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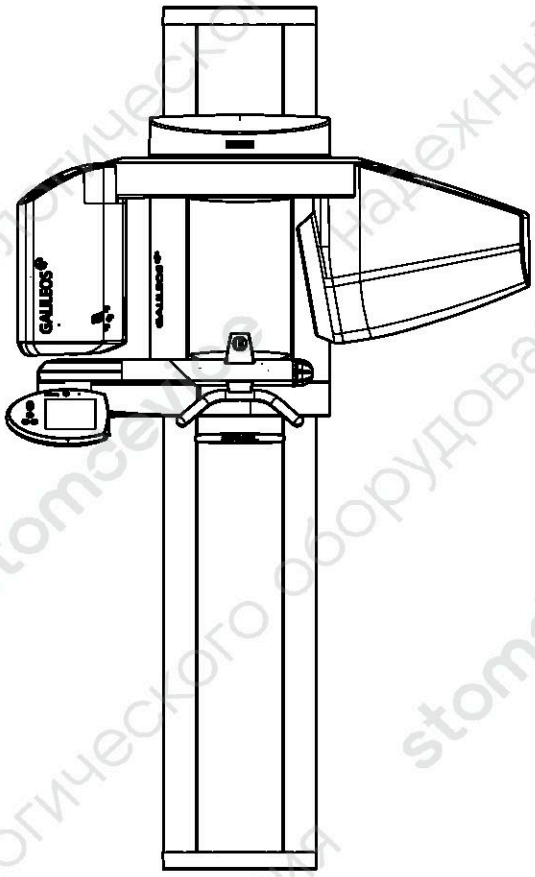
New as of: 10.2018

sirona
The Dental Company

GALILEOS

Operating Instructions GALILEOS Comfort PLUS

English



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Table of contents

1 General information 6
1.1 Dear Customer, ... 6
1.2 Contact information 6
1.3 General information about this operating manual 7
1.4 Other valid documents 7
1.5 Warranty and liability 8
1.6 Obligation of system owner and personnel 8
1.7 Intended use 9
1.8 Indication and contraindication 9
1.9 Structure of the document 10
1.9.1 Identification of the danger levels 10
1.9.2 Formats and symbols used 10
2 Safety information 11
2.1 Information on the unit 11
2.2 Ventilation slots 11
2.3 Condensation 11
2.4 Qualifications of operating personnel 12
2.5 Switch on the unit 12
2.6 Radiation protection 12
2.7 Emergency Stop 12
2.8 Laser light localizer 13
2.9 Hygiene 13
2.10 Touchscreen 13
2.11 Trouble-free operation 14
2.12 Interference with electronic devices 14
2.13 Risks of electromagnetic fields 14
2.14 Combination with other equipment 14
2.15 Changes to the unit 15
2.16 Structural alterations 15
2.17 Electromagnetic compatibility 15
2.18 Electrostatic charge 16
2.18.1 ESD protective measures 16
2.18.2 About the physics of electrostatic charges 16

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3 Technical description 18
3.1 Technical data 18
3.2 Diagrams 21
3.3 Values of the secondary scattered radiation 23
3.4 Certification and registration 24
4 Controls and functional elements 25
4.1 Operating and display elements on the GALILEOS 25
4.2 Operating and display elements on the head fixation device 26
4.3 Control and display elements on the Easypad with touchscreen 27
4.4 General touchscreen functions on the Easypad 28
4.4.1 Program settings (Level 2) 29
4.4.2 Service start settings (Level 4) 30
4.4.3 Service menu 30
4.4.4 Touchscreen settings 31
4.4.5 Closing menu cells 31
4.4.6 Info screen 32
5 Accessories 33
5.1 Bite blocks, supports and fasteners 33
5.2 Accessories for head fixation device 34
5.3 Hygienic protective sleeves 35
5.3.1 Hygienic protective sleeves for bite blocks, supports, and fasteners 35
5.3.2 Hygienic protective covers for head fixation device 36
5.4 Test phantom for acceptance/constancy test 37
6 Programs 38
6.1 VO5: standard volume program 38
6.1.1 HC mode: high contrast mode 39
6.1.2 HD mode: high definition mode 39
6.2 VOG: volume program for template scan 40
7 Operation 41
7.1 Preparing the exposure 41
7.1.1 Fitting the accessories 41
7.1.2 Inserting the head fixation device 43
7.1.3 Switching the unit on 45
7.1.4 Display on the Easypad touchscreen 46
7.1.5 Switching SIDEXIS 4 to ready for exposure state 47
7.1.6 Switch SIDEXIS to ready for exposure state 47

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7.2 Pediatric exposure 48
7.3 Selecting acquisition parameters (kV/mAs/dose values) 50
7.4 Setting high contrast 52
7.5 Setting HD mode 53
7.6 Adjusting the mechanical diaphragm 54
7.7 Positioning the patient 55
7.7.1 Positioning the patient - with bite block 56
7.7.1.1 Aligning the patient - with standard bite block 56
7.7.1.2 Aligning the patient - with chin rest, bite block, and contact bar 57
7.7.2 Positioning the patient - with head fixation device (e.g. for orthodontics) 58
7.7.3 Positioning patients - with spherical bite block 60
7.7.4 Display of midsagittal line 61
7.8 Releasing the exposure 62
7.9 Remote control 65
8 List of messages 66
8.1 List of help messages 66
8.2 Error message structure 67
8.2.1 Ex 67
8.2.2 yy 68
8.2.3 zz 68
8.3 Error message E1 10 07 69
9 Maintenance 70
9.1 Cleaning and care 70
9.1.1 Cleaning 70
9.1.2 Disinfecting 70
9.1.3 Sterilization 72
9.2 Inspection and maintenance 73
10 Dismantling and disposal 74
10.1 Dismantling and reinstallation 74
10.2 Disposal 74
10.2.1 GALILEOS X-ray tube 75
11 Dose information 76

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1 General information

1.1 Dear Customer,

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

The GALILEOS system comprises an X-ray unit that uses a rotating X-ray beam and an optics system. It prepares two-dimensional images and three-dimensional reconstructions, and/or the surface of the head region (including dentomaxilliofacial and ENT areas) for planning and diagnostics.

The system also includes a package with software modules 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 Comfort PLUS system.

Your GALILEOS Team

1.2 Contact information

Customer service center

For technical questions, use the contact form on the internet at the following address:
http://srvcontact.sirona.com

Manufacturer's address



Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

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

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1.3 General information about this operating manual

Observe the Operating Instructions

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

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

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

Online portal for technical documents

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

Help

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

1.4 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

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1.5 Warranty and liability

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 is responsible for making sure that all scheduled inspections and preventive maintenance activities are performed.

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

Exclusion of liability

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

Certificate of work

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

1.6 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 the patient is pregnant, a risk/benefit analysis must be performed.

According to the X-ray Ordinance 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.

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1.7 Intended use

The GALILEOS system comprises an X-ray unit that uses a rotating X-ray beam. It prepares two-dimensional images and three-dimensional reconstructions of the head region (including dentomaxilliofacial and ENT areas) for planning and diagnostics.

The system also includes a package with software modules 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.

1.8 Indication and contraindication

Indication in the areas:

- Conservative dentistry
- Endodontics
- Periodontology
- Prosthodontics
- Functional diagnosis and treatment of craniomandibular dysfunctions
- Surgical dentistry
- Implantology
- Oral and maxillofacial surgery
- Orthodontics
- ENT (middle and inner ear, paranasal sinuses, main nasal cavity, maxillary sinus, ethmoidal cells, sphenoidal sinus, frontal base of the skull, frontal sinus)

Contraindications:

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

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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 information provided in these operating instructions. Such information is highlighted as follows:

⚠ DANGER

An imminent danger that could result in serious bodily injury or death.

⚠ WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION

A possibly dangerous situation that could result in slight bodily injury.

NOTE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT

Application instructions and other important information.

Tip: Information for simplifying work.

1.9.2 Formats and symbols used

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

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Prompts you to do something.
See "Formats and symbols used [→ 10]"	Identifies a reference to another text passage and specifies its page number.
• List	Designates a list.
"Command / menu item"	Indicates commands / menu items or quotations.

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2 Safety information

2.1 Information on the unit

The following symbols are applied to the unit:

Accompanying documents



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

Meaning: Observe the Operating Instructions when operating the unit.



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

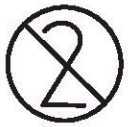
Meaning: The accompanying documents are available on the manufacturer's homepage.

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

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2.4 Qualifications of operating personnel

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

Personnel, who are to be trained, taught, instructed or are taking part in a general training, may operate the device only under the supervision of an experienced person.

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 Switch on the unit

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 release button permits.

With the exception of the patient, no other persons without radiation protection are allowed to stay in the room during an exposure. In exceptional cases, a third person may provide assistance, but not the practice staff. 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

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 (not included in the scope of supply)!

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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.

2.9 Hygiene

The protective sleeves must be reapplied for each patient, all auxiliary exposure tools must also be disinfected to avoid potential transmission of pathogens that may 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 [→35]“, “Preparing the exposure [→41]“, “Sterilization [→72]“.

2.10 Touchscreen

The Easypad monitor is equipped with touch-sensitive control technology.

The touchscreen must not be operated with pointed objects such as ball-point pens, pencils, etc. Such objects could damage or scratch its surface. Always operate the touchscreen by pressing it gently with your fingertip.

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2.11 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.

The travel range of the unit must be kept free from foreign matter.

Do not leave the patient at the unit unattended.

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

2.12 Interference with electronic devices

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

2.13 Risks of electromagnetic fields

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

2.14 Combination with other equipment

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

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

- IEC 60950-1 or IEC 62368-1 for information technology equipment and
- IEC 60601-1 for medical electrical equipment

To this end, refer to the ‘Installation requirements’ and compatibility list/ declaration of conformity by the system integrator.

If in doubt, contact the manufacturer of the system components.

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2.15 Changes 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.

2.16 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 re-adjusted and re-calibrated if necessary.

2.17 Electromagnetic compatibility

The GALILEOS Comfort PLUS 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".

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2.18 Electrostatic charge

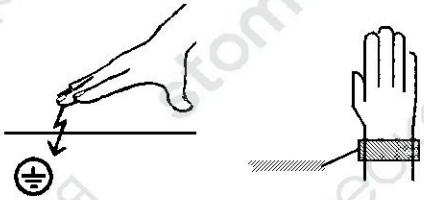
2.18.1 ESD protective measures

ESD

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

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.

Training

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.

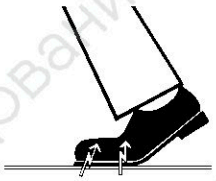
The content of this training is explained in the Chapter "About the physics of electrostatic charges" [→ 16].

2.18.2 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:

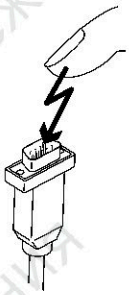
- perceptible at 3,000 V or higher
- audible at 5,000 V or higher (cracking, crackling)
- visible at 10,000 V or higher (arc-over)

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.

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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.

