VistaRay 7

EN

Installation and operating instructions

CE 0297

9000-618-197/30

DÜRR DENTAL

2002V012

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Important information

1 About this document

These installation and operating instructions represent part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

The German version of the installation and operating instructions is the original manual. All other languages are translation of the original manual. These installation and operating instructions apply to:
VistaRay 7
Order number: 2121-130-62; 2121-130-63

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.
The following warning symbols are used:

General warning symbol

The warnings are structured as follows:

> **SIGNAL WORD**
> **Description of the type and source of danger**
>
> Here you will find the possible consequences of ignoring the warning
>
> › Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:
- **DANGER**
  Immediate danger of severe injury or death
- **WARNING**
  Possible danger of severe injury or death
- **CAUTION**
  Risk of minor injuries
- **NOTICE**
  Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Refer to Operating Instructions.

Refer to the accompanying electronic documents.

CE xxxx CE labelling with the number of the notified body

Manufacturer

Date of manufacture

Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).

Protection class II

Type BF application part

Wear protective gloves.

Use a mask.

Wear protective goggles.

Use protective clothing.

Do not reuse

REF Order number

SN Serial number

MD Medical device

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HIBC Health Industry Bar Code (HIBC)

1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this unit so that when used properly and for the intended purpose it does not pose any danger to people or property.
Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to electric shock
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects on skin
- Personal injury due to lack of hygiene, e.g. infection

2.1 Intended purpose

The intraoral sensor is intended to convert x-ray photons into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

2.2 Intended use

The intraoral sensor is used to generate intraoral X-ray images in conjunction with an intraoral X-ray unit. Hygienic protective covers must be used.
Only those accessories or parts specifically mentioned in the Installation and Operating Instructions may be used with the device.
The device must only be cleaned and disinfected using the disinfectants and cleaning agents that are listed in the Installation and Operating Instructions.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damage resulting from improper usage.
In such cases, the user/operator will bear the sole risk.
The intraoral sensor is not suitable for monitoring patients over a long-term period.

2.4 General safety information

› Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.

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› Check the function and condition of the unit prior to every use.
› Do not convert or modify the unit.
› Comply with the specifications of the Installation and Operating Instructions.
› The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

2.5 Specialist personnel

Operation

Unit operating personnel must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

The following groups are not permitted to operate or use a commercially operated unit:

– People without the necessary experience and knowledge
– People with reduced physical, sensory or mental capabilities
– Children

Installation and repairs

› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.6 Electrical safety

› Observe and comply with all the relevant electrical safety regulations when working on the unit.
› Replace any damaged cables or plugs immediately.

Observe the EMC rules concerning medical devices

› The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, potential effects on electromagnetic compatibility must be taken into account.
› Do not operate the unit in the vicinity of HF surgical instruments or MRT equipment.
› Maintain a minimum distance of at least 30 cm between the unit and other electronic devices.
› Note that cable lengths and cable extensions have effects on electromagnetic compatibility.
› No maintenance measures are required to maintain the EMV basic safety.

NOTICE

Negative effects on the EMC due to non-authorised accessories

› Use only Dürr Dental parts or accessories specifically approved by Dürr Dental.
› Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

NOTICE

Erroneous operation mode due to use immediately adjacent to other devices or with other stacked devices

› Do not stack the unit together with other devices.
› If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

NOTICE

Reduced performance characteristics due to insufficient distance between unit and portable HF communication devices

› Keep a distance of at least 30 cm between the unit (including parts and cables of the unit) and portable HF communication devices (wireless units) (including their accessories such as antenna cables and external antennas).

2.7 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3.
The unit complies with the requirements according to IEC 60601-1-2:2014.

2.8 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.9 Only use original parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.

› Only use only original wear parts and replacement parts.

Dürr Dental accepts no liability for damages or injury resulting from the use of non-approved accessories or optional accessories, or from the use of non-original wear parts or replacement parts.

The use of non-approved accessories, optional accessories or non-genuine wear parts / replacement parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

2.10 Transport

The original packaging provides optimum protection for the unit during transport.
If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental will not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

› Only transport the unit in its original packaging.

› Keep the packing materials out of the reach of children.

2.11 Disposal

Unit

The unit must be disposed of properly. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

An overview of the waste keys for Dürr Dental products can be found in the download area at www.duerrdental.com (document no. P007100155).

