VistaScan Mini Easy



Installation and operating instructions

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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.

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



Warning – risk of dangerous electric voltages



Warning - laser beam

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.



Please read all of the accompanying documents.



Wear protective gloves.



Switch off and de-energise the device (e. g. unplug from mains).



CE labelling



Manufacturer



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



Do not reuse



Order number



Serial number

1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright.

The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.

!

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. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

VistaScan Mini Easy

The unit is intended exclusively for use in dental applications for the scanning and processing of image data on an image plate.

Light protection cover

The light protection cover protects the image plate against light.

2.2 Intended use

VistaScan Mini Easy

The unit may only be operated using accessories and optional accessories specifically approved by Dürr Dental.

The unit may only be cleaned using the disinfectants and cleaning agents specified or approved by Dürr Dental.

Light protection cover

The light protection cover is a disposable item. The light protection cover is designed exclusively for use with Dürr Dental image plate scanners and Dürr Dental image plates in dental applications.

2.3 Improper usage

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from improper usage. In these cases the user/operator will bear the sole risk.

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

This unit must not be operated in operating theatres or similar rooms, in which dangers may arise from the combustion of flammable materials.

2.4 General safety notes

- 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.
- 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.

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 Protection from electric shock

- Comply with all the relevant electrical safety regulations when working on the unit.
- Never touch the patient and unshielded plug connections on the device at the same time.
- Replace any damaged cables or plugs immediately.

Observe the EMC rules concerning medical devices

Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "16 Information about EMC in accordance with EN 60601-1-2".

!

2.7 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 MEDICAL 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 FMC.

2.8 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 quarantee.

- Only transport the unit in its original packaging.
- > Keep the packing materials out of the reach of children.
- Do not expose the unit to any strong vibrations or shocks.

2.9 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).

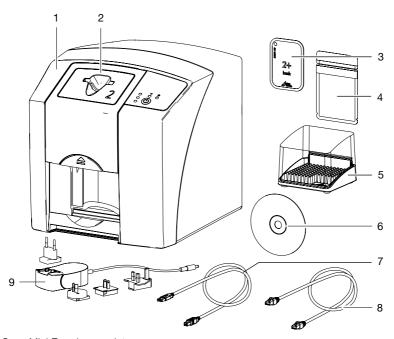
If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

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 090199 "Wastes not otherwise specified". Disposal as domestic waste is possible.

3 Overview



- 1 VistaScan Mini Easy image plate scanner
- 2 Input unit cover
- 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 supply unit with country-specific adapter



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):

VistaScan Mini Easy image plate scanner
VistaScan Mini Easy image plate scanner
VistaScan Mini Easy image plate scanner
 Light protection covers Plus: Size 0 Size 2 Storage box Protection cover Image plate cleaning wipes Installation and operating instructions Quick start instructions

3.2 Accessories

The following items are required for operation of the device, depending on the application:

Image plates Plus image plate, size 0 2 x 3 cm (2 pcs.)
3 x 4 cm (4 pcs.)2130-042-60
Light protection covers Light Protection Cover Plus size 0 2 x 3 cm (100 pcs.)
2 x 3 cm (100 pcs.)2130-080-50
Light Protection Cover Plus size 2, white 3 x 4 cm (300 pcs.)
3.3 Optional accessories
The following optional articles can be used with the unit:

The following optional articles can be used with
the unit:
Wall bracket
Storage box
Image plate and film holder
system set2130-981-50
Image plate and film holder system
conversion 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 tests Intra / extra digital test body 2121-060-54



3.4 Consumables

The following materials are consumed during operation of the device and must be reordered separately:

Cleaning and disinfection

Image plate cleaning wipes (10 pcs.)	CCB351B1001
FD 350 Classic disinfection	
wipes	CDF35CA0140
FD 333 rapid surface	
disinfectant	CDF333C6150
FD 322 rapid surface	
disinfectant	CDF322C6150
FD 366 quick-acting disinfectant	for
sensitive surfaces	CDF366C6150

Light protection covers

see "3.2 Accessories"

3.5 Wear parts and replacement parts

Image plates

see "3.2 Accessories"



Information about replacement parts is available from the portal for authorised specialist dealers at:

www.duerrdental.net.



Technical data 4

4.1 Image plate scanner

Electrical data for the device			
Voltage	V DC	24	
Max. current consumption	А	1.25	
Output	W	< 30	
Type of protection		IP20	

V AC	100 - 240
Hz	50/60
	II
	IP20
	II
W	< 40
А	0.8
	Hz

Classification	
Medical Devices Directive (93/42/EEC)	Class I
Laser class (unit)	
in accordance with EN 60825-1	1

Laser source		
Laser class		
in accordance with EN 60825-1		3B
Wavelength λ	nm	635
Output	mW	10

Noise level		
Ready to scan	dB(A)	approx. 37
During scanning	dB(A)	approx. 55

mm	226 x 234 x 243
kg	approx. 6.5
W	< 40
min	25
%	25
μm	12.5 - 50
Line pairs/ mm (Lp/mm)	approx. 40
	kg W min % µm Line pairs/

Network connection		
LAN technology		Ethernet
Standard		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45
Type of connection		Auto MDI-X
Cable type		≥ CAT5
Ambient conditions during oper	ration	

Ambient conditions during opera-	tion	
Temperature	°C	+10 to +35
Relative humidity	%	20 - 80
Air pressure	hPa	750 - 1060
Height above sea level	m	< 2000
Ambient conditions during stored	and transport	

Ambient conditions during storage	ge and transport	
Temperature	°C	-20 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/EEC	C)	Class IIa	
Ambient conditions during operation	on		
Temperature	°C	18 - 45	
Relative humidity	%	< 80	
Ambient conditions during storage	and transport		
Temperature	°C	< 33	
Relative humidity	%	< 80	
Dimensions of intraoral image plate	es		
Size 0	mm	22 x 35	
Size 2	mm	31 x 41	

4.3 Light protection cover

Classification	
Medical Devices Directive (93/42/EEC)	Class I

4.4 Type plate

The type plate is located on the rear of the device.



