

VistaScan Mini Easy

EN



Installation and Operating Instructions



9000-618-210/02



1208V001

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Important information

1 Documentation

These Installation and Operating Instructions form an integral part of the unit. They conform to the relevant version of the equipment and the status of technology valid at the time of first operation.



Dürr Dental cannot guarantee smooth operation and safe function of the unit and will not accept any liability where the instructions and notes contained in these installation and operating instructions are not strictly observed.

This translation has been carried out in all good faith. The original German version is decisive. Dürr Dental accepts no liability for incorrect translation.

1.1 Warnings and symbols

Warnings

The warnings in this document are there to point out possible injury to persons or damage to machinery.

The following warning symbols are used:



General warning symbol



Danger; electrical current



Warning of laser beam

The warnings are structured as follows:



SIGNAL WORD

Description of type and source of danger

Possible consequences of ignoring the safety warning here

- Measures to be taken to avoid any possible danger.

The signal word differentiates between different levels of danger:

- DANGER** High risk of danger of serious injury or death
- WARNING** Possible risk of danger of serious injury or death
- CAUTION** Risk of danger of minor injuries
- NOTICE** Risk of serious damage

Further symbols

These symbols are used within the documentation and on the unit itself:



Notes, e.g. special instructions concerning economical use of the unit.



Observe the accompanying documentation.



CE-labeling



Date of manufacture



Dispose of product correctly and in accordance with EU directive (2002/96/EG-WEEE).



Only use once.



Wear protective gloves.



Unplug at the mains and remove all power.

1.2 Notes on copyright

All circuits, processes, names, software and appliances quoted are protected under industrial property rights.

Any reprinting of the technical documentation, in whole or in part, is subject to prior approval of Dürr Dental being given in writing.

2 Safety

Dürr Dental has designed and constructed this appliance so that when used correctly there is no danger to people or property. Nevertheless, there are residual risks. Please follow the instructions below carefully.

2.1 Correct use

The appliance is intended exclusively for the scanning and processing of image data on an image plate under dentistry conditions.

2.2 Incorrect use

Any use of this appliance/these appliances above and beyond that laid down in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.



WARNING

Risk of explosion due to inflammation of combustible materials

- Do not use the appliance in rooms in which combustible mixtures may be present, e.g. in operating theatres.

This appliance is not suitable for monitoring patients over longer periods of time.

2.3 General safety notes

- Before using the appliance observe any and all guidelines, laws, regulations and other restrictions which may apply to the appliance.
- Before each use check the function and condition of the appliance.
- Do not convert or change the appliance in any way.
- Observe the Installation and Operating Instructions precisely.
- Keep the Installation and Operating Instructions in an accessible place so that the operator has instant access to them.

2.4 Qualified personnel

Instructions for use

Persons who operate the appliance must, on the basis of their training and knowledge, ensure safe and correct handling of the appliance.

- Ensure personnel are trained in the correct usage of the appliance.

Installation and repair

- Installation, resetting, alterations, extensions and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.5 Protection against electrical current

- When working on and with the appliance always observe the local electrical safety procedures.
- Never come into contact with patients and open plug-in connections on the appliance at the same time.
- Damaged supply lines and connections must be replaced immediately.

Observe guidelines for electro-magnetic compatibility for medical devices

- Heed special precautionary measures with regard to electromagnetic comparability (EMC) for medical products, see "16 Information on EMC according to EN 60601-1-2".

2.6 Only use original parts

- Only Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental may be used.
- Only use original working parts and spare parts.



Dürr Dental cannot accept any liability for damage caused by the use of accessories and special accessories not specifically approved by Dürr Dental or not using original working parts and spare parts.

2.7 Transport

The original packaging offers the optimum protection for the appliance during transport. If required, the original packaging for the unit can be ordered at Dürr Dental.



Dürr Dental cannot accept any liability for damage caused during transport by the use of unsuitable packaging, this is also valid during the warranty term.

- Only transport the appliance in its original packaging whenever possible.
- Keep the packing materials out of the reach of children.
- Do not expose the appliance to any strong shocks.

2.8 Disposal

Appliance



Dispose of the appliance correctly. Within the European Union dispose of the appliance according to EU directive 2002/96/EG (WEEE).

- If you have any questions concerning correct disposal, please contact Dürr Dental or your usual dental supplier.

Image plate

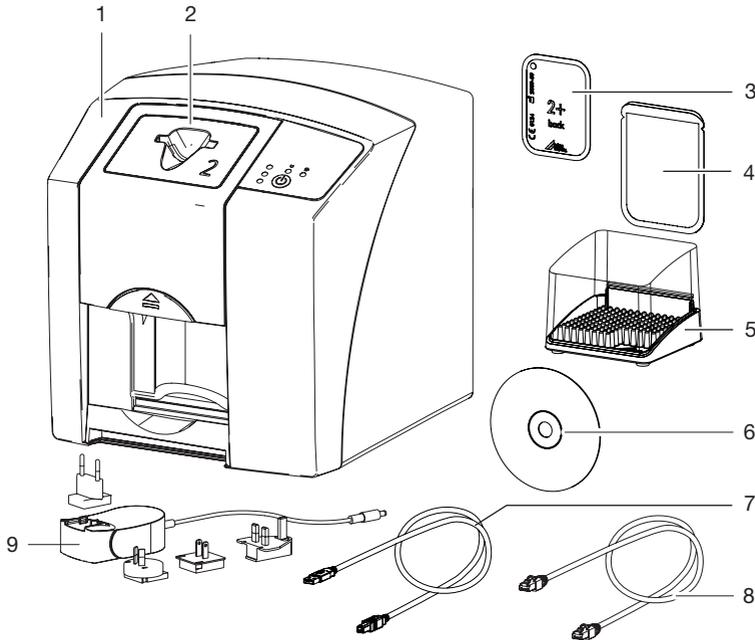
The image plate contains barium compounds.

- Dispose of the image plate properly in accordance with the locally applicable regulations.
- In Europe, dispose of the image plate in accordance with waste code 090108.



Product description

3 Overview



- 1 VistaScan Mini Easy image plate scanner
- 2 Cover input unit
- 3 Plus intraoral image plate
- 4 Light protection cover intraoral
- 5 Storage box
- 6 DBSWIN imaging software DVD
- 7 USB cable
- 8 Network cable
- 9 Power unit with country adapter

3.1 Delivery Contents

The following parts are included in the scope of delivery:

VistaScan Mini Easy

image plate scanner 2143-61

- VistaScan Mini Easy base station
- Power unit
- USB cable
- Network cable
- DBSWIN imaging software DVD
- Cover input unit for image plate Size 0
- Cover input unit for image plate Size 2
- Plus image plate:
 - Size 0 (2 pcs.)
 - Size 2 (4 pcs.)
- Light protection covers:
 - Size 0 (100 pcs.)
 - Size 2 (300 pcs.)
- Storage box
- Protective cover
- Image plate cleaning cloth (10 pcs.)
- Installation and Operating Instructions
- Quick start instructions

3.2 Accessories

The following items are required for operating the appliance, depending on the application:

Image plates

- Plus image plate Size 0
- 2 x 3 cm (2 pcs.) 2130-040-50
- Plus ID image plate Size 0
- 2 x 3 cm (2 pcs.) 2130-040-60
- Plus image plate Size 2
- 3 x 4 cm (4 pcs.) 2130-042-50
- Plus image plate Size 2
- 3 x 4 cm (12 pcs.) 2130-042-55
- Plus ID image plate Size 2
- 3 x 4 cm (4 pcs.) 2130-042-60

Light protection cover

- Light protection cover Size 0
- 2 x 3 cm (100 pcs.) 2130-070-00
- Light protection cover white Size 0
- 2 x 3 cm (100 pcs.) 2130-070-50
- Light protection cover Size 2
- 3 x 4 cm (300 pcs.) 2130-072-00
- Light protection cover Size 2
- 3 x 4 cm (1000 pcs.) 2130-072-55
- Light protection cover white Size 2
- 3 x 4 cm (300 pcs.) 2130-072-50

3.3 Special accessories

The following items can be optionally used with the appliance:

- Wall mounting bracket. 2141-001-00
- Image plate and film handling system set 2130-981-50
- Image plate and film handling upgrade set for endo-exposures . . 2130-981-51
- Copper dot set, self-adhesive . . . 2130-006-00
- Mobile Connect (for using apps for mobile appliances, e. g. Dürr Dental Imaging iPad App). 2100-725-12FC

Commissioning and intraoral constancy checks

- Test specimen Intra / Extra Digital . 2121-060-54

3.4 Disposable materials

The following materials are used during operation of the appliance and must be re-ordered:

Cleaning and disinfecting

- Image plate cleaning cloth (10 pcs.) CCB351B1001
- FD 350 Classic disinfectant wipes CDF35CA0140
- FD 333 surface disinfectant CDF333C6150
- FD 322 surface disinfectant CDF322C6150

Light protection cover

see "3.2 Accessories"

3.5 Working parts and spare parts

Image plates

see "3.2 Accessories"



Information concerning spare parts can be found in the spare parts catalogue under: www.duerr.de/etk.

