ENGLISH

DIGORA® Optime

Digital intraoral imaging plate system

User Manual

208396 rev. 2

Copyright

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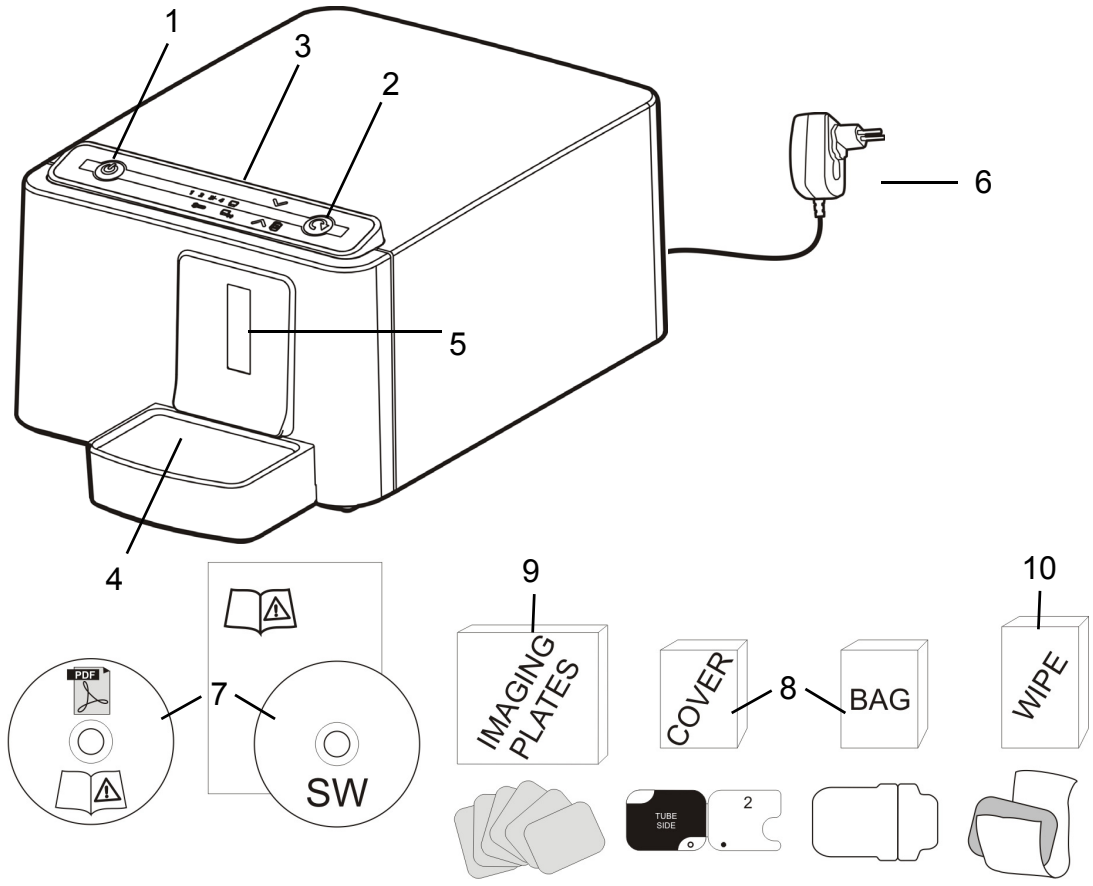
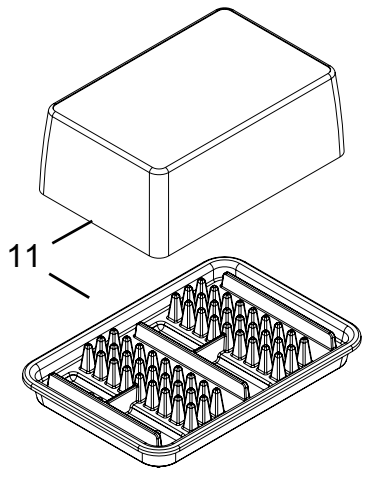
1 Introduction

SOREDEX® DIGORA® Optime system is intended to be used only by dentist and other qualified dental professionals to process x-ray images exposed to the imaging plates from the intraoral complex of the skull.

1.1 Unit with accessories



1. ON/OFF key
2. START key
3. Control panel
4. Imaging plate collector
5. Plate slot and plate carrier
6. Power supply
7. Documentation and imaging application software media
8. Hygiene accessories
9. Imaging plates
10. Imaging plate cleaning wipe samples
11. Imaging plate storage box



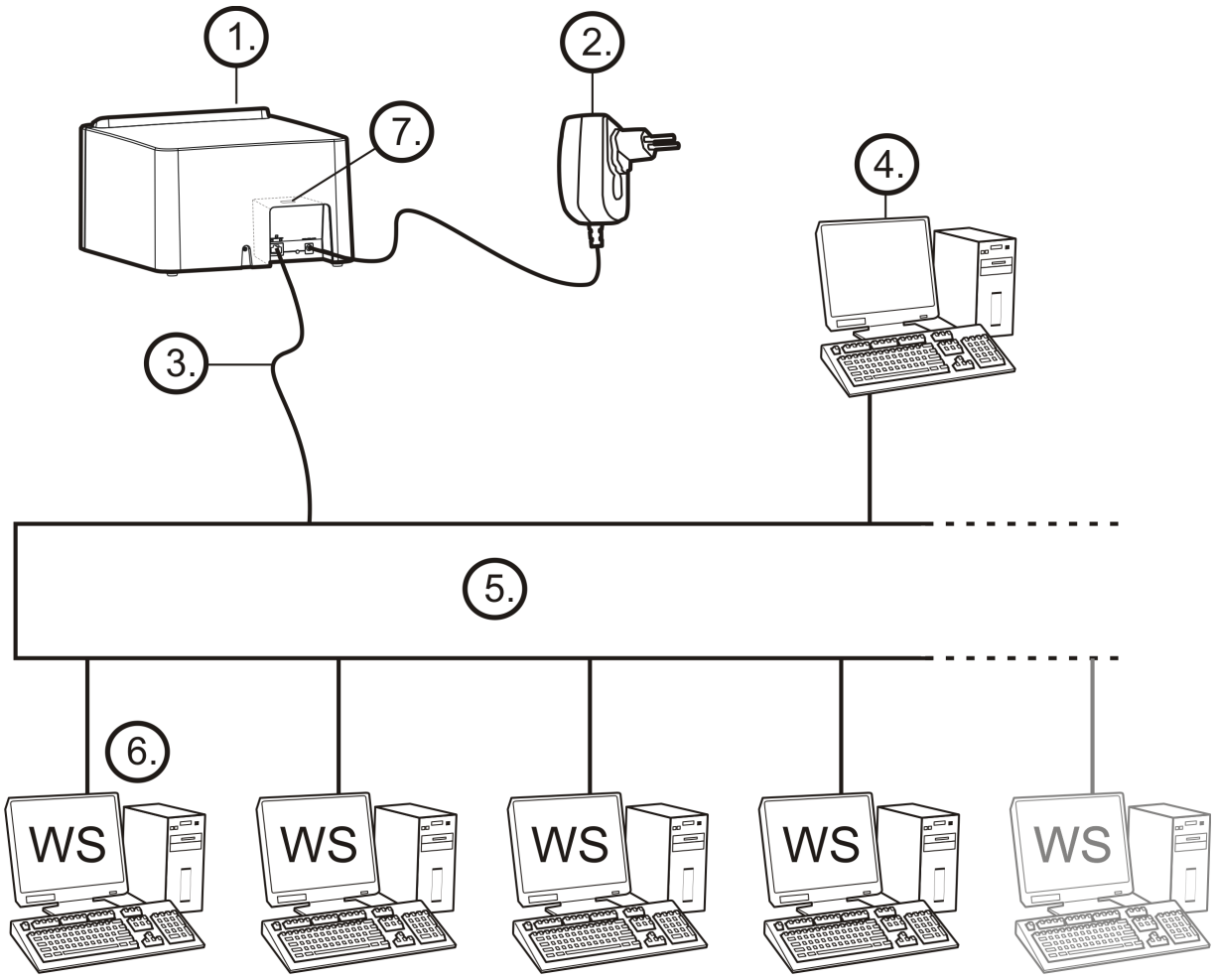
1.2 System setup

1. DIGORA® Optime unit
2. Power supply unit (PSU)

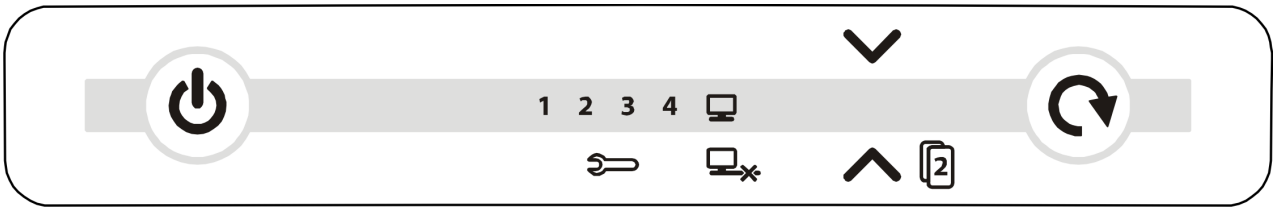
   CAUTION:
   Only use the PSU supplied with the unit or an approved spare PSU supplied by an authorized distributor (See chapter Technical Specifications).

3. Ethernet cable (not included)
4. Workstation (WS) computer (not included)
5. Optional local network switch (not included)
6. Optional workstations (WS) computers (not included)
7. Kensington security slot for securing unit in its place

For more details of installing and setting up the system see chapters Installation and Technical specification.



1.3 Controls and indicators



All indicators lit shortly when powering up the unit.

NOT LIT

LIT

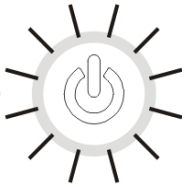
BLINKING

ON/OFF key

Unit is NOT powered

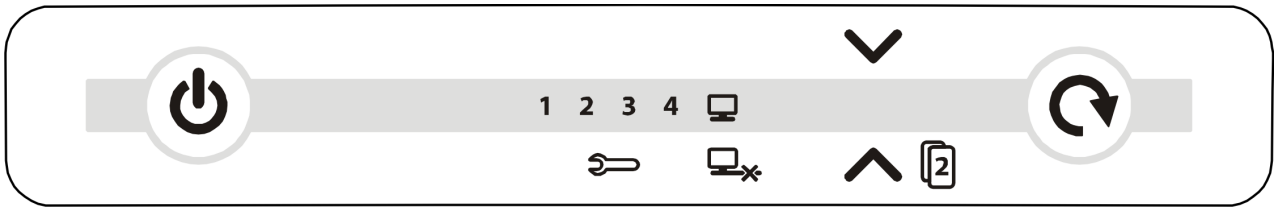
Unit is powered

Light dim and brighten again in sequence:


Unit is in standby mode (Press ON/OFF or START key OR activate from imaging software).

