VistaScan Combi View,
VistaScan Omni View,
VistaScan Pano View

EN

Installation and Operating Instructions

CE

2151100035L02

DÜRR DENTAL

1701V004SE

Contents

EN

Important information

Product description

Installation

Operation

EN

Troubleshooting

Appendix

1 About this document

These installation and operating instructions form 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 – dangerous high voltage


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.

CE labelling

Date of manufacture

Manufacturer

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

Do not reuse

Wear hand protection.

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

Comply with the specification in the accompanying documents.

REF Order number

SN Serial number

HIBC Health Industry Bar Code (HIBC)

1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

EN

2.1 Intended purpose

VistaScan Combi View, VistaScan Omni View, VistaScan Pano View

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

2.2 Intended use

VistaScan Combi View, VistaScan Omni View, VistaScan Pano View

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

The device may only be operated using accessories and optional accessories specified or approved by Dürr Dental.The unit may only be cleaned and disinfected using those disinfectants and cleaning agents specified or approved by Dürr Dental.

2.3 Improper use

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.

The unit is not designed for operation within the patient environment.

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.

The touch screen only shows a preview, which provides an initial impression of the X-ray image. For purposes of diagnosis the X-ray image must be viewed on a diagnostic monitor. The preview of the X-ray image on the touch screen is not suitable for the purposes of diagnosis.

2.4 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.5 Qualified personnel

Operation

Persons who operate the units 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

› When working on the units observe all the relevant electrical safety regulations.
› Never touch the patient and unshielded plug connections on the device at the same time.
› Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

› The appliance is designed for the use in health care establishments (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, potential effects on electromagnetic compatibility must be taken into account.
› Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "18 Information about EMC in accordance with EN 60601-1-2".

NOTICE
Negative effects on the EMC due to non-authorised accessories

› Use only Dürr Dental parts or accessories specifically approved by Dürr Dental.
› If other accessories are used, note any negative consequences to the function of the unit.

2.7 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
› Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.
The use of non-approved accessories, special accessories or non-genuine working parts / spare parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

2.8 Transport

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

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

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

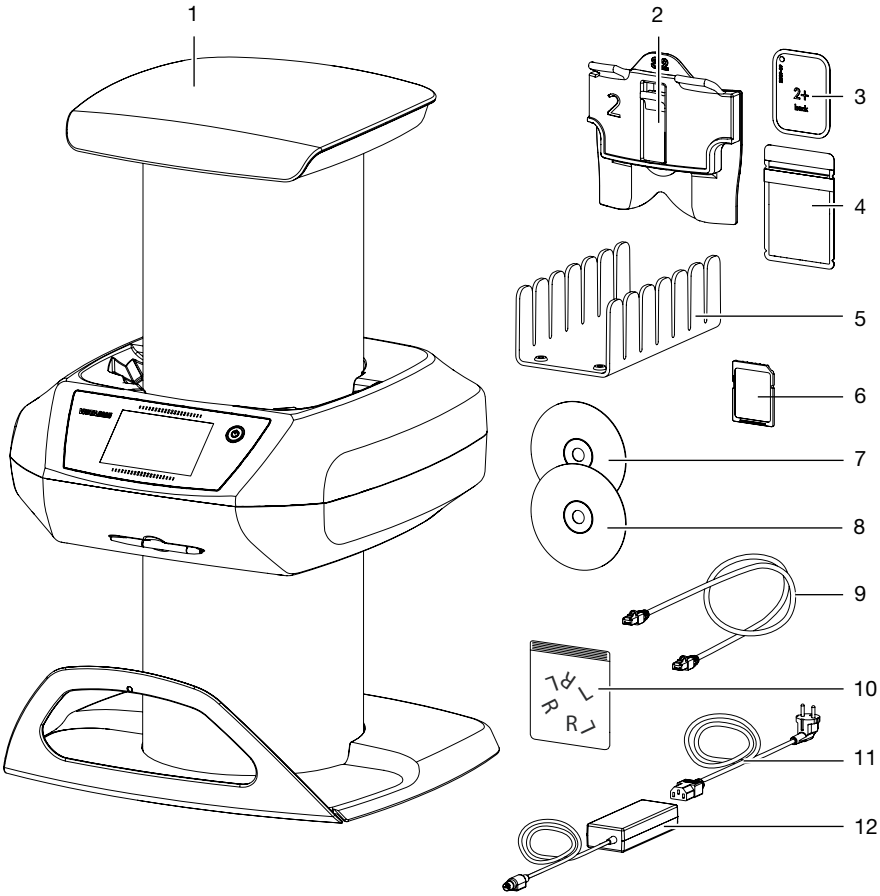
› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

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.

EN

3 Overview



1 VistaScan View Image plate scanner
2 Foil cassette, intraoral
3 Image plate intraoral
4 Light protection cover intraoral
5 Holding tray for intraoral foil cassettes
6 SDHC memory card
7 DBSWIN Imaging Software DVD
8 VistaSoft Imaging Software DVD
9 Network cable
10 Lead letters
11 Mains cable (country specific)
12 Power supply unit

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 Combi View
Image plate scanner 2151-01

– VistaScan View Basic unit
– Network cable
– SDHC memory card
– Stylus
– Collector mat
– Collector bar
– Power supply unit
– Mains cable (country specific)
– VistaSoft Imaging Software DVD
– DBSWIN Imaging Software DVD
– Lead letters
– Holding tray for intraoral foil cassettes
– Plus image plate:
  - Size 0 (2 pcs.)
  - Size 2 (4 pcs.)
– Foil cassettes:
  - Size 0 (2 pcs.)
  - Size 2 (4 pcs.)
– Light protection covers:
  - Size 0 (100 pcs.)
  - Size 2 (300 pcs.)
– Image plate cleaning wipes (10 pcs)
– Installation and operating instructions
– Quick start instructions

VistaScan Pano View
Image plate scanner 2151-11

– VistaScan View Basic unit
– Network cable
– SDHC memory card
– Stylus
– Collector mat
– Collector bar
– Power supply unit
– Mains cable (country specific)
– VistaSoft Imaging Software DVD
– DBSWIN Imaging Software DVD
– Lead letters
– Installation and operating instructions
– Quick start instructions

VistaScan Omni View
Image plate scanner 2151-21

– VistaScan View Basic unit
– Network cable
– SDHC memory card
– Stylus
– Collector mat
– Collector bar
– Light protection screen
– Power supply unit
– Mains cable (country specific)
– VistaSoft Imaging Software DVD
– DBSWIN Imaging Software DVD
– Lead letters
– Holding tray for intraoral foil cassettes
– Plus image plate:
  - Size 0 (2 pcs.)
  - Size 2 (4 pcs.)
– Foil cassettes:
  - Size 0 (2 pcs.)
  - Size 2 (4 pcs.)
– Light protection covers:
  - Size 0 (100 pcs.)
  - Size 2 (300 pcs.)
– Image plate cleaning wipes (10 pcs)
– Installation and operating instructions
– Quick start instructions

3.2 Accessories

The following articles are necessary for the operation of the unit, depending on the application:

SDHC memory card 9000-134-18
Lead letters. 2130-005-00

Image plates

Plus image plate, size 0
2 x 3 cm (2 pcs.). 2130-040-50
Plus image plate, size 1
2 x 4 cm (2 pcs.). 2130-041-50
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 image plate, size 3
2.7 x 5.4 cm (2 pcs.). 2130-043-50
Plus image plate, size 4
5.7 x 7.6 cm (1 pc.). 2130-044-50
Plus ID image plate, size 0
2 x 3 cm (2 pcs.). 2130-040-60
Plus ID image plate, size 2
3 x 4 cm (4 pcs.). 2130-042-60

EN

Image plate for OPG
12.7 x 30.5 cm
inc. Foil cassette, extraoral 2130-050-00
Image plate for OPG
15 x 30 cm
inc. Foil cassette, extraoral 2130-051-00
Image plate for Ceph
18 x 24 cm
inc. Foil cassette, extraoral 2130-052-00
Image plate for Ceph
24 x 30 cm
inc. Foil cassette, extraoral 2130-053-00
Image plate for Ceph
20 x 24 cm
inc. Foil cassette, extraoral 2130-054-00
Image plate for Ceph
13 x 18 cm
inc. Foil cassette, extraoral 2130-055-00

Foil cassettes

Foil cassette size 0
2 x 3 cm (1 piece) 2130-010-00
Foil cassette size 1
2 x 4 cm (1 piece) 2130-011-00
Foil cassette size 2
3 x 4 cm (1 piece) 2130-012-00
Foil cassette size 3
2.7 x 5.4 cm (1 piece) 2130-013-00
Foil cassette size 4
5.7 x 7.6 cm (1 piece) 2130-014-00
Foil cassette OPG
12.7 x 30.5 cm 2130-021-00
Foil cassette OPG
15 x 30 cm 2130-022-00
Foil cassette Ceph
18 x 24 cm 2130-023-00
Foil cassette Ceph
24 x 30 cm 2130-024-00
Foil cassette Ceph
20 x 24 cm 2130-025-00
Foil cassette Ceph
13 x 18 cm 2130-026-00