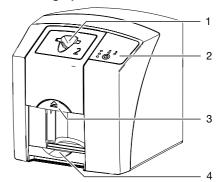
REF Order number SN Serial number

4.5 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

5.1 Image plate scanner



- 1 Intake slot
- 2 Operating elements
- 3 Release key
- 4 Collection tray

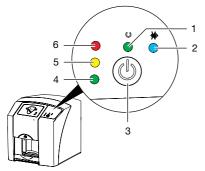
The image plate scanner is used to read image data stored on an image plate and to transfer the data to the imaging software (e.g. VistaSoft) on a computer.

The transport mechanism guides the image plate through the device. The image plate is read using a laser inside the scanner unit. 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 is erased with the aid of bright light.

The image plate is then ejected for re-use.

Operating elements



- 1 Green operating LED
- 2 Blue communication indicator
- 3 On / off switch
- 4 Green status LED
- 5 Yellow status LED
- 6 Red status LED

The status LEDs display the following status messages:





Ready for operation





Not ready for communication





Device currently switching off





Cover missina

Image plate currently being processed

Image plate currently being processed

Light protection cover can be removed and the next image plate can be insert-

and the next image plate can be inserted

Input unit ready for operationThe next image plate can be inserted

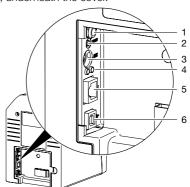
- Device starting up from standby mode

- Status LED flashing

O Status LED off

Connections

The connections are located on the rear of the unit, underneath the cover.



- 1 Connection for power supply unit
- 2 Reset button
- 3 AUX connection for diagnostic units
- 4 Network connection status LEDs
- 5 Network connection
- 6 USB port

5.2 Image plate

The image plate stores X-ray energy, which is re-emitted in the form of light after excitation via the laser. This light is then converted to image information in the image plate scanner.

The image plate has an active side and an inactive side. The image plate must always be exposed on the active side.

When used properly, image plates 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. if the protective layer is damaged or there are visible scratches that could interfere with the diagnosis.

Intraoral



1 Inactive side

Black, printed with the word "back" and the size and manufacturer's information

2 Active side

Light blue, with positioning aid



The positioning aid \bigcap is visible on the X-ray image and makes it easier to align the image correctly during diagnosis.

Exposure from the wrong side

A marker is attached to the inactive side of the image plate.



1 Marker

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



1 Marker visible as a shadow

The image can be corrected by mirroring it in the software. If a diagnosis is not possible in the area of the marker then the image will need to be acquired again.



With the aid of the copper dots set you can retrospectively add a marker to image plates (see "3.3 Optional accessories").

Clear assignment of image plate to image (Image Plate Plus ID only)

On the Image Plate Plus ID there is also a hexadecimal code on the image plate in addition to the marker. This code can be seen in the X-ray image.

This code allows you to clearly assign the correct image plate to the X-ray image.



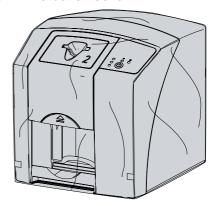
Hexadecimal code

5.3 Light protection cover

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

- Protection against sunlight and UV light, and therefore protection against accidental erasure
- Protection against mechanical damage
- Protection against contamination and soiling
 The light protection cover is a disposable item.

5.4 Protection cover



The protective cover protects the device against dust and dirt, for example during extended periods in which it is not in use.

5.5 Storage box

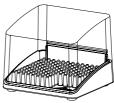


Image plates packaged in light protection covers can be stored in the storage box until they are next used. The storage box protects the image plate and the light protection cover against contamination and dirt.





Only qualified specialists or employees trained by Dürr Dental are permitted to install, connect and start using the unit.

6 Requirements

6.1 Installation/setup room

The room chosen for set up must fulfil the following requirements:

- Closed, dry, well-ventilated room
- It should not be a room made for another purpose (e.g. boiler room or wet cell).
- Max. light intensity 1000 Lux, no direct sunlight at the place of installation of the unit
- There should be no large fields of interference (e.g. strong magnetic fields) present that can interfere with the correct operation of the unit.
- Refer to the requirements for environmental conditions in "4 Technical data".

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).

6.3 Monitor

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

Strong ambient light, sunlight falling directly onto the monitor and reflections can make it harder or even impossible to perform a diagnosis based on the X-ray images.

7 Installation

7.1 Carrying the unit



NOTICE

Risk of damage to sensitive components in the unit as a result of shocks or vibrations

- Do not expose the unit to any strong vibrations or shocks.
- Do not move the unit during operation.

7.2 Setting up the unit

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

- Do not stack the unit next to or together with other appliances.
- If, however, this unit is operated next to other units or stacked with other units, monitor the unit carefully in the configuration selected in order to ensure normal operation.

The unit can be set up as a tabletop unit or mounted on a wall using the wall bracket.

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

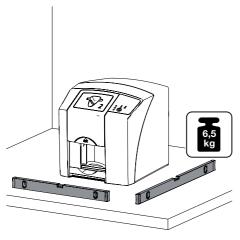
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Setting the unit on a table



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

> Place the unit on a firm, horizontal surface.



