (b) | Power max. (W) | Distance (m) | Immunity test level (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380 - 390 | TETRA 400 | Pulse modulation (b)<br>18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM(c)<br>± 5 kHz stroke<br>1 kHz sinus | 2 | 0.3 | 28 |
| 710<br>745<br>780 | 704 - 787 | LTE band 13, 17 | Pulse modulation (b)<br>217 Hz | 0.2 | 0.3 | 9 |
| 810<br>870<br>930 | 800 - 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5 | Pulse modulation (b)<br>18 Hz | 2 | 0.3 | 28 |
| 1720<br>1845<br>1970 | 1700 - 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS | Pulse modulation (b)<br>217 Hz | 2 | 0.3 | 28 |
| 2450 | 2400 - 2570 | Bluetooth, WLAN, 802,11 b/g/n, RFID 2450, LTE band 7 | Pulse modulation (b)<br>217 Hz | 2 | 0.3 | 28 |
| 5240<br>5500<br>5785 | 5100 - 5800 | WLAN 802.11 a/n | Pulse modulation (b)<br>217 Hz | 0.2 | 0.3 | 9 |

Note:
If necessary, the distance between the transmitting antenna and the ME unit or ME system can be reduced to 1 m in order to achieve the immunity test level. The 1 m test distance conforms to IEC 61000-4-3.

(a) For some radio services, only the frequencies for the radio link between the mobile communication device and the base station (uplink) have been recorded in the table.

(b) The carrier must be modulated with a square-wave signal with 50% duty cycle.

(c) Alternatively to the frequency modulation (FM), a pulse modulation with 50% duty cycle at 18 Hz can be used, as this, if not the actual modulation, would represent the worst case.

# 5.4 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.


D3507.021.01.06.02 07.2016

Sprache: englisch
Ä.-Nr.: 122 391

Printed in Germany

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