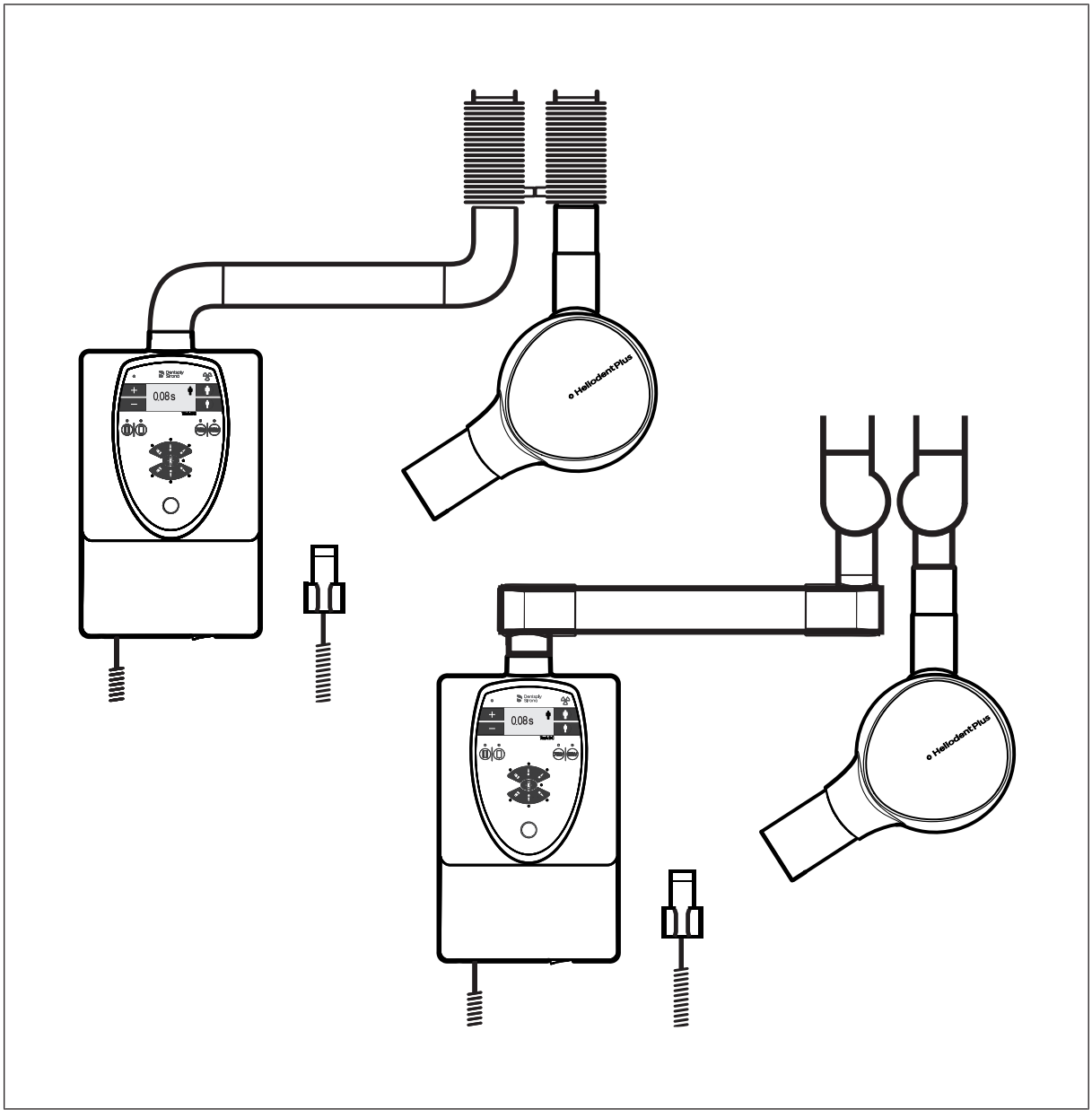
New as of: 2023-04

Dentsply Sirona

Heliodent Plus

Operating Instructions

English



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1 General data

1.1 Preface

Dear Customer,

Thank you for purchasing the Heliodent Plus X-ray system.

This system can be used to take intraoral X-rays.

Please familiarize yourself with the unit by reading through these **Operating Instructions** before taking any X-rays of patients.
Please comply with the applicable **radiation protection regulations** and **warnings** at all times.

Dentsply Sirona requires regular constancy tests to ensure image quality.

Your Heliodent Plus team,

1.2 General information about this operating manual

Follow the instructions for use

Please familiarize yourself with the unit by reading through these instructions for use before putting it into operation. It is essential that you comply with the warning and safety information listed.

Always keep the Operating Instructions handy in case you or another user require(s) information at a later point in time. Save the Operating Instructions on the PC or print them out.

If you sell the unit, make sure that the Operating Instructions are included with it either as a hard copy or on an electronic storage device so that the new owner can familiarize himself with its functions and the specified warning and safety information.

Online portal for technical documents

We have set up an online portal for the Technical Documents at www.dentsplysirona.com/manuals. From here, you can download these Operating Instructions along with other documents. Please complete the online form if you would like a hard copy of a particular document. We will then be happy to send you a printed copy free of charge.

Help

If you continue to have difficulties despite having thoroughly studied the Operating Instructions, please contact your dental depot.

1.3 Contact information

Customer Service Center

In the event of technical queries, please use our online contact form at the following address:
http://srvcontact.sirona.com

Manufacturer's address



Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Tel.: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
e-Mail: contact@dentsplysirona.com
www.dentsplysirona.com

1.4 Warranty and liability

Maintenance

As manufacturers of medical electrical equipment we can assume responsibility for the safety-related features of the equipment only if maintenance and repair are carried out only by ourselves or agencies expressly authorized by us, and if components affecting safe operation of the system are replaced with original spare parts upon failure.

Exclusion of liability

In the event that the system owner fails to fulfill the obligation to perform scheduled inspections and preventive maintenance activities or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for damages.

Certificate of work

We suggest that you request a certificate, showing the nature and extent of the work performed, from those who carry out such work, and specify that the certificate show any changes in rated parameters or working ranges, as well as the date, the name of the firm and a signature.

1.5 Intended use

The Heliodent Plus is an X-ray device for established dental surgeries and clinics intended to be used for intraoral radiography for examination and diagnosis of diseases of the teeth, jaw, and oral structures.

1.5.1 Indication and contraindication

Indications in the areas:

- Conservative dentistry
- Caries diagnosis, especially of proximal lesions
- Endodontics
- Periodontology
- Prosthodontics
- Functional diagnosis and therapy of craniomandibular dysfunctions
- Surgical dentistry
- Implantology
- Oral and maxillofacial surgery
- Orthodontics

Contraindications:

- Display of cartilage structures
- Display of soft tissue

1.6 Structure of the document

1.6.1 Identification of danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in this document. All such information is labeled 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

Instructions for use and other important information.

Tip: Information on facilitating work.

1.6.2 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	Prompts you to do something.
See “Formats and symbols used [→ 8]”	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 information

2.1 Basic safety information

NOTICE

This unit must not be operated in areas subject to explosion hazards.

2.2 Information on the unit

Accompanying documents

This symbol can be found next to the rating plate on the unit.



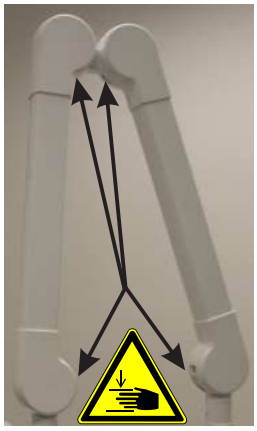
Meaning: Observe the Operating Instructions when operating the unit.



This symbol can be found on the rating plate on the unit.

Meaning: The accompanying documents are available on the manufacturer's homepage.

2.3 Risk of crushing



⚠ CAUTION

When moving the angular scissor arm, gaps appear at the inner joints.

Fingers may be crushed in these gaps.

➢ Never place your fingers in the gaps between the joints, neither during operation nor for cleaning purposes.

2.4 Condensation

Extreme temperature fluctuations may cause condensation inside the unit. Do not switch the unit on before it has reached normal room temperature. Also see the section "Technical data".

2.5 Qualifications of operating personnel

The unit may only be operated by skilled or properly trained personnel.

2.6 Radiation protection

The valid radiation protection regulations and measures must be observed. The statutory radiation protection equipment must be used. In

order to reduce radiation exposure, Dentsply Sirona recommends using bismuth or lead shields or aprons, especially for pediatric patients.