Light protection covers

Light Protection Cover Plus size 0
2 x 3 cm (100 pcs.) 2130-080-00
Light Protection Cover Plus size 1
2 x 4 cm (100 pcs.) 2130-081-00
Light Protection Cover Plus size 2
3 x 4 cm (300 pcs.) 2130-082-00
Light Protection Cover Plus size 2
3 x 4 cm (1000 pcs.) 2130-082-55
Light Protection Cover Plus size 3
2.7 x 5.4 cm (100 pcs.) 2130-083-00
Light Protection Cover Plus size 4
5.7 x 7.6 cm (100 pcs.) 2130-084-00
Light Protection Cover Plus size 0,
white
2 x 3 cm (100 pcs.) 2130-080-50
Light Protection Cover Plus size 2,
white
3 x 4 cm (300 pcs.) 2130-082-50

3.3 Special accessories

The following optional items can be used with the device:

Wall bracket 2151-001-00
Retrofitting set Combi for VistaScan Pano View 2151-955-50
Storage box 2141-002-00
Bite protector, size 4 (100 pcs) . . . 2130-074-03
Network cable (5 m) 9000-118-036
Image plate and film holder system set 2130-981-50
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

X-ray cartridge without intensification plate, straight

X-ray cartridge without intensification plate, straight
12.7 x 30.5 cm 2130-993-01
X-ray cartridge without intensification plate, straight
15 x 30 cm 2130-993-02
X-ray cartridge without intensification plate, straight
18 x 24 cm 2130-993-03

Commissioning and intraoral constancy tests

Intra / Extra Digital test body 2121-060-54

Acceptance and consistency check extraoral

A test body holder must be ordered in addition to the test body set.

Test body sets

Test body set for Pano 2121-060-55
Test body set for Pano + Ceph . . . 2121-060-56

Test body holder

Test body holder for Sirona / Siemens Orthophos and Planmeca PM2002EC / CC Panorama devices 2130-994-05
Test body holder for Gendex, Philips, Soredex Panorama devices. 2130-994-06
Test body holder for instruments OP 100 / OP 10 2130-994-07
Ceph Universal test body holder . . 2130-996-00
Test body holder for Gendex SD / 9200. 2130-994-08

3.4 Disposable materials

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

Cleaning and disinfection

Image plate cleaning wipe (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 spare parts

Image plates

see "3.2 Accessories"

Foil cassette OPG/Ceph

see "3.2 Accessories"

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

4.1 Image plate scanner

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Electrical data for the device			
Voltage	V DC		24
Max. current consumption	A		5
Output	W		< 120
Type of protection			IP20

Electrical data – power supply unit			
Nominal voltage	V AC		100 - 240
Frequency	Hz		50/60
Max. current consumption	A		2.5

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		15

Noise level			
Standby	dB(A)		0
Ready to scan	dB(A)		approx. 37
During scanning	dB(A)		approx. 55

General technical data			
Dimensions (W x H x D)			
VistaScan Combi View, VistaScan Pano View	cm	38 x 63 x 41	
VistaScan Omni View	cm	38 x 71 x 41	
Weight			
VistaScan Combi View, VistaScan Pano View	kg	approx. 21	
VistaScan Omni View	kg	approx. 21.5	
Max. feeding width for image plates	cm		30
Heat output	W		< 140
Duty cycle S2 (in accordance with VDE 0530-1)	min		60
Duty cycle S6 (in accordance with VDE 0530-1)	%		70
Pixel size (selectable)	µm		12.5 - 130
Max. resolution (depending on image plate)	Line pairs/ mm (Lp/mm)		approx. 40

Network connection		
LAN technology		Ethernet
Default		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45
Type of connection		Auto MDI-X
Cable type		≥ CAT5
WLAN connection		
WLAN technology		802.11b/g
Encryption		WPA, WPA2
Memory card		
Type		SDHC
Maximum memory capacity	GB	32
File system		FAT32
Performance class	Class	≥ 4
Ambient conditions during operation		
Temperature	°C	+10 to +35
Relative humidity	%	20 - 80
Air pressure	hPa	750 - 1060
Height above sea level	m	< 2000
Ambient conditions during storage 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

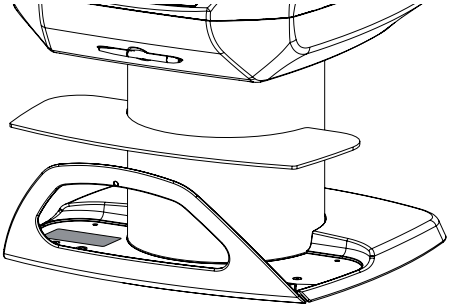
Classification		
Medical Devices Directive (93/42/EU)		Class IIa
Ambient conditions during operation		
Temperature	°C	18 - 45
Relative humidity	%	< 80
Ambient conditions during storage and transport		
Temperature	°C	< 33
Relative humidity	%	< 80
Dimensions of intraoral image plates		
Size 0	mm	22 x 35
Size 1	mm	24 x 40
Size 2	mm	31 x 41
Size 3	mm	27 x 54
Size 4	mm	57 x 76
Dimensions of image plates extraoral		
OPG 12,7 x 30.5	mm	125 x 286
OPG 15 x 30	mm	148 x 298
Ceph 13 x 18	mm	127 x 177
Ceph 18 x 24	mm	178 x 227
Ceph 20 x 24	mm	202 x 241
Ceph 24 x 30	mm	238 x 298

4.3 Light protection cover

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

4.4 Type plate

The type plate is located on the upper side of the device base plate.

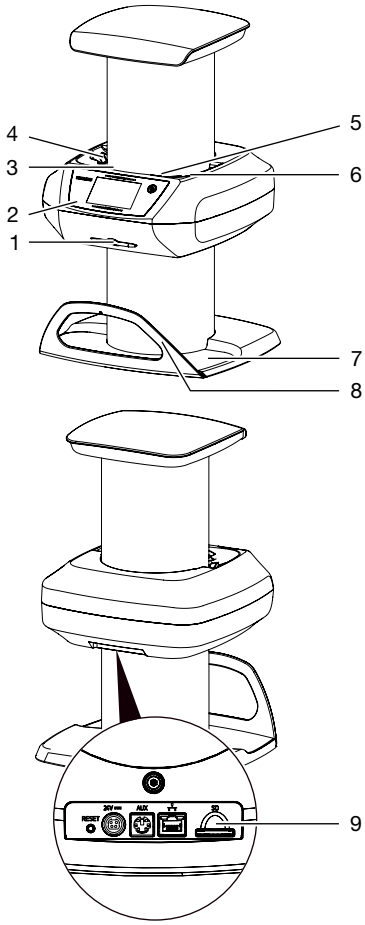


4.5 Conformity assessment

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 Stylus
2 Operating elements
3 - 6 Entry slots
7 Collector mat
8 Collector bar
9 Memory card slot

The image plate scanner is used to read image data stored on the image plate.

The unit can be used in two different ways: via the imaging software (e.g. VistaSoft) on a PC or directly via the touch screen on the unit.

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The transport mechanism guides the image plate through the unit. The image plate is read using a laser inside the scanner unit. The scanned data is converted into a digital image.

If a scanning job is started via the imaging software, the image is automatically transmitted to the computer.

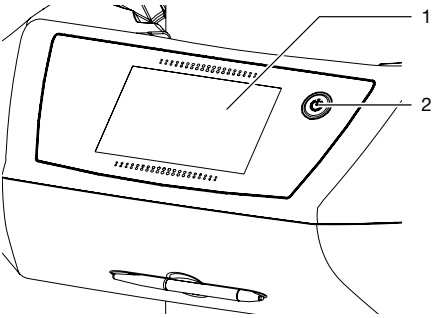
If a scanning job is started via the touch screen, the image is saved to the memory card and then needs to be transferred to the computer.

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.

The unit can scan up to four image plates (depending on the sizes) simultaneously with the same resolution.

Operating elements



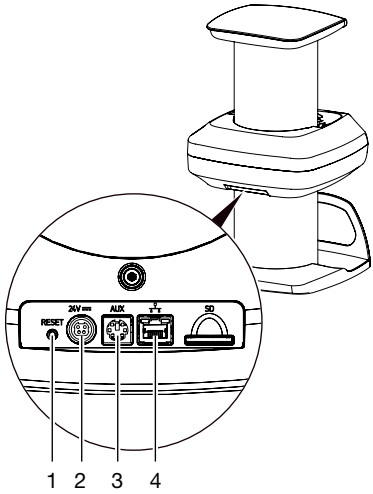
1 Touch screen
2 On / off switch

The touch screen allows the unit to be operated when it is not connected to a computer. Instructions can be entered on the touch screen either with the tip of a finger or the stylus.

The *Help* button can be used to open a help page for the relevant screen. The *Messages* button is used to call up current messages.

Connections

The connections are located on the rear of the unit.



1 Reset button
2 Connection for power supply unit
3 AUX connection for diagnostic units
4 Network connection with status LED

ScanManager

When the ScanManager is enabled, more than one X-ray job can be transmitted to the unit from different computers simultaneously. The unit manages the X-ray jobs in a waiting list from which the required X-ray job can be selected using the touch screen and then executed.

Without ScanManager the unit processes one image at a time and is blocked until this job has been completed. During this time no further X-ray jobs can be transmitted to the unit from other computers.

ScanManager can be enabled via *Settings* > *System Settings*> *Operating Mode*.