2.12 Protection from threats from the Internet

The unit is to be connected to a computer that can be connected to the Internet. Therefore, the system needs to be protected from threats from the Internet.

› Use antivirus software and update it regularly. Look for evidence of possible virus infection and, if applicable, check with the antivirus software and remove the virus.

› Perform regular data backups.

› Restrict access to units to trustworthy users, e.g. via a user name and password.

› Make sure that only trustworthy content is downloaded. Only install software and firmware updates that have been authenticated by the manufacturer.

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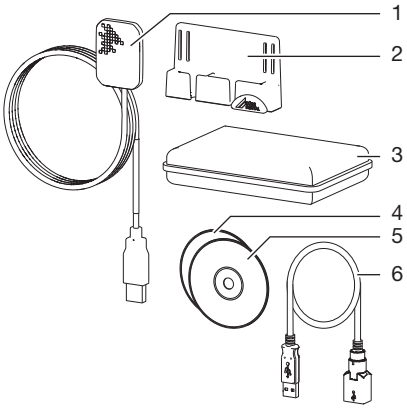
Product description

3 Overview



1 Sensor
2 Sensor holder
3 Hygienic protective covers in box
4 Imaging Software DVD
5 Calibration CD
6 USB extension

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

Sensor 7.1
VistaRay 7 size 1 2121-100-70
– Sensor 7.1
– Calibration CD
– Sensor holder
– Adhesive pad
– Velcro strip
– Cable holder
– USB extension 1 m
– Hygienic protective covers (qty. 100)
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD
– Installation and operating instructions
– EN Installation and configuration manual

Sensor 7.2
VistaRay 7 size 2 2121-100-71
– Sensor 7.2
– Calibration CD
– Sensor holder
– Adhesive pad
– Velcro strip
– Cable holder
– USB extension 1 m
– Hygienic protective covers (qty. 100)
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD
– Installation and operating instructions
– EN Installation and configuration manual

3.2 Accessories

Hygienic protective covers
(qty. 100) 2121-010-50
Hygienic protective covers
(qty. 500) 2121-010-51

3.3 Optional items

The following optional items can be used with the unit:
Intra / extra digital test body 2121-060-54
VistaRay sensor holder system set . 2121-981-70
Accessories for each further workstation for VistaRay 7 2121-100-80
VistaRay Sensor 7.1 2121-130-62
VistaRay Sensor 7.2 2121-130-63
VistaRay 7 System Kit 2121-180-54

3.4 Consumables

The following materials are consumed during operation of the unit and must be reordered separately:
Hygienic protective covers
(qty. 100) 2121-010-50
Hygienic protective covers
(qty. 500) 2121-010-51
FD 322
rapid surface disinfection CDF322C6150
FD 333
rapid surface disinfection CDF333C6150
FD 333 forte wipes
Quick-acting disinfection CDF33FW0150
FD 350 Classic
disinfection wipes CDF35CA0140

FD 366 sensitive
rapid surface disinfection CDF366C6150
ID 212
Instrument disinfection CDI212C6150
ID 212 forte
Instrument disinfection CDI212F6150

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4 Technical data

Electrical data		
Nominal voltage	V DC	5
Nominal current	mA	100

Klassifizierung		
Medizinprodukt Klasse		IIa

4.1 Sensor 7.1

General technical data		
Dimensions W x H x D	mm	27.4 x 39.0 x 6.3
Cable length sensor	m	2.5
Max USB cable extension	m	1
Computer connection		USB 2.0 Compatible with USB 3.0

Sensor characteristics		
Active sensor size W x H	mm	20 x 30
Min. pixel size	µm	19
Max. no. pixels		1050 x 1580
Theoretical resolution	LP/mm	26.3
Sensor type		CMOS
Scintillator		Structured CsJ scintillator on fibre-optics

4.2 Sensor 7.2

General technical data		
Dimensions W x H x D	mm	33.1 x 44.7 x 6.3
Cable length sensor	m	2.5
Max USB cable extension	m	1
Computer connection		USB 2.0 Compatible with USB 3.0

Sensor characteristics		
Active sensor size W x H	mm	26 x 36
Min. pixel size	µm	19
Max. no. pixels		1368 x 1896
Theoretical resolution	LP/mm	26.3
Sensor type		CMOS
Scintillator		Structured CsJ scintillator on fibre-optics

4.3 Electromagnetic compatibility (EMC)

The information on electromagnetic compatibility (EMC) applies to VistaRay sensors 7.1 and 7.2.

