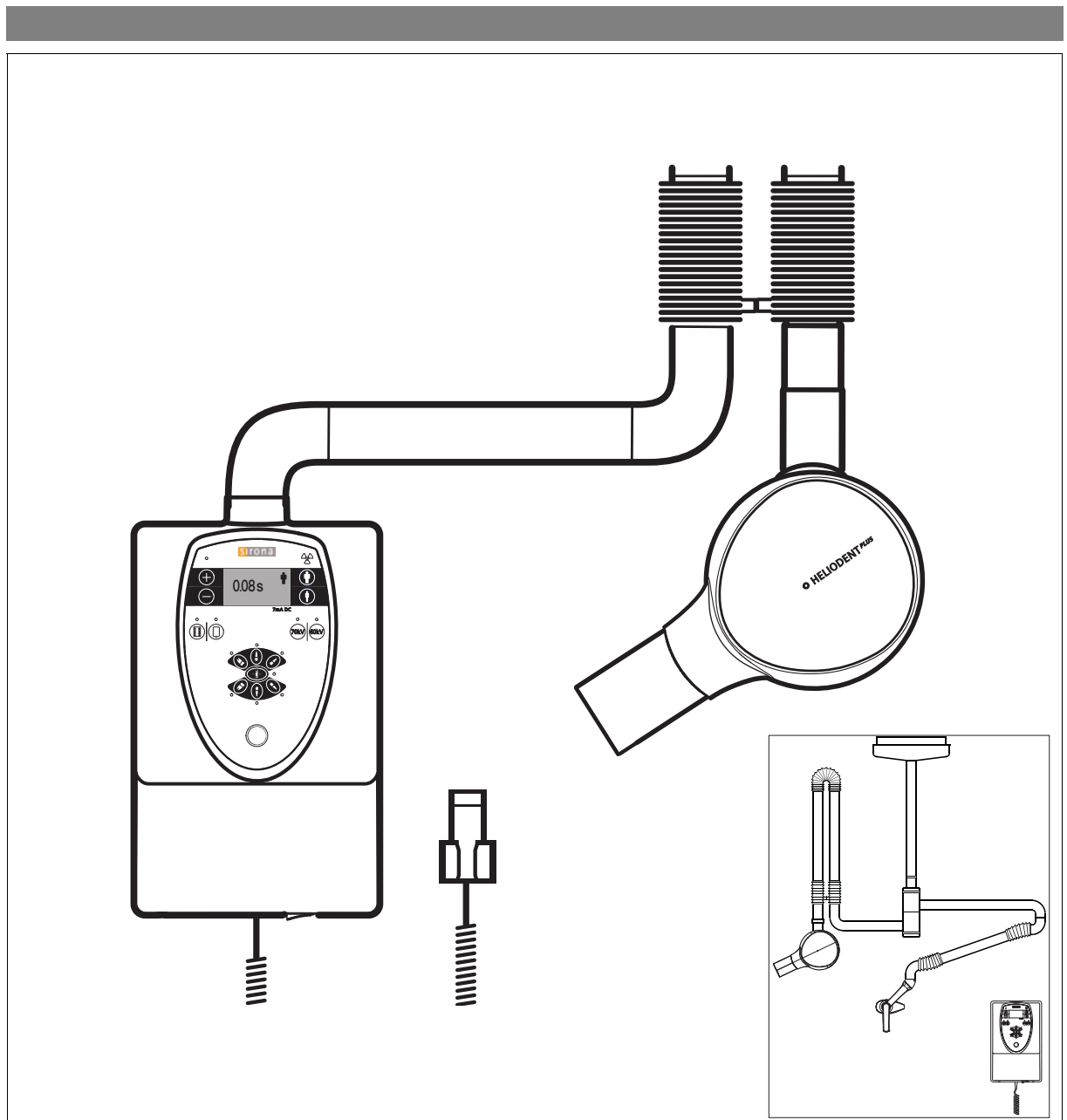


HELIODENT^{PLUS}

Inspection and maintenance and
safety-related checks



Dear Customer,

You are no doubt eagerly looking forward to using your **Sirona** X-ray unit for some time to come.

Safety and reliability are essential in order to achieve this.

Your dental depot offers you service by specially trained engineers for this purpose.

This maintenance service will ensure that your product is always safe and ready to use. All components which are subject to normal wear and tear are checked and, if necessary, replaced.

Maintenance work may be performed by the system owner only if this has been described by Sirona Dental Systems GmbH; in all other cases, only authorized service engineers of Sirona Dental Systems GmbH or of its authorized dealers may be commissioned to perform such work.

If you have not concluded a service agreement, please contact the customer service department of your dental depot.

All maintenance work performed must be recorded in this document and kept near the unit.

We wish you much success and pleasure with this 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.
- 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 3 "Safety-related checks performed by the service engineer"** should be helpful here.
- In addition, your **dental depot offers you maintenance** of the system by specially trained engineers; see **Chapter 4 "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:	

System data*			
Serial no. of system:			
Serial no. of tube assembly:			
Serial no. of test phantom:			

*** Information for the service engineer: Please update the serial no. when replacing a component.**

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 Report/Warranty Passport available and completely filled out?										
Installation requirements available?										
X-ray system logbook regularly updated (Germany/Austria/Switzerland)?										