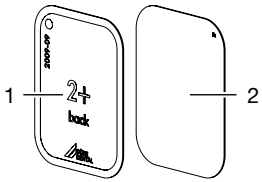
5.2 Image plate

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

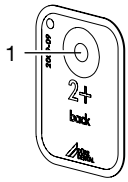


1	Inactive side	Black, printed with the word "back" and the size and manufacturer's information
2	Active side	Light blue, with positioning aid

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

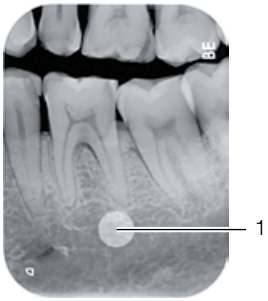
Exposure from the wrong side

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

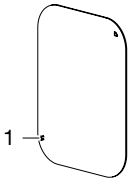
The image can be corrected by mirroring it in the software. If a diagnosis is not possible in the area of the marker then the image will need to be acquired again.

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



1 Hexadecimal code

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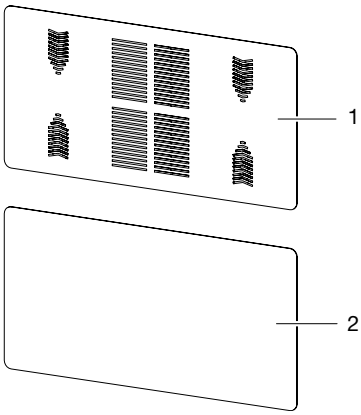
Extraoral



1	Inactive side	black, with manufacturer's information printed on it The surface is fitted with a "grip structure" which facilitates the insertion of the image plate from the foil cassette into the device.
2	Active side	White

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 Stylus

The touch screen can be operated using the stylus as an alternative to the tip of a finger.

5.5 Storage box (optional)

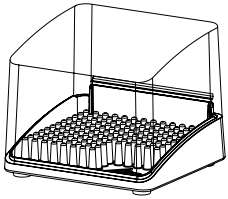
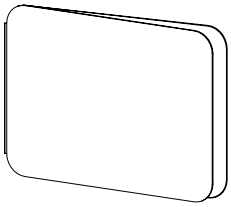


Image plates packaged in light protection covers can be stored in the storage box until they are next used. The storage box protects the image plate and the light protection cover against contamination and dirt.

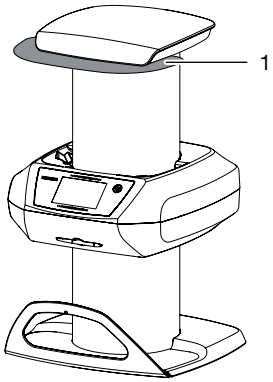
5.6 Bite protector (optional)



The bite protector protects the image plate size 4 as well as the light protection cover against heavy mechanical damage, e.g. if the patient bites down too hard during the X-ray exposure.

5.7 Light protection screen (only VistaScan Omni View)

The light protection screen reduces the amount of light falling entering the entry slot of the device.



1 Light protection screen

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 should 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".
– Do not select the installation location within the patient environment

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.

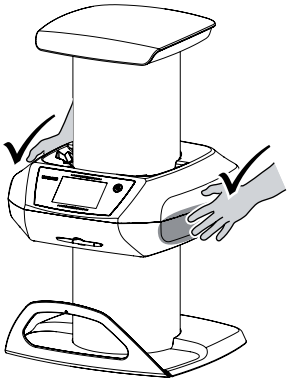
7 Installation

7.1 Carrying the unit

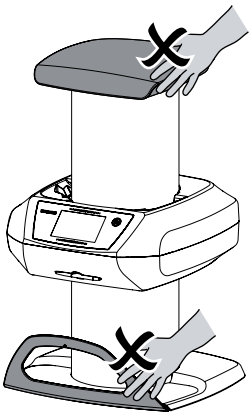
NOTICE
Risk of damage to sensitive components in the unit as a result of shocks or vibrations

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

› Only carry the unit by the transport drum on the sides.

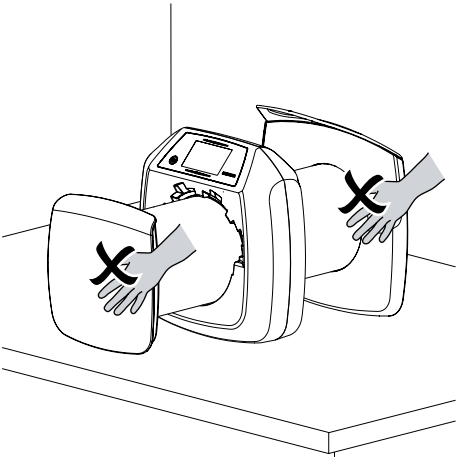


› Do not hold the device by its cover or collector bar.



EN

› Do not carry the unit on its side.



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.

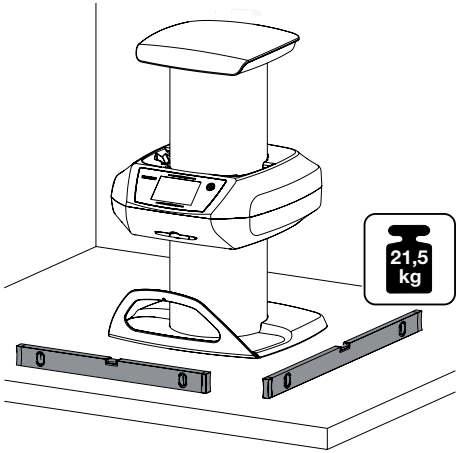
The unit can be set up as a tabletop unit or mounted on a wall using the wall bracket.

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

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.



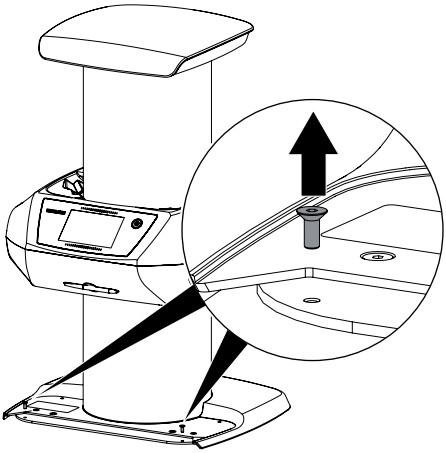
Installing the unit with the wall mounting bracket

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

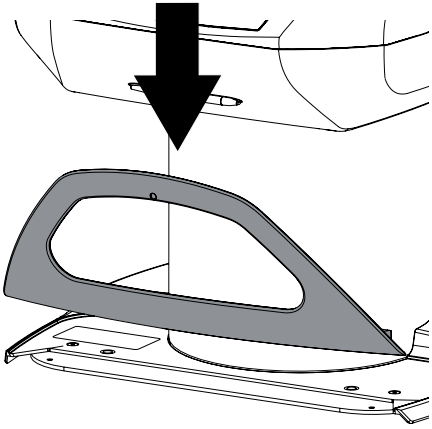
For installation refer to the installation instructions for the wall mounting (order number 9000-618-219)

7.3 Mount the connector bar

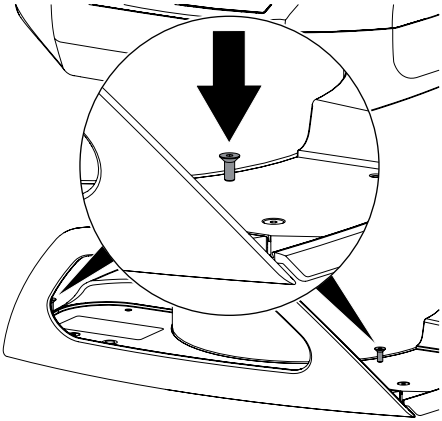
› Unscrew the screws from the base plate.



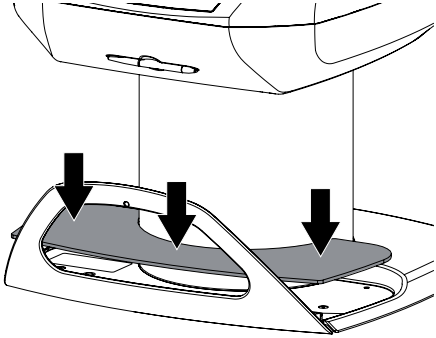
› Place the connector bar on the base plate.



› Fasten the connector bar to the base plate using the screws.



› Place the collector mat in the appropriate recess.

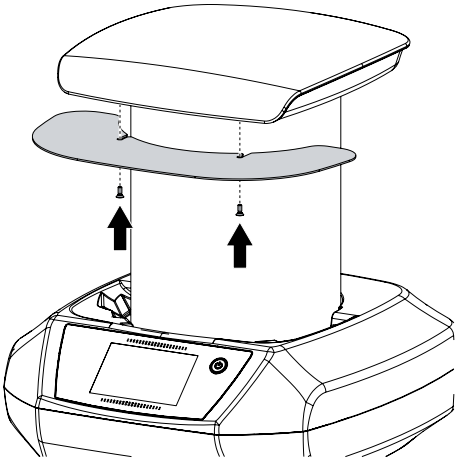


7.4 Mount the light protection screen (only VistaScan Omni View)

Some device designs requires the light protection screen for operation. This is included in the scope of delivery and must be mounted on the device.