Installing the unit with the wall mounting bracket

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



For installation refer to the installation instructions for the wall mounting (order number 9000-618-162)

7.3 Electrical connections

Safety when making electrical connections

- The device must only be connected to a correctly installed power outlet.
- Do not place non-fixed multi-socket units on the floor. Follow the requirements in section 16 of IEC 60601-1 (EN 60601-1).
- Do not operate any other systems using the same multiple socket.
- Make sure that none of the electrical cables leading to the unit are under any mechanical tension.
- Defore initial start-up check that the mains supply voltage and the voltage stated on the type plate match (see also "4. Technical data").

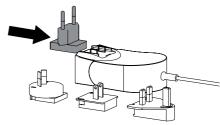
Connecting the unit to the mains supply



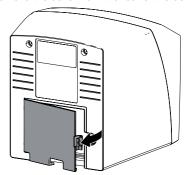
The unit has no main power switch. For this reason it is important that the unit is be set up in such a way that the plug can be easily accessed and unplugged if required.

Requirements:

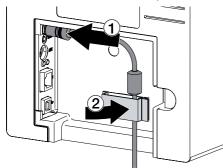
- Properly installed power outlet close to the unit (observe the max. mains cable length)
- Easily accessible power outlet
- Mains voltage must match the information shown on the type plate of the power supply unit
- Attach the matching country-specific adapter to the power supply unit.



> Remove the cover from the rear of the device.



- ٦
- Plug in the connecting plug of the power supply unit into the socket connection of the device.
- > Secure the cable with a cable clip.



- > Plug the mains plug into the power outlet.
- > Refit the cover.



The cover on the rear must be correctly fitted when the device is operated within the patient environment.

7.4 Connecting the unit

The device can be connected either via the USB port or via the network connection. If you are using VistaSoft/VistaConnect, the device can only be operated via the network. The cables are included in the scope of delivery.



Do not connect the device via the USB port and via the network connection at the same time.

If the device is connected via the USB port and via the network connection at the same time, the network connection will take priority.

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.
- Safety and essential performance features are independent of the network. The device is designed for operation independent of a network. However, some of the functions are not available in this case.
- Incorrect manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
- The data connection utilizes part of the bandwidth of the network. Interactions with other medical devices cannot be completely excluded. Apply the IEC 80001-1 standard for risk assessment.
- The device is not suitable for direct connection to the public internet.
- Always comply with the relevant requirements from of IEC 60601-1-1 (EN 60601-1-1) when connecting the unit to other appliances, e.g. to a computer system, both inside and outside of the patient environment.



> Only connect peripheral units (e.g. computer, monitor, printer) that conform at least to the requirements set out in IEC 60950-1 (EN 60950-1).

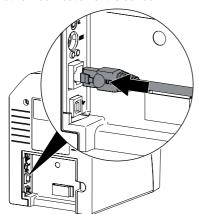


A copy of the system manufacturer's declaration in accordance with Article 12 of Directive 93/42/EEC can be found in our download section at www.duerrdental.com (document no. 9000-461-264).

Connecting the unit via the network cable Purpose of the network connection

The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

- Display parameters
- Select operating modes
- Indicate messages and error situations
- Change unit settings
- Activate test functions
- Transmit data for archiving
- Provide documents concerning the units
- Remove the cover from the rear of the device.
- > Connect the supplied network cable to the network connection of the device.



> Refit the cover.



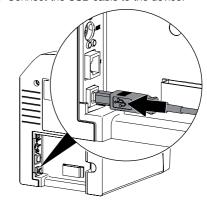
The cover on the rear must be correctly fitted when the device is operated within the patient environment.

Connecting the unit via the USB port



Only connect the USB cable to the computer when the installation wizard asks vou to do so.

- > Remove the cover from the rear of the device.
- Connect the USB cable to the device.



The cover on the rear must be correctly fitted when the device is operated within the patient environment.

Refit the cover.

8 Commissioning



NOTICE

Short circuit due to the build up of condensation

Do not switch on the unit until it has warmed up to room temperature and it is dry.

The unit supports the following imaging programs:

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

8.1 Set up the network (only with network connection)

Network configuration

Various options are available for network configuration:

- Automatic configuration via DHCP.
- Automatic configuration via Auto-IP for direct connection of unit and computer.
- Manual configuration.
- Configure the network settings of the unit using the software or, if applicable, the touch screen.
- Check the firewall and release the ports, if applicable.

Network protocols and ports

Port	Purpose	Serv- ice
45123 UDP, 45124 UDP	Unit recognition and configuration	
2006 TCP	Unit data	
514 ¹⁾ UDP	Event protocol data	Syslog
2005 TCP, 23 TCP	Diagnosis	Telnet, SSH

The port can vary depending on the configuration.



When the unit is first connected to a computer, it applies the language and time settings of the computer.

8.2 Driver installation (USB port only)



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

- > Close all programs.
- Insert the supplied DBSWIN DVD (version 5.3.1 or higher) into the DVD drive.

The start window opens.

- If the DVD does not start to play automatically, double-click the file CD_Start.exe.
- > Select the required language.
- > Open the Drivers tab.



Click Duerr Dental Driver Installation.



- Dick OK to confirm. The Dürr Dental Driver Setup installation wizard opens.
- Follow the instructions of the installation wizard.



8.3 Configuring the unit in VistaSoft

Configuration is performed directly in VistaSoft.

- > Select the unit.
- Mark the connected unit in the list.



- Click on Edit connection settings.
- The unit name (designation) can be changed and information queried working under General
- An IP address can be entered manually and DHCP can be activated / deactivated working under Connection.
- Extended functions e. g. IP address 2 can be set working under Extended.

