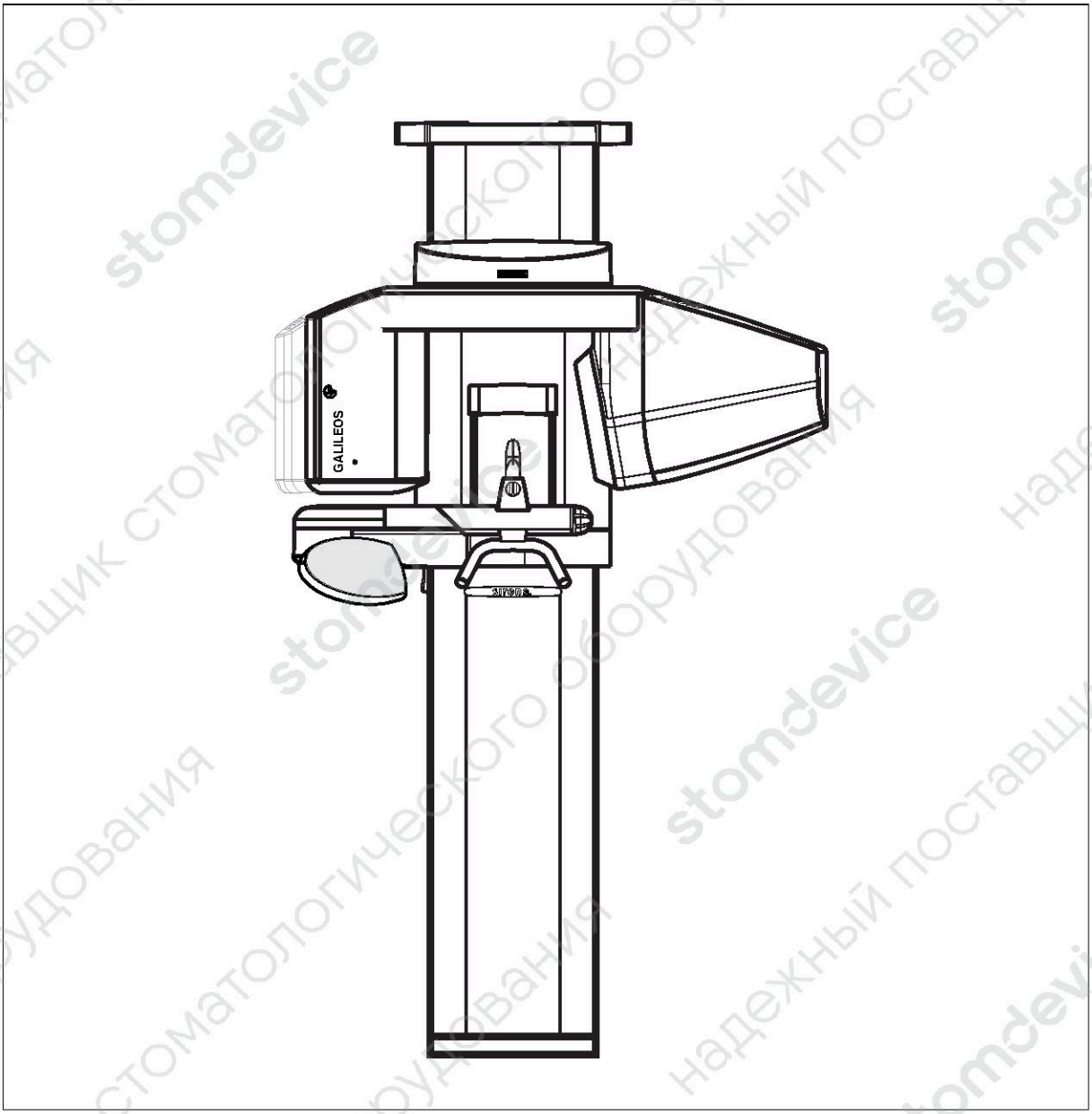
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sirona
The Dental Company

GALILEOS

Inspection and maintenance and safety-related checks



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Dear customer

You would like to have and will have many years of satisfaction with your **Sirona** X-ray unit.

