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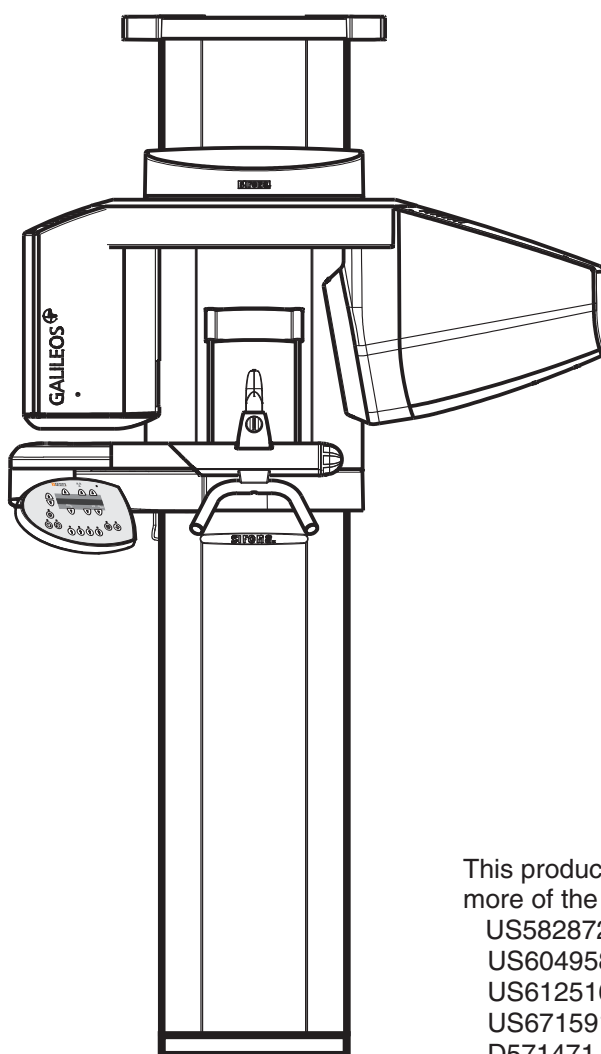
sirona

The Dental Company

GALILEOS

Operating Instructions GALILEOS Compact

English



This product is covered by one or more of the following US patents:

US5828721
US6049582
US6125163
US6715918
D571471

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1 General information

1.1 Dear Customer,

We are pleased that you have equipped your practice with the GALILEOS Compact X-ray system from Sirona.

The GALILEOS system comprises an X-ray unit that uses a rotating beam to produce two-dimensional images and three-dimensional reconstructions of the head region, including the dental/maxillofacial regions, for planning and diagnostics.

The system also includes a package with software modules (GALAXIS, RECO software) which extends SIDEXIS to include the processing of 3D data. This includes 3D reconstruction, storage, recall, display and processing of 3D image data.

These Operating Instructions are designed to assist you prior to initial use and whenever you require information later on.

We wish you every success with using your GALILEOS Compact system.

Your GALILEOS Team

1.2 Contact information

For technical questions, use the contact form on the internet at www.sirona.com. Follow the menu items "*CONTACT*" "*Customer Service Center*" on the navigation bar and click on the "*CONTACT FORM FOR TECHNICAL QUESTIONS*" button.

Sirona Dental Systems
Fabrikstrasse 31
64625 Bensheim
Germany

Phone: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
By e-mail: contact@sirona.com
www.sirona.com

Customer service center

Manufacturer's address



1.3 General information on the Operating Instructions

Observing the operating instructions

Please familiarize yourself with the unit by reading through these operating instructions before putting them into operation. It is essential that you comply with the specified warning and safety information.

Keep documents safe

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.

Should you subsequently sell the unit, ensure that the operating instructions are included with the unit in paper form or as electronic storage media so that the new owner can be suitably informed about the function of the unit and the warning and safety information provided.

Online portal for technical documents

For technical documents, we have created an online portal at <http://www.sirona.com/manuals>. There, you can download these operating instructions and further documents. If you prefer a document in paper format, please fill out the web form. We would be delighted to send you a printed copy, free of charge.

Help

If you reach an impasse despite having thoroughly studied the operating instructions, please contact your dental depot.

1.4 Other valid documents

The X-ray system includes other components, such as PC software, which are detailed in other documents. Instructions and warning and safety information provided in the following documents must be taken into account:

- SIDEXIS Operator's Manual
- GALAXIS Operator's Manual
- Software Components Operating Instructions
- Facescan Operating Instructions

1.5 Warranty and liability

Warranty Passport

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.

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.

As manufacturers of medical electrical equipment, we can assume responsibility for the safety properties of the system only if maintenance and repair work on the system is performed by ourselves or by agencies expressly authorized by us, and if components affecting safe operation of the system are replaced by original spare parts in case of failure.

Exclusion of liability

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.

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; 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.

1.6 Obligation of system owner and personnel

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

Prior to the exposure, please ask women of a childbearing age as to whether they are pregnant or not. If they are pregnant, do not carry out the X-ray exposure.

According to the X-ray Ordinance of the Federal Republic of Germany, owners of X-ray equipment must perform constancy tests at regular intervals in order to ensure the safety of operating staff and patients. Sirona recommends monthly testing.

1.7 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 with software modules (GALAXIS, RECO software) which extends SIDEXIS to include the processing of 3D data. This includes 3D reconstruction, storage, recall, display and processing of 3D image data.

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

With room temperatures > 35°C (> 95°F) Sirona recommends the use of an air conditioning system. Recommended operating temperature: < 35°C (< 95°F)

For the USA only:

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

1.8 Indication and contraindication

Indication in the areas:

- Conservative dentistry
- Endodontics
- Periodontology
- Prosthodontics
- Functional diagnosis and therapy of craniomandibular dysfunctions
- Surgical dentistry
- Implantology
- Oral and maxillofacial surgery
- Orthodontics


Contraindications:


- Caries diagnosis, especially of proximal lesions
- Display of cartilage structures
- Display of soft tissue


1.9 Structure of the document

1.9.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety instructions provided in this document, which are highlighted as follows:

 DANGER
Imminent danger that could result in serious bodily injury or death.

 WARNING
Potentially dangerous situation that could result in serious bodily injury or death.

 CAUTION
Potentially dangerous situation that could result in slight bodily injury.

NOTICE
Potentially 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 for simplifying work.

1.9.2 Formats and symbols used

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

<ul style="list-style-type: none"> ✓ Prerequisite 1. First action step 2. Second action step or > Alternative action ↪ Result 	Requests you to do something.
See "Formats and symbols used [→ 10]"	Identifies a reference to another text passage and indicates the relevant page number.
• List	Identifies a list item.
"Command / menu item"	Identifies commands / menu items or a quote.

2 Safety information

2.1 Information on the unit

The following symbols are applied to the unit:

Accompanying documents



This symbol is affixed next to the unit rating plate.

Meaning: When operating the unit, observe the operating instructions.



This symbol is affixed on the unit rating plate.

Meaning: The accompanying documents are available on the homepage of Sirona.

Electrostatic discharge (ESD)



Connector pins or sockets bearing ESD warning labels must not be touched or interconnected without ESD protective measures. See also "Electrostatic Discharge" and "Electromagnetic Compatibility".

Identification of single use devices



Prior to each exposure, the hygienic protective sleeves (single use devices) must be fitted.

Single use devices are identified with the symbol shown on the left. They must be disposed of immediately after use. Do not use single use devices more than once.

2.2 Ventilation slots

Under no circumstances may the ventilation slots on the unit be covered, since otherwise the air circulation will be obstructed. This can cause the unit to overheat.

Do not spray into the ventilation slots

Do not spray liquids such as disinfectants into the ventilation slots. This may lead to malfunctions. Use wipe disinfection only in the vicinity of the ventilation slots.



2.3 Condensation

Extreme fluctuations of temperature may cause condensation inside the unit. Do not switch the unit on before it has reached normal room temperature. See the chapter on "Technical data".

2.4 Qualifications of operating personnel

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

Personnel undergoing education or training, or who are using the device as part of general training may only operate the unit under the constant supervision of properly trained personnel.

To operate the unit, the operating personnel must:

- have read and understood the Operating Instructions
- be familiar with the fundamental structure and functions of the unit
- be able to recognize irregularities in the functioning of the unit and implement the appropriate measures where necessary

2.5 Switching the unit on

No patient may be positioned in the unit while it is booting up. The patient could be injured in case of malfunction.

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 the unit is switched back on.

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, Sirona recommends using bismuth or lead shields or aprons, especially for pediatric patients.

During an exposure, the operator should move as far away from the X-ray tube assembly as the coiled cable of the manual release 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. Visual contact with the patient and the unit must be maintained throughout the entire exposure.

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

2.7 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!



2.8 Laser light localizer

The system incorporates Class 1 laser products.

The light localizers are intended for correct patient positioning. They must not be used for any other purposes.

A minimum distance of 10 cm (4") is required between the eye and the laser. Do not stare into the beam.

The light localizers may be switched on only when functioning perfectly. Repair work must be carried out by authorized staff only.

Do not use the system with any other lasers, and do not make any changes to settings or processes that are not described in these operating instructions. This may lead to a dangerous exposure to radiation.