Entering a fixed IP address (recommended)



To reset the network settings, keep the unit reset key pressed for 15 - 20 seconds while switching on.

- > Working under Connection, deactivate DHCP.
- Enter the IP address, subnet mask and gateway.
- Navigate back to *Units* via the navigation bar or close Flyout using .

The configuration is saved.

Testing the device

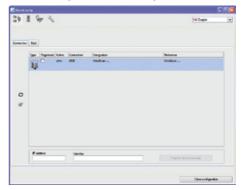
You can scan in an X-ray image to check that the unit is properly connected.

- > Open VistaSoft.
- > Create an X-ray station for the connected unit.
- Log-in the demo patient (patient ID: DEMO0001).
- > Select the image type (e. g. Intraoral).
- Scan an image plate, see "10.3 Scanning the image data".

8.4 Configuring the appliance in DBSWIN

Configuration is carried out using VistaNetConfig, which is automatically installed during installation of DBSWIN or VistaEasy.

> Select Start > All Programs > Dürr Dental > VistaConfig > VistaNetConfig.



Click C.

The list of connected units is updated.

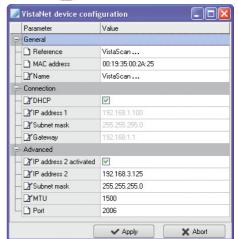
Activate the connected unit in the Registered column.

You can also register multiple units.

Configuring the device with a USB port

In the *VistaNet device configuration* window you can change the device *Name* and check the configuration.

> Click on

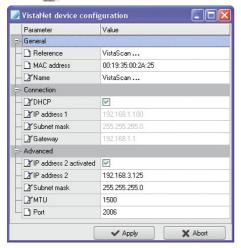


- If necessary change the name.
- Click Apply to save the configuration.

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Configuring the device with a network connection

The *VistaNet device configuration* window allows you to change the device name (*name*), manually enter an IP address or call up information.



- > If necessary change the name.
- > Click Apply to save the configuration.

Entering a fixed IP address (recommended)



To reset the network settings, keep the unit reset key pressed for 15 - 20 seconds while switching on.

- > Deactivate DHCP.
- Enter the IP address, subnet mask and gateway.
- > Click on Apply.

The configuration is saved.

Testing the device

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

> Select the Test tab.



- > Select the unit from the Registered Units list.
- > Select the mode class.
- > Select the mode.
- > Click on Scan Image.
- Scan an image plate, see "10.3 Scanning the image data".

ΕN



8.5 X-ray unit settings

Intraoral X-ray units

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

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

The following table shows the standard values for the exposure time and the dose area product of an image plate for an adult patient.

	DC emitter, 7 mA Tube length 20 cm					
		X-ray field itation	X-ray fi	eld limitation 2x3	X-ray	field limitation 3x4
	60 kV	mGycm ²	60 kV	mGycm ²	60 kV	mGycm ²
Incisors	0.08 s	14.6	0.08 s	3.1	0.08 s	6.2
Premolars	0.12 s	21.9	0.12 s	4.6	0.12 s	9.3
Molars	0.17 s	31.1	0.17 s	6.6	0.17 s	13.2
Bite wing	0.18 s	32.9	0.18 s	7.0	0.18 s	14

		DC emitter, 6 mA Tube length 30 cm				
		X-ray field tation	X-ray fi	eld limitation 2x3	X-ray f	field limitation 3x4
	70 kV	mGycm ²	70 kV	mGycm ²	70 kV	mGycm ²
Incisors	0.13 s	11.8	0.13 s	2.5	0.13 s	5.0
Premolars	0.18 s	16.4	0.18 s	3.4	0.18 s	6.9
Molars	0.25 s	22.8	0.25 s	4.8	0.25 s	9.6
Bite wing	0.27 s	24.6	0.27 s	5.2	0.27 s	10.4

The following table shows the standard values for the exposure time and the dose area product of an image plate for a child patient.

	DC emitter, 7 mA Tube length 20 cm					
		X-ray field itation	X-ray fi	eld limitation 2x3	X-ray 1	ield limitation 3x4
	60 kV	mGycm ²	60 kV	mGycm ²	60 kV	mGycm ²
Incisors	0.05 s	9.1	0.05 s	1.9	0.05 s	3.8
Premolars	0.07 s	12.8	0.07 s	2.7	0.07 s	5.4
Molars	0.11 s	20.1	0.11 s	4.2	0.11 s	8.5
Bite wing	0.11 s	20.1	0.11 s	4.2	0.11 s	8.5



	DC emitter, 6 mA Tube length 30 cm Without X-ray field X-ray field limitation X-ray field limitation limitation 2x3 3x4					
	70 kV	mGycm ²	70 kV	mGycm ²	70 kV	mGycm ²
Incisors	0.08 s	7.3	0.08 s	1.5	0.08 s	3.1
Premolars	0.11 s	10.0	0.11 s	2.1	0.11 s	4.2
Molars	0.14 s	12.8	0.14 s	2.7	0.14 s	5.4
Bite wing	0.14 s	12.8	0.14 s	2.7	0.14 s	5.4

> Check and adjust the specific X-ray unit in accordance with the standard values.

8.6 Acceptance tests

The required tests (e.g. acceptance tests) must be carried out in accordance with local rules and regulations.

- > Find out which tests are required.
- > Carry out testing in accordance with local rules and regulations.

Acceptance test



The Intra / Extra Digital test body is required for acceptance tests with the image plate and sensor as receivers, and possibly also the corresponding test body holder.

> Before the unit is started up and used for the first time, the acceptance test of the X-ray system must be carried out in accordance with national regulations.