Safety and reliability are necessary to ensure this.

Your dental dealership offers you service by specially trained engineers for this purpose.
The maintenance should ensure that your product is permanently safe and operational. All components subject to normal wear and tear are checked and, if necessary, replaced.
Maintenance work may be performed by the operator only if this is described on the part of Sirona Dental Systems GmbH, otherwise only authorized service engineers of Sirona Dental Systems GmbH or its authorized dealers may be entrusted with the work.
In case you have not concluded a maintenance contract, please contact the customer service department of your dental dealership.
The performed maintenance must be documented in this document, which must be kept with the unit.

We wish you much success and pleasure with your quality product
from **SIRONA Dental Systems.**

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1 General information

1.1 Inspection and maintenance and safety-related checks

Inspections, preventive maintenance and safety-related checks must be performed **at scheduled intervals** to protect the health and safety of patients, users and other persons.

- In order to ensure the operational safety and functional reliability of your product, you as the **system owner should inspect the equipment at least once a year** or commission your dental depot to do so.
  The information provided in **Chapter 2** "**Annual inspection performed by the system owner or other authorized persons**" should be helpful here. If one or more checks to be performed do not lead to satisfactory results, please contact your dental depot.
- In addition to the yearly inspection performed by the system owner, **a yearly calibration is to be performed by the service engineer**.
  The information provided in **Chapter 3** "**Yearly calibration by the service engineer (for the USA, see the Maintenance Instructions)**" should be helpful here.
- Medical devices are designed in such a way that the first occurrence of a fault does not create a hazard to the safety of the patient, the user or other persons. Hence it is important to detect such faults before a second fault occurs, which might then lead to safety hazards. For that reason it is essential to **perform safety checks** aimed particularly at detecting electrical faults every 2 years.
  The information provided in **Chapter 4** "**Safety-related checks by the service engineer in compliance with standard IEC 62353**" should be helpful here.
- In addition, your **dental depot offers you maintenance** of the system by specially trained engineers; see **Chapter 5** "**Maintenance by the service engineer**".

All inspection and maintenance work and safety-related checks performed by the system owner or service engineer must be recorded in this document and kept near the unit.

1.2 Please fill in the required general information

Customer	
Last name:	
First name:	
Street:	
City/State/Postal (ZIP) code:	
Phone:	

Space for practice stamp

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2 Annual inspection performed by the system owner or other authorized persons

2.1 Technical documentation

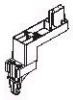
Technical documents	Answer questions with yes (✓) or no (–)											
Date (please enter month/year)												
Operating Instructions available?												
Installation requirements available?												
Installation Report/Warranty Passport available and completely filled out?												
Declaration of Conformity by system integrator available?												
X-ray System Logbook available (for Germany only)?												

If no ⇨ Order missing documents from your dental depot.

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2.2 System accessories

System accessories (see operating instructions) Not all of the accessories listed here are included in the scope of supply, cross out what does not apply.		**Answer questions with yes (✓) or no (-)**										
Date (please enter month/year)												
	Test phantom available? (worldwide, incl. Germany)											
	Test phantom available? (Germany, as from 07.2015)											
	Geometry phantom available?											
	Forehead support available?											
	Rigid bite block available?											
	Head fastening strap available?											
	Complete chin rest available?											
	Mandibular bite plate holder available?											
	Maxillary bite plate holder available?											

If no ⇨ Order missing accessories from your dental depot.