Electromagnetic compatibility (EMC) Interference emission measurements	
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Group 1, Class B

Electromagnetic compatibility (EMC) Interference immunity measurements cover	
Immunity to interference, discharge of static electricity IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to interference, high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010 3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz	Compliant
Immunity to interference, near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 See immunity to interference table, near fields of wireless HF communication devices.	Compliant

Immunity to interference table, near fields of wireless HF communication devices

Radio service	Frequency band MHz	Test level V/m
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	1700 - 1990	28

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Immunity to interference table, near fields of wireless HF communication devices		
Radio service	**Frequency band MHz**	**Test level V/m**
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP	
Immunity to interference, discharge of static electricity IEC 61000-4-2:2008 ± 8 kV contact ± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant

4.4 Ambient conditions

Ambient conditions during operation		
Temperature	°C	10 - 35
Relative humidity	%	< 80
Air pressure	hPa	750 - 1160
Height above sea level	m	< 2000

Ambient conditions during storage and transport		
Temperature	°C	-20 to +60
Relative humidity	%	< 95
Air pressure	hPa	750 - 1160
Height above sea level	m	< 16000

4.5 Type plate

The type plate is located on the sensor cable and on the case.

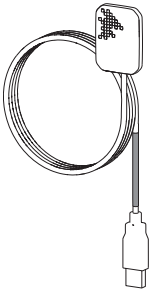

Fig. 1: Type plate on the sensor cable

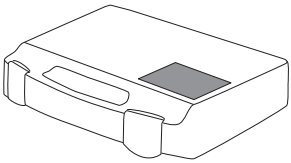

Fig. 2: Type plate on the case

REF	Order number/type number
SN	Serial number

4.6 Evaluation of conformity

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation

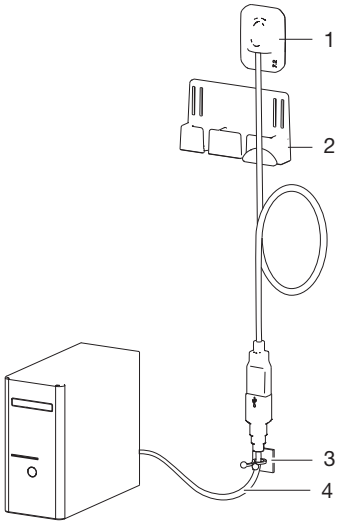

Fig. 3: VistaRay 7

1 X-ray sensor
2 Sensor holder
3 Cable holder
4 USB extension

The X-ray sensor is connected to the computer via the sensor cable, and if required, the USB extension.
The sensor is equipped with a hygienic protective cover and placed in the mouth of the patient. It is activated via imaging software (e. g. VistaSoft). During the X-ray procedure, the x-rays are received by the scintillator (luminescent material) installed on the sensor and are converted into beams of light. These light beams are recorded by the sensor as image information, digitalised and transferred to the computer. If an error occurs during the transfer, the image information is sent again.
No further X-ray image is possible during data transmission.
The application part BF in accordance with IEC 60601-1 is the X-ray sensor.

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Assembly

6 Requirements

6.1 Installation/setup room

› The unit may only be used in a room that has been set up for the purpose (e. g. an x-ray room). Do not use in the open.
› Do not subject the unit to direct sunlight or heat.
› The setup room may not contain any major interference fields (e. g. strong magnetic fields). They could cause faults in the unit.

6.2 System requirements

The system requirements for the computer systems can be found in the download area at www.duerrdental.com (document no. 9000-618-148).

7 Installation

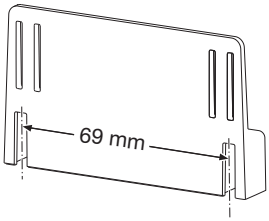
7.1 Fitting the sensor holder

The sensor holder and the cable holder can be secured to the wall or treatment unit using either the adhesive pad or with screws and plug.
The sensor holder can also be fitted to the lamp stand using the Velcro strip.

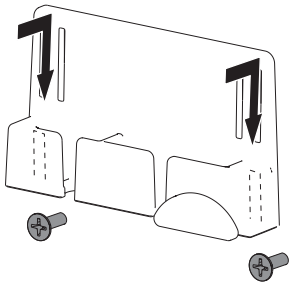
Fasten the sensor holder with screws

Use screws and plugs which are suited to the base surface.

