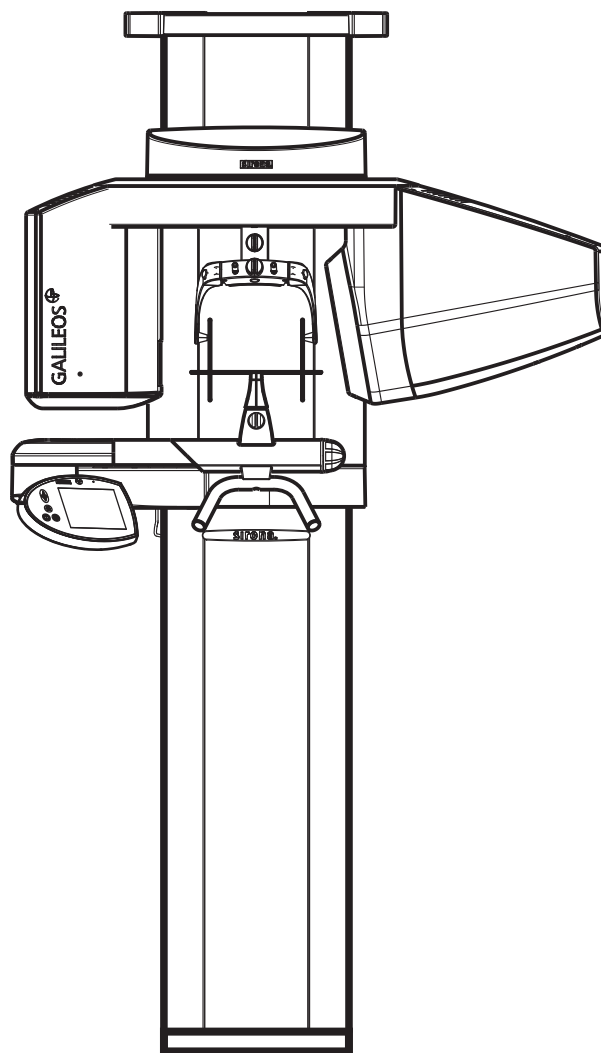


GALILEOS

Operating Instructions

English





General information

Dear Customer,

Thank you for purchasing your **GALILEOS** X-ray device.

The GALILEOS system consists of an X-ray device that uses a cone beam with a rotational sequence to provide two dimensional images and three dimensional volume reconstructions of the head area, including both the ENT and the dentomaxillofacial areas, for use in planning and diagnostic support.

The system also includes a package of PC software modules (GALAXIS, REKO Software) which extend the capabilities of SIDEXIS to include the handling of 3D data. This includes the 3D reconstruction, storage, retrieval, viewing and processing of 3D image data.

The **technical documentation** supplied is also part of the product. Keep these documents handy at all times.

To safeguard your warranty claims, please complete the attached "**Installation Report/Warranty Passport**" together with the service engineer immediately after the installation of your unit.

Please familiarize yourself with the unit by reading through these **Operating Instructions** before taking any X-rays of patients. Always observe the valid **radiation protection regulations** and **warnings**.

These operating instructions presuppose that you are familiar with the use of the SIDEXIS software.

SIRONA requires regular constancy tests to ensure the image quality.

Your **GALILEOS** Team

Maintenance

In the interest of the safety and health of patients, users and other persons, inspection and preventive maintenance must be performed at scheduled intervals to ensure the operational reliability and functional safety of your product (IEC 60601-1 / DIN EN 60601-1 etc.).

The system owner must ensure that all inspections and maintenance events take place.

If the system owner fails to fulfill the obligation to have inspections and maintenance work performed or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for resulting damage.



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1 Warning and safety information

1.1 General safety information

Identification of warning and safety information

To prevent any personal injury or material damage, please observe the warning and safety information provided in the present operating instructions. All such information is highlighted by the signal words **NOTE**, **CAUTION** or **WARNING**.

Symbols used



Observe accompanying documents
(on rating plate)

Intended use

The GALILEOS system consists of an X-ray device that uses a cone beam with a rotational sequence to provide two dimensional images and three dimensional volume reconstructions of the head area, including both the ENT and the dentomaxillofacial areas, for use in planning and diagnostic support.

The system also includes a package of PC software modules (GALAXIS, REKO Software) which extend the capabilities of SIDEXIS to include the handling of 3D data. This includes the 3D reconstruction, storage, retrieval, viewing and processing of 3D image data.

This system must not be used in areas subject to explosion hazards.

With room temperatures $> 35^{\circ}\text{C}$ ($> 95^{\circ}\text{F}$) Sirona recommends the use of an air conditioning system.

Recommended operating temperature: $< 35^{\circ}\text{C}$ ($< 95^{\circ}\text{F}$)

Caution:

Federal Law (USA) restricts sale of this device to or on the order of a physician, dentist or licensed practitioner.

Maintenance and repair

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.

We suggest that you request a certificate showing the nature and extent of the work performed from those who carry out such work; it must contain any changes in rated parameters or working ranges (if applicable), as well as the date, the name of the company and a signature.

Modifications to the system

Modifications to this system 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.

Combination with other equipment

Permissible combinations are specified in the Declaration of Conformity and confirmed by the system integrator (service engineer).

Ventilation slots

Under no circumstances may the ventilation slots on the unit be covered, since otherwise the air circulation will be obstructed.

Do not spray disinfectants or other similar products into the ventilation slots.

X-raying of patients

X-rays of patients must be taken only when the system works without errors.

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

The movements of the unit must not be obstructed by physical constitution nor clothing, dressings, wheelchairs or hospital beds!

Do not leave the patient unattended in the unit.

Electromagnetic compatibility (EMC)

The GALILEOS X-ray unit complies with the requirements of IEC 60601-1-2: 2001.

Medical electrical equipment is subject to special precautionary measures regarding EMC. It must be installed and operated as specified in the document "Installation Requirements".

If high-voltage systems, radio link systems or MRI systems are located within 5 m of the unit, please observe the guidelines the installation requirements.

Portable and mobile RF communications equipment may interfere with medical electrical equipment. Therefore, the use of mobile wireless phones in practice or hospital environments must be prohibited.

Please also observe the ESD protective measures in Chapter 1.2.

Precautionary measures when switching on the unit

Following extreme temperature fluctuations, condensation may occur; therefore please do not switch on the system until it has reached normal room temperature (see chapter "Technical Description").

No patient may be positioned in the unit during power-on.

In case of an error that requires switching the unit off and back on again, the patient must be removed from the unit, at the latest before switching the unit on again!

Emergency stop (not included in the scope of supply)

If any parts of the unit touch the patient during the rotary movement, let go of the exposure release button (X-Ray) immediately or stop the unit at once by actuating the unit main switch or an Emergency Stop switch!

Disturbance of electronic devices worn on the patient's body

To prevent the malfunctioning of electronic devices and data storage devices, e.g. radio-controlled watches, telephone cards, etc., these objects must be removed prior to X-raying.

Radiation protection

The valid radiation protection regulations must be observed.

The operator should move as far away from the X-ray tube assembly as allowed by the coiled cable of the exposure release button.

The statutory radiation protection equipment must be used.

With the exception of the patient, no other persons without radiation protection are allowed to stay in the room. In exceptional cases, a third person may provide assistance, but not the practice staff. During the whole exposure, visual contact with the patient and the unit must be maintained.

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

Hygiene information

The bite block should be resterilized for each new patient to prevent any possible transmission of infective agents which might under certain circumstances cause serious illnesses.

Also be sure to use hygienic protective sleeves.

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

Structural alterations

If structural alterations are made in the immediate vicinity of the unit, a technical check must be made by the service engineer.

Dismantling and reassembly

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

The X-ray unit must be recalibrated whenever structural alterations in the area surrounding the X-ray room or new installations have been performed.

Disposal

It generally applies that any disposal of this product must comply with the relevant national regulations. Please observe the regulations applicable in your country.

Within the European Economic Community, Council Directive 2002/96/EU (WEEE) requires environmentally sound recycling/disposal of electrical and electronic devices.



Your product is marked with the adjacent symbol. Disposal of your product with domestic refuse is not compatible with the objectives of environmentally sound recycling/disposal.

The black bar underneath the "garbage can" symbol means that it was put into circulation after Aug. 13, 2005. (see EN 50419:2005)

Please note that this product is subject to Council Directive 2002/96/EU (WEEE) and the applicable national law of your country and must be recycled or disposed of in an environmentally sound manner.

The X-ray tube assembly of this product contains a tube with a potential implosion hazard, a small amount of beryllium, a lead lining and mineral oil.

Please contact your dealer if final disposal of your product is required.

The system incorporates Class 1 laser products.

The light localizer is used for correct patient positioning. It must not be used for any other purposes.

A minimum distance of 100mm (4") between the eye and the laser is required. Do not stare into the beam. Its safe operation is described in chapter 6.3 "Positioning the patient".

The light localizer may be switched on only if it is functioning properly and faultlessly. Repair work must be carried out by authorized staff only.

Do not look directly into the beam.



CAUTION

Do not use any other lasers and avoid changing any settings or processes not described in these instructions, as such actions could result in hazardous radiation exposure.

Laser light localizer used



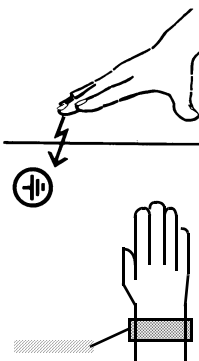
1.2 ESD protective measures

ESD stands for **E**lectro**S**tatic **D**ischarge.



CAUTION

*Connector pins or sockets bearing ESD warning labels must not be touched or interconnected **without ESD protective measures**.*



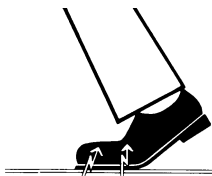
ESD protective measures include:

- Procedures for preventing electrostatic charge build-up (e.g. air conditioning, air moistening, conductive floor coverings and non-synthetic clothing)
- Discharging the electrostatic charges of your own body on the frame of the unit, the protective ground wire or large metallic objects
- Connecting yourself to ground using a wrist band.

We therefore recommend that all persons working with this system be instructed on the significance of this warning label. Furthermore, they also should receive training in the physics of electrostatic discharges which can occur in the practice and the destruction of electronic components which may result if such components are touched by electrostatically charged USERS.

The content of this training is explained in Chapter 1.3.

1.3 About the physics of electrostatic charges



ESD stands for **E**lectro**S**tatic **D**ischarge. Electrostatic discharge must be preceded by electrostatic charging.

Static electric charges generally build up whenever two bodies are rubbed against each other, e.g. when walking (shoe soles against the floor) or driving a vehicle (tires against the street pavement). The amount of charge depends on several factors:

Thus the charge is higher in an environment with low air humidity than in one with high air humidity; it is also higher with synthetic materials than with natural materials (clothing, floor coverings).

The following rule of thumb can be applied to assess the transient voltages resulting from an electrostatic discharge.

An electrostatic discharge is:

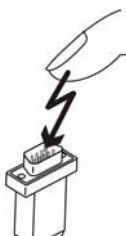
- perceptible at 3,000 V or higher
- audible at 5,000 V or higher (cracking, crackling)
- visible at 10,000 V or higher (arc-over)

**1 nanosecond = 1/1,000,000,000 second =
1 billionth of a second**

The transient currents resulting from these discharges have a magnitude of 10 amperes. They are not hazardous for humans because they last for only several nanoseconds.

Voltage differentials exceeding 30,000 volts per centimeter may lead to a charge transfer (electrostatic discharge, lightning, arc-over).

Integrated circuits (logical circuits and microprocessors) are used in order to implement a wide variety of functions in dental/X-ray/CEREC systems. The circuits must be miniaturized to a very high degree in order to include as many functions as possible on these chips. This leads to structure thicknesses as low as a few ten thousandths of a millimeter.



It is obvious that integrated circuits which are connected to plugs leading outside of the unit via cables are sensitive to electrostatic discharge. Even voltages which are imperceptible to the user can cause breakdown of the structures, thus leading to a discharge current which melts the chip in the affected areas. Damage to individual integrated circuits may cause malfunction or failure of the system.

To prevent this from happening, the ESD warning label next to the plug warns of this hazard.

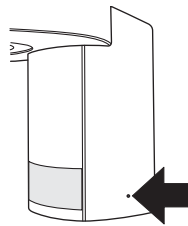
2 Technical description

Chassis:	Model designation	GALILEOS
	Nominal voltage:	200 – 240V
	Permissible deviation:	±10%
	Permissible drop under load:	10%
	Rated current:	6A
	Nominal power output X-ray tube:	0.6kW at 85kV/7mA
	Current time product X-ray tube:	42mAs
	Nominal frequency:	50/60 Hz
	Internal line impedance:	max. 0.8Ohm
	Main building fuse:	25A slow-blow (16A for standalone connection)
	Power consumption:	0.9kVA
X-ray tube assembly:	Focal spot size acc. to IEC 60336, measured in the central X-ray beam:	0.5
	kV:	85 kV
	mA:	5/7 mA
	Pulsed mode:	10 ms – 30 ms
	Total filtration of X-ray tube assembly	> 2.5 Al/90 IEC 522
	Cone-beam angle:	collimated to approx. 24°
Detector:	Type: Image intensifier (I.I.), Thales	
	Active input window size:	215 mm (8 1/2") diameter
	Camera:	Pixels: 1000 ²
		FPS: 15 – 30
Geometry:		Dynamics: 12 bits, (4096 brightness values), 60 dB
	Source-I.I. converter coating distance (central X-ray beam)	510 mm (20 1/16")
	Source-isocenter distance (central X-ray beam)	333 mm (13 1/8")
	Source-skin distance (minimum distance)	approx. 220 mm (8 5/8")
Scanning operation:	Orbital angle	204°
	Scan time	approx. 14 s
	Number of single exposures	200

Reconstruction:

Marking of focal spot:

Filtered backprojection



Automatic exposure blocking (see page 46):

The duration of automatic exposure blocking (cooling period) depends on the set **kV/mA** level and the actual exposure time. Depending on the tube load, a pause duration of 8 s to 300 s is automatically set by the system.

Class I equipment
Degree of protection against electric shock:


Type B equipment



Degree of protection against ingress of water:

Ordinary equipment
(without protection against ingress of water)

Year of manufacture

 **20xx**
(on the rating plate)

Mode of operation:

Continuous operation

Long-term power output:

100W

Anode material:

Tungsten

Exposure parameters for determining leakage radiation:

7 mA/85 kV

Long time current for leakage radiation measurement:

0,14 mA

Transport and storage temperature:

Basic unit

-40°C – +70°C (-40°F – 158°F)

Detector

-30°C – +55 °C (-22 °F – 131 °F)

Air humidity:

10% – 95% without condensation

Admissible operating temperature:

from +10 °C to +35 °C (50 °F – 95 °F)

X-ray tube:

DF-151R – from Toshiba

**Minimum requirements for reconstruction PC
(included in the scope of supply):**

Processor:

2x 3.0 GHz, alternatively dual-core

RAM:

2 GB RAM

Hard disks:

> 200 GB

Operating system:

Windows XP Professional Service Pack 2 or newer

External drive:

1x DVD writer, dual-layer

**Minimum requirements for
SIDEXIS visualization PC
(included in the scope of supply):**

See SIDEXIS XG Operator's Manual.