During the exposure, the operator is required to remove themselves as far from the X-ray tube assembly as the coiled cable of the release button permits.

With the exception of the patient, no other persons without radiation protection are allowed to stay in the room during an exposure. In exceptional cases, a third person may provide assistance, but not the practice staff.
If the patient is within reach of the unit including its operating elements, they must be supervised. Visual contact with the patient and the unit must be maintained throughout the entire exposure.

In case of malfunctions, stop the exposure immediately by letting go of the exposure release button.

2.7 Hygiene

Suitable hygienic measures must be taken to prevent cross contamination among patients, operators and other persons.

Before positioning the patient in the unit, you must ensure that

- all auxiliary X-ray equipment is used and prepared (sterilized and/or disinfected) in accordance with manufacturer specifications (e.g. hygienic protective sleeves).

Compliance with the hygienic measures prevents the transmission of infections that can trigger severe illnesses.

2.8 Trouble-free operation

Use of this system is permissible only if it works properly without malfunctions. If trouble-free operation cannot be ensured, the unit must be taken out of service, checked by authorized technicians for malfunctions and, if necessary, repaired.

The device may only be operated with a complete cover and protective hood.

2.9 Interference with electronic devices

To prevent the malfunctioning of electronic devices and data memories, these objects must be removed prior to the X-ray exposure.

2.10 Risks of electromagnetic fields

The function of implanted systems (cardiac pacemakers or cochlear implants, for example) can be affected by electromagnetic fields. Before commencing treatment, ask if the patient has a cardiac pacemaker or any other implanted system.
Any prevailing risks are listed in the documentation provided by the implant manufacturer.

2.11 Modifications to the product

Modifications to this product which may affect the safety of the operator, patients or third parties are prohibited by law!

2.12 Electromagnetic compatibility

The acquisition unit complies with the requirements of IEC 60601-1-2.

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). They must be installed and operated as specified in the "Installation Requirements" document.

Portable and mobile RF communications equipment may affect medical electrical devices.

If the installation requirements and the following recommendations are not observed, there is a risk of incorrect exposure of the X-ray images. The accuracy of the radiation parameters and the repeatability of the dose values in particular may be affected.

Operate only units approved by Dentsply Sirona at a distance of < 30 cm from the X-ray unit. The Dentsply Sirona intraoral sensors are approved for this.

In case of repairs, use only replacement parts approved by Dentsply Sirona.

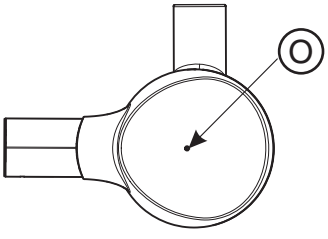
Use only disinfectants approved by Dentsply Sirona so as not to damage electrical insulation.

Portable HF equipment must not be placed within a 30 cm radius of the X-ray unit.

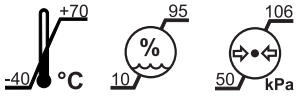
HF surgery units and X-ray units may not be operated at the same time.

3 Technical description

3.1 Technical data

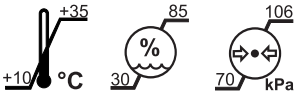
Nominal voltage:	120 V, 200 V– 240 V
Permissible fluctuation:	± 10%
Nominal current:	at 120 V: 10 A at 200 – 240 V: 6 – 5 A
Nominal frequency:	50 Hz / 60 Hz
Internal line impedance:	At 120 V 0.3 ohms At 200 – 240 V 0.8 Ohm
Main building fuse:	16 A slow blow
Power input during radiation:	1.2 kW
Power input in standby mode:	< 20 W
Tube voltage:	60 kV / 70 kV switchable (max. tolerance ± 5 kV)
Tube current:	7 mA (max. tolerance ± 1.4 mA)
High-voltage waveform:	DC high frequency residual ripple value ≤ 4 kV
High voltage generation frequency:	50 kHz - 70 kHz
Radiation time:	0.01 – 3.2 s (max. tolerance ± 10% +1 ms)
Pulse/pause ratio:	automatic monitoring from 1:1 to 1:60
Total filtration of X-ray tube assembly:	> 1.5 Al / 70 IEC 60522
Radiation field:	Ø < 60 mm
Dose rate:	8.5 mGy/s ±40% at 60 kV 11 mGy/s ±40% at 70 kV
Measuring instruments:	PTW Nomex with an ionization space of 1 cm^3 or Unfors mult-o-meter
Measuring conditions:	200 mm focus-meter space 230 V nominal voltage
Focal spot size as specified in IEC 60336:	0.4
Focal spot marking **O**:	

Source-skin distance:	FHA 200 mm (8") - standard or 300 mm (12")
Class I device Degree of protection against electric shock:	Type B device
Degree of protection against ingress of water:	Ordinary device (without protection against ingress of water)
Year of manufacture:	**20XX** (on the rating plate)
Operating mode:	Continuous operation
X-ray tube:	Petrick P470/8.35/12G
Nominal continuous power rating of the X-ray tube:	26 W
Power rating of X-ray tube (70 kW/7 mA):	490 W
Anode material:	Tungsten
Anode angle:	12°
Exposure parameters for determining leakage radiation:	0.12 mA / 70 kV
Leakage radiation at 1 m distance:	< 0.25 mGy/h



Transport, storage and operating conditions:

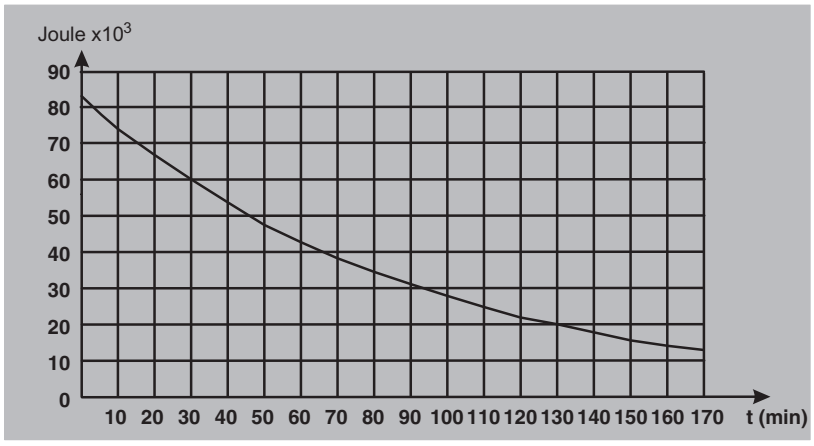
Transport and storage conditions:	Temperature: -40°C – +70°C (-40°F – 158 F)
	Relative humidity: 10% – 95%
	Air pressure: 500 hPa – 1060 hPa



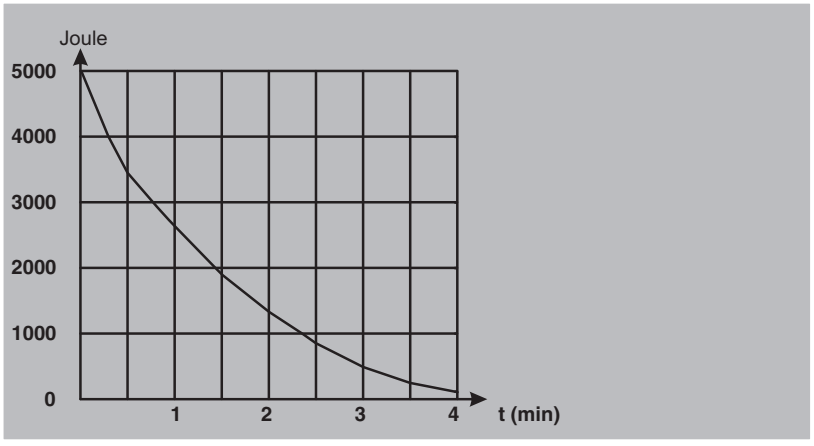
Operating conditions:	Ambient temperature +10°C – +35°C (50°F – 95°F)
	With room temperatures > 35°C (> 95°F) Dentsply Sirona recommends the use of an air conditioning system.
	Relative humidity: 30% - 85% (no condensation)
Operating altitude:	≤ 3000 m