4 Technical data

4.1 Image plate scanner

Electrical data of the unit

Voltage	V DC	24
Max. supply voltage fluctuation	%	± 10
Max. current consumption	A	1.25
Output	W	< 30
Fuse type		IP20

Electrical data power supply unit

Voltage	V AC	100 - 240
Max. supply voltage fluctuation	%	± 10
Frequency	Hz	50 - 60
Protection class		II
Fuse type		IP20
Overvoltage category		II
Output	W	< 40
Max. current consumption	A	0.8

Classification

Medical devices directive (93/42/EU)	Class I
Laser class (appliance) according to EN 60825-1:1994-03 + A1:2002-07 + A2:2001-03	1

Electromagnetic compatibility (EMC)*

HF transmissions according to CISPR 11		Group 1 Class B
Harmonic limits according to IEC 61000-3-2		Not applicable
Voltage fluctuations/flicker according to IEC 61000-3-3		Not applicable
Directed HF interference V_1 acc. to IEC 61000-4- 6	V_{eff}	3
Transmitted HF interference E_1 according to IEC 61000-4-3	V/m	4

*see also "16 Information on EMC according to EN 60601-1-2"

Laser source

Laser class according to EN 60825-1:1994-03 + A1:2002-07 + A2:2001-03		3B
Wavelength λ	nm	635
Output	mW	10

Sound pressure level

Standby	dB(A)	0
Ready to scan	dB(A)	approx. 37
During readout	dB(A)	approx. 55

General technical data

Dimensions (W x H x D)	mm	226 x 234 x 243
Weight	kg	approx. 6.5
Heat output	W	< 40
Duty cycle S2 (acc. to VDE 0530-1)	min	25
Duty cycle S6 (according to VDE 0530-1)	%	25
Pixel size (selectable)	µm	12.5 - 50
Max. resolution (depending on image plate)	Line pairs/mm (Lp/mm)	approx. 40

Ambient conditions for operation

Temperature	°C	+10 up to +35
Relative humidity	%	20 - 80
Air pressure	hPa	750 - 1060
Height above sea level	m	< 2000

Ambient conditions for storage and transport

Temperature	°C	-20 up to + 60
Relative humidity	%	10 - 95
Air pressure	hPa	750 - 1060
Height above sea level	m	< 16000

4.2 Image plate**Classification**

Medical devices directive (93/42/EU)	Class IIa
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Ambient conditions for operation

Temperature	°C	18 - 45
Relative humidity	%	<80

Ambient conditions for storage and transport

Temperature	°C	<33
Relative humidity	%	<80

Dimensions of intraoral image plates

Size 0	mm	22 x 35
Size 2	mm	31 x 41

4.3 Light protection cover**Classification**

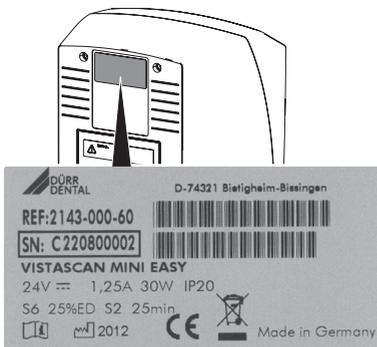
Medical devices directive (93/42/EU)	Class I
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4.4 Hygienic protective cover**Classification**

Medical devices directive (93/42/EU)	Class I
--------------------------------------	---------

4.5 Model identification plate

The model identification plate is located on the rear side of the appliance.



REF Order number

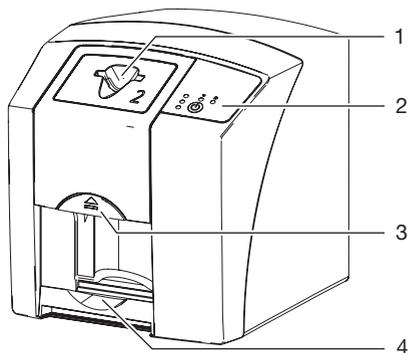
SN Serial number

4.6 Note on Conformity

This appliance has been tested according to the relevant directive of the European Union and the required conformity acceptance procedure. This appliance meets all the necessary requirements.

5 Function

5.1 Image plate scanner



- 1 Intake slot
- 2 Operating panels
- 3 Unlocking button
- 4 Collection tray

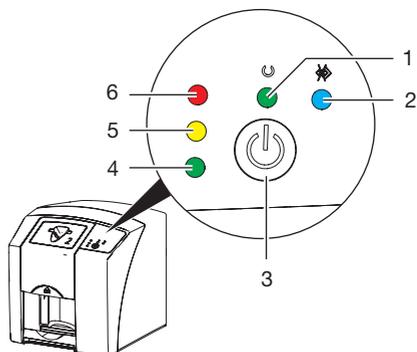
With the image plate scanner, image data stored on an image plate are read and transferred to imaging software (e. g. DBSWIN) on a computer.

The transport mechanism guides the image plate through the scanner. In the scanner unit a laser scans the image plate. The scanned data is converted into a digital image and transferred to the imaging software.

After scanning, the image plate runs through the erasure unit. Image data still held on the image plate will be erased by intense light.

The image plate is then output to be used again.

Operating panels



- 1 Operating display, green
- 2 Communication display, blue
- 3 Press the on/off switch
- 4 Status display, green
- 5 Status display, yellow
- 6 Status display, red

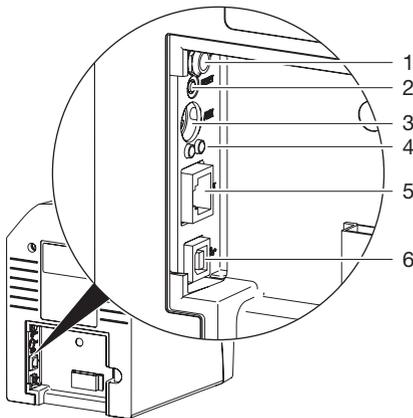
The LED indicator lights show the following status messages:

	Ready for operation
	Communication not ready
	Appliance in switch-off process
	

	Problem
	Cover missing
	Image plate being processed
	Image plate being processed
	Light protection cover can be removed and the next image plate inserted
	Input unit ready for operation Image plate can be inserted
	Start process from standby
	Display flashes
<input type="radio"/>	Display off

Connections

The connections are on the rear side of the appliance under the cover.



- 1 Connection for power unit
- 2 Reset button
- 3 AUX connection for diagnostic appliances
- 4 Status displays network connection
- 5 Network connection
- 6 USB connection

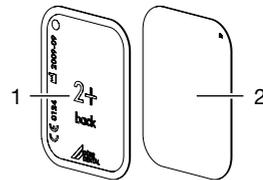
5.2 Image plate

The image plate stores X-ray energy which is re-emitted in the form of light due to excitation with a laser. This light is converted into image information in the image plate scanner.

The image plate has an active and an inactive side. Exposure of the image plates must take place on the active side.

When used properly, the image plate can be exposed, read and erased several hundred times provided there is no mechanical damage. The image plate must be replaced if there are any signs of damage (e.g. protective layer is damaged or visible scratches) which could interfere with diagnosis.

Intraoral

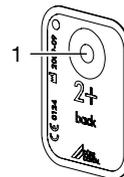


- 1 Inactive side: black, printed with "back", size and manufacturer information
- 2 Active side: light blue, with positioning aid 

The positioning aid  is visible on the X-ray image and makes orientation easier during diagnosis.

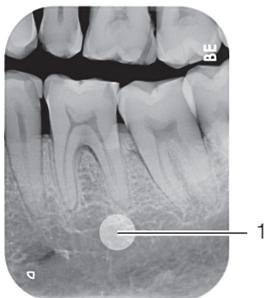
Exposure on the wrong side

A marker is placed on the inactive side of the Plus ID image plate.



- 1 Marker

If the image plate has been exposed on the wrong side, the marker is visible as a shadow on the X-ray image.



1 Marker visible as a shadow

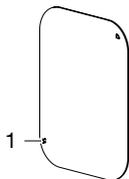
The exposure can be corrected by mirroring in the software. If it is not possible to diagnose in the area of the marker, the exposure must be repeated.

 Image plates can be retrofitted with a marker using the copper dot set (see "3.3 Special accessories").

Unique assignment of image plate and image (Plus ID image plate only)

In addition to the marker, a hexadecimal code which is visible on the X-ray image is applied on the Plus ID image plate.

This code ensures a unique correlation between image plate and X-ray image.



1 Hexadecimal code

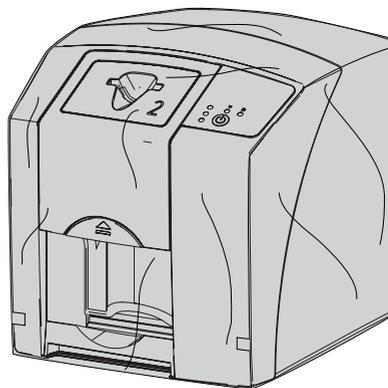
5.3 Light protection cover

The light protection cover provides several protection functions for the intraoral image plate:

- Protection against sunlight and UV light and hence against unwanted erasure
- Protection from physical damage
- Protection from contamination and soiling

The light protection cover is a disposable item.