The constancy tests, which must be carried out at regular intervals by the surgery personnel, are based on the results of the acceptance test.

Electrical safety checks

- > Carry out the electrical safety check according to the national law (e. g. in accordance with IEC 62353).
- > Document the results.



9 Correct use of image plates



CAUTION

Image plates are toxic

Image plates that 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 lots of water. Do not swallow the water in the process.
- Image plates are flexible like X-ray film. However, the image plates should not be bent.



Do not scratch the image plates. Do not subject 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 image plates in a light protection cover or foil cassette of the correct size.
- Image plates will be pre-exposed on exposure to natural radiation and stray x-ray radiation. Protect erased and exposed image plates from X-ray interference.
 - If the image plate has been stored for longer than one week, erase the image plate prior to use.
- Do not store image plates under hot or moist conditions. Observe the correct 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) that could interfere with the diagnosis.
- Image plates that have a production or packaging defect will be replaced by Dürr Dental in the same quantity. Claims can only be accepted within 7 working days after receipt of the goods.
- Clean image plates properly (see "11 Cleaning and disinfection").

10 Operation

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CAUTION

The image data on the image plate is not permanent.

The image data is altered by light, natural X-ray radiation and scattered X-ray radiation. This will lead to a reduction in diagnostic information and clarity.

- 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 or after the scanning process.
- Do not X-ray during the scanning process if the unit is in the same room as the X-ray tube.

10.1 Changing the input unit cover

The device can be used to scan image plates size 2 and size 0. Each size of image plate requires the matching size cover.

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



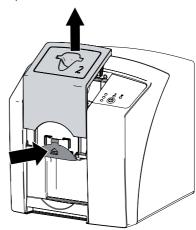


CAUTION

Loss of image information and equipment damage if an incorrect cover is used

- Always use the correct size of cover for the image plate being used.
- Defore each scanning process, compare the image plate size with the markings on the cover.

- > Check that the green status LED is lit.
- Press the release button and remove the cover upwards at the same time.



The red status LED flashes.

Place the cover into position from above. The green status LED lights up. The input unit is ready.

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10.2 X-ray



The procedure is described using a size 2 Image Plate Plus as an example.

Required accessories:

- Image plate
- Light protection cover the same size as the image plate



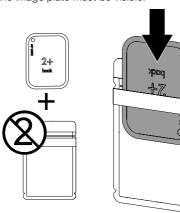
WARNING

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

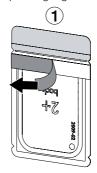
- Do not use an image plate without a light protection cover.
- Do not use the light protection cover more than once (disposable item).

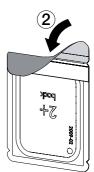
Preparing the X-ray

- The image plate has been cleaned.
- The image plate is not damaged.
- The marker (if present) is stuck in the correct position on the image plate. If the marker peels off, replace the image plate.
- If using it for the first time or if it has been stored for over a week: erase the image plate (see "10.4 Erasing the image plate").
- Completely slide the image plate into the light protection cover. The black (inactive) side of the image plate must be visible.



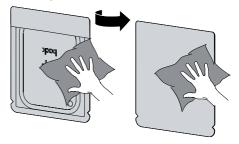
Pull off the adhesive strip, fold down the flap and close the light protection cover tightly by pressing together firmly.





The light protection cover must be disinfected using a disinfectant wipe immediately before it is positioned inside the patient's mouth (e.g. with Dürr FD 350).

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



Taking the X-ray



NOTICE

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

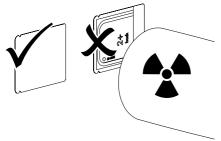
- Only use holding systems that will not damage the light protection cover or the image plates in any way.
- Do not use holding systems with sharp edges.



Wear protective gloves.

Place the image plate in the light protection cover into the patient's mouth.

When doing this, make sure that the active side of the image plate points towards the X-ray tube.



- Set the exposure time and setting values on the X-ray unit (see "8.5 X-ray unit settings").
- Record an X-ray image. The image data must be scanned within 30 minutes.

Preparing for scanning



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 with the light protection cover from the patient's mouth.



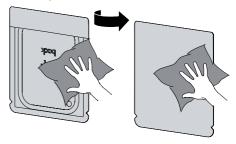
WARNING

Contamination of the unit

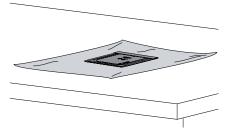
Clean and disinfect the light protection cover before removing the image plate.

- 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) can be used on a soft, lint-free cloth.



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



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



NOTICE

Powder from the protective gloves on the image plate can damage the unit during scanning

- Completely clean all traces of the protective glove powder from your hands before handling the image plate.
- > Tear off the light protection cover.





10.3 Scanning the image data

Starting the image plate scanner and software



The reading-out process is described using the VistaSoft imaging software.

For further information on using the imaging software, refer to the relevant manual.

- Press the on / off switch() to switch on the device.
- > Switch on the computer and monitor.
- > Start VistaSoft.
- > Select the patient.
- Select the corresponding image type in the menu bar.
- > Select the device.
- Set acquisition mode.
 Recording starts directly.

Result:

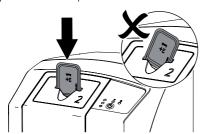
The status LED illuminates green.

Scanning the image plate

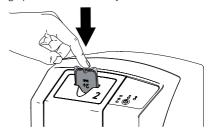


To avoid the mix up of X-ray images, only scan the X-ray images from the selected patient.

Place the light protection cover with the image plate centrally and straight onto the input unit. The opened side of the light protection cover faces down, the inactive side of the image plate faces the operator.



Slide the image plate out of its light protection cover downwards into the device until the image plate is automatically drawn in.