2.2 System accessories

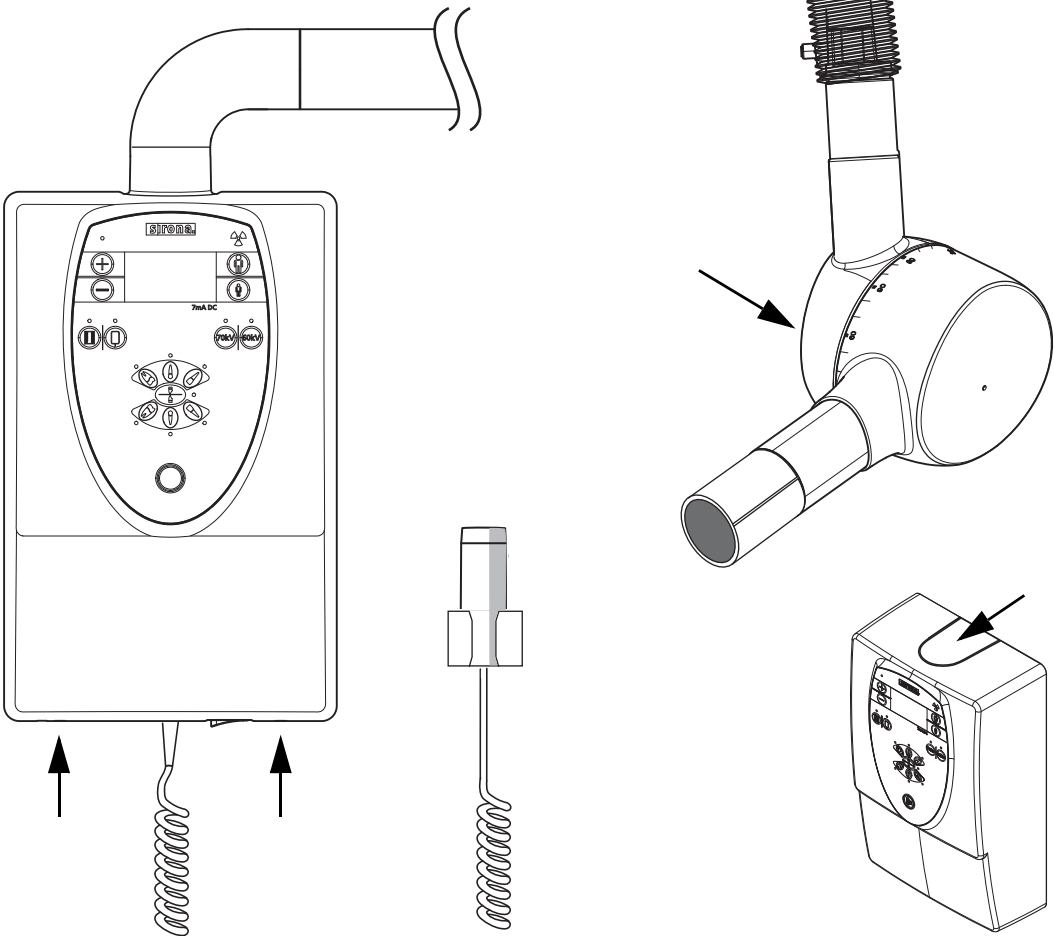
Accessories (see Operating Instructions) Not all of the accessories listed here are included in the scope of supply, cross out if not applicable.	Answer questions with yes (✓) or no (–)									
Date (please enter month/year)										
Conventional test phantom available?										
Digital test phantom available?										
300 mm (12") cone available?										
300 mm (12") square cone available?										
Radiation field limiter blue 3x4 cm present?										
Radiation field limiter black 2x3 cm present?										

[illegible][illegible]

Please enter changes here:			
X-ray tube unit		Date	Signature
Serial no.			
Serial no.			
Serial no.			
Tube			
Serial no.			
Serial no.			
Serial no.			
Radiation field limiter blue 3x4 cm			
Serial no.			
Serial no.			
Serial no.			
Radiation field limiter black 2x3 cm			
Serial no.			
Serial no.			
Serial no.			
300 mm (12") cone			
Serial no.			
Serial no.			
Serial no.			
300 mm (12") square cone			
Serial no.			
Serial no.			
Serial no.			
Wall adapter/Ceiling model			
Serial no.			
Serial no.			
Serial no.			

2.4 Surfaces of the unit

Cover parts	Answer questions with yes (✓) or no (–)									
Date (please enter month/year)										
Are all cover parts present?										
Are the cover parts free of damage?										
Do the cover parts fit properly?										
Do the cover on the wall adapter for the ceiling model fit properly and is firmly glued?										
Are the cover parts clean?										
Are all screws present and tightly screwed in? (See arrows.)										
Is the scale on the tube assembly legible?										



