Scan eXam™ One

Digital Intraoral Imaging Plate System
User Manual

REF 224301-PTU rev. 1

ENGLISH

NEW VERSION AVAILABLE | NEUE VERSION VERFÜGBAR | NOUVELLE VERSION DISPONIBLE | NUOVA VERSIONE DISPONIBILE | NUEVA VERSIÓN DISPONIBLE

DEXIS™

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Code: 224301-PTU rev 1.

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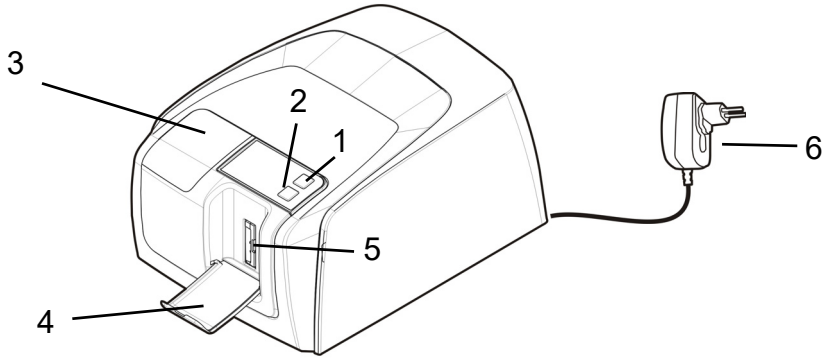
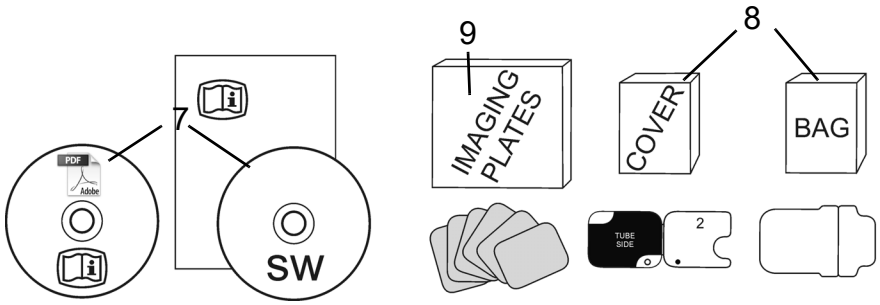
1 Introduction

Scan eXam™ One system is intended to be used by dentist and other qualified dental professionals to process x-ray images exposed to the imaging plates from the intraoral complex of the skull.

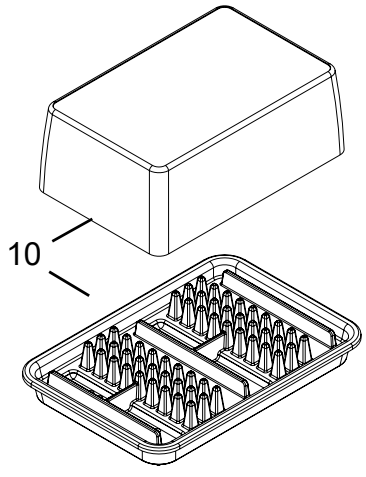
1.1 Unit with accessories





1. ON/OFF key
2. START key
3. Display
4. Imaging plate collector
5. Plate slot and plate carrier
6. Power supply

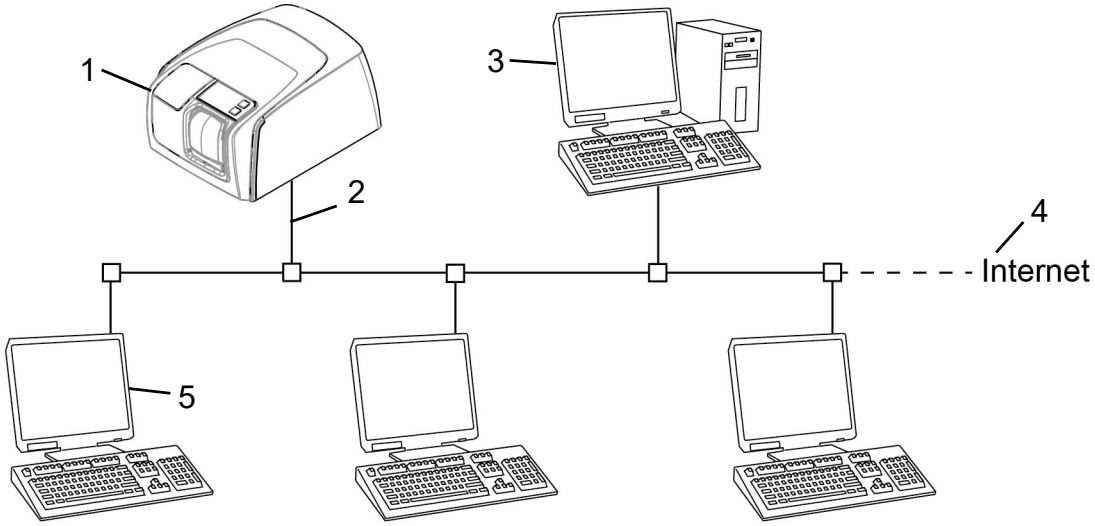
CAUTION:
Only use the power supply delivered with the unit or an approved spare power supply supplied by an authorized distributor (See chapter 9 Technical specifications).



7. Documentation and imaging application software media
8. Hygiene accessories
9. Imaging plates
10. Imaging plate storage box

1.2 System setup

An example of a typical system set up in a local area network (LAN).

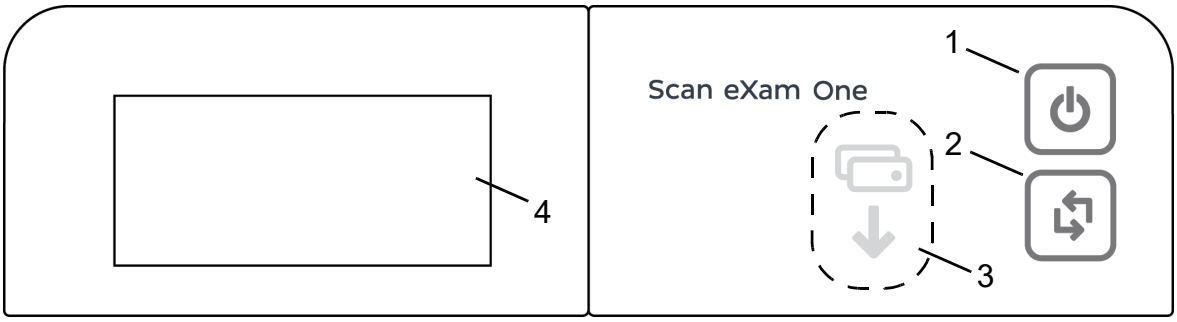


1. Scan eXam™ One unit
2. Ethernet cable
3. Workstation (WS) computer (not included) contains
   - patient data, images and a license server
4. Internet connection (optional, recommended)
5. Optional workstation (WS) computers (not included)

For more options and details of installing and setting up the Scan eXam™ One system see chapters 6 Installation of the imaging plate system and 9 Technical specifications.