5.4 Protective cover



The protective cover protects the appliance against dust and dirt, e. g. if not used for some time.

5.5 Storage box

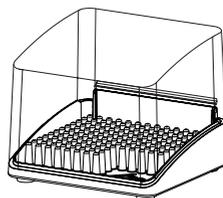


Image plates packed in light protection covers can be placed in the storage box until the next use. The storage box protects the image plate and light protection cover from contamination and soiling.



Mounting



Only fully-qualified or from Dürr Dental trained personnel may set-up, install or operate this appliance.

6 Prerequisites

6.1 Area of installation

The installation room must fulfil the following requirements:

- Closed, dry, well-ventilated room
- No purpose-built room (e. g. boiler room or wet room)
- Max. illuminance 1000 Lux, no direct sunlight where the appliance is installed
- No large interference fields (e. g. strong magnetic fields) present which can interfere with the functioning of the appliance.
- Corresponding ambient conditions "4 Technical data".

6.2 System requirements



System requirements for computer systems for imaging see leaflet (order number 9000-618-148).

6.3 Monitor

The monitor must comply with the requirements for digital X-ray with higher light intensity and high contrast range.

Strong ambient light, sunlight falling directly onto the monitor and reflections can reduce the diagnosability of the X-ray images.

7 Installation

7.1 Carrying the appliance



NOTICE

Damage of sensitive appliance components from shocks

- Do not expose the appliance to any strong shocks.
- Do not move the appliance during operation.

7.2 Setting up the appliance

Portable and mobile HF communication appliances can interfere with the effectiveness of electrical medical appliances.

- Do not stack the appliance next to or with other appliances.
- If the appliance is to be used stacked next to or used with other appliances, monitor the appliance in this configuration to ensure normal operation.

The appliance can be installed as a tabletop appliance or mounted on the wall with the wall mounting bracket.

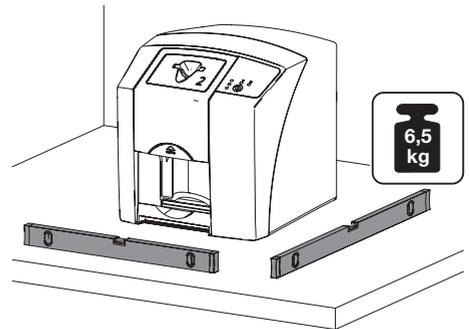
The load-bearing capacity of the table or the wall must be suitable for the weight of the appliance (see "4 Technical data").

Place the appliance on a table



To prevent errors when scanning the image data, install the appliance so it is not exposed to vibrations.

- Place the appliance on a firm, horizontal surface.



Attaching the appliance with the wall mounting bracket

The appliance can be mounted on a wall with the wall mounting bracket (see "3.3 Special accessories").



For installation, see installation instructions for the wall mounting bracket (order number 9000-618-162)

7.3 Electrical connection

Safety for the electrical connection

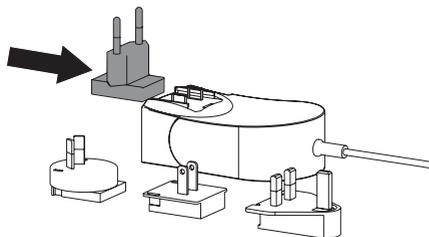
- The appliance may only be connected to a correctly installed electrical socket outlet.
- Do not lay multi-socket units on the floor. Specifications of EN 60601-1-1 apply.
- Other systems should not be plugged into the same multi-socket unit.
- All cables, etc. must be laid so that no mechanical tension is exerted on them.
- Before start-up or first use, check the mains voltage against the voltage indicated on the model identification plate (see also "4. Technical Data").

Connecting the appliance to the power supply

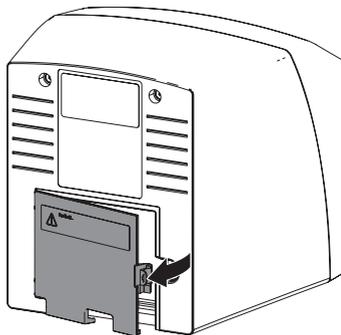
 The appliance has no main power switch. The appliance must, therefore, be installed so that the socket outlet is easily accessible and can be unplugged if necessary.

Requirements:

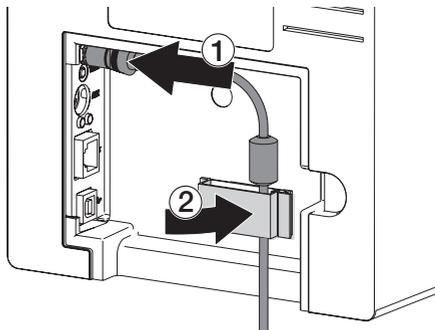
- ✓ Properly installed socket outlet close to the appliance (max. mains cable length 1.8 m)
- ✓ Easily accessible socket outlet
- ✓ Supply voltage matches the details on the model identification plate of the power unit
- Insert the matching country adapter in the power unit.



- Remove the cover from the rear side of the appliance.



- Insert the connecting plug of the power unit in the socket of the appliance.
- Secure the cable with a cable clip.



- Plug the power plug into the mains supply socket outlet.
- Replace the cover.

 When operating the appliance in the vicinity of the patients, the rear cover must be in place.

7.4 Connecting up the device

The appliance can be connected to the USB or network. The cables are contained in the scope of delivery.



Do not connect the appliance to the USB and to the network at the same time.

The network connection has priority if the appliance is connected both to the USB and the network.

Safe connection of appliance

Connecting appliances together or to parts of other units can cause danger to arise (e.g. leakage current).

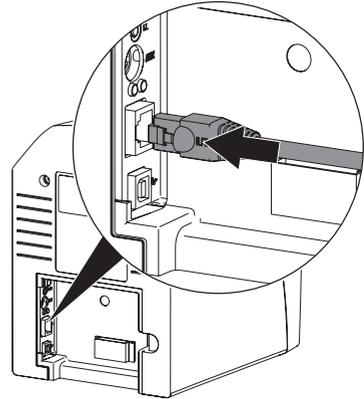
- Only connect units together where it is certain that there will be no danger to operator or to patient.
- Only connect units together where it is certain that there will be no danger to the environment.
- Where the possible risk of danger cannot be ruled out and is not clear from the appliance data then technical advice from an expert (e.g. manufacturer) should be called to ensure safe connection of units.
- When connecting the appliance to other appliances, e.g. a computer system, the respective provisions of IEC 60601-1-1 (EN 60601-1-1) must be heeded both inside and outside the vicinity of the patients.
- Only connect additional appliances (e.g. computer, monitor, printer) which at least comply with the IEC 60950-1 (EN 60950-1) standard.



A template for the system manufacturer's declaration as per Article 12 of Directive 93/42/EU (order number 9000-461-264) can be found in the download area at www.duerr.de.

Connecting up the appliance with network cable

- Remove the cover from the rear side of the appliance.
- Insert the network cable supplied into the network socket of the appliance.



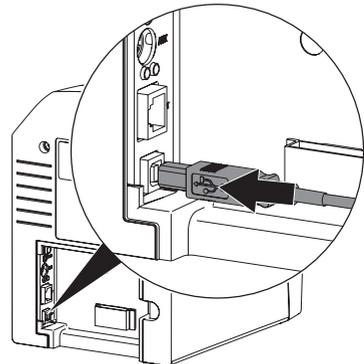
- Replace the cover.



When operating the appliance in the vicinity of the patients, the rear cover must be in place.

Connecting the appliance to a USB port

- Remove the cover from the rear side of the appliance.
- Connect the USB cable to the appliance.



- Replace the cover.



When operating the appliance in the vicinity of the patients, the rear cover must be in place.



Only connect the USB cable to the computer when the installation assistant asks you to do so.

8 Operation



NOTICE

Short circuit due to build up of condensation

- The appliance can only be put into operation once it has warmed up to room temperature and it is dry.

8.1 Installing and configuring the appliance

The appliance can be operated with the following imaging programs:

- DBSWIN from Dürr Dental
- VistaEasy from Dürr Dental
- Third-party software on request

Driver installation (only for USB connection)

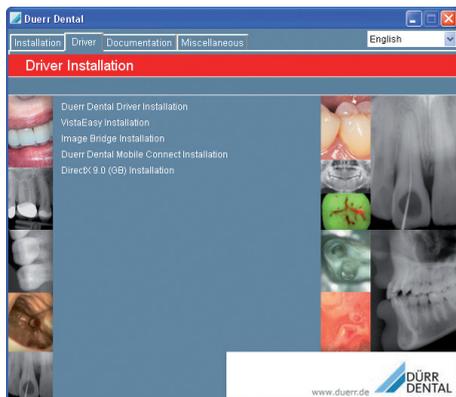


Only connect the USB cable to the computer when the installation assistant asks you to do so.