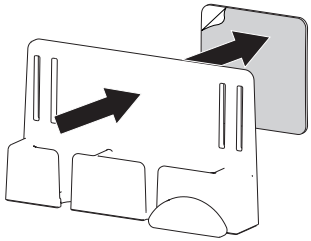
› Screw the screws into the wall with the same gap as that between the slits. Screw the screws in only until the screw head can be hooked into the slits.



› Place the sensor holder on the screw heads from above.

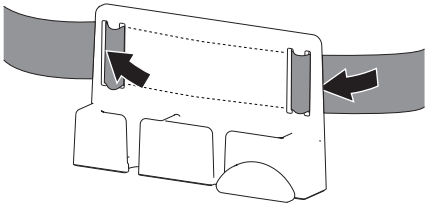


Fasten the sensor holder with the adhesive pad

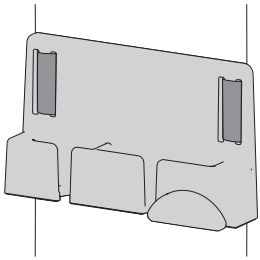


Fasten the sensor holder using the Velcro strip

› Thread the Veclro strip into the sensor holder.



› Fasten the sensor holder with the Velcro strip.



7.2 Electrical connections

Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

› Only connect units when there can be no question of danger to operator or to patient.

› Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.

› If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe.

› When connecting the unit to other devices, such as a PC system, comply with the requirements set out in section 16 of IEC 60601-1 (EN 60601-1).

› When setting up the PC system in the vicinity of the patients:
Only connect components (e.g. computer, monitor, printer) that comply with the standard IEC 60601-1 (EN 60601-1).

› When setting up the PC system outside of the vicinity of the patients:
Connect components (e.g. computer, monitor, printer) that comply at least with the standard IEC 60950-1 (EN 60950-1) at least.

Connecting the unit to the computer

NOTICE

Damage to the sensor

The interior parts of the sensor can be damaged by mechanical forces.

› Do not drop the sensor.

› Do not subject the sensor to any pressure.

› Do not fold, clamp or crush the cable.

› Do not carry the sensor by the cable.

› Connect the sensor USB connector to a free socket on the computer.

› If necessary, extend the cable using the 1 m USB extension included in the scope of delivery.
Further extensions are not permitted.

The USB extension can also be used if the device needs to be plugged and unplugged regularly and the USB port on the computer is not easily accessible. This protects the USB connection on the computer.

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8 Commissioning

NOTICE

Short circuit due to the build up of condensation

Strong temperature fluctuations can damage the unit.

- Only commission the unit once it has warmed up to room temperature.
- Do not subject the unit to strong temperature differences (heating max. 3 °C/min). Exception: Standard heating from room temperature approximately 20° C to body temperature approximately 37 °C during application.

- Before starting every time, check the entire system for damage.
- Calibrate the sensor using the calibration CD and commission the unit, see installation and configuration manual (order number 9000-618-198/01).
- Perform and document safety checks in accordance with the national regulations (VDE 0751-1, IEC 60601-1).
- Carry out and document an acceptance test in accordance with national regulations.
  In the Federal Republic of Germany, it is necessary to perform an acceptance test and monthly consistency checks in accordance with X-ray regulations (RöV). Acceptance and consistency checks require the test body (order number 2121-060-54).

Usage

9 Operation

CAUTION

A damaged sensor can result in the issue of materials which damage health

› Check the sensor and cable for damage before every use.
› Do not use a damaged sensor.
› Use a right-angle holder.

NOTICE

Damage to the sensor

The interior parts of the sensor can be damaged by mechanical forces.

› Do not drop the sensor.
› Do not subject the sensor to any pressure.
› Do not fold, clamp or crush the cable.
› Do not carry the sensor by the cable.

We recommend using the sensor with a right-angle holder. This avoids positioning errors and protects the sensor against mechanical damage (e.g. through an alarmed patient biting the sensor).
If VistaRay is operated with DBSWIN or via VistaEasy, you can generate X-ray images in two acquisition modes:
– Standard (26.3 LP/mm)
– Low resolution (13.15 LP/mm)
The transmission time takes only a few seconds depending on the size of the sensor and the settings.

9.1 Taking an X-ray image

Check before every use:
✓ The sensor and cable are not damaged.
✓ The sensor and cable have been cleaned and disinfected.


Wear protective gloves.