3.2 Diagrams

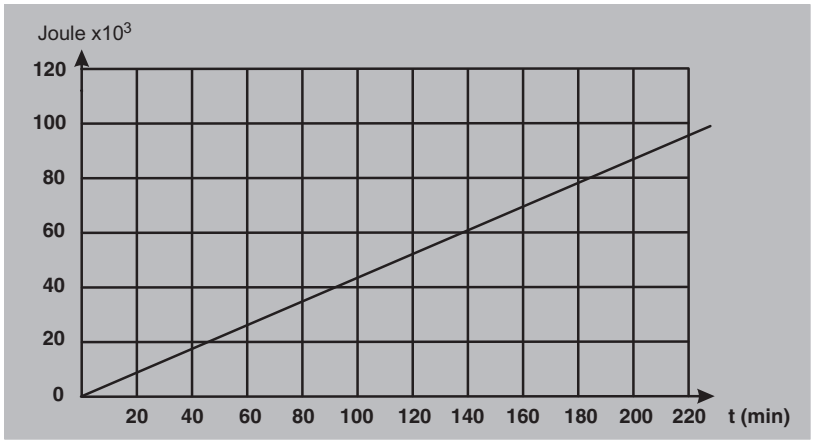
Cooling curve of tube housing



Cooling curve of X-ray tube



Heating curve of tube housing



3.3 Certification, registration and standards

The dental X-ray equipment for intraoral radiography Heliodent Plus complies with the following standards:

- IEC 60601-1
- IEC 60601-1-3
- IEC 60601-2-65

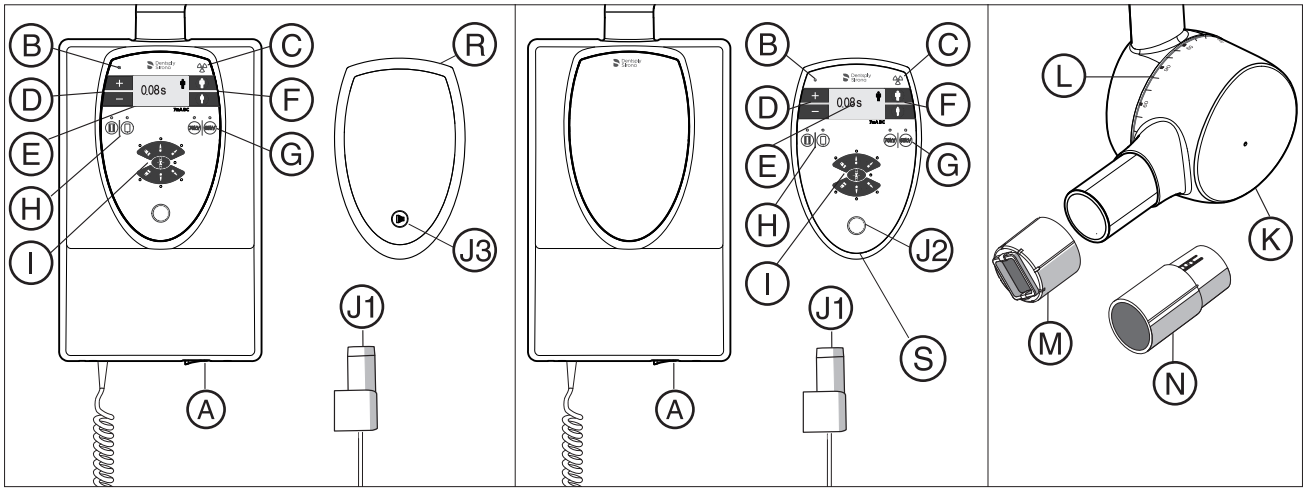
Original language: German

CE
0123

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

4 Controls and functional elements

4.1 Operating and Display Elements



A	Main ON/OFF switch	
B	Readiness for operation indicator (LED)	
C	Optical radiation indicator for X-ray	
D	Plus/minus keys for exposure time	
E	Digital display of exposure time	
F	Child/Adult pre-selection key	
G	Pre-selection keys and display of 60 kV/70 kV	
H	Pre-selection keys and display of digital mode and film mode	
I	Keys and display for tooth selection/image type	
J1	Release button on J1 coiled cable	Depending on the installed version
J2	Release button J2 on the Remote Timer	
J3	Release button J3 on the remote control	
K	X-ray tube assembly	
L	Scale for adjusting the angle of inclination	
M	Radiation field limiter	
N	Cone extension	
R	Remote control	
S	Remote Timer	

4.2 Meaning of the icons

Patient symbol



Adult



Child



Plus key



Minus key



Exposure release button



Maxillary front tooth



Maxillary canine/premolar



Maxillary molar



Bite-wing exposure



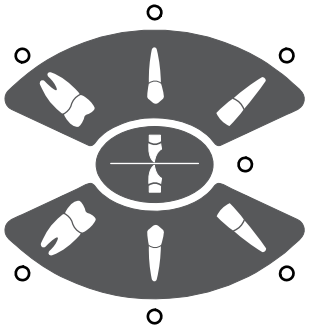
Mandibular front tooth



Mandibular canine/premolar



Mandibular molar



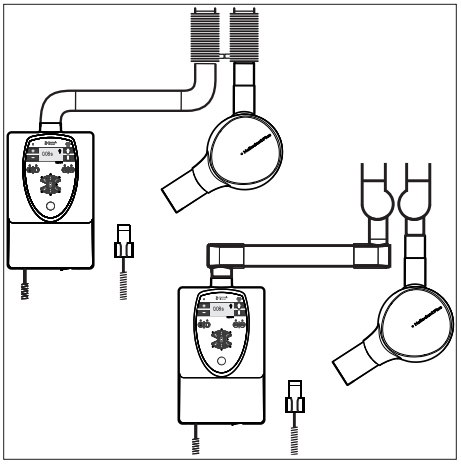
4.3 Display structure

The background lighting of the display indicates the current status of the unit.

Background color	Meaning
Blue	Ready for radiation
Yellow	Radiation
White	Service
Red	Error

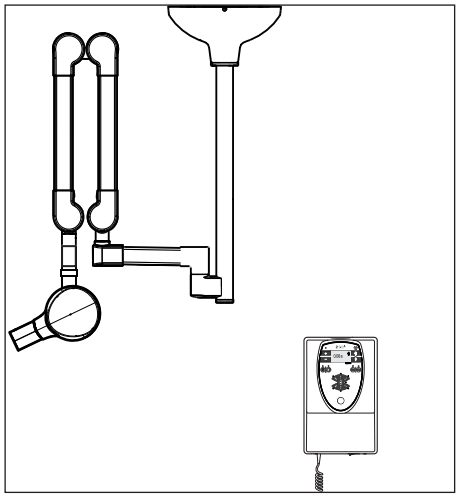
4.4 Wall model version

Wall model

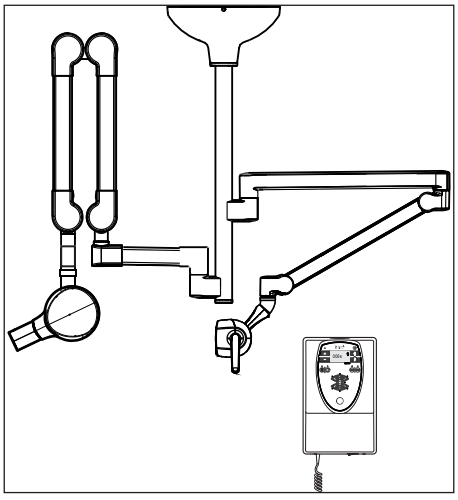


4.5 Version Ceiling model/Ceiling combination

Ceiling model

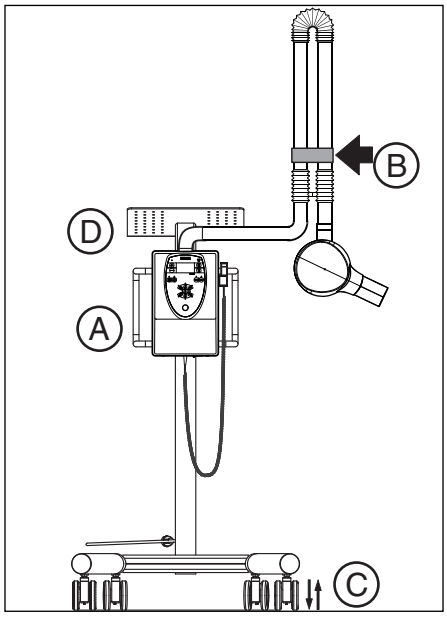


Ceiling combination with LEDview Plus



4.6 Mobile stand variant

Mounting of the wall model with round or angular support arm (only support arm length M possible) on a mobile stand for mobile use.



Secure the tube assembly with the fastening strap (B).

Use the two handles (A) on the side to move the mobile stand.

The mobile stand must be moved **slowly** on an **even** surface.