START key

Manual start selected
Unit ready
(Insert imaging plate and press
START to begin processing)



No connection

Connected to imaging application sw.
Not ready for processing

Open imaging software
- Check workstation
- Image memory full or plate detected without patient selected

Ready to process
(Insert imaging plate)

Unit in setup mode
(See chapter *Advanced use*)

4 Ready to Process
Image goes to workstation 4
(Insert imaging plate)

Blinking in sequence:
- Imaging plate wrong way round

Remove protective cover

1 2 3 4 Error number

Manual plate removal selected (Remove plate)

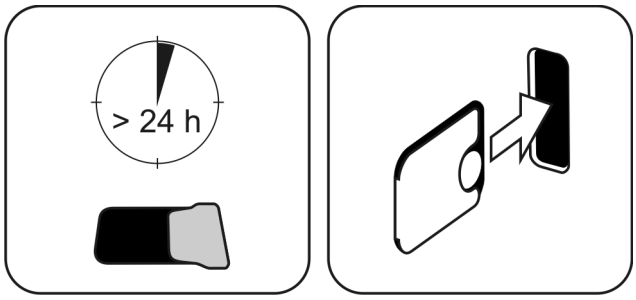
Waiting for 2nd size 3 plate to make Comfort Occlusal™ 4C image (Insert 2nd size 3 OR press START to cancel)

2 Basic use

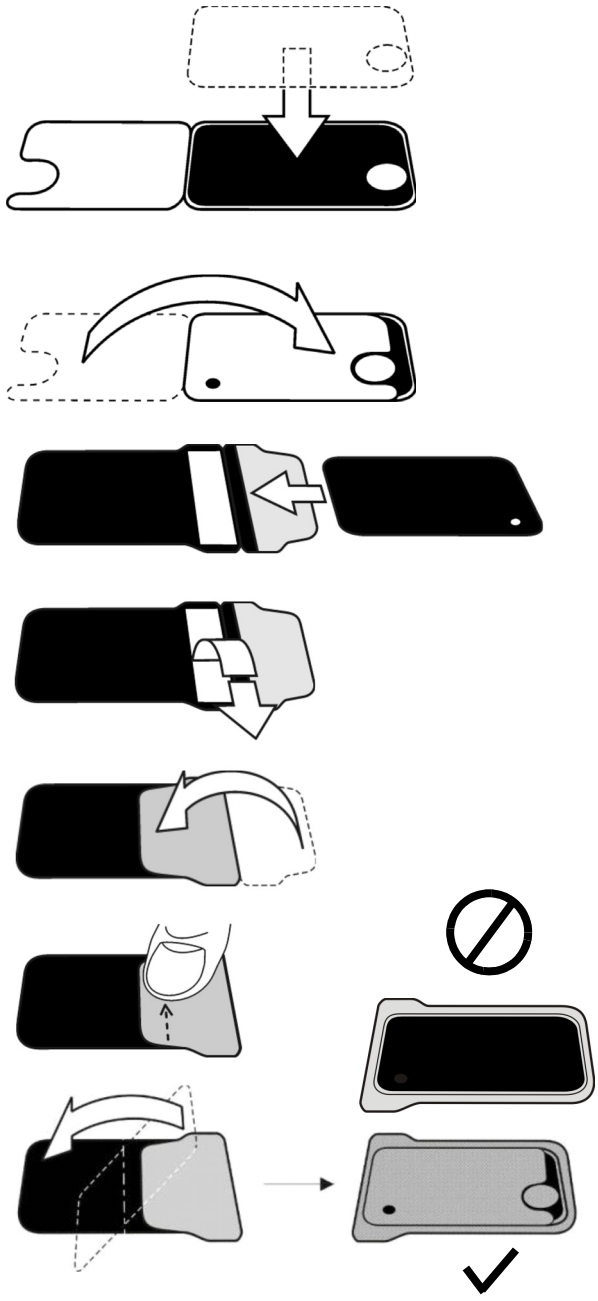
Process imaging plate(s) in the unit before packing and exposure if:

- Using a new imaging plate for the very first time
- Imaging plate has been packed for over 24 hours
- Unpacked imaging plate has been stored in dark (not exposed to ambient light) for over 24 hours

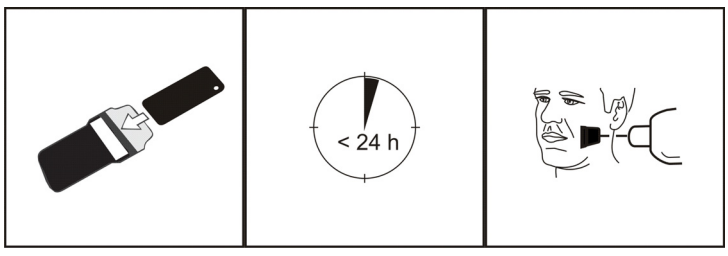
By doing this, the erasing procedure will remove any fogging collected to the imaging plate due to natural background radiation.



2.1 Imaging plate packing

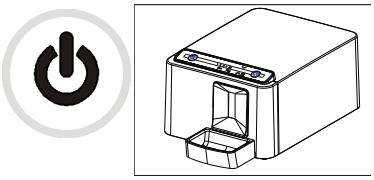


Note! *Do the packing before the patient enters the reception room, but no more than 24 hours before.*



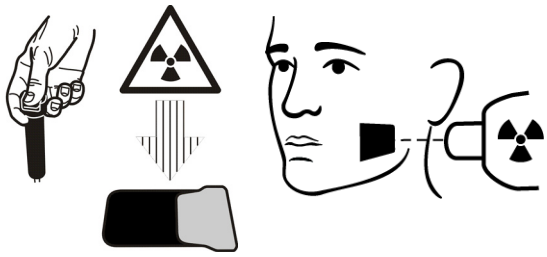
2.2 Taking and processing an image

Power on the unit.



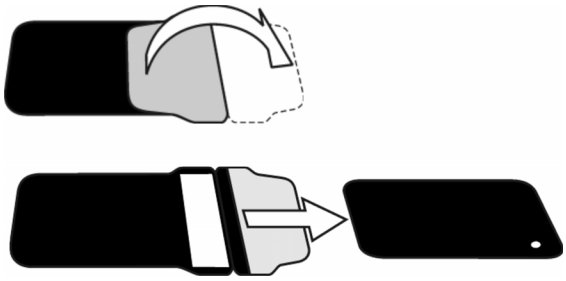
Launch the imaging application software.
Select a patient.

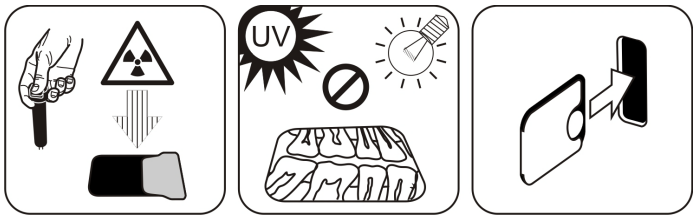
Make an exposure.



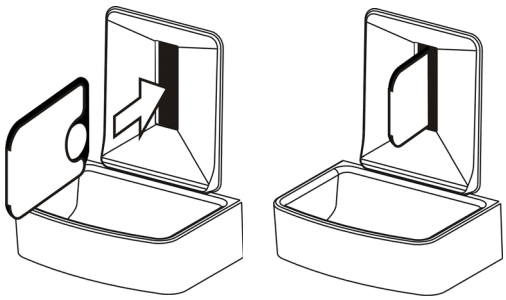
Check that the ready arrow is lit in the unit.

Unpack the imaging plate.

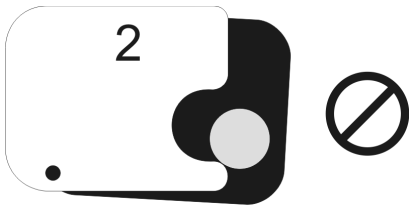




Note! *Ambient light harms the image information.*

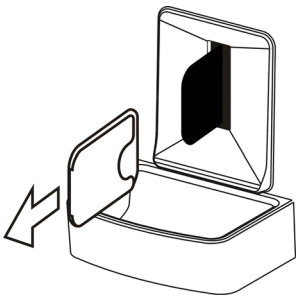


Insert the imaging plate with the cover.



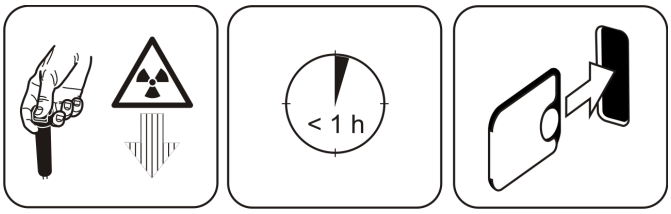
Note! *Do not partially slide the imaging plate from the cover. You can place the plate with cover and leave it to the plate carrier. Unit will not start the processing before removing the cover.*

Remove the cover.

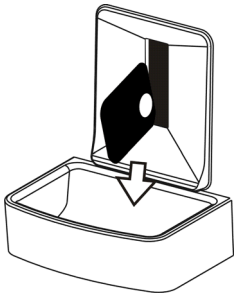


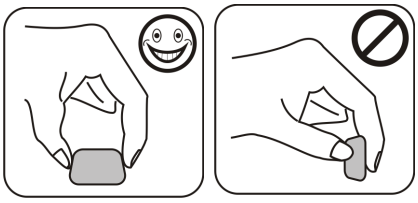
The image appears on the imaging application screen.

Note! *Process within one hour after exposure.*



Processed imaging plate is ready to be packed and exposed again.





2.3 Exposure guidelines

Recommended exposure values (s) for DC x-ray units.

Exposure settings found good for F-speed (Insight) film can be used (for AC x-ray units increase exposure time by 30%).