1.3 Controls and indicators

Control panel layout



1. ON/OFF key
2. START key
3. Plate feeding indicator
4. Status display

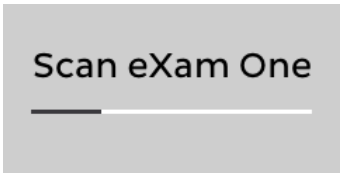
ON/OFF key

- Press ON/OFF key to turn the unit on.
- Press and hold for 3 seconds to turn the unit off.
- They key has a light when the unit is on.
- The light is softly blinking when the unit is in a stand by mode.
- Press the ON/OFF key or the START key to wake the unit.

START key

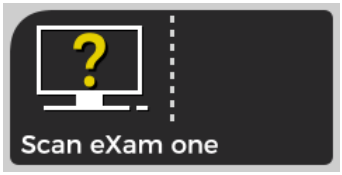
- Use the start key to wake the unit from the stand by mode or
- to start processing in the manual mode or to cancel (skip) the 2nd plate in the Occlusal 4C mode.
- to access startup screen-information (IP, serial number) when the scanner is not reserved by any user.

Display and plate feeding indicators



Startup

During startup the unit serial number, IP address and other information will appear on the unit display.



Waiting dental imaging software

Software not open, not ready or waiting for user action. Unit name is displayed.

Software active

Unit has a connection to a software. Unit not in use.

Express Share reservation

The unit has been reserved using Express Share. The workstation identifier is shown in the padlock. The name of the current patient is shown.

The green plate feeding indicator is showing readiness for plate insert.

Express Share ready

Unit has a connection to a software using Express Share.
The unit is not reserved by any workstation in the system.

Unit is activated

The unit is activated for image processing. The name of the current patient is shown.

The green plate feeding indicator is showing readiness for plate insert.

Insert 2nd plate

Insert the second plate of the Occlusal 4C format.

Press **Start** to treat the first plate as a single size 3 image.

Image processing complete

Exposure level OK.

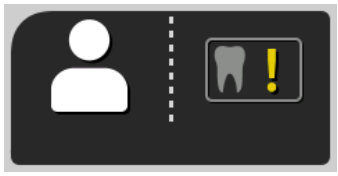
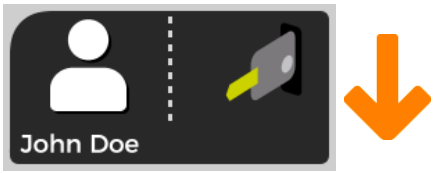


Image processing complete

Image considered over exposed. Check exposure settings.

Image processing complete

Image considered under exposed. Check exposure settings.

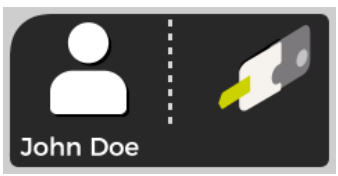


Remove plate

Remove the imaging plate from the plate carrier.

Rotate the plate

Rotate the imaging plate. Light blue side to the left.



Remove cover

Remove the hygienic cover gently leaving the imaging plate in the plate carrier.

Unit disconnected

Missing ethernet connection. Check the connectors, cables and the network.

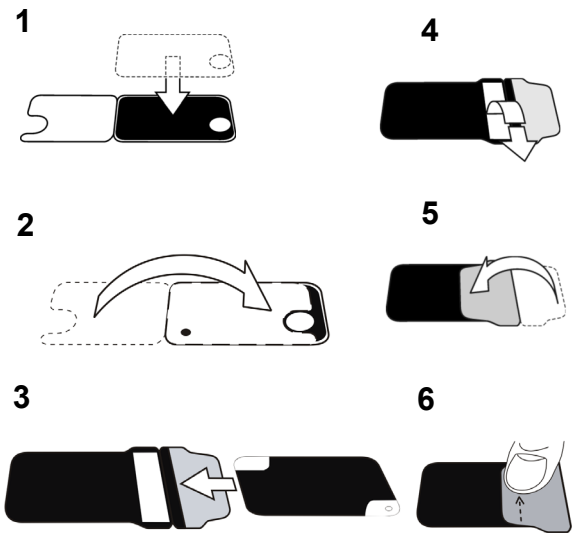
Error

Error ID and a short description is displayed. Contact service.

Press START

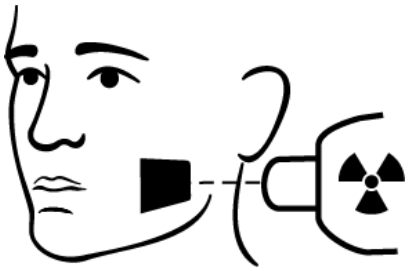
Press the START button to wake the unit from a standby mode.

2 Basic use

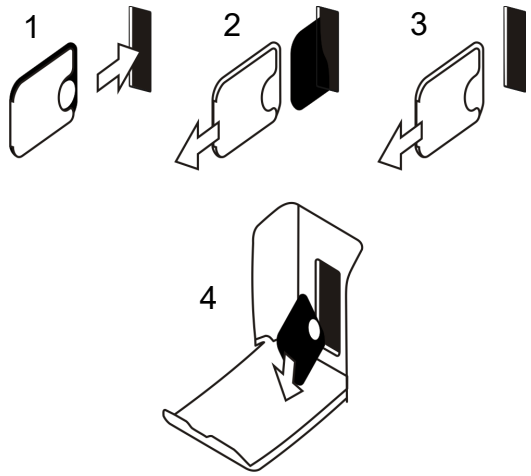


Prepare imaging plates.
See chapter 2.1 for more information.

Activate the Scan eXam One from the imaging application.
Refer to the application software manual for more information.



Position and take an exposure.
See chapter 2.2 for more information.

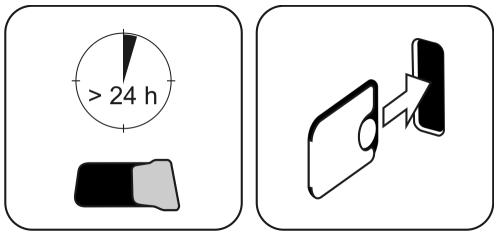


Process the imaging plate.
See chapter 2.3 for more information.