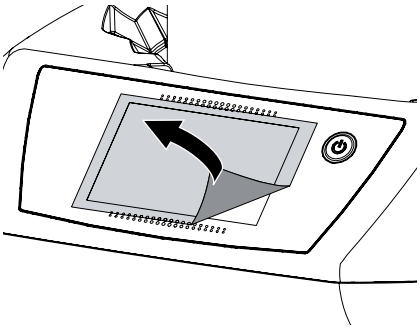
EN

› Place on the light protection screen and secure with the screws.



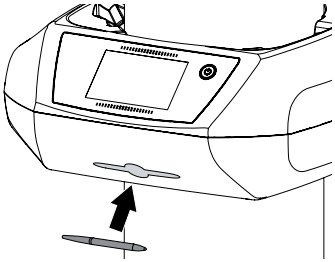
7.5 Removing the protective film from the touch screen

› Grasp one corner of the protective touch screen film and peel it off carefully.



7.6 Attaching the stylus

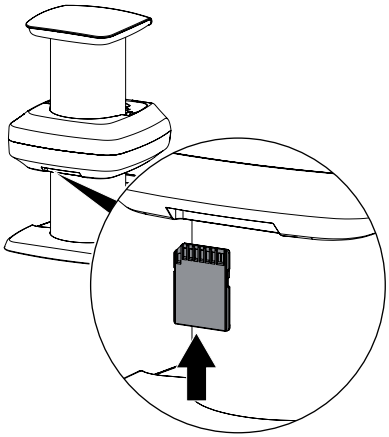
› The stylus is held on the unit by a magnet. Place the stylus in the indentation provided.



7.7 Checking the memory card

NOTICE
Loss of image data due to unexpected insertion or removal of the memory card
› Only insert or remove the memory card when unit is switched off.

› Check whether the memory card has been inserted in the unit correctly. If the memory card has been inserted in the unit incorrectly, take it out again and re-insert it properly.



7.8 Electrical connections

Electrical safety when making connections

› The unit 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.
› Before initial start-up check that the mains supply voltage and the voltage stated on the type plate match (see also "4. Technical data").

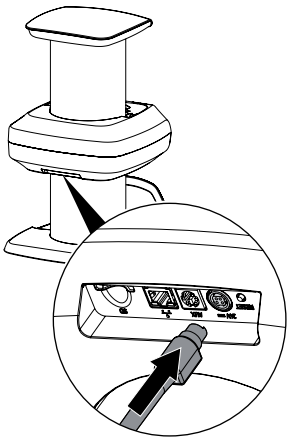
Connecting the unit to the mains

The unit has no main power switch. For this reason the unit must be set up in such a way that the power outlet is easily accessible so that the unit can be unplugged if necessary.

Requirements:

– Properly installed power outlet close to the unit (max. mains cable length 3 m)
– Easily accessible power outlet
– Mains voltage must match the information shown on the type plate of the power supply unit

› Plug the mains cable (included in the scope of delivery) into the power supply.
› Plug in the connecting plug of the power supply unit into the socket connection of the device.



› Plug the mains plug into the power outlet.
The connection plug has a lock. To unplug the unit, slide back the plug housing. Do not pull on the cable.

7.9 Connecting the unit to the network

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

The unit can be connected to the network with a network cable or via WLAN.

For information on connection via WLAN see "8.1 Installing and configuring the unit".

Combining devices safely

› 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.

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 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.

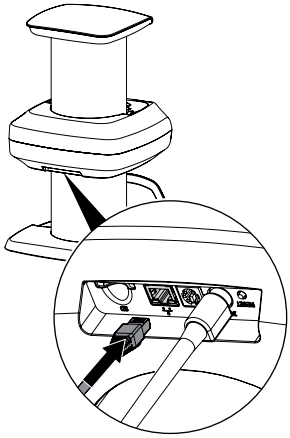
› Always comply with the relevant requirements from of IEC 60601-1-1 (EN 60601-1-1) when connecting the unit to other appliances, e.g. to a computer system, both inside and outside of the patient environment.

› 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

› Connect the supplied network cable to the network connection of the device.



8 Commissioning and first start-up

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.

8.1 Installing and configuring the unit

The device supports the following imaging programs:

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

Configuring the network

› Switch on the network devices (router, PC, and switch).

› Check that TCP port 2006 and UDP port 514 are enabled in the firewall; release them if necessary.

If you are using the Windows firewall, you do not need to check the ports since you will be asked whether you want to enable them during the driver installation process.

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

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	Service
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

[1] The port can vary depending on the configuration.

Configuring WLAN on the unit

If the unit is to be operated via WLAN, the connection to the unit needs to be configured.

In order to establish a secure WLAN connection, we recommend encrypting the WLAN network with WPA2.

The quality and transmission range of the WLAN connection can be reduced by environmental conditions (e.g. thick walls, other WLAN devices). When selecting a suitable location for set up, take the signal strength into consideration.

Requirements:

– You need to be registered on the unit as Administrator or Service Technician (***Settings*** > ***Access Levels*** > ***Administrator/Service Technician)***.

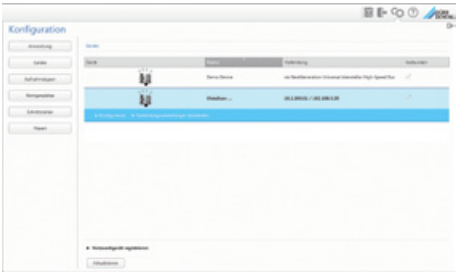
› Check the WLAN settings with you Network Administrator.
› Tap the following on the touch screen: ***Settings*** > ***System Settings*** > ***Network***.
› Under ***Interface*** select the option ***WLAN*** and confirm with ***OK***.
› Configure the WLAN.
› Confirm with ***OK***.

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.

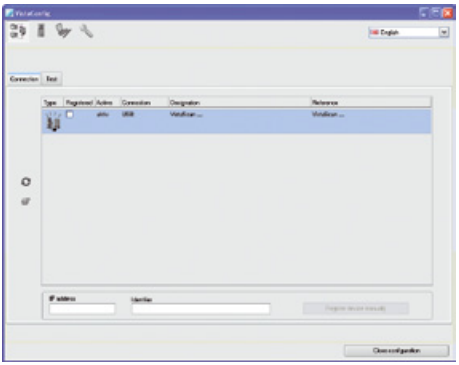
› Open VistaSoft.
› Create an X-ray station for the connected unit.
› Log-in the demo patient (patient ID: DEMO0001).
› Select the image type (e. g. Intraoral).
› Scan an image plate, see "11.2 Scanning the image data via a computer".

Configuring the appliance in DBSWIN

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

EN

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



› Click .

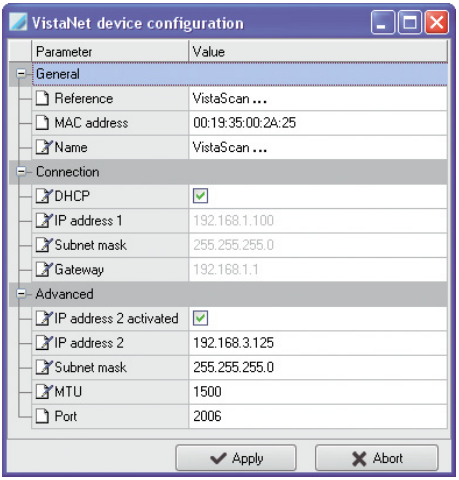
The list of connected units is updated.

› Activate the connected unit in the *Registered* column.

You can also register multiple units.

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

› Click .



› 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.

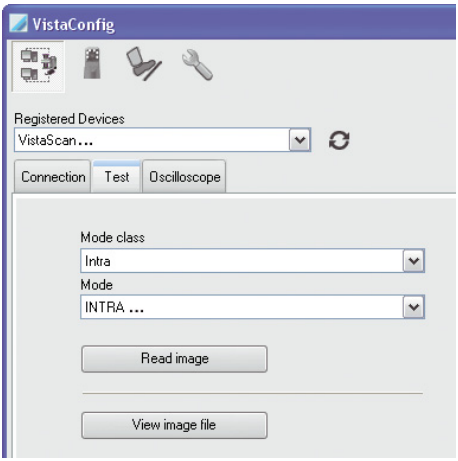
› Click on *Apply*.

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 Devices* list.

› Select the mode class.

› Select the mode.

› Click on *Scan Image*.

› Scan an image plate, see "11.2 Scanning the image data via a computer".

8.2 Prepare the X-ray cartridge for an extraoral image plate

The existing X-ray cartridges used with X-ray film can be retrofitted to enable the use of image plates.

› Remove all intensification plates from the X-ray cartridge.
› Remove the type plate of the X-ray film from the X-ray cartridge.
› Record the serial number, date of manufacture and day of commissioning on the type plate of the image plate included in the scope of delivery.
› Adhere the type plate to the X-ray cartridge.
Do not apply the type plate to the side of the X-ray cartridge pointing to the X-ray tube assembly.

8.3 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.

EN

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					
	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	mGycm²	60 kV	mGycm²	60 kV	mGycm²
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
Bitewing	0.18 s	32.9	0.18 s	7.0	0.18 s	14

	DC emitter, 6 mA Tube length 30 cm					
	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	70 kV	mGycm²	70 kV	mGycm²	70 kV	mGycm²
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
Bitewing	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					
	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	mGycm²	60 kV	mGycm²	60 kV	mGycm²
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
Bitewing	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 limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	70 kV	mGycm²	70 kV	mGycm²	70 kV	mGycm²
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

	DC emitter, 6 mA Tube length 30 cm					
	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	70 kV	mGycm²	70 kV	mGycm²	70 kV	mGycm²
Molars	0.14 s	12.8	0.14 s	2.7	0.14 s	5.4
Bitewing	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.