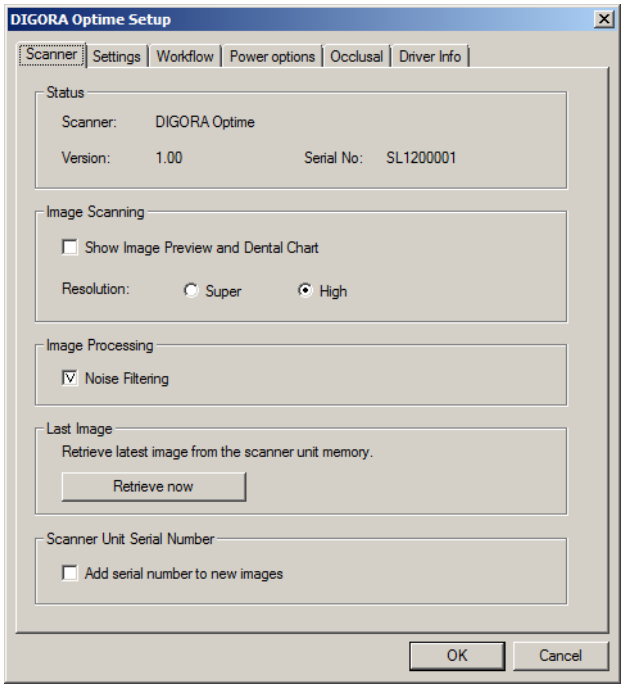
	7mA kV				
229mm (9”) SSD DC	60	0,12 ⋮ 0,20	0,16 ⋮ 0,25	0,16 ⋮ 0,32	0,16 ⋮ 0,25
	70	0,06 ⋮ 0,10	0,08 ⋮ 0,12	0,08 ⋮ 0,16	0,08 ⋮ 0,12
305mm (12”) SSD DC	60	0,25 ⋮ 0,40	0,32 ⋮ 0,50	0,32 ⋮ 0,63	0,32 ⋮ 0,50
	70	0,12 ⋮ 0,20	0,16 ⋮ 0,25	0,16 ⋮ 0,32	0,16 ⋮ 0,25
		~AC +30%			

3 Advanced use

3.1 DIGORA® Optime setup options

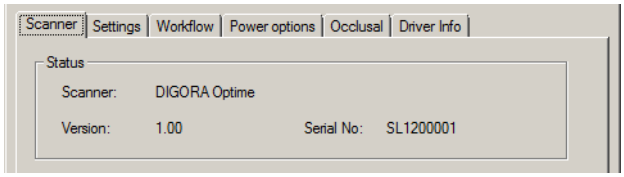
The DIGORA® Optime setup options allow you to configure the DIGORA® Optime to the user's clinical preferences.

From the imaging application software you are using select unit Setup/Scanner page (for more instruction on how to access setup page review application software manual).

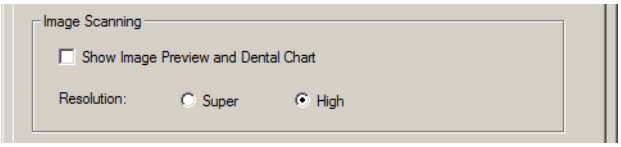


3.1.1 Status

Shows the scanner type, firmware version and unit serial number.



3.1.2 Image Scanning



If Show Image Preview and Dental Chart is selected a preview image with a dental chart for tooth numbering appears before the image is saved.

3.1.3 Using the dental chart

1. After an imaging plate has been processed a window opens that shows a preview image and a dental chart.

2. Click the tooth / teeth on the chart that correspond to the tooth / teeth in the image. Tooth numbers are assigned to the selected teeth.

   The tools at the top of the window allow the image to be manipulated.

3. Click **OK** to save the image and tooth numbers.

3.1.4 Resolution

Super gives a pixel size of 30 µm. This results in images with better resolution, but may require longer exposure time to compensate.

High (recommended default) gives a pixel size of 60 µm. This results in images with less noise especially if short exposure times are used.

3.1.5 Image Processing - Noise Filtering

Noise Filtering selected (recommended default), makes images smoother when they are taken at short exposure times.

3.1.5.1 Retrieve last image

If the last image processed is not transferred to the PC because of a network, communication, PC or software failure, the last image processed can be retrieved.

Note! *The LAST processed image can only be retrieved if the unit is left on. If the unit is switched off the image is lost.*

To retrieve the last processed image:

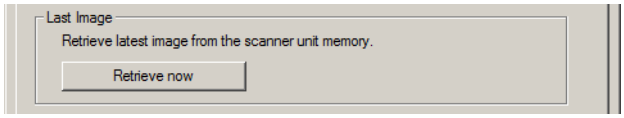
1. Correct the problem that caused the communication failure. When the connection between the unit and the PC is re-established the last processed image is automatically transferred to the PC.

2. **PC**: If the image is not automatically transferred to the PC, select the Setup > Scanner page from the imaging application software your are using.

3. **PC**: In the Last Image field, click **Retrieve now** to retrieve the last processed image.

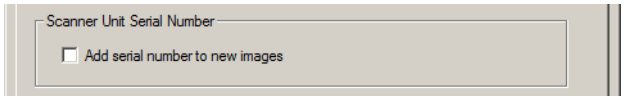
Note! *If required you can select different parameters (e.g. resolution, show image preview etc.) for the image to be retrieved.*

4. **PC**: Click **OK** to close the Setup window. The last processed image is transferred to the PC.



3.1.6 Scanner Unit Serial number

Adds the unit serial number to all new images.

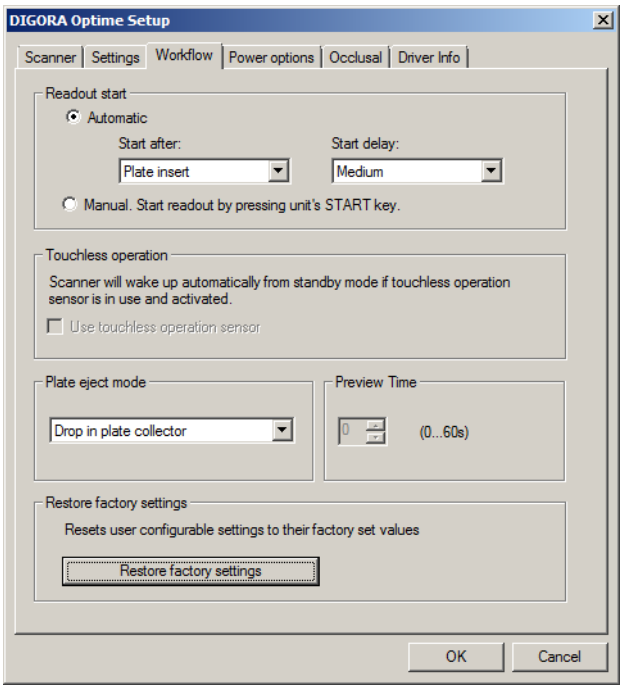


3.2 Settings

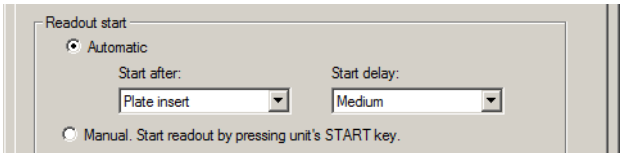
See chapter Installation for more information on connecting the unit to a PC/LAN.

3.3 Workflow

From the imaging application software you are using select unit Setup / Workflow page.



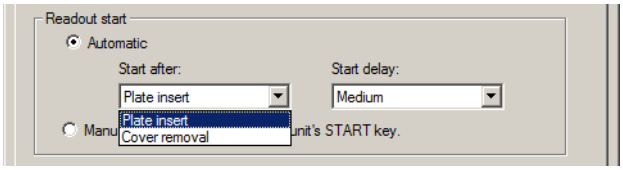
3.3.1 Readout start



Select **Automatic** if you want the unit to start automatically image plate processing.

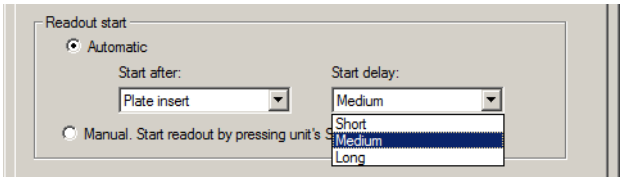
The **Start** after options allow to select when the unit starts image plate processing:

- After Plate insert: processing starts automatically when it detects right way inserted imaging plate in the plate carrier.
- After Cover removal: after the imaging plate and protective cover have been inserted into the plate carrier,
  processing starts automatically when the protective cover is removed.



The Start delay options allow the start delay time to be selected.

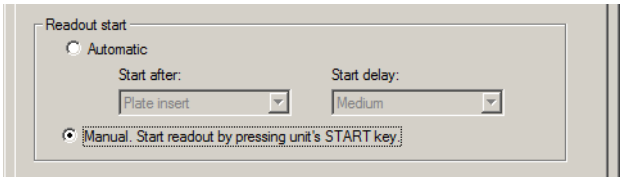
- Short = approximately 0.2 seconds
- Medium = approximately 0.4 seconds (recommended default)
- Long = approximately 0.6 seconds



Select **Manual** if you want processing to start only when the **START** key is pressed.

Note! *Processing starts even if the plate is:*

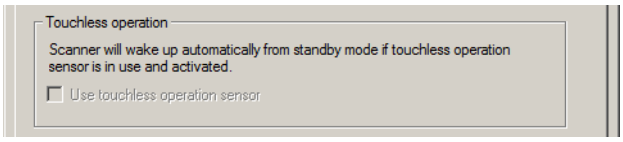
- Wrong way round
- Not detected
- Not inserted at all



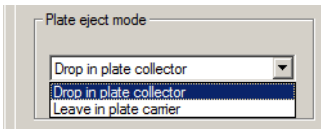
Note! *Unit turns off in manual mode if user is pressing ON/ OFF key regardless of imaging plate sensing in the plate carrier.*

3.3.2 Touchless operation

Note! *This system does not support touchless operation.*



3.3.3 Plate eject mode

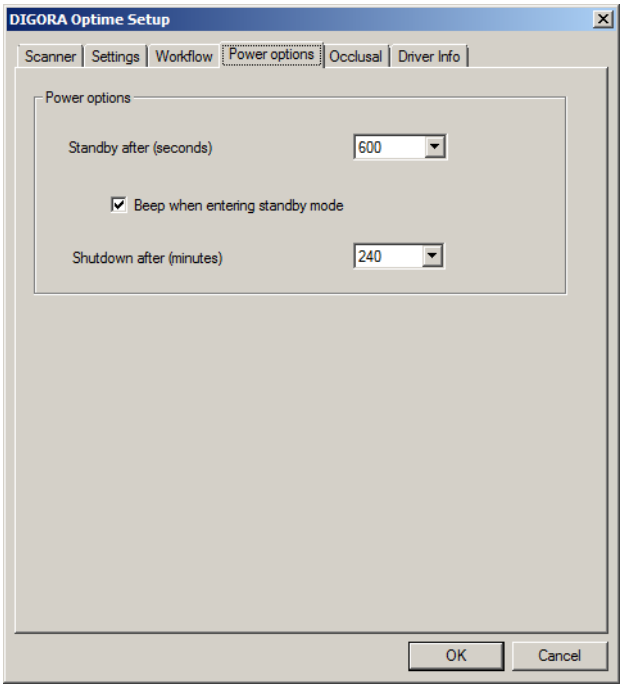


The options are:

- **Drop in plate collector:** the imaging plate is ejected into the plate collector after the imaging plate has been processed.
- **Leave in plate carrier:** the imaging plate remains in the plate carrier after the imaging plate has been processed.
  The **Leave in plate carrier** option is recommended for users who want to handle the imaging plates with more care and reduce wear and tear on them. This option extends service life of the imaging plates and allows greater hygiene standards to be observed.

3.4 Power options

From the imaging application software you are using select unit Setup / Power options page.