- Close all programs.
- Place the provided DBSWIN DVD (from Version 5.3.1) in the DVD drive.

The start window opens.

- If the DVD does not start automatically, double-click the file *CD_Start.exe*.
- Select the required language.
- Go to the *Driver* tab.



- Click *Duerr Dental Driver Installation*.



- Confirm the message with *OK*. The *Dürr Dental Driver Setup* installation assistant starts.
- Follow the instructions of the installation assistant.

Setting up the network

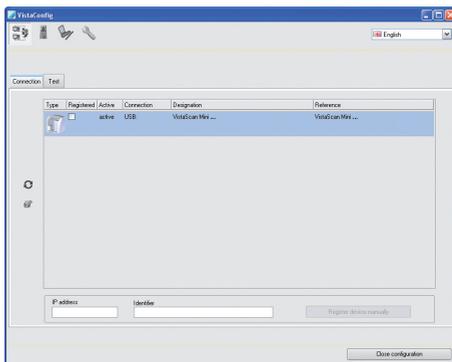
- Switch on the network appliances (router, PC, and switch).
- Check that TCP port 2006 and UDP port 514 are released in the firewall that is used; if not, release them.

If you are using the Windows firewall, it is not necessary to check the ports since you are asked if you want to release them during the driver installation process.

Configuring the appliance

Configuration is carried out with VistaNetConfig which is automatically installed during the installation of DBSWIN or VistaEasy.

- Click *Start > All Programs > Dürr Dental > VistaConfig > VistaNetConfig*.

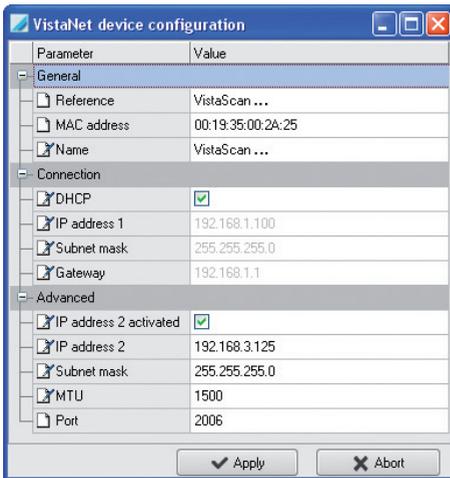


- Click on . The list of connected appliances is updated.
- Activate the connected appliance in the *Registered* column. You can also register multiple appliances.

Configuring the appliance with a USB connection

You can change the device name (*Name*) and query the configuration in the *VistaNet device configuration* window.

- Click on *Edit*

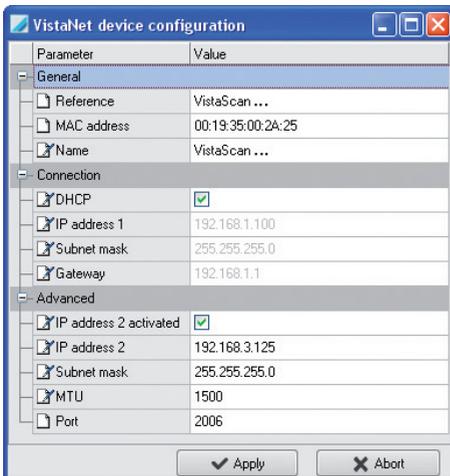


- If necessary, change the *Name*.
- Click *Apply* to save the configuration.

Configuring the appliance with a network connection

You can change the device (*name*), manually enter an IP address and query information in the *VistaNet device configuration* window.

- Click on .



Entering a permanent IP address (recommended)

- Deactivate *DHCP*.
- Enter an IP address, subnet mask and gateway.
- Click *Apply*.

The configuration is saved.

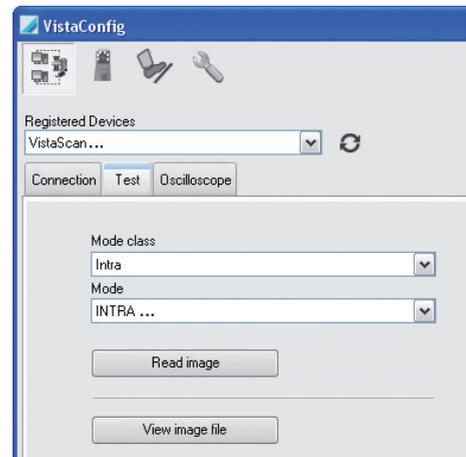


To restore the appliance to the factory settings, hold down the reset button on the appliance for 15 to 20 seconds while switching the appliance on.

Testing the device

You can read in an X-ray image to check that the appliance is properly connected.

- Select the *Test* tab.



- Select the appliance from the *Registered Devices* options list.
- Select the mode class.
- Select the mode.
- Click *Read image*.
- To read the image plate, see "10.3 Reading the image data".

8.2 X-ray appliance settings

Intraoral X-ray appliances

The following table shows the standard values for the exposure time of an adult patient.

	DC radiator, 7 mA Tube length 20 cm		DC radiator, 7 mA Tube length 30 cm	
	60 kV	70 kV	60 kV	70 kV
Upper jaw				
Incisor	0.1 s	0.08 s	0.2 s	0.16 s
Pre-molar	0.125 s	0.1 s	0.25 s	0.2 s
Molar	0.16 s	0.125 s	0.32 s	0.25 s
Bite wing	0.16 s	0.125 s	0.32 s	0.25 s
Lower jaw bone				
Incisor	0.1 s	0.08 s	0.2 s	0.16 s
Pre-molar	0.125 s	0.1 s	0.25 s	0.2 s
Molar	0.125 s	0.1 s	0.25 s	0.2 s
Bite wing	0.16 s	0.125 s	0.32 s	0.25 s



If 60 kV can be set on the X-ray appliance, this setting is preferred.

The standard exposure values for F-speed film (e. g. Kodak Insight) can be used.

- Check and adjust X-ray appliances in accordance with the following standard equipment-specific values.

8.3 Tests for start-up

The necessary tests (e. g. acceptance test) are regulated by the locally applicable national law.

- Find out which tests are to be made.
- Carry out tests in accordance with national law.

Acceptance test



The Intra / Extra Digital test body (order-no. 2121-060-54) and, where necessary, the matching test body holder are required for the acceptance test.

- Prior to start-up, carry out the acceptance test of the X-ray appliance in accordance with the relevant national law.

The constancy checks which are carried out at regular intervals by the dental surgery personnel are based on the test results of the acceptance test.

Electrical safety check

- Carry out an electrical safety check according to all national regulations (e.g. patient conductivity, conductivity of housing).
- Document the results.



Usage

9 Use image plates correctly

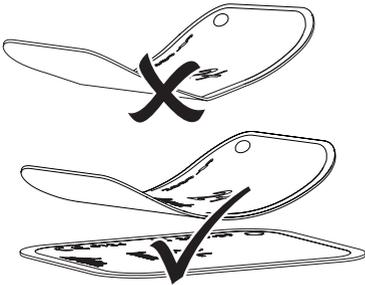


CAUTION

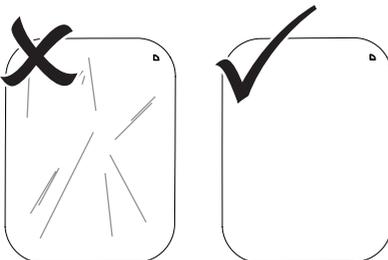
Image plates are toxic

Image plates which are not packed in a light protection cover can lead to poisoning when placed in the mouth or swallowed.

- Only place image plates in the patient's mouth in a light protection cover.
 - Do not swallow the image plate or parts of it.
 - If the image plate or parts of it have been swallowed, consult a specialist doctor immediately and remove the image plate.
 - If the light protection cover has been damaged in the patient's mouth, rinse the mouth thoroughly with water. Do not swallow the water.
- Image plates are flexible like an X-ray film. But do not fold the image plate.



- Do not scratch the image plates. Do not expose the image plates to pressure from hard or pointed objects.



- Do not soil the image plates.
- Protect the image plates against sunlight and ultraviolet light.
Store intraoral image plates in a matching light protection cover, extraoral image plates in matching foil cassettes.
- Image plates are pre-exposed by natural radiation and scattered X-ray radiation. Protect erased or exposed image plates against X-ray radiation.
If the image plate has been stored for longer than one week, erase the image plate prior to use.
- Do not store image plates in hot or moist conditions. Heed the ambient conditions (see "4 Technical data").
- When used properly, image plates can be exposed, read and erased several hundred times provided there is no mechanical damage.
Replace the image plate if there are any signs of damage (e.g. protective layer is damaged or visible scratches) which could interfere with diagnosis.
- Clean image plates properly (see "11 Cleaning and disinfecting").