CAUTION! *Process unexposed imaging plates to erase potentially accumulated background radiation when*

- *Taking new imaging plates into use.*
- *Imaging plates have been packaged and unused for more than 24 hours.*
- *Imaging plates have stored in dark (not exposed to ambient light) susceptible for background radiation for more than 24 hours.*

This will remove any potential fogging due to collected natural background radiation.



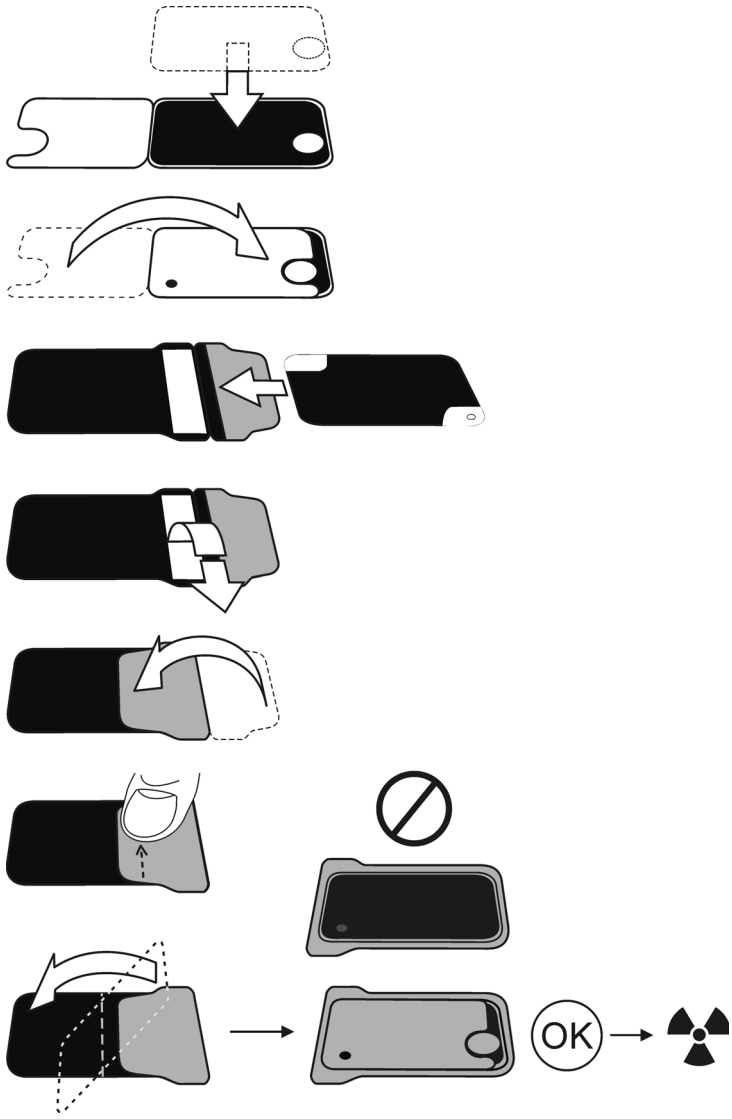
2.1 Preparing the imaging plates

Apply protective cover and package the plates into the original hygiene bag.

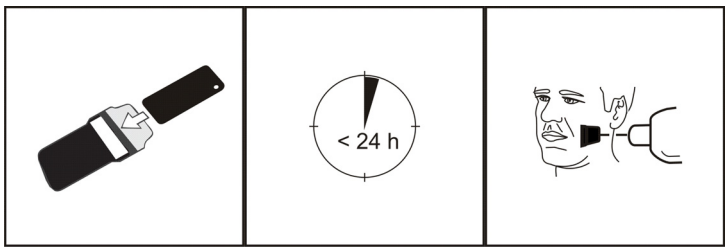
Seal the bag properly.

Observe the orientation of the plates, cover and the bag.

Active side of the imaging plate has a light blue color.



NOTICE! *Keep the imaging plates packed max. 24 hours before using. Packaged plates accumulate radiation from the background. Plates can be erased by reading the plate.*



2.2 Positioning and exposure

Position the imaging plate according to the anatomical area of interest. Holders (petitioners) are recommended for the best positioning accuracy. See the chapter 4.4 Holders, for more information.

Apply X-ray according to the anatomical area of interest and on the intraoral X-ray tube in use.

Find guidelines of exposure times in seconds for a standard DC X-ray unit in the table below.

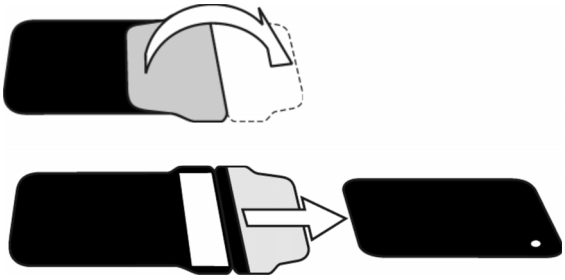
Correct exposure settings depend on the X-ray unit type in use. For an AC-unit or for a low tube current (i.e. portable X-ray) apply higher exposure times.

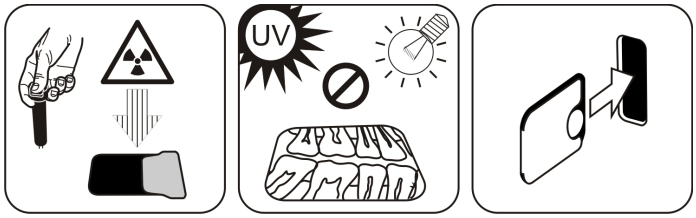
Exposure factors close to F-speed film are often appropriate.

	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%			

2.3 Processing the imaging plates

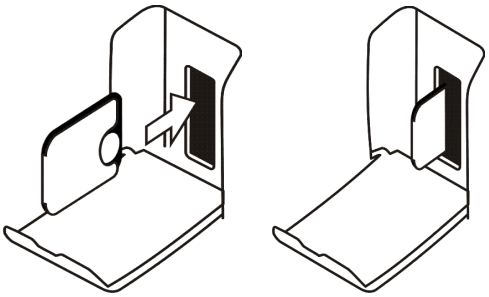
Unpack and process the imaging plates immediately after unpacking.

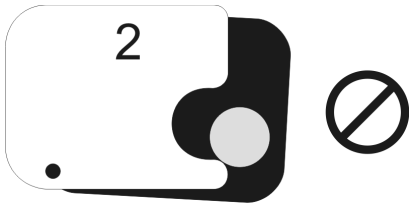




NOTICE! Ambient light harms the image information when not protected by the protective cover.

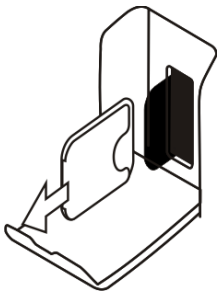
1. Insert the imaging plate with the cover.