For the USA only:

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

2.9 Hygiene

The protective sleeves must be exchanged and all auxiliary exposure equipment must also be disinfected for each new patient in order to prevent any possible transmission of infective agents which might cause serious illnesses.

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

The following chapters contain more information about sterilization and hygienic protective sleeves: Hygienic protective sleeves [→ 25], Preparing the exposure [→ 29], Sterilization [→ 54] .

2.10 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.

X-rays of patients may be taken only when the system is working trouble-free.

The movements of the unit must not be obstructed by physical constitution, clothing, dressings, wheelchairs or hospital beds.

Do not leave the patient at the unit unattended.

2.11 Interference with electronic devices

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.

2.12 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 equipment manufacturer.

2.13 Combination with other equipment

Any person who assembles or modifies a medical electrical system complying with the standard IEC 60601-1-1 (safety requirements for medical electrical equipment) by combining it with other equipment is responsible for ensuring that the requirements of this regulation are met to their full extent for the safety of the patients, the operators and the environment.

If any devices not approved by Sirona are connected, they must comply with the applicable standards:

- IEC 60950-1 for information technology equipment and
- IEC 60601-1 for medical electrical equipment

See "Installation requirements" and the compatibility list/conformity declaration by the system integrator.

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

2.14 Modifications to the unit

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

For reasons of product safety, this product may be operated only with original Sirona accessories or third-party accessories expressly approved by Sirona. The user is responsible for any damage resulting from the use of non-approved accessories.

2.15 Structural alterations

If structural changes are made in the vicinity of the X-ray unit which result in the device being exposed to very high levels of vibration or even impact, the device must be inspected by a service engineer and recalibrated if necessary.

2.16 Electromagnetic compatibility

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

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

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

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

Please also observe the ESD protective measures described in the section "Electrostatic Discharge".

2.17 Electrostatic charge

2.17.1 ESD protective measures

ESD

ESD protective measures



Training

ESD stands for **ElectroStatic Discharge**.

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.

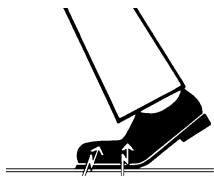
The content of this training is explained in the Chapter "About the physics of electrostatic charges" [→ 16].

2.17.2 About the physics of electrostatic charges

What is an electrostatic charge?

An electrostatic charge is a voltage field on and in an object (e.g. a human body) which is protected against conductance to ground potential by a nonconductive layer (e.g. a shoe sole).

Formation of an electrostatic charge



Electrostatic 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).

Amount of charge

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).

Electrostatic discharge must be preceded by electrostatic charging.

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)

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.

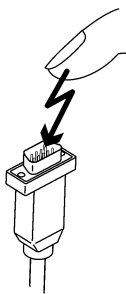
Background

Integrated circuits (logical circuits and microprocessors) are used to implement a wide variety of functions in dental/X-ray/CAD/CAM 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. ESD stands for **E**lectro**S**tatic **D**ischarge.

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

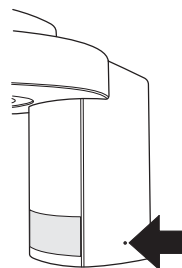
3 Technical description

3.1 Technical data

Chassis:	Model designation Nominal voltage: Permissible fluctuation: Permissible drop under load: Rated current: Nominal power output: Current time product: Nominal frequency: Internal line impedance: Main building fuse: Power consumption:	GALILEOS Compact 200 V – 240 V ±10% 10% 6 A 0.6 kW at 85 kV/7mA 42 mAs 50 Hz / 60 Hz max. 0.8 ohms 25 A slow-blow (16 A for single line) 0.9 kVA
X-ray tube assembly:	Focal spot size acc. to IEC 60336, measured in the central X-ray beam: kV: mA: Pulsed mode: Total filtration of X-ray tube assembly Cone-beam angle: High voltage generation frequency:	0,5 85 kV 5 mA / 7 mA 10 ms – 30 ms > 2.5 Al / 90 IEC 60522 collimated to approx. 24° 80 kHz – 100 kHz
Detector:	Type: Image intensifier (I.I.), Thales or Siemens Active input window size: Camera:	215 mm (8 1/2") diameter Pixels: 1000 ² FPS: 15 – 30 Dynamics: 12 bits, (4096 brightness values), 60 dB
Geometry:	Source-I.I. converter coating distance (central X-ray beam) Source-isocenter distance (central X-ray beam) Source-skin distance (minimum distance)	510 mm (20 1/16") 333 mm (13 1/8") approx. 220 mm (8 5/8")
Scanning process:	Orbital angle Scan time Number of single exposures	204° approx. 14 s 200

Reconstruction:

Marking of focal spot:




Automatic exposure blocking:

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, interval times of 8 s to 300 s are automatically set by the system.

Class I device

Degree of protection against electric shock:

Type B device 

Degree of protection against ingress of water:

Ordinary equipment (without protection against ingress of water)

Year of manufacture:



(on the rating plate)

Mode of operation:

Continuous operation

Long-term power output:

100 W

Anode material:

Tungsten

Exposure parameters for determining leakage radiation:

7 mA / 85 kV

Continuing current for leakage radiation measurements:

0.14 mA

Transport and storage temperature:

Basic unit

-40°C – +70°C (-40.00 °C – 70.00 °C)

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)

Operating altitude:

≤ 3000 m

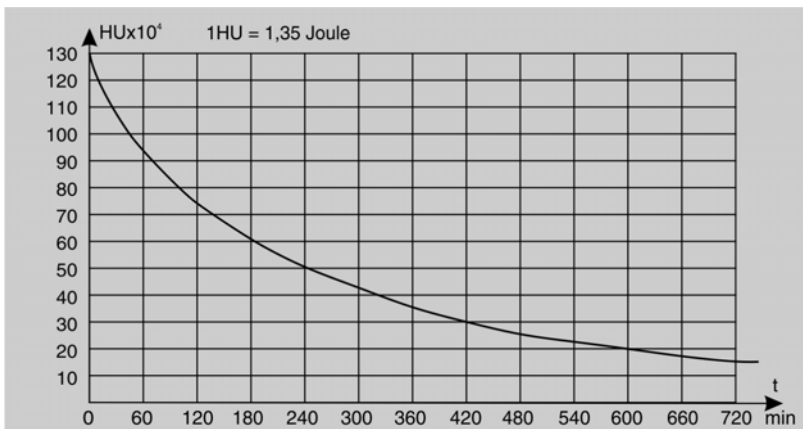
X-ray tube:

Toshiba DF-151R
or
Siemens SR 120/15/60

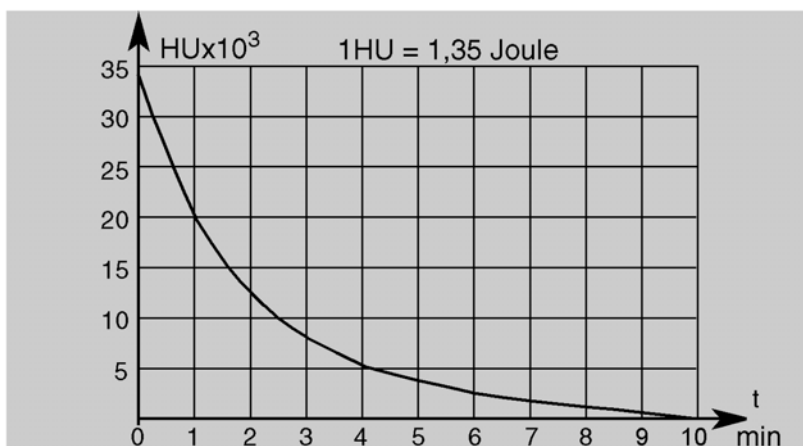
Minimum requirements for reconstruction PC (included in the scope of supply):	Processor:	DualCore from 2 GHz
	RAM:	4 GB RAM
	Hard disks:	> 500 GB
	Operating system:	Windows XP Professional SP3 or Windows 7 Professional
	External drive:	1x DVD-ROM, dual-layer
Minimum requirements for SIDEXIS visualization PC (not included in the scope of supply):	See SIDEXIS XG Operator's Manual. The system requirements are also listed under www.sidexis.com	
	Network:	100 MB Ethernet, 1 Gbit Ethernet recommended
	Communication interface:	RJ45 for LAN cable

3.2 Diagrams

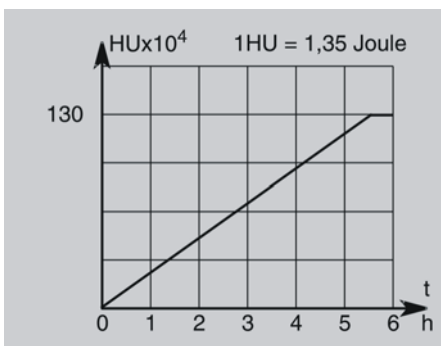
Cooling curve of tube housing



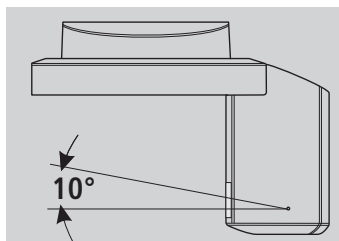
Cooling curve of X-ray tube



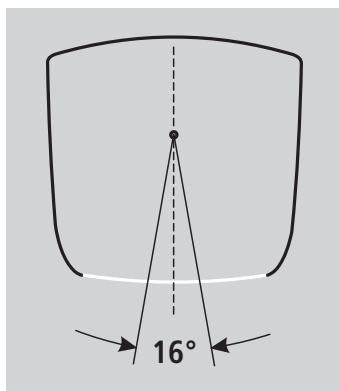
Heating curve of tube housing



Central X-ray beam



Anode angle



3.3 Certification

The **GALILEOS** X-ray unit complies with IEC 60601-1

The **GALILEOS** X-ray unit complies with IEC 60601-1-3 / 2008

The **GALILEOS** X-ray unit complies with IEC 60601-2-63 / 2012

The **GALILEOS** D3437 dental X-ray unit for extra-oral radiography complies with IEC 60601-2-63: 2012