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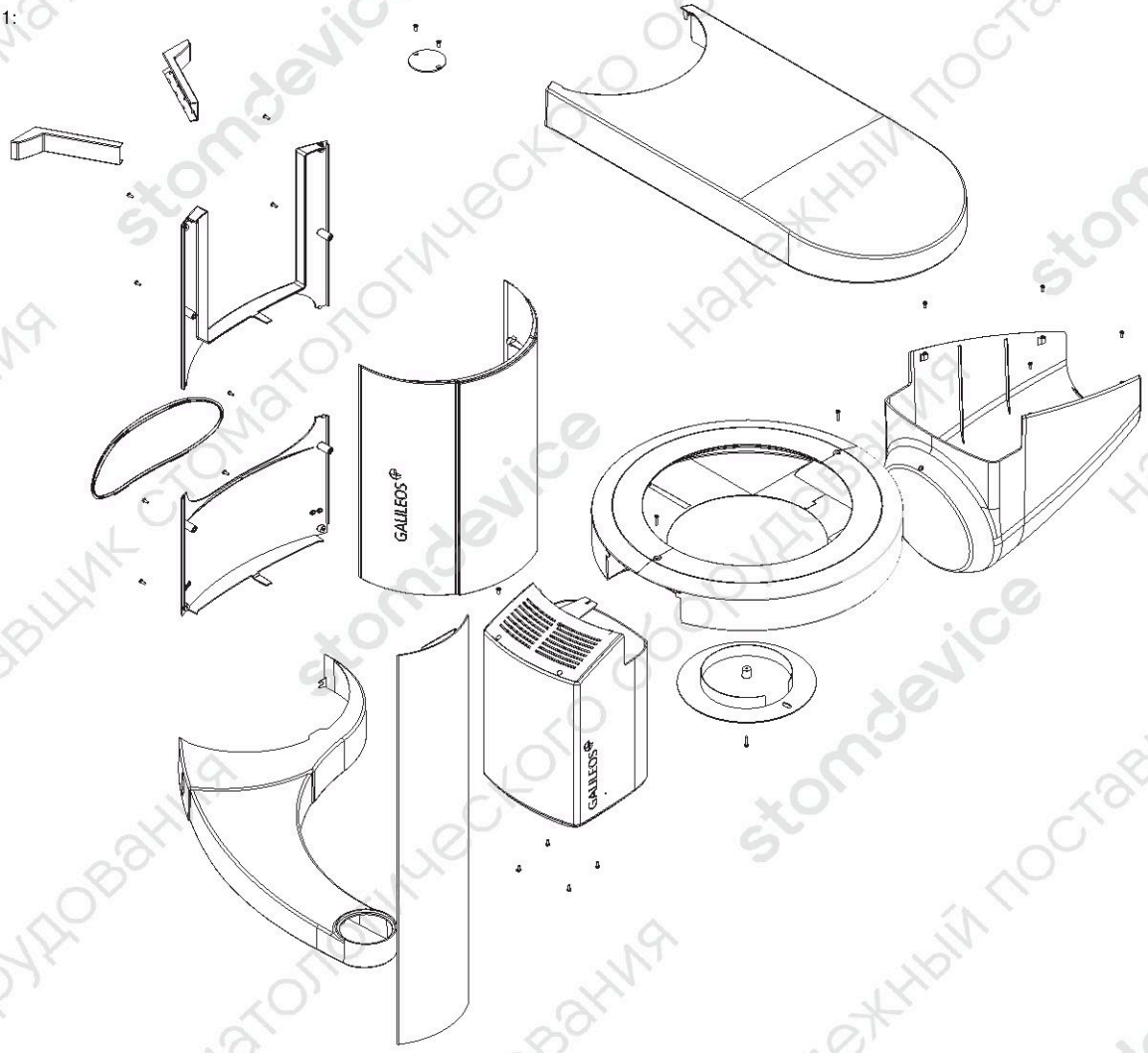
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2.3 Surfaces of the unit

Cover parts	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
All cover parts attached to the X-ray unit (Fig. 1)?											
All screws on unit housing available?											
Cover parts and mirrors free of damage (no surface damage, e.g. scratches)?											
All cover parts in clean condition? Clean X-ray unit with the recommended cleaning agents (See operating instructions).											

If no ⇨ Inform your dental depot.

Fig. 1:



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2.4 X-ray unit

X-ray tube assembly and stand condition	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Tube assembly housing perceptibly/visibly oil-free (Fig. 1)?											

If no ⇨ Inform your dental depot.