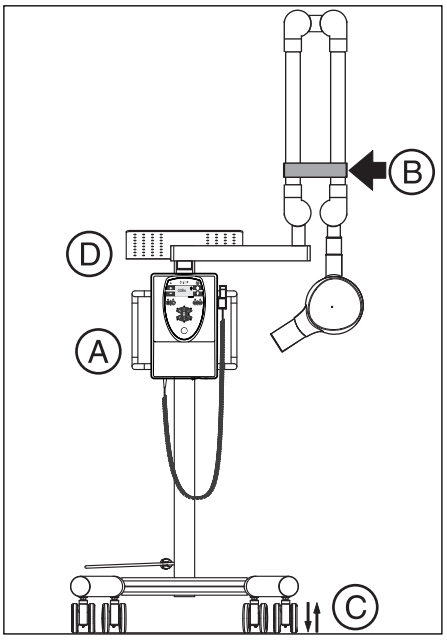
⚠ CAUTION

Risk of injury!

When changing the treatment station, the stay arm must be secured with the fastening strap provided (B).
The mobile stand must be moved extremely carefully using the handholds provided (A).
Particular care must be taken when crossing floor beams. The mobile stand may need to be lifted a little if necessary.

The mobile stand has 4 rollers with brakes.

To lock the rollers in place, press the locking lever (C) down ↓, and to release lift it up ↑ .



⚠ CAUTION

Always apply the brakes (C) before setting up the X-ray tube assembly.

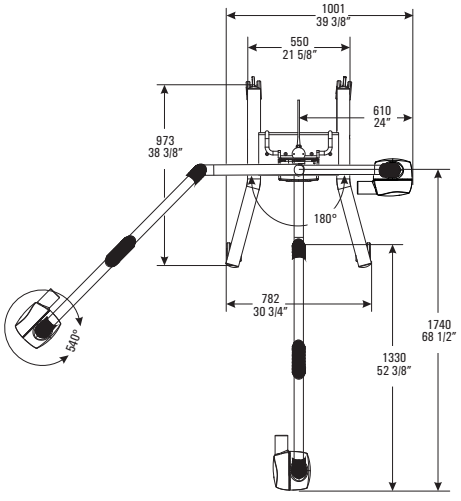
The mobile stand can be fitted with a tray (D).

⚠ CAUTION

This tray may hold a maximum of 5 kg.

End stop

Rotation option of the round/angular support arm is 180°.



⚠ CAUTION

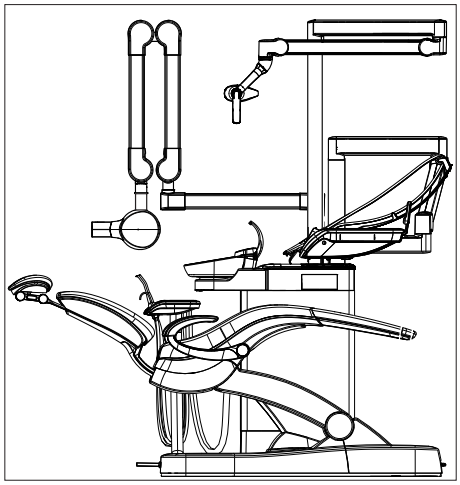
When the angular support arm moves, gaps are created between the support arm and the tray.

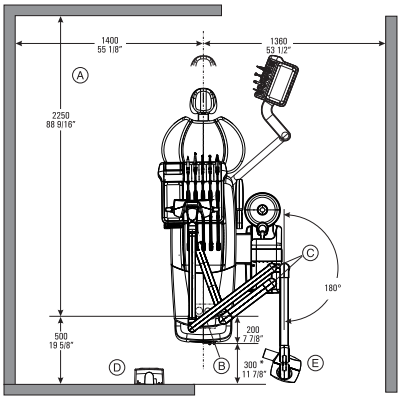
Fingers can be crushed in these gaps.

➢ Be careful not to put your fingers in the space between the moving arm and the tray, either during operation or when cleaning.



4.7 Version Unit model



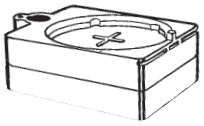


Heliodent Plus at a treatment center, only possible with angular support arm system.

Rotation option of the angular support arm is 180°.

4.8 Accessories

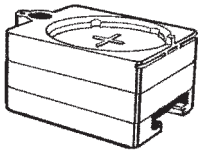
IMPORTANT
Not all of the accessories listed here are included in the scope of supply.



Only required in countries in which the constancy test is mandatory.

Phantoms for constancy tests for conventional imaging technology

Order no. 59 69 779

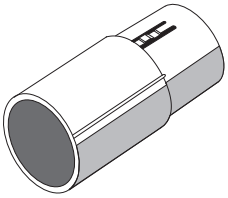


Only required in countries in which the constancy test is mandatory.

Phantoms for constancy tests for the Xios XG sensor
Order no. 64 00 449

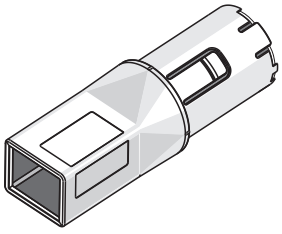
Phantoms for constancy tests for the Xios Plus sensor
Order no. 62 09 634

Phantoms for constancy tests for the Xios sensor
Order no. 61 37 447



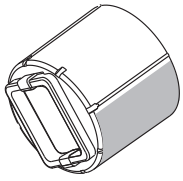
Cone extension to 300 mm FHA (12")

Order no. 62 41 983



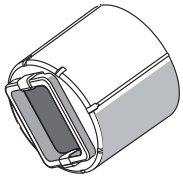
Square cone extension to 300 mm FHA (12")

Order no. 62 41 975



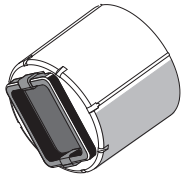
Radiation field limitation **white** size 0 (1.8 x 2.4 cm) with rotary handle for
Xios XG size 0 sensor and conventional imaging technology

Order no. 64 00 142



Radiation field limitation **blue** size 2 (3 x 4 cm) with rotary handle for Xios XG size 2 sensor,
Xios Plus / Xios size 2 sensor and conventional imaging technology

Order no. 62 41 991



Radiation field limitation **black** size 1 (2 x 3 cm) with rotary handle for Xios XG size 1 sensor,
Xios Plus/ Xios size 1 sensor and conventional imaging technology

Order no. 62 42 007

4.9 Exposure times

4.9.1 Possible exposure times in seconds

0,01	0,02	0,03	0,04	0,05	0,06	0,08	0,10	0,12	0,16	0,20	0,25	0,32	0,40	0,50	0,64	0,80	1,00	1,25	1,60	2,00	2,50	3,20

4.9.2 Pre-programmed exposure times for films of sensitivity class E and with a 200 mm (8") FHA cone

	Upper jaw								
	Lower jaw								
	Upper jaw								
	Lower jaw								
Exposure time in seconds with:									
60 kV		0,06	0,08	0,10	0,12	0,16	0,20	0,25	0,32
70 kV		0,03	0,04	0,05	0,06	0,08	0,10	0,12	0,16
Freely programmed values									

NOTICE

For film of sensitivity class F: Set the exposure time one level lower with the minus button.
For films of sensitivity class D: Set the exposure time four levels higher with the plus button.
Using a film holder: Set the exposure time one or two levels higher with the plus button.

4.9.3 Pre-programmed exposure times for films of sensitivity class E and with a 300 mm (12") FHA cone

	Upper jaw								
	Lower jaw								
	Upper jaw								
	Lower jaw								
Exposure time in seconds with:									
60 kV		0,12	0,16	0,20	0,25	0,32	0,40	0,50	0,64
70 kV		0,06	0,08	0,10	0,12	0,16	0,20	0,25	0,32
Freely programmed values									

NOTICE

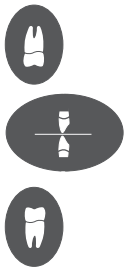
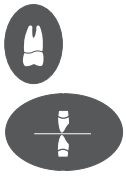
For film of sensitivity class F: Set the exposure time one level lower with the minus button.
For films of sensitivity class D: Set the exposure time four levels higher with the plus button.
Using a film holder: Set the exposure time one or two levels higher with the plus button.