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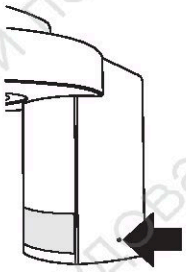
3 Technical description

3.1 Technical data

Chassis:	Model designation	GALILEOS Comfort PLUS
	Nominal voltage:	200 V – 240 V
	Permissible fluctuation:	±10%
	Permissible drop under load:	10%
	Rated current:	6A
	Nominal power output:	0.6 kW at 98 kV/6 mA
	Current time product:	30 mAs
	Nominal frequency:	50 Hz / 60 Hz
	Internal line impedance:	max. 0.8 ohms
	Main building fuse:	25 A slow-blow (16 A for single line)
	Power consumption:	0.9 kVA
X-ray tube assembly:	Focal spot size as specified in IEC 60336, measured in the central X-ray beam:	0.5 mm
	kV:	98 kV
	mA:	3 mA – 6 mA
	Pulsed mode:	10 ms – 14 ms
	min. permanent filtering:	2.8 mm Al / 98 IEC 60522
	min. Half-value layer:	3.9 mm Al
	Integrated filter:	0.2mm Cu
	Cone-beam angle:	collimated to approx. 24°
	High voltage generation frequency:	80 kHz – 100 kHz
Detector:	Type: Image intensifier (I.I.), Siemens	
	Active input window size:	215 mm (8 1/2") diameter
	Camera:	Pixels: 1000^2
		FPS: 15 – 30
		Dynamics: 12 bits, (4096 brightness values), 63 dB
Geometry:	Source-I.I. converter coating distance (central X-ray beam)	590 mm (23 1/4")
	Source-isocenter distance (central X-ray beam)	413 mm (16 1/4")
	Source-skin distance (minimum distance)	approx. 300 mm (11 13/16")

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Scanning process:	Orbital angle	204°
	Scan time	approx. 14 s
	Number of single exposures	200 HD-Modus 357
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.
	Equipment class:	IPX0
	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:	 20XX (on the rating plate)
	Operating mode:	Continuous operation
	Long-term power output:	100 W
	Anode material:	Tungsten
	Exposure parameters for determining leakage radiation:	6 mA / 98 kV
	Continuing current for leakage radiation measurements:	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:	between +10 °C and +35 °C (50 °F – 95 °F) At a room temperature of > 35 °C (> 95 °F), Sirona recommends using an air conditioning system.
	Operating altitude:	≤ 3000 m

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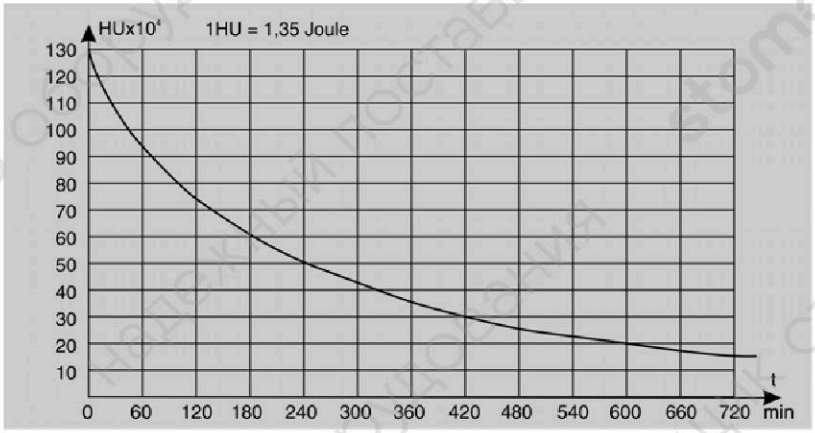
X-ray tube:	Siemens SR 120/15/60	
Minimum requirements for reconstruction PC (included in the scope of supply):	Processor:	QuadCore Intel i5
	RAM:	8 GB RAM
	Hard disks:	1 TByte
	Operating system:	Windows 7 64-bit (mandatory)
	External drive:	1x DVD-ROM, dual-layer
	Graphics card:	explicit (not onboard), at least 1 GB RAM
Minimum requirements for Sidexis visualization PC (not included in the scope of supply):	see the Sidexis Operator's Manual. The system requirements are also listed under www.sidexis.com	
Network:	Network:	100 MB Ethernet, 1 Gbit Ethernet recommended
	Communication interface:	RJ45 for LAN cable

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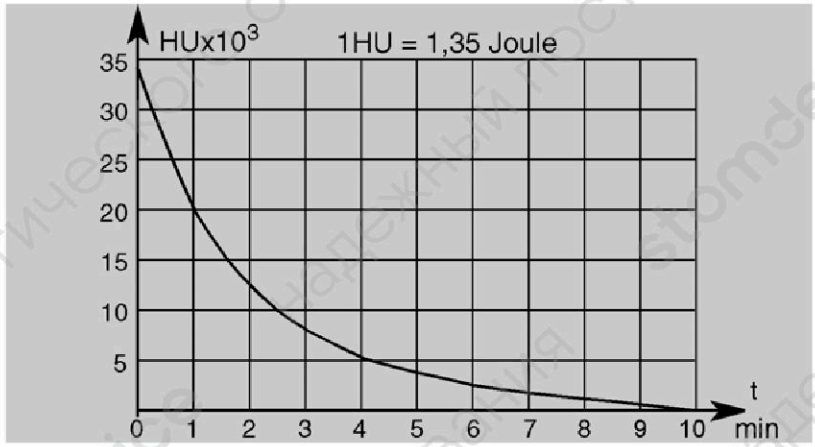
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3.2 Diagrams

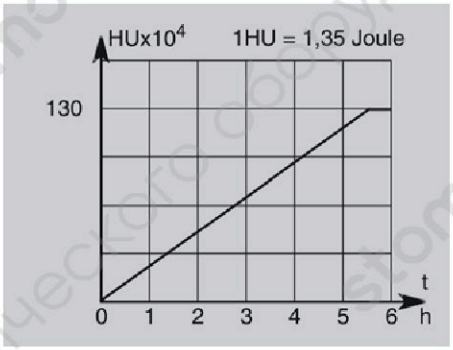
Cooling curve of tube housing



Cooling curve of X-ray tube



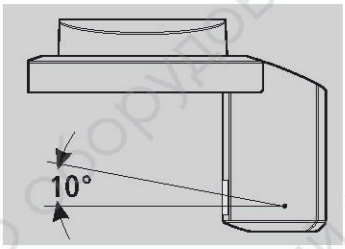
Heating curve of tube housing



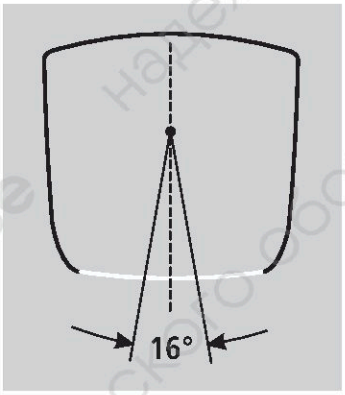
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Central X-ray beam



Anode angle

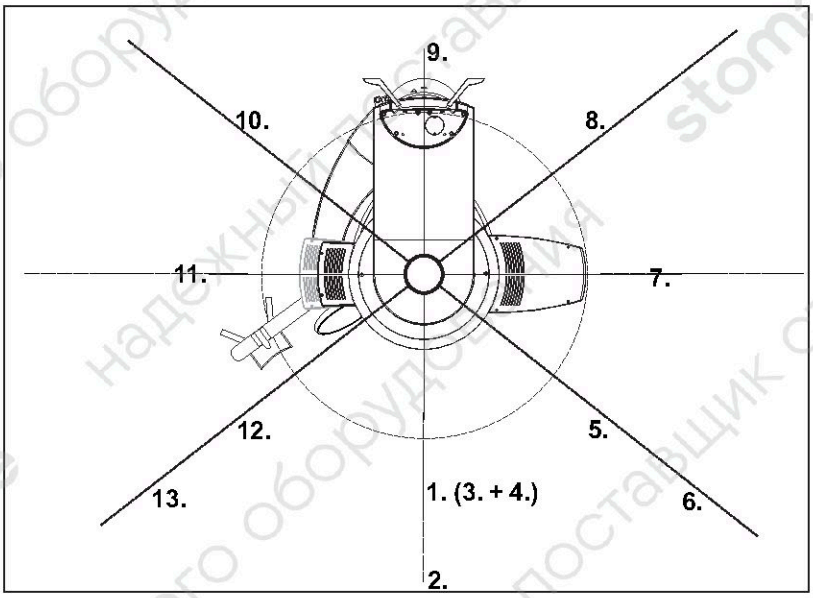


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3.3 Values of the secondary scattered radiation

Values of the secondary scattered radiation



The following parameters were set for the scattered radiation measurements:
Tube voltage 98 kV,
tube current 6 mA,
radiation time 5,1 s (corresponds to a current-time product of 30.6 mAs).

Angle [°]	Measuring point	Distance [m]	Measured dose [µSv]	Dose/mAs [µSv]
0	1	1	3.46	0.113
	2	2	0.96	0.0314
	3	1 (45° below)	2.91	0.0951
	4	1 (45° above)	1.14	0.0372
45	5	1	4.09	0.114
	6	2	1.16	0.0379
90	7	1	4.89	0.160
135	8	1	6.07	0.198
180	9	1	0.45	0.0148
225	10	1	5.64	0.184
270	11	1	4.81	0.157
315	12	1	3.92	0.128
315	13	2	1.09	0.0356

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3.4 Certification and registration

The **GALILEOS** X-ray unit complies with IEC 60601-1:2005 + A1:2012

The **GALILEOS** X-ray unit complies with IEC 60601-1-3:2008 + A1:2013

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

Original language: German

CE
0123

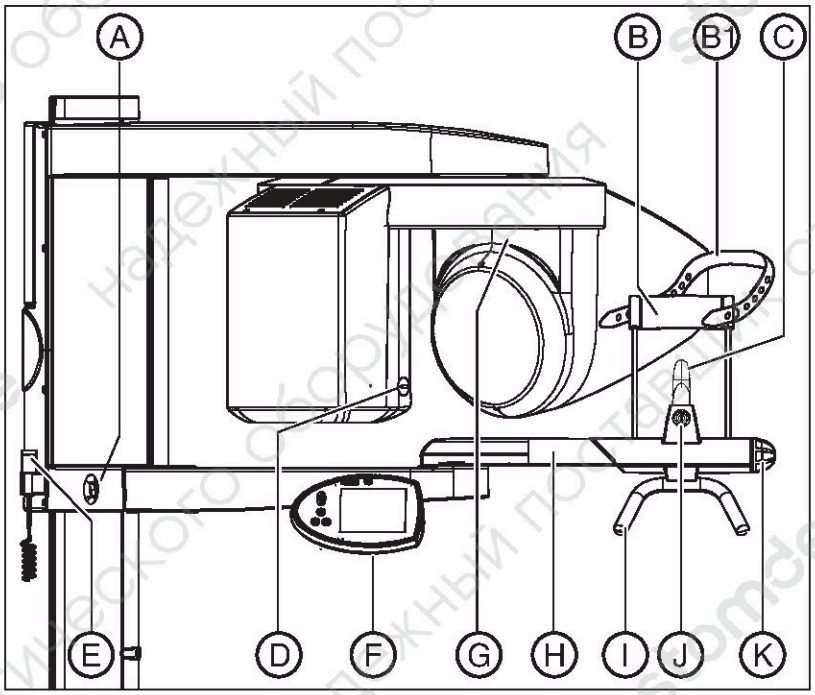
This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

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4 Controls and functional elements

4.1 Operating and display elements on the GALILEOS



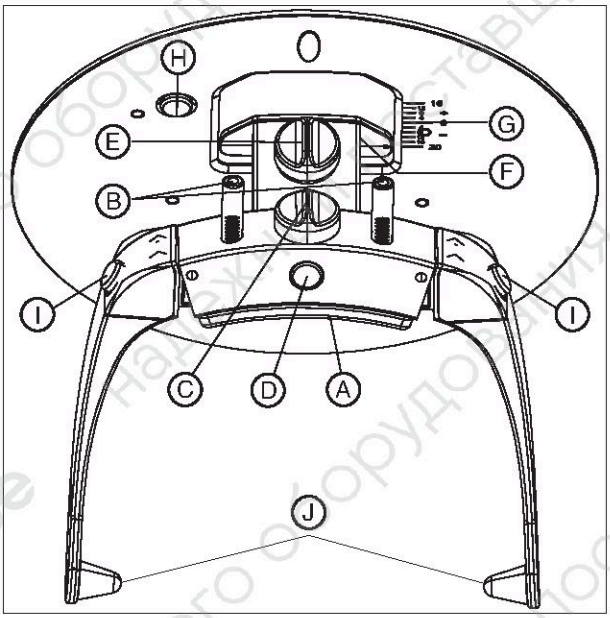
A	Main switch
B	Forehead support (contact upholstery detachable)
B1	Head fastening strap
C	Bite block (sterilizable)
D	Adjustment button for mechanical diaphragm adjustment
E	Release button [1]
F	Easypad (swiveling control panel)
G	Light localizer central laser line for face center
H	Swivel arm for patient 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.