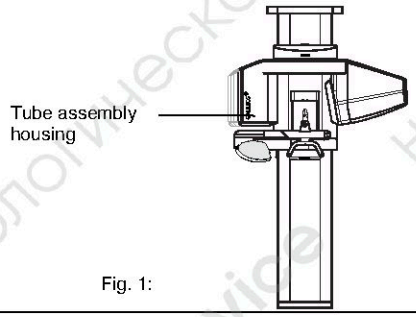


Fig. 1:

2.5 System safety

Safety	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Coiled cable with strain relief and anti-kink sleeve OK (Fig. 1)?											
Power cable and 2nd protective ground wire free of damage (Fig. 1)?											
Power cable free of damage (Fig. 1)?											
Are all of the screws for fastening the X-ray unit to the wall and mounting bracket and/or for fastening the unit securely to the floor stand securely tightened (Fig. 2)?											
Only for Japan: Is the unit switched off when the Emergency Stop switch is pressed?											

If no ⇨ Order repair by a service engineer immediately.

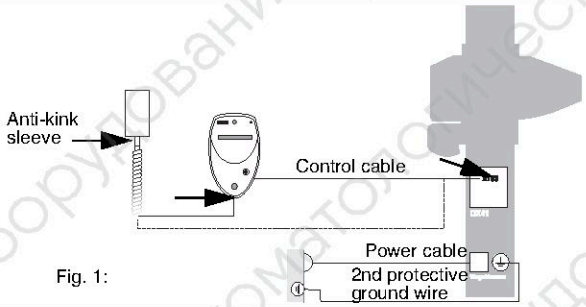


Fig. 1:

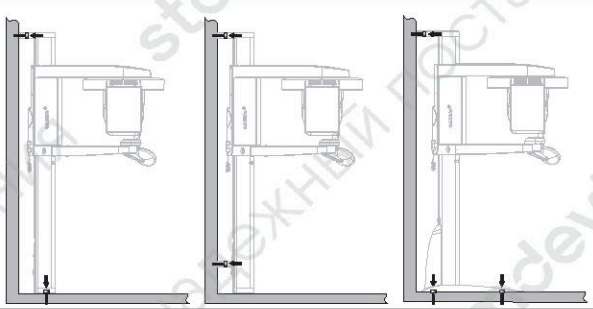


Fig. 2:

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2.6 Exposure safety

Exposure safety	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
No repeated occurrence of a certain error message (Fig. 1/2)?											
Optical and acoustic signal present when radiation is released (Fig. 1/2)?											
Is the release button free of cleaning agent residues and freely movable?											
Exposure is interrupted immediately when release button is released prematurely (Fig. 1/2)?											
Does the rotary movement occur without any atypical running noises?											

If no ⇨ Inform your dental depot.

GALILEOS Easypad

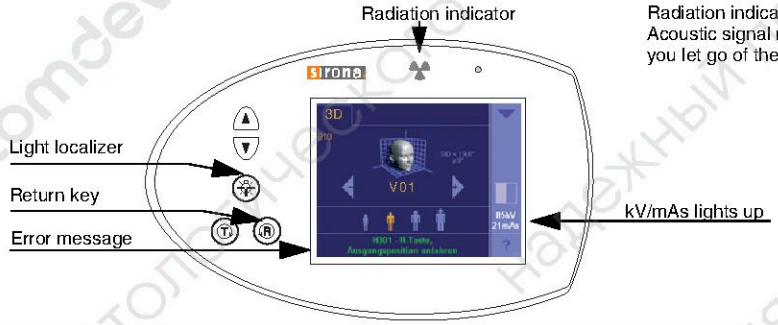


Fig. 1:

GALILEOS Multipad

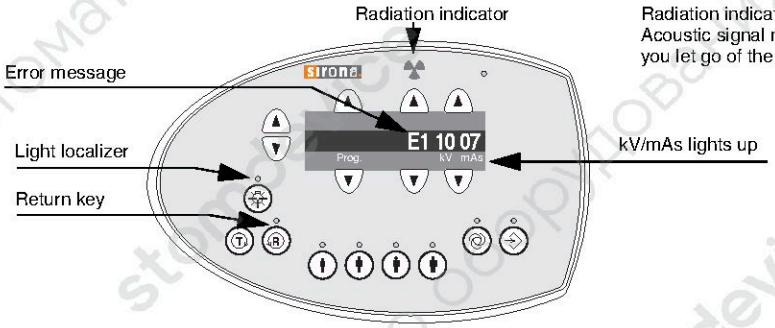


Fig. 2:

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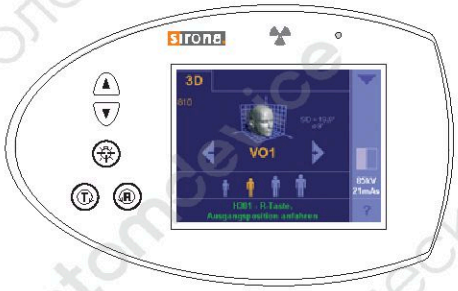
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2.7 Key functionality

Key functionality	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Membrane foil of the Easypad/ Multipad keys without cracks or holes (Fig. 1)?											
All numbers and letters on the Easypad/Multipad are displayed completely?											
Can the Easypad/Multipad be positioned reliably and does it remain in the desired position?											

If no ⇨ Inform your dental depot.

GALILEOS Easypad



GALILEOS Multipad

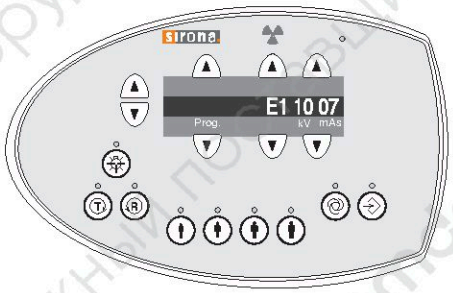


Fig. 1:

2.8 Light localizer functionality

Light localizer	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Vertical light beam is centered on the bite block (Fig. 1)?											

If no ⇨ Inform your dental depot.

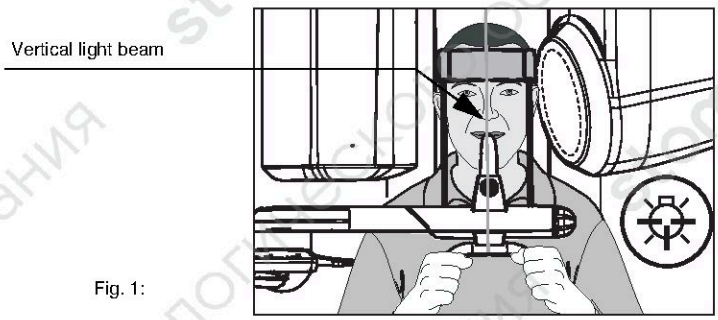


Fig. 1:

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2.9 Swivel arm/bite block/forehead support functionality

Swivel arm/bite block/forehead support	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Can the swivel arm be easily swiveled, is the locking mechanism OK, does the swivel arm lock into position (Fig. 1)?											
When swiveled out, is return movement not possible?											
Does the clamping device for the bite block work correctly?											
Does the clamping device for the forehead support work correctly?											

If no ⇨ Inform your dental depot.

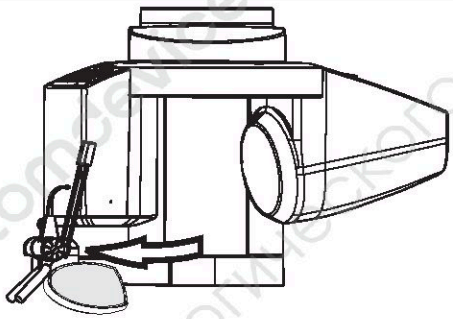


Fig. 1:

2.10 Image quality

Image quality	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Typical exposure parameters e.g. mAs are not adjusted in order to achieve a constant image quality?											
No recurring deterioration of the image sharpness or contrast?											

If no ⇨ Inform your dental depot.

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2.11 Height adjustment functionality

Height adjustment	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Acoustic signal sounds when height is adjusted?											
Height adjustment works without jolting and without atypical running noises (e.g. clacking, scuffing)?											
Does the set height remain unchanged even when the unit is switched off for longer periods of time?											
No jerking at beginning of soft start after key is pressed?											
Soft start does begin after key is pressed?											
No follow-up movement of height adjustment after height adjustment keys are released?											

If no ⇨ Inform your dental depot.

2.12 Facescan functionality (option)

Facescan	Answer questions with yes (✓) or no (–)										
Date (please enter month/year)											
Are all Backlight LEDs illuminated?											
Are the glass panes fog-free, clean and without scratches?											

If no ⇨ Inform your dental depot..

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2.13 Documenting your annual inspection

The undersigned confirms that he/she has checked the unit for the above criteria and that he/she has informed the competent dental depot in case of any defects.

Year	Inspection date:	Name:	Signature:
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			

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3 Yearly calibration by the service engineer

(for the USA, see the Maintenance Instructions)

3.1 General information for the service engineer

The **Service Manual for** GALILEOS (order No. 61 25 665 and 64 26 345) is indispensable for performing the calibration. All of the measures required for the calibration are described there in the Chapter "Calibrating the unit".
Furthermore, the operating instructions are required.

Should it be necessary to replace defective components along with parts subject to wear, this must be agreed previously with the customer or dental practice staff.

If components bearing a serial number are replaced, the new serial number must be recorded in the table in Chapter 5.5, "Serial numbers of the system".

Discontinuation of spare part deliveries:
Deliveries of spare parts are discontinued after a certain period of time for every system. The system owner will be responsible for safety-relevant failures of systems which continue in operation after that time and can no longer be serviced due to missing spare parts.

3.2 Calibrating the X-ray unit

Assessing X-ray exposures	**Answer questions with yes (✓) or no (–)**									
Date (enter month/year)										
Mechanical unit adjustment OK? See service manual										
Diaphram exposure OK? See service manual										
Beam field OK? See service manual										
Dosimetry OK? See service manual										
Sensor calibration OK? See service manual										
Iris calibration OK? See service manual										
Shading calibration OK? See service manual										
Distorsion calibration OK? See service manual										
Geometric calibration OK? See service manual										
Calibration of touchscreen OK? See service manual										

	If no ⇨ Correct fault.

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3.3 Documenting the yearly calibration

The undersigned confirms that he/she has checked the unit for the above criteria and that he/she has informed the competent dental depot in case of any defects.

Year	Date of check:	Geometry phantom serial No.:	Distorsion phantom serial No.:	Name:	Dealer:	Signature:
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						

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4 Safety-related checks by the service engineer in compliance with standard IEC 62353

4.1 General information for the service engineer

The **Service Manual** for GALILEOS (order No. 61 25 665 and 64 26 345) is absolutely essential for performing safety-related checks, as the protective ground wire and device leakage current tests are described in this document.

Measurements

Switch the power OFF at the main switch of the building installation, see Service Manual.

Select the correct current/voltage type and adjust the measuring range to match the expected readings.

Perform continuity tests only on units which are switched off.

ATTENTION

When opening the unit:
Please observe the usual precautionary measures for handling printed circuit boards (ESD).
Touch a ground point to discharge static electricity before handling any components.



ATTENTION

If the dental treatment center does not pass the safety tests, it must not be operated any longer!
You must advise the user of this fact in your capacity as service engineer. Corresponding repair work by an authorized service engineer is required before putting the system into service again.

NOTE

The safety checks correspond to the standard IEC 62353:2007
(DIN EN 62353/VDE 0751-1:2008).
If you use an automatic tester, you can program it according to these standards.
– Application components Type B
– Permanently attached unit
– Protection Class I

The measurements to be performed are complex and time-consuming.
Sirona therefore explicitly recommends using an automatic tester.

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4.2 Intervals for safety-related checks

It is essential to perform safety checks aimed particularly at detecting electrical faults during **initial startup** and then **every 2 years**. All inspections and measurements are performed by the authorized service engineer. They are specified in the following.

Safety-related checks are performed on the following occasions:

- **Initial startup**
- **Regularly every 2 years**
- **After extensions/upgrades (conversion)**
- **After repair work**

4.3 Safety-related check

(see Service Manual, chapter on Maintenance)

Equipment safety	**Answer questions with yes (✓) or no (-) Enter measured values**							
Maintenance interval after X years	**Initial startup**	**2**	**4**	**6**	**8**	**10**	**12**	**14**
Date (please enter month/year)								
Ground wire test OK? Enter measured values:								
A and **B** (GNYE wire) Measured value less than 0.1 ohms								
A and **C** (2nd ground wire) Measured value less than 0.1 ohms								
A and **D** (housing DX32) Measured value less than 0.2 ohms								
A and **E** (tube assembly housing) Measured value less than 0.2 ohms								
Unit leakage current test OK, measured value less than 5 mA? Enter measured values:								
Facescan (option) Ground wire test OK? Enter measured values:								
A and **F** (housing POE) Measured value less than 0.2 ohms								
A and **G** (stand arm) Measured value less than 0.2 ohms								
A and **H** (image intensifier chassis) Measured value less than 0.2 ohms								

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4.4 Documenting the safety-related check

The undersigned confirms that he/she has checked the unit for the above criteria.
If any question is answered with No, the fault must be eliminated.

Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	
Date:		**Engineer's name:**		**Signature:**	

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5 Maintenance by the service engineer

5.1 General information for the service engineer

The **Service Manual** for GALILEOS (order No. 61 25 665 and 64 26 345) is indispensable for performing maintenance. All of the maintenance measures required are described there in the Chapter entitled "Maintenance". Furthermore, the operating instructions are required.

Measurements

Always switch the unit OFF before connecting the measuring instruments.

Select the correct current/voltage type and adjust the measuring range to match the expected readings.

Perform continuity tests only on units which are switched off.

If several exposures with radiation must be taken to check a measurement, make sure that the prescribed cool-down intervals are observed.

ATTENTION



Observe the radiation protection guidelines before releasing radiation.

ATTENTION



When opening the unit:
Please observe the usual precautionary measures for handling printed circuit boards (ESD).
Touch a ground point to discharge static electricity before handling any components.



Before starting maintenance work, always perform a functional test and advise the customer or dental practice staff about any defects found.

Should it be necessary to replace defective components along with parts subject to wear, this must be agreed previously with the customer or dental practice staff.

If components bearing a serial number are replaced, the new serial number must be recorded in the table in Chapter 5.5, "Serial numbers of the system".

Discontinuation of spare part deliveries:
Deliveries of spare parts are discontinued after a certain period of time for every system. The system owner will be responsible for safety-relevant failures of systems which continue in operation after that time and can no longer be serviced due to missing spare parts.

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5.2 Maintenance interval

NOTE

In addition to the yearly inspection carried out by the system owner, safety-related checks must be performed by the service engineer after 4, 7 and 10 years, and then at two-year intervals.

5.3 Checking the records

In the chapter "**Annual inspection performed by the system owner or other authorized persons" on page 6**, in the chapter "**Yearly calibration by the service engineer (for the USA, see the Maintenance Instructions)" on page 15** and in the chapter "**Safety-related checks by the service engineer in compliance with standard IEC 62353" on page 17**.

Checking the records of the yearly inspection by the system owner	**Answer questions with yes (✓) or no (–)**									
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**					
Date (enter month/year)										
Annual inspection performed by the system owner (see Chapter 2)?										
Yearly calibration has been performed by the service engineer (see Chapter 3 or Maintenance Instructions)?										
Have all safety-related checks been carried out and did the measured values remain constant?										
Records complete?										
All questions answered with **yes**?										
All work required due to a negative result during the checks has been performed?										

If no ⇨ Perform annual inspection and calibration prior to maintenance.

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5.4 Labels on the system

Compare labels on system with Installation Report/Warranty Passport	Answer questions with yes (✓) or no (–)								
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**				
Date (enter month/year)									
All labels according to Installation Report/Warranty Passport affixed (Fig. 1)?									
All labels legible?									

If no ⇨ Replace missing and/or illegible labels.

Fig. 1:



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5.5 Serial numbers of the system

Please enter new serial no. here when replacing a component:			
X-ray device		**Date**	**Signature**
Serial no. (for startup)			
Serial no.			
Serial no.			
X-ray tube unit		**Date**	**Signature**
Serial no. (for startup)			
Serial no.			
Serial no.			
Serial no.			
Serial no.			
Tube		**Date**	**Signature**
Serial no. (for startup)			
Serial no.			
Serial no.			
Serial no.			
Serial no.			
Remote		**Date**	**Signature**
Serial no. (for startup)			
Serial no.			
Serial no.			
Serial no.			
X-ray detector		**Date**	**Signature**
Serial no. (for startup)			
Serial no.			
Serial no.			
Test phantom		**Date**	**Signature**
Serial no. (for startup)			
Serial no.			
Serial no.			

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5.6 Functional test

A functional test always must be performed before beginning maintenance work.

In doing so, it is helpful to read out any error messages which may be present.
See Service Manual Chapter Service".

Inform the customer or dental practice staff about any defects you have detected.

Checking system functions (observe operating instructions)	**Answer questions with yes (✓) or no (-)**									
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**					
Date (enter month/year)										
No visible signs of abrasion or hardened grease on HV motor and threaded rod? See service manual										
No atypical running noises audible during height adjustment?										
Jolt-free fine positioning possible during height adjustment?										
Is there still enough lubricant between the sliding surfaces?										
Does the set height remain unchanged even when the unit is switched off for longer periods of time?										
Limit switch for height adjustment functioning?										
Acoustic signal sounds when height is adjusted?										
Does the clamping device for the forehead support work correctly?										
Does the clamping device for the bite block work correctly?										
Can the swivel arm be easily swiveled, is the locking mechanism OK, does the swivel arm lock into position?										
Facescan (option) Is the Facescan securely screwed together with the the X-ray detector?										
Are the glass panes on the Facescan clean inside and outside?										

	If no ⇨ Correct fault.

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5.7 Checking the tube data

Checking the tube data	Answer questions with yes (✓) or no (–)									
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**					
Date (enter month/year)										
Actual mAs values OK?										
Is the fan functioning? See service manual										
Does the temperature sensor in the tube assembly indicate a value between approx. 18° and 65 °C? See service manual										

	If no ⇨ Correct fault.

5.8 Checking the cables for damage

Checking the cables	Answer questions with yes (✓) or no (–)									
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**					
Date (enter month/year)										
Power cable OK? See service manual										
Is the power cable connected with a fixed connection? See service manual										
Protective ground wire OK?										
Control cable OK?										
Data cable OK?										

	If no ⇨ Correct fault.

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5.9 Safety-related check

Move unit to working height. Switch the power OFF at the main switch of the building installation or disconnect the power plug. Remove covers from the unit.

Performing safety checks	**Answer questions with yes (✓) or no (–)**									
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**					
Date (enter month/year)										
Idling roller free from damage? See service manual										
Grounding straps and cable shields have complete and firm contact?										
Cable shielding OK?										
Protective ground wire connections properly attached?										
	If no ⇨ Correct fault.									

5.10 Final steps

Final work (observe operating instructions)	**Answer questions with yes (✓) or no (–)**								
Maintenance interval (after years)	**4**	**7**	**10**	**12**	**14**				
Date (enter month/year)									
System cleaned?									
	If no ⇨ Clean system.								

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5.11 Documenting maintenance work

The undersigned confirms that he/she has checked the unit for the above criteria and that he/she has handed over the unit in fully functional condition.

Date of maintenance	Name of engineer	Name of dealer	Signature of engineer

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

© Sirona Dental Systems GmbH 2015
D 3437.105.01.11.02 09.2016
Sprache: englisch
Ä.-Nr.: 122 808
Printed in Germany
Imprimé en Allemagne

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