Network:

Network: 100 MB Ethernet, 1 Gbit Ethernet recommended
Communication interface: RJ45 for LAN cable

The GALILEOS X-ray unit complies with IEC 60601-2-28/1993

The GALILEOS X-ray unit complies with IEC 60601-1-3/1994

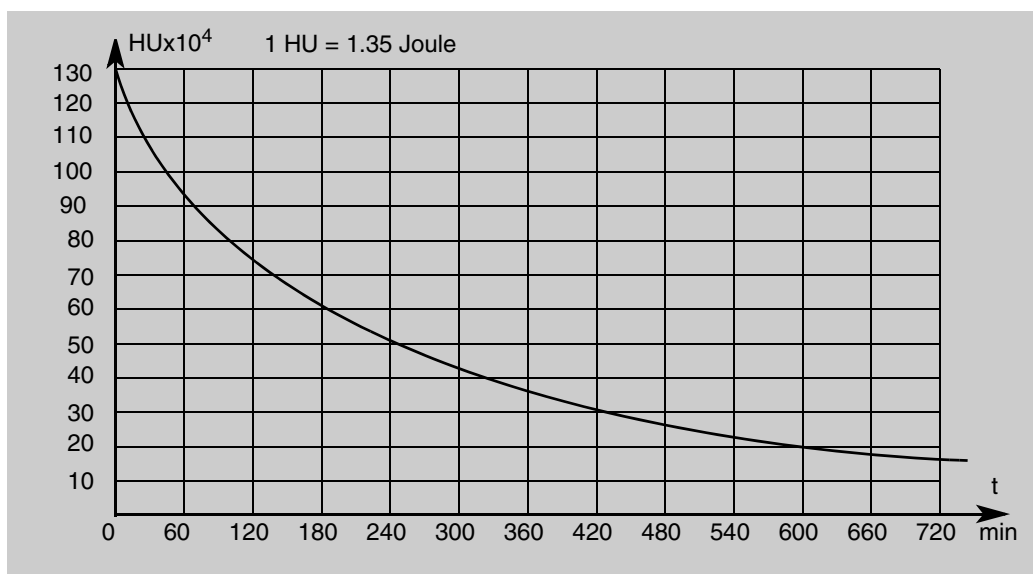
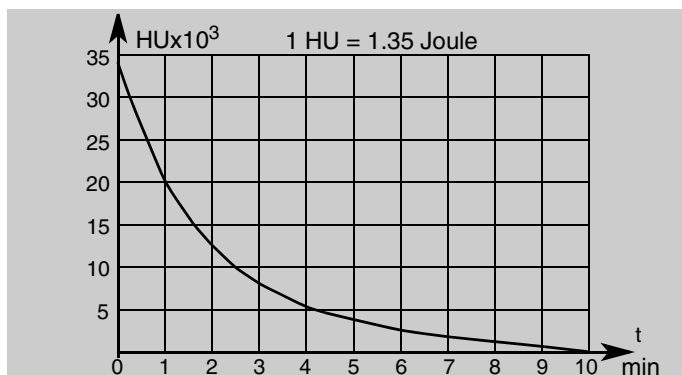
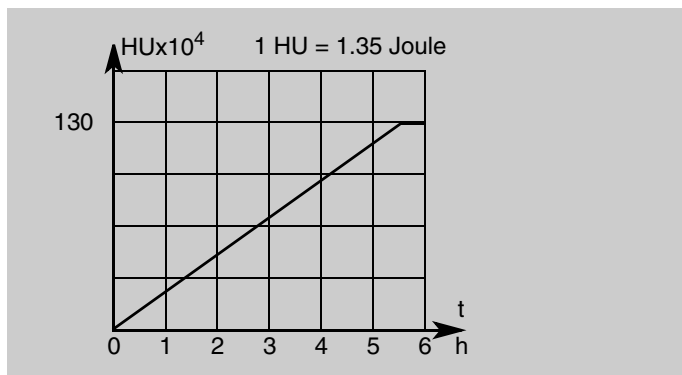
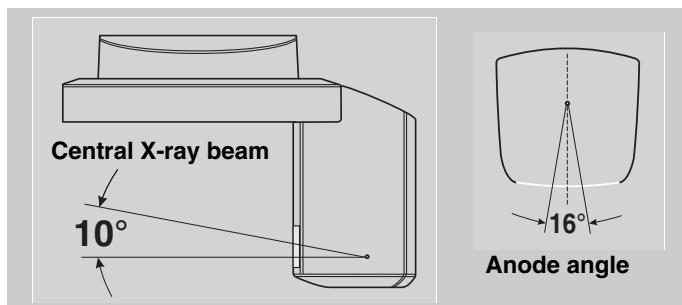
The GALILEOS X-ray unit complies with IEC 60601-2-7/1998

The GALILEOS X-ray unit complies with AS / NZS 3200.1.0

Original language: German

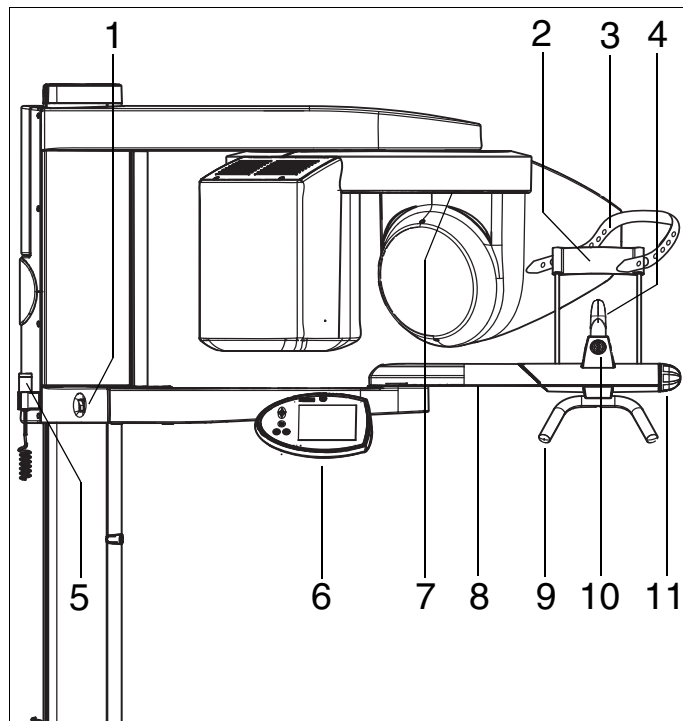


This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

Cooling curve of tube housing**Cooling curve of X-ray tube****Heating curve of tube housing****Central X-ray beam/anode angle**

3 Controls and functional elements

3.1 Operating and Display Elements



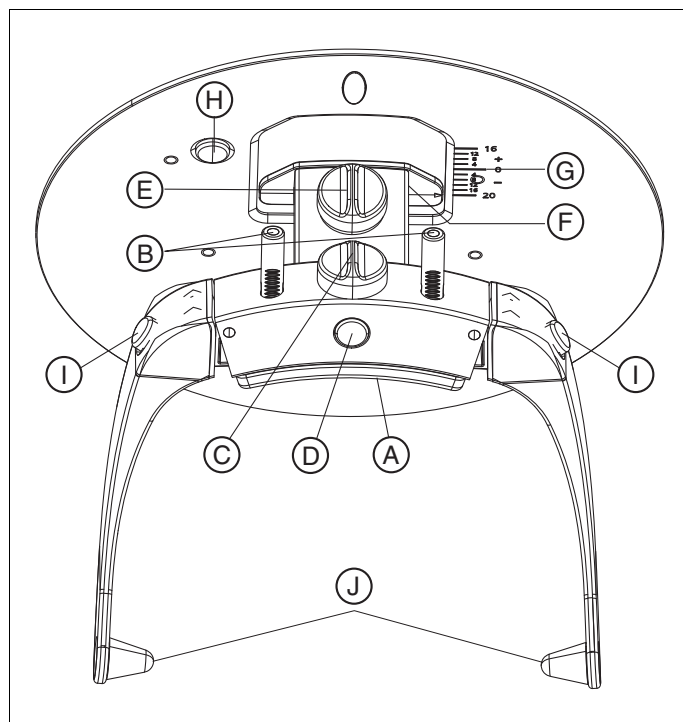
on the GALILEOS

- 1 Main switch
- 2 Forehead support (contact upholstery detachable and sterilizable)
- 3 Head fastening strap
- 4 Bite block (sterilizable)
- 5 Release button

i NOTE

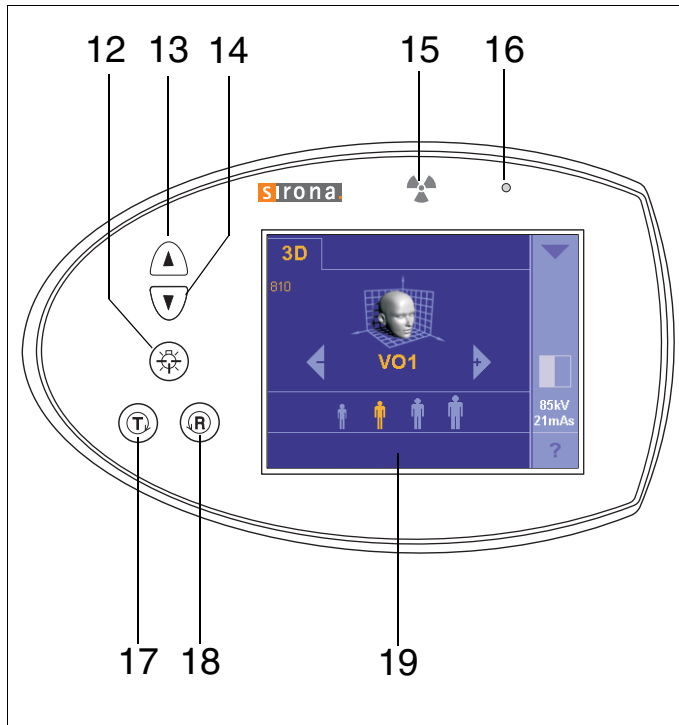
If the system is installed with a remote control, the release button is attached to the remote control.

- 6 EasyPad (swivelable control panel)
- 7 Light localizer, central light beam for face center
- 8 Swivel arm for patient immobilization
- 9 Handles for patient
- 10 Rotary knob for bite-block locking device
- 11 Rotary knob for swivel-arm lock and forehead support setting



on the head fixation device

A	Forehead rest (in two versions)
B	Forehead rest adjustment
C	Headband adjustment
D	Pushbutton for resetting forehead rest
E	Lock for vertical adjustment
F	Scale for vertical adjustment (adjustment range +/- 10 mm)
G	Scale for horizontal adjustment (adjustment range +16 mm /-20 mm)
H	Locking button for horizontal adjustment and unlocking head fixation device for removal
I	Locking buttons for headband
J	Ear plugs



Controls and displays on the Easypad with touchscreen

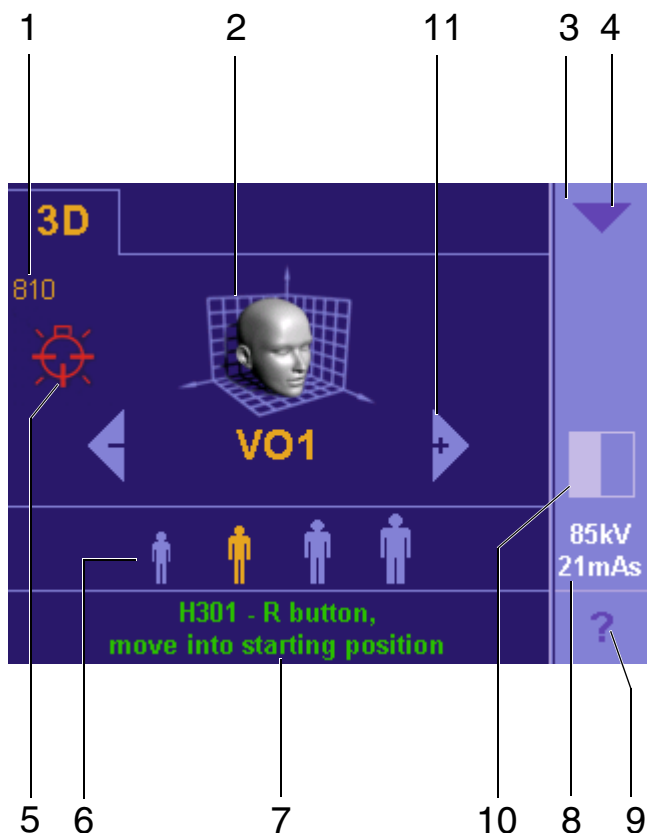
- 12** Light localizer ON/OFF
- 13** “Unit up” arrow key
- 14** “Unit down” arrow key
- 15** Optical radiation indicator
- 16** “Unit ON” LED
- 17** “T” key for test cycle without radiation
- 18** “R” key for unit return
- 19** Touchscreen – touch-sensitive screen



CAUTION

Never touch the touchscreen with sharp or pointed objects (ball-point pens, pencils, etc.)!

3.2 General touchscreen functions on Easypad



Touchscreen = touch-sensitive screen, i.e. different functions can be triggered by touching the screen surface.

Color codes:

orange – selected
white – presets
light blue – selectable
gray and white – auxiliary symbols

Touchscreen symbols

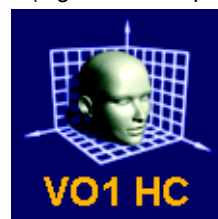
- 1 Display of height setting value
- 2 Display of program VO1, VO1 HC (with high contrast option) or VO2, VO2 HC (with high contrast option).

The grid contrast shows the corresponding contrast option.

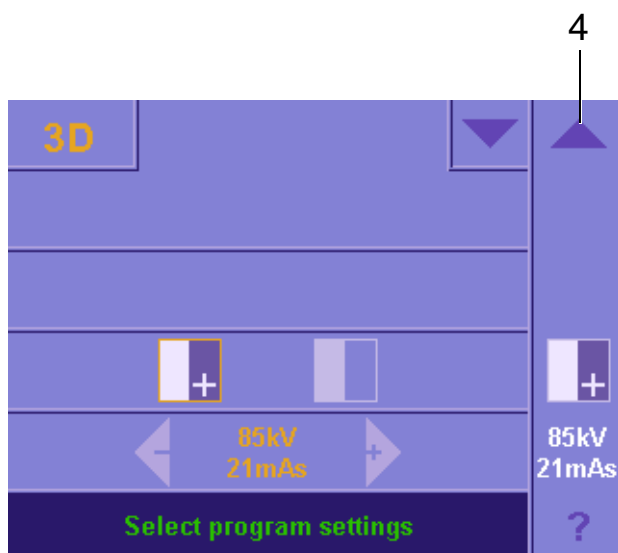
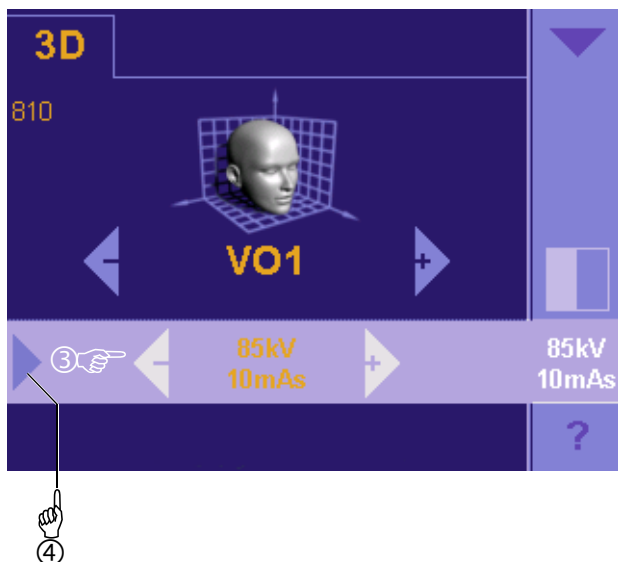
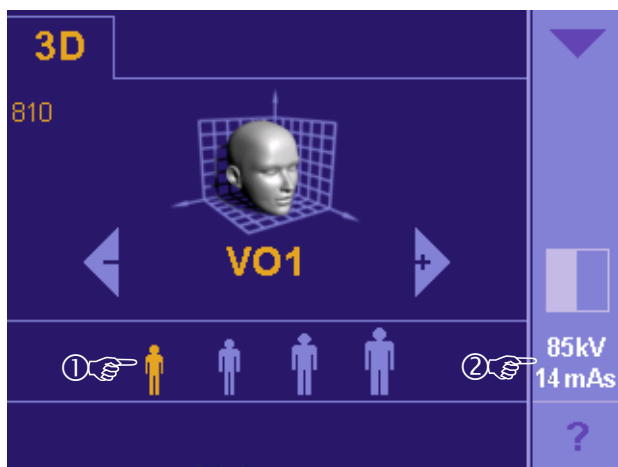
Normal contrast (without high contrast option):



High contrast (high contrast option (HC)):



- 3 Submenu column (options)
- 4 Blue arrows: Select submenu, close menu
- 5 Red symbol for light localizer ON (is displayed as long as the laser light of the light localizer is switched on)
- 6 Patient symbol keys for selecting preset exposure parameters
- 7 Comment line for help and error messages
- 8 Display/setting of exposure parameters (kV/mAs)
- 9 When you touch the ? symbol, the help or info screen is displayed
- 10 Display/settings of the high contrast option
- 11 Program selection keys –/+



Setting the exposure parameters (kV/mAs values) (level 1)

The preset exposure parameters are selected with the patient symbol keys.

85kV/ 10mAs	85kV/ 14mAs	85kV/ 21mAs	85kV/ 28mAs	85kV/ 35mAs	85kV/ 42mAs

If the default kV/mA combinations do not provide satisfactory results, you also can set two additional combinations (85 kV/10 mAs and 85 kV/42 mAs).