Extraoral X-ray units

Most extraoral X-ray units can be operated using the same settings as for analogue films. The sensitivity of the image plate scanner has been optimised for film-foil system of the class 200.

› Set the X-ray unit to sensitivity class 200 (film-foil system).

› If the x-ray unit does not use the sensitivity class to 200 (film-foil system), adapt the sensitivity of the image plate scanner using the HV-settings.

Consult Dürr Dental for the precise settings.

› If deviations occur (see "14.1 Poor X-ray image"), adapt the image plate scanner to the x-ray unit (e. g. HV-setting, scanning mode).

8.4 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.

EN

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

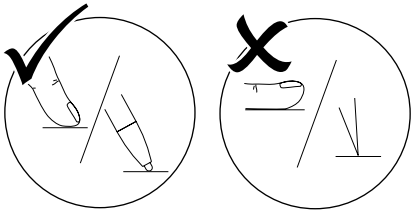
› Carry out the electrical safety check according to the national law (e. g. in accordance with IEC 62353).
› Document the results.

9 Operating the touch screen

NOTICE
Damage to the touch screen due to incorrect handling

- Only operate the touch screen using your fingertips or the stylus.
- Do not use a sharp instrument (e.g. ballpoint pen) to operate the touch screen.
- Protect the touch screen against water.

› Operate the touch screen by tapping it with a fingertip or the stylus to select a menu or input field.



› For further information about any window tap on the *Help* field.

9.1 Navigating

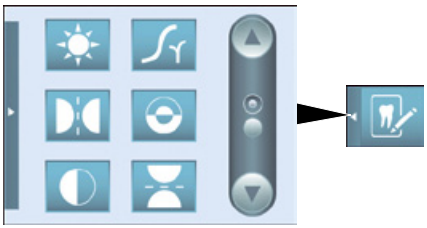
If the contents of the window cannot be completely displayed on the touch screen, a scroll bar appears.

› Tap ▼ or ▲ to move the displayed section of the window.

9.2 Using menus

The integrated menus within the main window contain additional commands, which can be selected as required.

› To open the menu, touch ◀.



› Select a command.

9.3 Entering text in the field

› If an input is required, you can type information into the relevant field.

The keyboard-window will open.

123	Switch to numbers/special characters
⇧	Shift key
äöü àêó	Switch to German mutated vowels ("umlauts")
⇦	Delete
✕	Cancel input and close keyboard
✓	Confirm input and close keyboard
␣	Space bar

EN

9.4 Calling up messages on the touch screen

The *Messages* view shows an overview of all previous messages. Here, the messages are divided into the following categories:

Fault	Unit will no longer function. When the error has been remedied, it may be necessary to acknowledge the error message.
Notice	After acknowledgement the unit will continue to work, but only with limited functions.
Information	Important information for the operator, e.g. about the current status of the device. The unit continues to operate.
Note	Information for the operator. The unit continues to operate.
Normal operation	

› Tap on *Messages*.

The message is displayed. If there are several messages, the most current with the highest priority is displayed first.

› For more information about the message, touch *Help*.

10 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.

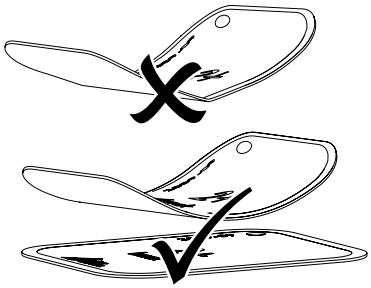
› Only place image plates in the patient's mouth in a light protection cover.

› Do not swallow the image plate or parts of it.

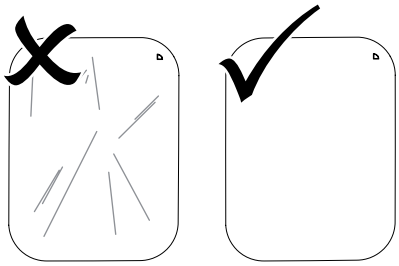
› If the image plate or parts of it have been swallowed, consult a specialist doctor immediately and remove the image plate.

› 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 "12 Cleaning and disinfection").

11 Operation

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.

11.1 X-ray

Intraoral 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
– Foil cassette of 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 "11.4 Erasing the image plate").

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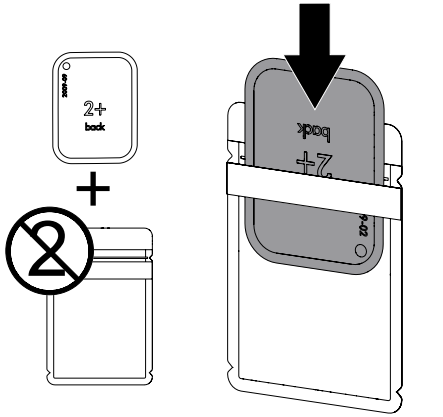
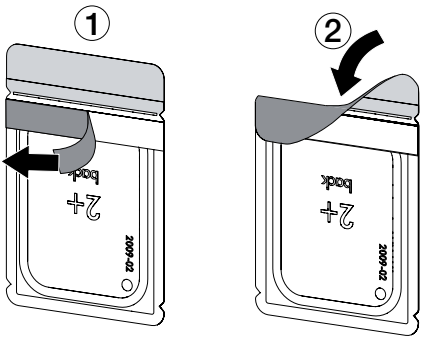
› Completely slide the image plate into the light protection cover. The black (inactive) side of the image plate must be visible.

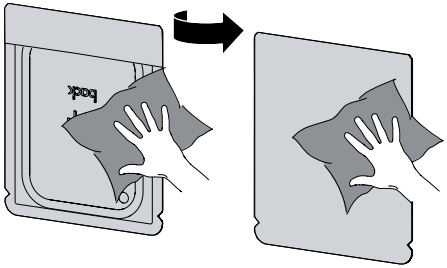


› Pull off the adhesive strip, fold down the flap and close the light protection cover tightly by pressing together firmly.



› 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 FD 366 sensitive) can be used on a soft, lint-free wipe.



› In the case of image plates Plus size 4, place the bite protector around the light protection cover with image plate if necessary.

Taking the X-ray

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

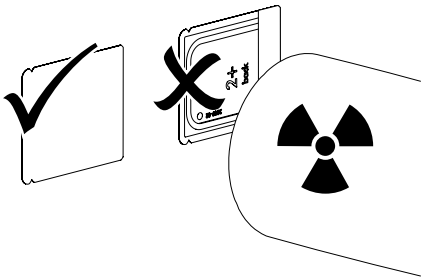
› Only use holding systems that will not damage the light protection cover or the image plates in any way.

› Do not use holding systems with sharp edges.

Wear hand protection.

› 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 "8.3 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

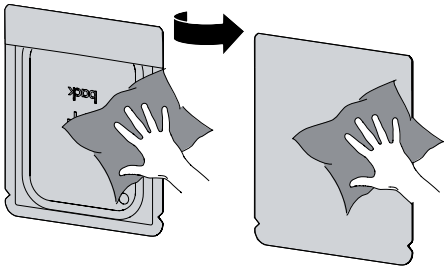
› Never handle exposed image plates without either a light protection cover or a foil cassette.

Wear hand protection.

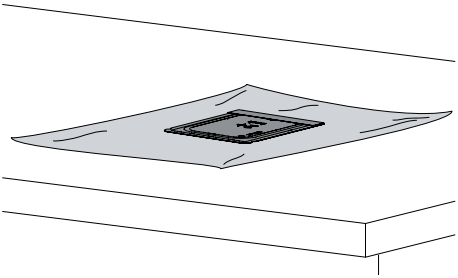
› Remove the image plate with the light protection cover from the patient's mouth.

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 FD 366 sensitive) can be used on a soft, lint-free wipe.



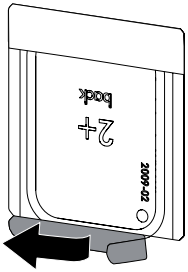
› Place the light protection cover with the image plate on the disinfection wipe.



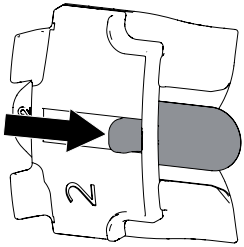
› Allow the light protection cover to fully dry.
› Pull off the protective gloves, disinfect and clean the hands.

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.

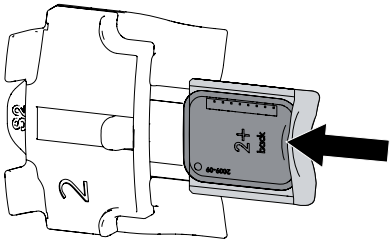
› Tear off the light protection cover.



› Slide the lever on the foil cassette downwards to its fullest extent. The tongue must be completely visible.



› Place the image plate in the light protection cover on the tongue. The inactive side must be visible.
› Immediately slide the image plate out of the light protection cover to its fullest extent and into the foil cassette.



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Extraoral X-ray

The procedure is described using an image plate Plus OPG as an example.