Standby after (seconds): Allows you to select the period of time the unit remains unused before it enters the

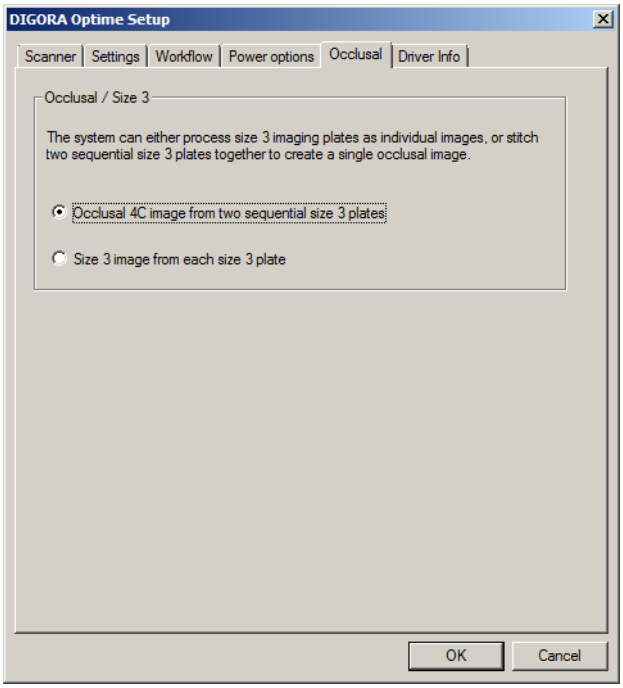
standby mode (plate carrier is driven inside the unit, door is closed and ON/OFF key dims on and off). Press ON/OFF key to recover.

Beep when entering standby mode: Audible signal is heard before the unit enters the standby mode.

Shutdown after (minutes): Allows you to select the period of time the unit remains in standby mode before automatically switching itself off.

3.5 Comfort Occlusal™ projection imaging (not included in delivery)

To change Comfort Occlusal™ 4C projection imaging settings select from the imaging application software unit Setup / Occlusal page.



Comfort Occlusal™ 4C projection image is formed from two sequential size 3 plates. Image plates are processed separately and then stitched together to form a single Comfort Occlusal™ 4C projection image. Following text shortly describe how Comfort Occlusal™ 4C projection image is taken. For more information refer to instructions supplied with the Comfort Occlusal™ 4C kit.

1. Place two size 3 imaging plates into their corresponding protective covers.

2. Slide the two size 3 imaging plates and protective covers into the Comfort Occlusal™ 4C bite protector.

3. Insert the Comfort Occlusal™ 4C bite protector and imaging plates into the Comfort Occlusal™ 4C hygiene bag.

4. Seal the bag. Place the sealed Comfort Occlusal™ 4C hygiene bag into the patient's mouth and take an exposure.

5. Remove the sealed Comfort Occlusal™ 4C hygiene bag from the patient's mouth. Open it.

6. Remove each individual imaging plate from the Comfort Occlusal™ 4C bite protector and process one at a time.

7. Comfort Occlusal™ 4C image appear on the imaging application software.

Note! *When you are in the* ***Occlusal 4C*** *mode it is possible to temporarily override the mode and process a single size 3 imaging plate. Insert the size 3 imaging plate into the unit so that it can be processed. When the insert second plate symbol appears on the unit user interface press the start key. This cancels the* ***Occlusal 4C*** *mode for this operation and produce a single size 3 image.*
Size 3 image *mode from each size 3 plate allows size 3 imaging plates to process as individual imaging plates.*

Note! Due to Comfort Occlusal™ 4C projection imaging geometry and imaging plate positioning, accurate distance and angle measurements cannot be taken from Comfort Occlusal™ 4C projection images.

3.6 Full Mouth Series (FMS) imaging

For US only. To fully support FMS template feature in imaging application SW magnetic FMS template for 18 imaging plates is available (PN0202398).

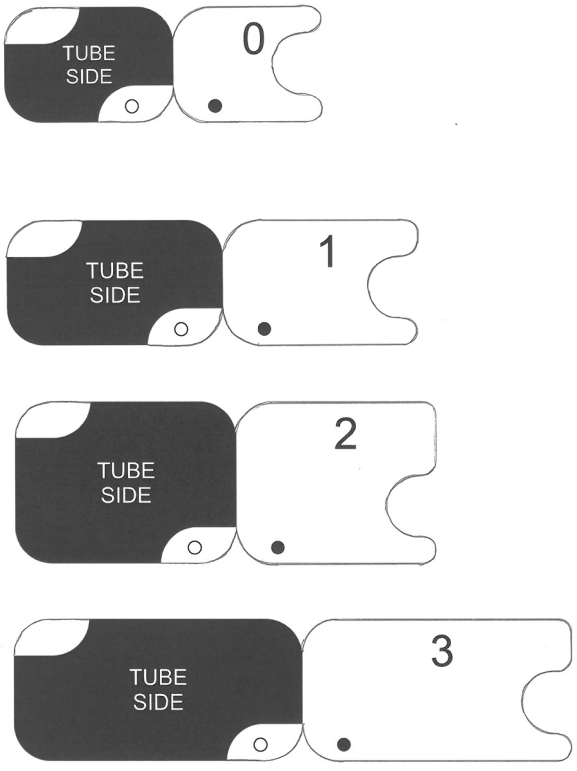
4 Accessories introduction

Note! *USE ONLY GENUINE SOREDEX® ACCESSORIES to ensure the optimum clinical results, safe use of the system and long service life for the imaging plates.*

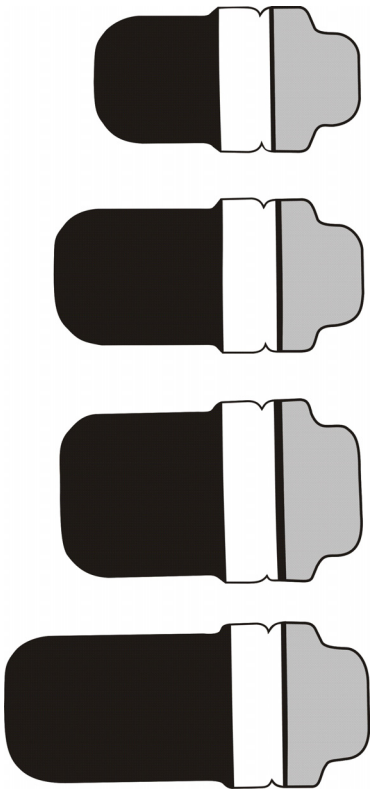
Note! *Never use hygiene accessories more than once.*

4.1 Hygiene accessories

Protective covers

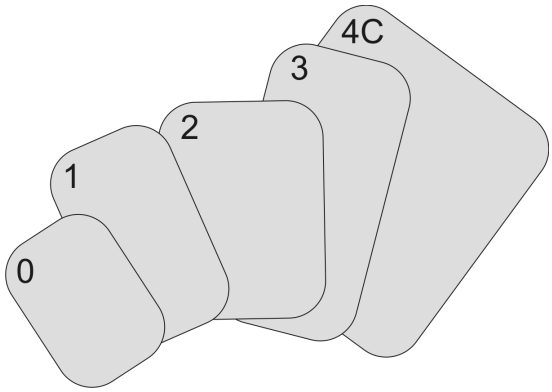


Hygiene bags

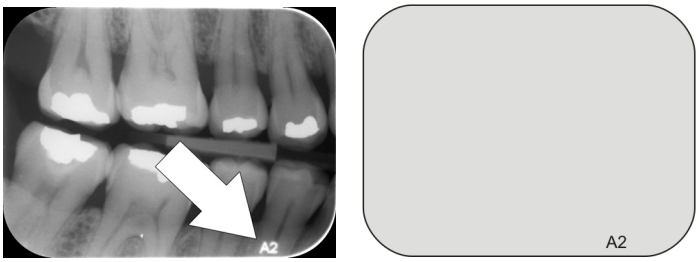


4.2 Imaging plates

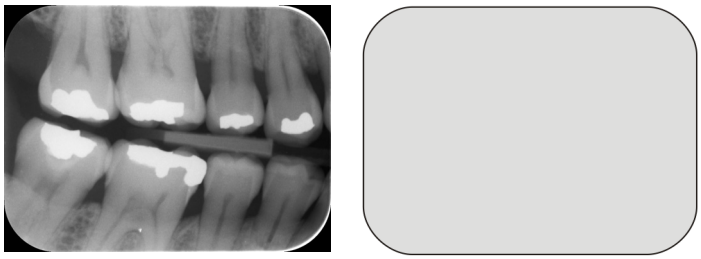
Compatible with all intraoral sizes equal to film: 0, 1, 2, 3 and Comfort Occlusal™ 4C, all with film-like usability.



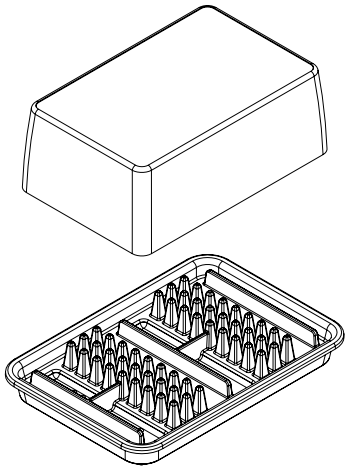
IDOT™ imaging plates (optional) have individual identification marking that appear on the images.



Standard (STD) imaging plates has no identification mark on the sensitive side of the plate.



4.3 Imaging plate storage box

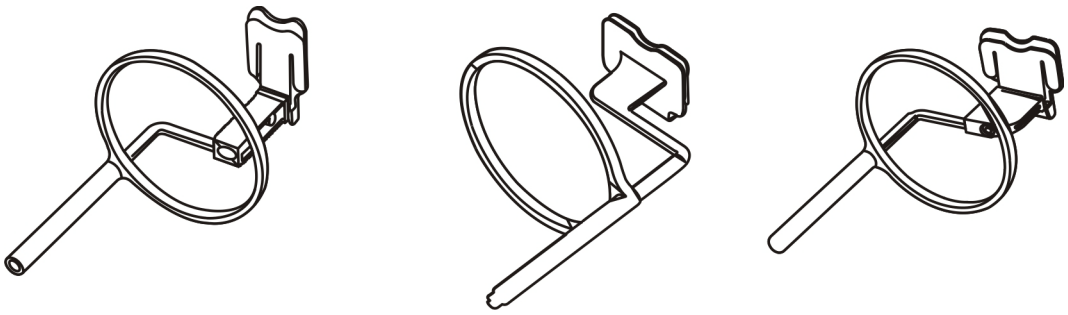


Practical, dedicated storage box keeps imaging plates clean and ready for use by protecting the plates from:

- Dust (which will be visible in the image)
- Airborne contamination
- Fogging caused by background radiation (which may decrease image quality)
- Ultraviolet radiation (which is harmful for the imaging plates)

Base part of the storage box is autoclavable at 121 °C (250 F) or 134 °C (272 F).

4.4 Holders



It is recommended to use imaging plate holders to ensure accurate patient positioning and consistently good image quality. Problems caused by manually positioning the imaging plate include:

- incorrect vertical alignment
- distortion

- cone cut off
- poor projection standardization
- inferior image quality
- contamination risk

Contact your distributor for more information on imaging with plate holders.

4.5 Occlusal projection imaging with Comfort Occlusal™ 4C start-up kit and accessories

The complete image is produced automatically from two size 3 imaging plates. The plates are shielded from biting damage with a rigid bite protector. For more information see instructions provided with the Comfort Occlusal™ kit and on chapter *Advanced use*.

4.6 Microfibre cloth

Imaging plate microfibre cloth is used for dry cleaning of the imaging plates (comparable to eyeglasses cleaning).

4.7 Optiwipe™ imaging plate cleaning wipes

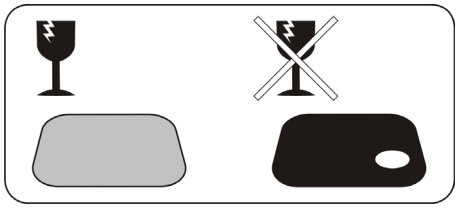
Optiwipe™ cleans imaging plates efficiently and safely but does not damage the imaging plates.

- Content: Ethanol (EtOH) 82% + Chlorhexidine Digluconate 0,5% (Chlorhexidine is a chemical antiseptic, used safely in many products, such as mouthwash and contact lens solutions).
- Absorbed in lint-free, non abrasive tissue.
- Each individual wipe package has clear illustrated cleaning instructions

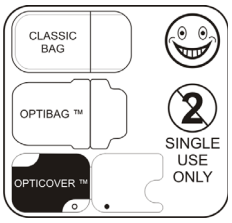
Note! *Unsuitable cleaning solutions/methods may damage or destroy the imaging plate or leave residues (from glycerol etc.) on the sensitive surface, which may appear on the images.*

Item number 900667, box of 50 individually packed wipes.

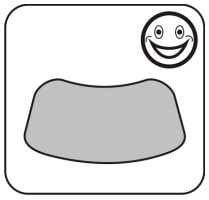
4.8 Imaging plate care



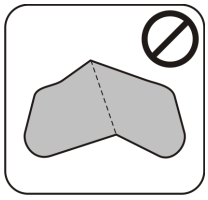
Sensitive surface, handle with care



Use only original accessories. Single use only!



You can bend.

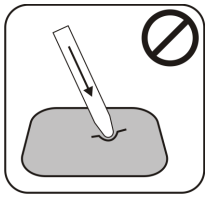


Do not fold or bend excessively.

Touch the edges only.

Do not touch the sensitive surface.

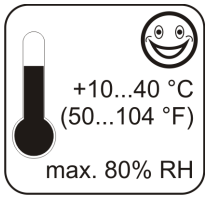
Do not scratch.



Do not stab.

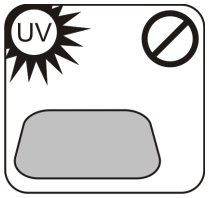
Avoid moist and water.

Do not sink.



Allowed temperature.

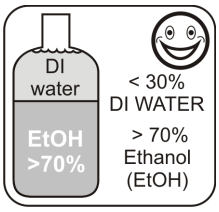
Avoid dust.



Avoid direct sunlight and UV radiation.

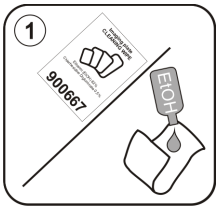
Not household waste.

4.9 Imaging plate cleaning

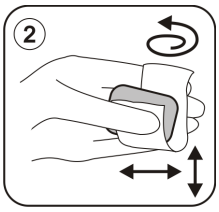


Use ONLY > 70% Ethanol

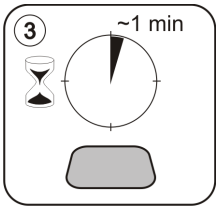
Do not apply Ethanol directly on the plate.



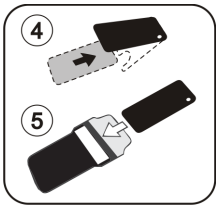
Apply Ethanol on lint free soft fabric.



Wipe the plate gently.

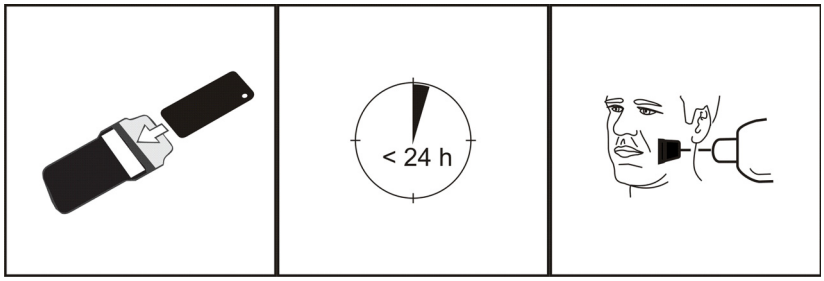


Wipe dry or let dry for 1 minute.



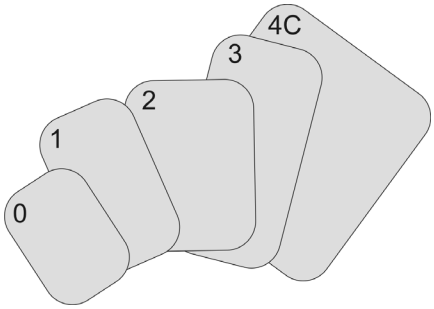
Pack the plate.

Note! *Pack the imaging plates in advance, but no longer than 24 hours before the exposure.*



5 Introduction to imaging plate technique

5.1 Imaging plate

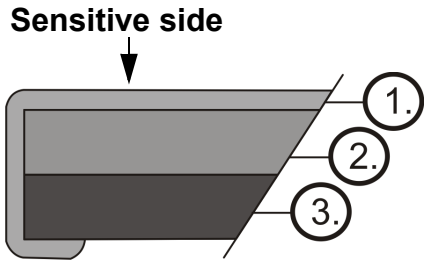


Imaging plate is a film-like thin, flexible and wireless phosphorescent plate, which works as a wireless receptor. Imaging plate is better than film because:

- no need for film development chemicals and dark-room.
- tolerates wider range of exposure values, both overexposure and underexposure are practically eliminated.
- All benefits of digital images.

Imaging plate sizes:

- 0 child
- 1 small adult
- 2 large adult
- 3 bitewing
- 4C comfort occlusion



1. Protective (topcoat) layer

2. Photo-stimulable layer

3. Support material layer (=back side, black)

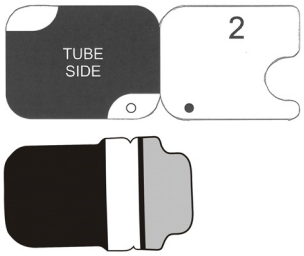
The support base material is black plastic. On top of the base material is blueish photo-stimulable layer (does not contain any prosphor/phosphorus). On top of the blueish material is a top coat protective layer and the edges are closed with lacquer.

The phosphorescent side of the plate records and stores the image. This side is sensitive and should be protected against dust and dirt.

Visible light clears the image information from the plate, so it must be protected from ambient light between exposure and processing.

Even when packed properly, the image starts to fade out slightly within time.

5.2 Hygiene accessories



The imaging plate is protected with a protective cover and a hygiene bag before the exposure. Protective cover and hygiene bag are protecting the plate from:

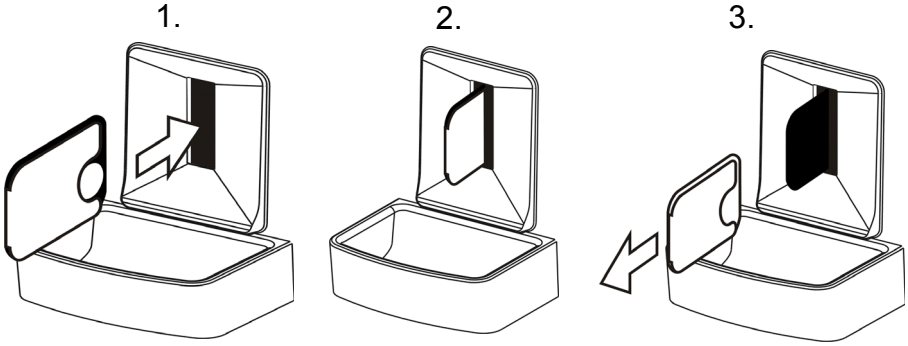
- Ambient light
- Contamination
- Mechanical wearing
- Moisture

Note! *USE ONLY GENUINE, ORIGINAL HYGIENE ACCESSORIES AND IMAGING PLATES DESIGNED FOR THIS SYSTEM AND SUPPLIED BY AUTHORIZED DISTRIBUTOR. The manufacturer of this system will not be held responsible for any problems caused by using accessories from other manufacturers. PROPER USE OF ORIGINAL HYGIENE ACCESSORIES ENSURES THE BEST IMAGE QUALITY AND MAXIMUM SERVICE LIFE OF THE IMAGING PLATES.*

The packed imaging plate is positioned with a holder in the patient's mouth. The exposure is made as with film. The hygiene bag should be disinfected after exposure and disposed off after single use.

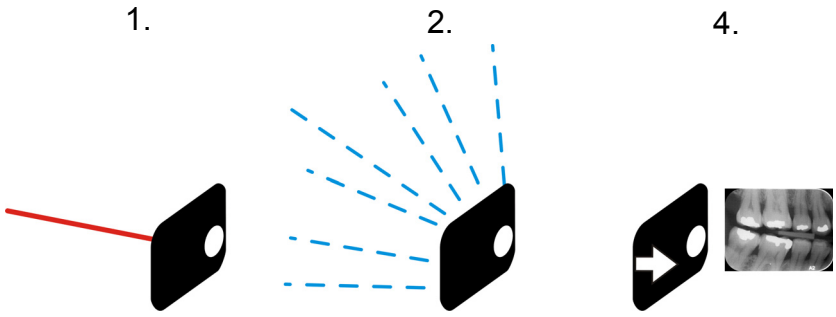
1. Imaging plate is inserted together with the protective cover all the way into the plate slot.
2. Magnet on the plate carrier grabs the imaging plate.
3. Processing starts automatically after you remove the protective cover.

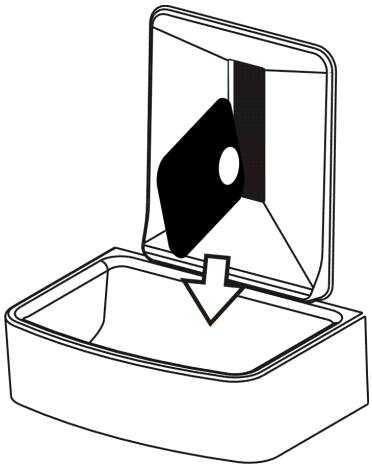
Dispose protective cover after single use.



5.3 Processing

1. Red laser light stimulates the sensitive surface of the imaging plate.
2. Imaging plate glows blue light in relation to the amount of X-ray information stored to the plate.
3. Glowing blue light is optically collected pixel by pixel (line by line) and measured with extremely sensitive photodetector.
4. Digital image is formed from the measured light intensity variation.





After stimulating, imaging plate is exposed to bright light, which clears the remaining image information from the plate. The imaging plate is dropped out of the unit.

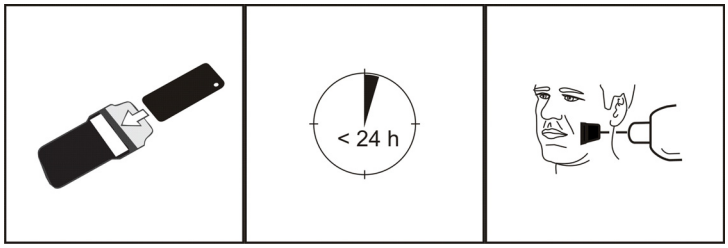
X-ray exposures and processing are not aging the imaging plate, so it is re-usable hundreds of times. In practice, mechanical wearing limits the service life of the plate.

5.4 Background radiation

The user can pack imaging plates ready for use.

However, it is not recommended to store pre-packed plates more than 24 hours.

Note! *Imaging plates react sensitively to natural background radiation, which may cause "fogging" and lack of contrast on the image.*



The X-ray dose of single intraoral imaging is approximately the same as the dose one person gets from natural background radiation during one day.

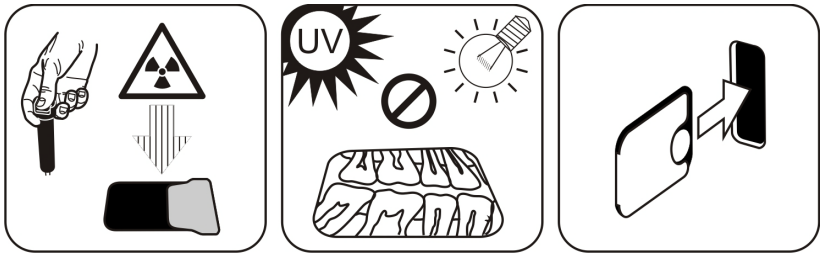
Imaging plates may gather radiation also during transportation from the manufacturer. Therefore it is recommended to perform initial erasing for the new plates. This means that all imaging plates should be processed once prior to use.

5.5 Light

Ambient light is good when storing the imaging plates:
it keeps the plates clean from background radiation “fogging”.

Note! *Ambient light is harmful for the image information on the plate between the exposure and processing.*

Note! *UV light is harmful for the imaging plates.*



6 Installation of the imaging plate system

Imaging plate system is formed of PC(s) connected to unit through ethernet switch or without it. See chapter system setup image.

6.1 Positioning the unit

Note! *Always position the unit so that you can easily detach the power supply unit (PSU) from the supply mains.*

Do not position the unit in direct sunlight or near bright light. Sunlight or bright light must not be allowed to shine directly on the unit door into which the imaging plates are inserted.

Position the unit on a stable flat surface so that vibrations will not degrade the image quality. The unit can also be attached to a wall, under or on a shelf with the optional mounting kit.

The unit must not be positioned so that it it touching other equipment. It must not be placed on top of or under other equipment.

The unit can be positioned within the environment in which the patient is examined and treated (patient environment).

6.2 Positioning the PC/network switch

The PC/network switch connected to the unit should not be used in the patient environment. The minimum horizontal distance between the patient and the PC is 1.5 m (4.5 ft). The minimum vertical distance between the patient and the PC is 2.5 m (6.5 ft).

6.3 Connecting the unit to a PC / LAN

The procedure for connecting the unit to a single PC or several PCs in a local area network (LAN) is exactly the same except that every PC in the LAN needs to be given a unique ID number.

6.3.1 Direct connection method (uses the unit s/n)

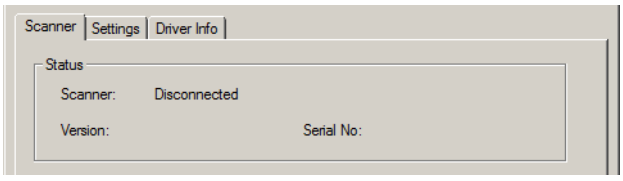
Note! *It may not be possible to connect the unit to the PC using the direct connection method if another device is already connected to the PC using direct connection. If the direct connection field is not active (greyed out) or the system does not work correctly after the unit has been connected, reconnect the unit using the imaging plate connection method.*

1. After positioning the unit connect it to the PC(s) in the local area network using the Ethernet cable (not included in delivery).

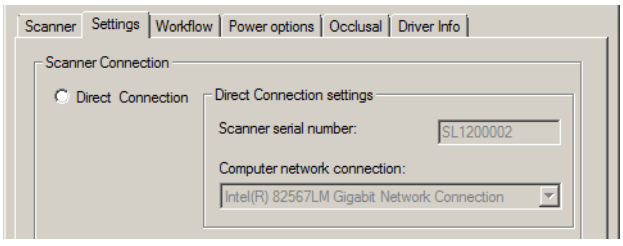
2. Switch the unit on. The imaging application software symbol appears in the unit user interface. This indicates that the unit is not communicating with the PC(s) in the network.

3. **PC**: Install the imaging application software to be used in the PC(s).

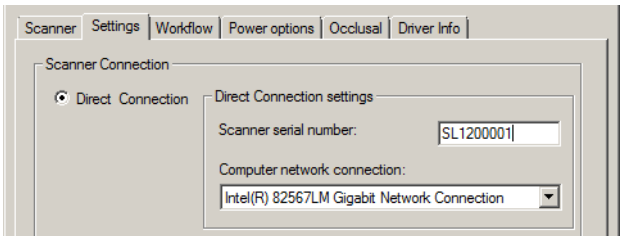
4. **PC**: Open the imaging application software and select the scanner setup window.



5. **PC**: From the scanner setup window select the Settings tab to open the Scanner Connection page.



6. **PC**: Select Direct Connection.



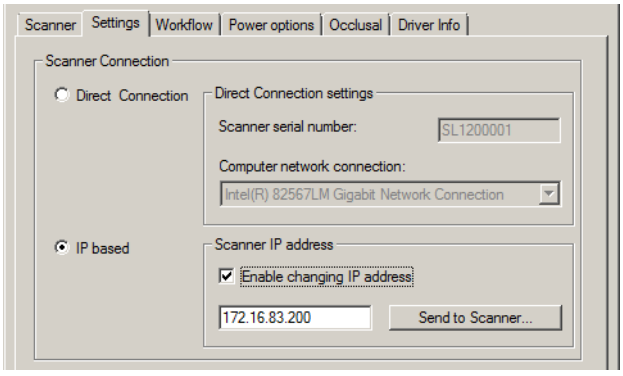
Key the serial number of the unit into the Scanner serial number field. The serial number of the unit appears on the type label on the back of the unit. Make sure that the Computer network connection that provides the LAN network connection is selected.

6.3.2 IP method (using the unit IP address)

If your system does not allow the direct connection method to be used to connect the PC(s), connection can be done using an IP address.

1. Follow steps 1 to 5 from the previous section, Direct connection method (uses the unit s/n).

2. **PC**: From the Settings tab select IP based and then select the Enable changing IP address box.



Obtain an IP address for the unit from your network administrator and key it into the IP field in the Scanner IP address area.

Note! *The PC and the unit must be in the same subnet when setting the IP address of the unit.*

3. **PC** + **Unit**: Press and hold down the Start key on the unit and then click **Send to Scanner** on the settings window.

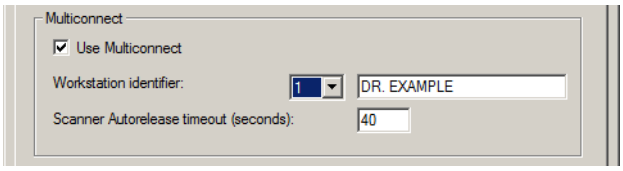
You hear a beep which indicates that the PC is now sending the IP address the unit.

4. **PC:** Click **OK** to connect the PC to the unit.

5. Now connect the other PCs in the network to the unit. Just enter the IP address into the IP field and then click **OK** to connect the PC to the unit (it is not necessary to hold down the Start key and click **Send to Scanner** with the other PCs once the unit has already got an IP address).

6.3.3 Multiconnect

1. **PC**: If the unit is to be used with several PCs select the Use Multiconnect check box and select a unique Workstation identifier number (between 1 and 4), for the PC being configured, from the drop down list. Addition workstation information, for example, user name, location etc, can be entered into the field next to the work station identifier number.



Note! *If only one PC is connected to the unit do not select the Use Multiconnect check box.*

The Scanner Autorelease timeout is the length of time that the unit remains reserved and unused by a PC before the PC automatically released the unit so that it can be used by another PC in the system (the scanner can be reserved in advance from another PC). The default setting is 40 seconds. This can be changed by keying in a new value

2. Click **OK** to connect the PC to the unit.

Note! *An automatic technique automatically locates the unit within the local area network and connect the PC.*

3. Repeat the above process for all the other PCs in the network. Make sure that you give each PC a different Workstation identifier.

4. Check the installation by starting image capture using the imaging application software. If the Use Multiconnect was selected the Workstation identifier of the PC (1 - 4) being used appears on the unit user interface.

6.4 Other devices

DO NOT connect any other devices to the unit or the PC connected to the unit that are:

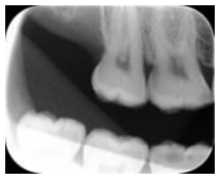
- not part of the supplied system
- not supplied by the manufacturer of the unit
- not recommended by the manufacturer of the unit.

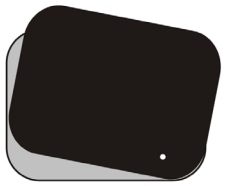
The PC connected to the unit should not be used in the patient environment. The minimum horizontal distance between the patient and the PC is 1.5 m (4.5 ft). The minimum vertical distance between the patient and the PC is 2.5 m (6.5 ft).

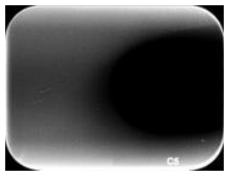
7 Troubleshooting

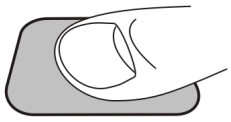
7.1 Error images

7.1.1 Improper use of the hygiene accessories and imaging plates





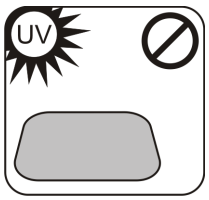




Decreased contrast, shadows or shading, ghost images…

Shows a “ghost image” (having shape of the plate or other object). Plate not properly shielded from light between exposure and process. Part of the image erased by ambient light.

- Protective cover misused or not used at all.
- Hygiene bag not sealed properly.
- Improper, non-genuine hygiene accessories use.



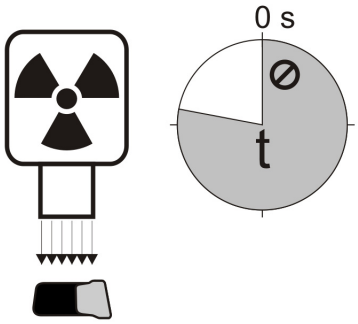
- Improper storing of the imaging plates or excessively high X-ray dose used.
- Imaging plate has been exposed to ultraviolet (UV) radiation.
- Imaging plate has collected background radiation because:
  - Plate has been stored near X-ray unit
  - Plate has been stored in the bag or in dark too long
- Use dedicated imaging plate storage box to avoid these.
- Alternatively, perform initial erasing for the plate(s) if they have been stored in dark and/or near X-ray unit.

7.1.2 Application errors

Improper x-ray settings used

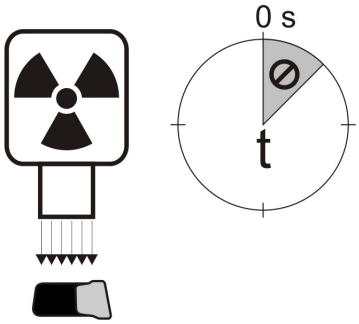
Too dark image. Some areas showing uniform “black”. Decreased diagnostic value.

- Too long exposure time/too high X-ray dose.

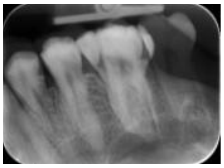


Too light, noisy image with decreased diagnostic value. Showing only part of the image.
Showing wrong size of the image (Image smaller than imaging plate).

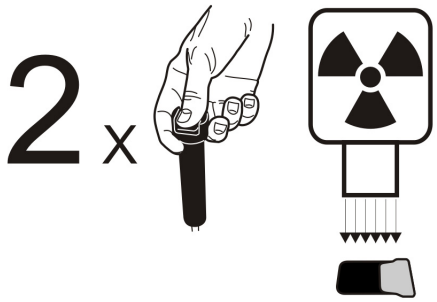
- Too short exposure time / Too low X-ray dose.



Ghost images, shadows

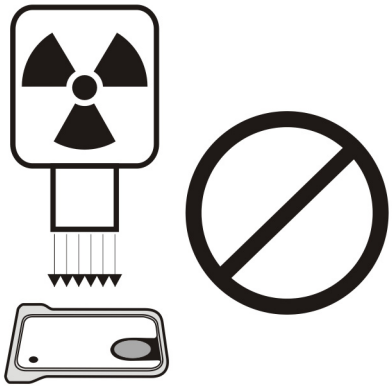


- Imaging plate has been exposed twice without processing in between.
- More than one image exposed to the same plate.
- Imaging plate has not been erased properly after processing.
- Unit erasing leds are monitored during normal operation. If leds are defected, application SW shows warning.

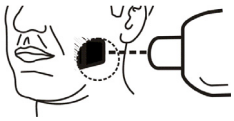


Circular shape on the image

Imaging plate has been exposed from the wrong side, which shows the phantom of the metal disc on the rear side of the plate.



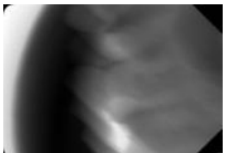
Cone cut

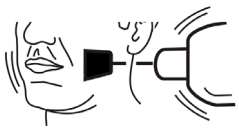


X-ray beam has exposed only part of the imaging plate surface. Image may show on different (smaller) size than the imaging plate used.

- Check exposure procedure.
- Use of proper holder avoids this.

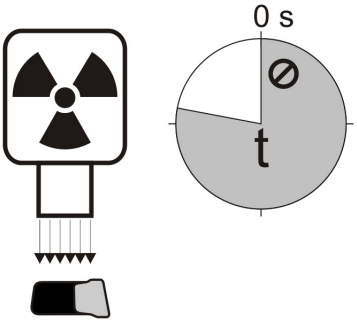
Unsharp or blurred images, motion artefact



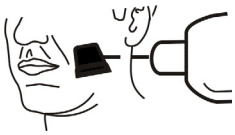


Patient or X-ray cone has moved during the exposure.

- Check exposure procedure.
- Check the stability of your intraoral X-ray unit.
- Use proper holders.
- Too long exposure time may have been used. Use shorter exposure time (increase kV if necessary to compensate effect of shorter exposure time).



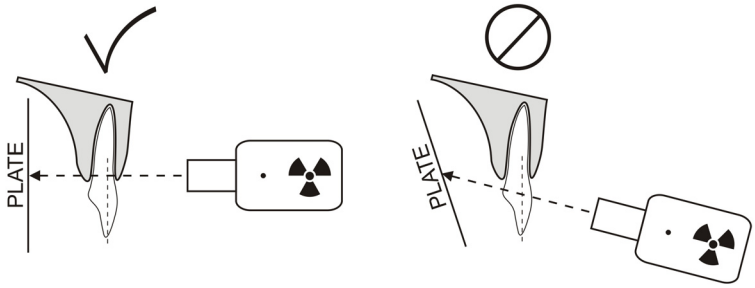
Geometry distortion



Improper patient positioning.

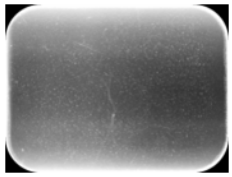
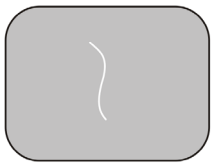
- Use proper holders to avoid this.

Note! Never do accurate measurements on intraoral images unless having known size of reference object in the imaging plane.

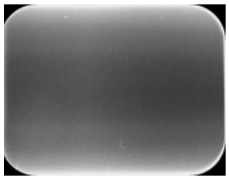
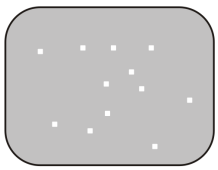


7.1.3 Imaging plate wearing

White or grey dots, spots or stains in images

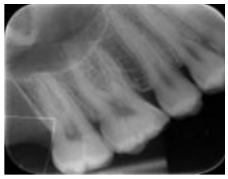
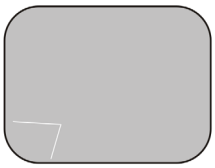
- Dust or stains on the imaging plates.
- Any extra particle on top of the active sensitive surface of the plate is visible on the image.

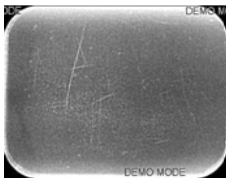
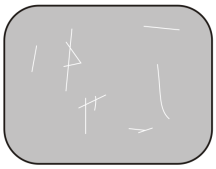
- Clean the plate(s).
- Replace if cleaning does not help.
- Pay attention on handling, storing and maintenance. Ensure that only the genuine hygiene accessories are used.

Wearing of the imaging plate

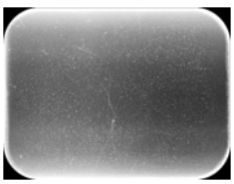
Scratches

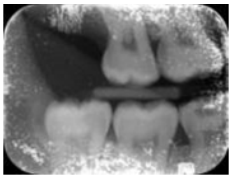
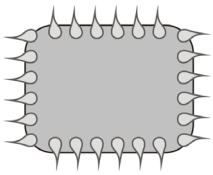
- Clean the plate(s).
- Replace if cleaning does not help.
- Pay attention on handling, storing and maintenance. Ensure that only the genuine hygiene accessories are used.

Spots, dots (white or gray) or any visible pattern.



- Most probably caused by wearing of the imaging plate.
- Can be caused by moisture or improper cleaning.

- Clean the plate(s), ONLY >70% ETHANOL MUST BE USED.
- Replace if cleaning does not help.
- Pay attention on handling, storing and maintenance. Ensure that only the genuine hygiene accessories are used.

7.2 Error messages

In unit user interface the wrench symbol and error number indicates the error.

1 2 3 4

Number	Description
1	K100 error (CPU / main controller error)
2	PMT error (imaging plate information cannot be read due to photo detector not working)
3	Laser error (imaging plate information cannot be read due to laser not working)
4	Resonator error (imaging plate information cannot be read due mirror not moving properly)
12	K200 board not connected properly (laser detection, erasing & movement control)
13	K300 board not connected properly (imaging plate sensing / detection)
23	K200 error (erase LED, linear movement detection sensor or laser synchronization error)
24	Plate carrier movement error
34	Plate sensor error (imaging plate cannot be detected)
123	Door movement error (position of the door not detected or movement is blocked)
124	Safety cover error (light cover inside the unit is not in its place / not detected)
234	K400 control panel error (control panel button defected / stuck)
1234	Other, see driver status window

Turn power off and on to see if the unit recovers. If not, please contact local dealer or distributor.

8 Other information

8.1 Quality control

To ensure maximum system performance

1. Observe IQO (Image Quality Optimizer) indication on the application SW to see that the x-ray settings are optimal.
2. Perform self quality control regularly according instructions provided with quality control test set SP00204 (SDX Intra digi QC IEC phantom w. instructions).

8.2 Device care

WARNING!

Switch the unit off and disconnect it from the main power supply before cleaning or disinfecting the unit. Do not allow liquids to enter the unit.

8.3 Device cleaning

To clean the unit use a non abrasive cloth moistened with:

- cool or lukewarm water
- soapy water
- mild detergent
- isopropyl alcohol
- or ethanol (ethyl alcohol) 70 - 96%
- Optiwipe™
- CaviCide®, CaviWipes® by Metrex
- FD322 by Dürr Dental
- Easydes by Kiilto

After cleaning wipe the unit with a non abrasive cloth moistened with water. Never use solvents or abrasive cleaners to clean the unit. Never use unfamiliar or untested cleaning agents. If you are not sure what the cleaning agent contains, DO NOT use it.

If you use a spray cleaning agent DO NOT spray it directly into the unit door.

8.4 Disinfecting the unit

CAUTION:
Wear gloves and other protective clothing when disinfecting the unit.

Wipe the unit with a cloth dampened with a suitable disinfectant solution such as ethanol 96%. Never use abrasive, corrosive or solvent disinfectants. All surfaces must be dried before the unit is used.

WARNING:
Do not use any disinfecting sprays as the vapor could ignite and cause injury.

Disinfecting techniques for both the unit and the room where the unit is used must comply with all local and national regulations and laws concerning such equipment and its location.

8.5 Maintenance

The unit does not require any maintenance.

8.6 Repair

The unit does not require any maintenance. If the unit is damaged or malfunctions in any way it must only be repaired by service personnel authorized by the manufacturer of the unit.