The light protection cover is held at the intake slot and is not drawn into the device.

The yellow status LED lights up.

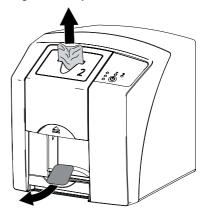
The image data is automatically transmitted to the imaging software. The progress of the scanning process is displayed in the preview window on the monitor.

After it has been scanned, the image plate is erased and drops into the collection tray.

- > While the yellow status LED is lit up: Do not remove the light protection cover, and do not insert a new image plate.
- When the green and yellow status LEDs light up:

Remove the empty light protection cover.

- When the green status LED lights up: Save the X-ray image.
- Remove the image plate and prepare it for taking a new X-ray.



10.4 Erasing the image plate

The image data is automatically erased after scanning.

The special ERASE mode only activates the erasure unit of the image plate scanner. No image data is read.

The image plate needs to be erased using the special mode in the following cases:

- The first time the image plate is used, or if it is stored for longer than a week.
- Due to an error, the image data on the image plate has not been erased (software error message).
- > Select the special ERASE mode in the soft-
- Insert the image plate (see "Scanning the image plate").

10.5 Switch off the unit.

> Press the on/off switch (1) for 3 seconds. While the unit is shutting down the operating and communication LEDs flash.

As soon as the unit has shut down it switches off completely. The LEDs go out.

Use of a protective cover

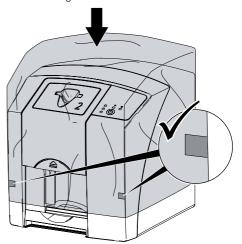
The protective cover protects the device against dirt and dust during extended periods in which it is not used.



WARNING

Danger of suffocation

- > Store the protective cover out of the reach of children.
- > Pull the protective cover over the device so that it is completely covered. Make sure that the markings are at the front.



> Store the protective cover in a safe place when it is not in use.

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11 Cleaning and disinfection

Unless specified otherwise, use the following cleaning agents and disinfectants for the device and its accessories:

- FD 322 rapid surface disinfectant
- FD 333 rapid surface disinfectant
- FD 350 Disinfection wipes
- FD 366 quick-acting disinfectant for sensitive surfaces



NOTICE

The use of unsuitable agents and methods can damage the unit and accessories.

- 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.



Wear protective gloves.

11.1 Image plate scanner

Unit surfaces

The unit surface must be cleaned and disinfected of any contamination or visible soiling.



NOTICE

Liquid can cause damage to the unit.

- Do not spray the unit with cleaning and disinfectant agents.
- Make sure that liquid does not get inside the unit.
- Remove any soiling with a soft, damp, lint-free cloth.
- Disinfect the surfaces using a disinfection wipe. Alternatively, use a spray disinfectant on a soft, lint-free wipe. Comply with the operating instructions for the disinfectant when doing this.

Input unit

The input unit must be cleaned and disinfected if there are indications of contamination or visible dirt

Use the following cleaning and disinfecting immersion disinfectants:

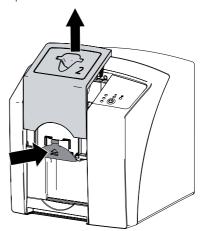
- ID 213 Instrument disinfection
- ID 212
- ID 212 forte



NOTICE

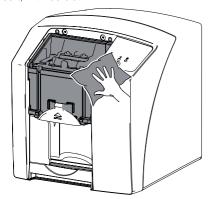
Heat can damage plastic parts.

- Do not use a thermal disinfector or steam steriliser on any parts of the device.
- Switch off the device by pressing the on/off switch (1) for 3 seconds.
- > Wait until the operating and communication LEDs go out and the device is completely switched off.
- Press the release 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, use a spray disinfectant on a soft, lint-free wipe. Comply with the operating instructions for the disinfectant when doing this.

The cover can also be disinfected in an immersion disinfection system.

> Remount the cover.

11.2 Light protection cover

The surface of the unit must be cleaned and disinfected if it is contaminated or visibly soiled.

- Disinfect the light protection cover using a disinfection wipe before and after placement. Alternatively, use a spray disinfectant on a soft, lint-free wipe. Comply with the operating instructions for the disinfectant when doing this.
- Allow the light protection cover to completely dry before using it.

11.3 Image plate

Use the following cleaning agents only:

- Image plate cleaning wipes



NOTICE

Heat or humidity will damage the image plate.

- > Do not steam sterilise the image plate.
- Do not immersion-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 wipe prior to every use.

- Remove resistant or dried on dirt with the image plate cleaning wipe. When doing this, observe the instructions for use for the cleaning wipe.
- Allow the image plate to completely dry before using it.

11.4 Protection cover

Use the following cleaning agents:

- FD 350 Disinfection wipes
- Clean the protective cover and inside parts with a moist, soft, lint-free cloth.
- Disinfect the protective cover using a disinfection wipe.

11.5 Storage box with image plate storage tray

Clean and disinfect the surface of the storage box and the internal image plate storage tray in the event of contamination or visible soiling. Use the following cleaning materials for the storage box:

FD 366 Sensitive disinfection of sensitive surfaces

Use the following cleaning materials 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 dampened, soft, lint-free cloth.
- Disinfect the storage box with spray disinfectant on a soft, lint-free cloth. Comply with the operating instructions for the disinfectant when doing this.
- Disinfect the image plate storage tray using a disinfection wipe.

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

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12 Maintenance

12.1 Recommended maintenance schedule



Only trained specialists or personnel trained by Dürr Dental may service the unit.



Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

The recommended maintenance intervals are based on using the device for 15 intraoral images per day and 220 working days per year.

Maintenance interval	Maintenance work	
Annually	> Visually inspect the device.	
	> Check the image plates for signs of scratches and change if necessary.	
	> Check the belt drives, transport belts and springs, and replace if necessary.	
> Remove dust and dirt from accessible parts.		
	Carry out a system check.	
Every 3 years	> Replace the light protective cover.	
	Change the roller fixtures.	
	> Change the drive belt.	

Troubleshooting

13 Tips for operators and service technicians



Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.



Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

13.1 Poor X-ray image

Fault	Probable cause	Solution
X-ray image does not appear on the monitor after scanning	Image plate not fed in straight and inactive side scanned	Scan the image plate again im- mediately, making sure you feed it in correctly in the process.
	Image data on the image plate has been erased, e.g. by ambient light	Always scan the image data of the image plate as quickly as possible.
	Fault on the unit	Inform a Service Technician.
	No image data on image plate, image plate not exposed	> Expose the image plate.
	X-ray unit is faulty	> Inform a Service Technician.
	Incorrect cover, light protection cover was also drawn into the unit	> Use the correct cover for the size of image plate being used.
X-ray image too dark	X-ray dose too high	> Check X-ray parameters.
	Incorrect brightness/contrast settings in the software	Adjust the brightness of the X- ray image in the software.
X-ray image too bright	Exposed image plate has been exposed to ambient light	Always scan the image data of the image plate as quickly as possible.
	X-ray dose too low	> Check X-ray parameters.
	Incorrect brightness/contrast settings in the software	Adjust the brightness of the X- ray image in the software.
X-ray image only shadowy	The X-ray dose on the image plate was insufficient	> Increase X-ray dose.
	Amplification (HV value) is set too low in the software	> Increase amplification (HV value).
	Unsuitable scanning mode selected	Select a suitable scanning mode.
	The setting for the threshold value is too high	> Reduce the threshold value.



Fault	Probable cause	Solution
Top or bottom bulge in the X-ray image	Image plate fed in off-centre and at an angle	Insert the image plate centrally and straight.
X-ray image is mirror- inverted	Image plate exposed on the wrong side.	Insert the image plate correctly in the light protection cover.
		Position the image plate correctly.
Round shadow on the X-ray image	Plus ID image plate (with marker) exposed on the wrong side	When taking an X-ray, make sure that the active side faces towards the X-ray tube.
Ghosting or double exposure on X-ray image	Image plate exposed twice	Only expose the image plate once.
	Image plate not sufficiently erased	 Check the erasure unit is working correctly. Inform a service technician if the problem persists.
X-ray image mirrored in one corner	Image plate bent during X-ray exposure	> Do not bend the image plate.



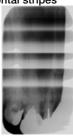
Fault	Probable cause	Solution
Shadow on the X-ray image	Image plate removed from the light protection cover before scanning	 Do not handle image plates without a light protection cover. Store the image plate in a light protection cover.
X-ray image cut off, part missing	The metal part of the X-ray tube is in front of the X-ray beam	When taking an X-ray, make sure there are no metal parts between the X-ray tube and the patient.
440		Check X-ray tube.
	Faulty edge masking in imaging software	> Deactivate edge masking.
Software unable to combine the data to make a	The X-ray dose on the image plate was insufficient	> Increase X-ray dose.
complete image	Amplification (HV value) is set too low in the software	> Increase amplification (HV value)
	Unsuitable scanning mode selected	Select a suitable scanning mode.
	The setting for the threshold value is too high	> Reduce the threshold value.
X-ray image has strips on image	Image plate has been pre-ex- posed, e.g. by natural radiation or stray X-ray radiation	If the image plate has been stored for longer than one week, erase the image plate prior to use.
	Parts of image plate exposed to light during handling	Do not expose used image plates to bright light.Scan image data within half an hour after the exposure.
	Image plate dirty or scratched	Clean the image plate.Replace scratched image plates.
Light strips in the scan- ning window	Too much incident ambient light during the scanning process	Darken the room.Turn the unit so that the light does not fall directly onto the input unit.



Fault	Probable cause	Solution
Horizontal, grey lines on the X-ray image, extending beyond the left and right image edge	Transport slipping	Clean the transport mechanism, replace the transport belts if necessary.



X-ray image is stretched lengthwise with bright, horizontal stripes



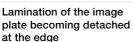
Incorrect light protection cover or > Only use original accessories. image plate used

into two halves



X-ray image split vertically Dirt in the laser slit (e.g. hair, dust) > Clean the laser slit.

X-ray image with small bright spots or clouding





Micro scratches on the image plate

Incorrect retainer system used

Image plate handled incorrectly.

> Replace the image plate.

Only use original image plates and film retainer systems.

- > Use the image plate correctly.
- > Observe the operating instructions for the image plates and film retainer systems.

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13.2 Software error

	B	0.1.11		
Fault	Probable cause	Solution		
"Too much ambient light"	Unit exposed to too much light	Darken the room.Turn the unit so that no light can fall directly into the entry slot.		
"Incorrect power supply unit"	Incorrect power supply unit connected	Use the supplied power supply unit.		
"Overtemperature"	Laser or erasure unit too hot	Switch off the unit and allow it to cool.		
"Erasure unit fault"	LED defective	Inform a Service Technician.		
Imaging software does not	Unit not switched on	> Switch on the unit.		
recognise the unit	Connecting cable between device and computer not correctly connected	> Check the connecting cable.		
	Computer does not detect any connection to the unit.	Check the connecting cable.Check the network settings (IP address and subnet mask).		
	Hardware fault	> Inform a Service Technician.		
	The IP address of the device is being used by another unit	 Check the network settings (IP address and subnet mask) and assign a unique IP address to every device. Inform a service technician if the problem persists. 		
The unit does not appear in the options list in Vista-Config	Unit is connected behind a router	 Configure the IP address without an intermediate router on the unit. Reconnect the router. Manually enter the IP address in VistaConfig and register the unit. 		
	The IP address of the device is being used by another unit	 Check the network settings (IP address and subnet mask) and assign a unique IP address to every device. Inform a service technician if the problem persists. 		
The unit appears in the VistaConfig options list but connection is not possible	Subnet masks of the computer and the unit do not match	Check subnet masks, adjust if necessary.		
Error message "E2490"	The connection to the unit was interrupted while the software was still attempting to communicate with the unit	Restore the connection to the unit.Repeat the process.		