10 Instructions for use



CAUTION

Image data on the image plate are not resistant

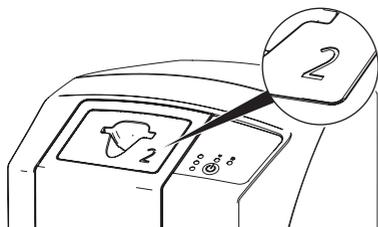
The image data is altered by light, natural X-ray radiation and scattered X-ray radiation. This could interfere with diagnosis.

- Read the image data within 30 minutes of exposure.
- Never handle exposed image plates without the light protection cover.
- Do not subject an exposed image plate to X-ray radiation before and after the reading process.
- Do not X-ray during the reading process if the appliance is in the same room as the X-ray tube.

10.1 Changing the input unit cover

The appliance can read size 2 and size 0 image plates. Each size of image plate requires a matching size cover.

The size of the image plate is clearly marked on the cover.

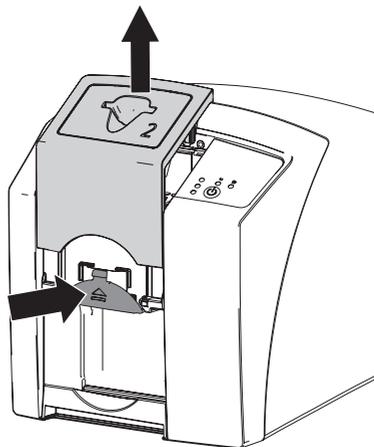


CAUTION

Loss of image information and damage to the appliance if the incorrect cover is used

- Always use the correct size of cover for the image plate that is used.
- Compare the image plate size with the marking on the cover before each reading.
- Check that the green status display lights.

- Press the unlocking button and remove the cover upwards at the same time.



The red status display flashes.

- Place the cover in position from above. Check that the green status display lights. The input unit is ready.

10.2 Taking an X-ray



The sequence is described using an example of a size 2 Plus image plate.

Required accessories:

- Image plate
- Light protection cover in the size of the image plate



WARNING

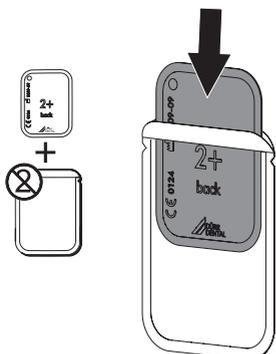
Danger of cross contamination when not using the light protection cover or when using the light protection cover more than once

- Do not use an image plate without a light protection cover.
- Do not use the light protection cover more than once (disposable item).

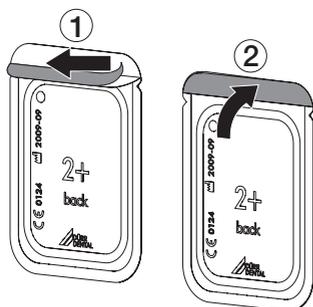
Preparing the X-ray

- ✓ Image plate is clean.
- ✓ Image plate is not damaged.
- ✓ Marker (if present) adheres to the correct position on the image plate. If the marker becomes detached, replace the image plate.
- If used for the first time or if stored for more than a week, erase image plate (see "10.4 Erasing the image plate").

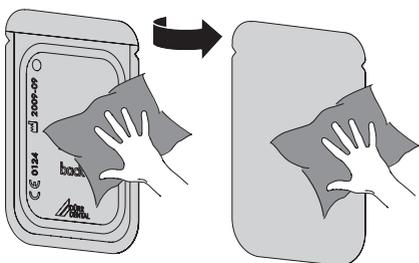
- Slide the image plate fully into the light protection cover. The black (inactive) side of the image plate must be visible.



- Pull off adhesive strips and firmly seal the light protection cover by pressing together.



- Immediately before placing in the patient's mouth, disinfect the light protection cover with a disinfection wipe (e. g. FD 350). Alternatively, a spray disinfectant (e. g. FD 322, FD 333) on a soft, lint-free cloth can be used.



Producing an X-ray exposure



NOTICE

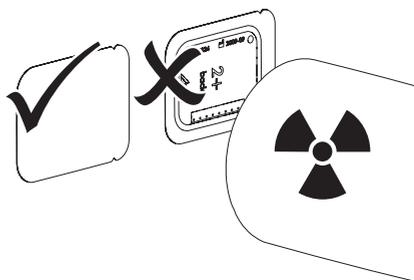
Damage to the image plate by the sharp-edged holding system

- Only use holding systems which will not damage the light protection cover or the image plates in any way.
- Do not use sharp-edged holding systems.



Wear protective gloves.

- Place the image plate in the patient's mouth in the light protection cover. Make sure that the active side of the image plate points towards the X-ray tube.



- Set exposure times and setting values on the X-ray appliance (see "8.2 X-ray appliance settings").
- Produce an X-ray exposure. The image data must be read within 30 minutes.

Preparing reading



CAUTION

Light erases the image data on the image plate

- Never handle exposed image plates without the light protection cover.



Wear protective gloves.

- Remove the image plate from the patient's mouth with the light protection cover.



WARNING

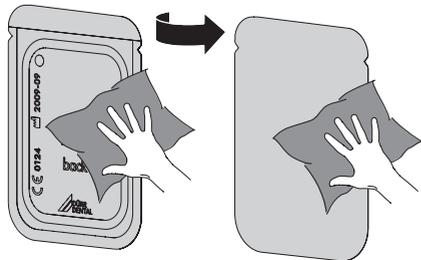
Contamination of the appliance

- Clean and disinfect the light protection cover before removing the image plate.

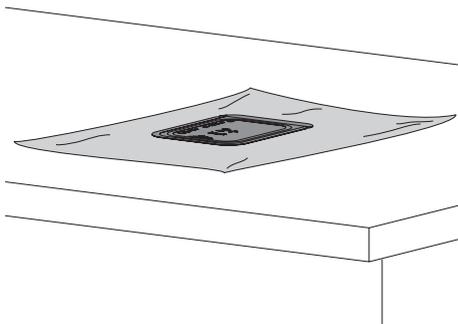


- In the event of heavy soiling, e. g. from blood, dry clean the light protection cover and protective gloves, e. g. wipe with a clean cellulose cloth.
- Disinfect the light protection cover and protective gloves with a disinfection wipe (e. g. FD 350).

Alternatively, a spray disinfectant (e. g. FD 322, FD 333) on a soft, lint-free cloth can be used.



- Place the light protection cover with the image plate on the disinfection wipe.



- Allow the light protection cover to fully dry.
- Pull off protective gloves, disinfect and clean hands.

**NOTICE**

Powder of the protective gloves on the image plate damages the appliance when reading

- Completely clean the hands of the protective glove powder before handling the image plate.

- Tear open the light protection cover along the adhesive edge.

**10.3 Reading the image data****Start the image plate scanner and software**

Reading is described with the DBSWIN imaging software.

For further information on using the imaging software, see respective manual.

Requirement:

- ✓ Cover corresponds to the size of the image plate (see "10.1 Changing the input unit cover")
- Press the on/off switch  to switch on the appliance.
- Switch on the computer and monitor.
- Start DBSWIN.
- Select the patient.
- Select the exposure values in the X-ray module.
- Select the desired resolution.
- Click the *Scan* button.

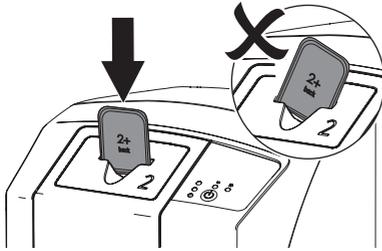
Check that the green status display lights.

Scanning the image plate

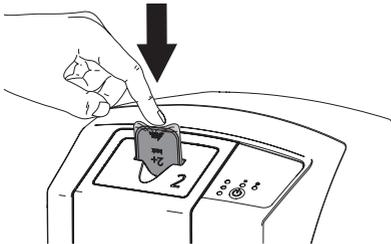


To avoid mixing up the X-ray images, only read the X-ray images of the selected patient.

- Place the light protection cover with its image plate central and aligned straight on the input unit. The open side of the light protection cover faces downwards, the inactive side of the image plate points towards the operator.



- Press the image plate downwards out of its light protection cover into the unit until the image plate is automatically drawn into the unit.



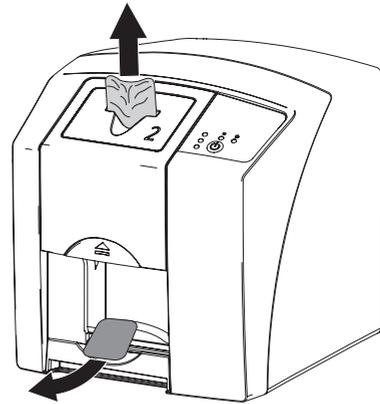
The light protection cover is held at the intake slot and is not drawn into the appliance. Yellow status display lights.

The image data are automatically transferred to the imaging software. The actual progress of the scanning process is displayed in a preview window on the monitor.

After reading, the image plate is erased and falls into the collecting plate.

- As long as the yellow status display lights:
Do not remove the light protection cover or insert a new image plate.
- When the green and yellow status display lights:
Remove the empty light protection cover.
- When the green status display lights:
Save the X-ray image.