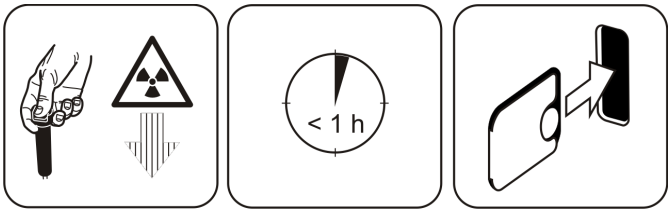
NOTICE! Do not partially slide the imaging plate from the cover. You can place the plate with cover and leave it to the plate carrier. Unit will not start the processing before removing the cover.

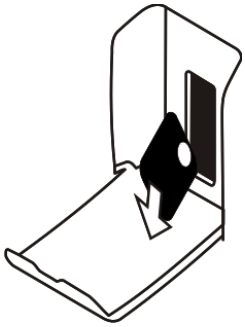
2. Remove the cover.



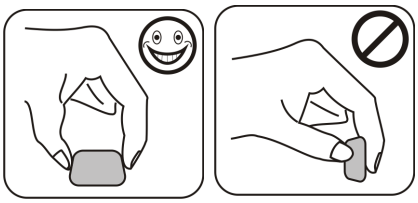
The image appears on the imaging application screen.

NOTICE! *Process within one hour after exposure.*





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

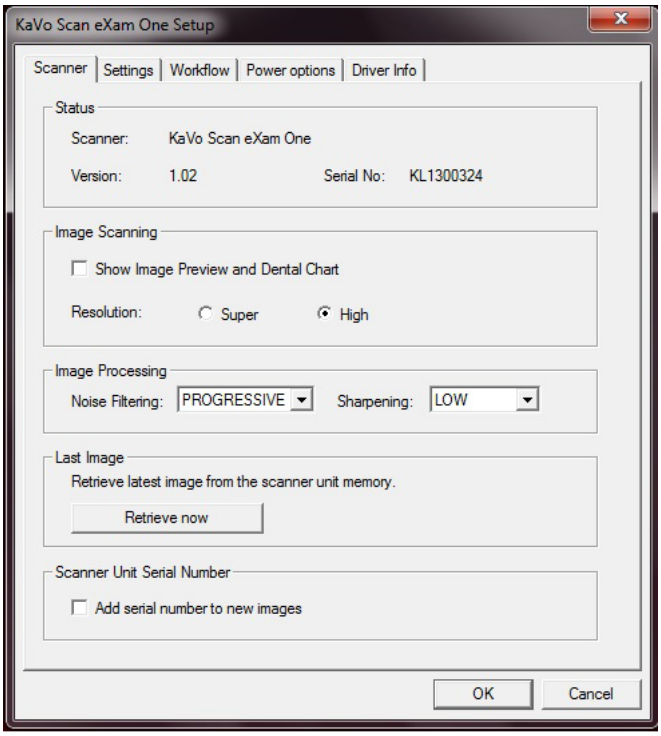


3 Advanced use

3.1 Scan eXam One setup options with CLINIVIEW™

The Scan eXam One setup options allow you to configure the Scan eXam One to the user's clinical preferences.

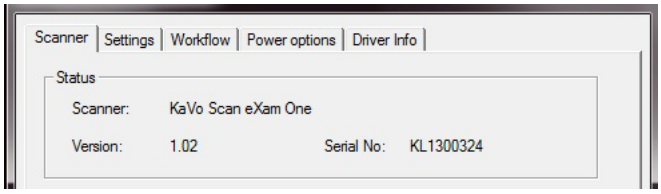
From the imaging application software you are using select unit Setup/Scanner page (for more instruction on how to access setup page review application software manual).



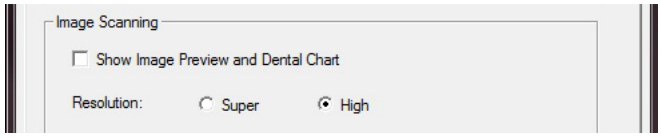
3.1.1 Scanner

3.1.1.1 Status

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



3.1.1.2 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.

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.

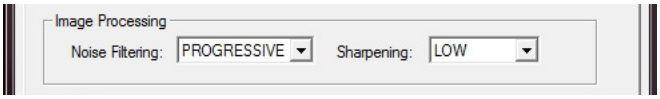
3. Click OK to save the image and tooth numbers.

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.

3.1.1.3 Image Processing

Noise filtering makes images smoother when they are taken at short exposure times.



There are two options available:

Classic mode offers traditional noise filtering algorithms that has been applied to all previous models of imaging plate systems.

Progressive mode applies another algorithm that reduces noise while efficiently retaining image clarity. The progressive algorithm requires appropriate exposure level for efficient performance.

Ensure that the exposure level indicator is OK.

3.1.1.4 Retrieve last image

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

NOTICE! *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:

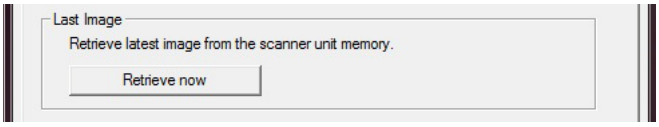
1. Correct the problem that caused the communication failure. When the connection between the unit and the workstation is re-established the last processed image is automatically transferred to the workstation.

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

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

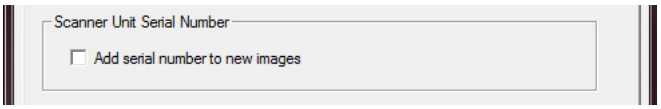
   NOTICE! *If required you can select different parameters (e.g. resolution, show image preview etc.) for the image to be retrieved.*

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



3.1.1.5 Scanner Unit Serial number

Adds the unit serial number to all new images.