- Select one of the outer patient symbol keys.
 - Far left patient symbol key:
Sets to 85 kV/10 mAs
 - Far right patient symbol key:
Sets to 85 kV/42 mAs
- Touch the exposure parameter display in the submenu column.
The submenu line for selecting the exposure parameters appears.
- Use the –/+ keys in the kV/mAs submenu line to select the exposure parameters:
 - 85 kV/10 mAs
(left patient symbol key, then – key) or
 - 85 kV/42 mAs
(right patient symbol key, then + key)
- Close the kV/mAs submenu line by touching the blue arrow (on the left in the line).
The currently selected exposure parameters are displayed on the right in the submenu column.

i NOTE

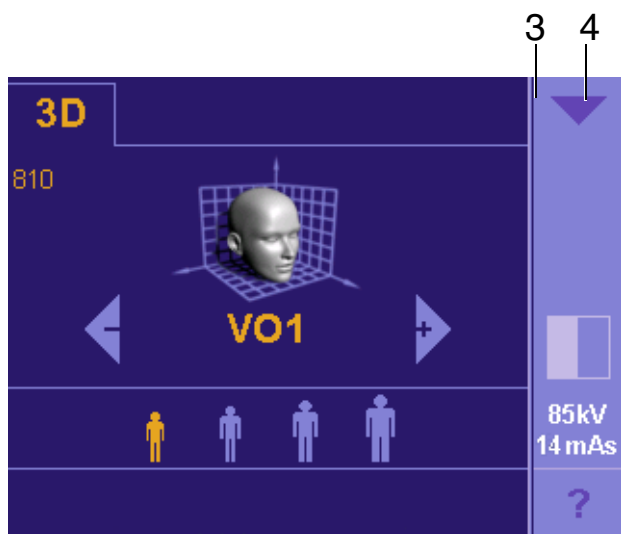
This setting is only temporarily valid for this exposure. It will then be reset to the factory setting immediately afterwards. To permanently change the setting, you must edit the factory-adjusted exposure parameter settings (see page 19).

Program settings (Level 2)

You can also display all of the program settings and make the settings described above in a second program level.

To access the second program level, touch the blue arrow (4) in the upper right corner of the touchscreen; the arrow will point upward then.

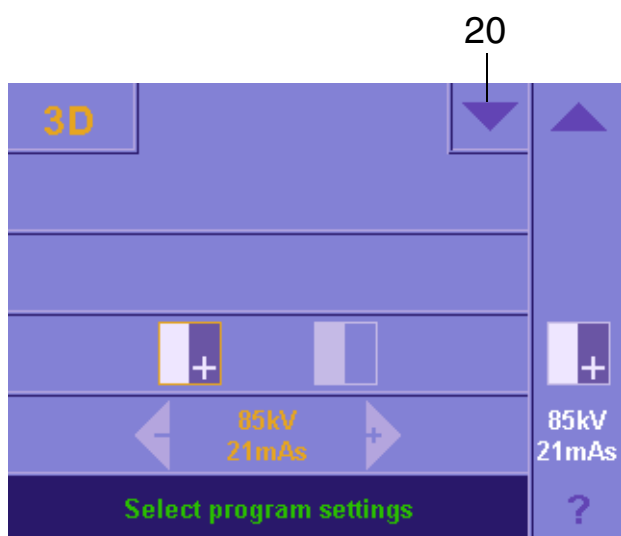
After having made your selections, you can return to program level 1 only by touching the blue arrow (4) once again.



Basic settings menu (Level 3)

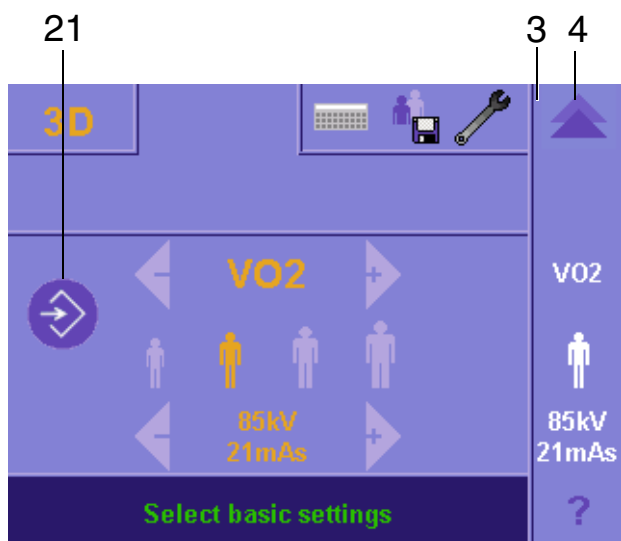
In a third level, you can freely select and then program specific exposure parameters for the program.

To access the third program level, touch the arrow pointing downward (4) at the top of the submenu column (3) in Level 1.



Level 2 is displayed.

Touch the blue arrow (20) on the left.



Level 3 is displayed.

You can enter the new kV/mAs values for the respective preselected patient symbol here.

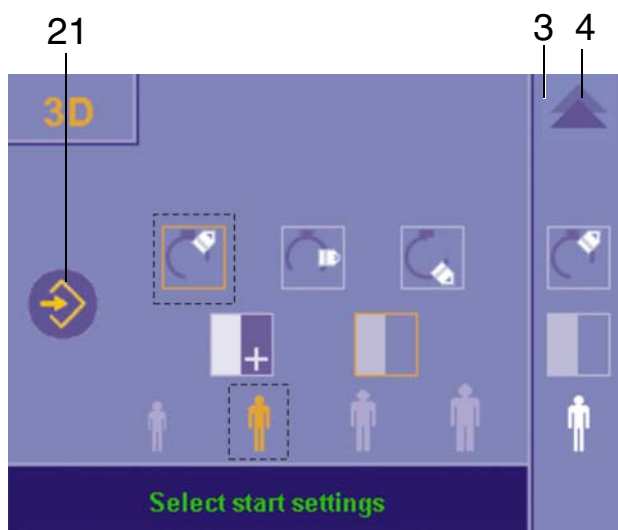
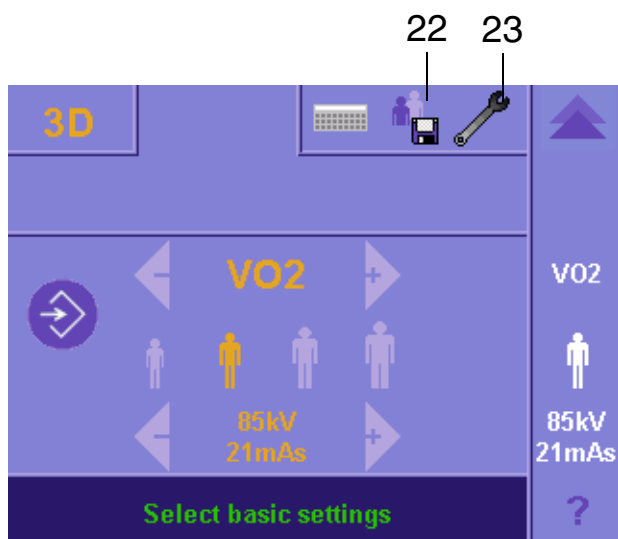
Programming is done by touching the memory symbol (21).

The respective patient symbol and the corresponding kV/mAs value are displayed on the right in the submenu column.

i NOTE

This setting is now permanently stored. The original factory setting has been overwritten.

Switch back to Level 1 by touching the blue double arrow (4) at the top of the submenu column on the right.



Service start settings (Level 4)

Various factory preset start parameters can be reprogrammed in level 4. They will then become effective after each unit power-on resp. after each new exposure.

You can reach Level 4 by touching the disk icon (22) in the basic settings menu (Level 3).

In Level 4, you can reprogram the starting or entry position (icon on left as per factory setting) and the patient icon preference (2nd icon from left as per factory setting).

Using this function, you can adapt the patient entry position to the local space conditions.

The open segment of the ring in the icons indicates the direction of patient entry.

To perform a particular change, touch the desired icon; the icon then turns orange and is also displayed in the submenu column (4).

The Memory icon (21) then turns and stays yellow until the new default setting has been saved by touching the Memory icon (21).

You can close this menu again only by touching the blue double arrow (4) in the upper right corner.

The display always returns to the standard menu (program level 1).

i NOTE

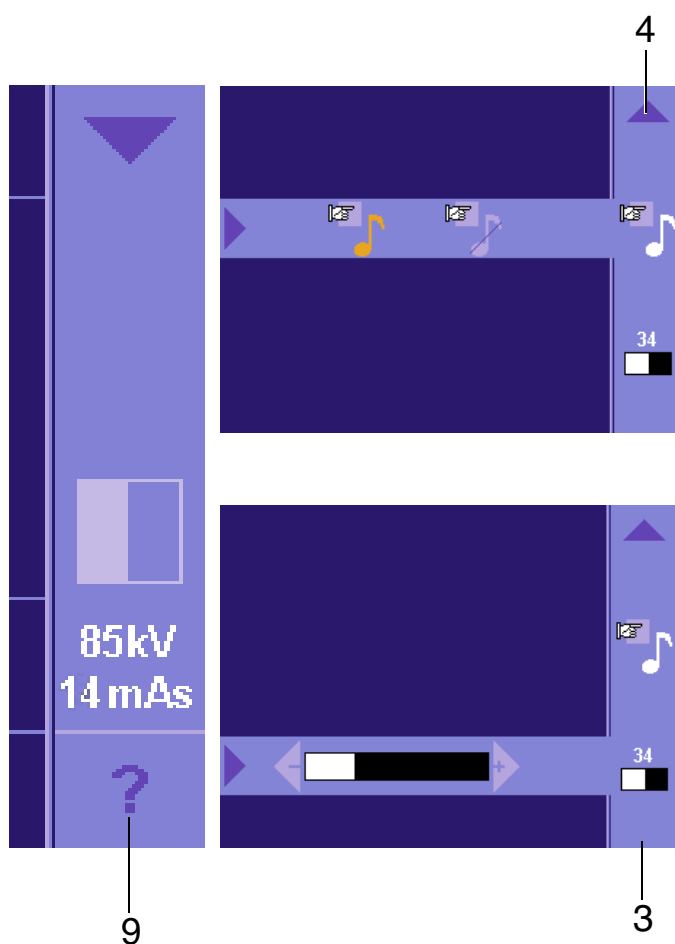
The icons framed with a broken line represent the factory settings.

Service menu

The Service menu is intended **only for the service engineer**.

The service engineer can go to the Service menu from the Basic Settings menu (Level 3) via the **wrench symbol** (23) and a special input algorithm.

The **service engineer** can obtain more information on calling up the service menu and service routines by referring to the **Service Manual**.



Touchscreen settings

When you touch the question mark (9) in the lower right corner of the touchscreen, a touchscreen setting menu appears starting in the first level.

You can open two menu lines here by touching the corresponding symbols in column (3).

In the upper menu line, you can switch off the clicking tone of the touchscreen by activating the crossed-out musical note symbol.

In the lower menu line, you can adjust the intensity of the touchscreen display with the $-/+$ keys. During this adjustment a reference value appears above the symbol in column (3).

i NOTE

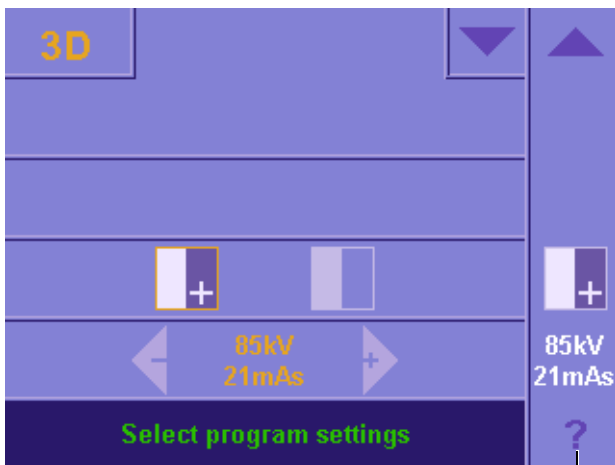
Switch the unit on for at least 10 minutes before adjusting the touchscreen intensity to ensure that the touchscreen has reached its full brightness. The contrast setting has been blocked until now (as denoted by an hour glass displayed above the contrast symbol).

To close the respective menu line, touch the blue arrow at the left end of the corresponding line or the relevant symbol in column (3).

To return to the previous level, touch the blue arrow (4) at the top of column (3).

Closing menu lines

- by touching the blue arrows
- by touching the corresponding symbol in the light blue area at the right margin.



9

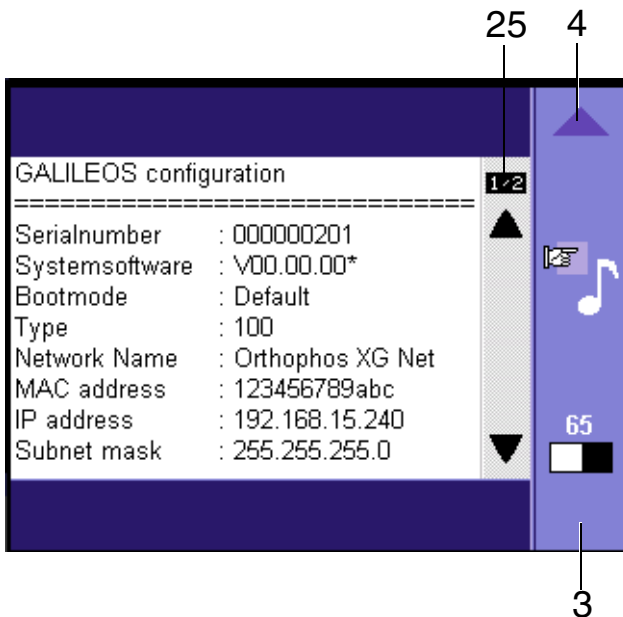
Info screen

Starting at level 2, the “**GALILEOS configuration**” info screen is displayed when you touch the question mark (9) in the lower right corner of the touchscreen.

System data which may be useful when contacting your service engineer are displayed here.

If this list is too long to be displayed all at once, a scroll bar for paging up or down appears on the right.

You can activate the “touchscreen click tone” and “touchscreen intensity setting” menu lines from the help screen in column (3) here as well.

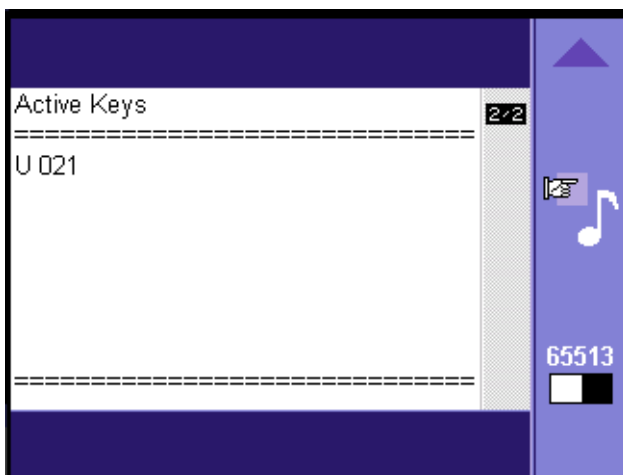


3

Checking the function activation

The page number and number of pages are displayed in a small black field (25) located at the top right of the info screen.

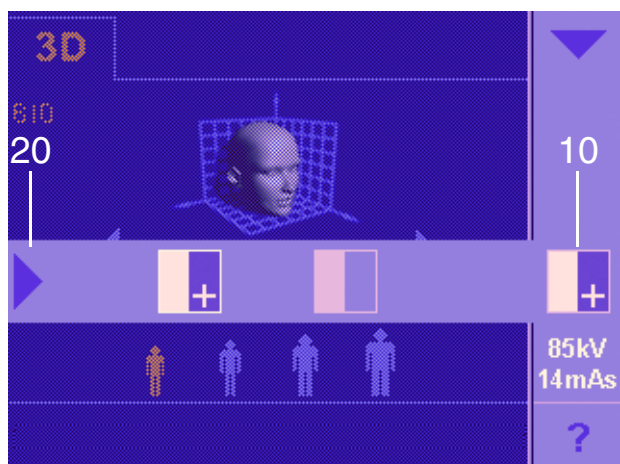
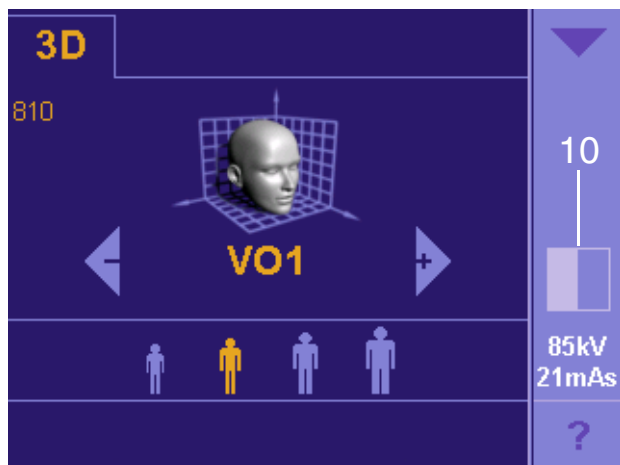
Press this field to scroll through the pages until the “Active Keys” page appears.