Original language:

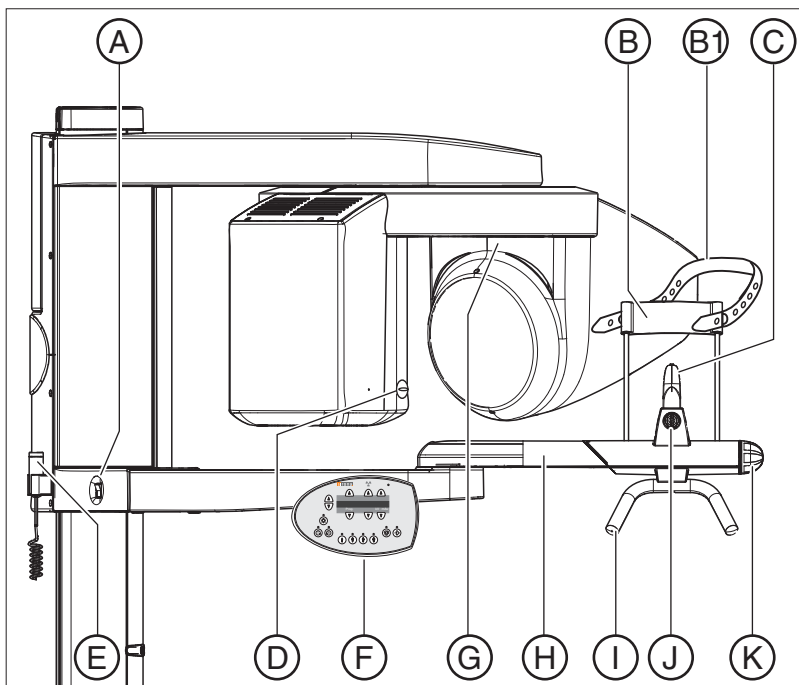
German



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

4 Controls and functional elements

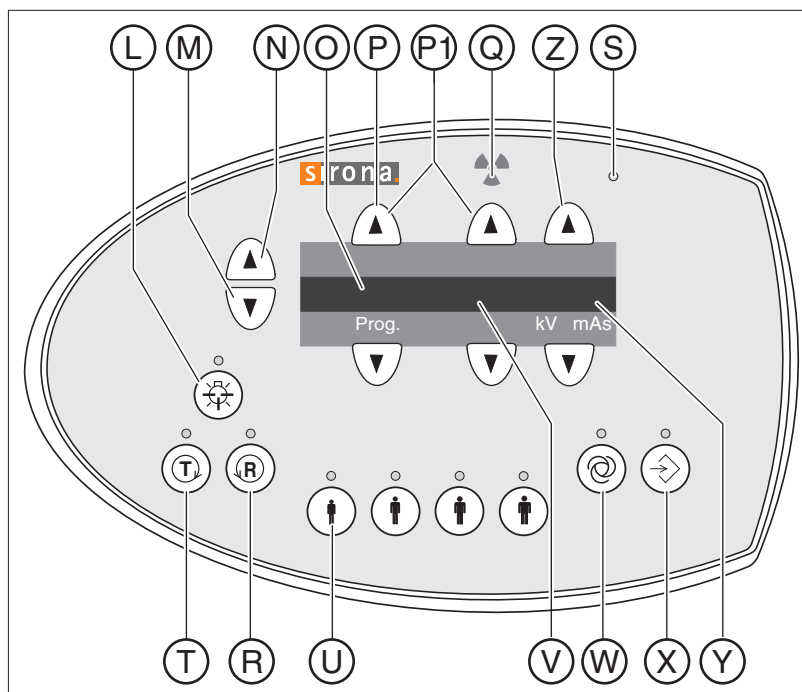
4.1 Operating and display elements on the GALILEOS



A	Main switch
B	Forehead support (removable contact upholstery)
B1	Head fastening strap
C	Bite block (sterilizable)
D	Adjustment button for mechanical diaphragm adjustment
E	Release button ¹
F	Multipad (swiveling control panel)
G	Light localizer, central light beam for face center
H	Swivel arm for patient immobilization
I	Handles for patient
J	Rotary knob for bite-block locking device
K	Rotary knob for swivel-arm lock and forehead support setting

¹ If the system is installed with a remote control, the release button is attached to the remote control.

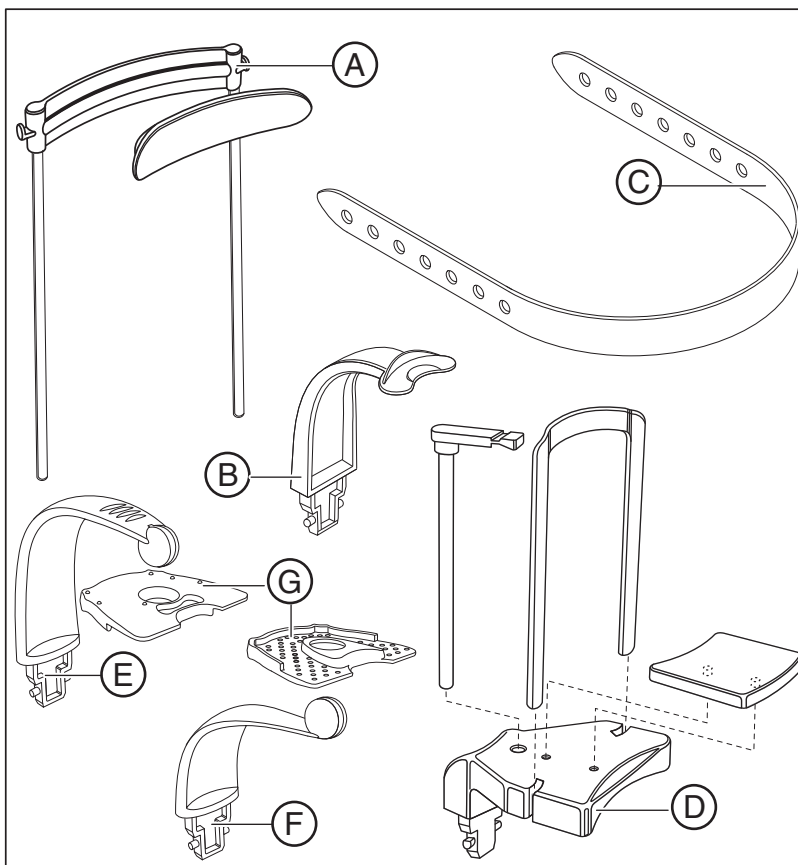
4.2 Operating and display elements on the Multipad



L	Light localizer ON/OFF
M	"Unit down" key
N	"Unit up" arrow key
O	Program display / help message
P	Program selection key
P1	Service keys in the service mode
Q	Optical radiation indicator
R	"R" key for return of the unit
S	"Unit ON" LED display
T	"T" key for test cycle without radiation
U	Row of patient symbol keys with LEDs
V	Radiation time in seconds; transfer rate in percent
W	Key for service menu display with LED
X	Key for save function with LED
Y	Display of kV/mA combinations
Z	Manual adjustment of kV/mAs key combinations

5 Accessories

5.1 Bite blocks, supports and fasteners



A	Forehead support (contact upholstery can be removed for cleaning and disinfection) (1 pc) Order No. 61 34 931
B	Rigid bite block (can be removed for cleaning and sterilization by rotating the locking knob) (5 pcs) Order No. 61 34 949
C	Head fastening strap (2 pcs) Order No. 61 34 956
D	Chin rest, complete (1 pc) Order No. 59 81 472
E	Mandibular bite block plate holder (with symbol for LJ) (1 pc) Order No. 61 50 226
F	Maxillary bite block plate holder (with symbol for UJ) (1 pc) Order No. 61 50 218
G	Spherical bite block plate - For single use only (not sterilizable) - Can be obtained from dental dealers.