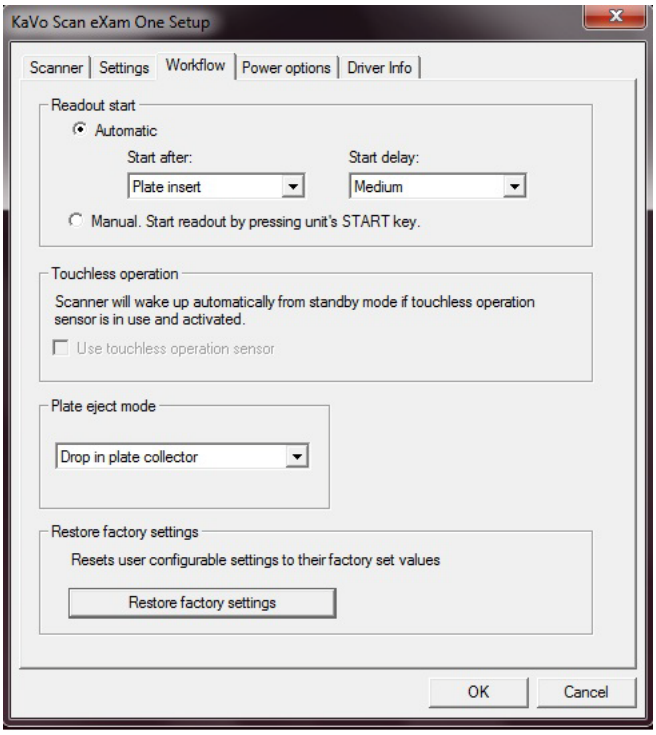


3.1.2 Settings

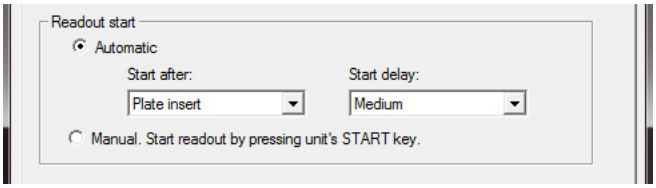
See chapter 6 Installation of the imaging plate system for more information on connecting the unit to a workstation/ LAN.

3.1.3 Workflow

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



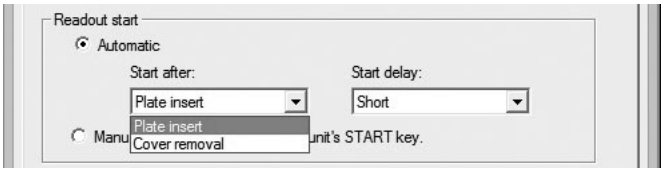
3.1.3.1 Readout start



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

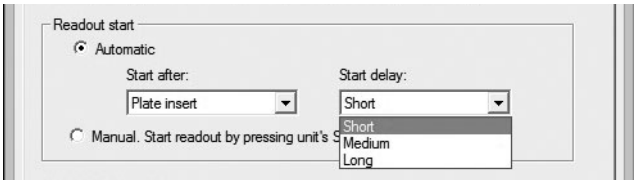
The **Start** after options all ow to select when the unit starts image plate processing:

- 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.

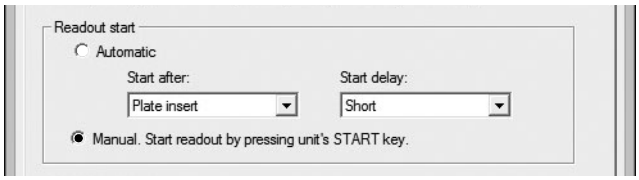
- Short = approximately 0.2 seconds
- Medium = approximately 0.4 seconds (recommended default)
- Long = approximately 0.6 seconds



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

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

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



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

3.1.3.2 Plate eject mode

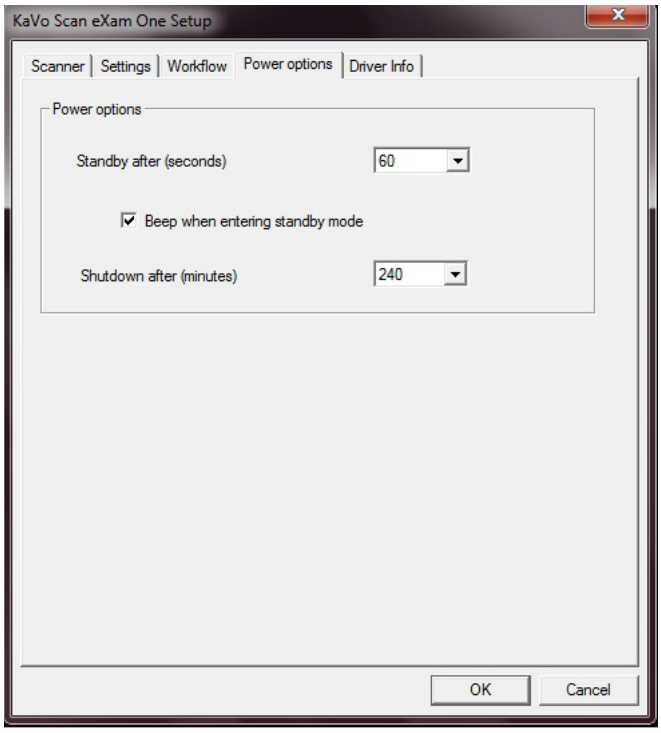
The options are:

- **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.

3.1.4 Power options

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



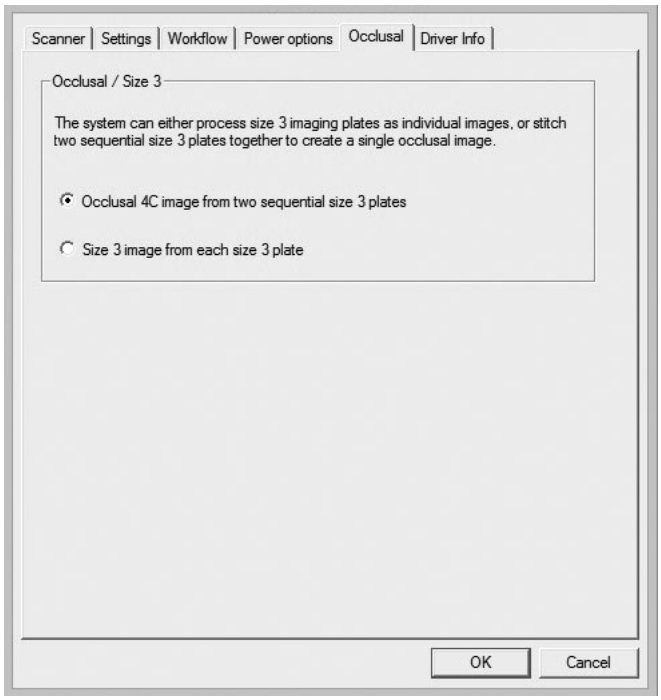
Standby after (seconds): Allows you to select the period of time the unit remains unused before it enters the standby mode (plate carrier is driven inside the unit, door is closed and ON/OFF key dims on and off). Press ON/OFF key to recover.

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.

3.1.5 Occlusal 4C projection imaging (not included in delivery)

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



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 Occlusal 4C projection image. Following text shortly describe how Occlusal 4C projection image is taken. For more information refer to instructions supplied with the 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 Occlusal 4C bite protector.

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

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

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

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

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

NOTICE! 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.