Information on function activation is displayed here.

To return to the previous level, touch the blue arrow (4) at the top of column (3).

3.3 High contrast option



Setting up the high contrast option (Level 1)

To select the high contrast option, proceed as follows:

Additional information on the indication: See the descriptions of the programs.

1. Touch the contrast symbol (10).
The submenu line to select the contrast level will be displayed.
2. Select the desired contrast level by touching the corresponding symbol:

High contrast:



Normal contrast:

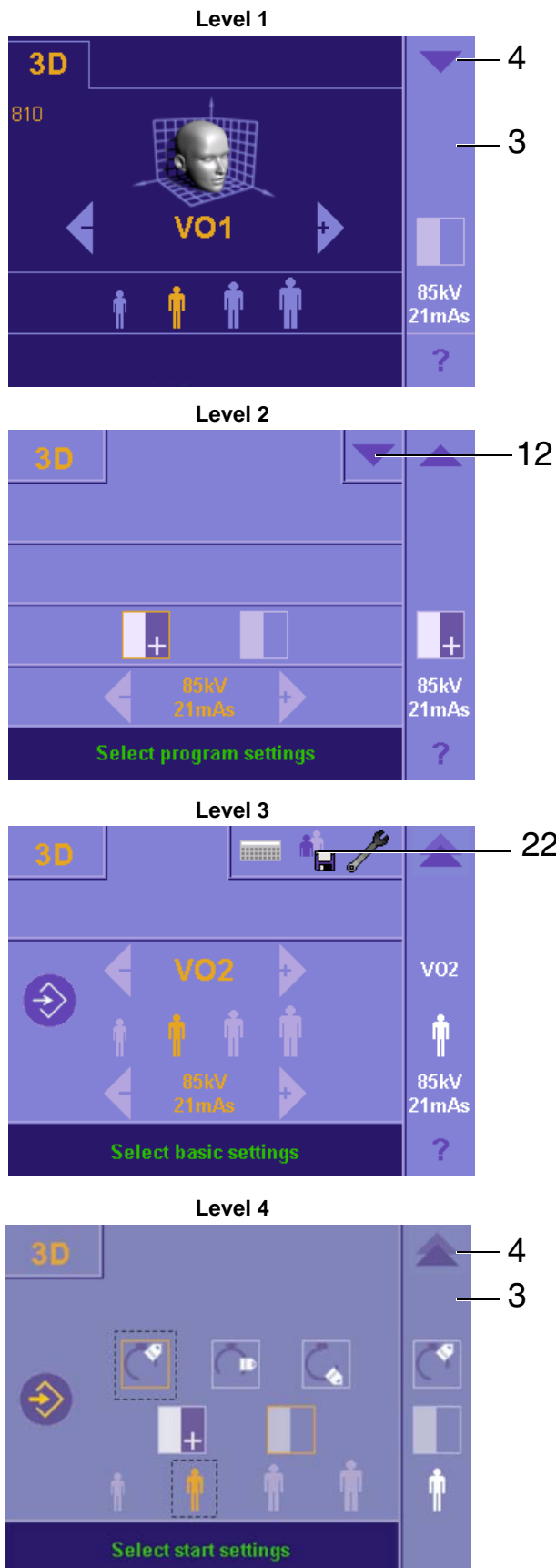


3. Close the submenu line Contrast Level by touching the blue arrow (20).

The currently selected contrast level is displayed with the corresponding contrast symbol (10) in the Submenu column on the right.

i NOTE

These settings only apply temporarily to the current exposure. After that, the settings return to the default values. To change the settings permanently, you have to change the default values for the contrast.



Changing the default setting for the high contrast option (Level 4)

Upon system delivery, the high contrast option will be disabled by default.

To generally activate the high contrast option, proceed as follows:

1. Touch the blue arrow (4) in the Submenu column (3).
Level 2 will be displayed.
2. Touch the blue arrow on the left (12).
Level 3 will be displayed.
3. Touch τη φλοππν δισκ συμβολ (22) in menu Basic Settings menu.
Level 4 will be displayed.
4. Select the desired contrast level in Level 4 by touching the corresponding symbol:

High contrast:



Normal contrast:



5. Change back to Level 1 by touching the blue double arrow (4) above the Submenu column (3).

The new default setting for the contrast level is displayed with the corresponding contrast symbol in the Submenu column on the right.



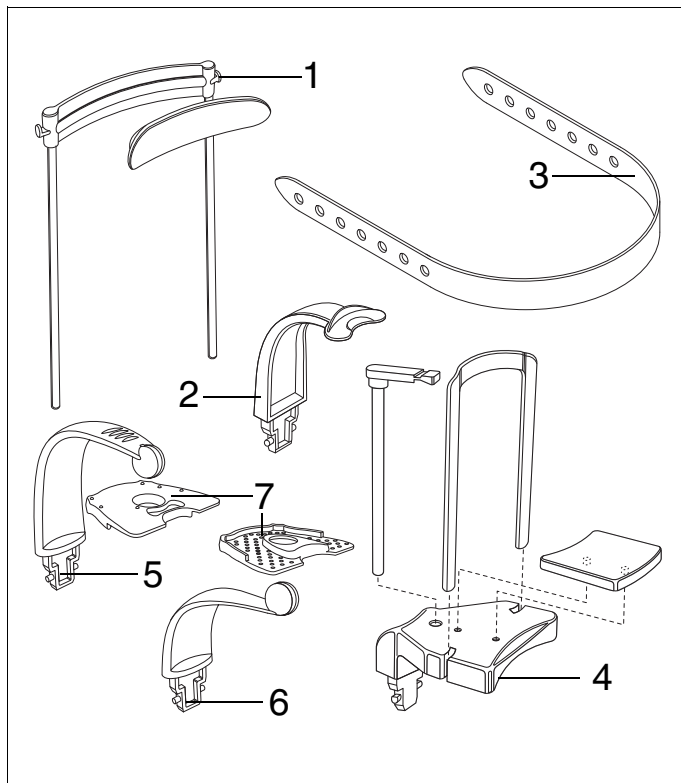
CAUTION

This setting has now been saved as the permanent value. The original factory default setting has been overwritten.

If the high-contrast option is changed again, repeat the same procedure and select another contrast level.

4 Accessories

4.1 Bite blocks, supports and fasteners

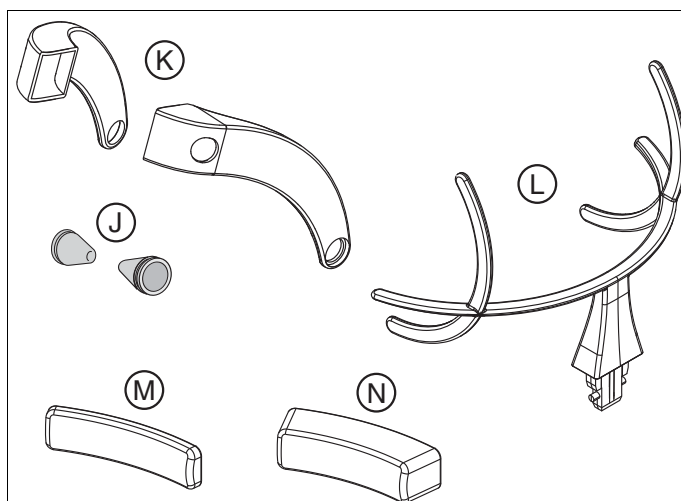


The accessories can be removed for cleaning.
The bite block and the ear plugs can be sterilized.

**Sterilize only in an autoclave at
134 °C (273 °F) and 2.1 bar for 3 min.**

For reorders:

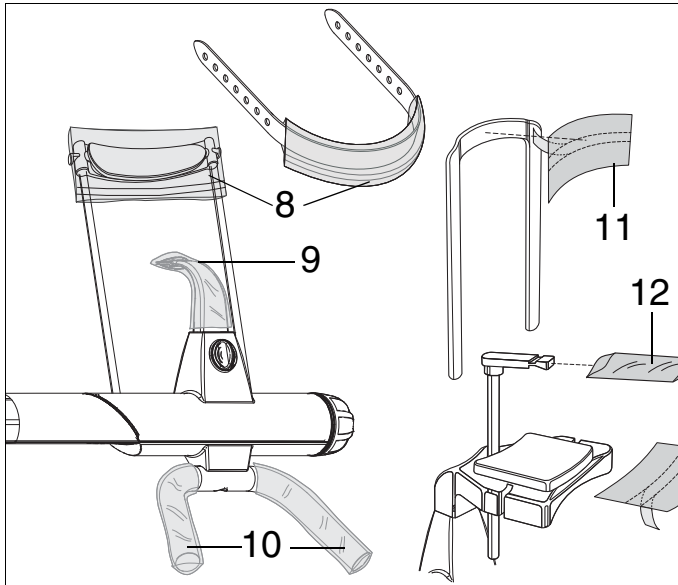
- 1 Forehead support
(contact upholstery can be removed
for cleaning and disinfection)
(1 pc) Order No. 61 34 931
- 2 Rigid bite block
(can be removed for cleaning and sterilization by ro-
tating the locking knob)
(5 pcs) Order No. 61 34 949
- 3 Head fastening strap
(2 pcs) Order No. 61 34 956
- 4 Chin rest, complete
(1 pc) Order No. 59 81 472
- 5 Spherical mandibular bite block holder (with symbol
for lower LJ) (1 pc) Order No. 61 50 226
- 6 Spherical maxillary bite block holder (with symbol for
UJ) (1 pc) Order No. 61 50 218
- 7 Spherical bite block plate
 - For single use only (not sterilizable)
 - Available from a specialized dealer.



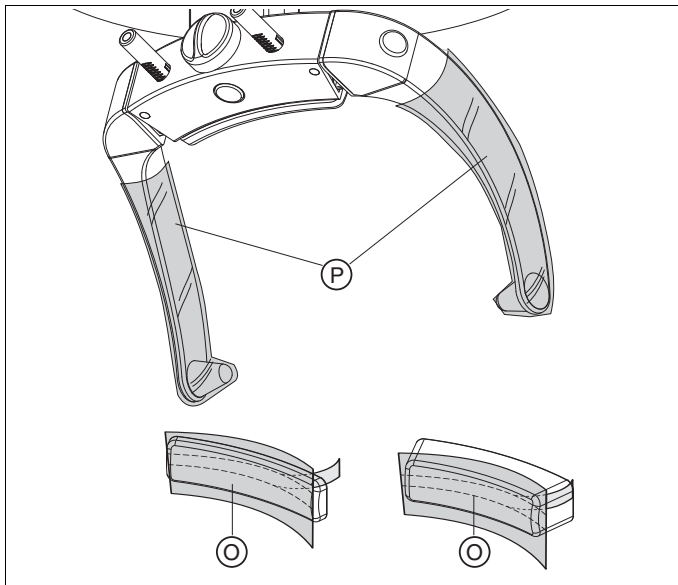
Accessories for head fixation device.

- J Ear olives
(10 pcs) Order No. 18 88 838
- K Headband (right and left)
The headbands can be removed for cleaning after
pressing the corresponding locking button.
(2 pcs) Order No. 62 27 040
- L Volume control
(1 pc) Order No. 62 17 611
- M Forehead pad
(contact pad can be removed for cleaning and
disinfection)
(5 pcs) Order No. 62 27 057
- N Forehead pad plus (child)
(contact pad can be removed for cleaning and
disinfection)
(5 pcs) Order No. 62 27 065

4.2 Hygienic protective sleeves



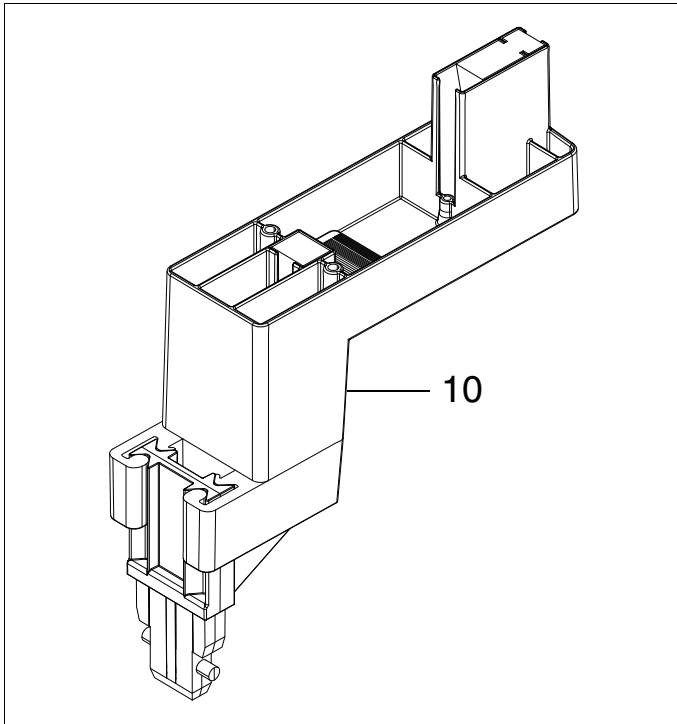
- 1** Hygienic protective sleeves for forehead support and Head fastening strap
(100 pcs) Order No. 61 84 894
- 2** Hygienic protective sleeves for bite block
(500 pcs) Order No. 61 27 745
- 3** Hygienic protective sleeves for handles
(500 pcs) Order No. 61 84 902
- 4** Hygienic protective sleeves for chin rest support and bar
(100 pcs) Order No. 59 32 603
- 5** Hygienic protective sleeves for bite block chin rest
(500 pcs) Order No. 33 14 072



for head fixation device

- O** Hygienic protective covers for forehead pads
(100 pcs) Order No. 62 34 392
Dimensions: 75 mm x 60 mm
- P** Hygienic protective covers for headbands
(500 pcs) Order No. 62 34 400
Dimensions: 150 mm x 47 mm

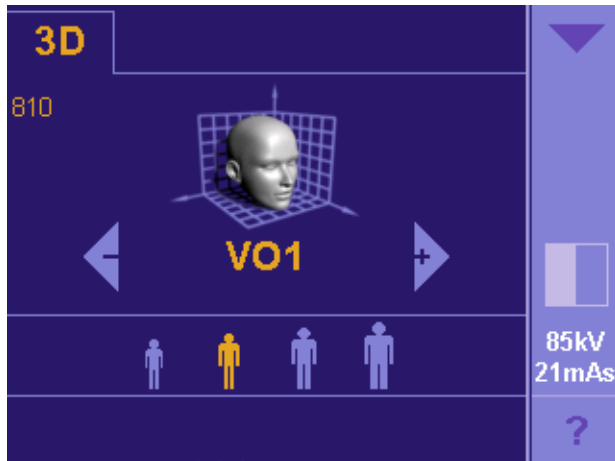
4.3 Test phantom for acceptance/constancy test



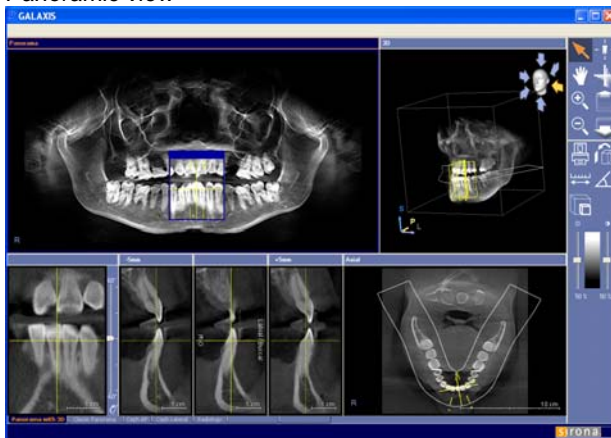
- 1 GALILEOS constancy test phantom replacement
(1 pc) Order No. 61 40 813

5 Programs

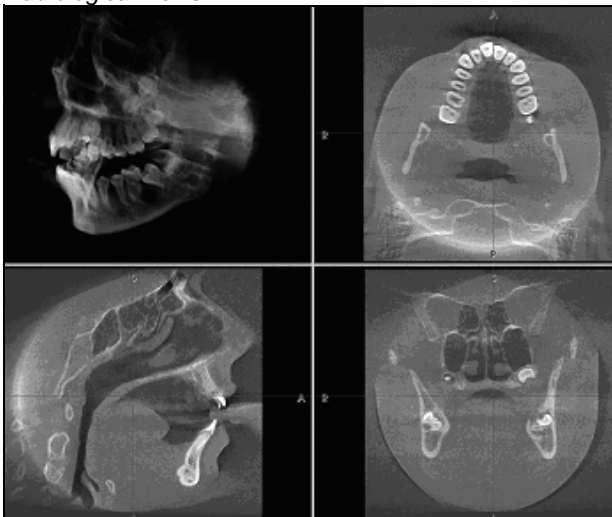
5.1 VO1: Volume 1 (High-resolution program)



Panoramic view



Radiological views



High-resolution scan with the possibility of generating secondary reconstructions (detail reco) with maximum resolution.