- Remove the image plate and prepare for taking a new X-ray.



10.4 Erasing the image plate

The image data are automatically erased being read.

The special **ERASE** mode only activates the erasure unit of the image plate scanner. Image data are not read.

In the following cases, the image plate must be erased with the special mode:

- When the image plate is used for the first time or if stored for more than a week.
- Due to a fault, the image data on the image plate has not been erased (error message in the software).
- Choose the special "**ERASE**" mode in the software.
- Insert the image plate (see "Scanning the image plate").

10.5 Switching off the appliance

- Press the on/off switch  for 3 seconds.

The operating and communication displays flash while the appliance shuts down.

As soon as the appliance has shut down, it switches off completely. The displays are off.

Using the protective cover

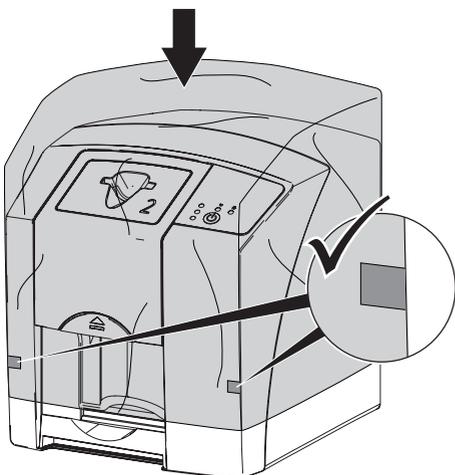
For longer holding time, the protective cover protects the unit from dirt and dust.



WARNING

Danger of suffocation!

- Store the protective cover out of the reach of children.
- Pull the protective cover over the unit until it is entirely covered. Take care that the yellow markings are to the front.



- When not in use, store the cover in a clean location.

11 Cleaning and disinfecting



NOTICE

Unsuitable agents and methods can damage the appliance and accessories

- Only use the disinfection and cleaning agents specified or approved by Dürr Dental.
- Heed the operating instructions of the disinfection and cleaning agent.



Wear protective gloves.

11.1 Image plate scanner

Unit surfaces

The unit surface must be cleaned and disinfected of contamination or soiling. Use the following cleaning and disinfectant agents:

- ✓ FD 322 Quick-acting disinfection
- ✓ FD 333 Quick-acting disinfection
- ✓ FD 350 Disinfection wipes



NOTICE

Liquid can cause damage to the appliance

- Do not spray the appliance with cleaning and disinfectant agents.
- Make sure that liquid does not get inside the appliance.
- Remove any soiling with a soft, wet, lint-free cloth.
- Disinfect the surface with a disinfection wipe. Alternatively, a spray disinfectant on a soft, lint-free cloth can be used. Heed the operating instructions of the disinfectant.

Input unit

The input unit must be cleaned and disinfected if there is any sign of contamination or visible dirt.

For wiping disinfection, use the following cleaning and disinfectant agents:

- ✓ FD 322 Quick-acting disinfection
- ✓ FD 333 Quick-acting disinfection
- ✓ FD 350 Disinfection wipes

For immersion disinfection, use the following cleaning and disinfectant agents:

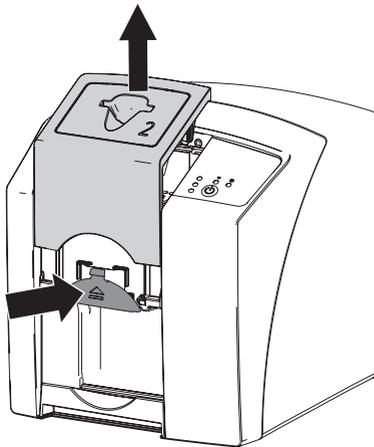
- ✓ ID 213 Instrument disinfectant



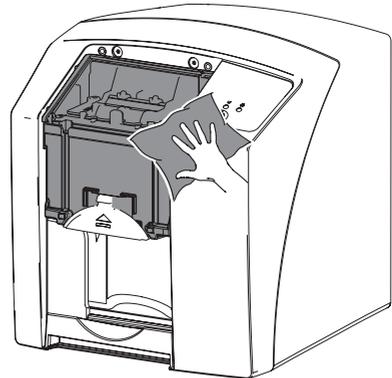
NOTICE

Heat damages plastic parts

- Do not treat parts of the appliance with a thermal disinfectant or steam steriliser.
- Press the on/off switch  for 3 seconds to switch off the appliance.
- Wait until the operating and communication displays are off and the appliance is completely switched off.
- Press the unlocking button and remove the cover upwards at the same time.



- Clean the cover and inside parts with a moist, soft, lint-free cloth.



- Disinfect the cover and inside parts with a disinfection wipe. Alternatively, a spray disinfectant on a soft, lint-free cloth can be used. Heed the operating instructions of the disinfectant. The cover can also be disinfected in an immersion disinfection system.
- Replace cover.

11.2 Light protection cover

The surface must be cleaned and disinfected of contamination or soiling. Use the following cleaning and disinfectant agents:

- ✓ FD 322 Quick-acting disinfection
- ✓ FD 333 Quick-acting disinfection
- ✓ FD 350 Disinfection wipes
- Disinfect the light protection cover with a disinfection wipe before and after placement. Alternatively, a spray disinfectant on a soft, lint-free cloth can be used. Heed the operating instructions of the disinfectant.
- Allow the light protection cover to dry fully before using.



11.3 Image plate

Use the following cleaning agents:

- ✓ Image plate cleaning cloth



NOTICE

Heat or humidity damages the image plate

- Do not steam sterilise the image plate.
- Do not immerse-disinfect the image plate.
- Only use approved cleaning agents.
- Soiling on both sides of the image plate should be cleaned off with a soft, lint-free cloth prior to each use.
- Remove resistant or dried on dirt with the image plate cleaning cloth. Heed the operating instructions of the cleaning cloth.
- Allow the image plate to dry fully before use.

11.4 Protective cover

Use the following cleaning agents:

- ✓ FD 350 Disinfection wipes
- Clean the protective cover with a soft, wet, lint-free cloth.
- Disinfect the protective cover with a disinfection wipe.

11.5 Storage box with image plate storage tray

If the surface of the storage box and the inside image plate storage tray shows signs of contamination or visible soiling, clean and disinfect.

Use the following cleaning agents for the storage box:

- ✓ FD 366 Sensitive disinfection for sensitive surfaces

Use the following cleaning agent for the image plate storage tray:

- ✓ FD 350 Disinfection wipes
- Clean the surface of the storage box and the image plate storage tray with a soft, moist, lint-free cloth.
- Disinfect the storage box with spray disinfectant on a soft, lint-free cloth. Heed the operating instructions of the disinfectant.
- Disinfect the image plate storage tray with a disinfection wipe.

Alternatively, the image plate storage tray can be treated in the thermal disinfectant or steam steriliser. Do not exceed a temperature of 134 °C.

12 Maintenance

12.1 Recommended maintenance schedule



Only specialist or personnel trained by Dürr Dental may maintain the appliance.



Before opening the appliance, power it down (e. g. remove plug).

The recommended maintenance intervals are based on operating the appliance with 15 intraoral images per day and 220 working days per year.

Maintenance interval	Maintenance activity
Annual	<ul style="list-style-type: none"> • Visually inspect appliance. • Check image plates for scratches, replace if necessary.
Every 3 years	<ul style="list-style-type: none"> • Replace light protector. • Replace roll holder. • Replace drive belt.



Trouble-shooting

13 Tips for Operators and Technicians



Repairs above and beyond simple maintenance may only be carried out by a qualified technician or one of our service technicians.



Before working on the appliance unplug at the mains and remove all power.

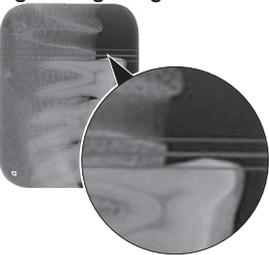
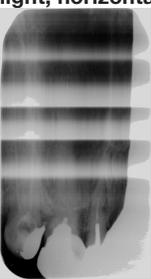
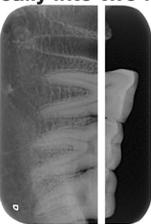
13.1 Defective radiograph

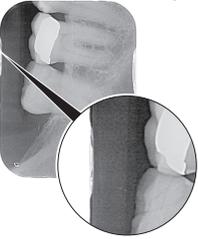
Problem	Probable cause	Solution
X-ray image does not appear on the monitor after scanning	Image plate has been fed the wrong way round and the inactive side has been read out	<ul style="list-style-type: none"> • Immediately read the image plate again, inserting the image plate correctly.
	Image data on the image plate was erased, e.g. by ambient light	<ul style="list-style-type: none"> • Always read the image data of the image plate as quickly as possible.
	Fault in the appliance	<ul style="list-style-type: none"> • Inform service technician.
	No image data on image plate, image plate not exposed	<ul style="list-style-type: none"> • Expose image plate.
	X-ray appliance is faulty	<ul style="list-style-type: none"> • Inform service technician.
X-ray image too dark	Wrong cover, the light protection cover has also been drawn in	<ul style="list-style-type: none"> • Use a cover matching the size of the image plate.
	X-ray dose too high	<ul style="list-style-type: none"> • Check X-ray parameters.
X-ray image too bright	Incorrect brightness/contrast setting in the software	<ul style="list-style-type: none"> • Set the brightness of the radiograph in the software.
	Exposed image plate subject to effects of ambient light	<ul style="list-style-type: none"> • Always read the image data of the image plate as quickly as possible.
	<ul style="list-style-type: none"> • X-ray dose is too low 	<ul style="list-style-type: none"> • Check X-ray parameters.
X-ray image only shadowy	Incorrect brightness/contrast setting in the software	<ul style="list-style-type: none"> • Set the brightness of the radiograph in the software.
	X-ray dose on the image plate too low	<ul style="list-style-type: none"> • Increase X-ray dose.
	Amplification level (HV value) set too low in the software	<ul style="list-style-type: none"> • Increase amplification (HV value).
	Unsuitable scanning mode selected	<ul style="list-style-type: none"> • Select a suitable scanning mode.
	Threshold setting too high	<ul style="list-style-type: none"> • Reduce threshold setting.