4.9.4 Pre-programmed exposure times for Xios XG sensors with 200 mm (8") FHA cone

Possible exposure times in seconds

The recommended exposure times are limited to the following values selected from the possible exposure times:

0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40

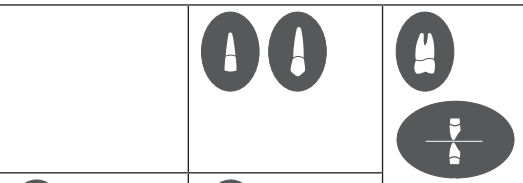
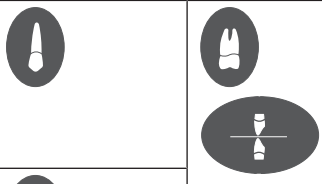
	Upper jaw					
	Lower jaw					
	Upper jaw					
	Lower jaw					
Exposure time in seconds with:						
60kV		0.06	0.08	0.10	0.12	0.16
70kV		0.03	0.04	0.05	0.06	0.08
Freely programmed values						

4.9.5 Pre-programmed exposure times for Xios XG sensors with 300 mm (12") FHA cone (round or square cone)

Possible exposure times in seconds

The recommended exposure times are limited to the following values selected from the possible exposure times:

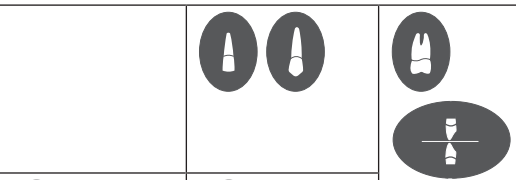
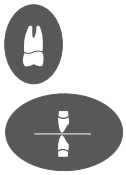
0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64

	Upper jaw					
	Lower jaw					
	Upper jaw					
	Lower jaw					
Exposure time in seconds with:						
60kV		0.12	0.16	0.20	0.25	0.32
70kV		0.06	0.08	0.10	0.12	0.16
Freely programmed values						

4.9.6 Pre-programmed exposure times for Xios AE sensors with 200 mm (8") FHA cone

Possible exposure times (in seconds)

0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40

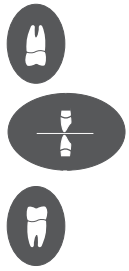
	Upper jaw					
	Lower jaw					
	Upper jaw					
	Lower jaw					

Exposure time in seconds with:					
60kV	0.04	0.05	0.06	0.08	0.10
70kV	0.02	0.03	0.04	0.05	0.06
Freely programmed values					

4.9.7 Pre-programmed exposure times for Xios AE sensors with 300 mm (12") FHA cone

Possible exposure times (in seconds)

0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64	0.80

	Upper jaw					
	Lower jaw					
	Upper jaw			 		
	Lower jaw					

Exposure time in seconds with:					
60kV	0.08	0.10	0.12	0.16	0.20
70kV	0.04	0.06	0.08	0.10	0.12
Freely programmed values					

5 Operation

5.1 General

Heliodent application

- Recommendations for cone length.
  - The cone length to be used varies depending on the exposure technique, X-ray unit and radiation protection.

    In Germany, for example, the 20 cm standard cone is used primarily.
- Setting the exposure times and cone voltage
  - The exposure times to be set depend on the person, the tooth region and the image receiver used.
  - The cone voltage (kV) depends on the indication.
- Using the radiation field limitation
  - The radiation field limitation is to be selected according to the size of the intraoral image receptor (3x4 or 2x3).
  - The radiation field limitation is to be turned in the direction of the intraoral image receptor.

    The parallelism of the tube assembly, holder systems and image receptor must be taken into account.

Intraoral sensor positioning

The sensor positioning for intraoral X-rays is explained in a video.

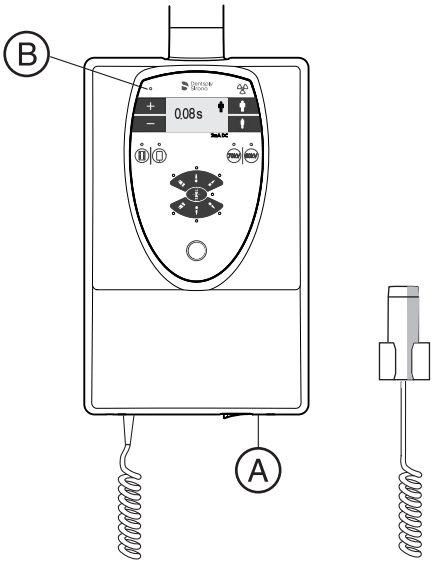
https://www.youtube.com/playlist?app=desktop&list=PLDZOLTDcHkCpm8oJ71yMxG8c82OVB2Z0X

Tips and Tricks

- The radiation field limitation is to be used with a holder, otherwise the collimator might be in the path of the rays.
- Parallel alignment is important to avoid overlays and distortion.
- The white hood of the radiation field limitation is **not** used to reduce radiation.
  It is intended only for use with certain holder systems.

5.2 Preparing the exposure

5.2.1 Switch the unit on



Switch on the unit with the main switch (A) (Position I).

During this process none of the keys of the operating panel must be pressed.

After the unit is switched on, a self-test runs.
After approximately 20 seconds, the operational readiness LED (B) is continuously lit and the background lighting of the display changes to blue. The most recent exposure parameters set are displayed.

The unit is ready for radiation.

NOTICE

Error message after the self-test

If an error was detected during the self-test, a corresponding error code is shown on the display. (See chapter entitled "Error Messages"). The LED (B) flashes and the background lighting changes to red. The unit is not ready for operation.

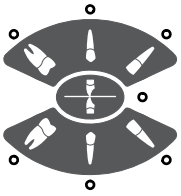
Switch unit OFF and ON again at the main switch (A).

⚠ CAUTION

Error message after a repeated self-test

If the error re-occurs, please call your service engineer.

5.2.2 Selecting the tooth icon



Press the key with the tooth icon to denote the region in which you want to take an X-ray.

The programmed exposure time is indicated.

The LED above/below the tooth icon lights up. During bite-wing exposures, the LED to the right of the icon lights up.

5.2.3 Selecting the patient symbol



Press the button with the adult patient icon if you wish to take an X-ray of an adult.

The programmed exposure time is indicated.



Press the button with the child patient icon if you wish to take an X-ray of a child.

The programmed exposure time is indicated.

5.2.4 Checking the kV value:



Check to see which kV value is set.

Press the 60 kV key to switch to 60 kV.

The exposure time for greater contrast is displayed.



Press the 70 kV button to switch to 70 kV.

The exposure time for enhanced detail recognition with a low level of exposure to radiation is displayed.

5.2.5 Plus/Minus keys



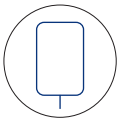
If you want to increase the exposure time, press the key with the plus symbol until the desired value is displayed.



If you want to decrease the exposure time, press the key with the minus symbol repeatedly until the desired value is displayed.

IMPORTANT
The LEDs above/below the tooth icon previously selected and the patient icon on the display go out.

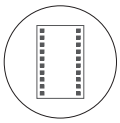
5.2.6 Checking the imaging technology



If you are working with a digital imaging system (e.g. XIOS XG), the sensor indicator should be lit on the unit. To switch, press the key with the sensor icon.

The exposure time for digital images is displayed.

Set the radiation field limitation for digital imaging technology.



If you wish to take conventional X-ray images (with film), the film indicator should light up on the unit. To switch, press the key with the film icon.

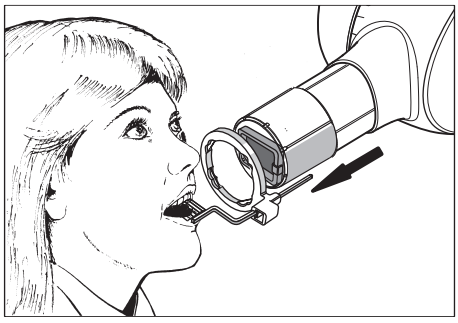
The exposure time for conventional exposures is displayed.

Set the radiation field limitation for conventional imaging technology.

5.3 Positioning the patient/X-ray tube assembly

Ask the patient to take a seat on the chair.
The operating elements of the unit should be out of reach of the patient.

Touch the tube assembly with both hands to position the tube.

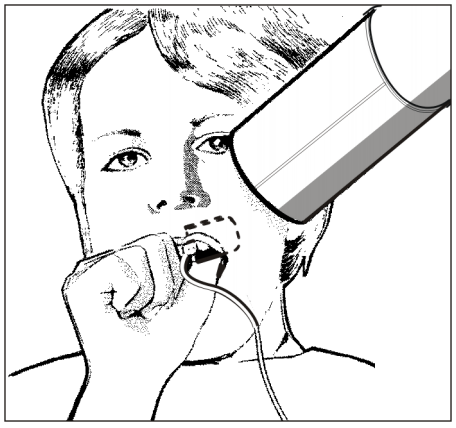


- **Parallel technique (with radiation field limitation)**

  Position the film or the X-ray sensor using a holding system for the parallel technique.