Indication: Cases where maximum resolution is required. E.g. endodontic treatments, evaluations of the smallest structures.

i NOTE

This program is optimal for ordering drilling templates from GALILEOS:

This program is used to create a volume data set of the patient with 512 x 512 x 512 volume elements (voxels).

The resolution in the volume (voxel size) equals 0.3 x 0.3 x 0.3 mm³.

Scan time:	14 seconds
Effective radiation time:	2...6 seconds
Reconstruction time:	approx. 2.5 minutes
Data volume:	up to 500 MB
comprising:	
Patient volume:	approx. 180 MB
Panoramic slice:	approx. 4MB
Lateral cephalometric image:	approx. 5 MB
Radiological views:	approx. 5 MB
Detailed reconstruction:	approx. 30 MB
Corrected raw data:	approx. 220 MB (erasable)

i NOTE

A high-resolution secondary reconstruction can be generated via Galaxis diagnostic software only with this exposure.

See Galaxis Operator's Manual.

5.2 VO1 HC: Volume 1 (High contrast option (HC))



The VO1 HC (high contrast) program is selected on the touchscreen, using the icon for the high contrast option (see also section "High contrast option" on page 22).

Compared to the standard settings, the high contrast setting VO1 HC offers an improved display of hard structures such as bones and teeth.

- The settings may result in an inferior display of the soft tissue, especially in terms of the soft tissue silhouette.

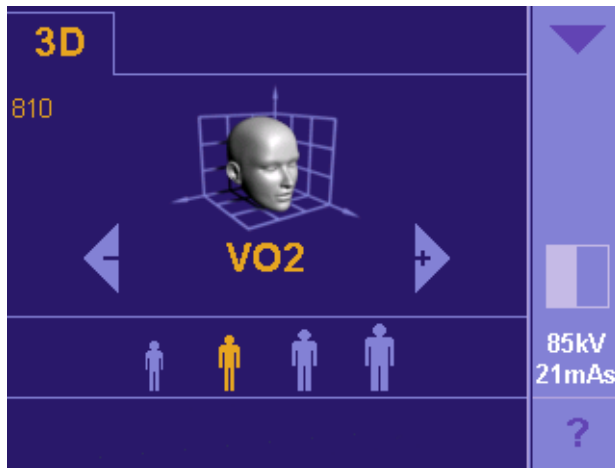
The high contrast option is particularly suitable for the evaluation of bone and tooth structures, e.g. after bone augmentations, when the correct display of the soft tissue silhouette is negligible.

Additionally, the feature is particularly useful for the DICOM export function to other implant planning programs (such as Nobel Guide or Siplant).

i NOTE

If the VO1 HC program is used for a DICOM export to a third-party implant planning software, always choose the setting value 42 mAs for optimal results.

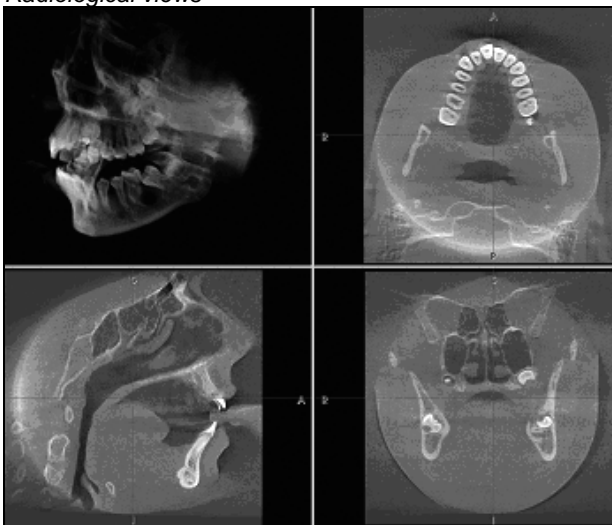
5.3 VO2: Volume 2 (standard program)



Panoramic view



Radiological views



Standard scan for fast provision of views

Indication: for all exposures for which no detailed reconstruction is planned. E.g. implant planning, overview exposures and postoperative control exposures.

This program is used to create a volume data set of the patient with 512 x 512 x 512 volume elements (voxels).

The resolution in the volume (voxel size) equals 0.3 x 0.3 x 0.3 mm³.

Scan time:	14 seconds
Effective radiation time:	2...6 seconds
Reconstruction time:	approx. 1:20 minutes
Data volume:	up to 500 MB
Comprising:	
Patient volume:	approx. 180 MB
Panoramic slice:	approx. 4MB
Lateral cephalometric image:	approx. 5 MB
Radiological views:	approx. 5 MB
Detailed reconstruction:	approx. 30 MB
Corrected raw data:	approx. 60 MB (erasable)

5.4 VO2 HC: Volume 2 (High contrast option (HC))



The VO2 HC (high contrast) program is selected on the touchscreen, using the icon for the high contrast option (see also section "High contrast option" on page 22).

Compared to the standard settings, the high contrast setting VO2 HC offers an improved display of hard structures such as bones and teeth.

- The settings may result in an inferior display of the soft tissue, especially in terms of the soft tissue silhouette.

The high contrast option is particularly suitable for the evaluation of bone and tooth structures, e.g. after bone augmentations, when the correct display of the soft tissue silhouette is negligible.

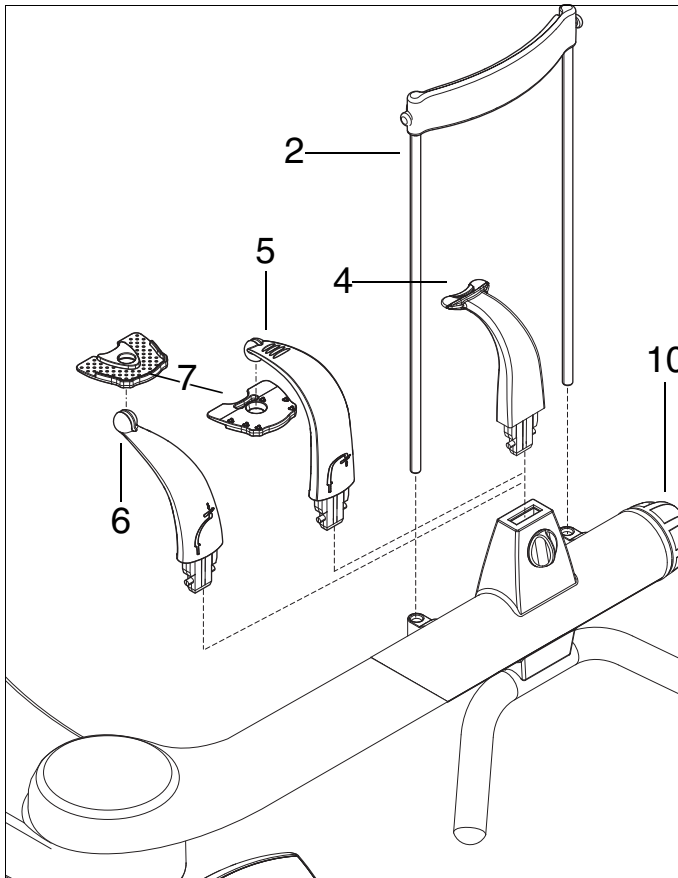
Additionally, the feature is particularly useful for the DICOM export function to other implant planning programs (such as Nobel Guide or Simplant).

i NOTE

If the VO2 HC program is used for a DICOM export to a third-party implant planning software, always choose the setting value 42 mAs for optimal results.

6 Operation

6.1 Preparing the exposure



Fitting the accessories to the bite block

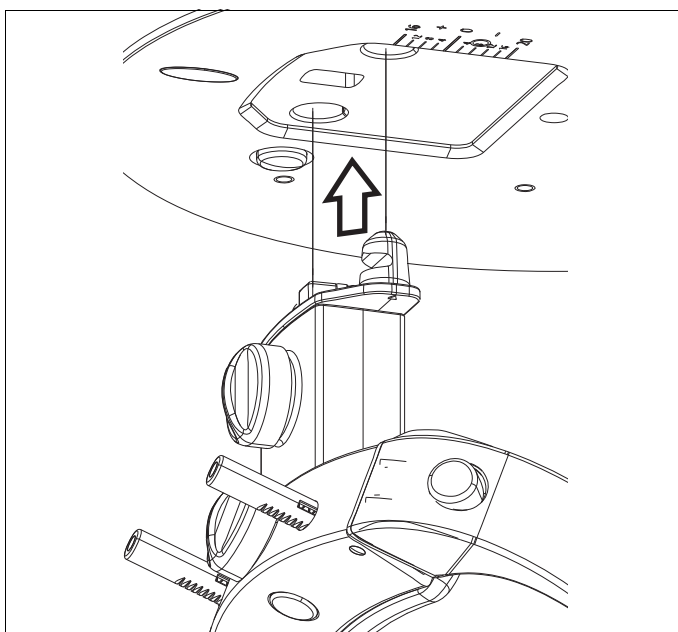
CAUTION

For each new patient...
...the bite block should be sterilized.
...the handles, head fastening strap (if used) and contact upholstery of the forehead support must be disinfected.

- Insert the bite block (4) up to the stop and lock it with the rotary knob (10).
- Insert the forehead support (2).
- Slide on the hygienic protective sleeves.

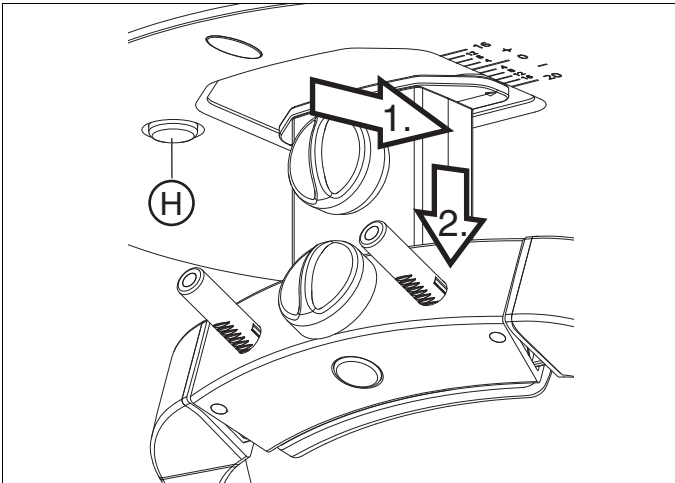
or for creating a drilling template:

- Insert spherical mandibular bite block (5) or
- spherical maxillary bite block (6) up to the stop and lock it with the rotary knob (10).
- Clamp the spherical bite block plate (7) for the upper jaw or for the lower jaw to the sphere of the corresponding bite block as shown.



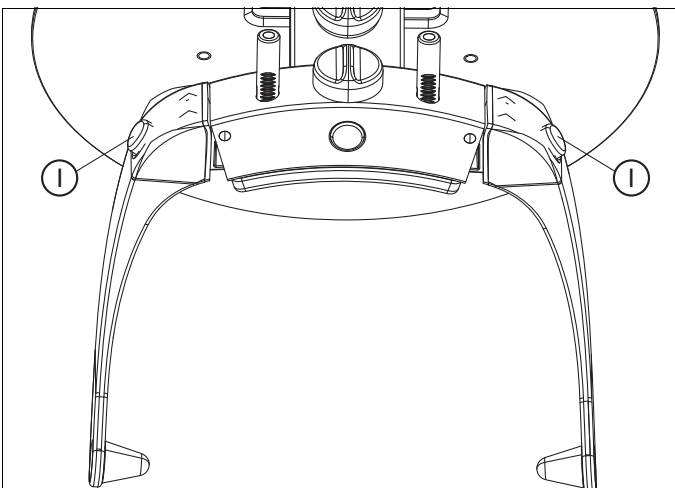
Inserting the accessories to the head fixation device

- Insert the head fixation device until it easily snaps in place.



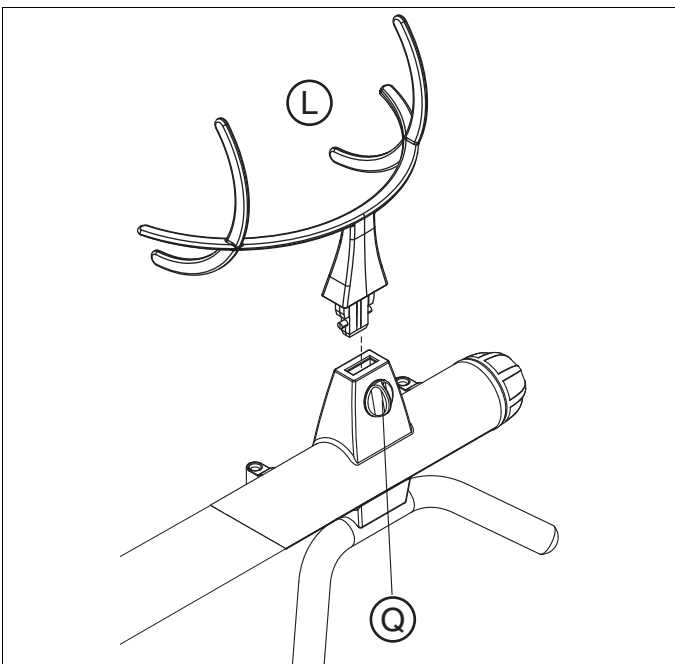
Removing the head fixation device

- To remove the head fixation device, press the locking button (H) and push the head fixation device all the way to the rear (1.) past a pressure point; then pull it off straight down (2.).



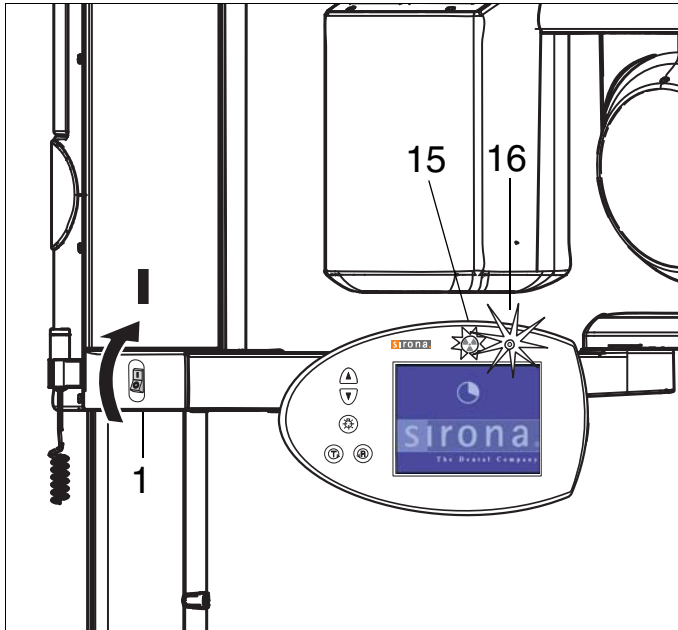
Removing or inserting the head bar

- Press the respective locking button (I) to remove or insert the headbands.



Fitting the volume control

- Insert the volume control (L) as far as it will go and lock it with the rotary knob (Q)



Switch the unit on

⚠ CAUTION

Following extreme temperature fluctuations, condensation may occur; therefore please do not switch the system on until it has reached normal room temperature (see chapter 2 "Technical description").

- Set main switch (1) to position I and wait approx. 1 minute.

i NOTE

In case of longer periods of disuse (> 200 hours), the X-ray detector (sensor) will require a preparation time of up to ten minutes. The system will display the message "Sensor preparation in progress." If the system is set to readiness for exposure during that time, the error message E1 10 07 will display. For further details, see "Error message E1 10 07" on page 44.

i NOTE

Due to the warm-up phase of the screen backlight, screen readability is poor for a few minutes after switching on the system.

- The LED (16) at the top of the Easypad lights up.
- The radiation indicator (15) lights up for approx. one second for a function test.

⚠ CAUTION

No patient may be positioned in the unit during power-on. In case of an error that requires switching the unit off and back on again, the patient must be removed from the unit, at the latest before switching the unit on again!