Required accessories:

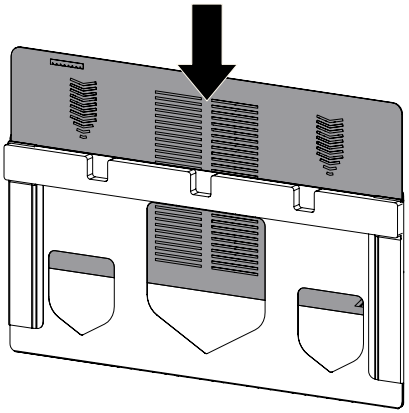
– Image plate
– Foil cassette of the same size as the image plate
– X-ray cartridge without intensification plate, (see "3.3 Special accessories" or "8.2 Prepare the X-ray cartridge for an extraoral image plate")

If the image plate for Ceph 24 x 30 cm is to be used, the device must be fitted with the retrofitting set Omni (see "3.3 Special accessories").

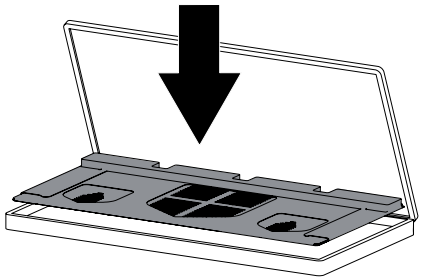
Preparing the X-ray

– The image plate has been cleaned.
– The image plate is not damaged.

› If using it for the first time or if it has been stored for over a week: erase the image plate (see "11.4 Erasing the image plate").
› Slide the image plate completely into the flexible foil cassette. The black (inactive) side of the image plate must be visible.



› Insert the foil cassette in the X-ray cartridge. The foam rubber side of the foil cassette must point in the direction of the cover of the X-ray cartridge.



› Where required, mark the correct position of the image plate (left or right side) with the lead letters included in the scope of delivery.

Taking the X-ray

› Insert the X-ray cartridge into the x-ray unit.
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 "8.3 X-ray unit settings").
› Record an X-ray image.
The image data must be scanned within 30 minutes.

11.2 Scanning the image data via a computer

Starting the image plate scanner and software

The reading-out process using the VistaSoft imaging software is described.
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.
› Launch VistaSoft .
› Select the patient.
› Select the corresponding image type in the menu bar.
› Select the device.
› Set acquisition mode.
Recording starts directly.
› When ScanManager is enabled the X-ray jobs can be selected via the touch screen of the unit.

Result:

The touch screen will display an animated visual symbol requesting insertion of the image plate.

Only insert the image plate when the bar above the animated sequence has turned to green.

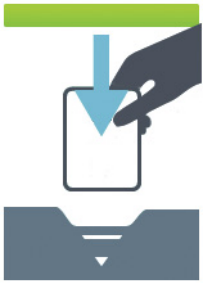
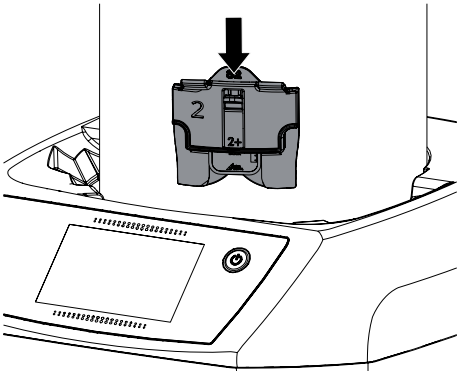


Figure 1: Example of the animation requesting insertion of the image plate

Read-in an intraoral image plate

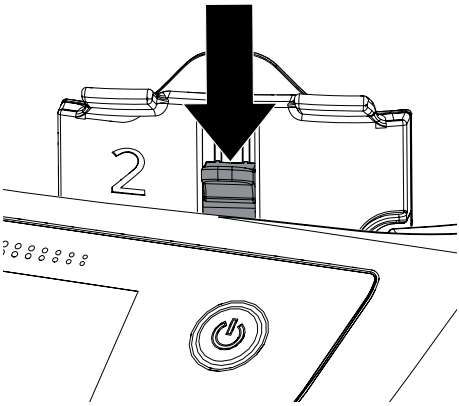
In order not to mix up X-ray exposures, only scan X-ray images from the selected patient.

› Place a foil cassette with an image plate into one of the free entry slots on the transport drum until it engages.



CAUTION
Loss of image data caused by light entering the device
› Remove the foil cassette only after the image plate has dropped into the collecting tray.

› Press down the lever down until the image plate is automatically drawn in.



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Scanning progress is displayed on the touch screen. The image data is saved automatically.

The touch screen only shows a preview, which provides an initial impression of the X-ray image. Limitations to image previews occur due to image size and/or exposure conditions. For purposes of diagnosis the X-ray image must be viewed on a diagnostic monitor.

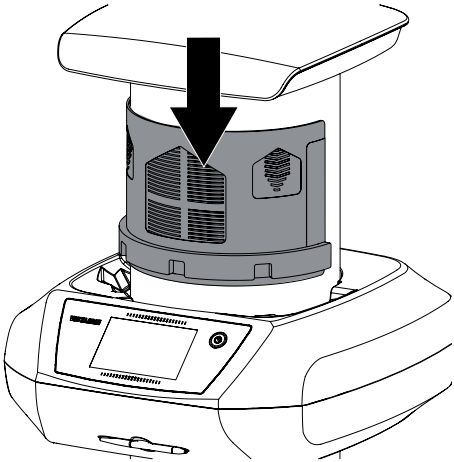
After it has been scanned, the image plate is erased and drops into the collecting tray.

› Save the X-ray image.
› Remove the image plate and prepare it for taking a new X-ray.
› Remove the foil cassette after the insertion status LED of the entry slot on the touch screen switches to green.

Read in the extraoral image plate

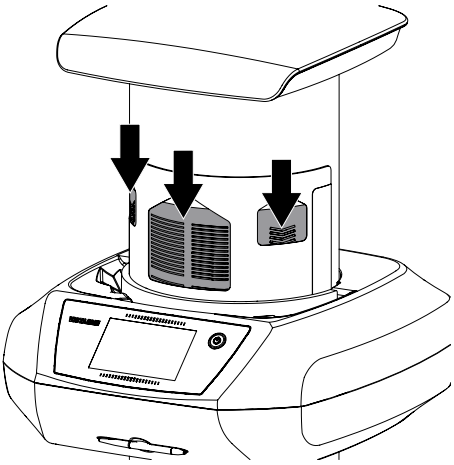
In order not to mix up X-ray exposures, only scan X-ray images from the selected patient.

› Remove the foil cassette from the X-ray cartridge.
› Place the foil cassette with the image plate in the entry slot of the transport drum.



CAUTION
Loss of image data caused by light entering the device
› Remove the foil cassette only after the image plate has dropped into the collecting tray.

› Place the fingers on the printed surface of the image plate at the same time pushing downwards until the image plate is drawn in automatically.



Scanning progress is displayed on the touch screen. The image data is saved automatically.

The touch screen only shows a preview, which provides an initial impression of the X-ray image. Limitations to image previews occur due to image size and/or exposure conditions. For purposes of diagnosis the X-ray image must be viewed on a diagnostic monitor.

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

› Save the X-ray image.
› Remove the image plate and prepare it for taking a new X-ray.
› Remove the foil cassette.

11.3 Scanning image data via the touch screen on the unit

Starting the image plate scanner

When scanning the image data via the touch screen, there is no need for a PC connection. The image data is stored locally on the memory card. In order to transfer the image data to the imaging software, the unit must be connected to a computer.

Scanning via the touch screen can be done in two ways:

Scanning:
Before scanning the image data, the patient data and exposure settings of the image are entered and then saved with the image data.

If no patient data and exposure settings of the image are entered then the image is saved to a folder with date and time.

Rapid scanning:
The image data is saved to a folder with the date and time and no additional information.

Use *Help* on the touch screen for further information on operating the unit via the touch screen.

Requirements:

– Memory card (SDHC, max. 32 GB) in the slot on the unit.

› Press ⏻ to switch on the unit.

Start scanning:

› On the touch screen tap on *Scan*.

› Enter the patient data.

› Select the image settings and scanning mode.

The touch screen will display an animated visual symbol requesting insertion of the image plate.

Only insert the image plate when the bar above the animated sequence has turned to green.

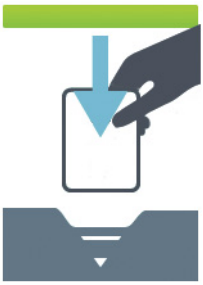


Figure 2: Example of the animation requesting insertion of the image plate

Start rapid scanning:

› On the touch screen tap on *Rapid scan*.

› Select the scanning mode.

The touch screen will display an animated visual symbol requesting insertion of the image plate.

Only insert the image plate when the bar above the animated sequence has turned to green.

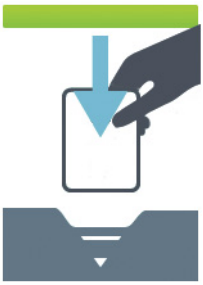


Figure 3: Example of the animation requesting insertion of the image plate

Read-in an intraoral image plate

In order not to mix up X-ray exposures, only scan X-ray images from the selected patient.

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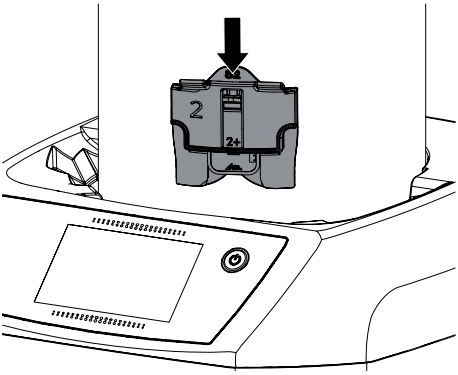
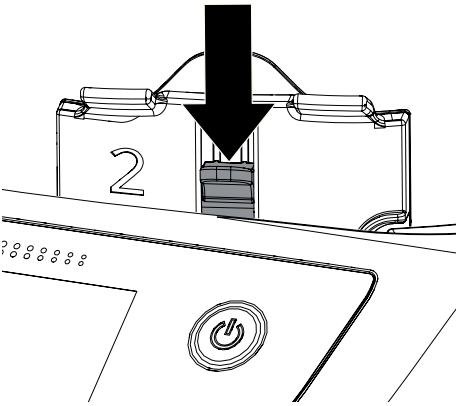
› Place a foil cassette with an image plate into one of the free entry slots on the transport drum until it engages.



CAUTION
Loss of image data caused by light entering the device

› Remove the foil cassette only after the image plate has dropped into the collecting tray.

› Press down the lever down until the image plate is automatically drawn in.



Scanning progress is displayed on the touch screen. The image data is saved automatically.

The touch screen only shows a preview, which provides an initial impression of the X-ray image. Limitations to image previews occur due to image size and/or exposure conditions. For purposes of diagnosis the X-ray image must be viewed on a diagnostic monitor.

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

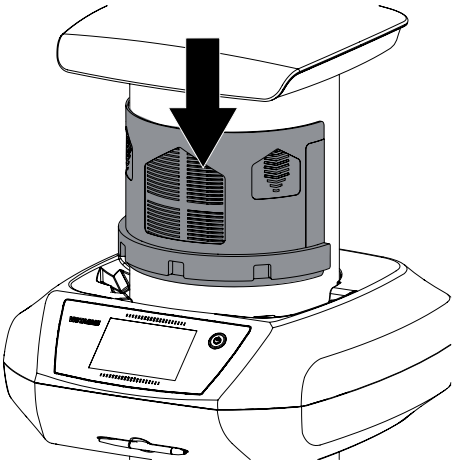
› Save the X-ray image.
› Remove the image plate and prepare it for taking a new X-ray.
› Remove the foil cassette after the insertion status LED of the entry slot on the touch screen switches to green.

Read in the extraoral image plate

In order not to mix up X-ray exposures, only scan X-ray images from the selected patient.

› Remove the foil cassette from the X-ray cartridge.

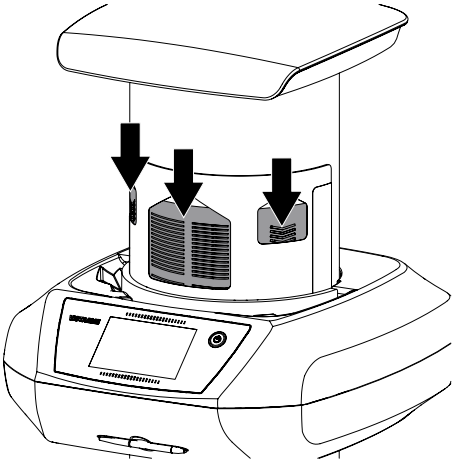
› Place the foil cassette with the image plate in the entry slot of the transport drum.



CAUTION
Loss of image data caused by light entering the device

› Remove the foil cassette only after the image plate has dropped into the collecting tray.

› Place the fingers on the printed surface of the image plate at the same time pushing downwards until the image plate is drawn in automatically.



Scanning progress is displayed on the touch screen. The image data is saved automatically.

The touch screen only shows a preview, which provides an initial impression of the X-ray image. Limitations to image previews occur due to image size and/or exposure conditions. For purposes of diagnosis the X-ray image must be viewed on a diagnostic monitor.

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

› Save the X-ray image.

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

› Remove the foil cassette.

Transmitting image data to the computer

X-ray images generated via the touch screen on the unit are saved to the SD card. These X-ray images can be imported to the imaging software via a network connection (e.g. VistaSoft).

› Connect the unit to the network.

› Start the imaging software.

› Start the image import via the imaging software (further information can be found in the manual of the imaging software).

› Save the image data.

The image data on the memory card is erased automatically as soon as the transfer has been successfully completed.

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11.4 Erasing the image plate

The image data is automatically erased after scanning.

If you do not want the image data to be erased, this function can be disabled for the current scanning process by selecting *Disable erasing light* on the touch screen of the unit.

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).

Erasing the image plate via a computer

› Select the special *ERASE* mode in the software.
› Scan the image plate (see "11.2 Scanning the image data via a computer").

Erasing the image plate via the touch screen

› On the touch screen tap on *Rapid scan*.
› Select the scanning mode *ERASE*.
› Scan the image plate (see "11.3 Scanning image data via the touch screen on the unit").

11.5 Switch off the unit.

› Press the on/off switch ⏻ for 3 seconds.

As soon as the unit has shut down it switches off completely. The touch screen is off.

12 Cleaning and disinfection

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

– FD 322 Quick-acting surface disinfection
– FD 333 Quick-acting surface disinfection
– FD 350 Disinfection wipes
– FD 366 sensitive Quick-acting surface disinfection

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 safety gloves.

12.1 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 cloth. Comply with the operating instructions for the disinfectant when doing this.

12.2 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 cloth. Comply with the operating instructions for the disinfectant when doing this.

› Allow the light protection cover to completely dry before using it.

12.3 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.

12.4 Foil cassette

The foil cassette can be cleaned disinfected with disinfectant wipes. Alternatively, the foil cassette can also be disinfected in an immersion disinfection system.

Use the following cleaning agents and disinfectants for immersion disinfection:

– ID 212 forte Instrument disinfection

NOTICE
Heat damages the foil cassette

› Do not steam sterilise foil cassettes.

› Remove any soiling from both sides of the foil cassette with a soft, damp, lint-free wipe.

› Disinfect the foil cassette 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.

Intraoral foil cassettes can also be disinfected in a disinfectant bath.

› Allow the foil cassettes to dry fully before use.

12.5 Stylus

The stylus can can be cleaned in the same way as the unit (see "12.1 Image plate scanner").

13 Maintenance

13.1 Recommended maintenance schedule

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

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 operation of the device with 25 intraoral and 10 extraoral images per day and 220 working days per year.

Maintenance interval	Maintenance work
Annually	› Visually inspect the device.
	› Check the image plates and foil cassettes for scratches, and replace if necessary.
	› Check the light protection brushes, cut any protruding hairs and remove them.
	› Check the belt drives, transport belts and springs, and replace if necessary.
	› Disassemble the transport drum.
	› Remove dust and dirt from accessible parts.
	› Mount the transport drum.
	› Carry out a system check.
Every 3 years	› Replace the pressure roller unit.
	› Replace the transport belts and tension springs.
	› Replace the toothed belt.

14 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).

14.1 Poor X-ray image

Fault	Probable cause	Solution
X-ray image does not appear on the monitor after the scanning	Image plate not fed in straight and inactive side scanned	› Scan the image plate again immediately while feeding it in correctly.
	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 image plate.
	X-ray unit is faulty	› Inform a service technician.
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.
X-ray image is mirror-inverted	Image plate not inserted straight in foil cassette or light protection cover.	› Insert image plate correctly.
	Image plate not placed straight.	› Position the image plate correctly.

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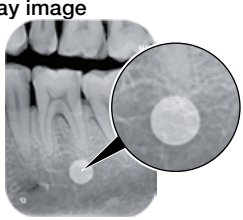
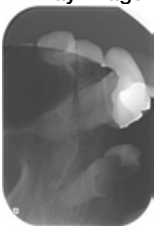
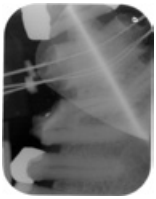
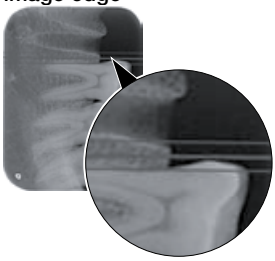
Fault	Probable cause	Solution
Round shadow on the X-ray image 	Plus ID image plate (with marker) exposed on the wrong side	› When taking an X-ray, make sure that the active side faces towards the X-ray tube.
Ghosting or double exposure on X-ray image 	Image plate exposed twice	› Only expose the image 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.
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.
		› Check X-ray tube.
	Faulty edge masking in imaging software	› Deactivate edge masking.

Fault	Probable cause	Solution
Software unable to combine the data to make a complete image	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.
X-ray image has strips on image	Image plate has been pre-exposed, 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 scanning 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.
Horizontal, grey lines on the X-ray image, extending beyond the left and right image edge 	Transport slipping	› Clean transport mechanism, replace belts if necessary.

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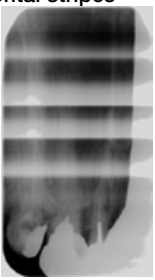
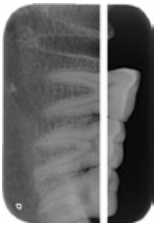
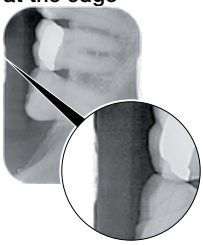
Fault	Probable cause	Solution
X-ray image is stretched lengthwise with bright, horizontal stripes 	Incorrect light protection cover or image plate used	› Only use original accessories.
X-ray image split vertically into two halves 	Dirt in the laser slit (e.g. hair, dust)	› Clean the laser slit.
X-ray image with small bright spots or clouding	Micro scratches on the image plate	› Replace the image plate.
Lamination of the image plate becoming detached at the edge 	Incorrect retainer system used	› Only use original image plates and film retainer systems.
	Image plate handled incorrectly.	› Use the image plate correctly. › Observe the operating instructions for the image plates and film retainer systems.

14.2 Software error

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.
"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.

Fault	Probable cause	Solution
Imaging software does not recognise the unit	Unit not switched on	› Switch on the device.
	Connecting cable between unit 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 unit is being used by another appliance.	› Check the network settings (IP address and subnet mask) and assign a unique IP address to every appliance. › Inform a service technician if the problem persists.
The unit does not appear in the options list in VistaConfig	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 unit IP address is being used by another appliance.	› Check the network settings (IP address and subnet mask) and assign a unique IP address to every appliance. › 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.
Error during data transmission between unit and computer. Error message "CRC error timeout"	Connecting cable used is incorrect or too long	› Only use original cables.

14.3 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 touch screen does not light up, replace the power supply.
		› 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 supply voltage.
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 procedure has finished.
	Unit is blocked by the firewall	› Enable the ports for the unit in the firewall settings.
Unit is on, but there is no display on the touch screen	Touch screen initialisation fault	› Switch the unit off and back on again.
	Touch screen brightness set too dark	› Update the firmware. › Increase the brightness of the touch screen.
	Touch screen defective	› Inform a service technician.

14.4 Error messages on the touch screen

Fault	Probable cause	Solution
Error code 1008	Connection interrupted	› Update the firmware.
Error code 1010	Temperature of unit too high	› Allow the unit to cool down. › Inform a service technician.
Error code 1022	Subassembly not initialised	› Fault in software, update the software if required. › Inform a service technician.
Error code -1024	Internal data communication fault	› Switch the unit off and back on again. › Update the firmware. › Darken the room. › Turn the unit so that no light can fall directly into the entry slot.
Error code -1026	Incorrect acquisition mode	› Select a different acquisition mode › Inform a service technician. › Update the firmware. › Reset the scanning modes to the factory settings via the unit interface or the Imaging Software.
Error code 1100	Permitted time for scan process exceeded	› Inform a service technician. › Check the belt drive. › Check for blockage, remove image plate from unit.
Error code 1104	Erasure unit fault	› Inform a service technician. › Replace the erasure unit.
Error code 1153	Unit fault	› Switch the unit off and back on again. › Update the firmware.
Error code 1154	Internal data communication fault	› Switch the unit off and back on again. › Update the firmware.
Error code 1160	Final radiation deflector rotation speed not attained	› Inform a service technician. › Update the firmware. › Replace the radiation deflector subassembly if the problem occurs regularly.
Error code 1170	SOL sensor timeout Fault on the laser, SOL sensor or radiation deflector assembly	› Inform a service technician. › Update the firmware.
Error code -1172	SOL sensor timeout Fault on the laser, SOL sensor or radiation deflector assembly	› Inform a Service Technician. › Update the firmware.

Fault	Probable cause	Solution
Error code 10000	Unit exposed to too much light	› Darken the room. › Turn the unit so that no light can fall directly into the entry slot.
Error code 10009	Internal communication error warning; unit remains ready for operation	› Update the firmware.
Error code 10017	Unit shutting down	› Wait until the unit has shut down completely.
Error code 2	System error during startup of the unit	› Switch the unit off and back on again. › Update the firmware.
Error code 78	Memory card full	› Transfer the image data to the computer. › Insert an empty memory card.
	Fault during memory cleanup	› Press and hold the reset button while switching on the unit.
		› Update the firmware. › Press and hold the reset button while switching on the unit.
Firmware not running	A firmware update has been carried out.	› Switch the unit off and back on again.
	Internal communication fault	› Switch the unit off and back on again.
Settings (e.g. language) reset after unit restart	Faulty configuration file	› Update the firmware. › Reset the configuration to the factory settings and reconfigure.
Warning message during shutdown of the unit	Not a malfunction	› Update the firmware.

15 Settings menu layout

Unit information[1]	Unit data		
	Dealer information		
	Report		
Access level[1]	User		
	Administrator		
	Service Technician		
	Factory Technician		
System settings[2]	Language	German (DE) English (EN) ...	
	Date & time	Date	
		Time	
	Network	MAC address	
		Name	
		Interface	LAN
			WLAN
		DHCP	
		IP address	
		Subnet mask	
		Gateway	
	Settings for image acquisition workflow	Patient ID	
		Surname	
		First name	
		Date of birth	
		Pregnancy	
		Comment	
		X-ray station	
		X-ray parameters	
	X-ray stations	Room 1 Room 2 ...	
	Acquisition type	INTRA Child ...	
	Touch screen	Brightness	
		Touch screen calibration	
	Standby time	Standby time	
		Standby	
	Operating mode	ScanManager	

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Service menu[3]	Test		
	Scanning modes	Edit scanning modes	
		Display scanning modes	
	Maintenance	Firmware update	
		Reset maintenance interval	
	Diagnosis	Statistics	
		Manipulation	Transport settings
			Service mode
			Sensors
		Oscilloscope	
		Check touch screen	
		Display test images	
	Messages		
	Factory settings		

1 Visible from access level ***Operator*** or higher
2 Visible from access level ***Administrator*** or higher
3 Visible from access level ***Service Technician*** or higher

16 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.

16.1 Intraoral

Theoretical resolution (LP/mm)	40	20	10
Pixel size (µm)	**12.5**	**25**	**50**
Intra Size 0 (2 x 3)	55 s	27 s	14 s
Intra Size 1 (2 x 4)	61 s	30 s	15 s
Intra Size 2 (3 x 4)	61 s	30 s	15 s
Intra Size 3 (2.7 x 5.4)	78 s	39 s	20 s
Intra Size 4 (5.7 x 7.6)	103 s	51 s	26 s

16.2 Extraoral OPG

Theoretical resolution (LP/mm)	6.67	5.00	4.00
Pixel size (µm)	**75**	**100**	**125**
OPG (12.7 x 30.5)	28 s	21 s	17 s
OPG (15 x 30)	32 s	24 s	19 s

16.3 Extraoral Ceph

Theoretical resolution (LP/mm)	10.00	6.67	5.00
Pixel size (µm)	**50**	**75**	**100**
Ceph (18 x 24)	57 s	38 s	23 s
Ceph (24 x 30)	75 s	50 s	38 s
Ceph (20 x 24)	63 s	42 s	32 s
Ceph (13 x 18)	42 s	28 s	21 s

17 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.

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17.1 Intraoral

Theoretical resolution (LP/mm)	40	25	20	10
Pixel size (µm)	**12.5**	**20**	**25**	**50**
Intra Size 0 (2 x 3)	9.86 MB	3.85 MB	2.46 MB	0.62 MB
Intra Size 1 (2 x 4)	12.29 MB	4.80 MB	3.07 MB	0.77 MB
Intra Size 2 (3 x 4)	16.27 MB	6.36 MB	4.07 MB	1.02 MB
Intra Size 3 (2.7 x 5.4)	19.01 MB	7.43 MB	4.75 MB	1.19 MB
Intra Size 4 (5.7 x 7.6)	55.45 MB	21.66 MB	13.86 MB	3.47 MB

17.2 Extraoral OPG

Theoretical resolution (LP/mm)	6.67	5.00	4.00
Pixel size (µm)	**75**	**100**	**125**
OPG (12.7 x 30.5)	13.77 MB	7.75 MB	4.96 MB
OPG (15 x 30)	16.00 MB	9.00 MB	5.76 MB

17.3 Extraoral Ceph

Theoretical resolution (LP/mm)	10.00	6.67	5.00
Pixel size (µm)	**50**	**75**	**100**
Ceph (18 x 24)	34.56 MB	15.36 MB	8.64 MB
Ceph (24 x 30)	57.60 MB	25.60 MB	14.4 MB
Ceph (20 x 24)	38.40 MB	17.07 MB	9.60 MB
Ceph (13 x 18)	18.72 MB	8.32 MB	4.68 MB

18 Information about EMC in accordance with EN 60601-1-2

18.1 General information

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.

18.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_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_1	Compliance level for the test in acc. with IEC61000-4-3
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)

18.3 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	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The device uses HF energy exclusively for internal functions. As a result, HF-transmissions are very low and it is highly 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 connected to the public mains electricity supply that also supplies buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	Not applicable	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Not applicable	

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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 immunity 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 voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance 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 accordance with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains 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 immunity tests	IEC 60601 – Test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ = 4 V	$d = 0.88 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ = 4 V/m	$d = 0.88 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 1.75 \cdot \sqrt{P}$ 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[a].[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. 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 $[V_1]$ V/m.

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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 $d = 1.2 \cdot \sqrt{P}$	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 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.

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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