2.5 System functions

Condition of tube assembly/arm/ remote control/remote timer	Answer questions with (✓) or no (–)									
Date (please enter month/year)										
Loss of oil noticeable on tube assembly (outside of tube assembly housing)?										
Coiled cable and anti-kink sleeve OK?										
Power connection with strain relief OK (for surface installation)?										
Can scissor arm be moved without jolting?										

System functions	Answer questions with yes (✓) or no (–)									
Date (please enter month/year)										
Is the wall fastening in safe condition?										
Main switch functioning?										
Is the exposure canceled if you let go of the exposure release button prematurely (dead man's control)?										
Are the optical (X-ray lit) and acoustic signals present during radiation?										
Are all buttons and indicators functioning?										
Are all system functions executable based on the operating instructions?										
Is the image quality always constant?										

2.6 Documenting your yearly inspection

The undersigned confirms that he/she has checked the unit for the above criteria.

NOTE: If one of the questions is answered with NO or an error message occurs repeatedly, please contact your service engineer.

Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	
Inspection date:		Name:		Signature:	

3

Safety-related checks performed by the service engineer

3.1 General information for the service engineer

The **Service Manual for HELIODENT^{PLUS}** (order no. 62 15 102) is absolutely essential for performing safety-related checks, as the protective ground wire and device leakage current tests are described in this document.

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.

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.

3.2 Interval for safety-related checks

It is essential to perform safety-related checks aimed particularly at detecting electrical faults **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**

3.3 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, measured value less than 0.2 ohms? Enter measured values.								
Wall Model Unit leakage current test OK, measured value less than 0.55 mA? Enter measured values.								
Ceiling model Unit leakage current test OK, measured value less than 2 mA? Enter measured values.								

3.4 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:	

4

Maintenance by the service engineer

4.1 General information for the service engineer

The **Service Manual for HELIODENT^{PLUS}** (order no. 62 15 102) is absolutely essential for performing maintenance, as all of the maintenance required is described therein.

Furthermore, the Operating Instructions supplied with the unit are also 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, the consent of the customer or dental practice staff must be obtained first.

ATTENTION 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.

4.2 Maintenance interval



NOTE

In addition to the annual inspections to be carried out by the system owner or authorized persons, **safety-related checks must be performed by the service engineer after 4, 7 and 10 years, and then at two-year intervals.**

4.3 Checking the records

In the chapter “Annual inspection performed by the system owner or other authorized persons” on page 6 and in the chapter “Safety-related checks performed by the service engineer” on page 11

Checking the records	Answer questions with yes (✓) or no (–)							
Maintenance interval after X years	4	7	10	12	14			
Date (please enter month/year)								
Annual inspection performed by the system owner?								
Records complete?								
Were all questions answered with yes ?								
Has all work which led to a negative result during the checks been performed?								
Have all safety-related checks been carried out and did the measured values remain constant?								

4.4 Maintenance of wall adapter/remote timer

(see Service Manual, chapter on Maintenance)

Equipment safety		Answer questions with yes (✓) or no (–)						
Maintenance interval after X years	4	7	10	12	14			
Date (please enter month/year)								
Is the wall fastening in safe condition?								
Are the cover parts present and free of damage?								
Are all shielded connections tight?								
Are all protective ground connections tightly fitted?								
Damage-free, tight and proper seating of power cable.								
Exposure times and high voltage OK?								
Release button OK?								
Is front panel OK?								

4.5 Maintenance of arm/tube assembly

(see Service Manual, chapter on Maintenance)

Equipment safety		Answer questions with yes (✓) or no (–)						
Maintenance interval after X years	4	7	10	12	14			
Date (please enter month/year)								
Support arm OK?								
Can the support arm be moved smoothly, without jolting, easily and without running noises?								
Is the support arm in an upright position, are the stopper buffers exactly opposite each other?								
Are the moving support arm parts and cast parts free from mechanical damage?								
Is tube assembly joint OK?								
Tube assembly without oil loss?								
Are all protective ground connections in the tube assembly tight?								
Is the grounding strap for the protective conductor OK (light damage with no more than 20% cross-section loss is acceptable)?								
Is tube current OK?								

4.6 Maintenance Ceiling Model

Unit safety		Answer questions with yes (✓) or no (–)						
Maintenance interval after X years	4	7	10	12	14			
Date (Enter month/year)								
Is the mounting on the ceiling in a safe condition?								
Are all cover parts available and free of damage?								
Are all protective ground wire connections made firmly?								
Are the cables connected at terminal K10 connected free of damage, firmly and according to regulations.								

4.7 Final steps

Equipment safety		Answer questions with yes (✓) or no (–)						
Maintenance interval after X years	4	7	10	12	14			
Date (please enter month/year)								
Complete functional test performed? (see Operating Instructions)								
System cleaned?								

4.8 Documenting maintenance work

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 of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	
Date of maintenance:		Engineer's name:		Signature:	

Space for remarks

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

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