8.7 Disposal

At the end of the useful working life of the unit and/or its accessories make sure that you follow national and local regulations regarding the disposal of the unit, its accessories, parts and materials. The unit includes some or all of the following parts that are made of or include materials that are non-environmentally friendly or hazardous:

- electronic circuit boards
- electronic components
- imaging plates

9 Technical specifications

9.1 Device

Product name	DIGORA® Optime
Model	DXR-60
Product type	Intraoral digital imaging plate system
Intended use	System is intended to be used only by dentist and other qualified dental professionals to process x-ray images exposed to the imaging plates from the intraoral complex of the skull. *USA only* Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.
Manufacturer	SOREDEX, PaloDEx Group Nahkelantie 160 (P.O. Box 20) FIN-04300 Tuusula, FINLAND
Quality system	In accordance with ISO13485 and ISO9001 standard
Environmental management system	In accordance with ISO14001 standard
Conformity to standards	IEC 60601-1: 1988 and A1+A2 IEC 60601-1-1: 2000 IEC 60601-1-4: 1996 and A1 IEC 60601-1-2: 2001 IEC 60601-1: 2005 EN 60825-1: 2007 UL 60601-1: 2003 CAN/CSA –C22.2 No. 601-1-M90 and S1+A2 / DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. In conformity with the provisions of Council Directive 93/ 42/EEC as amended by the Directive 2007/47/ EC concerning medical devices..
DXR-60 Classification IEC60601-1	- Class 2 equipment - No applied part - Continuous operation - IPX0 (enclosed equipment without protection against ingress of liquids

Laser Safety Classification	CLASS 1 LASER PRODUCT, EN 60825-1 :2007
Dimensions (H x W x D)	152 mm x 227 mm x 308 mm (6.0 x 8.9 x 12.1 inches)
Weight	3,5 kg (7.7 lb)
Power supply unit (PSU)	CINCON TR30RAM240 FRIWO FW7362M/24 PHIHONG PSAM30R-240
Operating voltage	24 VDC (External PSU: 100 – 240 VAC, 50/60 Hz)
Operating current	Less than 1.25 A
Power consumption	Less than 30VA
Pixel size (selectable)	30 µm (Super resolution) / 60 µm (High resolution)
Bit depth	16-bit
Theoretical resolution	16,7 lp/mm
Firmware version	1.00
Interface connection	Connection type RJ-45 Unshielded CAT 6 Ethernet cable
Plastic materials	Used materials are phthalate free containing < 0.1% w/w of DEHP and is not manufactured from raw materials containing or derived from Bisphenol A (BPA).
Operating environment	+10°C - +40°C, 30 – 90 RH%, 700 – 1060 mbar
Storage / transportation environment	-10°C – +50°C, 0 – 90 RH%, 500 – 1080 mbar
Other	Integrated Kensington security slot for securing unit with Microsaver series locks.

9.2 System requirements and connections

Minimum requirements for the PC/laptop, network adapter and network switch	
PC / laptop network switch	Class I or Class II according IEC 60950
Network connection settings	10/100Mbs LAN UDP/IP protocol traffic allowed Traffic to UDP port 10000 allowed (unit UDP port) UDP broadcast traffic allowed CAT6 Ethernet cable DHCP server is recommended but not necessary
Use	Use antivirus software. Use firewall. When LAN configuration is changed or devices are added/removed, it may affect existing devices in the LAN. Therefore keep in mind that correct operation of the imaging system needs to be checked after changes are made. When adding new devices to LAN, make sure they all have unique IP address, otherwise they may cause communication problems with existing LAN devices. Place unit and PC with imaging application software to same subnet in LAN.
NOTE! *Image is not transferred from unit to PC imaging application software in case of connection lost during image processing. Image is stored in unit memory until it has been transferred to PC. Unit cannot be turned off in that case. When network is operational again, image is automatically transferred to imaging application software. Do not disconnect unit PSU adapter before network is operational and image has been transferred to imaging application software.*	
For more details of the hardware requirements running the imaging application software please refer to the user manual of it.	

9.3 Imaging plate specifications

Imaging plates						
Plate size		**Size 0**	**Size 1**	**Size 2**	**Size 3**	**Size 4C**
Dimensions (mm)		22 x 31	24 x 40	31 x 41	27 x 54	48 x 54 nominal
Image size (pixels) *		734 x 1034	800 x 1334	1034 x 1368	900 x 1800	1600 x 1800 nominal
Image size (MB) *		1.44	2.03	2.69	3.09	5.49 nominal
Environ-mental conditions	Storage and trans-portation	-10°C … +40 °C / max 80% RH / NO UV radiation				
	Use	+10°C …+40 °C / max 80% RH / NO UV radiation				
Material		Layer of small photo-stimulable particles (that exhibit the phe-nomenom of phosphorescence) uniformly coated on a support plastic material. Shielded with a protective top coat layer on the sensitive surface and encapsulated with lacquer around the edg-es. Imaging plates do not not include phosphorous / phosphorus (P).				
Use		The typical service life for an imaging plate is several hundreds of cycles provided that the imaging plate is handled with care and according to the supplied instructions. The use of genuine hy-giene accessories (protective covers and hygiene bags) will ex-tend the service life of the imaging plates.				
Disposal		Imaging plates are industrial waste and must be disposed of in accordance with local and national regulations concerning the disposal of such material. Never use damaged imaging plates.				

* High resolution mode image sizes are approximately half of the values in the table.

9.4 Hygiene bag specifications

Hygiene bags	
Material	Latex-free, food-grade polyethylene
Biocompatibility conformity to standard	Not having irritative, toxic or injurious effects on biological system in accordance with ISO 10993-1 and ISO 10993-5.
Packaging	Supplied in boxes
Use	For the best performance it is recommended the hygiene bags are used within two years from the date of manufacture. The date of manufacture is printed on the bottom of the box containing the hygiene bags (DDM-MYYXX). Extended storage time or exceeding the specified storage conditions may compromise the performance of the adhesive tape and/ or the plastic material from which the hygiene bags are made of.
Disposal	Observe relevant national requirements.

9.5 Electromagnetic Compatibility (EMC) tables

Note! Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.

Note! Mobile RF communications equipment can effect medical electrical equipment

Guidance and manufacturer's declaration - electromagnetic emissions		
The DXR-60 is intended for use in the electromagnetic environment specified below. The customer or the user of the DXR-60 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11E	Group 1	The DXR-60 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DXR-60 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The DXR-60 is intended for use in the electromagnetic environment specified below. The customer or the user of the DXR-60 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/ bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode line to line	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If user of the DXR-60 requires continued operation during power mains interruptions, it is recommended that the DXR-60 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The DXR-60 is intended for use in the electromagnetic environment specified below. The customer or the user of the DXR-60 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DXR-60, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DXR-60 is used exceeds the applicable RF compliance level above, the DXR-60 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the DXR-60. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the DXR-60.

The DXR-60 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DXR-60 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DXR-60 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter
in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10 Symbols and labeling

10.1 Symbols

Do not reuse (Single use)

Operating instruction
(More details in operation instructions)

CLASS II equipment
(Double insulated electrical appliance)

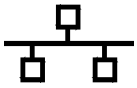
UL symbol

Indoor use

Dangerous voltage

Laser radiation

Direct current power supply unit inlet



Ethernet connector

CE (0537) Symbol MDD 93/42/EEC
This unit is marked according to the Medical Device Directive 93/42/EEC (if the unit contains the CE mark)

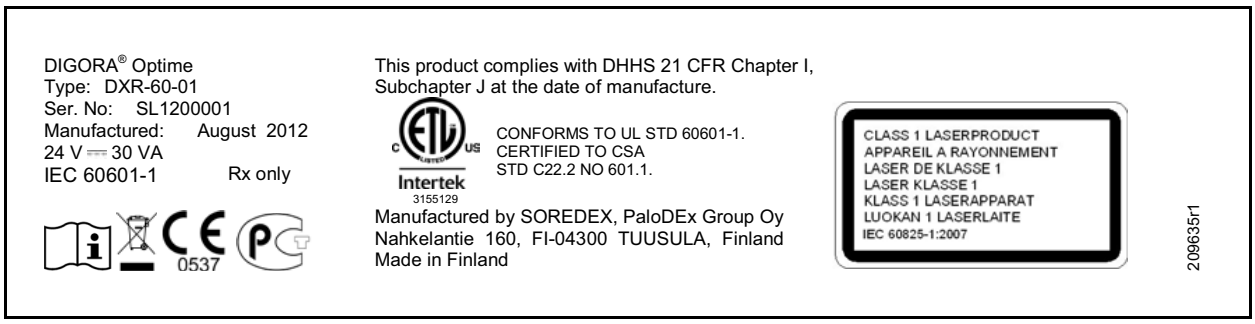
ETL symbol

GOST-R symbol

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

10.2 Main label

The unit is class I, type B and with IPX0 protection.



10.3 Warnings and precautions

THE UNIT IS A CLASS 1 LASER PRODUCT

Note! *When covers are removed the unit is a class 3B laser product – avoid exposure to the laser beam.*

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure or other non-compliance.

- When handling imaging plates, protective covers and hygiene bags always take the appropriate hygiene measures and precautions to prevent cross contamination. New protective cover must be used on every use.
- The imaging plates are harmful if swallowed.
- Do not move or knock the unit when it is processing an imaging plate.
- This unit must only be used to process image plates supplied by the manufacturer and must not be used for any other purpose.
- NEVER use imaging plates, protective covers or hygiene bags from other manufacturers.
- This unit, or its accessories, must not be modified, altered or remanufactured in any way.
- Only the manufacturer's authorized service personnel are authorized to carry out maintenance and repair of the unit. There are no user serviceable parts inside the unit.
- Unit is not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- In order to maintain safe and correct functioning of the unit, only the power supply unit (PSU) delivered with the unit or distributed by authorized dealers. Please refer to the unit technical specifications for a list of the PSUs.

- For ethernet connections, use an unshielded CAT6 RJ-45 LAN cable, so that multiple chassis must not be connected! The PC / Ethernet switch to which unit is connected to must be class I or class II according IEC 60950. After installation check that the IEC 60601-1 leakage current levels are not exceeded.

- If the PC/ Ethernet switch to which the device is connected to is used in the patient environment it should be approved appropriately and meet the requirements of 60601-1 standard.

- The PC and any other external device(s) connected to the system outside the patient area must meet the IEC 60950 standard (minimum requirement). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.

- The PC and any other external devices shall not be connected to an extension cable.

- Multiple extension cables shall not be used.

- If this device will be used with 3rd party imaging application software not supplied by the manufacturer, the 3rd party imaging application software must comply with all local laws on patient information software. This includes, for example, the Medical Device Directive 93/42/EEC and/or FDA if applicable.

- Do not position the PC where it could be splashed with liquids.

- Clean the PC in accordance with the manufacturer’s instructions.

- Image is not transferred from unit to PC imaging application software in case of connection lost during image processing. Image is stored in unit memory until it has been transferred to PC. Unit cannot be turned off in that case. When network is operational again, image is automatically transferred to imaging application software. Do not disconnect unit PSU adapter before network is operational and image has been transferred to imaging application software.