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

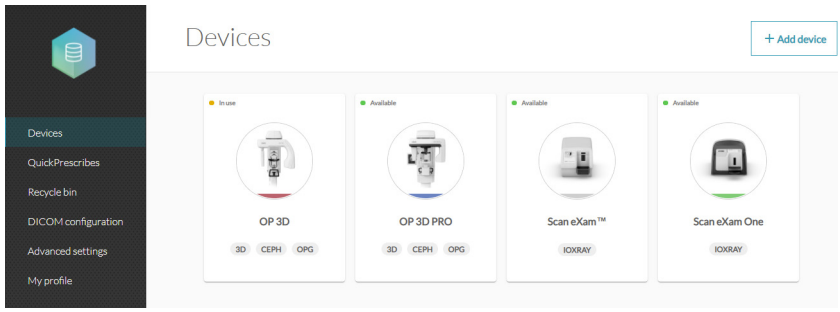
3.2 Scan eXam™ One settings with DTX Studio™ Core

You can view and change the device settings in DTX Studio™ Core by following the steps below.

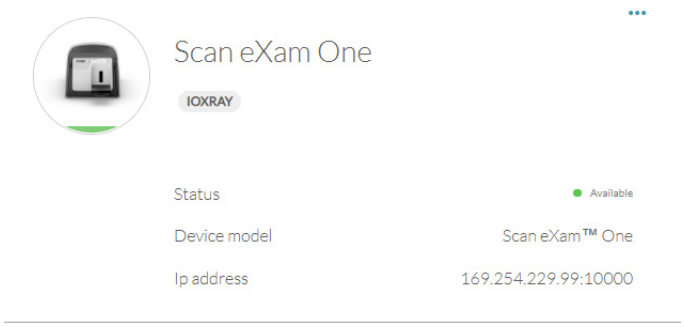
NOTICE! *For most accurate and up to date information, refer to DTX Studio™ Instructions for Use.*

1. Sign into DTX Studio™ Core with the same user credentials as you use to login to DTX Studio™.

2. Select **Manage devices** menu.



3. Click on the device image to open **Device details**.

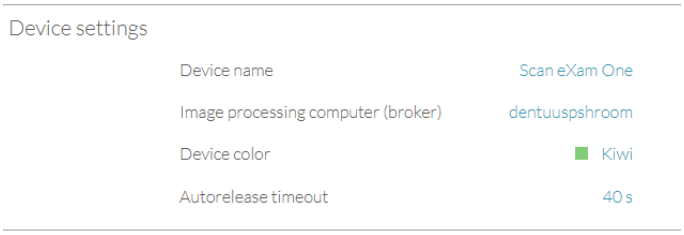


Status: Shows the status of the device (default: Available)

Device model: Shows the model of the device (Scan eXam™ One).

IP address: Shows the IP address of the device.

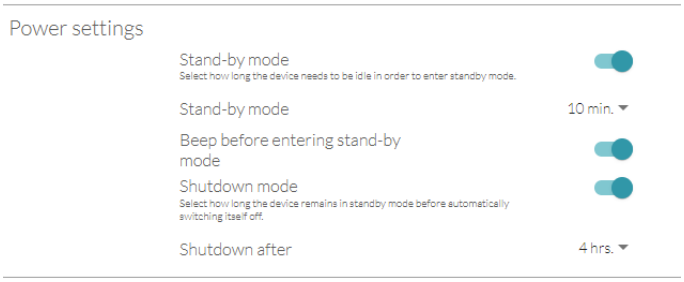
3.2.1 Device settings



In Device settings, you can view and set the following:

- **Device name**: Device identification shown in DTX Studio.
- **Image processing computer**: Normally, the workstation where DTX Studio™ Core is installed.
- **Device color:** Device identification shown in DTX Studio.
- **Autorelease timeout:** 40s default

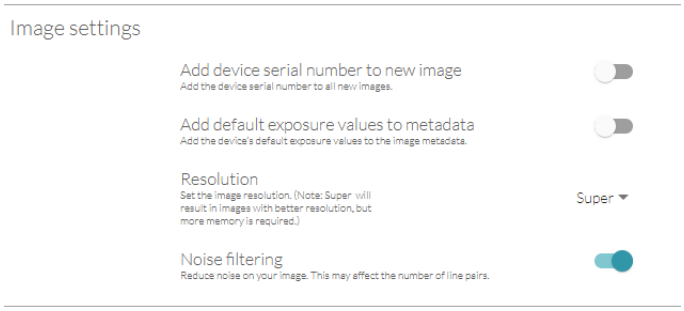
3.2.2 Power settings



In Power settings, you can view and set the following:

- **Stand-by mode**: Enable or disable device stand-by mode and select how long the device needs to be idle before entering stand-by mode (default: ON, 10 min.)
- **Beep before entering stand-by mode**: You can select the beep on or off.
- **Shutdown mode:** Enable or disable automatic shutdown for the device if it remains in stand-by mode for a long period.
- **Shutdown after:** Select how long the device remains in stand-by mode before it automatically switches itself off. (default: 4h)

3.2.3 Image settings

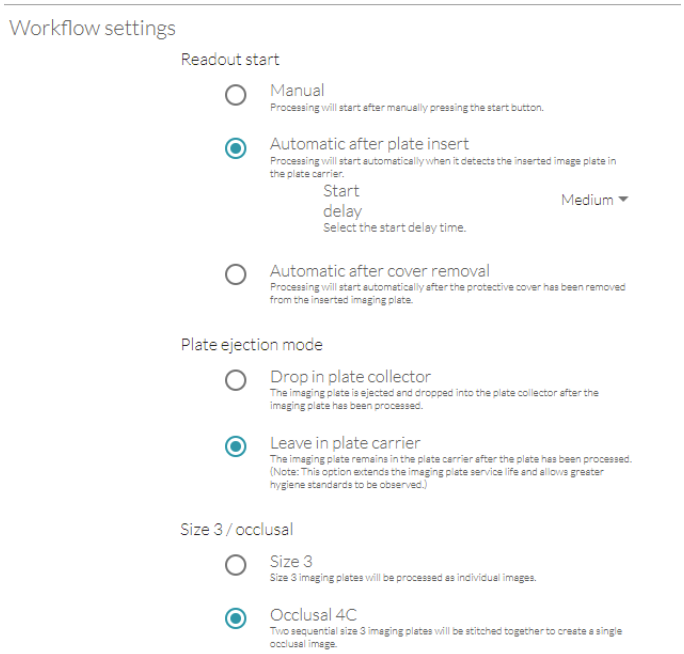


In Image settings, you can view and set the following:

- **Add device serial number to new image:** Enable or disable if the device serial number is added to all images.
- **Add default exposure values to metadata**: Enable or disable if the device's default exposure values (kV, mA, s) are saved to image metadata.

- **Resolution:** Set the image scanning resolution. ***Super*** resolution will result in better resolution images but requires more memory.
- **Noise filtering:** Reduce noise in images. In normal work the noise filtering should be enabled to ensure best clinical image quality (default) in all conditions.