5.2 Hygienic protective sleeves

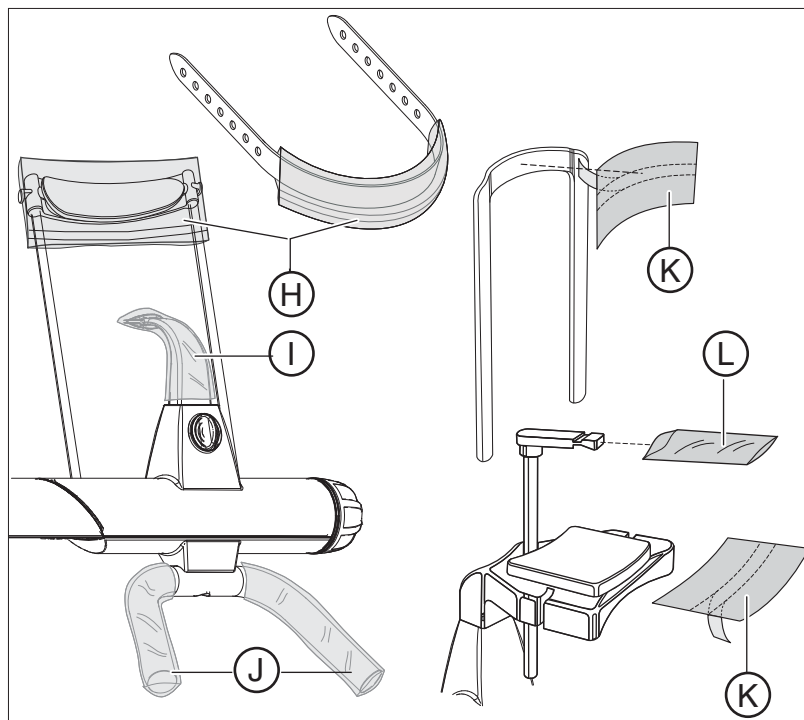
Identification of single use devices



Prior to each exposure, the hygienic protective sleeves (single use devices) must be fitted.

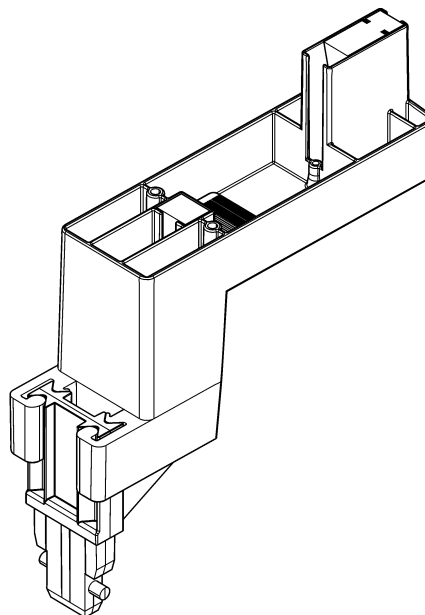
Single use devices are identified with the symbol shown on the left. They must be disposed of immediately after use. Do not use single use devices more than once.

Hygienic protective sleeves



H	Hygienic protective sleeves for forehead support and head fastening strap (100 pcs) Order No. 61 84 894
I	Hygienic protective sleeves for bite block (500 pcs) Order No. 61 27 745
J	Hygienic protective sleeves for handles (500 pcs) Order No. 61 84 902
K	Hygienic protective sleeves for chin rest support and bar (100 pcs) Order No. 59 32 603
L	Hygienic protective sleeves for bite block chin rest (500 pcs) Order No. 33 14,072

5.3 Test phantom for acceptance/constancy test

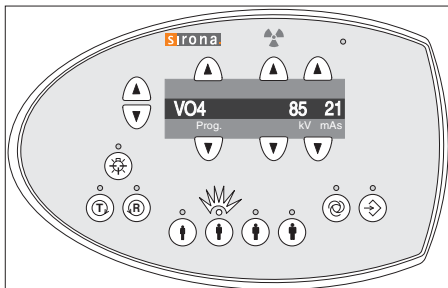


GALILEOS constancy test phantom

(1 piece) Order No. 61 40 813

6 Program

6.1 VO4: Volume 4 (standard program)



Standard scan, providing views very quickly.

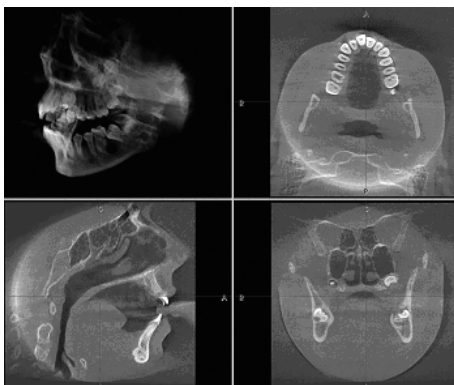
This program is used to create a volume data set of the patient with 512 x 512 x 512 volume elements (voxels).

The resolution in the volume (voxel size) equals $0.3 \times 0.3 \times 0.3 \text{ mm}^3$.

Scan time:	14 seconds
Effective radiation time:	2...6 seconds
Reconstruction time:	approx. 2.5 minutes
Data volume:	approx. 390 MB
comprising:	
Patient volume:	approx. 270 MB
Panoramic slice:	approx. 4 MB per 2D slice
Lateral cephalometric image:	approx. 5 MB per 2D slice
Radiological views:	approx. 5 MB per 2D slice
Corrected raw data:	approx. 105 MB (deletable)

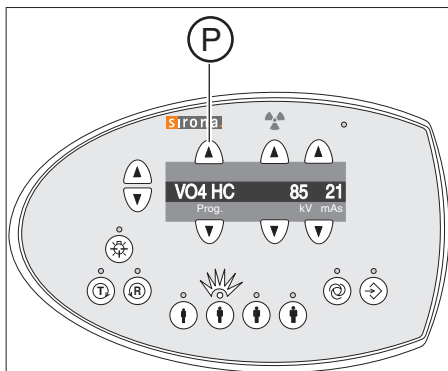


Panoramic view



Radiological views

6.2 VO4 HC: Volume 4 (high contrast option HC)



The program VO4 HC (high contrast) is selected with the program selection key (P).

Compared to the standard settings, the high contrast setting VO4 HC improves the display of hard structures such as bones and teeth. At the same time, it can also impair the display of soft tissues and especially soft tissue silhouettes.

The high-contrast option is therefore especially suitable in cases where bone or tooth structures must be evaluated, e.g. after bone augmentations, and a correct display of soft-tissue silhouettes is not of primary importance.

In addition, the high-contrast setting is especially suitable for the DICOM export function for further implant planning programs (e.g. Nobel Guide, Simplant).

CAUTION

If the V04 HC program is used for DICOM Export in third-party implant planning software, a unit setting of 42 mAs must be selected for an optimal result.

7 Operation

7.1 Preparing the exposure

7.1.1 Fitting the accessories

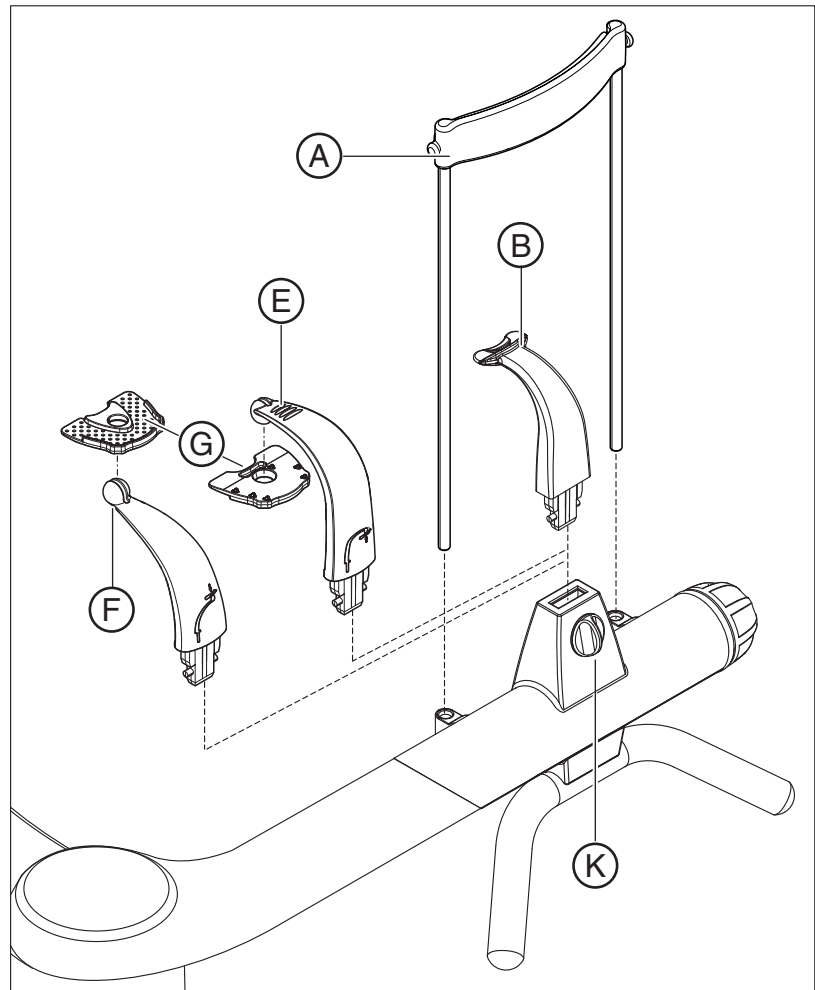
WARNING

Sterilizing and disinfecting accessories, hygienic protective sleeves

The bite block must be disinfected for each new patient.

The handles, head fastening strap (if used) and contact upholstery of the forehead support must be disinfected for each new patient.

Use hygienic protective sleeves.



- Insert the bite block **(B)** up to the stop and lock it with the rotary knob **(K)**.
- Insert the headrest support **(A)**.
- Slide on the hygienic protective sleeves.

or for creating a drilling template:

- Insert mandibular bite block plate holder **(E)** or
- maxillary bite block plate holder **(F)** up to the stop and lock it with the rotary knob **(K)**.
- Clamp the spherical bite block plate **(G)** for the upper jaw or for the lower jaw to the sphere of the corresponding bite block holder as shown.