Problem	Probable cause	Solution
<p>Top or bottom bulge in the X-ray image</p> 	<p>Image plate off-centre and fed at an angle</p>	<ul style="list-style-type: none"> • Centre image plate and feed straight.
<p>X-ray image is mirror-inverted</p>	<p>Image plate exposed on the wrong side.</p>	<ul style="list-style-type: none"> • Place image plate correctly in light protection cover. • Position image plate correctly.
<p>Round shadow on the X-ray image</p> 	<p>Plus ID image plate (with marker) exposed on the wrong side</p>	<ul style="list-style-type: none"> • When taking an X-ray make sure the active side points towards the X-ray tube.
<p>Ghost images or two exposures on the X-ray image</p> 	<p>Image plate double exposed Image plate not sufficiently erased</p>	<ul style="list-style-type: none"> • Only expose image plate once. • Check the erasure unit is working correctly. • Inform the service technician if reoccurs.
<p>X-ray image mirrored on a corner</p> 	<p>Image plate bent during X-ray exposure</p>	<ul style="list-style-type: none"> • Do not bent the image plate.

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Problem	Probable cause	Solution
<p>Shadow on the X-ray image</p> 	<p>Image plate removed from the light protection cover before reading</p>	<ul style="list-style-type: none"> • Do not handle an image plate without a light protection cover. • Store the image plate in a light protection cover.
<p>X-ray image cut off, a part missing</p> 	<p>Metal part of the X-ray tube is in front of the X-ray beam</p> <hr/> <p>Edge masking defective in the imaging software</p>	<ul style="list-style-type: none"> • When taking an X-ray, make sure there are no metal parts between the X-ray tube and patient. • Check the X-ray tube. • Deactivate edge masking.
<p>Software cannot combine the data to make a complete image</p>	<p>X-ray dose on the image plate too low</p> <hr/> <p>Amplification level (HV value) set too low in the software</p> <hr/> <p>Unsuitable scanning mode selected</p> <hr/> <p>Threshold setting too high</p>	<ul style="list-style-type: none"> • Increase X-ray dose. • Increase amplification (HV value). • Select a suitable scanning mode. • Reduce threshold setting.
<p>X-ray exposure has stripes on image</p>	<p>Image plate pre-exposed, e.g. by natural radiation or scattered X-ray radiation</p> <hr/> <p>Parts of the image plate were exposed to light during handling</p> <hr/> <p>Image plate was soiled or scratched</p>	<ul style="list-style-type: none"> • If the image plate has been stored for longer than one week, erase the image plate again prior to use. • Do not expose used image plates to bright light. • Read image data within 30 minutes of the exposure. • Clean image plate (see "11 Cleaning and disinfecting"). • Replace scratched image plate.
<p>Light stripes in the scanning window</p>	<p>Too much stray light entered during scanning</p>	<ul style="list-style-type: none"> • Darken the room. • Turn the appliance so that the light does not fall directly onto the input unit.

Problem	Probable cause	Solution
<p>Horizontal, grey lines on the X-ray image, beyond the left and right image edge</p> 	<p>Slipping transport</p>	<ul style="list-style-type: none"> • Clean transport mechanism, replace transport belts if necessary.
<p>X-ray image is distorted lengthways with light, horizontal stripes</p> 	<p>Wrong light protection cover or image plate used</p>	<ul style="list-style-type: none"> • Only use original accessories.
<p>X-ray image split vertically into two halves</p> 	<p>Dirt in the laser slit (e.g. hair, dust)</p>	<ul style="list-style-type: none"> • Clean laser slit.
<p>X-ray image has small light dots or clouding</p>	<p>Micro scratches on the image plate</p>	<ul style="list-style-type: none"> • Replace image plate.

Problem	Probable cause	Solution
Lamination of the image plate detached at the edge 	Wrong holding system used	<ul style="list-style-type: none"> • Only use original image plates and film holding system.
	Image plate handled incorrectly.	<ul style="list-style-type: none"> • Use the image plate correctly. • Heed the operating instructions of the image plate and film holding system.

13.2 Software error

Problem	Probable cause	Solution
"Too much ambient light"	Appliance is exposed to too much light	<ul style="list-style-type: none"> • Darken the room. • Turn the appliance so that the light does not reach the entry slot directly.
"Incorrect power unit"	Incorrect power unit has been connected	<ul style="list-style-type: none"> • Use the power unit provided.
"Excessive heating"	Laser or erasure unit too hot	<ul style="list-style-type: none"> • Switch off the appliance and allow to cool.
"Erasure unit fault"	LED soiled or defective	<ul style="list-style-type: none"> • Inform service technician.
Imaging software does not detect the appliance	Appliance not switched on	<ul style="list-style-type: none"> • Switch the appliance on.
	Connecting cable between appliance and computer not connected correctly	<ul style="list-style-type: none"> • Check the connecting cable.
	Computer does not detect connection to the appliance	<ul style="list-style-type: none"> • Check the connecting cable. • USB driver not installed or inactive. • Check network setting (IP address and subnet mask).
	Hardware fault	<ul style="list-style-type: none"> • Inform service technician.
Appliance does not appear in the VistaConfig options list	Appliance is set up behind a router	<ul style="list-style-type: none"> • Configure IP address without intermediate router on the appliance. • Connect the router in between again. • Manually enter the IP address in VistaConfig and register the appliance.

Problem	Probable cause	Solution
Appliance appears in the VistaConfig options list but connection is not possible	Subnet masks of the computer and the appliance do not agree	<ul style="list-style-type: none"> • Check subnet masks, match if necessary.
"E2490" error	Appliance connection has been lost while software still wants to contact the appliance	<ul style="list-style-type: none"> • Restore the appliance connection. • Repeat procedure.
Error in data transmission between appliance and computer. "CRC Error Timeout" error message	Wrong or too long connecting cable used	<ul style="list-style-type: none"> • Only use original cable.

13.3 Error on the appliance

Problem	Probable cause	Solution
Appliance does not switch on	No supply voltage	<ul style="list-style-type: none"> • Check mains cable and plug connection, replace if necessary. • Check power unit. • If the green display does not light, replace the power unit.
	On/off switch defective	<ul style="list-style-type: none"> • Check the main fuse box in building. • Inform service technician.
Appliance switches back off after a short time	Mains cable or one of the plugs has not been inserted correctly	<ul style="list-style-type: none"> • Check the mains cable and all connections.
	Hardware defective	<ul style="list-style-type: none"> • Inform service technician.
	Mains supply voltage too low	<ul style="list-style-type: none"> • Check the supply voltage.
Appliance is on but no display (status, error or operating display) lights	Display defective	<ul style="list-style-type: none"> • Inform service technician.
Loud noises during operation after switching on, longer than 30 seconds	Radiation deflector defective	<ul style="list-style-type: none"> • Inform service technician.
Appliance does not react	Appliance has not yet completed boot procedure	<ul style="list-style-type: none"> • Wait 20 - 30 seconds after switching on until the boot procedure has completed.
	Appliance is blocked by the firewall	<ul style="list-style-type: none"> • Enable the ports for the appliance in the firewall.
Image plate does not fit into the intake slot	Wrong cover used	<ul style="list-style-type: none"> • Use a cover matching the size of the image plate.
Light protection cover slips into intake slot together with image plate	Incorrect (too big) cover used	<ul style="list-style-type: none"> • Use a cover matching the size of the image plate.



Problem	Probable cause	Solution
Red status display flashes	Cover or light protector is missing or not correctly in position	<ul style="list-style-type: none">• Attach cover and light protector correctly.
Blue communication display flashes	No connection between appliance and computer	<ul style="list-style-type: none">• Check cable and cable connection.• Activate appliance via software.• Activate or install the USB driver.
	Data memory in the appliance is full.	<ul style="list-style-type: none">• Use software to set up state of readiness. The image data is automatically transferred from the appliance to the software.