3.2.4 Workflow settings



In Workflow settings, you can view and set the following:

Readout start:

- **Manual:** Imaging plate processing starts after ***start*** button is pressed.
- **Automatic after plate insert (default):** Processing will start automatically when the device detects an inserted imaging plate in the plate carrier.
- **Automatic after cover removal:** Processing starts automatically after the protective cover has been removed from the inserted imaging plate.

Plate ejection mode:

- **Drop in plate collector:** The imaging plate is ejected and dropped into the plate collector after the imaging plate has been processed.

- **Leave in plate carrier (default):** The imaging plate remains in the plate carrier after the plate has been processed. This option extends the service life of the imaging plate and allows higher hygiene standards to be followed.

Size 3/occlusal:

- **Size 3**: Size 3 imaging plates are processed as individual images.
- **Occlusal 4C**: Two sequential size 3 imaging plates are stitched together to create a single occlusal image.

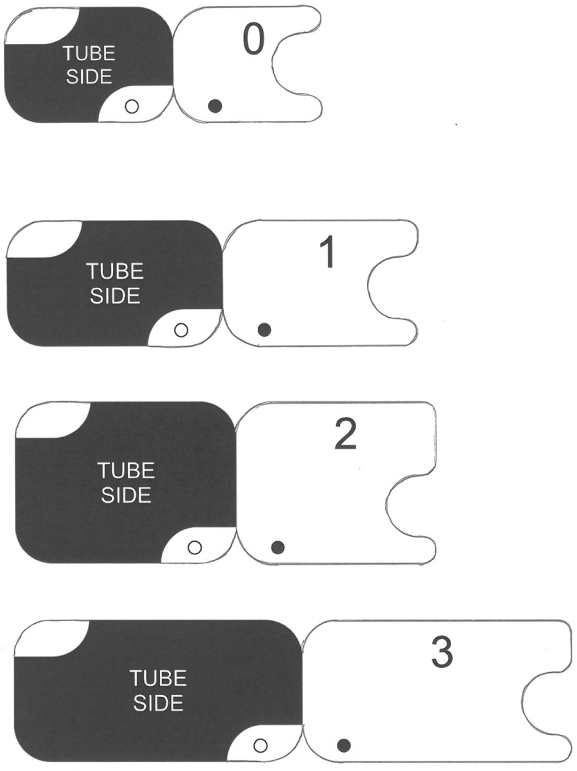
4 Accessories

NOTICE! *USE ONLY GENUINE ACCESSORIES FROM THE MANUFACTURER to ensure the optimal clinical results, safe use of the system and long service life for the imaging plates.*

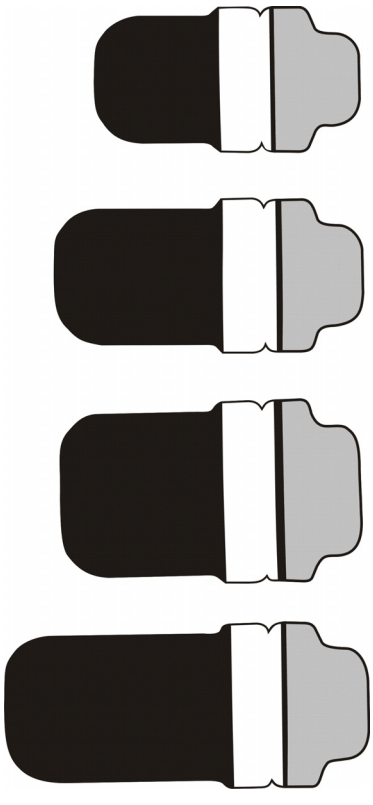
4.1 Hygiene covers

NOTICE! *Never use hygiene accessories more than once. Risk of infection.*

Protective covers



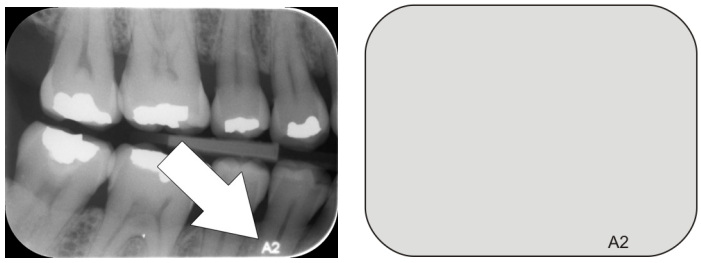
Hygiene bags



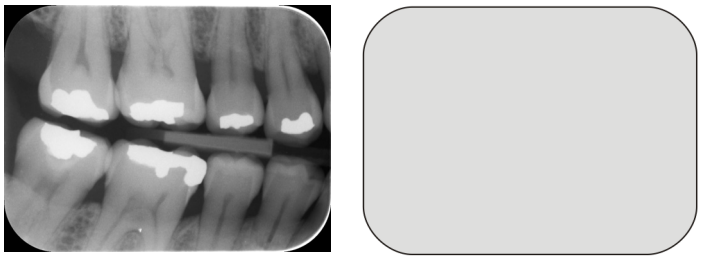
4.2 Imaging plates

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

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



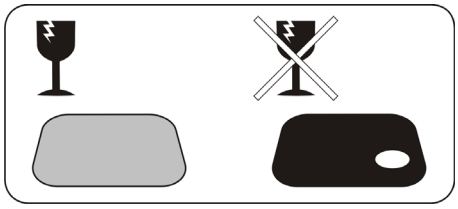
Standard (STD) imaging plates (optional) have no identification mark on the sensitive side of the plate.



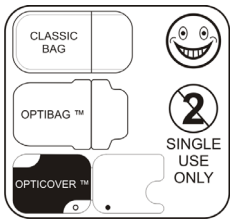
4.2.1 Imaging plate handling

NOTICE! Replace the imaging plate if the image shows scratches, spots, dots or other artefacts which do not disappear by proper cleaning.

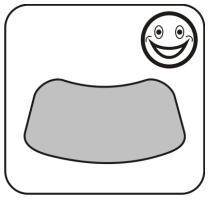
NOTICE! Replace the imaging plate is badly bent or damaged. Substance under the top coating of the imaging plate should not be swallowed.



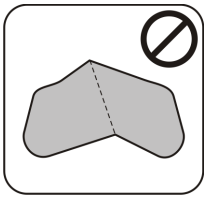
Sensitive surface, handle with care



Use only original accessories. Single use only!



You can bend.

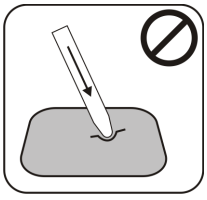


Do not fold or bend excessively.

Touch the edges only.

Do not touch the sensitive surface.

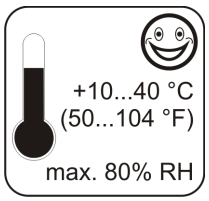
Do not scratch.