7.1.2 Switching the unit on

NOTICE

Extreme fluctuations of temperature may cause condensation. For this reason, do not switch the unit on before it has reached normal room temperature. See Technical description [→ 17] Section.

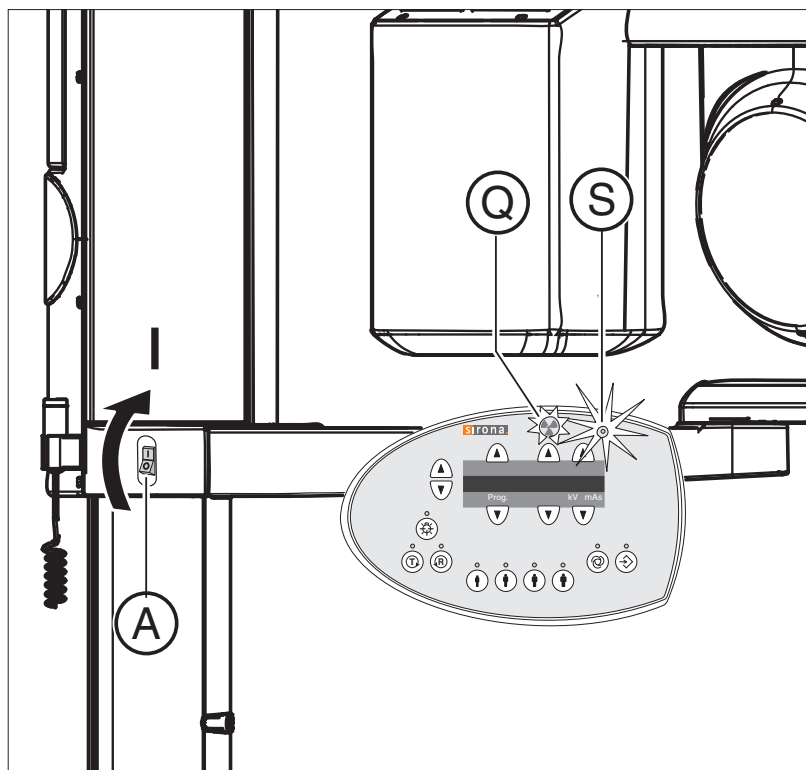
IMPORTANT

Following longer periods of disuse (> 200 hours), the X-ray detector (sensor) requires a preparation time of up to ten minutes. Message S1 50 (Sensor being prepared) is displayed. If exposure readiness is reached during this time, error message E1 10 07 appears. See Section Error message E1 10 07 [→ 51].

⚠ 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!



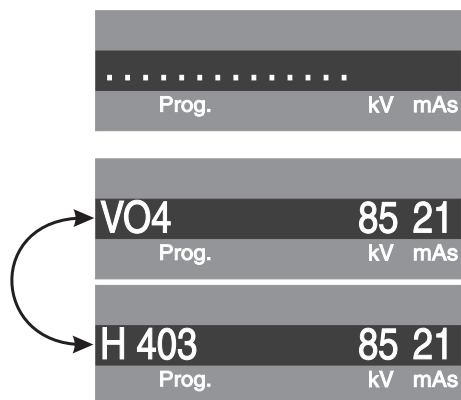
- Set main switch (A) to position I and wait approx. 1 minute.
- The LED at the top of the Multipad (S) lights up.
- The radiation indicator (Q) lights up for approx. one second for a function test.

NOTICE

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

7.1.3 Readings on the digital display

Readings on the digital display



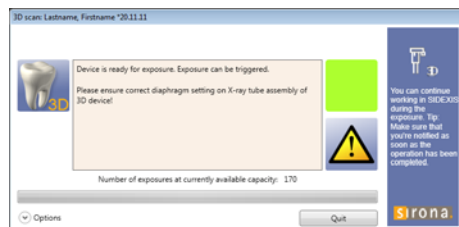
After power-on of the system, running dots initially appear on the digital display for a brief time.

Then the exposure program number and the kV/mAs combination stored for this exposure program are displayed.

If the exposure program number and a help message H... alternately appear on the digital display, the help message must be processed first.

The system is ready for operation only if the help message no longer appears.

7.1.4 Switch SIDEXIS to ready for exposure state









- To make the **SIDEXIS program on the PC ready for exposure**, see the SIDEXIS operator's manual.
- As long as there is no connection to SIDEXIS, error message "**H 403**" (Switch SIDEXIS to ready for exposure state) and the exposure program number will alternately appear on the digital display of the Multipad.



If you have a GALILEOS with Facescan, you can now select the exposure type on a PC in SIDEXIS. The exposure dialog box looks different with Facescan; see the Facescan Operating Instructions.

7.2 Selecting exposure parameters

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

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

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. Press the **Memory** key (X) briefly; the LED above the key then lights up.
2. Select one of the outer patient symbol keys.
Far left patient symbol key: Setting 85 kV/10 mAs
Far right patient symbol key: Setting 85 kV/42 mAs
3. Select the exposure parameters with the keys (Z).
85 kV/10 mAs (left patient symbol key, then  key)
85 kV/42 mAs (right patient symbol key, then  key)
4. Press the **Memory** key (X) briefly; the LED above the key briefly flashes and then switches off.
The new value is programmed.

7.3 Positioning the patient

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).

CAUTION

Parts of the dentist stool must not lie in the beam path and must not affect the movement of the unit.

Preparations

IMPORTANT

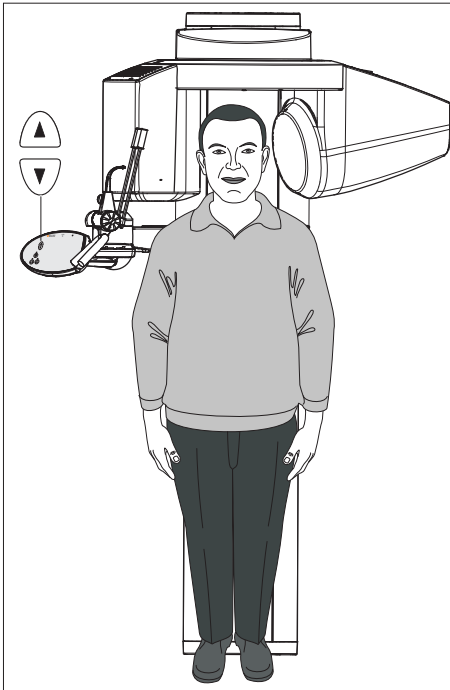
Note the diagnostic restrictions in the immediate vicinity of highly X-ray absorbent objects, e.g. metal. These diagnostic restrictions apply regardless of metallic artifact reduction sequence (MARS) and other selected filter settings. For patients with metallic implants, bridges and fillings, image quality can be affected, and thereby also the establishment of a diagnosis.

- 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.
- 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.
- 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 at the control panel.

IMPORTANT

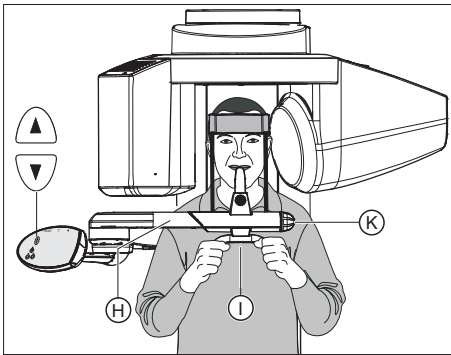
When the R key is pressed, the unit begins moving only if the swivel arm is located in one of the two end positions.

7.3.1 Positioning the patient - with bite block



- Press the **R** key to move the unit back to the entry position.
- The patient approaches 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 again.

7.3.1.1 Aligning the patient - with standard bite block



- Close the swivel arm (H) until it snaps in place.
- Using the "up" and "down" keys on the control panel, 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 (I) firmly.

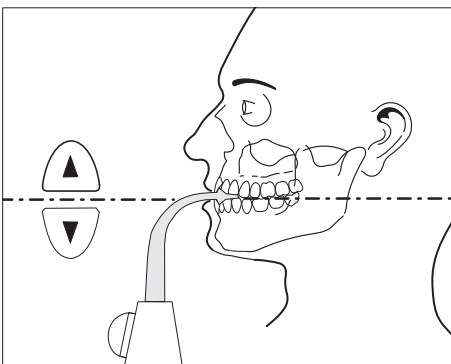
IMPORTANT

The patient must stand upright with a straight back and relaxed shoulders.

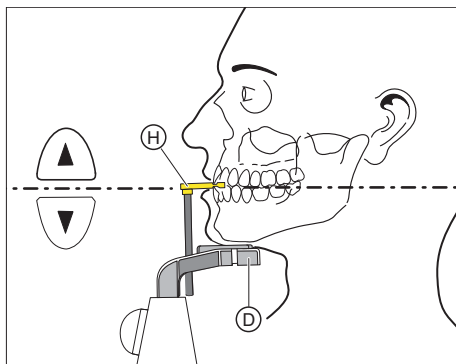
- Have the patient bite the spoon of the bite block.

IMPORTANT

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.