⚠ CAUTION

After switching the unit off with the main switch, you must wait for approx. 2 minutes before switching it back on.

i NOTE

After the unit is switched off with the main switch, the touchscreen on the Easypad remains illuminated for another 3 - 5 seconds.

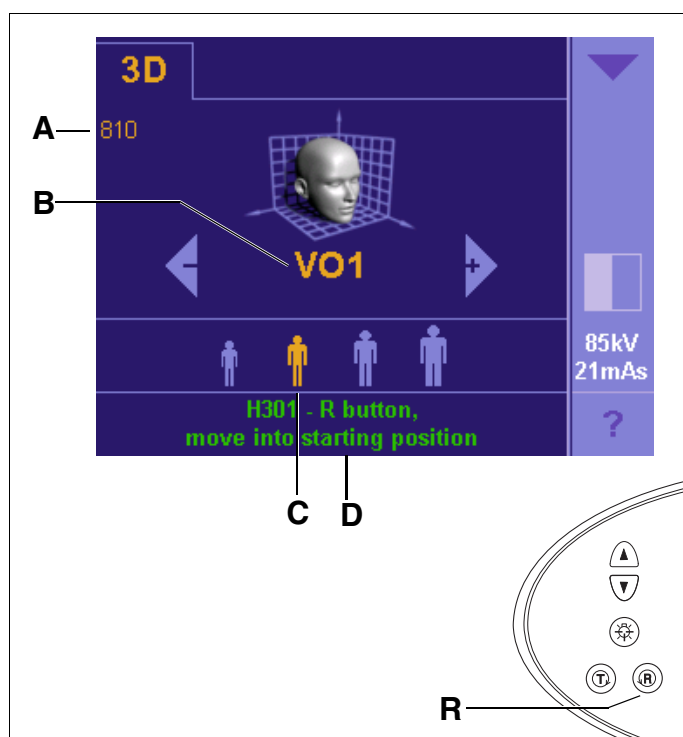


Displays on the Easypad touchscreen

When you switch the system on, the start screen appears briefly and automatically disappears again after approx. 1 minute.

i NOTE

The clock symbol shows the current status of system power-up.



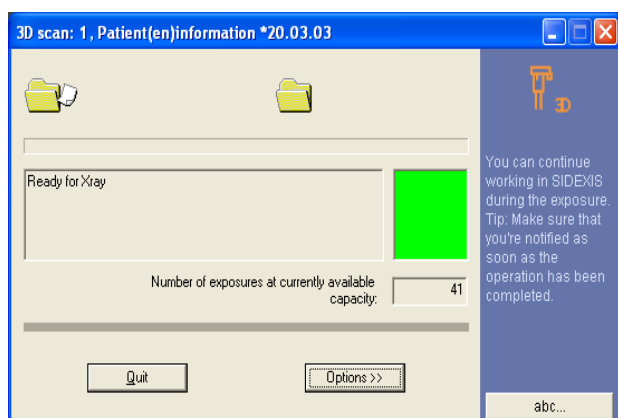
The selection screen appears.

The selection screen shows the following:

- A – Bite block height adjustment value in mm (ranging from 810 to 1815 mm) from the last patient set.
- B – Exposure program VO1 or VO2
- C – The patient symbol which was last preselected with the related kV/mA combination
- D – Help messages in the comment line

The preselected settings are represented in orange color.

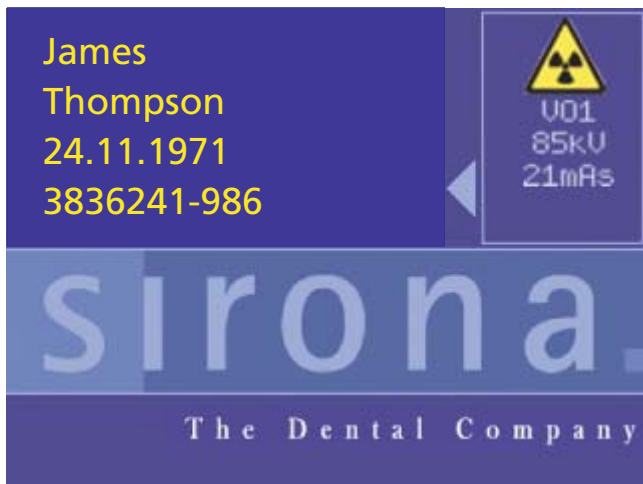
- Briefly press return key **R** to bring the rotating element into position for positioning.



Switch SIDEXIS to ready for exposure state

- Make the **SIDEXIS program on the PC ready for exposure**. (see **SIDEXIS Operator's Manual**).
As long as no connection has been made to SIDEXIS, the message "**Switch SIDEXIS to ready for exposure state**" is displayed in the comment line of the Easypad touchscreen.

Once SIDEXIS is ready for exposure, the welcome screen with the selected patient's data from SIDEXIS appears on the Easypad touchscreen.



It shows the **first name, last name, date of birth and card index number** of the patient currently registered in SIDEXIS.

The exposure data program, kV, mAs and a light blue radiation symbol are displayed in the upper right corner. When exposure readiness has been reached, the radiation symbol turns yellow.







When you touch the screen, the welcome screen disappears and the selection screen reappears.

i NOTE

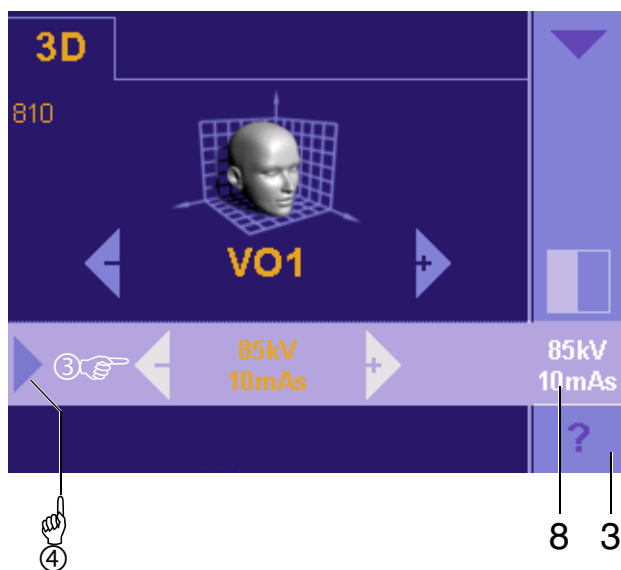
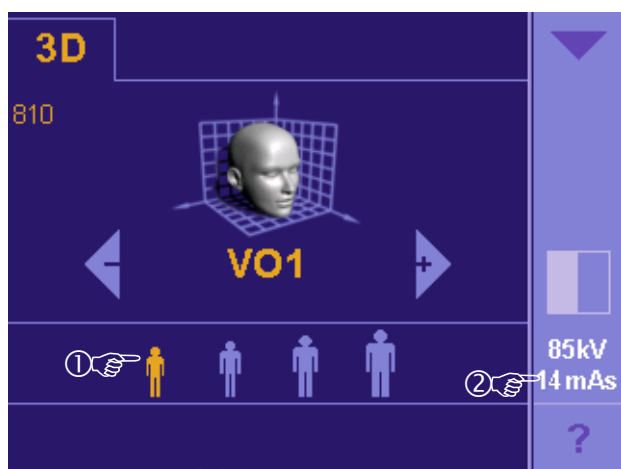
If you wish to suppress this entire screen display or individual pieces of information displayed there, your service engineer can disable the corresponding data upon request.

6.2 Selecting exposure parameters

The preset exposure parameters are selected with the patient symbol keys.

					
85 kV/ 10mAs	85 kV/ 14mAs	85 kV/ 21mAs	85 kV/ 28mAs	85 kV/ 35mAs	85 kV/ 42mAs

If the default kV/mA combinations do not provide satisfactory results, you also can set two additional combinations (85 kV/10 mAs and 85 kV/42 mAs).



1. Select one of the outer patient symbol keys.
 - Far left patient symbol key:
Sets to 85 kV/10 mAs
 - Far right patient symbol key:
Sets to 85 kV/42 mAs
2. Touch the exposure parameter display in the submenu column.

The submenu line for selecting the exposure parameters appears.
3. Use the –/+ keys in the kV/mAs submenu line to select the exposure parameters:
 - 85 kV/10 mAs
(left patient symbol key, then – key) or
 - 85 kV/42 mAs
(right patient symbol key, then + key)
4. Close the kV/mAs submenu line by touching the blue arrow (on the left in the line) or the kV/mAs symbol in the submenu column (3).

The currently selected exposure parameters are displayed on the right in the submenu column (8).

6.3 Positioning the patient

NOTE

In most cases, the X-ray exposure is performed on a standing patient. In special cases, you may also position a seated patient (using e.g. a dentist stool). You then must make sure that no parts of the dentist stool block the beam path or impair unit movements.

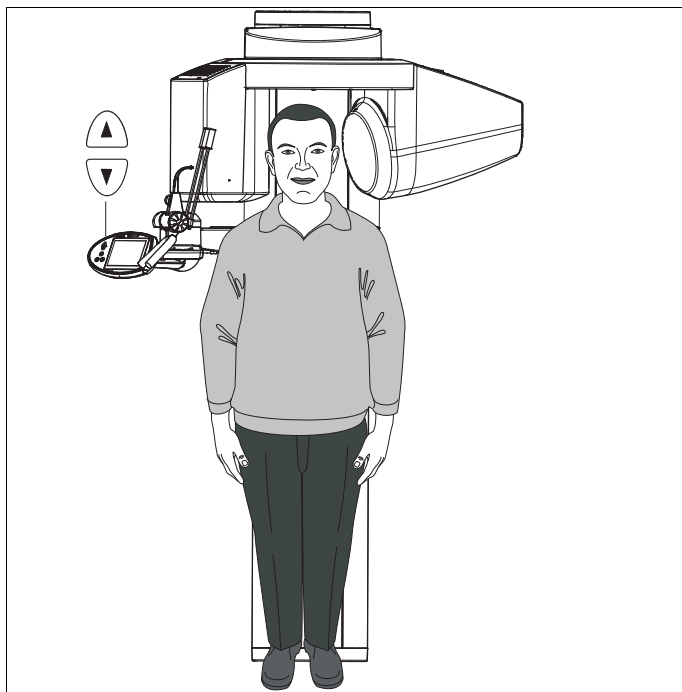
Preparations

- Ask the patient to **take off** all **metallic objects** such as glasses and jewelry in the head and neck area as well as all removable dental prostheses.
- For patients with metallic implants, bridges and fillings, image quality can be affected.
- The movements of the unit must not be obstructed by physical constitution nor clothing, dressings, wheelchairs or hospital beds! Perform a test cycle with the **T** key (see also chapter **1.1 "General safety information"**).
- Open the swivel arm of the unit completely.
- Adjust the height of the unit roughly to the patient's height using the **"up"** and **"down"** keys on the EasyPad.

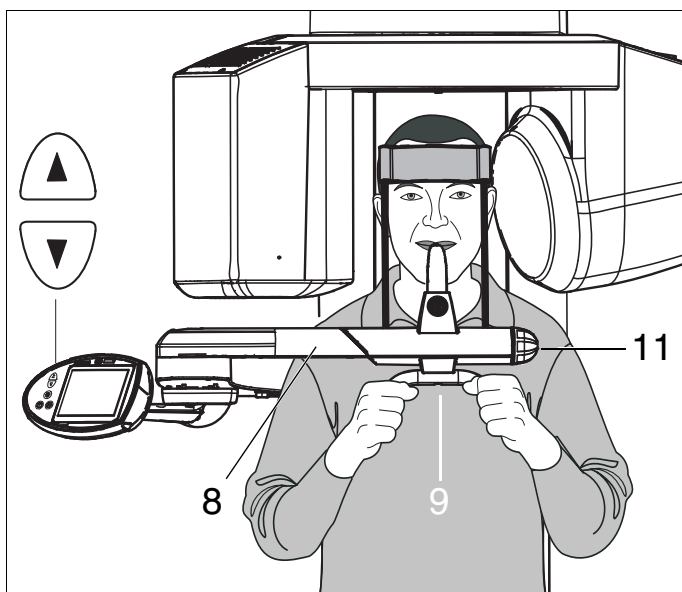
NOTE

*When the **R** key is pressed, the unit begins moving only if the swivel arm is located in one of the two end positions.*

6.3.1 Positioning the patient to the bite block



- Press the **R** key to move the unit back to the entry position.
- The patient approaches the unit moving backwards from one side, depending on the default setting of the entry position in Level 4 (select start settings).
- If the rotary ring was accidentally displaced while positioning the patient, the entry position can be approached again by pressing the “R” key once again.



Aligning the patient to the standard bite block

- Close the swivel arm (8) until it snaps in place.
- Using the “up” and “down” keys on the Easypad, move the X-ray unit so that **the bite block and the patient's front teeth are at the same height**.

The motor movement is accompanied by an acoustic signal.

CAUTION

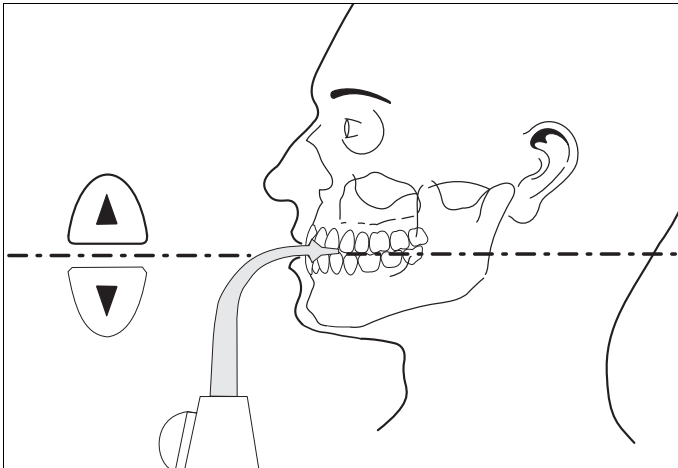
The height adjustment motor starts slowly and then increases its speed.

Press and hold down the height adjustment key until the unit has reached the desired height.

- The patient then approaches the bite block and holds the handles (9) firmly.

NOTE

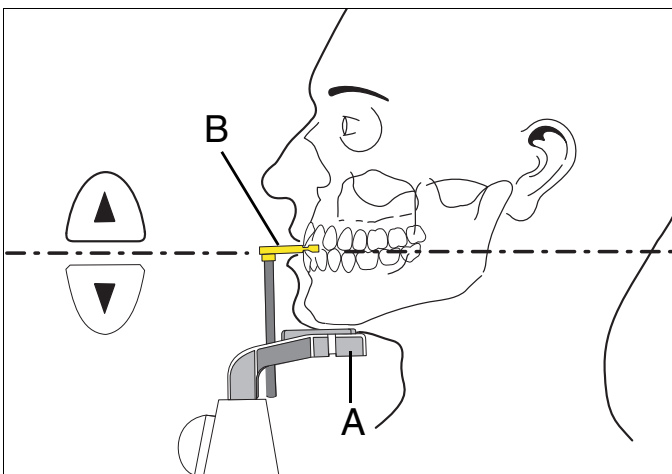
The patient must stand up with his back stretched perfectly straight and let his shoulders hang loosely.



- Have the patient bite the spoon of the bite block.

i NOTE

The height of the X-ray unit must be set so that the occlusal plane is perfectly horizontal after the patient bites the bite block.