› Start the computer.
› Start the imaging software.
› Select the desired acquisition mode.
› Make VistaRay ready for image acquisition in the imaging software.

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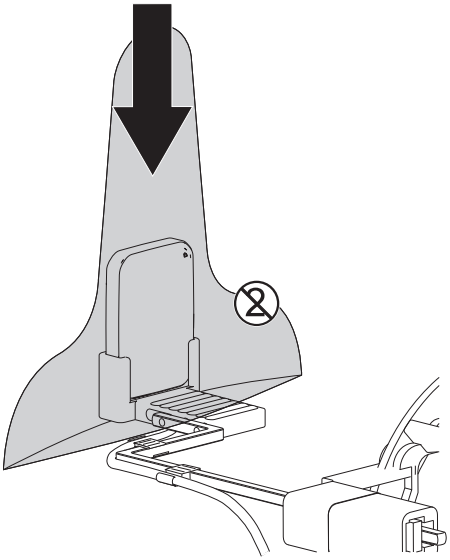
WARNING

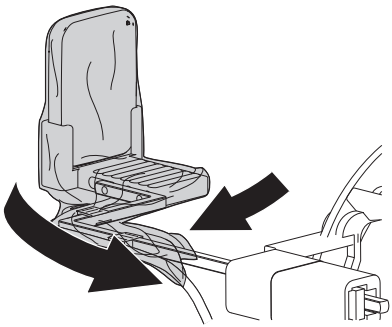
Danger of cross contamination when not using the hygienic protective cover or when using the hygienic protective cover more than once

The materials used for the hygienic protective cover are not suitable for reprocessing. This can result in malfunctions, leaks and material failure.

› Do not use the unit without the hygienic protective cover.
› Do not use the hygienic protective cover more than once (disposable item).

› Push the hygienic protective cover over the right-angle holder or over the sensor.





› Set the exposure values on the X-ray unit (see "13 Recommended exposure times").
› Place the sensor with the right-angle holder in the patient mouth.
› Trigger the X-ray capture.
The image is automatically transferred to the imaging software. No further X-ray image is possible during data transmission.

10 Cleaning and disinfection

NOTICE

The use of unsuitable agents and methods can damage the unit

- › Only use the disinfectants and cleaning agents specified or approved by Dürr Dental.
- › Comply with the specifications contained in the the operating instructions of the disinfectants and cleaning agents.
- › Do not steam sterilise the unit.
- › Do not clean or disinfect unit in ultrasonic bath.

Wear protective gloves.

Wear protective goggles.

Use a mask.

Use protective clothing.

10.1 Cleaning and disinfecting the unit

The unit can be disinfected using wipe disinfection and spray disinfection.
The sensor (without cable and sensor) can also be disinfected by immersion disinfection.

Wipe disinfection

Use the following disinfectant for the wipe disinfection:

- ✓ FD 322 premium wipes for quick-acting disinfection
- ✓ FD 333 wipes for quick-acting disinfection
- ✓ FD 333 forte quick-acting disinfection wipes
- ✓ FD 366 sensitive top wipes for surface disinfection
- ✓ FD 350 disinfection wipes

- › Remove any coarse soiling with a soft, lint-free cloth that has been dampened with cold tap water.
- › Then dry completely.
- › Wipe the sensor, cable and USB connector with a disinfectant. Comply with the operating instructions for the disinfectant when doing this.

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Immersion disinfection

Use the following disinfectants for immersion disinfection:

✓ ID 212 instrument disinfection

✓ ID 212 forte instrument disinfection

NOTICE

Equipment damage from moisture in the plug

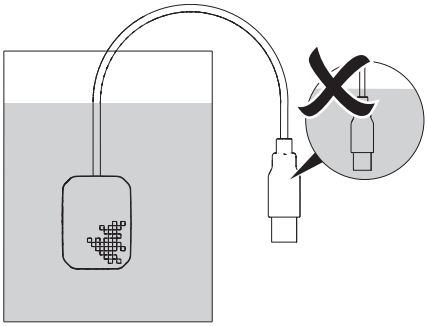
› Do not spray the USB connector.

› Do not immerse the USB connector in disinfectant.

› Remove any coarse soiling with a soft, lint-free cloth that has been dampened with tap water.

› Then dry completely.

› Immerse the sensor in the 2% disinfectant solution. Comply with the operating instructions for the disinfectant (immersion time).