14 Scan times

The scan time is the time from insertion of image plate until scanning of the image data is completed depending on the image plate format and pixel size.

The time for the image is significantly dependent on the computer system and its utilisation. Times stated are approximate.

Theoretical resolution (LP/mm)	40	25	20	10
Pixel size (µm)	12.5	20	25	50
Intra size 0 (2 x 3)	26 s	16 s	13 s	6 s
Intra size 2 (3 x 4)	32 s	20 s	16 s	8 s

15 File size (uncompressed)

The file sizes are dependent on the image plate format and the pixel size. The file sizes stated are approximate and have been rounded upwards.

With suitable compression methods the file size can be considerably reduced with no loss of data.

Theoretical resolution (LP/mm)	40	25	20	10
Pixel size (µm)	12.5	20	25	50
Intra size 0 (2 x 3)	10.4 MB	4.6 MB	2.6 MB	0.65 MB
Intra size 2 (3 x 4)	17 MB	6.4 MB	4.3 MB	1.1 MB

16 Information on EMC according to EN 60601-1-2

16.1 General notes

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical appliances. The information reproduced here should be observed during the installation of individual appliances and when combining Dürr Dental appliances with products of other manufacturers. If there is any question of doubt, the complete standard must be checked.

16.2 Abbreviations

EMC	Electro-magnetic compatibility
HF	High frequency
U_T	Voltage rating of appliance (supply voltage)
V_1, V_2	Level of consistency for testing according to IEC 61000-4-6
E_1	Level of consistency for testing according to IEC 61000-4-3
P	Rated power of transmitter in watts (W) according to manufacturer's information
d	Recommended safety distance in metres (m)

16.3 Guidelines and manufacturer's information

Electromagnetic transmissions for all appliances and systems

The appliance is designed for operation in one of the electromagnetic environments as outlined below. The customer/operator of such an appliance is obliged to ensure that the appliance is operated in such an environment.

Interference measurements	According to	Electro-magnetic environment – guidelines
HF transmissions according to CISPR 11	Group 1	The appliance employs HF energy exclusively for internal functions. Therefore, any HF transmissions are of extremely low nature and it is highly improbable that any other electronic components will receive any interference.
HF transmissions according to CISPR 11	Group 2	The appliance must transmit electromagnetic energy in order to fulfil the functions for which it has been designed. Other electronic appliances in the vicinity could be affected.
HF transmissions according to CISPR 11	Class [A or B]	The appliance is designed for use in all types of environment including those in residential areas and other suitable areas which are connected directly to the local power supply serving residential buildings.
Harmonic limits according to IEC 61000-3-2	[Class A, B, C, D or Not Applicable]	
Voltage fluctuations/flicker according to IEC 61000-3-3	[Fully compatible or not applicable]	

Table 1: Electromagnetic transmissions for all appliances and systems

Electromagnetic resistance for all appliances and systems

The appliance is designed for operation in one of the electromagnetic environments as outlined below. The customer/operator of such an appliance is obliged to ensure that the appliance is operated in such an environment.

Resistance to interference checks	IEC 60601 - test levels	Level of consistency	Electro-magnetic environment – guidelines
Discharge of static electricity (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV discharge to air	±6 kV contact discharge ±8 kV discharge to air	Floors should be of wood or concrete or be covered by ceramic tiles. If the floor is covered by synthetic material, the relative humidity must be at least 30%.
Rapid transient electrical bursts according to IEC 61000-4-4	±2 kV for mains connections ±1 kV at input and output connections	±2 kV for mains connections ±1 kV at input and output connections	The quality of the supply voltage should be that of a typical office building or of a hospital environment.
Surges according to IEC 61000-4-5	±1 kV voltage external-external conductor ±2 kV voltage external-ground conductor	±1 kV push-pull voltage ±2 kV push-pull voltage	The quality of the supply voltage should be that of a typical office building or of a hospital environment.
Voltage drops, interruptions and fluctuations according to IEC 61000-4-11	< 5% U_T (> 95% retardation of U_T) for 1/2 period 40% U_T (60% retardation of U_T) for 5 periods 70% U_T (30% retardation of U_T) for 25 periods < 5% U_T (> 95% retardation of U_T) for 5 s	< 5% U_T (> 95% retardation of U_T) for 1/2 period 40% U_T (60% retardation of U_T) for 5 periods 70% U_T (30% retardation of U_T) for 25 periods < 5% U_T (> 95% retardation of U_T) for 5 s	The quality of the supply voltage should be that of a typical office building or of a hospital environment. Where the operator of the appliance requires continued function even during a power out, we recommend that the appliance is supplied by an uninterrupted power supply, e.g. battery power.
Magnetic field under supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the supply voltage should have the values found in a typical office building or of a hospital environment.

Table 2: Electromagnetic resistance for all appliances and systems

Electromagnetic resistance to interference for non life-supporting appliances or systems

Portable and cordless radio appliances should not be used close to the appliance, including any electrical supply lines, as the recommended safety distance which has been calculated from the transmission frequency.

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Resistance to interference checks	IEC 60601 - test levels	Level of consistency	Recommended safety distance
Conductive HF interference factor according to IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	[V ₁] V	$d = [3.5 / V_1] \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$
Radiated HF interference factor according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E ₁] V/m	$d = [3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz
			$d = 1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz
			$d = [7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz
			$d = 2.3 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz

Table 3: Electromagnetic resistance to interference for non life-supporting appliances or systems

- P Rated power of transmitter in watts (W) according to manufacturer's information
- d Recommended safety distance in metres (m)



The field strength of stationary radio transmitters for all frequencies must be, according to investigation carried out on-site^a lower than the consistency level.^b
Some interference is possible in environments surrounding appliances where the following symbol is present.

- Note 1 Where 80 MHz and 800 MHz are present, the higher frequency range becomes valid.
- Note 2 These guidelines are not applicable for all possible situations. The exact amount of electromagnetic transmissions can be considerably influenced by the rate of absorption and reflection within the building, and the presence of objects and people.

^a The field strength of stationary transmitters, e.g. base station of radio telephones or cordless land-line phones, amateur radio stations, on AM and FM radio or TV, cannot be theoretically exactly calculated in advance. In order to establish the electromagnetic environment taking these stationary transmitters into account, a study of the electromagnetic phenomena of the actual location must be undertaken. If the field strength measured at the location where the appliance is used exceeds the above level of consistency, the appliance should be observed in order to demonstrate the intended function. If any unusual behaviour of the appliance is observed, additional steps will be required, e.g. changing the orientation or location of the appliance.

^b The field strength is less than [V₁] V/m over the frequency range of 150 kHz to 80 MHz.

Recommended safety distances between portable and mobile HF communications devices and the appliance

The appliance is designed for operation in one of the electromagnetic environments as outlined below in which the HF interference is controlled. The customer/operator of the appliance can help to prevent electromagnetic interference by maintaining minimum distances as recommended between portable and mobile HF communications devices (transmitters) and the appliance as outlined below according to the maximum output of the communications device.

Rated power of transmitter (W)	Safety distance dependent on transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 4: Recommended safety distances between portable and mobile HF communications devices and the appliance

For transmitters whose maximum rated current is not included in the table above the recommended safety distance d in metres (m) can be calculated using the following mathematical formula and the appropriate column, where P is the maximum rated current of the transmitter in watts (W) according to the information of the manufacturer of the transmitter.

- Note 1 Where 80 MHz and 800 MHz are present, the higher frequency range becomes valid.
- Note 2 These guidelines are not applicable to all possible situations. The exact amount of electro-magnetic transmissions can be considerably influenced by the rate of absorption and reflection within the building and the presence of objects and people.

16.4 Table of calculation

If the measured values deviate from the standard, the values in chapter "4 Technical data" are specified.

The safety distances can then be calculated in the tables shown below.

P :

V_1 :

E_1 :

P Rated power of transmitter in watts (W) according to manufacturer's information

V_1 Level of consistency for testing according to IEC 61000-4-6

E_1 Level of consistency for testing according to IEC 61000-4-3

Resistance to interference checks	IEC 60601- test levels	Level of consistency	Recommended safety distances
Conductive HF interference factor according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ V	$d = [3.5 / V_1] \cdot \sqrt{P}$
Radiated HF interference factor according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ V/m	$d = [3.5 / E_1] \cdot \sqrt{P}$ For 80 MHz to 800 MHz
			$d = [7 / E_1] \cdot \sqrt{P}$ For 800 MHz to 2.5 GHz

Rated power of transmitter (W)	Safety distance dependent on transmission frequency (m)		
	150 kHz to 80 MHz $d = [3.5/V_1] \cdot \sqrt{P}$	80 MHz to 800 MHz $d = [3.5/E_1] \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = [7 / E_1] \cdot \sqrt{P}$
0.01			
0.1			
1			
10			
100			

DÜRR DENTAL AG
Höpfigheimer Strasse 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerr.de
info@duerr.de