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4.2 Operating and display elements on the head fixation device

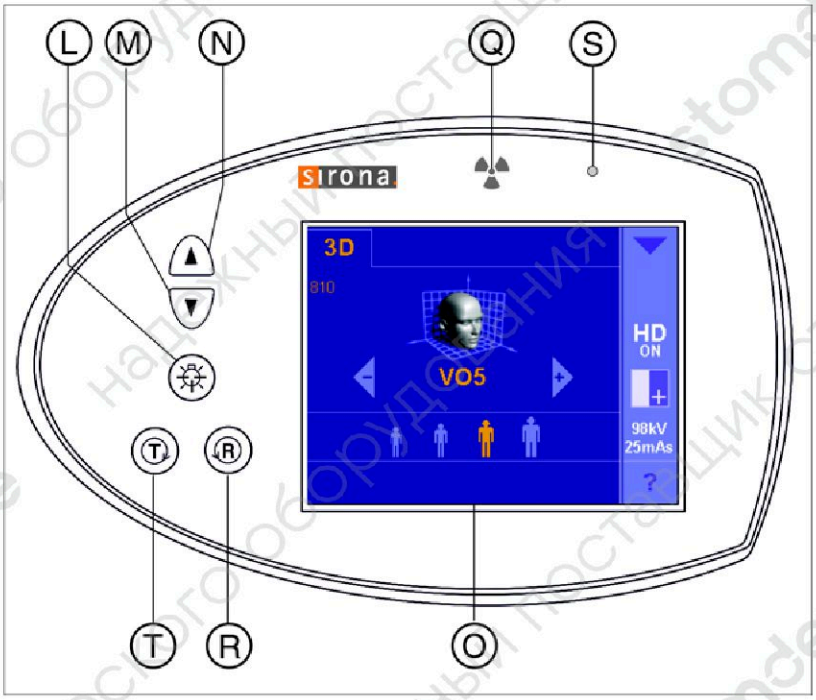


A	Forehead pads for adult or child
B	Forehead rest adjustment
C	Head holder adjustment
D	Pushbutton for resetting forehead rest
E	Lock for vertical adjustment
F	Scale for vertical adjustment (adjustment range +/- 10 mm)
G	Scale for horizontal adjustment (adjustment range +16 mm /-20 mm)
H	Locking button for horizontal adjustment and unlocking head fixation device for removal
I	Locking buttons for head holder
J	Ear olives

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4.3 Control and display elements on the Easypad with touchscreen



L	Light localizer ON/OFF
M	"Unit down" key
N	"Unit up" arrow key
O	Touchscreen - touch-sensitive screen
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

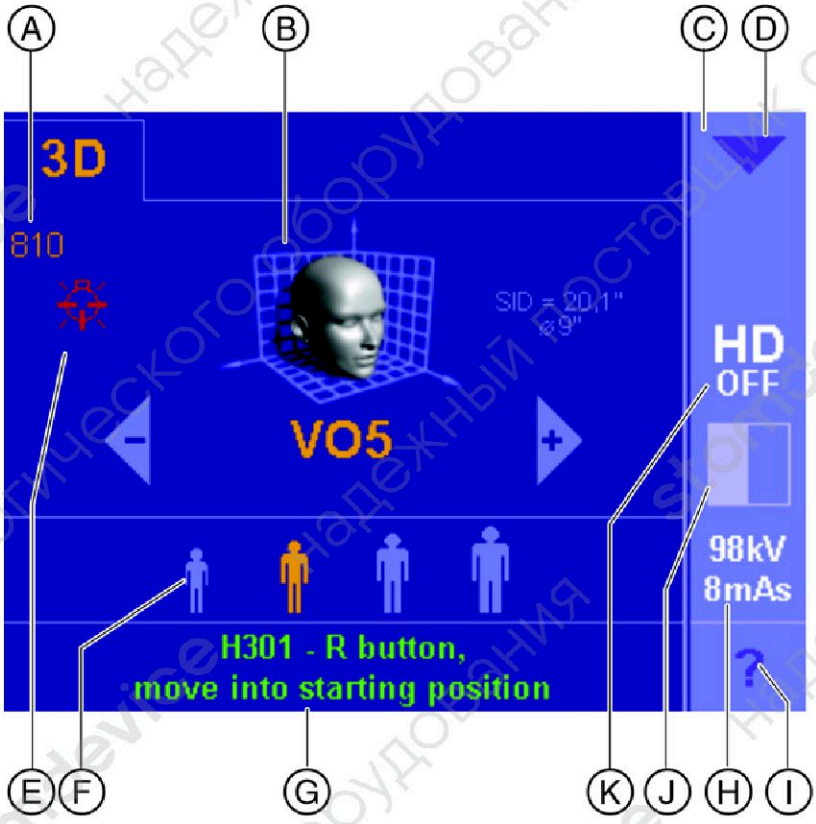
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4.4 General touchscreen functions on the Easypad

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

Color codes:	
orange	selected
white	Default settings
light blue	selectable
gray-white	Help symbols



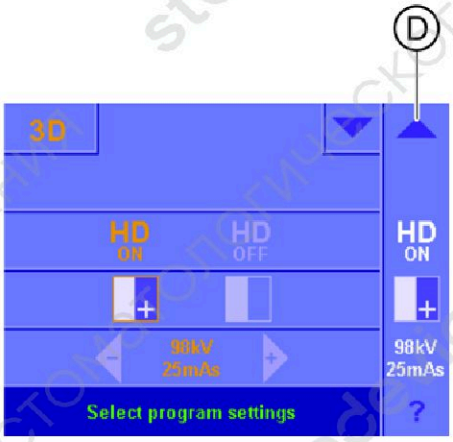
Touchscreen symbols	
A	Display of height setting value
B	Display of the VO5 or VOG program Depending on the option selected, the symbol contrast changes.
C	Submenu column (options)
D	Blue arrows: Select submenu, close menu
E	Red symbol for light localizer ON (is displayed as long as the laser light of the light localizer is switched on)
F	Patient symbol keys for selecting preset exposure parameters
G	Comment line for help and error messages
H	Display/setting of exposure parameters (kV/mAs)

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Touchscreen symbols	
I	When you touch the **?** symbol, the help or info screen is displayed
J	Display/setting of high-contrast option
K	Display/setting of HD mode (high definition mode)

4.4.1 Program settings (Level 2)



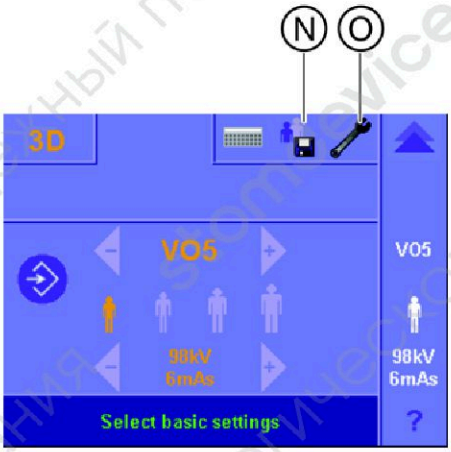
You can also display all of the program settings and select the settings in a second program level.

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

After making your selections, touch the blue arrow (D) again to return to program level 1.

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4.4.2 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.

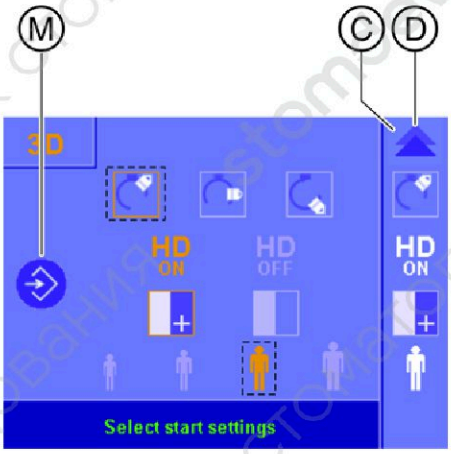
In order to access the fourth program level, you must select the third level first.

To access the 3rd program level, touch the blue arrow in the upper right corner of the touchscreen; the arrow will now point upward.

To access the fourth program level, touch the diskette symbol (N) in the level three.

In Level 4, you can reprogram the starting or entry position (icon on left as per factory setting) and the patient icon preference (3rd icon from left as per factory setting).

Using this function, you can adapt the position where the patient enters the device to the local space conditions.
The open segment of the ring in the icons indicates the direction of patient entry. The patient entry position can be at the front, on the right-hand side, or on the rear right.



To perform a particular change, touch the desired symbol; the icon will turn orange and will also be displayed in the Submenu column (D).

The Memory symbol (M) will stay yellow until the new default setting has been saved by touching the Memory icon (M).

This menu can only be closed by touching the blue double arrow (D) in the upper right corner. The display will always return to the standard menu (program level 1).

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

If the programming settings have been changed, they remain saved until they are changed again in this mode.

4.4.3 Service menu



The Service menu is exclusively intended for use by service engineers.

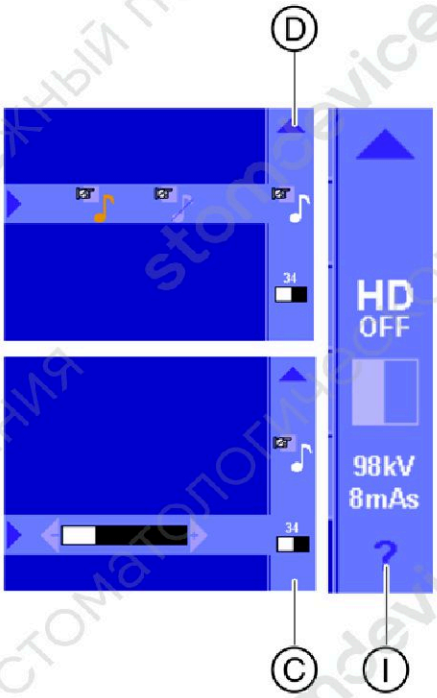
Service engineers can access the Service menu from the Basic Settings menu (Level 3) via the wrench icon (O) and a special input algorithm.

For further information on accessing the Service menu and individual service routines, please refer to the Service Manual.

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4.4.4 Touchscreen settings



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

You can open two menu lines by touching the corresponding icons in column (C).

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 the adjustment a reference value will appear above the symbol in column (C).

IMPORTANT
The unit must run 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 (C).

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

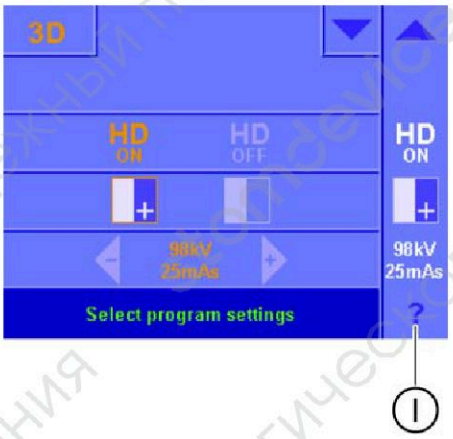
4.4.5 Closing menu cells

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

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4.4.6 Info screen



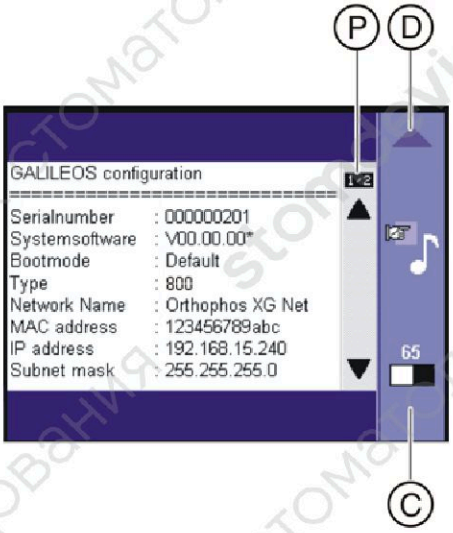
Starting at level 2, the "**GALILEOS configuration**" info screen is displayed when you touch the question mark (I) in the lower right corner of the touchscreen.

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 (C) as well.

Checking the function activation



The page number and number of pages are displayed in a small black field (P) 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 (D) at the top of column (C).

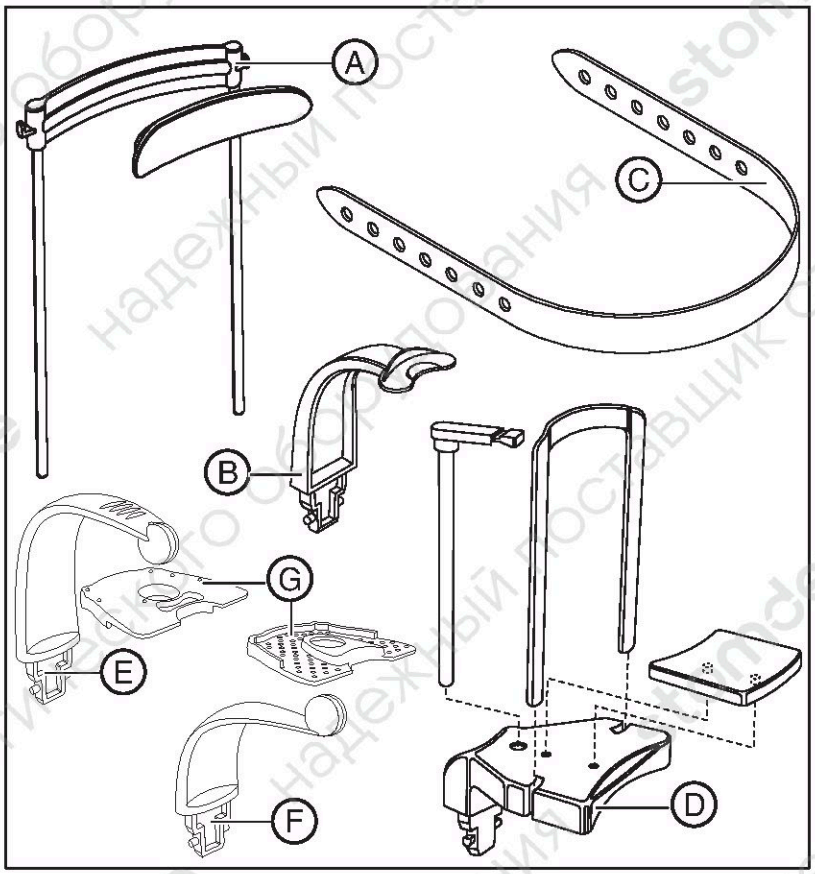
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5 Accessories

Please also see the chapter titled: “Cleaning and care”

5.1 Bite blocks, supports and fasteners

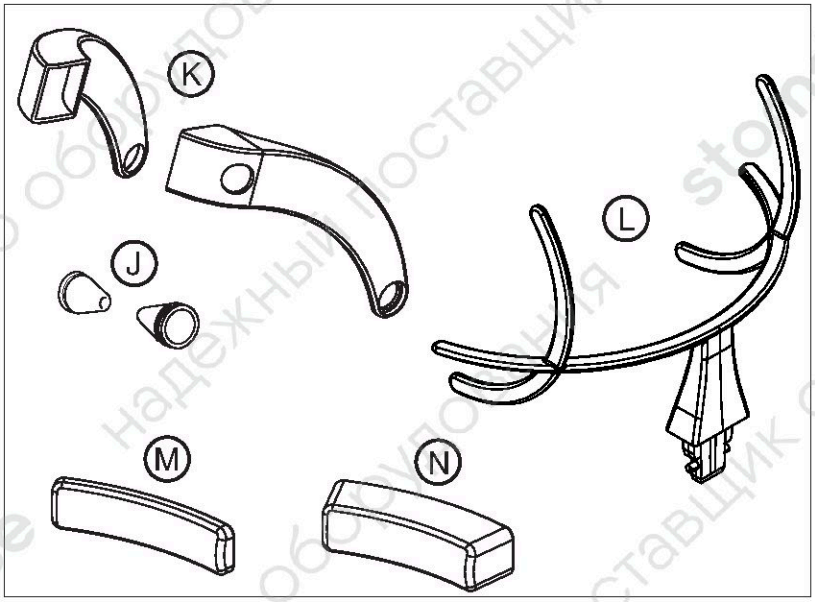


A	Forehead support (contact upholstery can be removed for cleaning and disinfection) (1 pc) Order No. 61 34 931
B	Rigid bite block (can be removed for cleaning and sterilization by rotating the locking knob) (5 pcs) Order No. 61 34 949
C	Head fastening strap (2 pcs) Order No. 61 34 956
D	Chin rest, complete (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.

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5.2 Accessories for head fixation device



J	Ear olives (10 pcs) Order No. 18 88 838
K	Head holders (right and left) The head holders 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 26 976
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

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5.3 Hygienic protective sleeves

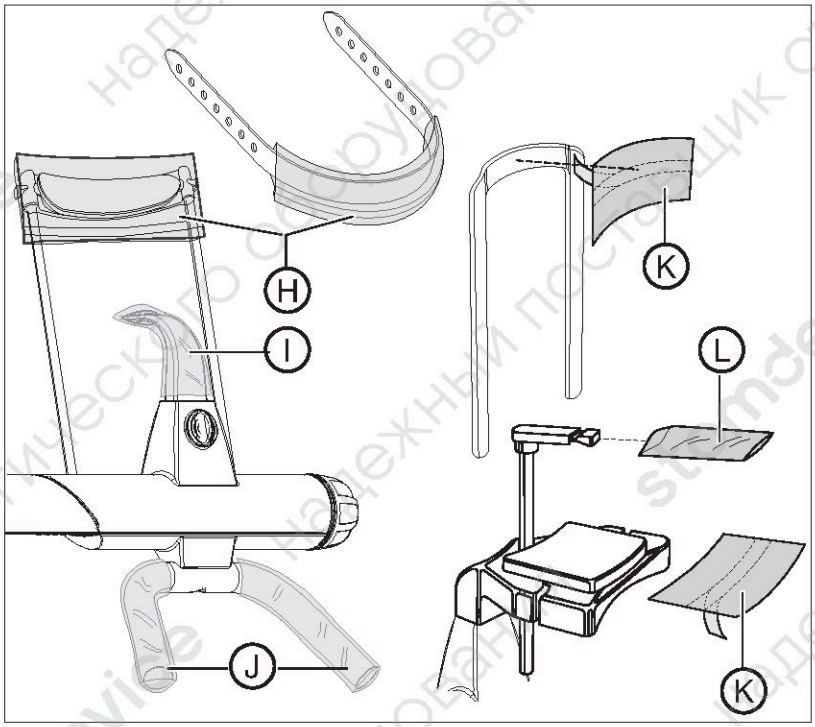
Identification of single use devices



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.

5.3.1 Hygienic protective sleeves for bite blocks, supports, and fasteners

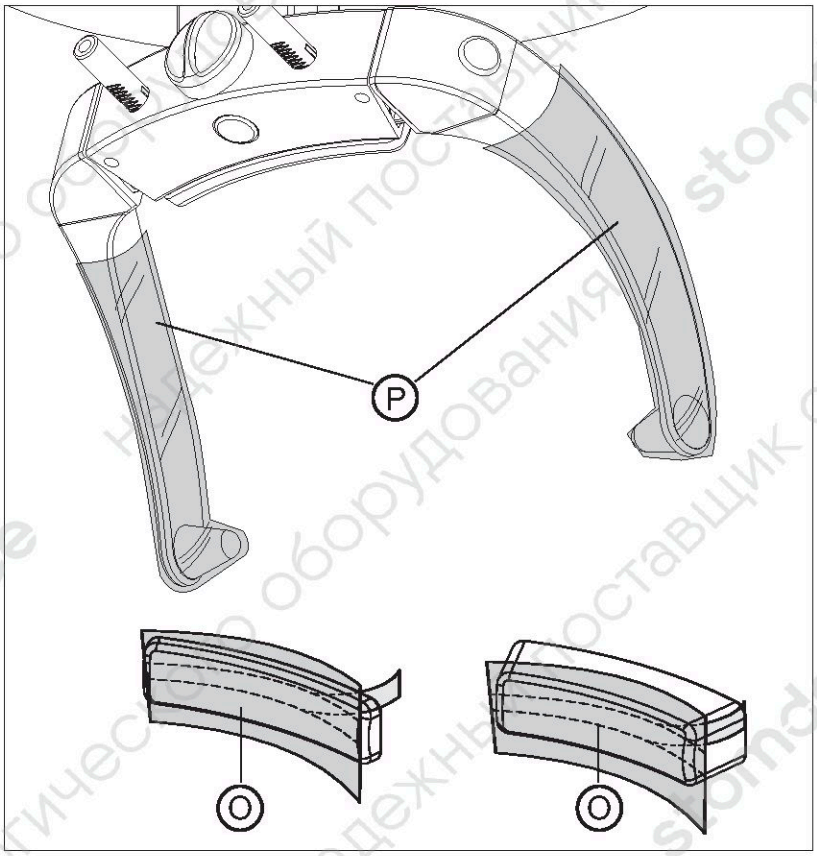


H	Hygienic protective sleeves for forehead support and head fastening strap (100 pcs) Order No. 61 84 894
I	Hygienic protective sleeves for bite block (500 pcs) Order No. 61 27 745
J	Hygienic protective sleeves for handles (500 pcs) Order No. 61 84 902
K	Hygienic protective sleeves for chin rest support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

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5.3.2 Hygienic protective covers for head fixation device



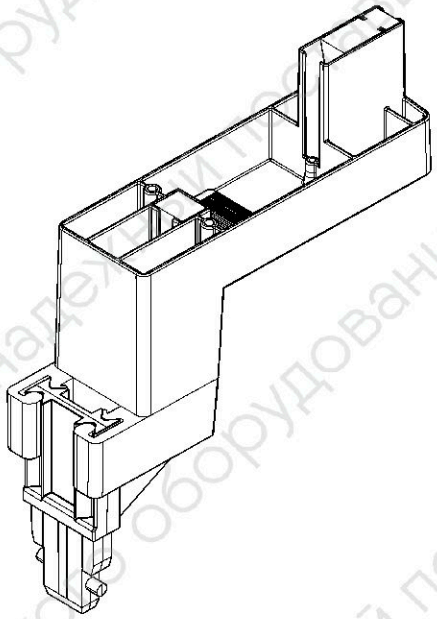
O	Hygienic protective covers for forehead pads (100 pcs) Order No. 62 34 392 Dimensions: 75 mm x 60 mm
P	Hygienic protective covers for head holders (500 pcs) Order No. 62 34 400 Dimensions: 150 mm x 47 mm

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5.4 Test phantom for acceptance/constancy test

Constancy test phantom worldwide



Constancy test phantom, replacement

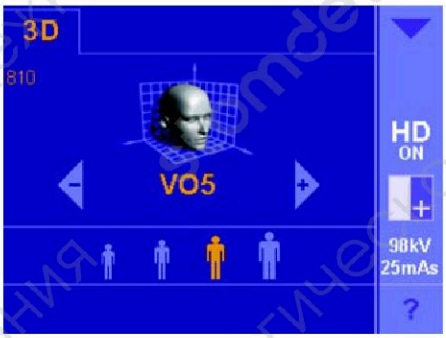
(1 piece) Order No. 61 40 813

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6 Programs

6.1 VO5: standard volume program

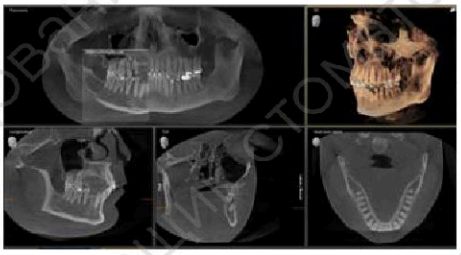


High-resolution scan with the possibility of generating secondary reconstructions (detail reco) with maximum resolution.

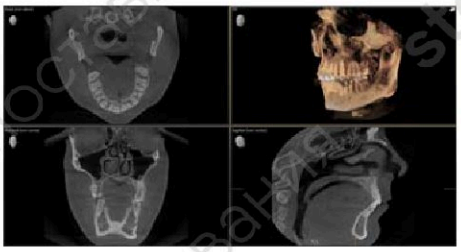
This program is used to create a volume data set of the patient with 616 x 616 x 616 volume elements (voxels).

The resolution in the volume (voxel size) equals 0.25 x 0.25 x 0.25 mm^3.

Scan time:	14 seconds
Effective radiation time:	2...5 seconds
Reconstruction time:	approx. 2.5 minutes
Data volume:	approx. 900 MB, HD mode approx. 1230 MB
comprising:	
Patient volume:	approx. 430 MB
Panoramic slice:	approx. 5 MB
Lateral cephalometric image:	approx. 6 MB
Radiological views:	approx. 6 MB
Detailed reconstruction:	approx. 30 MB
Corrected raw data:	approx. 420 MB HD mode approx. 750 MB (can be deleted)



Panoramic view



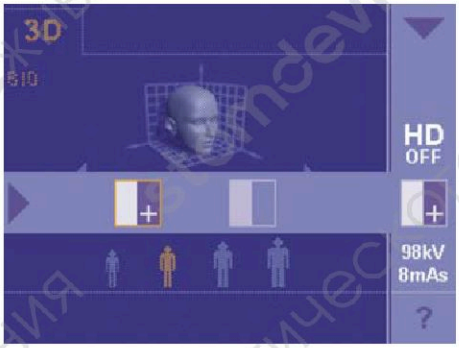
Radiological views

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6.1.1 HC mode: high contrast mode

The VO5 HC (high contrast) program is selected on the touchscreen, via the high contrast button. See the section "Selecting high contrast".

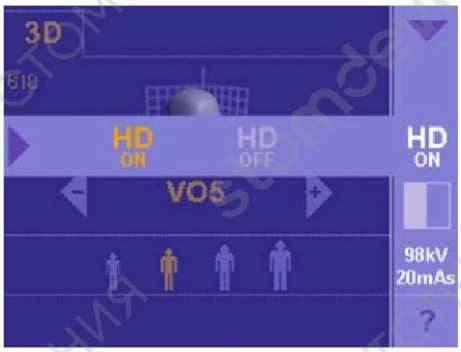


Compared to the standard settings, the high contrast setting VO5 HC is effective for the display of hard structures such as bones and teeth. At the same time, it can also impair the display of soft tissues and especially soft tissue silhouettes.

The high contrast setting 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.

6.1.2 HD mode: high definition mode

Select the VO5 HD program (high definition) on the touchscreen with the HD button. See section "Selecting HD mode".

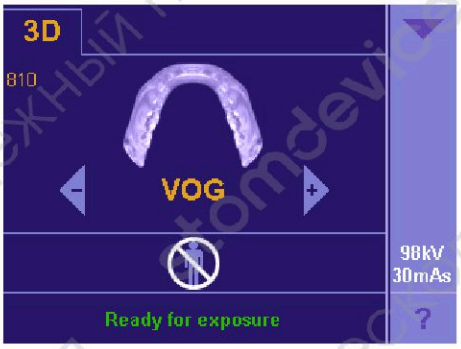


HD mode (high-definition mode):
For improved visualization of structures.
In HD mode, 1 3/4 (HD mode: 357 partial images, standard: 200 partial images) as many individual projections are created; these are used to ensure a more refined reconstructed image quality. This can reduce typical (CBCT) DVT/conebeam artifacts.
Please observe the maximum permissible patient dose, especially for pediatric applications.

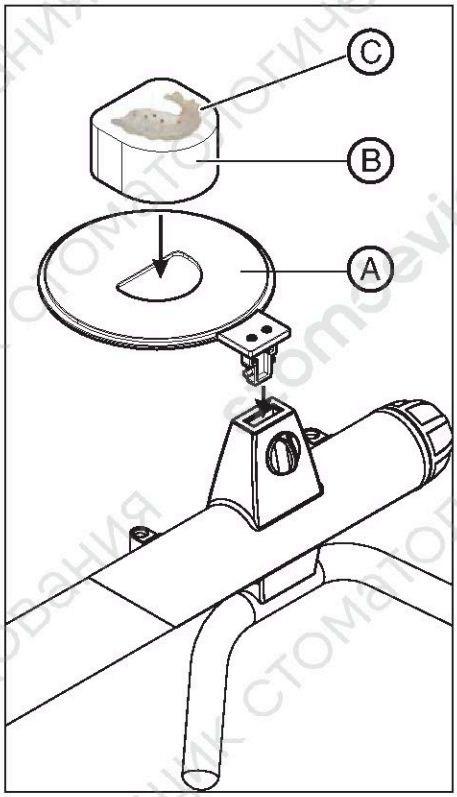
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6.2 VOG: volume program for template scan



The VOG program is suitable for scanning small objects. **It is not suitable for taking patient X-rays.**



A	Support plate (included in delivery)
B	Foam support (included in delivery)
C	X-ray template, customized for each patient

✓ In some implant planning procedures, an X-ray template is required, in which a second image is taken separately and must be exported.

1. A template holder without aluminum cylinders is needed to scan the X-ray template.

   Insert the template holder as follows:

   - Push the patient fixing system fully upward and remove the head band or the entire patient fixing system, so that you have enough space to position the template holder.
   - Insert the support plate (**A**) of the template holder up to the stop and lock it using the control knob, as shown in the figure.
   - Position the foam support **B** on the cutout of the support plate.
   - Position the X-ray template (**C**) on the foam support, in line with the position of the patient's jaw.

2. Now carry out the scan using the VOG program.
3. Export the data record using Sidexis.
   Menu command: Image -> Export -> Volumes for third-party manufacturers.

- The scan is now in DICOM format, suitable for further processing.

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7 Operation

7.1 Preparing the exposure

NOTE

For reasons of radiation protection, 3D X-ray images should not be taken simply to obtain a cephalic or panorama image.

7.1.1 Fitting the accessories

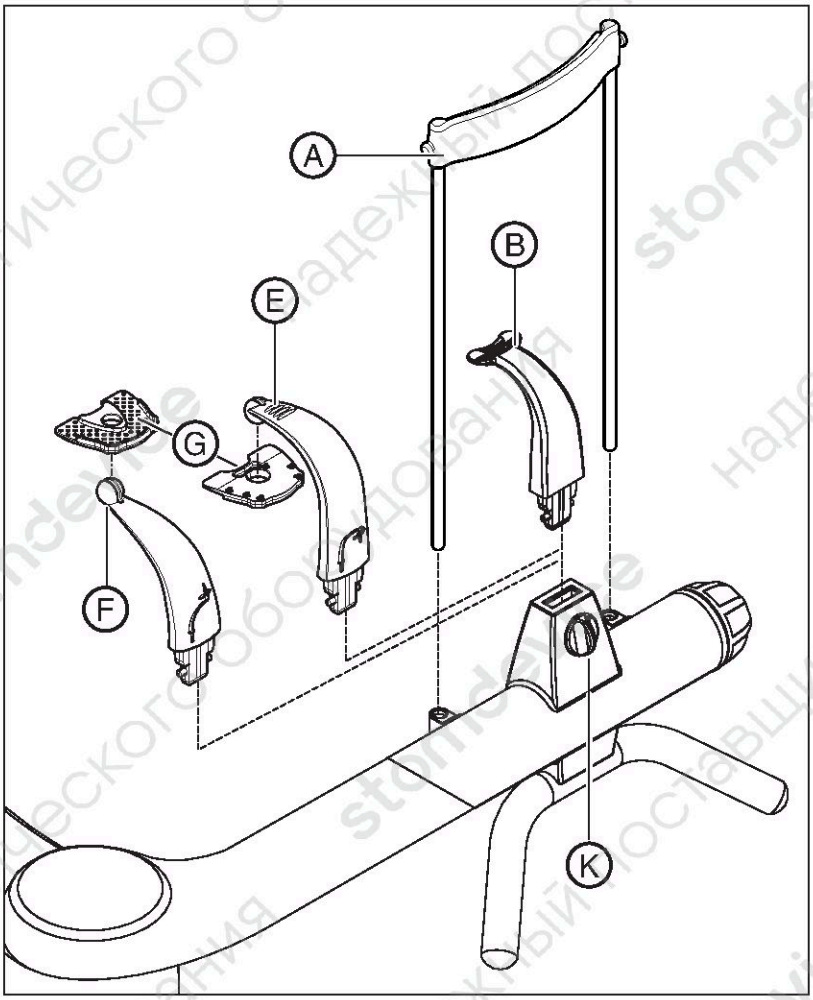
⚠ WARNING

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)**.

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- Insert the forehead support **(A)**.
- Slide on the hygienic protective sleeves

or for creating a drilling template:

- Insert the 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)**.
- Position 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.

or for ENT exposures:

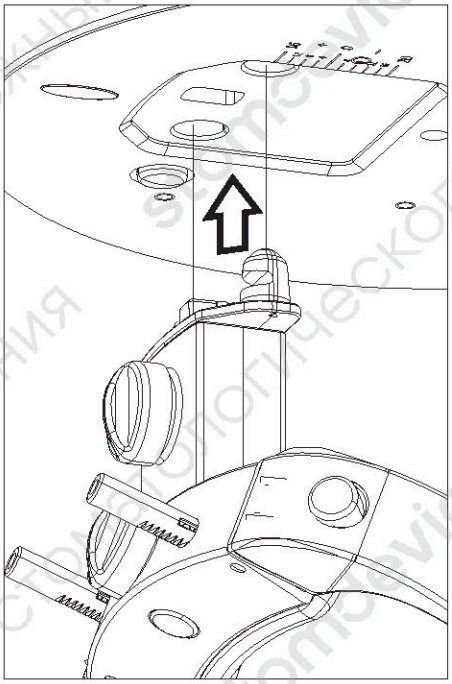
- Insert the bite block up to the stop and lock it with the rotary knob **(K)**.
- Insert the forehead support **(A)**.
- Slide on the hygienic protective sleeves

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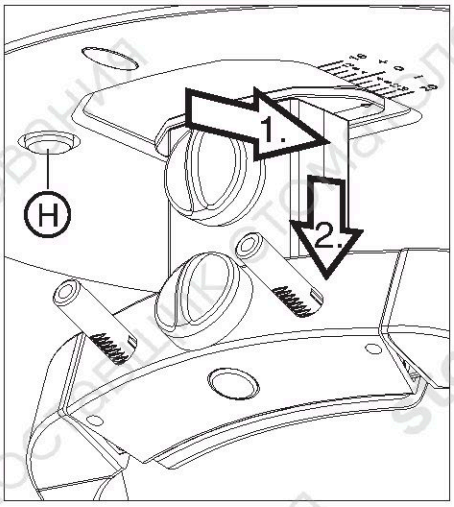
7.1.2 Inserting the head fixation device

Inserting the head fixation device



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

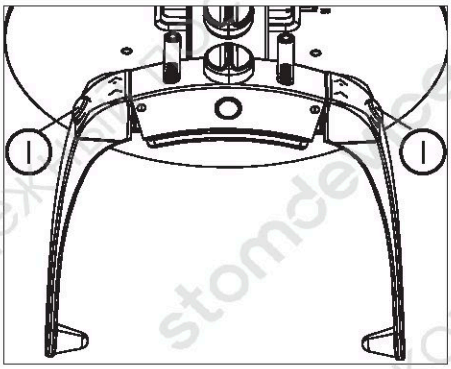
Removing the head fixation device



- 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.).

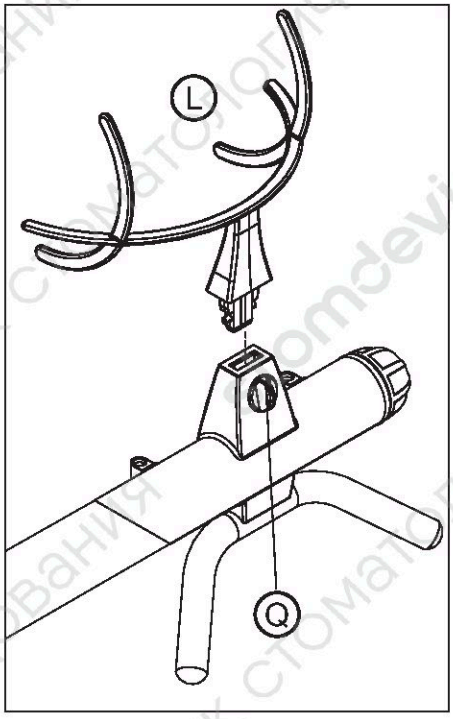
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- Press the respective locking button (I) to remove or insert the head holders.

Fitting the accessories



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

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7.1.3 Switching the unit on

NOTE

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 [→ 18] Section.

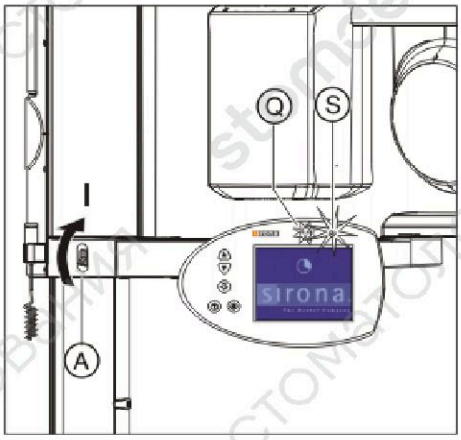
IMPORTANT

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 [→ 69].

⚠ 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 (S) at the top of the Easypad lights up.
- The radiation indicator (Q) lights up for approx. one second for a function test.

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

NOTE

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

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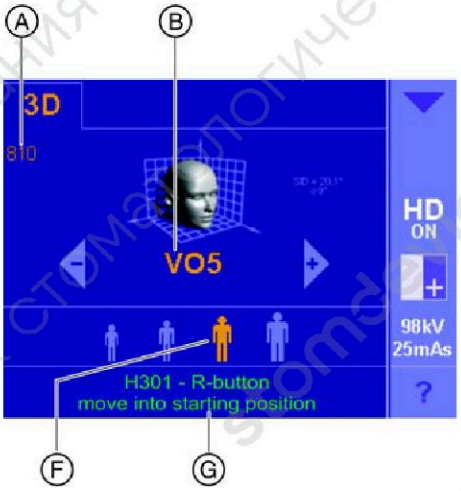
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7.1.4 Display on the Easypad touchscreen



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

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 approx. 810 to 1815 mm) from the last patient set.
B	The scan program
F	The patient symbol which was last preselected with the corresponding kV/mA combination
G	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.

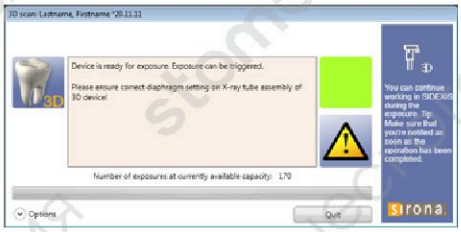
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7.1.5 Switching Sidexis 4 to ready for exposure state

Refer to the Sidexis 4 User Manual
http://www.dentsplysirona.com/manuals

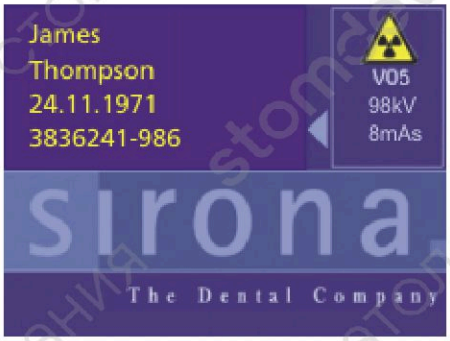
7.1.6 Switch Sidexis to ready for exposure state



- To make the **Sidexis program on the PC ready for exposure**, see the Sidexis operator's manual.
- As long as no connection with Sidexis is established, the message "**Switch Sidexis to ready for exposure state**" is displayed in the comment line of the Easypad touchscreen.

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.

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



It shows the **first name**, **last name**, **date of birth**, and the **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 will turn yellow.

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

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

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7.2 Pediatric exposure

Compared to middle-aged adults, children and adolescents are three times more at risk from radiation. A justifying indication requires that the health benefits of use outweigh the risk posed by radiation. Other procedures with similar health benefits that do not involve any, or only involve low-level, exposure to radiation must be preferred when weighing up the situation.

Medical radiation exposure as part of dental care provided to children and adolescents must produce sufficient benefits, whereby radiation exposure resulting from an X-ray examination is to be limited as much as can be accepted with the requirements of medical science (the ALARA principle).

Sirona offers numerous options for reducing the radiation exposure for adults, and especially for children and adolescents, to a necessary minimum. Furthermore, there are numerous options for simplifying the X-ray applications for children and adolescents.

Please observe the detailed descriptions on these in the respective chapters of these Operating Instructions!

Dose reduction

Overview of the options for reducing doses, in particular for children and adolescents, with the GALILEOS Comfort Plus:

- Selecting the relevant patient symbol for children/adolescents.
  - The two smallest patient symbols represent the exposure values for children/adolescents. Through their reduction in the mA values for these exposure parameters, the dose is lowered accordingly.
- Collimation of lower jaw or upper jaw:
  - The FOV level can be reduced by using the mechanical upper or lower jaw collimation. The dose is reduced as a result.
- Exposure mode HD on / HD off:
  - The dose can be reduced significantly by selecting Exposure mode HD off.

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Optimized X-ray applications

Overview of the options for simplifying X-ray applications for children/ adolescents with the GALILEOS Comfort Plus:

- Children and adolescents can often be positioned in a stiller and more stable position if they are seated. The GALILEOS Comfort Plus can therefore be brought down for an exposure in the seat to a bite block height of 80 cm.
- To explain the exposure and to alleviate any fears, a radiation-free test cycle can be started at any time.
- The GALILEOS Comfort Plus has been designed so that it functions openly and does not scare or induce fear in children and adolescents.
- There are no distressing cycle noises.
- Optimum and stable positioning options and adjustment tools prevent faulty exposures.
- The GALILEOS Comfort Plus does not require any target exposures to check the correct patient positioning. This means no unnecessary exposure to radiation.

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7.3 Selecting acquisition parameters (kV/mAs/dose values)

The preset exposure parameters are selected with the patient symbol keys. These have been assigned preset kV/mA combinations, selected according to the patient's size and weight. The symbols roughly correspond to child, youth/woman, woman/man, hefty persons.

⚠ CAUTION

The larger the patient icon (according to the icons for child, youth/woman, man/woman, strong people), the higher the dose for the patient. HD mode further improves the image quality significantly. However, it does increase the dose by a factor of 2 and more.

⚠ CAUTION

When X-raying children, be aware that, due to their physical constitution, they react more sensitively to X-ray radiation.

Standard mode: VO5 / VO5 HC

Program:	Child	Youth/Woman	Woman/Man	Strong person
	98 kV/3 mA	98 kV/4 mA	98 kV/5 mA	98 kV/6 mA
Set values:	6 mAs	8 mAs	10 mAs	12 mAs
Effective radiation time:	2 s	2 s	2 s	2 s
DAP:	222 mGycm^2	290 mGycm^2	356 mGycm^2	425 mGycm^2
DAP of LJ exposure*:	129 mGycm^2	168 mGycm^2	207 mGycm^2	247 mGycm^2
DAP of UJ exposure*:	171 mGycm^2	223 mGycm^2	274 mGycm^2	328 mGycm^2

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HD mode: V05 HD / VO5 HD HC

Program:	Child	Youth/woman	Woman/Man	Strong person
	98 kV/3 mA	98 kV/4 mA	98 kV/5 mA	98 kV/6 mA
Set values:	15 mAs	20 mAs	25 mAs	30 mAs
Effective radiation time:	5 s	5 s	5 s	5 s
DAP:	612 mGycm^2	780 mGycm^2	957 mGycm^2	1139 mGycm^2
DAP of LJ exposure*:	355 mGycm^2	452 mGycm^2	555 mGycm^2	660 mGycm^2
DAP of UJ exposure*:	471 mGycm^2	600 mGycm^2	737 mGycm^2	877 mGycm^2

Exposure method used:
FOV: Diameter 215 mm (8 1/2")

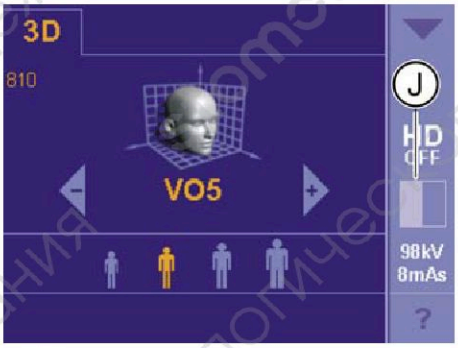
* LJ exposure: Lower jaw collimation
UJ exposure: Upper jaw collimation

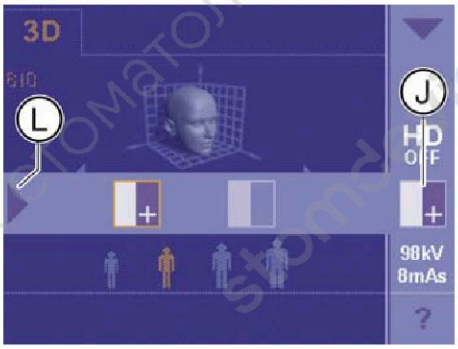
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7.4 Setting high contrast

See the program descriptions for further information on indications.





✓ You can choose between high contrast and normal contrast:

1. Touch the contrast symbol (J).
   ↳ The submenu line for selecting the contrast level appears.
2. Select the contrast level by touching the corresponding symbol:

   High-contrast 

   Normal contrast 

3. Close the Contrast Level submenu line by touching the blue arrow (L).
   ↳ The currently selected contrast level and the corresponding contrast symbol (J) are displayed on the right in the Submenu column.

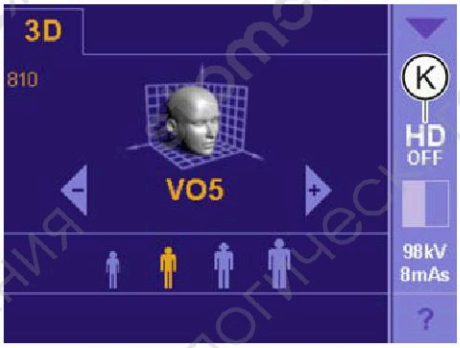
IMPORTANT

This setting is only temporarily valid for this exposure. It will then be reset to the factory setting immediately afterwards. To change the setting permanently, you have to edit the factory contrast setting.

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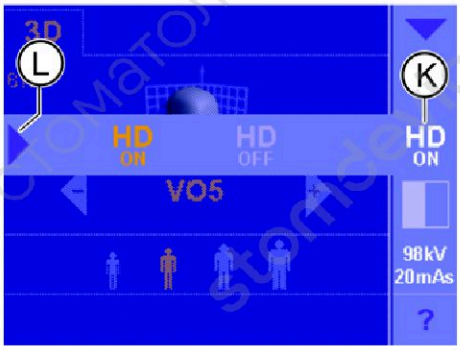
7.5 Setting HD mode

See the program descriptions for further information on indications.



✓ You can choose between HD mode "ON" and "OFF":

1. Touch the HD symbol (K).
   ↳ The submenu line for selecting the HD mode appears.
2. Select the HD mode by touching the corresponding symbol:
   HD ON
   HD OFF



3. Close the submenu line by touching the blue arrow (L).
   ↳ The currently selected HD mode and the corresponding symbol (K) are displayed on the right in the Submenu column.

IMPORTANT
This setting is only temporarily valid for this exposure. It will then be reset to the factory setting immediately afterwards. To change the setting permanently, you have to edit the factory contrast setting.

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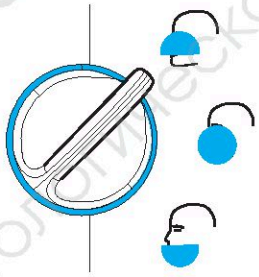
7.6 Adjusting the mechanical diaphragm

The mechanical diaphragm allows for three fixed settings.

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

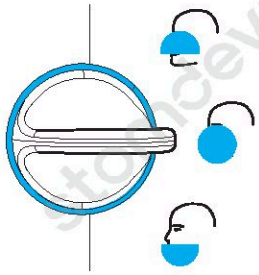
The collimation results in minimal radiation exposure to explore diagnostic questions in the upper and lower jaw.

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



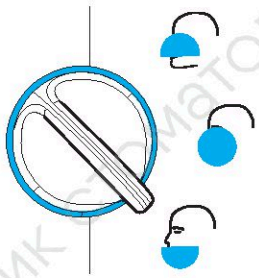
1. Upper jaw collimation (UJ)

   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 wisdom teeth lying transversally, 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.

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7.7 Positioning the patient

NOTE

For reasons of radiation protection, 3D X-ray images should not be taken simply to obtain a cephalic or panorama image.

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.

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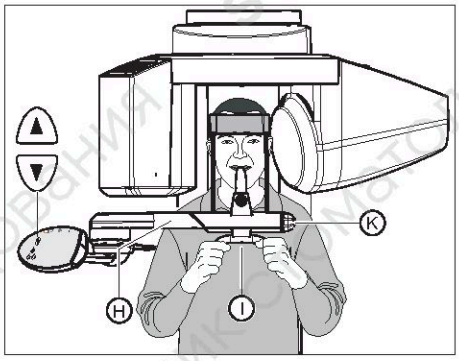
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7.7.1 Positioning the patient - with bite block



- 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.

7.7.1.1 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

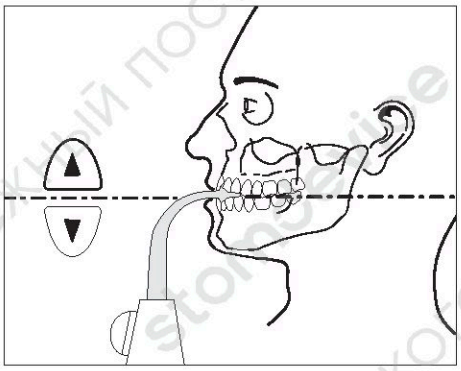
The height adjustment motor starts slowly and then increases its speed. Press and hold down the height adjustment key until the unit has reached the desired height.

- 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.

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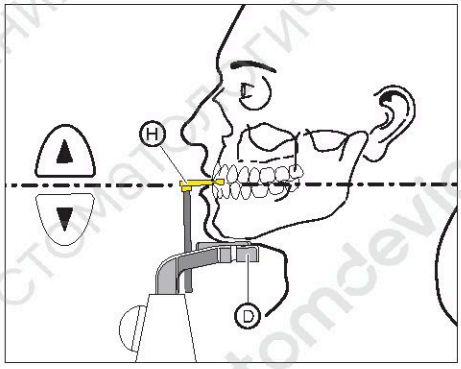


- Have the patient bite the spoon of the bite block.

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.

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

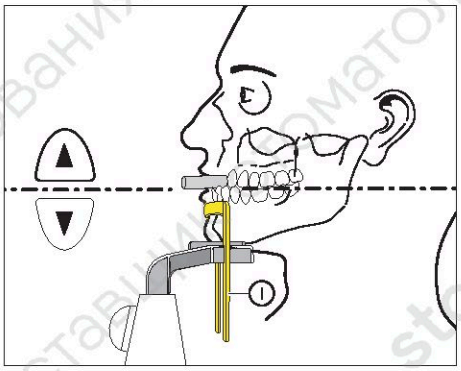


Indications:
– Toothless patients
– Temporomandibular diagnosis
– Cephalometry

- 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.

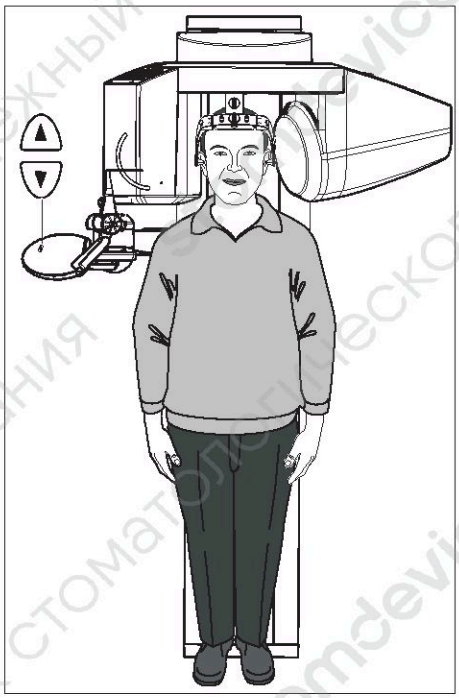


- Ask the patient to place his chin on the chin rest (D) with closed occlusion and to grasp the handles firmly.
- Swing in bite block (H).
- Have the patient bite into the indentation of the bite block (upper anterior teeth into the indentation, lower anterior teeth pushed forward as far as possible).
- 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.

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7.7.2 Positioning the patient - with head fixation device (e.g. for orthodontics)

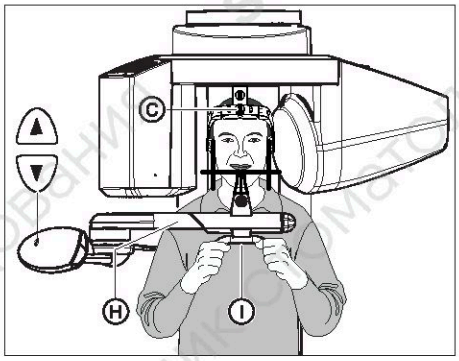


- Open the bands of the forehead support fully.
- Press the **R key** to move the unit back to the entry position.
- Attach the mandatory radiation protection equipment to the patient. Help the patient enter the unit moving backwards.
- If the rotary ring was accidentally displaced while positioning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

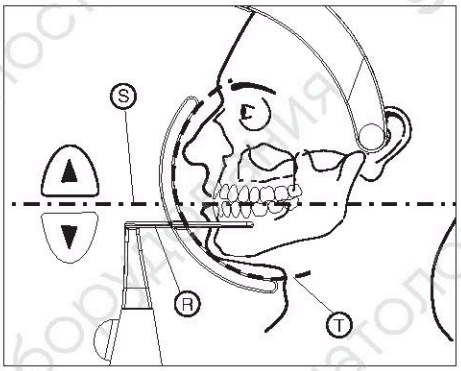
Aligning the patient



- 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 (H) until it snaps in place.
- The patient should grasp the handles (I) relaxed but securely.

IMPORTANT

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.

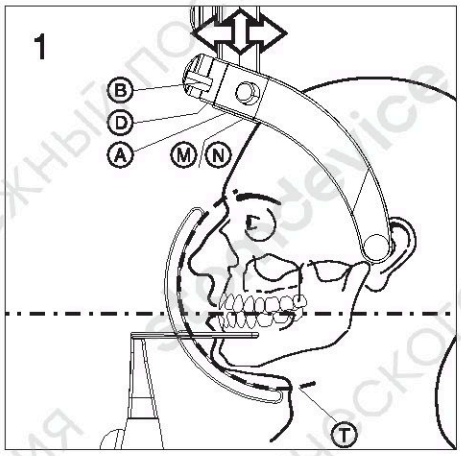
IMPORTANT

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

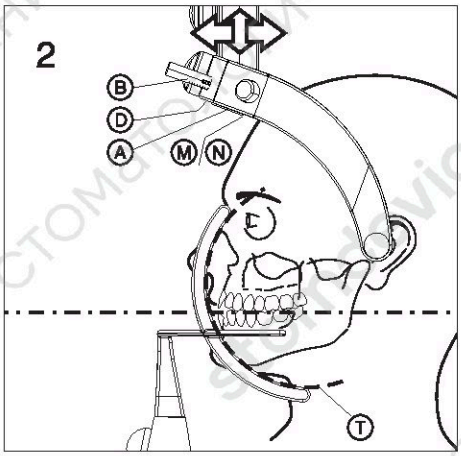
- The correct position for the indication can be set by laterally fixing the position with the volume control and using the vertical and horizontal adjustment options.
  The inner side (T) of the volume control should be regarded as the volume boundary.

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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. This can be done by pushing the tip of the patient's nose and the point of his chin out of the 3D volume.

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

NOTE

The latch of the pins (B) is damaged by pushing back the forehead rest by hand.

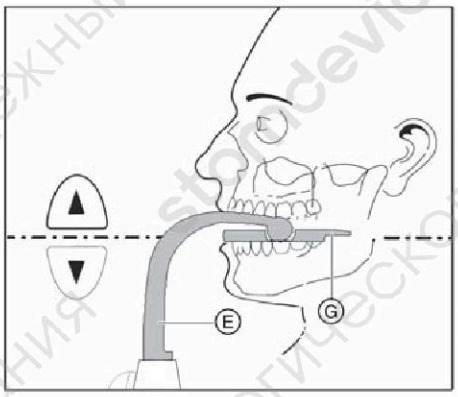
Always press the pushbutton (D) to unlatch the pins.

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7.7.3 Positioning patients - with spherical bite block

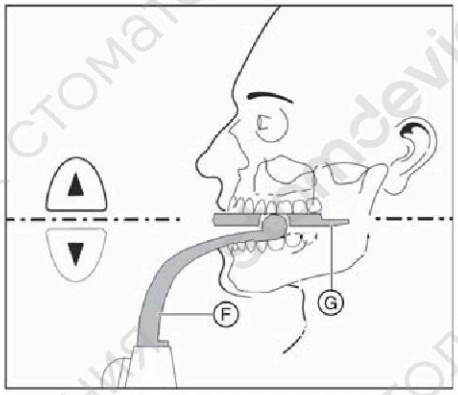
Using the spherical bite block to create an implant drilling template



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.

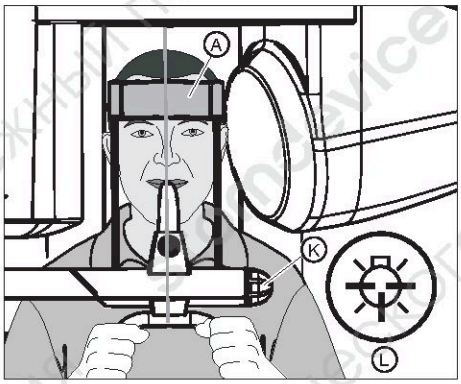
IMPORTANT

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.

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7.7.4 Display of midsagittal line



- 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).

As long as the light localizer is switched on, a red light localizer symbol is displayed on the touchscreen (see Section General touchscreen functions on the Easypad.

⚠ 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 [→ 33]).

Concluding the preparations

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

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7.8 Releasing the exposure

⚠ CAUTION

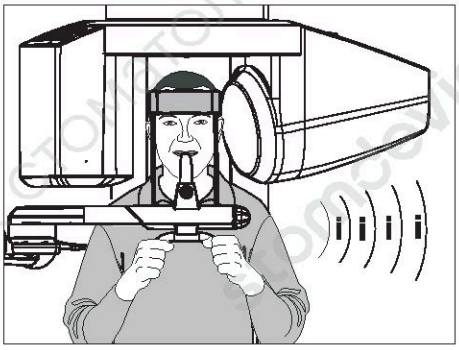
Be sure to observe the radiation protection regulations in your country, see also Radiation protection [→ 12].

IMPORTANT

No further help messages should appear in the comment line of the touchscreen. Only the "**Ready for exposure**" message should be displayed.

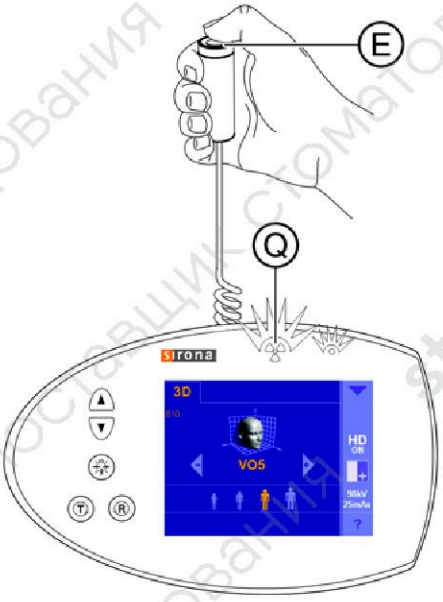
If the door of the X-ray room is not properly shut, the message "**Close the door**" will appear in the touchscreen comment line and **H321** as a coded message on the remote control.

- 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.
Explain this particularly carefully to children.



- 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 control panel 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.

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- The exposure is complete when ...
  - The comment line displayed on the touchscreen switches from "**Exposure in progress**" to "**R button, confirm exposure data**".
  - The message "**H 320**" and the program number are alternately displayed on the remote control.
  - The actual mAs value is shown next to the program number at the end of the exposure.
  - A short, pulsed tone sequence 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.

⚠ CAUTION

The exposure memory of the unit is cleared when the unit is switched off.

Images that have not been transferred to Sidexis are irretrievably lost. The exposure must be repeated.

➢ Wait until the exposure data have be completely transferred. Do not switch the unit off before the X-ray exposure is displayed on the Sidexis screen.

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.

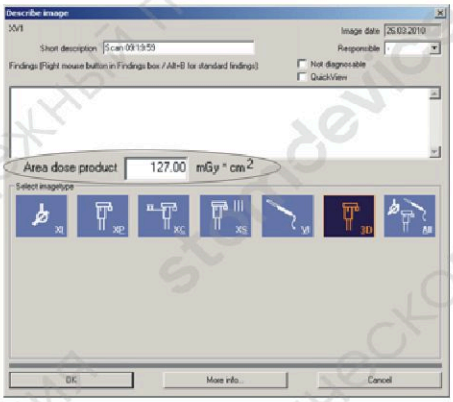
IMPORTANT

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

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Display *"Area dose product"* for SIDEXIS XG



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

Display *"Area dose product"* for Sidexis 4



Following the exposure, the *"Area dose product"* is displayed in Sidexis 4 in the *"Examination"* work phase in the *"Tools"* docking window in the *"Info"* tool palette.
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 message "**R button, 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.

The Ready LED above the "R" button 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" button on the control panel twice.
- After the rotating element has returned to its starting position, repeat the exposure.

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Automatic exposure blocking

(thermal protection of the tube)

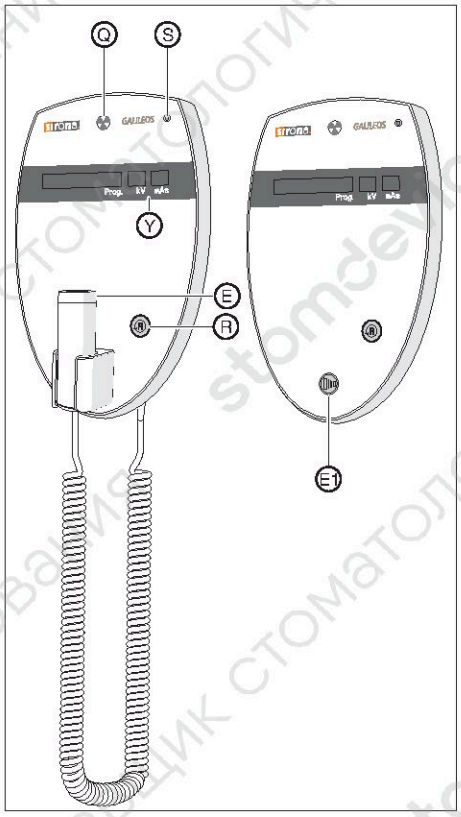
Premature release of a new exposure is prevented by the automatic exposure blocking function.

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 as "**X**".

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

7.9 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 VO5 with the corresponding values.

As long as plain-language **help messages** are displayed on the Easypad touchscreen, they also appear in coded form on the "**Prog.**" display, 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.

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8 List of messages

8.1 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. CAUTION Observe radiation protection measures.**.
  The **H3 / H4** .. message 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. IMPORTANT! To eliminate errors in the image database (rescue management), see "Software component operating instructions", REF 61 81 155. CAUTION Do not switch off the system before the rescue management is successfully completed.	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.

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8.2 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.

8.2.1 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. **NOTE! 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.

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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.

8.2.2 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).

8.2.3 zz

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

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8.3 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.

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9 Maintenance

9.1 Cleaning and care

9.1.1 Cleaning

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

NOTE

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

Electrical components of the system can be destroyed by liquids.

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

9.1.2 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.

NOTE

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 Dentsply Sirona.

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

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

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

REF **59 70 905**

Dentsply Sirona recommends the following disinfectants:

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

In the USA and Canada:

- CaviCide® or
- CaviWipes ™ .

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9.1.3 Sterilization

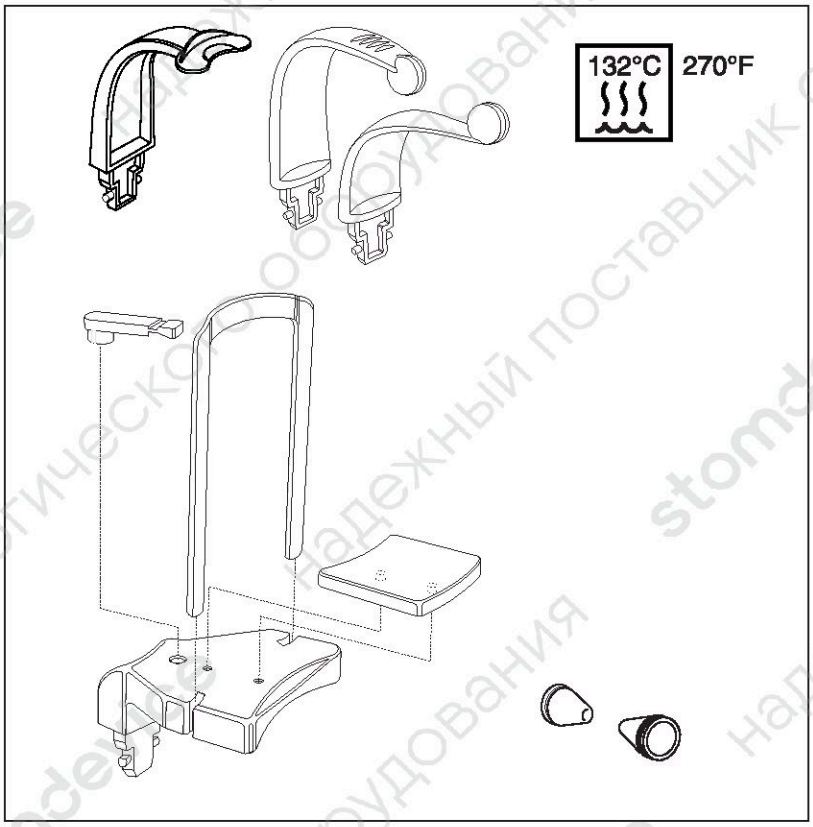
⚠ WARNING

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 132 °C (270 °F), with at least 4 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’ [→ 35].



⚠ WARNING

The hygienic protective sleeves are single use devices.

Contaminated hygienic protective sleeves can cause illness in patients.

➢ Replace the hygienic protective sleeves after each patient.

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9.2 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.

The information provided in the document *"Inspection and maintenance and safety-related checks"* REF *"61 25 533"* should be helpful here. The document can be downloaded at http://www.dentsplysirona.com/manuals.

Annual inspection

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

Maintenance by the service engineer

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

Checking image quality

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

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

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.

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10 Dismantling and disposal

10.1 Dismantling and reinstallation

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

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

10.2 Disposal



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

Disposal procedure

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

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

In Germany

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

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

  enretec GmbH
  Kanalstraße 17
  16727 Velten, Germany

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

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

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

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

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Other countries

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

10.2.1 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.

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11 Dose information

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 works with permanently set kV/mA combinations.

Standard mode: VO5 / VO5 HC

Program:	Child	Youth/Woman	Woman/Man	Strong person
	98 kV/3 mA	98 kV/4 mA	98 kV/5 mA	98 kV/6 mA
Set values:	6 mAs	8 mAs	10 mAs	12 mAs
Effective radiation time:	2 s	2 s	2 s	2 s
DAP:	222 mGycm^2	290 mGycm^2	356 mGycm^2	425 mGycm^2
DAP of LJ exposure*:	129 mGycm^2	168 mGycm^2	207 mGycm^2	247 mGycm^2
DAP of UJ exposure*:	171 mGycm^2	223 mGycm^2	274 mGycm^2	328 mGycm^2

HD mode: V05 HD / VO5 HD HC

Program:	Child	Youth/woman	Woman/Man	Strong person
	98 kV/3 mA	98 kV/4 mA	98 kV/5 mA	98 kV/6 mA
Set values:	15 mAs	20 mAs	25 mAs	30 mAs
Effective radiation time:	5 s	5 s	5 s	5 s
DAP:	612 mGycm^2	780 mGycm^2	957 mGycm^2	1139 mGycm^2
DAP of LJ exposure*:	355 mGycm^2	452 mGycm^2	555 mGycm^2	660 mGycm^2
DAP of UJ exposure*:	471 mGycm^2	600 mGycm^2	737 mGycm^2	877 mGycm^2

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Template scan: VOG

Program:	
	98 kV/6 mA
Set values:	30 mAs
Effective radiation time	5 s
DAP	1139 mGycm^2
DAP of LJ exposure*	660 mGycm^2
DAP of UJ exposure*	877 mGycm^2

* LJ exposure: Lower jaw collimation
UJ exposure: Upper jaw collimation

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 98 kV and 6 mA.

This results in the following dose values for GALILEOS Comfort PLUSStandard volume program:

Program				
Values	6 mAs	8 mAs	10 mAs	12 mAs
Full Effective dose value D_{eff}	28 µSv	38 µSv	47 µSv	56 µSv
Maxillar Effective dose value D_{eff}	20 µSv	27 µSv	34 µSv	41 µSv
Mandibular Effective dose value D_{eff}	22 µSv	29 µSv	37 µSv	45 µSv

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This results in the following dose values for GALILEOS Comfort PLUSStandard volume program:

Program				
Values	15 mAs	20 mAs	25 mAs	30 mAs
Full Effective dose value D_{eff}	78 µSv	106 µSv	130 µSv	154 µSv
Maxillar Effective dose value D_{eff}	62 µSv	84 µSv	103 µSv	122 µSv
Mandibular Effective dose value D_{eff}	68 µSv	92 µSv	113 µSv	133 µSv

Source

Study: “Comparative dosimetry of GALILEOS Dental CBCT imaging”, Prof. Dr. John B. Ludlow, Department of Diagnostic Sciences and General Dentistry, University of North Carolina School of Dentistry, Chapel Hill, North Carolina, USA

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

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