10.2 Clean and disinfect the accessories

The sensor holder surface, the cable and the USB connector can be disinfected with disinfectant wipes.

The following disinfectants are suitable for cleaning the surface:

✓ FD 322 premium wipes for quick-acting disinfection

✓ FD 333 wipes for quick-acting disinfection

✓ FD 333 forte quick-acting disinfection wipes

✓ FD 366 sensitive top wipes for surface disinfection

✓ FD 350 disinfection wipes

› Wipe the surface with a soft, lint-free cloth soaked in disinfectant or a disinfection wipe. Comply with the operating instructions for the disinfectant when doing this.

11 Maintenance

The appliance is maintenance-free.

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Troubleshooting

12 Tips for operators and service technicians

Any repairs exceeding routine maintenance may only be carried out by qualified personnel or our service.

12.1 Poor X-ray image

Error	Possible cause	Remedy
No image transmission, despite X-ray image having been triggered	X-ray dose too low	› Correct the exposure values (see "13 Recommended exposure times").
Artefacts in image	Sensor damaged	› Replace the sensor.
X-ray image too dark/bright	Incorrect exposure time set	› Correct the exposure time (see "13 Recommended exposure times").

12.2 Software error

Error	Possible cause	Remedy
The operating system does not recognise the unit	A different USB unit is blocking the USB port	› Remove the blocking USB unit.
Error code E-0012	The unit driver has not been installed correctly	› Install the unit driver afresh (see installation and configuration manual).
Error code E-0077	Software installation corrupt	› Inform your Service Technician.
Error code E-1001	The unit is not connected	› Connect the unit to the USB port.
	Incorrect sensor size selected in software	› Select the correct sensor size.
	Unit is defective	› Inform your Service Technician.
Error code E-1002	Multiple sensors are connected to the computer at the same time	› Disconnect the sensors not required. Only a single sensor may be connected to the computer at any one time.
Error code E-1008	Sensor connected with overlong or incorrect USB extension	› Only use the USB extension (1 m) included in the scope of delivery.
	The computer USB port is unsuitable for the data rate	› Connect the sensor to a different USB port.
Error code E-0012	The unit driver has not been installed correctly	› Install the unit driver afresh (see installation and configuration manual).

Error	Possible cause	Remedy
Error code E-1020	The current state of the sensor does not permit image acquisition	› Disconnect and reconnect the USB connection cable.
	Sensor defective	› Inform your Service Technician.
Error code E-1026	Incorrect acquisition mode	› Select a different acquisition mode › Inform your Service Technician.
Error code E-2006	No acquisition mode selected	› Select the desired acquisition mode.
Error code E-10014	Sensor calibration data not installed	› Install the sensor calibration data (see installation and configuration manual).
Error code E-10016	Sensor calibration data incorrect	› Inform your Service Technician.

EN

Appendix

13 Recommended exposure times

CAUTION

Over-long exposure times can render the X-ray image unusable

› Do not exceed the maximum exposure time of of 0.5 s.

The following table lists the exposure times for an adult patient.
The exposure time must be increased by 25% for adult patients with a high bone density.
The exposure time for children must be reduced by 30%.

	DC emitter, 7 mA Tube length 20 cm		DC emitter, 7 mA Tube length 30 cm	
	60 kV	70 kV	60 kV	70 kV
Upper jaw				
Incisors	0.080 s	0.080 s	0.160 s	0.100 s
Premolars	0.120 s	0.100 s	0.160 s	0.100 s
Molars	0.160 s	0.120 s	0.200 s	0.125 s
Bite wing	0.160 s	0.120 s	0.200 s	0.125 s
Lower jaw				
Incisors	0.080 s	0.080 s	0.160 s	0.100 s
Premolars	0.120 s	0.100 s	0.160 s	0.100 s
Molars	0.160 s	0.120 s	0.200 s	0.125 s
Bite wing	0.160 s	0.120 s	0.200 s	0.125 s

Tab. 1: Exposure time for adult patients

14 Handover record

This document confirms that a qualified handover of the medical device has taken place and that appropriate instructions have been provided for it. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

- ☐ Visual inspection of the packaging for any damage
- ☐ Unpacking the medical device and checking for damage
- ☐ Confirmation of the completeness of the delivery
- ☐ Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction:	Signature:

Name and address of the qualified adviser for the medical device:

Date of handover:	Signature of the qualified adviser for the medical device:

Hersteller/Manufacturer:

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL