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# VistaScan Nano Easy




EN Installation and operating instructions

CE

DÜRR DENTAL

2160100227L02 2302V010

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The current version of the installation and operating instructions is available in the Download Center:

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# Important information

## 1 About this document

These installation and operating instructions represent part of the unit.

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

The German version of the installation and operating instructions is the original manual. All other languages are translation of the original manual.
These operating instructions apply to the following VistaScan Nano Easy units:
Item number:
- 2160100500
- 2160100503
- 2160100505

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### 1.1 Warnings and symbols

**Warnings**

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

General warning symbol

The warnings are structured as follows:

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

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

**Other symbols**

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

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

REF Order number

SN Serial number

MD Medical device

LOT Lot designation

CE labelling

CE XXXX CE labelling with the number of the notified body

UK CA Conformity mark for the United Kingdom of Great Britain and Northern Ireland

CH REP Authorised representative for Switzerland

Manufacturer

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

Refer to the accompanying electronic documents.

Observe the operating instructions.

Refer to Operating Instructions.


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Wear protective gloves.


Disconnect all power from the unit.


Do not reuse



Health Industry Bar Code (HIBC)


DC current


Non-ionizing electromagnetic radiation


Warning – dangerous high voltage


Warning - laser beam


This way up / store and transport in an upright position


Keep dry


Stacking limits



Lower and upper humidity limits



Lower and upper temperature limits



Lower and upper atmospheric pressure limits


Fragile, handle with care


Keep away from sunlight

## 1.2 Copyright information

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

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



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# 2 Safety

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

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

## 2.1 Intended purpose

### VistaScan Nano Easy

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

### Light protection cover

The functions of the Light Protection Cover are:

- to protect the image plate from light and therefore against accidental erasure
- to protect against cross-contamination

## 2.2 Intended use

### VistaScan Nano Easy

The unit may only be operated using accessories and optional articles manufactured by or branded with Dürr Dental.
The unit may only be cleaned using the disinfectants and cleaning agents approved by and specified by the manufacturer.

### Light protection cover

The Light Protection Cover is a disposable item.
The Light Protection Cover is designed exclusively for use with image plate scanners manufactured by or branded with Dürr Dental and image plates manufactured by or branded with 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. The user bears the sole risk.

### VistaScan Nano Easy

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.

### Light protection covers

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.
Especially:

- The multiple use of this accessory and reprocessing contrary to the instructions of the manufacturer.

The use of the accessory in combination with other than image plate scanners manufactured by or branded with Dürr Dental and image plates manufactured by or branded with Dürr Dental.

## 2.4 General safety information

- Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
- Check the function and condition of the unit prior to every use.
- Do not convert or modify the unit.
- Comply with the specifications of the Installation and Operating Instructions.
- The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

## 2.5 Specialist personnel

### Operation

Unit operators must use their training and knowledge to ensure safe and correct handling.

- Instruct or have every operator instructed in the handling of 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.



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## 2.6 Electrical safety

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

**Observe the EMC rules concerning medical devices**

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

**NOTICE**

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

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

**NOTICE**

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

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

## 2.7 FCC note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- To comply with FCC RF exposure compliance requirements, a separation distance of at least 20 cm must be maintained between the internal antenna of this device and all persons.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

## 2.8 ISED Statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:


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1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

## 2.9 Essential performance characteristics

The VistaScan Nano Easy unit does not possess any significant performance characteristics as set out in IEC 60601-1 (EN 60601-1) section 4.3. The unit complies with the requirements according to IEC 60601-1-2:2014.

## 2.10 Notification requirement of serious incidents

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

## 2.11 Only use original parts

› Only use accessories and optional items that have been recommended or specifically approved by Dürr Dental.
› Only use only original wear parts and replacement parts.

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

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

## 2.12 Transport

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

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

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

## 2.13 Disposal

An overview of the waste keys for Dürr Dental products can be found in the download area:

*http://qr.duerrdental.com/P007100155*

**Unit**

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

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

**Image plate**

The image plate contains barium compounds.
› Dispose of the image plate properly in accordance with the locally applicable regulations.
› In Europe, dispose of the image plate in accordance with waste code 20 03 01 "Mixed municipal waste".

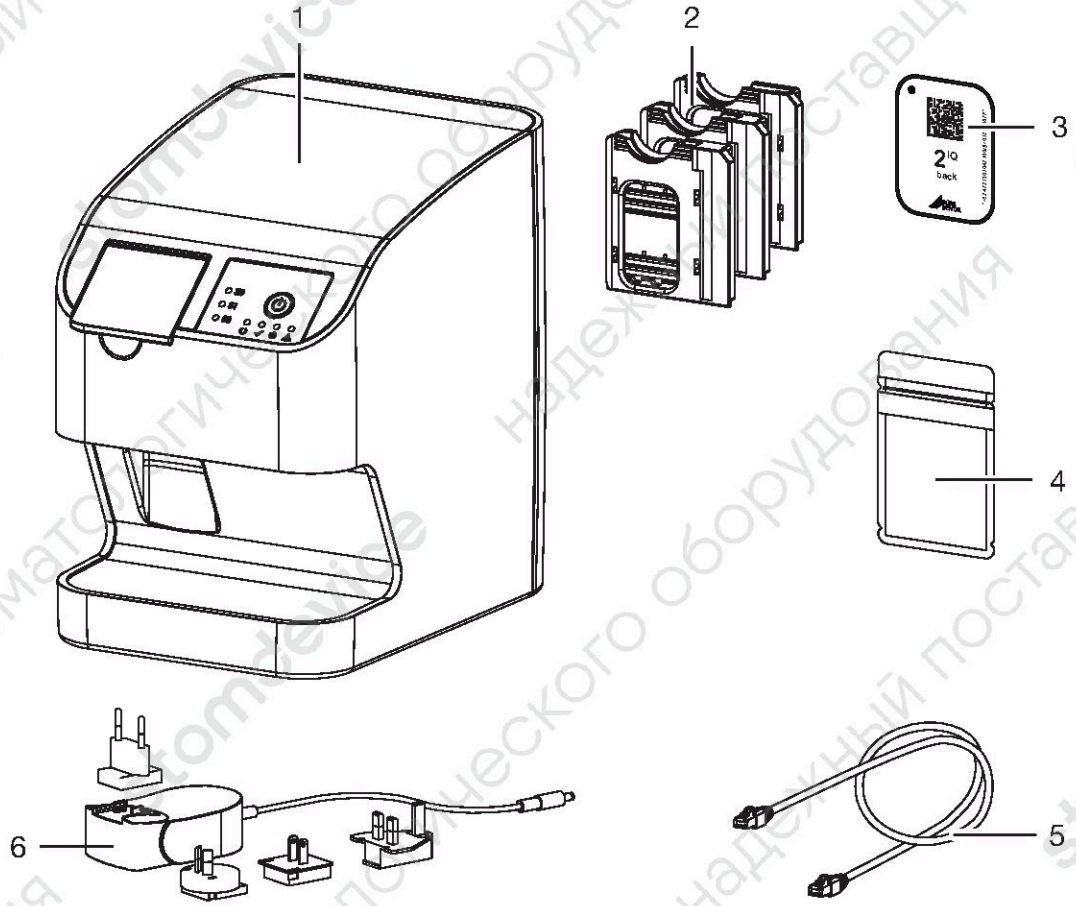
## 2.14 Protection from threats from the Internet

The unit is to be connected to a computer that can be connected to the Internet. Therefore, the system needs to be protected from threats from the Internet.
› Use antivirus software and update it regularly. Look for evidence of possible virus infection and, if applicable, check with the antivirus software and remove the virus.
› Perform regular data backups.
› Restrict access to units to trustworthy users, e.g. via a user name and password.
› Make sure that only trustworthy content is downloaded. Only install software and firmware updates that have been authenticated by the manufacturer.


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# Product description

## 3 Overview




1 VistaScan Nano Easy image plate scanner
2 Cartridge for image plates (S0 up to S2)
3 IQ image plate
4 Light protection cover Plus
5 Network cable (3 m)
6 Power supply unit with country-specific adapter


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## 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 Nano Easy image plate scanner . . . . . 2160110001**
**VistaScan Nano Easy image plate scanner . . . . . 2160110011**
**VistaScan Nano Easy image plate scanner . . . . . 2160110013**

- VistaScan Nano Easy basic unit
- Power supply unit
- Network cable (3 m)
- Collector mat (mounted in the device)
- Voucher for VistaSoft imaging software
- Cartridge for image plate size 2
- IQ image plates:
  - Size 2
- Light protection covers Plus:
  - Size 2
- Quick start instructions

## 3.2 Accessories

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

### Image plates

- IQ image plate, size 0
- IQ image plate, size 1
- IQ image plate, size 2

### Light protection covers

- Light Protection Cover Plus, size 0
- Light Protection Cover Plus, size 1
- Light Protection Cover Plus, size 2
- Light Protection Cover Plus, size 0, white
- Light Protection Cover Plus, size 2, white

## 3.3 Optional items

The following optional items can be used with the unit:

Wall bracket . . . . . 2160100210
Image Plate Storage Case . . . . . 2141-002-00
Image plate and film holder system set . . . . . 2130100015
Image plate and film holder system conversion set for endo-exposures . 2130100014
Mobile Connect (for using apps for mobile appliances, e.g. Dürr Dental Imaging iPad app) . . . . . 2100-725-12FC

### Commissioning and intraoral constancy tests

Intra / extra digital test body . . . . . 2121-060-54

## 3.4 Consumables

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

### Cleaning and disinfection

Image plate cleaning wipes (10 pcs.) . . . . . CCB351B1001
FD 333 forte wipes for quick-acting disinfection . . . . . CDF33FW0150
FD 350 Classic disinfection wipes . . . . . CDF35CA0140
FD 333 rapid surface disinfection . . . . . CDF333C6150
FD 322 rapid surface disinfection . . . . . CDF322C6150
FD 366 rapid disinfectant for sensitive surfaces . . . . . CDF366C6150
ID 212 Instrument disinfection . . . . . CDI212C6150
ID 212 forte Instrument disinfection . . . . . CDI212F6150
ID 213 Instrument disinfection . . . . . CDI213C6150

### Light protection covers

VistaScan light protection cover Plus S0 (100x) . . . . . 2130-080-00
VistaScan light protection cover Plus S1 (100x) . . . . . 2130-081-00
VistaScan light protection cover Plus S2 (100x) . . . . . 2130108251
VistaScan light protection cover Plus S2 (300x) . . . . . 2130-082-00
VistaScan light protection cover Plus S2 (1000x) . . . . . 2130-082-55
VistaScan light protection cover Plus white S0 (100x) . . . . . 2130-080-50
VistaScan light protection cover Plus white S2 (300x) . . . . . 2130-082-50


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## 3.5 Wear parts and replacement parts

### Image plates

VistaScan IQ pack S0
VistaScan image plate IQ S0 (2 x) +
VistaScan light protection cover
Plus S0 (1000 x) . . . . . 2130106051

VistaScan IQ pack S1
VistaScan image plate IQ S1 (2 x) +
VistaScan light protection cover
Plus S1 (1000 x) . . . . . 2130106151

VistaScan IQ pack S2
VistaScan image plate IQ S2 (2 x) +
VistaScan light protection cover
Plus S2 (1000 x . . . . . 2130106251

### Cartridges

Cartridge for image plate S0 . . . . . 2160100246
Cartridge for image plate S1 . . . . . 2160100247
Cartridge for image plate S2 . . . . . 2160100248

Information about replacement parts is available from the portal for authorised specialist dealers at:
*www.duerrdental.net*


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# 4 Technical data

## 4.1 Image plate scanner

| | | |
|---|---|---|
| **Electrical data for the unit** | | |
| Rated voltage | V DC | 24 |
| Max. current consumption | A | 0.5 |
| Max. power consumption | W | < 12 |
| **Electrical data – power supply unit** | | |
| Nominal input voltage | V AC | 100 - 240 |
| Frequency | Hz | 50/60 |
| Nominal output voltage | V DC | 24 |
| Max. output current | A | 0.5 |
| **General technical data** | | |
| Dimensions (W x H x D) | mm | 167 x 231 x 216 |
| | in | 6.57 x 9.09 x 8.50 |
| Weight | kg | approx. 4 |
| | lb | approx. 8.82 |
| Duty cycle | % | 100 |
| Max. theoretical resolution | Line pairs/mm (Lp/mm) | approx. 16.7 |
| **Noise level** | | |
| During scanning | dB(A) | approx. 45 |
| **Network connection** | | |
| LAN technology | | Ethernet |
| Standard | | IEEE 802.3u |
| Data rate | Mbit/s | 100 |
| Connector | | RJ45 |
| Type of connection | | Auto MDI-X |
| Cable type | | ≥ CAT5 |
| **Ambient conditions during operation** | | |
| Temperature | °C | +10 to +35 |
| | °F | +50 to +95 |
| Relative humidity | % | 20 - 80 |
| Air pressure | hPa | 750 - 1060 |
| Height above sea level | m | < 2000 |
| | ft | < 6562 |



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| | | |
|---|---|---|
| **Ambient conditions during storage and transport** | | |
| Temperature | °C | -18 to +60 |
| | °F | -4 to +140 |
| Humidity | % | 10 - 95, non-condensing |
| Air pressure | hPa | 500 - 1060 |
| **Classification** | | |
| Medical Device Class (MDR) | | I |
| Laser class (unit)<br>In accordance with IEC 60825-1:2014 | | 1 |
| **Laser source** | | |
| Laser class<br>In accordance with IEC 60825-1:2014 | | 3B |
| Wavelength λ | nm | 639 |
| Output | mW | <12 |
| **Technical data for the RFID module** | | |
| Frequency | MHz | 13.56 |
| Modulation | | ASK |
| Max. power | mW | 400 |
| **Electromagnetic compatibility (EMC)<br>Interference emission measurements** | | |
| High-frequency emissions in accordance with CISPR 11 | | Group 1<br>Class B |
| Interference voltage at the power supply connection<br>CISPR 11:2009+A1:2010 | | Compliant |
| Electromagnetic interference radiation<br>CISPR 11:2009+A1:2010 | | Compliant |
| **Electromagnetic compatibility (EMC)<br>Interference immunity measurements cover** | | |
| Immunity to interference, discharge of static electricity<br>IEC 61000-4-2:2008<br>± 8 kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | | Compliant |
| Immunity to interference, high-frequency electromagnetic fields<br>IEC 61000-4-3:2006+A1:2007+A2:2010<br>3 V/m<br>80 MHz - 2.7 GHz<br>80 % AM at 1 kHz | | Compliant |


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| Electromagnetic compatibility (EMC)<br>Interference immunity measurements cover | |
|---|---|
| Immunity to interference, near fields of wireless HF communication devices<br>IEC 61000-4-3:2006+A1:2007+A2:2010<br>See immunity to interference table, near fields of wireless HF communication devices | Compliant |

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

| Radio service | Frequency band MHz | Test level V/m |
|---|---|---|
| TETRA 400 | 380 - 390 | 27 |
| GMRS 460<br>FRS 460 | 430 - 470 | 28 |
| LTE band 13, 17 | 704 - 787 | 9 |
| GSM 800/900<br>TETRA 800<br>iDEN 820<br>CDMA 850<br>LTE band 5 | 800 - 960 | 28 |
| GSM 1800<br>CDMA 1900<br>GSM 1900<br>DECT<br>LTE band 1, 3, 4, 25<br>UMTS | 1700 - 1990 | 28 |
| Bluetooth<br>WLAN 802.11 b/g/n<br>RFID 2450<br>LTE band 7 | 2400 - 2570 | 28 |
| WLAN 802.11 a/n | 5100 - 5800 | 9 |

| Electromagnetic compatibility (EMC)<br>Interference immunity measurements supply input | |
|---|---|
| Immunity to interference, rapid transient bursts – AC voltage grid<br>IEC 61000-4-4:2012<br>± 2 kV<br>100 kHz repetition frequency | Compliant |
| Immunity to interference, surges<br>IEC 61000-4-5:2005<br>± 0.5 kV, ± 1 kV | Compliant |


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| Electromagnetic compatibility (EMC)<br>Interference immunity measurements supply input | |
|---|---|
| Immunity to interference, line-conducted disturbances induced by high-frequency fields – AC voltage grid<br>IEC 61000-4-6:2013<br>3 V<br>0.15 - 80 MHz<br>6 V<br>ISM frequency bands<br>0.15 - 80 MHz<br>80 % AM at 1 kHz | Compliant |
| Immunity to interference due to voltage dips, short interruptions and voltage variations<br>IEC 61000-4-11:2004 | Compliant |

| Electromagnetic compatibility (EMC)<br>Interference immunity measurements SIP/SOP | |
|---|---|
| Immunity to interference, discharge of static electricity<br>IEC 61000-4-2:2008<br>± 8 kV contact<br>± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air | Compliant |
| Immunity to interference, rapid transient bursts – I/O, SIP/SOP ports<br>IEC 61000-4-4:2012<br>± 1 kV<br>100 kHz repetition frequency | Compliant |
| Immunity to interference, line-conducted disturbances induced by high-frequency fields – SIP/SOP ports<br>IEC 61000-4-6:2013<br>3 V<br>0.15 - 80 MHz<br>6 V<br>ISM frequency bands<br>0.15 - 80 MHz<br>80 % AM at 1 kHz | Compliant |

## 4.2 Image plate

| Classification | | |
|---|---|---|
| Medical Device Class (MDR) | | IIa |
| **Ambient conditions during operation** | | |
| Temperature | °C | 18 - 45 |
| | °F | 64 - 113 |
| Relative humidity | % | < 80 |


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| Ambient conditions during storage and transport | | |
|---|---|---|
| Temperature | °C | < 45 |
| | °F | < 113 |
| Relative humidity | % | < 80 |

| Dimensions of intraoral image plates | | |
|---|---|---|
| Size 0 | mm | 22 x 35 |
| | inches | 0.86 x 1.38 |
| Size 1 | mm | 24 x 40 |
| | inches | 0.94 x 1.57 |
| Size 2 | mm | 31 x 41 |
| | inches | 1.22 x 1.61 |

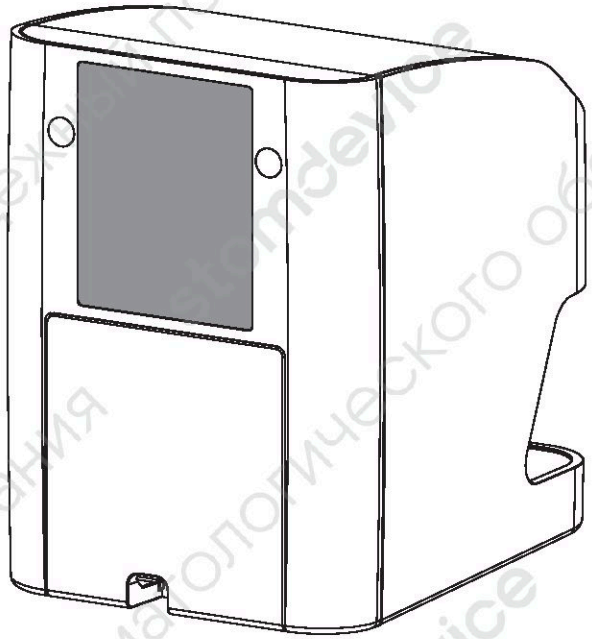
## 4.3 Light protection cover

| Classification | |
|---|---|
| Medical Device Class (MDR) | I |


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## 4.4 Type plate

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



REF Order number
SN Serial number

## 4.5 Evaluation of conformity

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

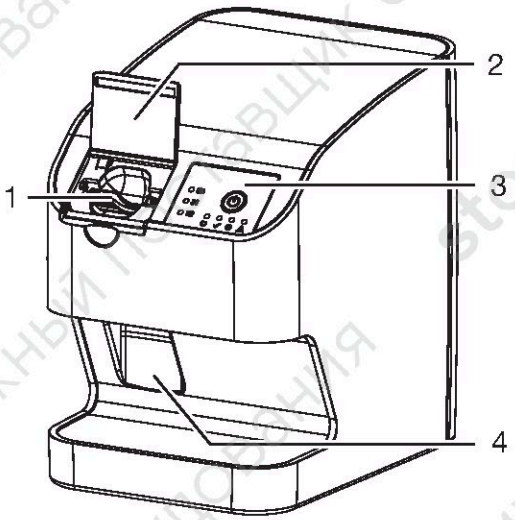
## 4.6 Simplified declaration of conformity

The manufacturer hereby declares that the unit complies with Directive 2014/53/EU as well as others.
The full text of the EU declaration of conformity can be viewed online at the Download Center:

*https://qr.duerrdental.com/conformity*

# 5 Operation

## 5.1 Image plate scanner

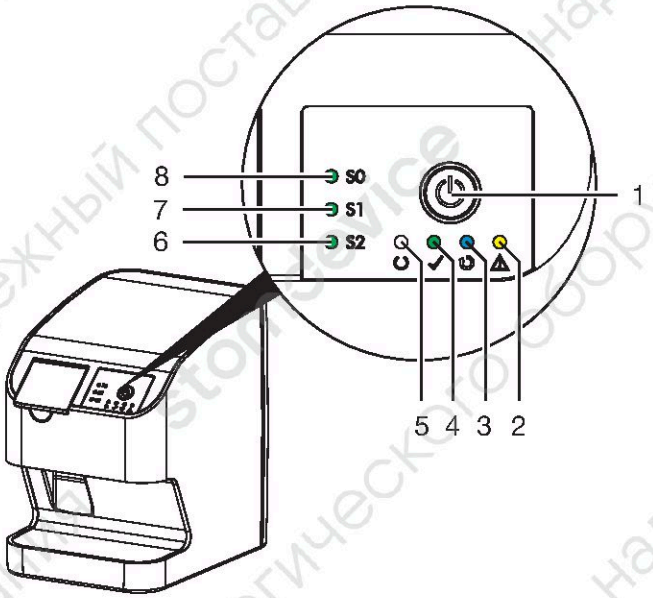



1 Input unit
2 Cover (open)
3 Operating elements
4 Collection tray

The image plate scanner is used to read image data stored on an image plate and to transfer the data to the imaging software (e.g. VistaSoft) on a computer.
The transport mechanism guides the image plate through the device. The image plate is read using a laser inside the scanner unit. The scanned data is converted into a digital image and transferred to the imaging software.
After scanning, the image plate runs through the erasure unit. Image data still held on the image plate is erased with the aid of bright light.
The image plate is then ejected for re-use.


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## Operating elements



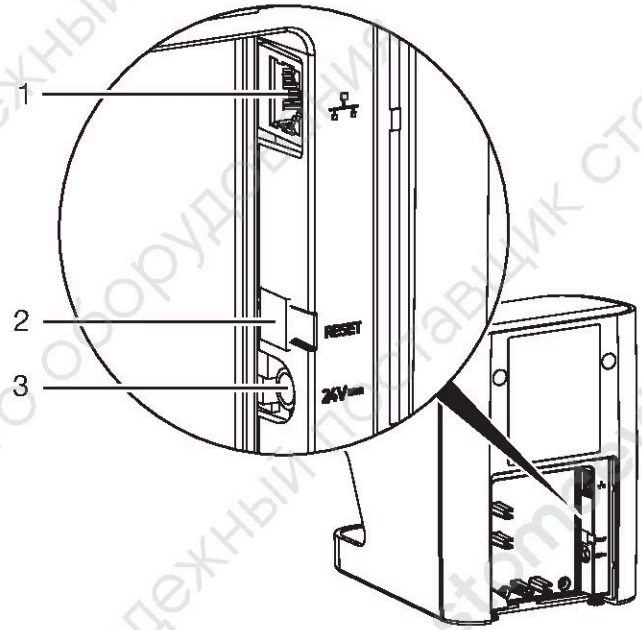

1 On / off switch
2 Error display yellow
3 Read display blue
4 Green status LED
5 Communication/standby display white
6 Display for cartridge S2
7 Display for cartridge S1
8 Display for cartridge S0

The status LEDs display the following status messages:

| | |
|---|---|
| ○ ☼ | Device starts |
| ○ ○ | Communication display Standby |
| ○ ○<br>✓ ● | Ready to scan |
| ○ ○<br>◔ ● | Image plate currently being processed |
| ○ ○<br>✓ ☼ | Cartridge for image plate missing |
| ○ ○<br>⚠ ● | Error<br>A message is displayed in the software |
| S0 ● | Cartridge for S0 image plate is in the device |
| S1 ● | Cartridge for S1 image plate is in the device |
| S2 ● | Cartridge for S2 image plate is in the device |
| ☼ | Status LED flashing |

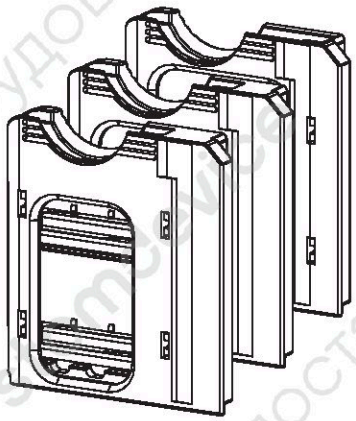
## Connections

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




1 Network connection
2 Reset button
3 Connection for power supply unit

## 5.2 Cartridges (S0-S2)



According to the image plate used, the cartridge corresponding to the size of the image plate must be inserted in the device. The cartridge that is currently in the device is indicated via the LEDs on the device.


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## 5.3 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**

| Inactive side | Active side |
|---|---|
|  |  |
| White, printed with the word "back" and the size and manufacturer's information | 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.

Use only IQ image plates with the unit. The unit is unable to read any other types of image plates.

## 5.4 Light protection cover

The light protection cover protects the image plate against light.

## 5.5 Image plate storage box

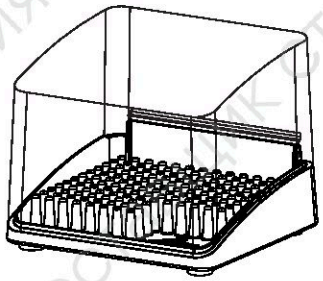
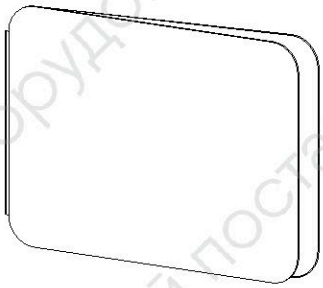


Image plates packed in light protection covers can be stored in the image plate storage box until the next use. The image plate storage box protects the image plate and the light protection cover against contamination and dirt.

## 5.6 Bite protector (optional)



The bite protector protects the image plate S4 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.


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# Assembly

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

# 6 Requirements

## 6.1 Installation/setup room

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

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

## 6.2 System requirements

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

## 6.3 Monitor

The monitor must comply with the requirements for digital X-ray with a high light intensity and wide contrast range.
Strong ambient light, sunlight falling directly onto the monitor and reflections can make it harder or even impossible to perform a diagnosis based on the X-ray images.

# 7 Installation

## 7.1 Setting up 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.

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

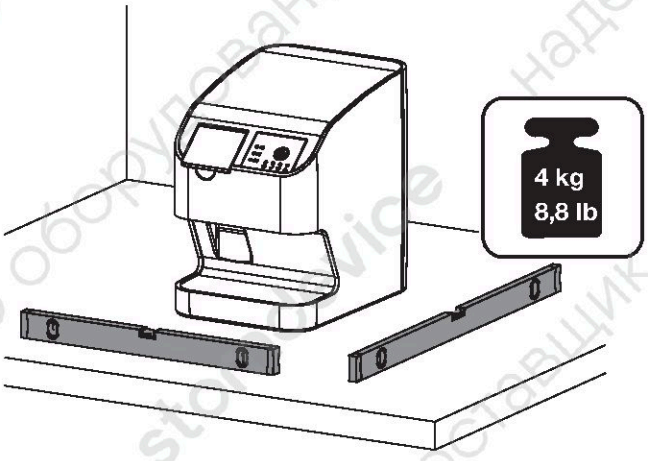
› Do not stack the unit next to or together with other appliances.
› If, however, this unit is operated next to other units or stacked with other units, monitor the unit carefully in the configuration selected in order to ensure normal operation.

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


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## 7.2 Electrical connections

### Safety when making electrical connections

› The device must only be connected to a correctly installed power outlet.
› Do not place non-fixed multi-socket units on the floor. Follow the requirements in section 16 of IEC 60601-1 (EN 60601-1).
› Do not operate any other systems using the same multiple socket.
› Make sure that none of the electrical cables leading to the unit are under any mechanical tension.
› 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 supply

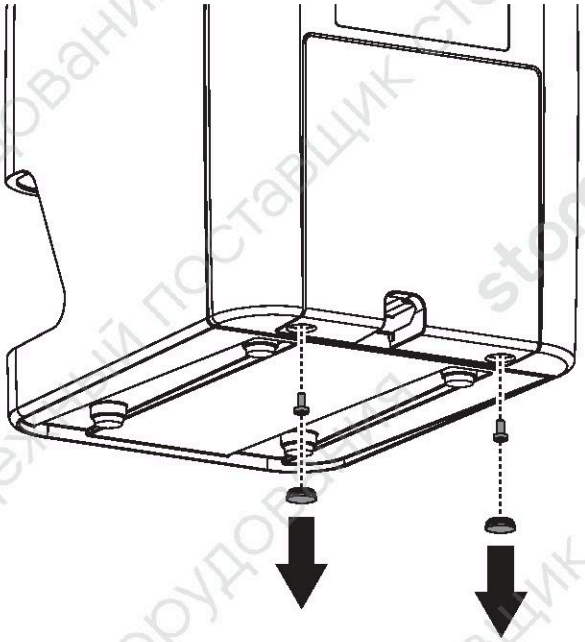
The unit has no main power switch. For this reason it is important that the unit is be set up in such a way that the plug can be easily accessed and unplugged if required.

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

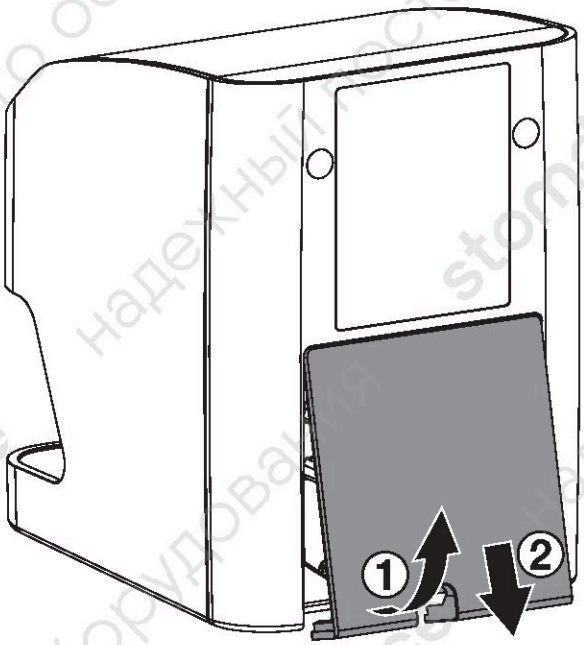
Only the supplied power supply unit may be used.

› Attach the matching country-specific adapter to the power supply unit.

› Remove the screw covers and screws from the bottom of the device.



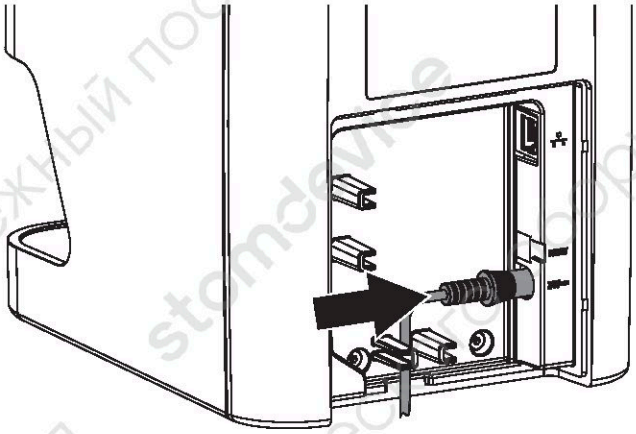
› Remove the cover from the rear of the device.





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› 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.
› Refit the cover.

The cover on the rear must be properly intalled when the device is operated within the patient environment.

## 7.3 Connecting the device 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.

**Combining devices safely**

– The overall safety of the unit and its main performance features are independent of the network.
– Incorrect manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
– If, for example, the following changes are made to the network, new risks can arise that require further analysis.
  – Changes in the IT network configuration
  – Connecting additional elements to the IT network
  – Removing elements form the IT network
  – "Update" of devices that are connected to the IT network
  – "Upgrade" of devices that are connected to the IT network
– The data connection utilises part of the bandwidth of the network. Interactions with other medical devices cannot be completely ruled out. Apply the IEC 80001-1 standard for risk assessment.
– The device is not suitable for direct connection to the public internet.

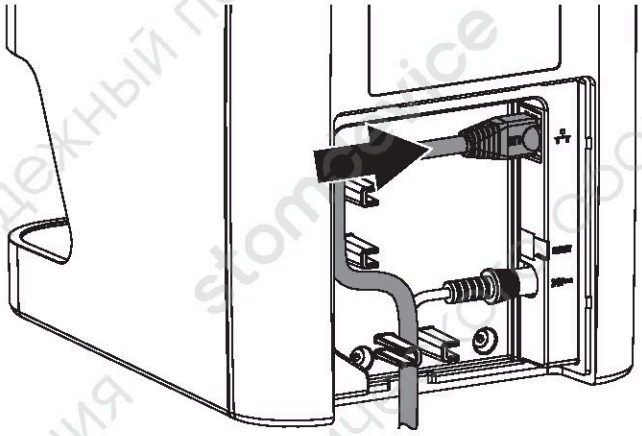
Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

› 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 when there is no risk of damage or harm to the surroundings.
› If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe.
› Observe the specifications of IEC 60601-1 (EN 60601-1) when connecting the appliance with other appliances, e.g. a PC system, both in and outside 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 or IEC 62368-1.
› The connected computer must conform to EN 55032 (class B) and EN 55024.


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### Connecting the unit via the network cable

› Remove the cover from the rear of the device.
› Connect the supplied network cable to the network connection of the device.



The cover on the rear must be properly installed when the device is operated within the patient environment.

› Refit the cover.

# 8 Commissioning

**NOTICE**

**Short circuit due to the build up of condensation**

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

The device can be operated with the following imaging software:
– VistaSoft from Dürr Dental
– DBSWIN from Dürr Dental
– Third-party software on request

Always use the current version of the imaging software when commissioning the unit. Download the current version of the imaging software in the Download Centre at www.duerrdental.com.

## 8.1 Configuring the network

### 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 | Device data | |
| 514[1)] UDP | Event log data | Syslog |
| n/a | Check that the device is switched on | ICMP / ping |

1) The port may vary depending on the configuration.

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

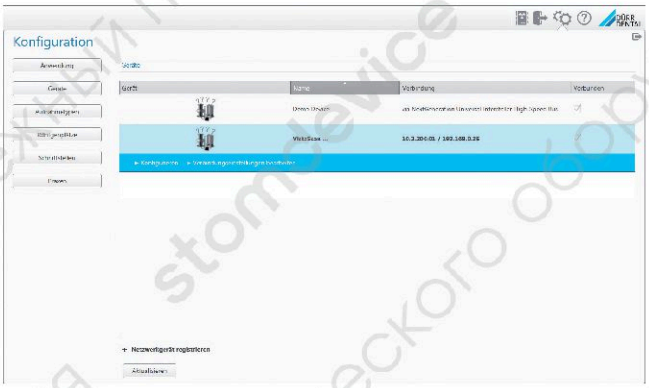

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## 8.2 Configuring the unit

Configuration is performed directly in VistaSoft.

› > *Choose* devices.

› 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*.

**Entering a permanent 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.

› Click *Save values*.
The configuration is saved.

## 8.3 Testing the device

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

› Open VistaSoft.

› Create an X-ray station for the connected unit.

› Log-in the demo patient (patient ID: DEMO0001).

› Select the image type (e. g. Intraoral).

› Scan an image plate, see "10.3 Scanning the image data".


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## 8.4 X-ray unit settings

If 60 kV can be set on the X-ray unit, this setting is preferred.
The standard exposure values for F-speed film (e. g. Kodak Insight) can be used.

The following table shows the standard values for the exposure time and the dose area product of an image plate for an adult patient. The values of exposure time and dose area product are based on used of a VistaIntra as X-ray unit.
µGy = Image receiver dose
mGycm2 = Dose area product

| | DC emitter, 7 mA<br>Tube length 20 cm | | | | | | |
|---|---|---|---|---|---|---|---|
| | Without X-ray field limitation | | | X-ray field limitation 2x3 | | X-ray field limitation 3x4 | |
| | 60 kV | µGy | mGycm² | 60 kV | mGycm² | 60 kV | mGycm² |
| Incisors | 0.10 s | 538.7 | 18.3 | 0.10 s | 3.8 | 0.10 s | 7.7 |
| Premolars | 0.14 s | 766.8 | 25.6 | 0.14 s | 5.4 | 0.14 s | 10.8 |
| Molars | 0.19 s | 1037 | 34.8 | 0.19 s | 7.3 | 0.19 s | 14.7 |
| Bitewing | 0.20 s | 1090 | 38.4 | 0.20 s | 8.1 | 0.20 s | 15.5 |

| | DC emitter, 6 mA<br>Tube length 30 cm | | | | | | |
|---|---|---|---|---|---|---|---|
| | Without X-ray field limitation | | | X-ray field limitation 2x3 | | X-ray field limitation 3x4 | |
| | 70 kV | µGy | mGycm² | 70 kV | mGycm² | 70 kV | mGycm² |
| Incisors | 0.15 s | 445 | 13.7 | 0.15 s | 2.9 | 0.15 s | 5.8 |
| Premolars | 0.20 s | 594 | 18.2 | 0.20 s | 3.8 | 0.20 s | 7.7 |
| Molars | 0.27 s | 806 | 24.6 | 0.27 s | 5.2 | 0.27 s | 10.4 |
| Bitewing | 0.28 s | 834 | 25.5 | 0.29 s | 5.6 | 0.28 s | 10.8 |

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

## 8.5 Acceptance tests

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

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

### Acceptance test

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


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### Electrical safety checks

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

› Document the results.

› Carry out and document the instruction and handover for the unit.

A sample handover report is included in the attachment.


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# Usage

## 9 Correct use of image plates

**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).

**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.
- Image plates must only be read using an image plate scanner that is approved by Dürr Dental.

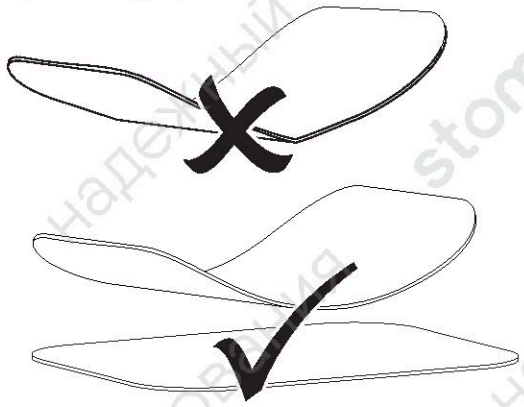
**CAUTION**

**Image plates are toxic**

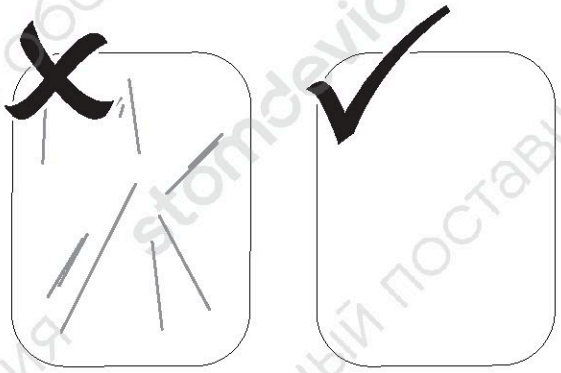
Image plates that are not packed in a light protection cover can lead to poisoning when placed in the mouth or swallowed.

- 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.


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- Protect the image plates against sunlight and ultraviolet light.
  Store image plates in a light protection cover or intraoral/extraoral 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. if the protective layer is damaged or there are visible scratches that impair the quality of the diagnosis.
  Also replace the image plate if the RFID tag is damaged or becoming detached.
- Image plates that have a production or packaging defect will be replaced by Dürr Dental in the same quantity. Claims can only be accepted within 7 working days after receipt of the goods.
- Clean image plates properly (see "11 Cleaning and disinfection").

# 10 Operation

**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.
- Image plates must only be read using an image plate scanner that is approved by Dürr Dental.

## 10.1 Changing the input unit cartridge

The device can be used to scan image plates size 0, size 1 and size 2. Each size of image plate requires the matching cartridge.
The size of the image plate is marked on the cartridge.

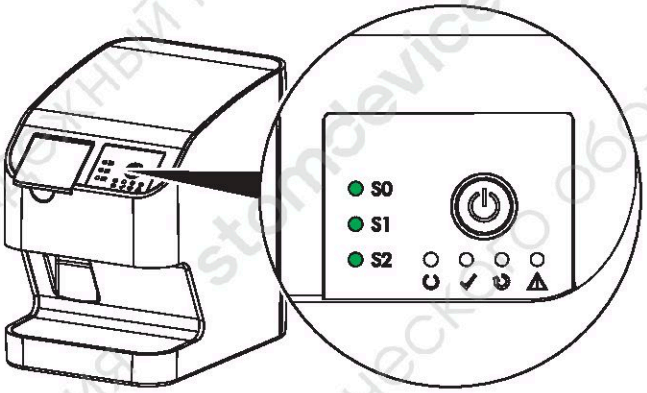
**CAUTION**

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

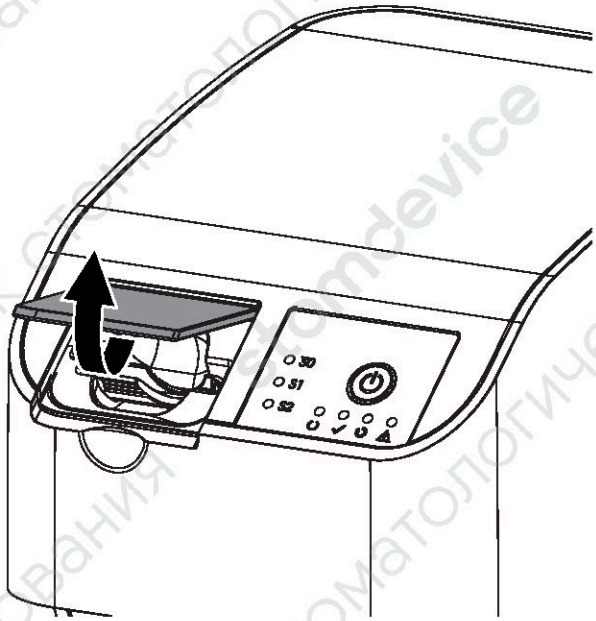
- Always use the correct size of cartridge for the image plate being used.
- Before each scanning process, compare the image plate size with the LED display on the control element.


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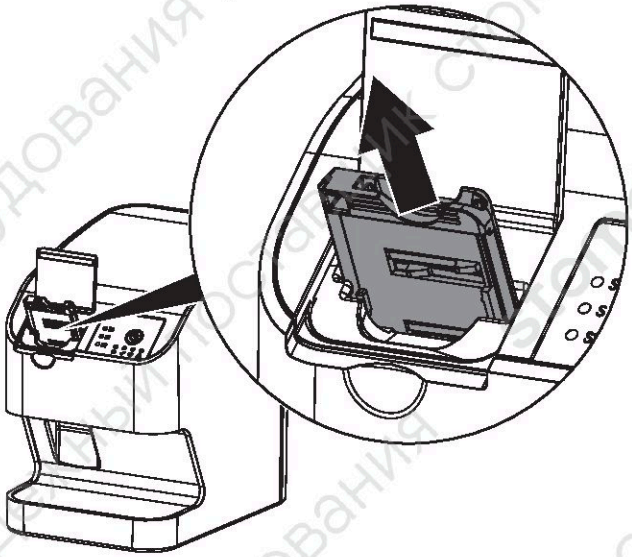
› Check that the correct cartridge has been inserted with the display (S0, S1, S2).
If the incorrect cartridge has been inserted, it must be removed and the correct cartridge inserted.




› Open the cover.

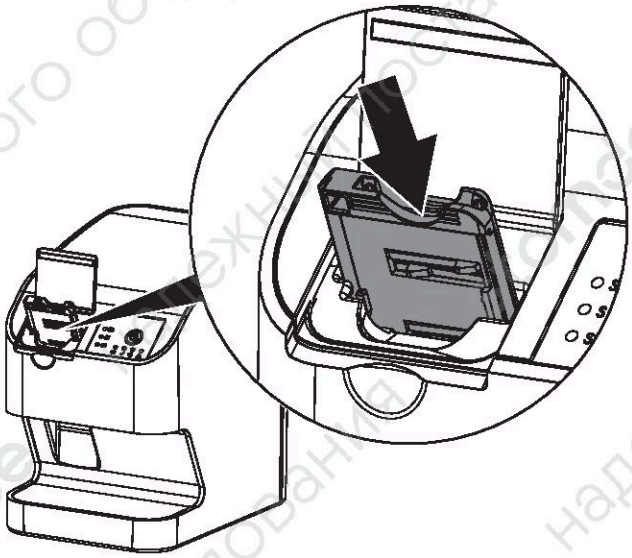


› Remove cartridge.



The green cartridge display extinguishes. If the unit is ready to take an image, the green status LED also flashes.

› Insert the appropriate cartridge.



The green display for the corresponding cartridge lights up. If the unit is ready to take an image, the green status LED also lights up. The input unit is ready.


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## 10.2 X-ray

The procedure is described using an IQ S2 image plate as an example.

Required accessories:
- Image plate
- Light protection cover the same size as the image plate

**WARNING**

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

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

**WARNING**

**Danger due to re-use of products intended for single use**

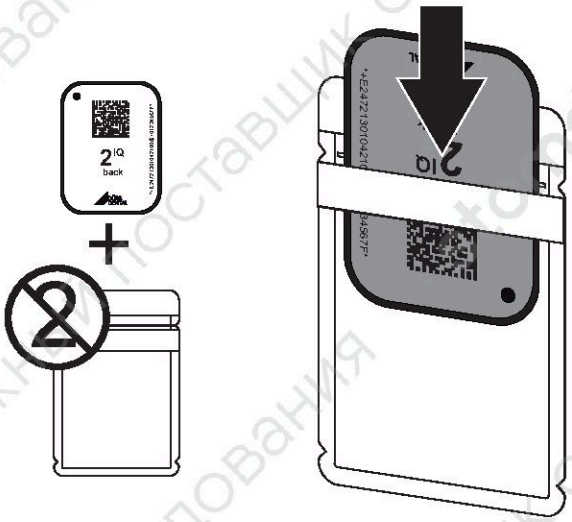
The disposable item is damaged after use and cannot be reused.

› Dispose of disposable items after use.

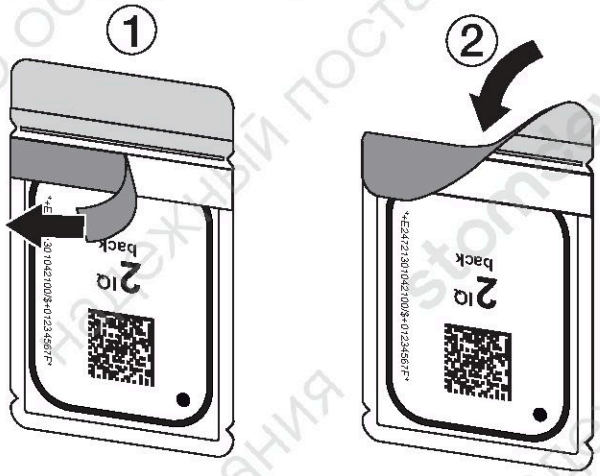
### Preparing the X-ray

✓ The image plate has been cleaned.
✓ The image plate is not damaged.
✓ The adhesive film adheres to the inactive side of the image plate. If the adhesive film peels off, replace the image plate.
› If using it for the first time or if it has been stored for over a week: erase the image plate (see "10.4 Erasing the image plate").

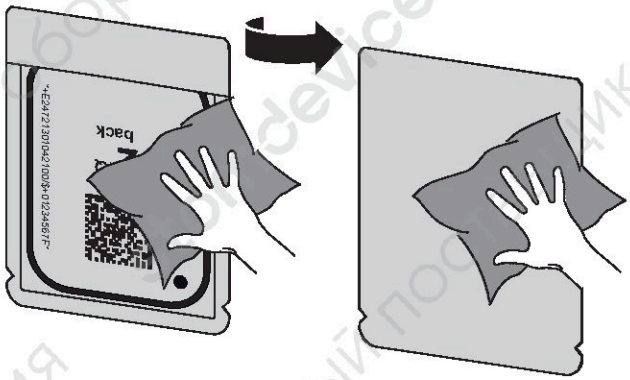
› Completely slide the image plate into the light protection cover. The white (inactive) side of the image plate must be visible.



› 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 suitable disinfectant wipe immediately before positioning it inside the patient's mouth (see "11.2 Light protection cover").



› Allow the light protection cover to fully dry.


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## Taking the X-ray image

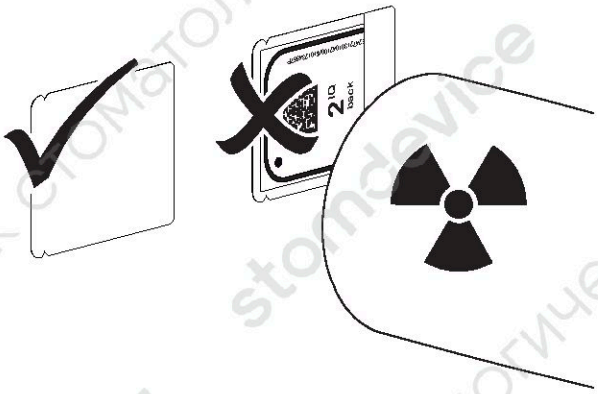
**NOTICE**

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

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

Wear protective gloves.

› Place the image plate in the light protection cover into the patient's mouth.
When doing this, make sure that the active side of the image plate points towards the X-ray tube.



› Set the exposure time and setting values on the X-ray unit (see "8.4 X-ray unit settings").
› Record an X-ray image.
The image data must be scanned within 30 minutes.

## Preparing for scanning

**CAUTION**

**Light erases the image data on the image plate**

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

Wear protective gloves.

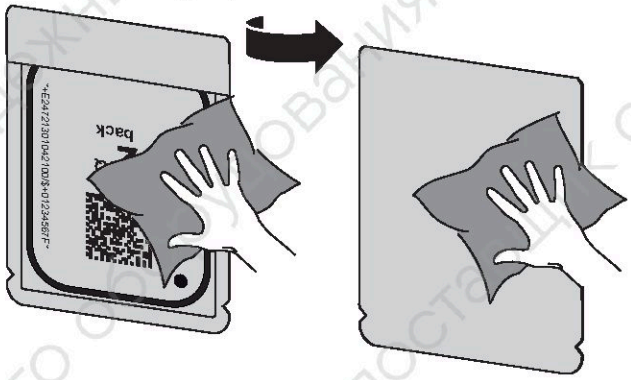
› Remove the image plate with the light protection cover from the patient's mouth.

**WARNING**

**Contamination of the unit**

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

› In the event of heavy soiling, e.g. from blood, dry clean the light protection cover and protective gloves, e.g. wipe with a clean cellulose cloth.
› Disinfect the light protection cover and protective gloves with a suitable disinfection wipe; see "11.2 Light protection cover".



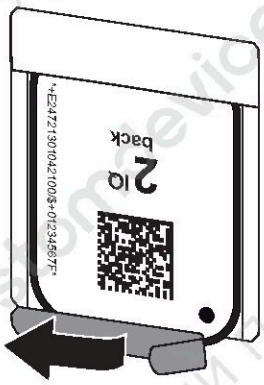
› Allow the light protection cover and image plate to dry completely.
› Pull off the protective gloves and disinfect the hands.

**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.




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## 10.3 Scanning the image data

### Starting the image plate scanner and software

The reading-out process is described using the VistaSoft imaging software.
For further information on using the imaging software, refer to the relevant manual.

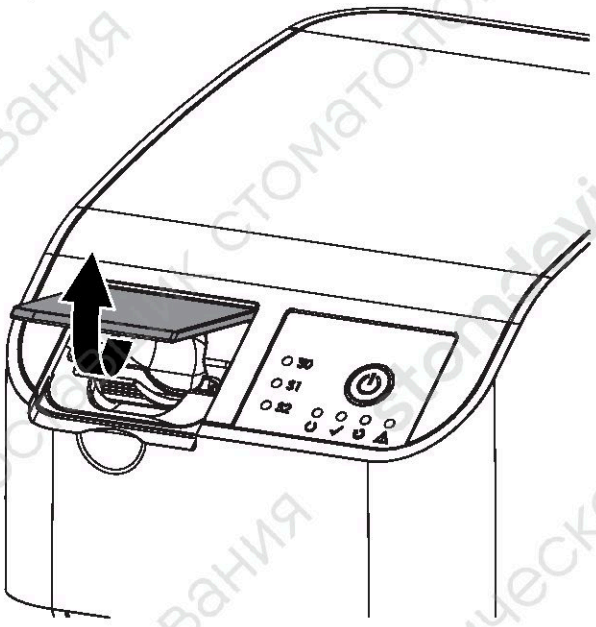
› Press the on / off switch ⏻ to switch on the device.
› Switch on the computer and monitor.
› Start VistaSoft.
› Select the patient.
› Select the corresponding image type in the menu bar.
› Select the device.
› Set acquisition mode.
Recording starts directly.

*Result:*
The green status LED lights up. Scan the image plate at this point (and not before).

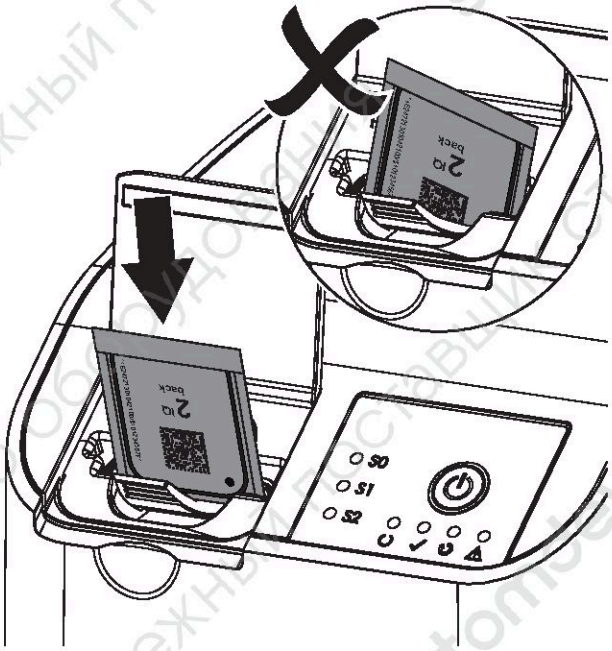
### Scanning the image plate

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

› Open the cover.

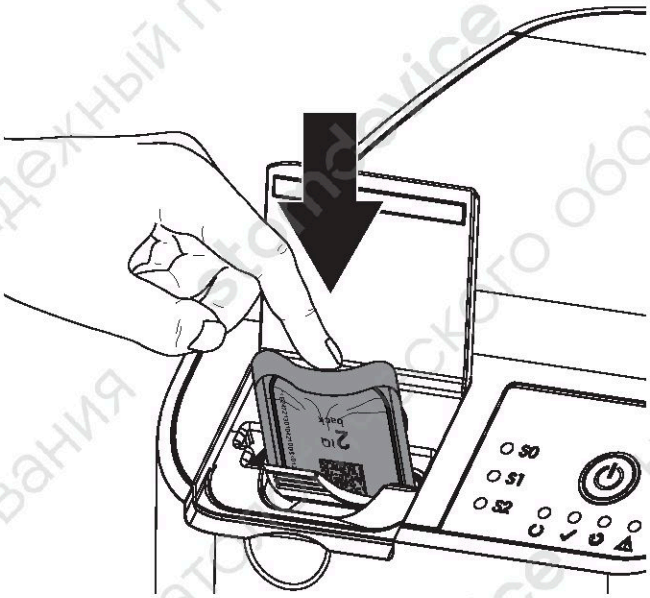


› Place the light protection cover with the image plate centrally and straight onto the input unit. The torn-off side of the light protection cover faces down; the inactive (back) side of the image plate faces the operator.
The image plate must not be pulled out of the light protection cover before placement on the input unit. There is the risk of image information being erased by ambient light (see "9 Correct use of image plates").



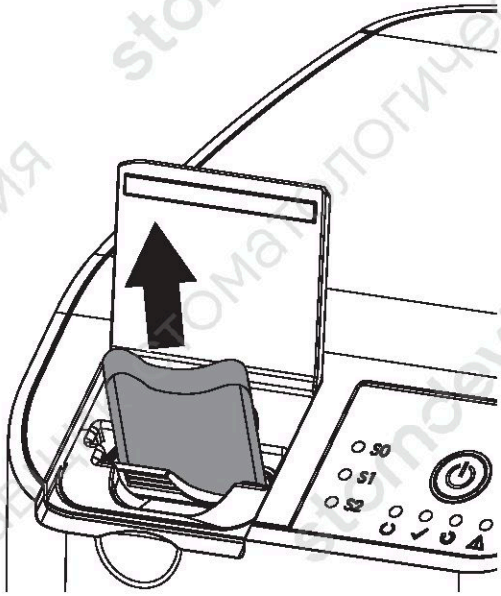

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› Slide the image plate out of the light protection cover downwards into the unit. The image plate must be inserted fully into the input unit.

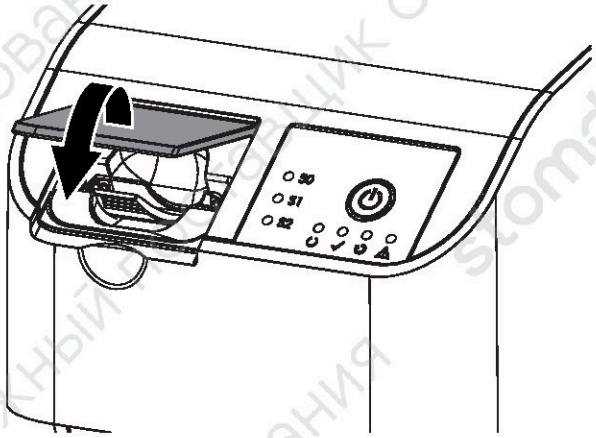


Make sure that only the image plate, and not the light protection cover, is inserted into the unit.

› Remove the empty light protection cover.



› Once the image plate has been inserted into the unit, close the cover and leave it closed throughout the entire scanning process.



The blue status LED lights up.
The image data is automatically transmitted to the imaging software. The progress of the scanning process is displayed in the preview window on the monitor.
After it has been scanned, the image plate is erased and drops into the collection tray.

› When the green status LED lights up:
Save the X-ray image.

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




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## 10.4 Erasing the image plate

The image data is automatically erased after scanning.
The special *ERASE* mode only activates the erasure unit of the image plate scanner. No image data is read.
The image plate needs to be erased using the special mode in the following cases:

– The first time the image plate is used, or if it is stored for longer than a week.
– Due to an error, the image data on the image plate has not been erased (software error message).

› Select the special *ERASE* mode in the software.
› Insert the image plate (see "Scanning the image plate").

## 10.5 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 LEDs go out.

# 11 Cleaning and disinfection

When cleaning and disinfecting the unit and its accessories, observe country-specific directives, standards and specifications for medical products as well as the specific specifications for dental practices and clinics.

**NOTICE**

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

Do not use any products based on phenolic compounds, halogen-releasing compounds, strong organic acids or oxygen-releasing compounds, as they may damage the materials.

› Dürr Dental recommends using disinfectants from the Dürr Dental product range. Only the products specified in these instructions have been subjected to material compatibility testing by Dürr Dental.
› Read the operating instructions for the disinfectants.

Wear protective gloves.

## 11.1 Image plate scanner

### Unit surfaces

The unit surface must be cleaned and disinfected of any contamination or visible soiling.
Dürr Dental recommends using the disinfectants FD 322, FD 333, FD 350 and FD 366 sensitive.

**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, lint-free cloth that has been dampened with cold tap water.
› Disinfect the surfaces using a disinfection wipe. Alternatively, use disinfectant on a soft, lint-free cloth.


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### Cartridges (S0-S2)

The cartridges can be cleaned and disinfected with a wipe disinfection or in an immersion disinfection system.

**NOTICE**

**Heat damages the cartridges**

› Do not thermally disinfect or steam sterilise the cartridges.

› Remove any soiling from the cartridge with a soft, lint-free cloth that has been dampened with cold tap water.

› Disinfect the cartridge using a disinfection wipe. Alternatively, use disinfectant on a soft, lint-free cloth. Comply with the operating instructions for the disinfectant when doing this.

› Dürr Dental recommends ID 213, ID 212 or ID 212 forte instrument disinfectants for the cartridges if an immersion disinfection system is being used. Dürr Dental has subjected these disinfectants to material compatibility testing.

› Allow the cartridges to completely dry before using them.

## 11.2 Light protection cover

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

› Disinfect the light protection cover using a disinfectant before and after placement. Dürr Dental recommends FD 333 forte wipes (virucidal), FD 350 (limited virucidal activity) and FD 322 premium wipes (limited virucidal activity).

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

## 11.3 Image plate

Cleaning and disinfection wipes are unsuitable for cleaning image plates and may cause damage to them.

Only use a cleaning agent that is compatible with the materials:

Dürr Dental recommends the image plate cleaning wipe (see "3.4 Consumables"). Only this product has been subjected to material compatibility testing by Dürr Dental.

**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 cleaning agents that are compatible with the materials.

› Soiling on both sides of the image plate should be cleaned off with a soft, lint-free wipe prior to every use.

› Remove resistant or dried on dirt with the image plate cleaning wipe. When doing this, observe the instructions for use for the cleaning wipe.

› Allow the image plate to completely dry before using it.

## 11.4 Image plate storage box

Clean and disinfect the surface of the image plate storage box and the internal image plate storage tray in the event of contamination or visible soiling.

Dürr Dental recommends the following disinfectants for the image plate storage box:

FD 366 sensitive

Dürr Dental recommends the following disinfectants for the image plate storage tray:

FD 350 and FD 366 sensitive

› Clean the surface of the image plate storage box and the image plate storage tray with a soft, lint-free cloth that has been dampened with cold tap water.

› Disinfect the surfaces of the image plate storage box using a disinfection wipe. Alternatively, use disinfectant on a soft, lint-free cloth.

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


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# 12 Maintenance

## 12.1 Recommended maintenance schedule



Prior to working on the unit or in case of danger, disconnect it from the mains.

The recommended maintenance intervals are based on using the device for 25 intraoral images per day on 220 working days per year.

| Maintenance interval | Maintenance work |
|---|---|
| Annually | › Visually inspect the device. |
| | › Check the image plates for signs of scratches and change if necessary. |
| | › Remove dust and dirt from accessible parts. |
| | › Carry out a system check. |
| Every 3 years | › Exchange the cartridges. |


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# Troubleshooting

## 13 Tips for operators and service technicians

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

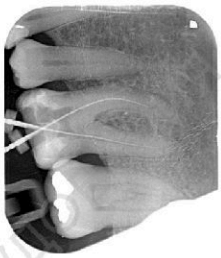


Prior to working on the unit or in case of danger, disconnect it from the mains.

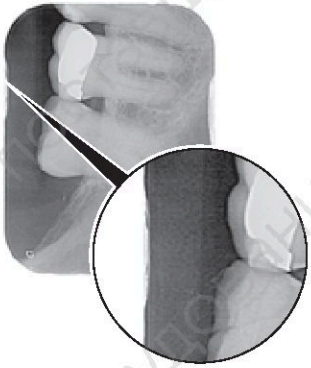
### 13.1 Poor X-ray image

| Error | Possible cause | Remedy |
|---|---|---|
| **Instead of the X-ray image, the software shows a completely white image or no image** | Image plate not fed in straight and inactive side scanned | › Scan the image plate again immediately, protecting it against ambient light and making sure you feed it in correctly in the process. |
| | Image data on the image plate has been erased, e.g. by ambient light | › Always scan the image data of the image plate as quickly as possible. |
| | Fault on the unit | › Inform a Service Technician. |
| | No image data on image plate, image plate not exposed or not sufficiently exposed | › X-ray tubes / check unit settings<br>› Expose the image plate. |
| | X-ray unit is faulty | › Inform a Service Technician. |
| | Incorrect cartridge, light protection cover was also pushed into the unit | › Use the correct cartridge for the size of image plate being used. |
| **Image plate falls out of the unit and no image appears on the monitor** | IQ image plate not used | › Only use Dürr Dental IQ image plates. |
| **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. |


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| Error | Possible cause | Remedy |
|---|---|---|
| **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. |
| **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.<br>› 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.<br>› 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.<br>› Check X-ray tube. |
| | Faulty edge masking in imaging software | › Deactivate edge masking. |


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| Error | Possible cause | Remedy |
|---|---|---|
| **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.<br>› Scan image data within half an hour after the exposure. |
| | Image plate dirty or scratched | › Clean the image plate.<br>› Replace scratched image plates. |
| | Unit was shaken by impact or input unit cover was closed during scanning process | › Set up the unit so that it cannot be shaken.<br>› Prevent the unit from being touched during the scanning process. |
| **Light strips in the scanning window** | Too much incident ambient light during the scanning process | › Darken the room.<br>› Turn the unit so that the light does not fall directly onto the input unit. |
| **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.<br>› Observe the operating instructions for the image plates and film retainer systems. |


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| Error | Possible cause | Remedy |
|---|---|---|
| **The X-ray image shows a pre-erasure at one end**<br> | After the barrier envelope has been torn off and before pushing the PSP into the input unit, the phosphor storage plate is pushed out of the light protection cover | › Do not push out the image plate until the torn-off light protection cover has been placed on the input unit. |

## 13.2 Software error

| Error | Possible cause | Remedy |
|---|---|---|
| **"Too much ambient light"** | Unit exposed to too much light | › Darken the room.<br>› 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. |
| **Imaging software does not recognise the unit** | Unit not switched on | › Switch on the unit. |
| | Connecting cable between device and computer not correctly connected | › Check the connecting cable. |
| | Computer does not detect any connection to the unit. | › Check the connecting cable.<br>› Check the network settings (IP address and subnet mask). |
| | Hardware fault | › Inform a Service Technician. |
| | The IP address of the device is being used by another unit | › Check the network settings (IP address and subnet mask) and assign a unique IP address to every device.<br>› Inform a service technician if the problem persists. |


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| Error | Possible cause | Remedy |
|---|---|---|
| **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.<br>› 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. |
| **Software message: "VistaSoft has detected that the image plate may have been exposed from the wrong side. Please check the orientation and the image quality before making a diagnosis."** | The image plate was exposed on the back (inactive) side while the X-ray was being taken. | › When diagnosing the X-ray image, note that the X-ray image is displayed mirror-inverted. |

## 13.3 Fault on the unit

| Error | Possible cause | Remedy |
|---|---|---|
| **Unit not shown in the imaging software** | Network cable not installed | › Install the network cable. |
| | No DHCP server connected | › It may take some time for the imaging software to detect the unit.<br>› Update the unit list. |
| | Network configuration incorrect | › Configure the network correctly. |
| **Unit does not switch on** | No mains voltage | › Check the mains cable and plug connection and replace if necessary. |
| | | › Check the power supply unit.<br>› If the green status LED does not light up, replace the power supply unit. |
| | | › Check the mains fuse in the building. |
| | On / off switch is defective | › Inform a Service Technician. |
| **Unit switches back off after a short time** | Mains cable or power supply unit plug not inserted correctly | › Check the mains cable and plug connections. |
| | Hardware fault | › Inform a Service Technician. |
| | Mains supply voltage too low | › Check the mains voltage. |
| **Unit is on but none of the indicator LEDs are lit up (status, error or operating LEDs)** | Display defective | › Inform a Service Technician. |


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| Error | Possible cause | Remedy |
|---|---|---|
| **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. |
| **Image plate does not fit into the intake slot** | Incorrect cartridge used | › Use the correct cartridge for the size of image plate being used. |
| **Light protection cover slips into intake slot together with image plate** | Incorrect cartridge used (too large) | › Use the correct cartridge for the size of image plate being used. |
| **Cartridge display does not light up** | Cartridge not inserted correctly | › Insert the cartridge correctly. |
| **Network connection has been disconnected** | Connecting cable between device and computer not correctly connected | › Check the connecting cable. |
| | The IP address of the device is being used by another unit | › Check the network settings (IP address and subnet mask) and assign a unique IP address to every device.<br>› Inform a service technician if the problem persists. |
| **Unit ejects the image plate without the image data being transmitted to the imaging software. Error message: "Incorrect image plate type inserted"** | IQ image plate not used | › Only use Dürr Dental IQ image plates<br>› The ejected image plate can be imported on a suitable image plate scanner (e.g. VistaScan Mini View). Make sure that the image plate is protected against ambient light. |


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# Appendix

## 14 Scanning times

The scanning time corresponds to the time taken for complete scanning of image data and depends on image plate format and pixel size.
The time to image will depend largely on the computer system used and its work load. Times stated are approximate.
For technical reasons, the surface of the largest size of image plate (size 2) is always scanned. As a result, the scan times are the same for all sizes of image plate.

| **Max. theoretical resolution (LP/mm)** | **16.7** | **10** |
|---|---|---|
| **Pixel size (µm)** | **30** | **50** |
| Intra Size 0 (2 x 3) to Intra Size 2 (3 x 4) | 20 s | 13 s |


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# 15 File sizes (uncompressed)

The actual file size will depend on the image plate format and the pixel size. File sizes stated are approximate and have been rounded upwards.
Suitable compression methods can considerably reduce the file size without loss of data.

| **Max. theoretical resolution (LP/mm)** | **16.7** | **10** |
|---|---|---|
| **Pixel size (µm)** | **30** | **50** |
| Intra Size 0 (2 x 3) | 1.8 MB | 1.1 MB |
| Intra Size 1 (2 x 4) | 2.3 MB | 1.4 MB |
| Intra Size 2 (3 x 4) | 3.0 MB | 1.8 MB |


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# 16 Handover record

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

| Product name | Order number (REF) | Serial number (SN) |
|---|---|---|
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- ☐ Visual inspection of the packaging for any damage
- ☐ Unpacking the medical device and checking for damage
- ☐ Confirmation of the completeness of the delivery
- ☐ Instruction in the proper handling and operation of the medical device based on the operating instructions

**Notes:**

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**Name of person receiving instruction:** **Signature:**

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

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

| | |
|---|---|
| | |


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| Country | Address |
|---|---|
| GB | **UK Responsible Person:**<br>Duerr Dental (Products) UK Ltd.<br>14 Linnell Way<br>Telford Way Industrial Estate<br>Kettering, Northants NN 16 8PS |
| UA | **Уповноважений представник в Україні:**<br>Приватне підприємство “Галіт”<br>вул. 15 квітня, 6Є, с. Байківці,<br>Тернопільський р-н,<br>47711, Україна<br>тел.: 0800 502 998;<br>+38 050 338 10 64<br>www.galit.te.ua;<br>e-mail: office@galit.te.ua<br><br>Виробник: Дюрр Дентал ЕсЕ<br>Хьопфігхаймер Штрассе 17,<br>Д-74321 Бітігхайм-Біссінген,<br>Німеччина<br>email: info@duerrdental.com |


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