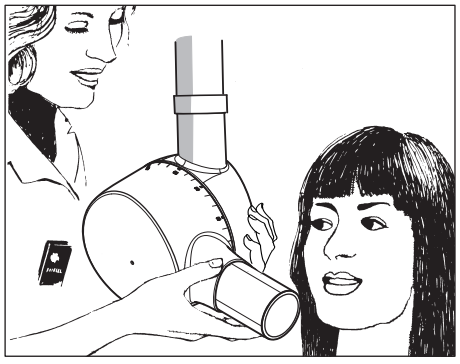
  For Sirona X-ray sensors, only the holding systems recommended by Sirona may be used.

  Please comply with the operating instructions for intraoral X-rays supplied with the sensors or films.



- **Half-angle technique (without radiation field limitation)**

  Position the film or the X-ray sensor.



- **Tilt angle**

  X-ray tube assembly at the occlusal plane

Upper jaw	
Molars	35°
Premolars and canines	45°
Anterior teeth	55°
Bite-wing exposure	10°
---	---
Bite-wing exposure	-0°
Anterior teeth	-20°
Premolars and canines	-10°
Molars	-5°
Lower jaw	

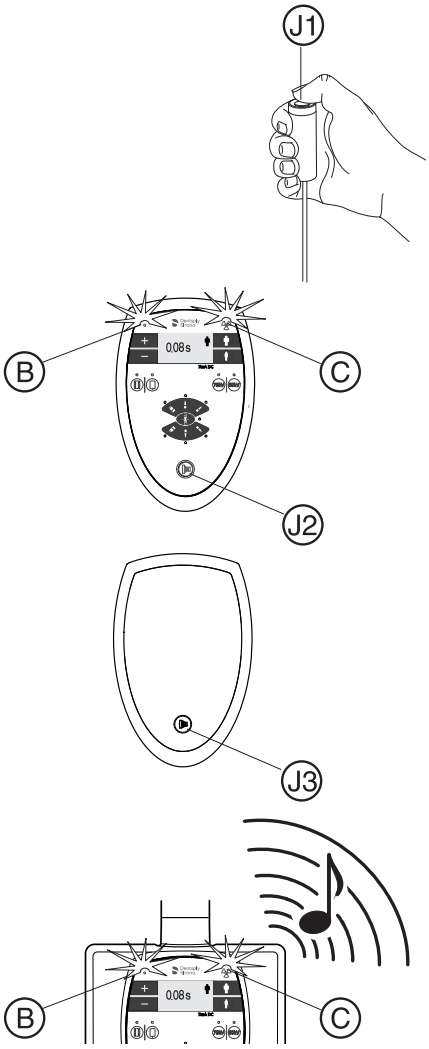
5.4 Releasing the exposure

⚠ CAUTION

Comply with the radiation protection provisions.

NOTICE

When using a digital sensor system, establish exposure readiness in Sidexis before you release the exposure, see Sidexis User Manual.



- Check the exposure data.
- Keep the patient and unit in sight.
- Press and hold down the release key **J1, J2 or J3**. The exposure is taken.

The (**X-RAY**) indicator **C** remains lit for the duration of the exposure. In addition, an acoustic signal sounds throughout the entire radiation time.

- The exposure has been completed when the radiation indicator goes out automatically and the acoustic signal stops.
- If the dose area product display is activated, the dose area product appears on the display.

If the release key is pressed again, the cooling-off period appears on the display The screen is then white.

The operational readiness LED **B** flashes until the automatic cooling-off period of the X-ray tube assembly has expired (automatic exposure block).

Canceling an exposure

If you let go of the exposure release button prematurely, the exposure is canceled. The elapsed exposure time flashes.
If the device is switched off at the main switch, the exposure is also canceled.

After any key (except for the release button) is pressed, the cooling time starts and the unit is once again ready for operation.

Repeat the X-ray if necessary.

If you are taking an X-ray with film, use a new film.

If you are taking a digital X-ray, ensure that the unit is ready to perform exposures.

NOTICE

Error message

If an error is detected during the exposure, the exposure is automatically canceled. The error code lights up on the digital display. At the same time, the operational readiness LED **(B)** flashes.
In the case of an error code, please call your service engineer.

IMPORTANT

Switch off

If the device is out of use for a lengthy period of time, it can be switched off at the main switch.

5.5 Adapting basic settings

Exposure times for the use of films with the sensitivity class E are factory pre-set, as well as the XIOS XG sensors.

IMPORTANT
The exposure times for sensor and film images are programmed separately. The factory pre-set sensor programming is configured for XIOS XG sensors.

The basic setting must be adjusted for other exposure conditions.

Deviating exposure conditions:

E for films of sensitivity class **E** such as Kodak Ekta Speed, Agfa-Dentus M2

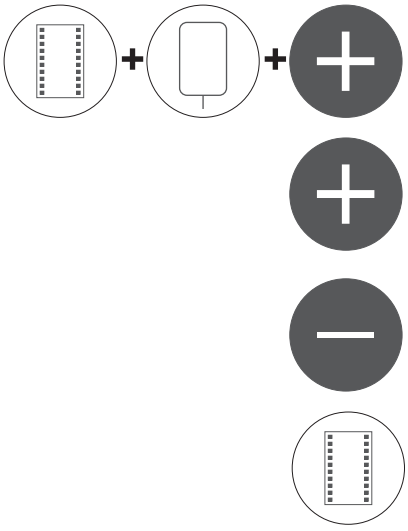
D for films of sensitivity class **D** such as Kodak Ultra Speed

Set the exposure time for films of sensitivity class **D** three levels higher with the plus button.

Film and development conditions

Varying film and development conditions can result in additional deviations of one time level up or down.

IMPORTANT
The configuration of the film and sensor keys permits flexible adjustment to various film sensitivity classes and sensors. It is also possible to set up the exposure adjustment for another film sensitivity class via the sensor key, if no sensor is being used.



✓ Reprogramming the base values

1. Press the **film**, **sensor** and **plus buttons at the same time**.
   Service S01 appears in the display.

2. Use the plus **or** minus key to select the base value that is to be changed:
   S01 corresponds to the base value for film
   S02 corresponds to the base value for sensor
   S03 corresponds to the software version

3. Confirm the entry with the Film key.
   The current base value for film or sensor is now displayed:



4. The base value can now be adjusted by pressing the plus or minus buttons.
   Each level corresponds to about a 25% extension or reduction in exposure time.
5. The entry can be confirmed by pressing the button with the adult patient icon. The new base value is now saved in the unit.
   To cancel this without changing, press the button with the child patient icon.
   In either case you will return to point 2 and can select the required base value again
   or
   conclude the process by switching the device off.

6 Hygiene and maintenance

6.1 General notes on cleaning and care

IMPORTANT

If necessary, suitable protective clothing must be worn and suitable protective equipment used at all times.

6.1.1 General notes on cleaning

Remove dirt, grime and disinfectant residue regularly using mild, commercially available cleaning agents.

NOTICE

When cleaning or disinfecting, liquids may enter the unit or the release button via the ventilation slots.

Electrical components of the system can be destroyed by liquids.

- ➢ Do not spray any liquids into the ventilation slots or the release button.
- ➢ First spray the liquid onto a cleaning cloth. Then wipe the ventilation slots or release button with the cleaning cloth.
- ➢ Make sure that no liquids run along the surface into the ventilation slots or release button.

6.1.2 General notes on disinfection

Only the external surfaces may be disinfected with approved chemical disinfectants.
Use only disinfectants that have been tested according to applicable national authorities or whose bactericidal, fungicidal, and virucidal properties have been verifiably tested and approved accordingly.

NOTICE

Cleaning, disinfection and care agents may contain aggressive ingredients.

Unsuitable cleaning, disinfection and care agents are harmful to health and attack the surface of the unit.

- ➢ Do NOT use: Substances containing phenol, peracetic acid, peroxide, or any other oxygen-splitting agents, sodium hypochlorite, or iodine-splitting agents.
- ➢ Use only care, cleaning and disinfection agents approved by Dentsply Sirona.

A continuously updated list of approved agents can be downloaded from the Internet on the online portal for technical documents. The portal can also be accessed directly via the following address: www.dentsplysirona.com/manuals
Click on the menu item *"General documents"* and then open the *"Care, cleaning and disinfection agents"* document.