7.3.1.2 Aligning the patient - with chin rest, bite block, and contact bar



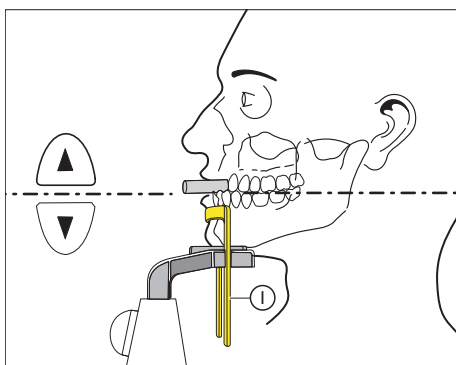
Indications:

- Toothless patients
- Temporomandibular diagnosis
- Cephalometry

- The patient enters the unit.
- Using the "Up" or "Down" keys, 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.

⚠ CAUTION

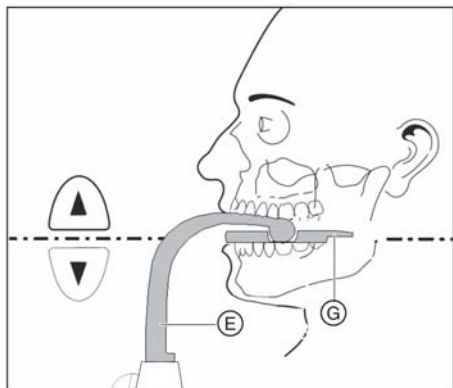
The height adjustment motor starts slowly and then increases its speed. Press and hold down the height adjustment key until the unit has reached the desired height.



- Ask the patient to place his chin on the chin rest (D) with closed occlusion and to grasp the handles firmly.
- Swing in bite block (H).
- 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 (I) (arch facing column).
- Please place the contact bar between the patient's chin and upper lip and insert a cotton roll.

7.3.2 Positioning patients - with spherical bite block

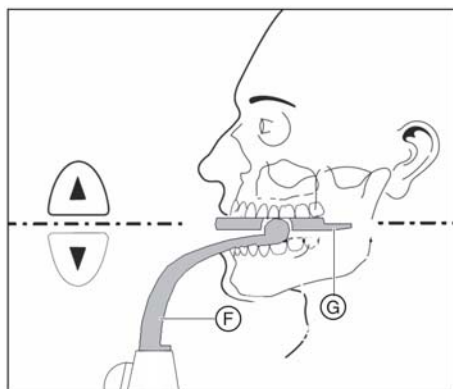
Using the spherical bite block to create an implant drilling template



Select the bite block plate holder appropriate for a scan with the spherical bite block. For exposures of the lower jaw, insert bite block plate holder (E). For exposures of the upper jaw, insert bite block plate holder (G).

The spherical bite block plate (G) contains 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 plate

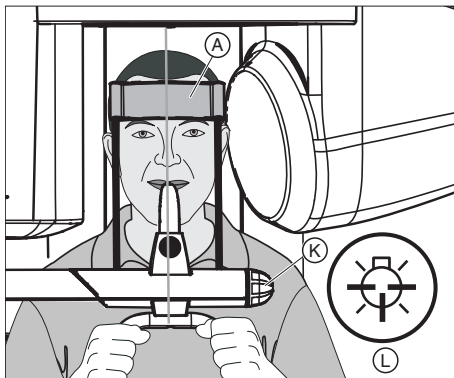


- Insert spherical bite block plate (G) with patient registration at the patient.
- Close swivel arm.
- Adapt unit height until sphere and incisors are at the same height. The spherical bite block plate should be aligned horizontally.
- Carefully lead the patient to the sphere of the bite block plate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

IMPORTANT

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

7.3.3 Display of midsagittals



- Switch on the **light localizer** with key (L) on the control panel. 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 (midsagittal symmetry).

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 (A) against the patient's forehead with the rotary knob (K).
- In some cases, it is also advisable to immobilize the patient's head with a head fastening strap as well (see chapter Bite blocks, supports and fasteners [→ 24]).

Concluding the preparations

- If the light localizer is still on, switch it off with key (L) on the control panel.

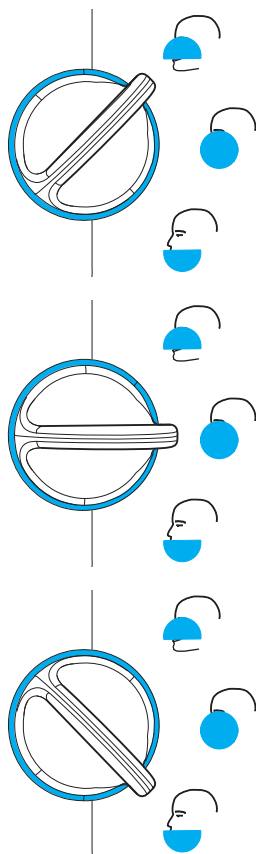
7.4 Adjusting the mechanical diaphragm

The mechanical diaphragm allows for three fixed settings.

The areas displayed in blue show the intended visible volume of the X-ray exposure.

The collimation results in minimal radiation exposure to explore diagnostic questions in the upper and lower jaw.

You can select the desired area by simply turning the switch on the X-ray tube assembly.



1. Upper jaw collimation (UJ)

If the "Upper jaw" setting is selected, the X-ray image will only show the area of the upper jaw. The height of the displayed volume is approx. 8.5 cm. The region of the lower jaw will not be included in the image.

2. Open diaphragm

When the "Open diaphragm" setting is selected, the full volume will be displayed in the X-ray image. No collimation occurs in this case.

3. Lower jaw collimation (LJ)

If the "Lower jaw" setting is selected, the X-ray image will only show the area of the lower jaw. The height of the displayed volume is approx. 8.5 cm. The region of the upper jaw will not be included in the image.

Tip: The open diaphragm is preferable for transverse wisdom teeth because when the upper jaw is collimated it is not completely displayed in some cases.

CAUTION

Check for the correct diaphragm setting prior to each exposure.

IMPORTANT

If the usual volume display shows considerable deviations with an adjusted diaphragm setting, the diaphragm may be maladjusted. In this event, contact your service engineer.

7.5 Releasing the exposure

⚠ CAUTION

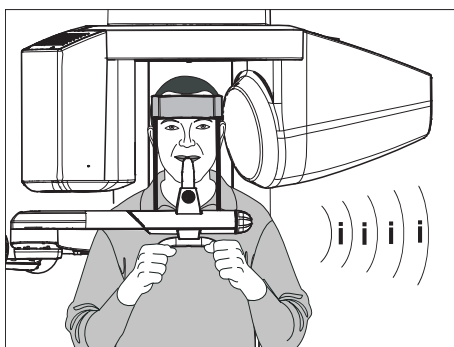
Be sure to observe the radiation protection regulations in your country, see also Radiation protection [→ 12].

IMPORTANT

If e.g. the door of the X-ray room is not properly shut, the message **H 321** (Close the door) appears on the digital display of the Multipad and on the remote control.

Help messages may no longer be displayed alternately.

- Check the program and exposure parameters.



⚠ 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 (E) directly on the X-ray unit or on the remote control.

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

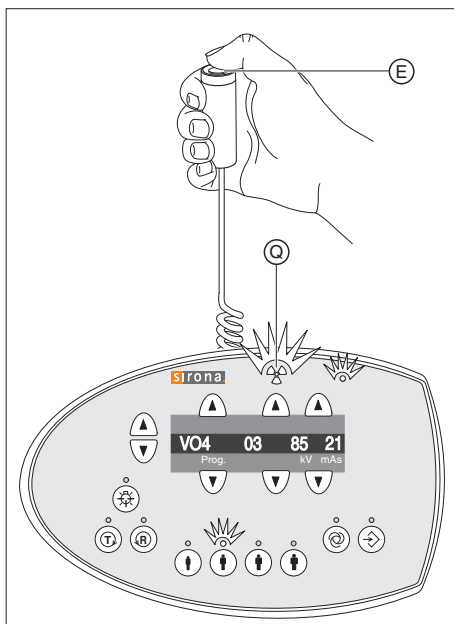
During radiation emission, the optical radiation indicator (Q) on the Multipad or on the remote control is illuminated. In addition, an **acoustic signal** sounds throughout the entire radiation time.

⚠ 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 is complete when...
 - The message "H 320" appears alternately with the program number on the remote control display and the Multipad.
 - The actual mAs value is shown next to the program number at the end of the exposure.
 - A short, pulsed series of tones can be heard at the end of the exposure (this function can be deactivated by the service engineer).



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

Press the "R" key to confirm the exposure.

Then press the "R" key again to move the unit to the entry position.

The patient can now step out of the unit.

CAUTION

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

After completion of the exposure

On 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.

IMPORTANT

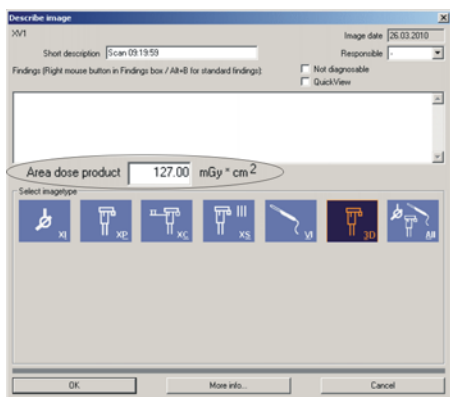
The operation of the visualization software is described in the attached GALAXIS Operator's Manual.