Fault	Probable cause	Solution
Error during data trans- mission between unit and computer. Error message "CRC error timeout"	Connecting cable used is incorrect or too long	Only use original cables.

13.3 Fault on the unit

Fault	Probable cause	Solution
Unit does not switch on	No mains voltage	Check the mains cable and plug connection and replace if necessary.
		 Check the power supply unit. If the green status LED does not light up, replace the power supply unit.
		Check the mains fuse in the building.
	On / off switch is defective	> Inform a Service Technician.
Unit switches back off after a short time	Mains cable or power supply unit plug not inserted correctly	> Check the mains cable and plug connections.
	Hardware fault	> Inform a Service Technician.
	Mains supply voltage too low	> Check the mains voltage.
Unit is on but none of the indicator LEDs are lit up (status, error or operating LEDs)	Display defective	> Inform a Service Technician.
Loud operating noises after switching on lasting more than 30 seconds	Radiation deflector defective	> Inform a Service Technician.
Unit not responding	The unit has not yet completed the startup procedure	After switching on, wait 20 - 30 seconds until the startup proce- dure has finished.
	Unit is blocked by the firewall	Enable the ports for the unit in the firewall settings.
Image plate does not fit into the intake slot	Incorrect cover used	> Use the correct cover for the size of image plate being used.
Light protection cover slips into intake slot to- gether with image plate	Incorrect cover (too big) used	> Use the correct cover for the size of image plate being used.
Red status LED flashes	Cover or light protection is missing or not correctly positioned	> Correctly attach the cover and light protection.

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Fault	Dualishia asses	Caladian
Fault	Probable cause	Solution
Blue communication indi- cator flashing	No connection between unit and computer	 Check the cables and cable connections. Enable the unit via the software. Enable or install the USB drivers.
	Unit data memory is full.	Check the software settings to make sure the system is ready and able to receive images. The image data is automatically transmitted from the unit to the imaging software.
Network connection has been disconnected	Connecting cable between device and computer not correctly connected	> Check the connecting cable.
	The IP address of the device is being used by another unit	Check the network settings (IP address and subnet mask) and assign a unique IP address to every device.
		Inform a service technician if the problem persists.

Appendix

14 Scanning times

The scanning time corresponds to the time taken for complete scanning of image data and depends on image plate format and pixel size.

The time to image will depend largely on the computer system used and its work load. 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

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Appendix

15 File sizes (uncompressed)

The actual file size will depend on the image plate format and the pixel size. File sizes stated are approximate and have been rounded upwards.

Suitable compression methods can considerably reduce the file size without 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 about EMC in accordance with EN 60601-1-2

16.1 General notes

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

16.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
$U_{\scriptscriptstyle T}$	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E,	Compliance level for the test in acc. with IEC61000-4-3
Р	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)
d	Recommended safety distance in metres (m)

16.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

Interference emission measurements	Compli- ance	Electromagnetic environment - guidelines
HF emissions in accord- ance with CISPR 11	Group 1	The unit uses HF energy exclusively for internal functions. For this reason, HF emissions are very low and it is unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Class B	The device is suitable for use in all facilities including those in living areas and areas that are directly connect-
Harmonics in acc. with IEC 61000-3-2	Not applica- ble	ed to the public mains electricity supply that also supplies buildings used for residential purposes.
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Not applica- ble	



Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference im- munity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull volt- age ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interrup- tions and fluctua- tions of the supply voltage in accord- ance with IEC 61000-4-11	$<5\%~U_{T}~(>95\%$ drop in U_{T}) for 1/2 period $40\%~U_{T}~(60\%~drop$ in U_{T}) for 5 periods $70\%~U_{T}~(30\%~drop$ in U_{T}) for 25 periods $<5\%~U_{T}~(>95\%~drop~in~U_{T})$ for 5 s	$ < 5\% \ U_{T} \ (> 95\%$ drop in U_{T}) for 1/2 period $ 40\% \ U_{T} \ (60\% \ drop$ in U_{T}) for 5 periods $ 70\% \ U_{T} \ (30\% \ drop$ in U_{T}) for 25 periods $ < 5\% \ U_{T} \ (> 95\% \ drop$ in U_{T}) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in ac- cordance with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at electrical frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 1: Resistance to electromagnetic interference (immunity) for all devices and systems



Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference im- munity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance varia- bles in accord- ance with IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	$[V_1] = 3 V$	$d = 1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3		$[E_{\scriptscriptstyle 1}] = 4 \; V/m$	$d = 0.9 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 1.8 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)



The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site^{8,b}

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

^a The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted theoretically. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

^b Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than [V,] V/m.



Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)			
	150 kHz to 80 MHz d = 1.2 ·√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 2: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1	The higher frequency range	applies for 80 MHz and 800 MHz.
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Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic

waves is affected by absorption and reflection on the building, objects and people.



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