Exposure with chin rest, bite block and contact bar

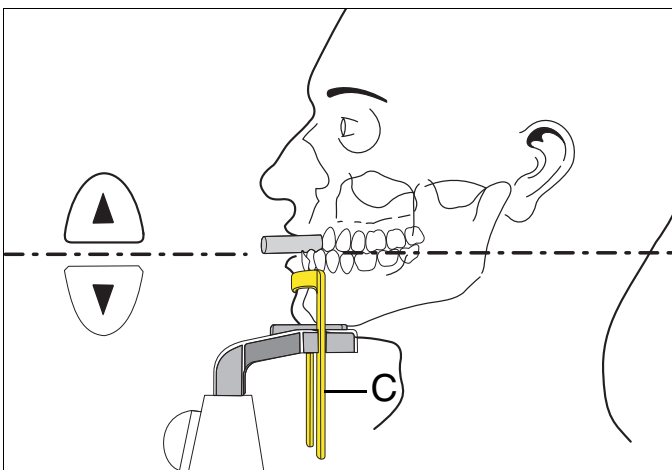
- Indications:**
- Toothless patients
 - Temporomandibular diagnosis
 - Cephalometry

- The patient enters the unit-
- Using the “upward movement” or “downward movement” key, adjust the height of the unit so that the patient's chin and the chin rest are at the same height.
- The motor movement is accompanied by an acoustic signal.

i NOTE

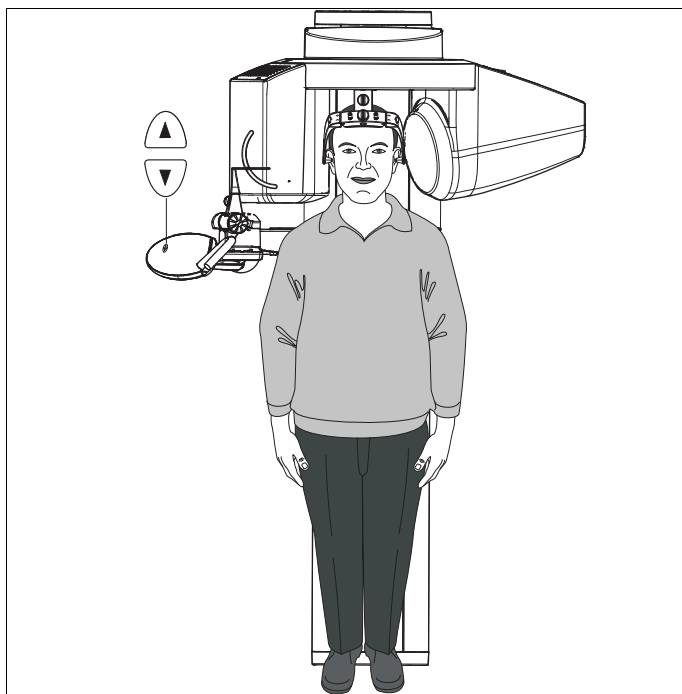
The height adjustment motor starts slowly and then increases its speed.

Press and hold down the height adjustment key until the unit has reached the desired height.



- Have the patient place his chin on the chin rest with closed occlusion (A) and grasp the handles firmly.
- Swing in bite block (B).
- Have the patient bite into the indentation of the bite block (upper anterior teeth into the indentation, lower anterior teeth pushed forward as far as possible).
- For patients with no anterior teeth, please insert contact bar (C) (arch facing column).
- Please place the contact bar between the patient's chin and upper lip and insert a cotton roll.

6.3.2 Positioning the patient to the head fixation device (e.g. for orthodontic image series)

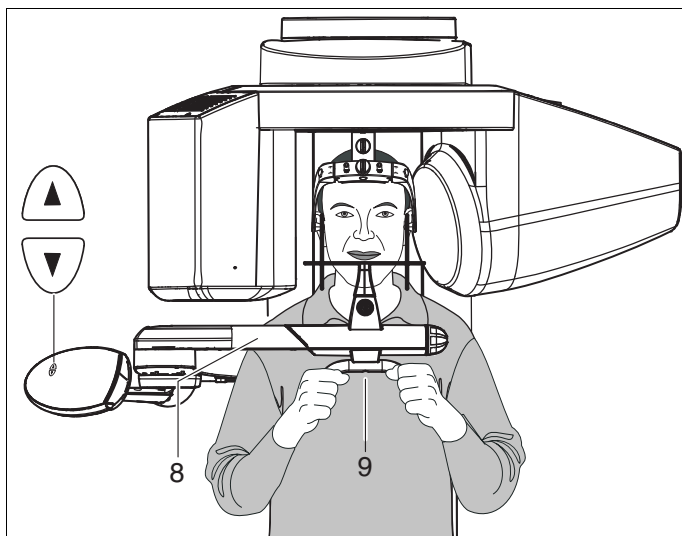


- Open the bands of the forehead support fully.
- Press the **R key** to move the unit back to the entry position.
- Attach the statutory radiation protection equipment to the patient. Help the patient enter the unit moving backwards.
- If the rotary ring was accidentally displaced while positioning the patient, the unit can be returned to the entry position by pressing the **R key** once again.



CAUTION

The height adjustment motor starts slowly and then increases its speed. Press and hold down the height adjustment key until the unit has reached the desired height.



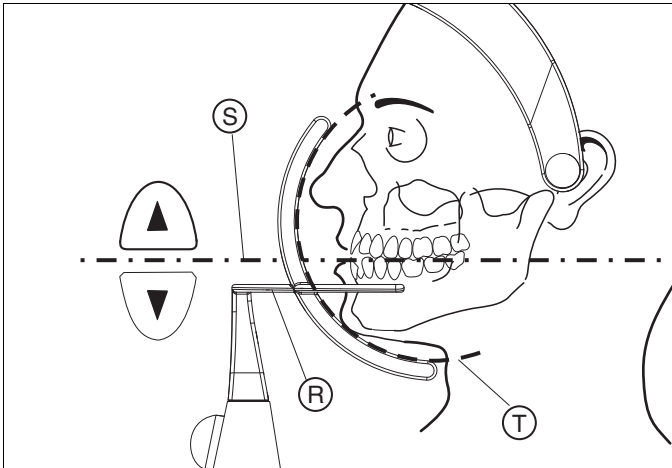
Aligning the patient to the head fixation device

- Using the "**up**" and "**down**" keys on the control panel, move the X-ray unit until **the centers of the ear plugs are located at the same height as the patient's outer auditory canals**.
The motor movement is accompanied by an acoustic signal.
- Open the headband (C) of the head fixation device until the ear plugs contact the patient's outer auditory canals.
- Close the swivel arm (8) until it snaps in place.
- The patient should grasp the handles (9) relaxed but securely.



NOTE

For an optimal exposure, the patient should stand up straight and let his shoulders droop loosely.

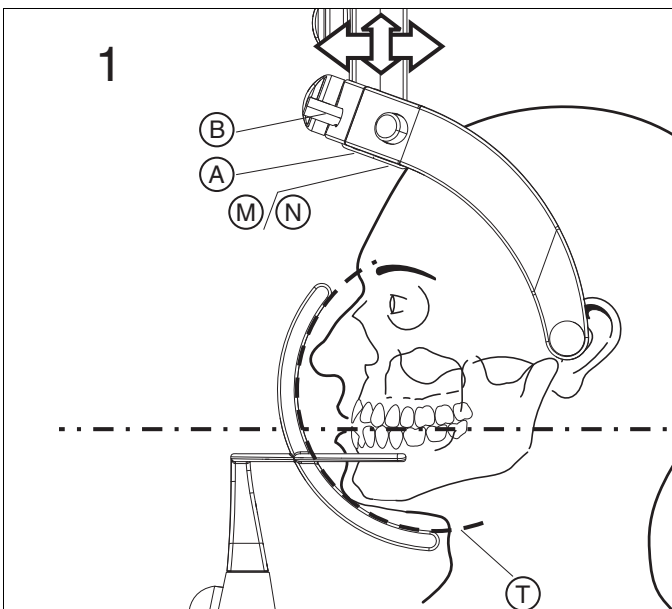


- Align the occlusal plane (S) of the patient's head parallel to the marking line (R) via fine adjustment of the "up" and "down" keys.

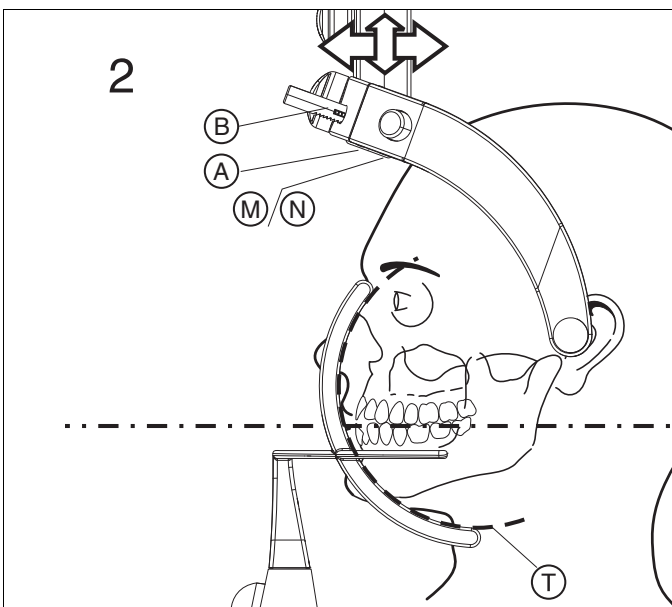
i NOTE

The height of the X-ray unit must be set so that the occlusal plane is perfectly horizontal following alignment.

- The correct position for the indication can be set by laterally fixing the position with the volume control and using the vertical and horizontal adjustment options.
The inner side (T) of the volume control should be regarded as the volume boundary.



Example 1: The patient's nose and the point of his chin are within the volume, e.g. for optimal display of the silhouette of a Ceph exposure.



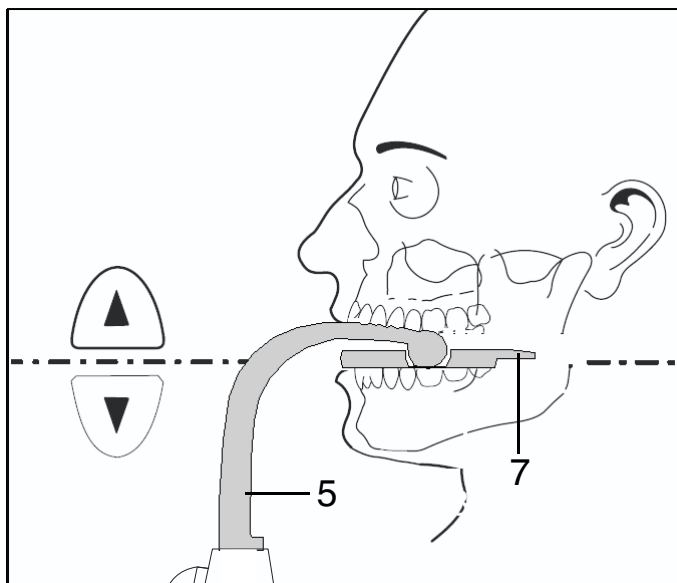
Example 2: The horizontal adjustability makes it possible to push the rear of the skull region (e.g. the temporomandibular joints) further into the volume. The tip of the patient's nose and the point of his chin are pushed out of the 3D volume in return.

- Finally, immobilize the patient's head by pushing the two pins (B) toward his forehead until the forehead rest (A) snugly fits against his head. Select the most suitable forehead pad, i.e. M or N.

i NOTE

The forehead rest can be returned to its zero position by pressing the pushbutton (D).

6.3.3 Positioning the patient to the spherical bite block



Using the spherical bite block to create an implant drilling template

Select the corresponding spherical bite block holder for the scan with the spherical bite block. For exposures of the lower jaw, insert spherical bite block holder (5). For exposures of the upper jaw, insert spherical bite block holder (6).

i NOTE

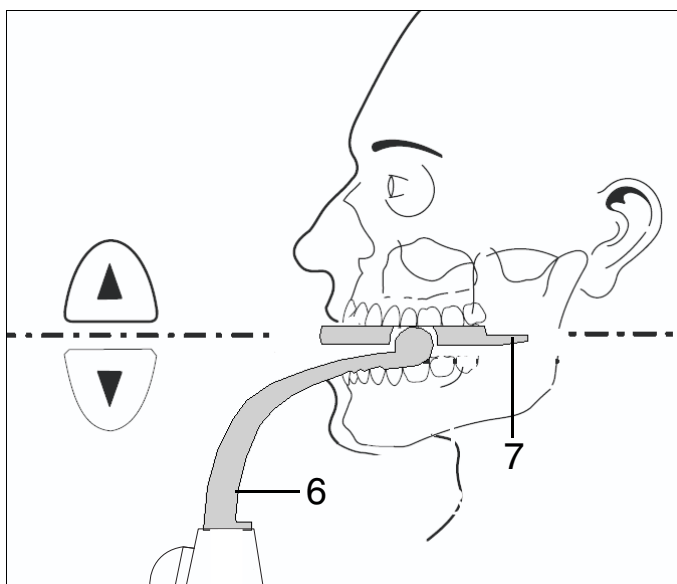
Spherical bite block plate (7) contains 6 radiopaque markers (spheres) which are used for orientation in the X-ray volume. Further applications can be set up on this spherical bite block plate.

Aligning the patient to the spherical bite block

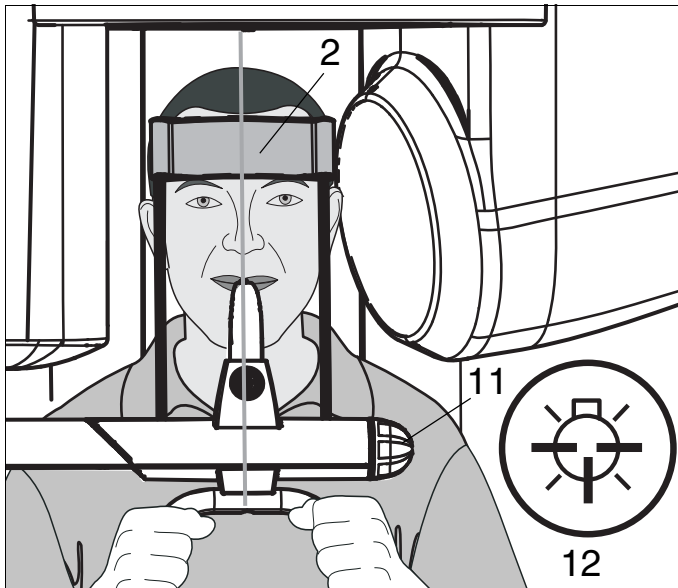
- Insert spherical bite block plate (7) with patient registration at the patient.
- Close swivel arm.
- Adapt unit height until sphere and incisors are at the same height. The spherical bite block plate should be aligned horizontally.
- Carefully lead the patient to the sphere of the spherical bite block holder with his mouth open.
- Have the patient gently bite onto the spherical bite block holder.

i NOTE

The spherical bite block plate may touch the spherical bite block holder only via the sphere. If it has contact at the front, the patient's position or the unit height must be corrected.



6.3.4 Display of the mid-sagittal plane



- Switch on the **light localizer** with key (12) on the Easypad. It is used for correct patient positioning.
- Align the patient so that the light beam strikes the center of the bite block and of the patient's face (mid-sagittal symmetry).

i NOTE

As long as the light localizer is switched on, a red light localizer symbol is displayed on the touchscreen (see page 17).

! CAUTION

Make sure that the light beam does not hit the patient's eyes (laser light). The light localizer switches off automatically after approx. 100 seconds.

- Fix the patient's position by tightening the forehead support (2) against the patient's forehead with the rotary knob (11).

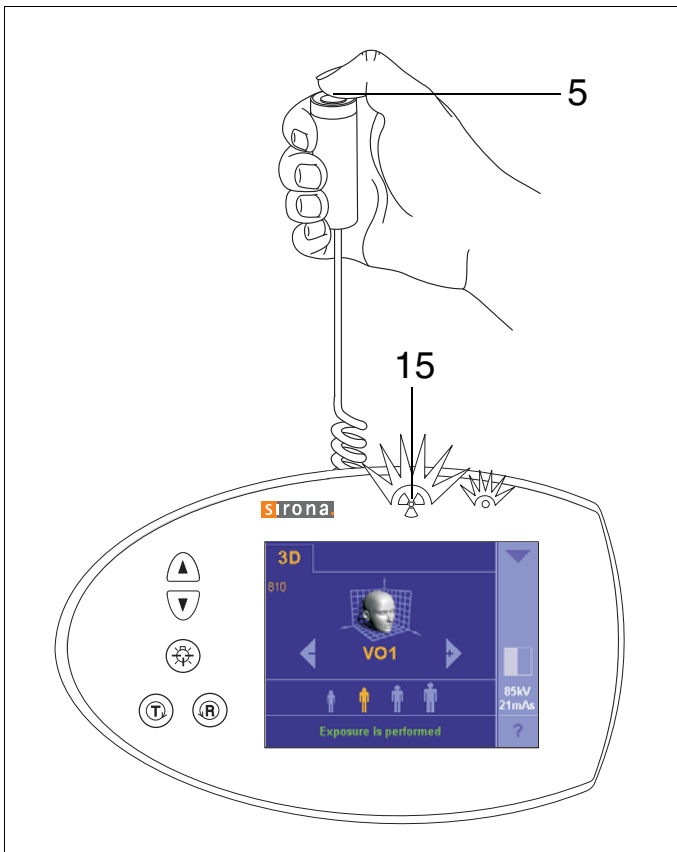
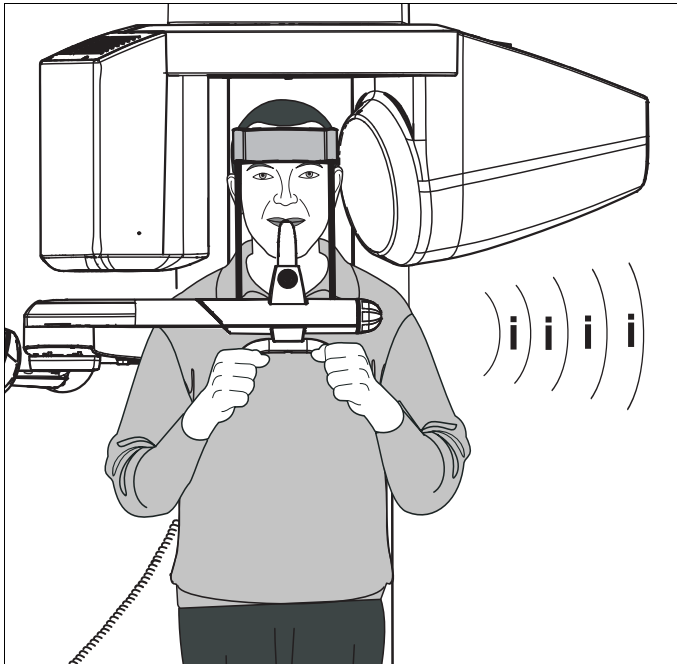
i NOTE

In some cases, it is also advisable to immobilize the patient's head with a head fastening strap as well (see chapter 4.1 "Bite blocks, supports and fasteners").