"Area dose product" display

Following the exposure, the "Area dose product" is displayed in the "Describe image" dialog box in SIDEXIS.

Open the dialog box via "[A]nalysis" → "Findin[g]s" or via an icon displayed at the upper edge of the window.

The displayed dialog box shows the available image information for the currently active X-ray.



Canceling an exposure

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

The digital display alternately shows the exposure time which had actually elapsed prior to exposure interruption and help message "H320".

The Ready LED above the "R" key starts flashing.

CAUTION

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

- Press the "R" key on the Multipad twice.
- After the rotating element has returned to its starting position, repeat the exposure.

Automatic exposure blocking

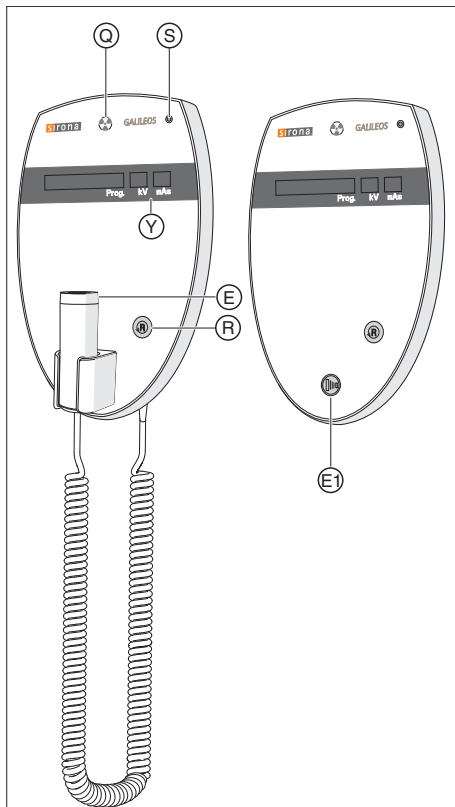
(thermal protection of the tube)

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

If the release button is pressed, the decrementing cooling time in seconds appears on the digital display.

Another exposure can be released only after the cooling period has elapsed.

7.6 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 this purpose, the **exposure release button (E)** can be detached from the unit and attached to the remote control (service engineer).

The **exposure release button (E1)** can be used if establishing visual contact with the patient does not require a longer cable.

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

After the unit is switched on, the LED (S) lights up.

The radiation indicator (Q) lights up for a longer period of time for a function test.

The three display fields on the display panel light up simultaneously.

A progress bar appears after approx. 10 seconds. After the system starts, the display switches to program VO4 with the corresponding values.

As long as **help messages** are displayed on the digital display of the Multipad, they also appear on the **"Prog."** display of the remote control, continuously **alternating** with the **program name**.

Once all **help messages** have been processed, the program name **"Prog."**, the **"kV"** and the **"mAs"** appear continuously on the **display panel**.

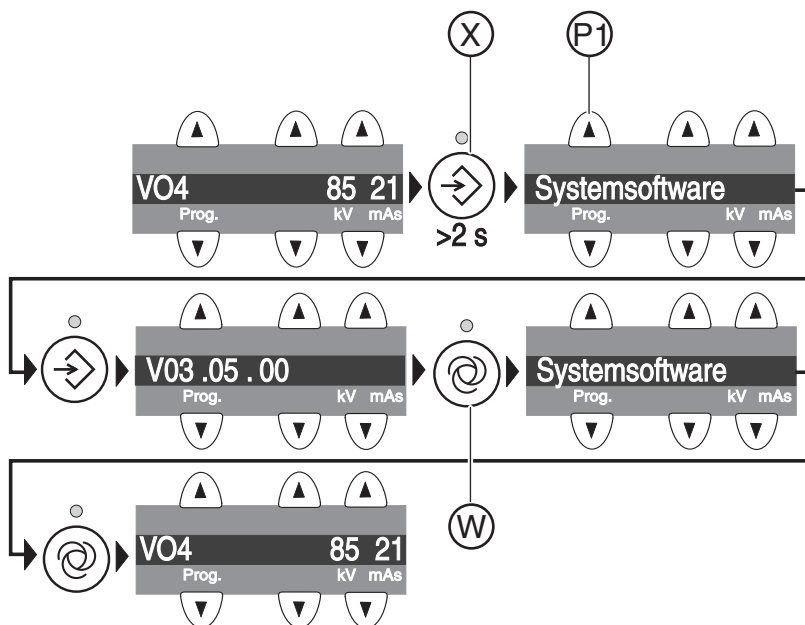
The exposure can be released now.

IMPORTANT

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.

8 Info and Service menus

8.1 Info menü



The info menu is intended for the dialog with the service engineer.

You can reach the Info menu by pressing the Memory button (X) > 2 seconds.

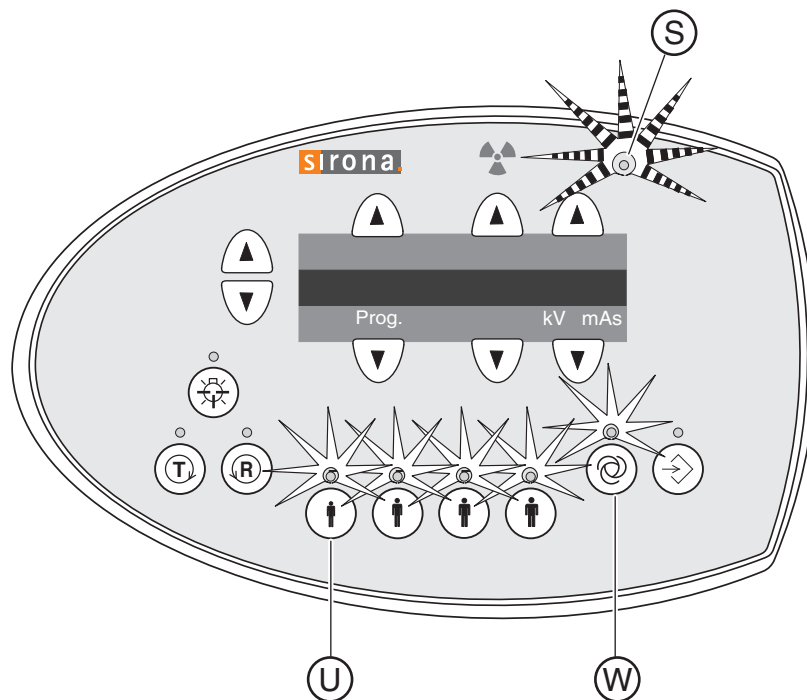
The Info menü appears on the digital display.

You can select different parameters from a list using the service keys (P1).

If you then briefly press the Memory button (X) again, a corresponding value appears on the digital display.

You can switch back to the parameter list by briefly pressing the Service menu key (W). Pressing this key again causes exposure readiness to reappear.

8.2 Service menu



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

The **service engineer** can reach the Service menu by pressing and holding the **Service menu key (W)** > 2 seconds.

The LED above the Service menu key lights up, followed by the LEDs above all patient symbol keys (U).

The ready-for-operation LED (S) starts flashing.

Then a PIN must be entered by the service engineer.

If an incorrect PIN is entered or no entry is made within 5 seconds, the program then returns to exposure readiness.

It is also possible to quit the Service menu by briefly pressing the **Service menu key (W)**.

9 List of messages

9.1 List of help messages

A number of H3 help messages may appear on the control panel when you attempt to release an exposure:

- Press the **release button**. **ATTENTION Observe radiation protection measures.**
 The message **H3 / H4 ..** – appears on the control panel.
- The list provided below explains how to proceed to make the system ready for exposure.

Help message	Description	Actions required
H3 01	The rotating element is not in the starting position.	R button, move into starting position.
H3 20	The exposure data have not been acknowledged yet.	R button, confirm exposure data.
H3 21	Check door contact of the X-ray room.	Close the door.
H3 23	Open or close the swivel arm completely.	Move the swivel arm into its end position.
H4 03	SIDEXIS is not ready for exposure.	Switching SIDEXIS to ready for exposure state
H4 20	The image could not be transferred to SIDEXIS. See SIDEXIS Operator's Manual. CAUTION Do not switch off the system before the help message has disappeared.	Call up existing exposure.
S1 50	The sensor is not yet ready for an exposure.	Wait until the sensor is ready for an exposure.

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.

IMPORTANT

To eliminate errors in the image database (rescue management), see "Software component operating instructions", REF 61 81 155.

9.2 Error message structure

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

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 identification

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

9.2.1 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, for example, temporary excess temperatures 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 unit off and then on again; if the error reoccurs inform customer services. NOTICE! After switching the unit off with the main switch, you must wait for approx. 2 minutes before switching it back on again.	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.
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.

Ex	Description	Actions required	Error group
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 reoccurs, 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; contact your Customer Service immediately.	This error group includes all errors which may occur spontaneously and without any related operator action. They may be caused by system self-tests. Further operation of the unit is not allowed for safety reasons.

9.2.2 yy

The 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 error
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	X-ray tube assembly
7/71	User interface
89	Sensor
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).

9.2.3 zz

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

9.3 Error message E1 10 07

Explanation

The possible causes of this error and its correction are described here.

Case 1

Following longer periods of disuse (> 200 hours), the X-ray detector (sensor) requires a preparation time of up to ten minutes. Message S1 50 (Sensor being prepared) is displayed.