If you do not have access to the Internet, you can order the list (REF **59 70 905**) in one of the following two ways:

- Order from your local dental depot
- Order from Dentsply Sirona:
  Phone: +49 (0) 62 51 / 16-16 70
  Fax: +49 (0) 62 51 / 16-18 18

6.1.3 Reprocessing of the sensor and film holder systems

IMPORTANT
For accessories, particularly those of sensor and film holder systems, note the instructions on reprocessing (cleaning, disinfection and sterilization) in the relevant instructions for use.

6.2 Reprocessing the parts of the X-ray unit with patient contact

Patients, users and users/third-parties come into contact with the X-ray unit. Contaminated surfaces are potential transmission paths.

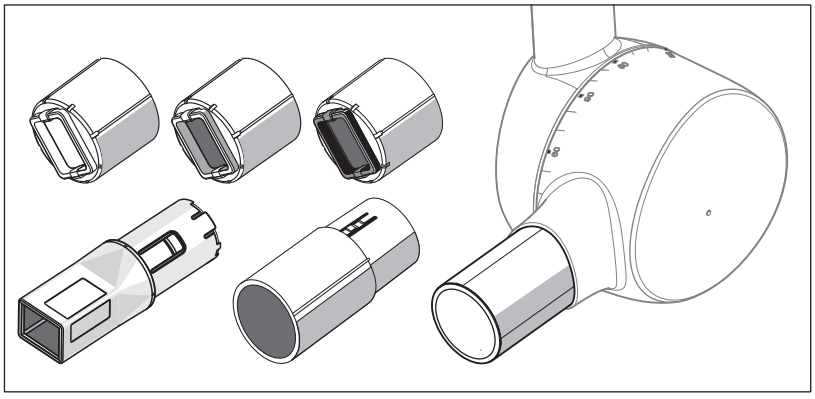
The risk of cross-contamination of patients, users or third parties is reduced by reprocessing combined with using disposable items (e.g. hygienic protective sleeves when applicable).

IMPORTANT
When reprocessing parts with patient contact, the instructions and regulations in the country-specific guidelines and standards must also be observed.

6.2.1 Manual cleaning and wipe disinfection

Manual cleaning and wipe disinfection

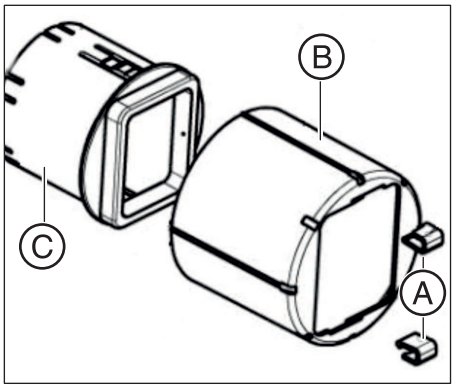
Valid for 8" cone, 12" cone extension round/square and radiation field limitations size 0+1+2.



NOTICE
Parts can be damaged
Use only 75% isopropanol, otherwise the parts may be damaged.

Instructions	
Initial treatment of the listed parts at the location of use	Directly after use, remove gross contamination with a disposable cloth or paper towel (if necessary).
Preparation for decontamination:	Not necessary except for the radiation field limitation (see notes on disassembly/ assembly).
Cleaning: manual	The parts can be cleaned manually. To do so, thoroughly wipe down and clean the components with a soft cloth soaked in water (at least drinking water quality) until there is no longer visible contamination.
Disinfection: manual	The parts can be manually wipe disinfected. After cleaning, perform wipe disinfection using 75% isopropanol. Ensure 10 minutes reaction time. After the reaction time elapses, remove disinfectant residues by wiping with a cloth soaked in water (at least drinking water quality).
Drying: manual	Wipe dry with a lint-free cloth.
Maintenance, inspection and testing	After every reprocessing operation, the parts must be checked for visible damage, cracks or discolorations before use. Parts with visible cracking, damage or discoloration may no longer be used and must be replaced.
Sterilization	Not applicable.
Storage	Store reprocessed parts in a dry, dust-free environment (if applicable).

6.2.2 Preparation for manual reprocessing of the radiation field limitation



1. Slide the two locking hooks (A) to the right or left until they come loose.
2. Detach the two locking hooks (A).
3. Slide the turning handle (B) of the insert (C) down.
4. The parts (A), (B) and (C) are now prepared for manual cleaning and disinfection.

Assembling the radiation field limitation

➢ Assemble in reverse order

6.2.3 End of service life

If the parts listed here are cleaned, disinfected, sterilized and maintained according to the instructions in this document, they are generally usable for the entire service life of the X-ray unit.
Dentsply Sirona does not define a maximum number of uses based on many years of experience with these reprocessable parts.

Nevertheless, the basic principle is that, when in doubt, the parts should be replaced early (see also information on maintenance, inspection and testing).

6.3 Inspection and maintenance

Inspection and preventive maintenance must be performed at scheduled intervals to protect the health and safety of patients, users, and other persons.

The information provided in the document *"Inspection and maintenance and safety-related checks"* REF 62 14 923 should be helpful here. The document can be downloaded at http://www.dentsplysirona.com/manuals.

Annual inspection

In order to ensure the operational safety and functional reliability of your product, you as the system owner should check the equipment at regular intervals (at least once a year) or commission your dental depot to do so.

In the event of visible external damage, commission your dental depot with an inspection of the unit.

Maintenance by the service engineer

In addition to the annual check to be carried out by the system owner or authorized persons, preventive maintenance must be performed after 4, 7 and 10 years, and then at two-year intervals.

Checking image quality

The image quality should be assessed by the system owner at regular intervals, at least once a year.

On digital image receptor systems, the degree of postprocessing (brightness or contrast adjustment) that is required in the image processing software (e.g. Sidexis) to produce satisfactory results is used as an assessment criterion.

Worldwide: Quality inspection

If a unit defect cannot be ruled out in the event of an image that cannot be evaluated, it is imperative a quality inspection is performed by an authorized service technician.

Germany: Constancy test

Unit:

Please note the legally required regular checks of the image quality of your X-ray device as stipulated in your country (e.g. the German Radiation Protection Ordinance). Dentsply Sirona provides you with the Sidexis software for easy implementation of this constancy test and for its documentation.
The required test specimen and the description of the constancy test come with the unit.

In the event of a constancy test that cannot be evaluated, the unit must be taken out of service. In this case, contact an authorized dealer.

Diagnostic monitor:

In Germany, a regular constancy test of the results monitor is required by the Radiation Protection Ordinance in accordance with DIN 6868-157. To easily implement the necessary legal requirements, Dentsply Sirona provides the Simocon 2 software. You can find this software and the operating instructions that belong to it on your Sidexis CD under the "Tools" section.

For conventional X-rays with film processing, the increase of the exposure time is used as an assessment criterion.

Country-specific requirements

Observe any possible additional country-specific requirements.

7 Error messages

Errors during the self-test are indicated by a five-digit number lighting up. The background color of the display is red.

⚠ CAUTION

If an error re-occurs after the unit has been switched off and switched on again, please call your service engineer.

Tell the service engineer which error message was displayed.

7.1 List of error messages

Error code	Reason and measures
E3 04 30	Release error - the release button may have been pressed during switch on Switch the device OFF and then ON again If the error persists, call a service engineer and report the error code
E1 11 88	Display mode ACTIVE - X-ray cannot be release Call a service engineer and report the error code
E1 04 03 E1 04 04 E1 04 06 E6 04 02	Internal error Press any button to acknowledge the error If the error persists, call a service engineer and report the error code
E5 04 50 E6 01 41 E6 01 61 E6 01 62 E6 04 01 E6 04 10 E6 04 11 E6 04 12 E6 04 20 E6 04 21 E6 04 40 E6 04 41 E6 04 42 E7 01 01 E7 01 21 E7 01 51	Internal error Switch the device OFF and then ON again and repeat the exposure If the error persists, call a service engineer and report the error code
E5 01 02 E5 01 12 E5 01 14 E5 01 22 E5 01 32 E5 01 42 E6 01 11 E6 01 13 E6 01 23 E6 01 31	Internal error Call a service engineer and report the error code

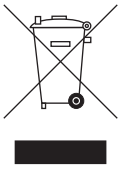
Error code	Reason and measures
E1 04 51	Safety circuit - the door switch may not be closed properly Switch the device OFF and then ON again, check the door switch If the error persists, call a service engineer and report the error code
E3 04 31	Button error - a button may have been pressed during switch on Switch the device OFF and then ON again If the error persists, call a service engineer and report the error code

8 Dismantling and disposal

8.1 Dismantling and reinstallation

When dismantling and reassembling the unit, proceed according to the installation instructions for new installation in order to guarantee its functioning and stability.