Concluding the preparations

- If the light localizer is still on, switch it off with key (12) on the Easypad. The light localizer symbol on the touchscreen disappears.

6.4 Releasing the exposure



⚠ CAUTION

Be sure to observe the radiation protection regulations applicable in your country (see also chapter 1 "Warning and safety information")

- Check the program and exposure parameters carefully (see chapter 6.2 "Selecting exposure parameters").

i NOTE

No further help messages may be displayed in the comment line of the touchscreen. The message "Ready for exposure" must appear.

i NOTE

If e.g. the door of the X-ray room is not properly shut, the message "Close the door" appears in the touchscreen comment line; at the same time, the coded message H321 is displayed on the remote control.

⚠ CAUTION

Advise the patient not to move his/her head in any way during the exposure and check to make sure that this does not happen!

In order to attain optimal image quality, the patient should avoid any unnecessary breathing or swallowing during the exposure.

- To release an exposure, press the exposure release button (5) directly on the X-ray unit or on the remote control.

The rotary movement of the selected exposure program is performed automatically.

While radiation is active, the optical radiation indicator (15) on the Easypad or on the remote control is illuminated.

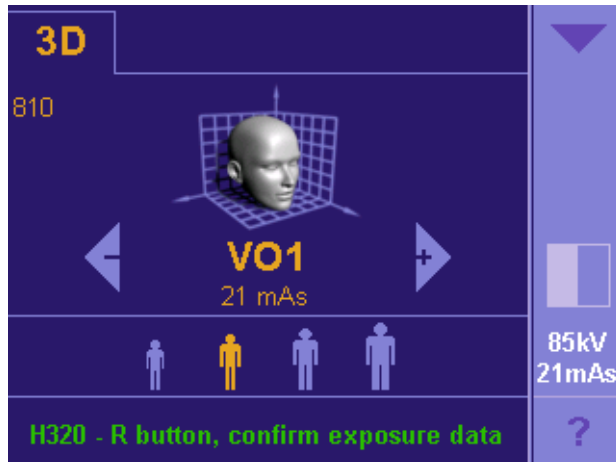
⚠ CAUTION

*In addition, an **acoustic signal** sounds throughout the entire radiation time.*

⚠ CAUTION

Take care not to let go of the exposure release button prematurely. Wait until the unit has completed the exposure cycle.

If the exposure is canceled prematurely, you will obtain a much poorer image quality, since not enough image data will be available for reconstruction of the volume.



- The exposure cycle is complete when...
... the touchscreen comment line switches from **“Exposure in progress”** to **“R key, confirm exposure data”**.
... message **“H 320”** appears alternately with the program number on the remote control display.
... the actual mAs value is displayed under the program number at the end of the exposure (see image).
... a short pulsed tone sequence also can be heard at the end of the exposure (this function can be deactivated by your service engineer).

i NOTE

The end of the exposure cycle can also be seen on the SIDEXIS monitor when the progress bar indicates 100 %.

Confirm the exposure by pressing the “R” key.
Then press the “R” key again to move the unit to the entry position.
The patient can now leave the unit.

! CAUTION

Never switch off the X-ray unit during transmission of an image. The scanning process takes approx. 2.5 minutes.

After completion of the exposure

the image is reconstructed and displayed in the reconstruction software. Depending on the program selected and the PC system used, it may take from 2.5 to 5 minutes to display all of the views on the screen.

i NOTE

The operation of the visualization software is described in the attached GALAXIS Operator's Manual.

Canceling an exposure

If you let go of the exposure release button prematurely, the exposure is canceled.

The message **“R key, confirm exposure data”** appears in the comment line and the actual mAs value flashes under the program number on the touchscreen as well as on the remote control.

- Press the **“R”** key on the Easypad twice.

i NOTE

Please note that any program settings which may have been changed must be preselected again before repeating the exposure.

- After the rotating element has returned to its starting position, repeat the exposure.

Automatic exposure blocking

(thermal protection of the tube)

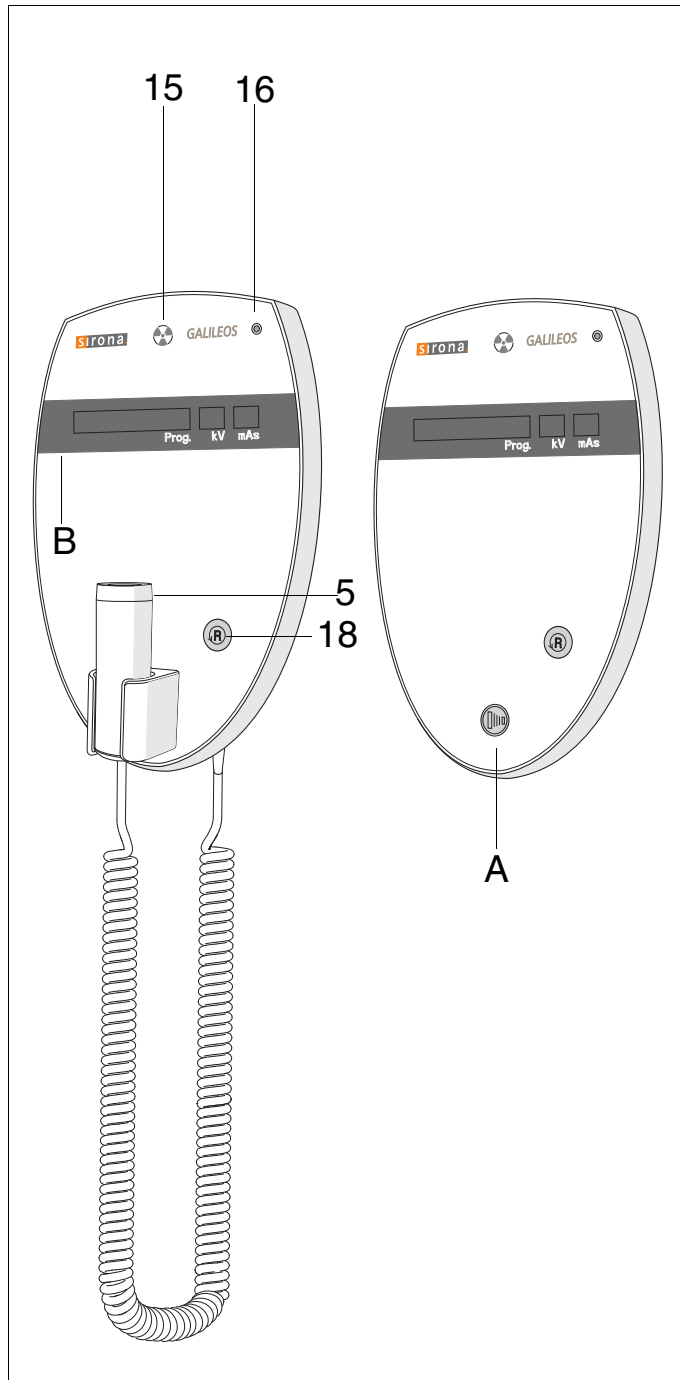
Premature release of a new exposure is prevented by the automatic exposure blocking function.

When you press the exposure release button, the message **“Ready for exposure in "X" seconds”** appears in the comment line of the touchscreen.

The remaining cooling time is counted down and is displayed under ‘x’.

Only after the cooling period has elapsed is it possible to release a new exposure.

6.5 Remote control



If the X-ray unit is located in an X-ray room which has a door and enables visual contact with the patient, you can use **remote control** to release the exposure.

For that purpose, the **exposure release button (5)** can be detached from the unit and attached to the remote control.

The **exposure release button (A)** can be used if a longer cable is not required to maintain visual contact with the patient.

The remote control has an "**R**" **key (18)** for acknowledging the exposure and resetting the unit to its starting position, an optical **radiation indicator (15)** and a "**Unit ON**" LED display (16).

After you switch on the system, the LED (16) lights up. The radiation indicator (15) lights up for a longer period of time for a function test.

The three display fields on the display panel (B) light up. A progress bar appears after approx. 10 seconds. After the system starts, the display switches to program VO1 with the corresponding values.

As long as plain-text **help messages** are displayed on the Easypad touchscreen, they also appear in coded form on the "**Prog.**" display field of the remote control, **alternating** with the **program name**.

Once all **help messages** have been processed, the **program name "Prog."**, the "**kV**" and the "**mAs**" values are constantly displayed on the **display panel (B)**. The exposure can be released.

i NOTE

If a row of dots appears in the **Prog.** field, this means that the system is currently in a preparatory phase (e.g. system movements, parameter changes, program loading times etc.). Just wait until the dots automatically disappear and the system signals that it is ready again.

7 List of messages

7.1 List of help messages

A number of H3 help messages may appear on the Easypad while you attempt to release an exposure:

- Press the **exposure release button**. **ATTENTION Observe radiation protection measures.**
The message **H3/H4 ...** – Message appears on the Easypad.
- See list below about how to proceed to make the system ready for exposure.

Help message	Actions required	Description
H3 01	R key, move into starting position.	The rotating element is not in the starting position.
H3 20	R key, confirm exposure data.	The exposure data have not been acknowledged yet.
H3 21	Close the door.	Check door contact of the X-ray room.
H3 23	Move the swivel arm into its end position.	Open or close the swivel arm completely.
H4 03	Switch SIDEXIS to ready for exposure state	SIDEXIS is not ready for exposure.
H4 20	Retrieve existing exposure.	The image could not be transferred to SIDEXIS. See SIDEXIS Operator's Manual. ATTENTION Do not switch off the system until the help message has disappeared.

The above measures clear those help messages that result from operator errors.

If it is not possible to clear the help message by taking the appropriate measure, another type of error is the cause.

To locate the error, proceed as described on the following pages.

NOTE

Separate operating instructions for troubleshooting in the image data path (Rescue Management) are attached to your documents.

Order No. 61 81 114

7.2 Error message structure

The error messages are displayed in the form of an error code. They are not provided in plain-text form.

13.2.1 The error message code has the following structure:

Ex yy zz

Ex	Error type/"troubleshooting" classification for the user
yy	Location; module; subsystem or logical function unit
zz	Consecutive number with error ID

All error messages of the system are grouped according to these criteria.

13.2.2 Ex

Digit (x) is intended to provide the user with quick help in deciding how to deal with this error.

Ex	Description	Actions required	Error group
1	System warning; system message	Acknowledge the error message. Contact your Customer Service. Continued operation of the system is ensured.	This error group includes all errors that indicate still acceptable tolerance variations, or messages about states which do not directly affect system operation.
2	Errors caused by system overload	Acknowledge the error message. Repeat the procedure step after a certain waiting time. If the error message reappears, prolong the waiting time. If the error state persists, contact your Customer Service.	This error group includes states that indicate e.g. temporary overtemperatures or the like. The cause of the error disappears automatically after a certain waiting time.
3	The system detects that a key was pressed during power-on.	Switch the system off and back on; if the error reoccurs without any user intervention, contact your Customer Service. CAUTION! After switching the unit off with the main switch, you must wait for approx. 2 minutes before switching it back on.	This error group includes all errors that indicate invalid signal states of keys and safety signals during power-on.
4	Malfunction or mechanical obstruction of unit movements	Acknowledge the error message; make sure that the movements of the unit are not obstructed. Repeat the last procedure step or exposure. If the error reoccurs without any identifiable cause -> contact your Customer Service	This error group includes all errors that indicate problems with the motor-controlled movements on the outside of the unit.

Ex	Description	Actions required	Error group
5	Malfunction during the exposure or during exposure preparation.	Acknowledge the error message to continue system operation. Repeat the last procedure step or exposure. If the error reoccurs -> contact your Customer Service.	This error group includes all errors resulting from a certain system action triggered by the user which could not be performed because a required (internal) partial function (SW or HW) is not ready or fails
6	Error during system self-test.	Acknowledge the error message to continue system operation. If the error occurs repeatedly, switch the system off and back on; if the error re-occurs -> contact your Customer Service.	This error group includes all errors which may occur spontaneously and without any related operator action. They may be caused by system self-tests.
7	Unrecoverable system error.	Switch off the system; immediately contact your Customer Service.	This error group includes all errors which may occur spontaneously and without any related operator action. They may be caused by system self-tests. In this case it is absolutely certain that continued system operation is not possible.

13.2.3 yy

Digits (yy) define the location or logical function unit where the error has occurred.

10	Central control DX 11; system hardware
11	Central control DX 11; system software
12	Central control DX 11; central CAN bus errors
13	Central control DX 11; DX11, DX1 periphery (motor system of stand, sensor system of stand)
14	Central control DX 11; digital extension (HSI, network...)
15	Central control DX 11; configuration (wrong software, wrong module constellation, etc.)
06	Tube assembly
07	User interface (Easypad)
89	Sensor
41	Media interface card
42	Remote

The location may be a DX module number standing for an entire HW function unit, or a logical SW function unit on the DX11 (central control).

13.2.4 zz

Digits (zz) show a consecutive number with the error ID.

7.3 Error message E1 10 07

Explanation

This section describes the possible causes and the correction of this error.

Case 1

In case of longer periods of disuse (> 200 hours), the X-ray detector (sensor) will require a preparation time of up to ten minutes.

The system will display the message "Sensor preparation in progress."

During that time, the device is not ready for operation.

If the system is set to readiness for exposure during that time, error message E1 10 07 will display.

Solution

Acknowledge the error message with the (R) key and wait until the message "Sensor preparation in progress" is deactivated.



NOTE

Decreasing the waiting time

Switching the unit on and off will not decrease the waiting time!

Case 2

If the error message E1 10 07 is displayed immediately after turning on the device without the user having established exposure readiness, please inform the responsible service engineer.

8

Care of outer surfaces

Cleaning

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

Do not allow liquids to penetrate into the ventilation slots!

Wipe off any medicaments that may come into contact with the surface immediately.

Disinfecting

Surfaces can be wiped with surface disinfectants. Observe manufacturer's instructions regarding restrictions for use!



CAUTION

Use only disinfecting, cleaning and care agents which are approved by Sirona!

A continuously updated list of approved agents can be downloaded from the internet at: **www.sirona.de / SERVICE / Downloads / Care & cleaning agents**

If you do not have access to the internet, you can request a list in one of the following two ways:

- Contact your dental depot.
- Order the list from Sirona
by phoning: ++49 (0) 62 51/16-16 16
or sending a fax to: ++49 (0) 62 51/16-18 18
REF 59 70 905
- Disinfect only the outer surfaces with tested chemical disinfectants. Use only disinfectants which comply with the laws and regulations applicable in your country or whose bactericidal, fungicidal and virucidal properties have been tested and certified accordingly.

Here are a few examples:

MinutenSpray classic from Alpro® or
MinutenWipes from Alpro®.

In the USA and Canada:

CAVICIDE® or **CAVIWIPES™**

Do not use: substances containing phenol, peracetic acid, peroxide or any other oxygen-splitting agents, sodium hypochlorite or iodine-splitting agents.

Sterilizing

The bite block should be sterilized for each new patient.

**Sterilize only in an autoclave at
134 °C (273 °F) and 2.1 bar.**

9

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.

9.1 Annual check performed by the system owner or other authorized persons

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

9.2 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.

9.3 Image quality check

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 post-processing (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.

If, after taking into account the patient's anatomy and excluding possible sources of error such as incorrect patient positioning, this criterion can be regarded as given, you should immediately contact your Customer Service to have possible system faults rectified.

Observe any possible additional national requirements.

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

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