During this time the unit is not ready for operation.

If exposure readiness is reached during this time, error message E1 10 07 appears.

Solution

Acknowledge this error message by pressing the R key and wait until the error message goes out.

IMPORTANT
Shortening the waiting time
Switching the unit off and on does not shorten the waiting time!

Case 2

If the error message E1 10 07 appears immediately after the unit is switched on and the user has not established exposure readiness, please inform the responsible service engineer.

10 Maintenance

10.1 Cleaning and care

10.1.1 Cleaning

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

NOTICE

During cleaning or disinfection, liquids may enter the manual release button or unit via ventilation slots.

Electrical components of the system can be destroyed by liquids.

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

10.1.2 Disinfecting

Only the external surfaces may be disinfected with approved chemical disinfectants. Use only disinfectants that comply with the valid requirements of the respective national regulatory body or whose bactericidal, fungicidal and virucidal properties have been verifiably tested and approved accordingly.

CAUTION

Cleaning and care agents may contain aggressive ingredients.

Unsuitable cleaning and care agents are detrimental 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 cleaning and disinfecting agents approved by Sirona!

A continuously updated list of approved agents can be downloaded from the Internet at:

"www.sirona.com" / "SERVICE" / "Care and cleaning" / "Care and cleaning agents"

If you do not have any access to the Internet, you can order the list in one of the following two ways:

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

Order No.: **59 70 905**

Sirona recommends the following disinfectants:

- MinutenSpray classic, by ALPRO®
- MinutenWipes, by ALPRO®

In the USA and Canada:

- CaviCide® or
- CaviWipes™ .

10.1.3 Sterilization

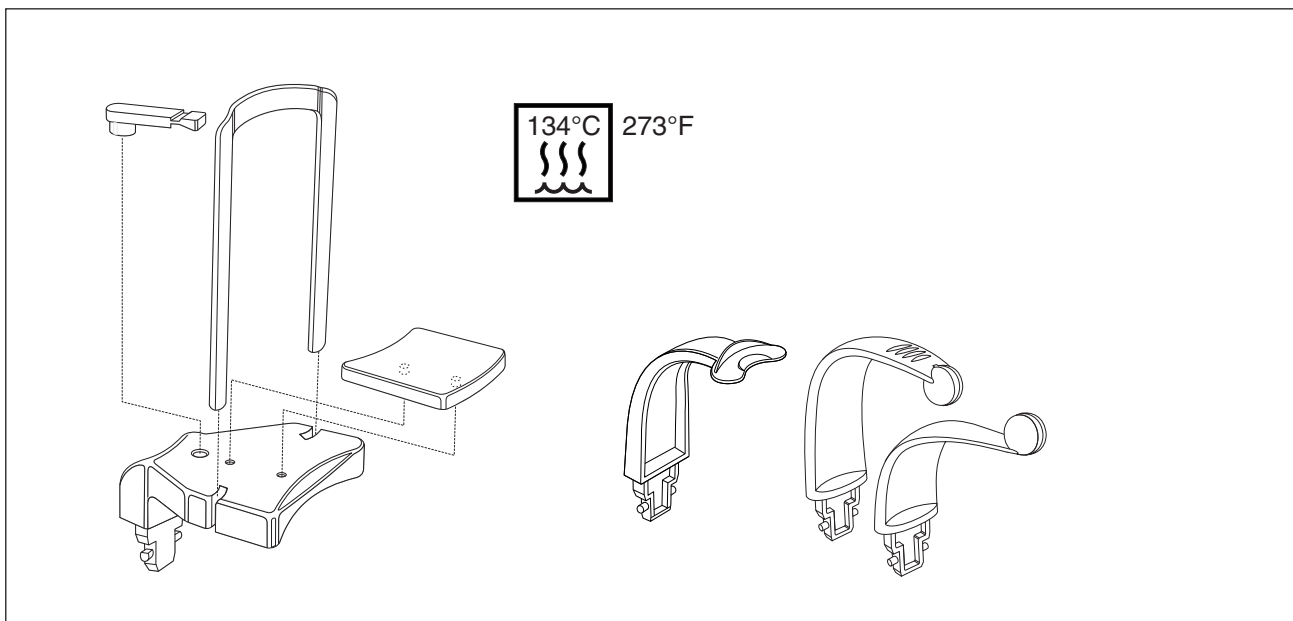
WARNING

Infections can be transmitted from patient to patient.

Accessories that are not sterilized correctly can cause illness in patients.

- All accessories that are suitable for sterilization should only be sterilized in an autoclave at 134 °C (273° F), with at least 3 minutes holding time and at 2.1 bar (30.5 psi) overpressure.

The following accessories can be sterilized:



In addition, also use the hygienic protective sleeves, see "Hygienic protective sleeves" [→ 25].



WARNING

The hygienic protective sleeves single use devices.

Unsterile hygienic protective sleeves can cause illness in patients.

- Replace the hygienic protective sleeves after each patient.

10.2 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.

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.

The information provided in the supplied document "Inspection and maintenance" should be helpful here.

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.

The information provided in the supplied document "Inspection and maintenance" should be helpful here.

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 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.

If, after taking into account the patient's anatomy and excluding possible sources of error such as incorrect patient positioning, this criterion seems to apply, immediately contact a service engineer to have potential system faults repaired.

Country-specific requirements

Observe any possible additional country-specific requirements.

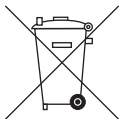
11 Dismantling and disposal

11.1 Dismantling and reinstallation

When dismantling and reinstalling 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.

11.2 Disposal



Your product is marked with the adjacent symbol. Within the European Economic Area, this product is subject to Directive 2002/96/EC as well as the corresponding national laws. This directive requires environmentally sound recycling/disposal of the product. The product must not be disposed of as domestic refuse!

Please observe the disposal regulations applicable in your country.

Disposal procedure

Please note that this product is subject to the stipulations in EC Directive 2002/96 governing waste electrical and electronic equipment and must be disposed of in line with these special requirements within the European Union (EU).

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

When disposing of equipment permanently, please proceed as follows:



In Germany:

To initiate return of the electrical device, please send a disposal order to "enretec GmbH".

1. You can find a form for placing a disposal order on the company's homepage (www.enretec.de) under the menu item "Entsorgung elektrischer und elektronischer Geräte" (Disposal of electric and electronic devices). The form can either be downloaded or completed online.
 2. Fill out the form with the corresponding details and send it as an online order or fax it to enretec GmbH at +49(0)3304 3919 590. You can also get in touch with the following contacts for disposal orders and any questions relating to this you may have:
Phone: +49(0)3304 3919 500;
E-mail: pickup@eomRECYCLING.com
Mailing address: enretec GmbH, Geschäftsbereich eomRECYCLING
Kanalstrasse 17, 16727 Velten
- ↳ Any nonpermanently installed equipment will be picked up at its installation site in the practice. Permanently installed equipment will be picked up curbside at your address by appointment.

All disassembly, transport and packaging costs are to be borne by the owner/operator of the equipment. The disposal itself is free of charge.

Worldwide (outside Germany):

Please contact your local dental equipment specialist for country-specific information on disposal.

11.2.1 GALILEOS X-ray tube

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

12 Dosage

Dose area product

The radiation exposure is indicated as the dose area product (DAP) of the energy dose (Gy x cm²) per mAs of every selectable level and diaphragm.

To offset measurement errors and system and device variations, a tolerance of 20% must be expected.

GALILEOS operates with fixed settings of 85 kV and 7 mA (at 10 mAs, 5 mA).

Program:	Additional					Additional
Set values:	10 mAs	14 mAs	21 mAs	28 mAs	35 mAs	42 mAs
Effective radiation time	2 s	2 s	3 s	4 s	5 s	6 s
DAP	211 mGy ^{cm} ²	268 mGy ^{cm} ²	400 mGy ^{cm} ²	520 mGy ^{cm} ²	660 mGy ^{cm} ²	800 mGy ^{cm} ²
DAP of LJ exposure	122 mGy ^{cm} ²	155 mGy ^{cm} ²	231 mGy ^{cm} ²	301 mGy ^{cm} ²	381 mGy ^{cm} ²	462 mGy ^{cm} ²
DAP of UJ exposure	167 mGy ^{cm} ²	213 mGy ^{cm} ²	318 mGy ^{cm} ²	413 mGy ^{cm} ²	524 mGy ^{cm} ²	635 mGy ^{cm} ²

Effective dose values

The radiation exposure can also be specified as effective dose value D_{eff} (μSv).

To offset measurement errors and system and device variations, a tolerance of 20% must be expected.

GALILEOS operates with fixed settings of 85 kV and 7 mA.

The following dose values thus result for the **GALILEOS Compact** with an open diaphragm:

Program	Additionally					Additionally
Values	10 mAs	14 mAs	21 mAs	28 mAs	35 mAs	42 mAs
Effective dose value D_{eff} ICRP 1990	9 μSv	12 μSv	18 μSv	24 μSv	30 μSv	36 μSv
Effective dose value D_{eff} ICRP 2007	13 μSv	19 μSv	28 μSv	37 μSv	46 μSv	56 μSv

Source

Study: "Comparison of the effective dose of different DVT systems",
Dr. Schulze, Freiburg University, Germany

IMPORTANT

When the maxillary or mandibular collimation is used, dose values can be reduced by approx. 15%.

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

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