8.2 Disposal



In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This has been expressed using the icon of the “crossed out trash can”.

Disposal procedure

We feel responsible for our products from the first idea to their disposal. For this reason, we give you an option to return our old electronic and electrical devices.

If you wish to dispose of your devices, please proceed as follows:

In Germany

To initiate return of the electrical device, please send a disposal request to enretec GmbH. You have the following options here:

- Use the “Returning an electrical device” button under the “eom” menu item on the enretec GmbH homepage (www.enretec.de).
- Alternatively, you can also contact enretec GmbH directly.

  enretec GmbH
  Kanalstraße 17
  16727 Velten

  Tel.: +49 3304 3919-500
  E-mail: eom@enretec.de

In accordance with the national disposal regulations regarding old electrical and electronic devices (ElektroG), as the manufacturer, we assume the costs for disposing of the electrical and electronic devices in question. Disassembly, transport and packaging costs shall be borne by the owner/operator.

Prior to disassembly/disposal of the product, it must be fully prepared (cleaned/disinfected/sterilized).

If your unit is not permanently installed, it will be collected from the practice. If it is permanently installed, it will be picked up curbside at your address by appointment.

Other countries

For country-specific information on disposal, contact your local dental dealers.

8.2.1 Disposal of the X-ray tube assembly

The X-ray tube assembly in this device contains a tube which can implode, a lead lining and mineral oil.

9 Dose area product (DFP)

Information on patient exposure

Explanation

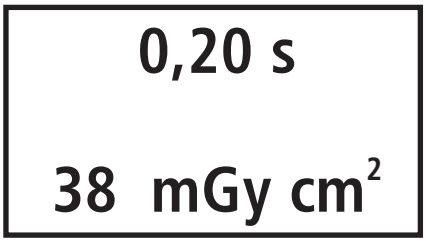
The patient's exposure to radiation can be determined in the tables below.

To compensate for measuring errors as well as for system and instrument variations, a tolerance of 20 % must be taken into account.

The radiation exposure is indicated as a dose area product (DFP) of the energy dose (mGy x cm^2) for every available kV level, cone length and aperture in the tables below.

Furthermore, the Heliodent Plus also permits the dose area product to be displayed immediately after exposure. The DFP appears on the display together with the exposure time used.
Ask your service engineer about any individual setting requests you may have.

Display (sample):



Tables with typical values for the dose area product (DFP)

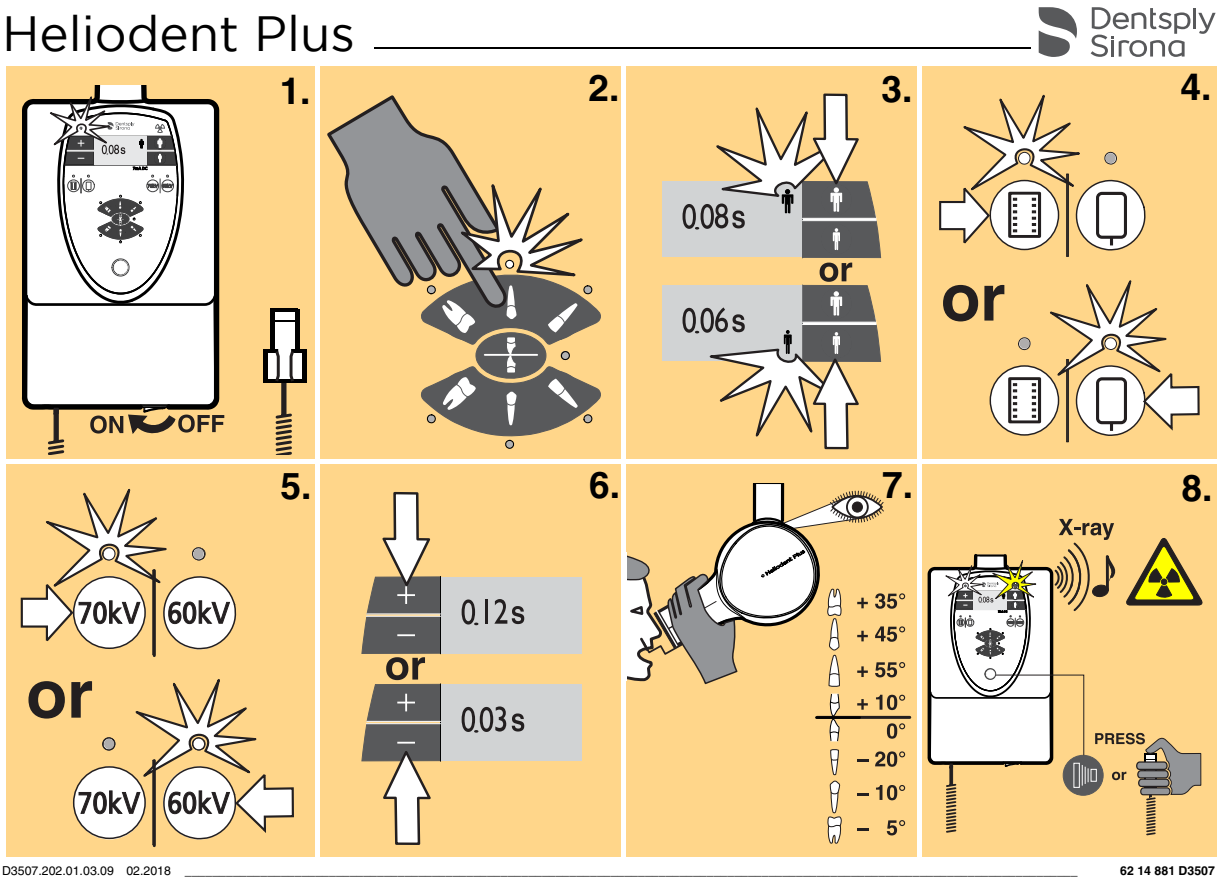
1st round cone 200 mm

	Round cone:		with radiation field limitation			
	200 mm (8")		Size 2 (3x4 cm)		Size 0 (1.8x2.4 cm) and size 1 (2x3 cm)	
	60kV	70kV	60kV	70kV	60kV	70kV
Time	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2
0.01	3	3	1	1	1	1
0.02	5	7	2	3	1	1
0.03	8	10	3	4	2	2
0.04	11	14	5	6	2	3
0.05	13	17	6	7	3	4
0.06	16	21	7	9	3	4
0.08	22	28	9	12	5	6
0.10	27	34	12	15	6	7
0.12	32	41	14	18	7	9
0.16	43	55	18	24	9	12
0.20	54	69	23	30	12	15
0.25	67	86	29	37	14	18
0.32	86	110	37	47	18	24
0.40	108	138	46	59	23	30
0.50	134	172	58	74	29	37
0.64	172	220	74	94	37	47
0.80	215	276	92	118	46	59
1.00	269	344	115	148	58	74
1.25	336	431	144	185	72	92
1.60	430	551	184	236	92	118
2.00	538	689	230	295	115	148
2.50	672	861	288	369	144	185
3.20	860	1102	369	472	184	236

2nd round cone 300 mm

	Round cone:		with radiation field limitation			
	300 mm (12")		Size 2 (3x4 cm)		Size 0 (1.8x2.4 cm) and size 1 (2x3 cm)	
	60kV	70kV	60kV	70kV	60kV	70kV
Time	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2
0.01	1	2	1	1	0	0
0.02	3	3	1	1	1	1
0.03	4	5	2	2	1	1
0.04	5	7	2	3	1	1
0.05	7	9	3	4	1	2
0.06	8	10	3	4	2	2
0.08	11	14	5	6	2	3
0.10	13	17	6	7	3	4
0.12	16	21	7	9	3	4
0.16	22	28	9	12	5	6
0.20	27	34	12	15	6	7
0.25	34	43	14	18	7	9
0.32	43	55	18	24	9	12
0.40	54	69	23	30	12	15
0.50	67	86	29	37	14	18
0.64	86	110	37	47	18	24
0.80	108	138	46	59	23	30
1.00	134	172	58	74	29	37
1.25	168	215	72	92	36	46
1.60	215	276	92	118	46	59
2.00	269	344	115	148	58	74
2.50	336	431	144	185	72	92
3.20	430	551	184	236	92	118

10 Brief Operating Instructions



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

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