Do not stab.

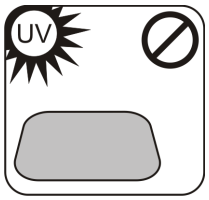
Avoid moist and water.

Do not sink.



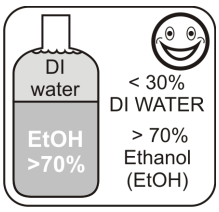
Allowed temperature.

Avoid dust.



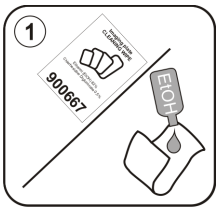
Avoid direct sunlight and UV radiation.

4.2.2 Imaging plate cleaning

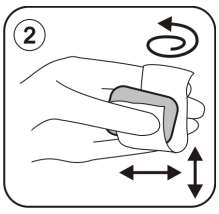


Use ONLY > 70% Ethanol

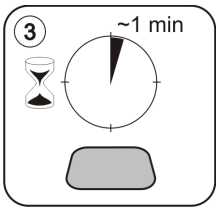
Do not apply Ethanol directly on the plate.



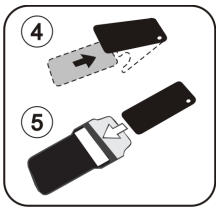
Apply Ethanol on lint free soft fabric.



Wipe the plate gently.

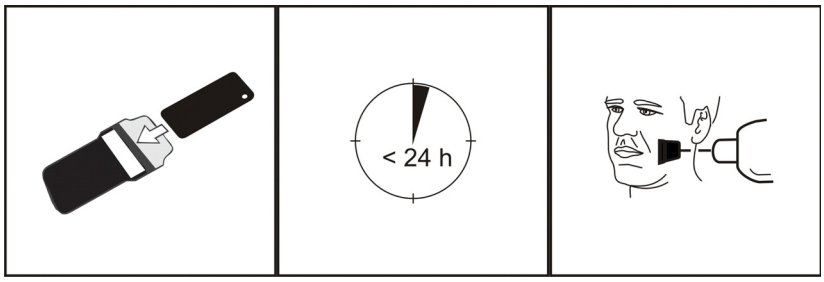


Wipe dry or let dry for 1 minute.

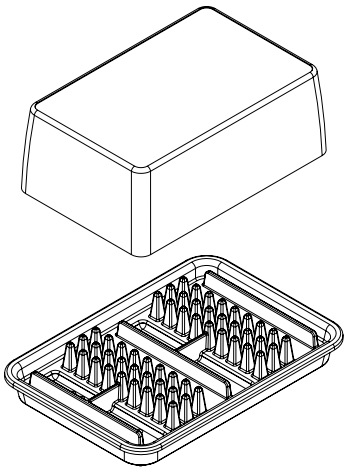


Pack the plate.

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



4.3 Imaging plate storage box

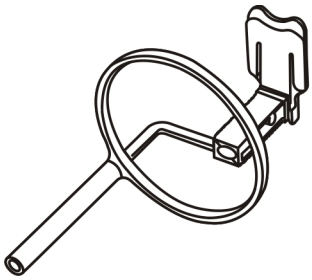


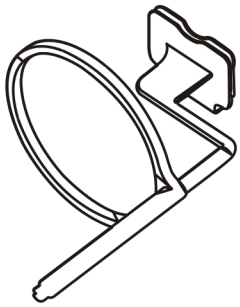
Practical, dedicated storage box keeps imaging plates clean and ready for use by protecting the plates from:

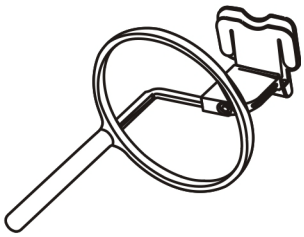
- Dust (which will be visible in the image)
- Airborne contamination
- Fogging caused by background radiation (which may decrease image quality)
- Ultraviolet radiation (which is harmful for the imaging plates)

Base part of the storage box is autoclavable at 121°C (250 F) or 134°C (272 F). The top cover cannot be autoclaved.

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 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 Occlusal 4C kit and on chapter 3 Advanced use.

4.6 Microfiber cloth

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

5 Introduction to imaging plate technique

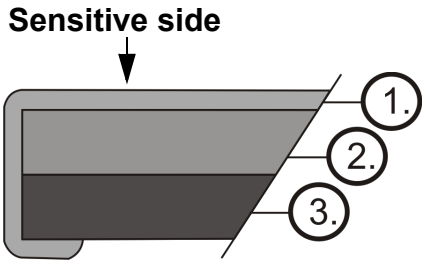
5.1 Imaging plate

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 darkroom.
- 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 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.

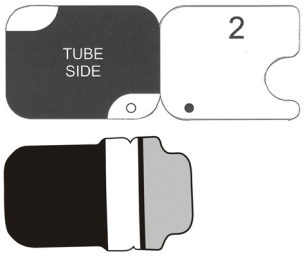
The phosphorescent side of the plate records and stores the image. This side is sensitive and should be protected against dust and dirt.

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.

NOTICE! If imaging plates show any signs of deterioration affecting image quality, do not use them.

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

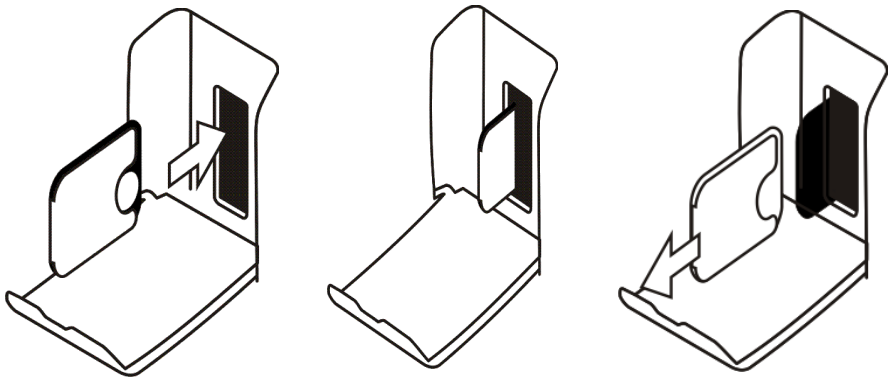
NOTICE! *USE ONLY GENUINE, ORIGINAL HYGIENE ACCESSORIES AND IMAGING PLATES DESIGNED FOR THIS SYSTEM AND SUPPLIED BY AUTHORIZED DISTRIBUTOR. The manufacturer of this system will not be held responsible for any problems caused by using accessories from other manufacturers. PROPER USE OF ORIGINAL HYGIENE 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 taken as with a traditional film.

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.

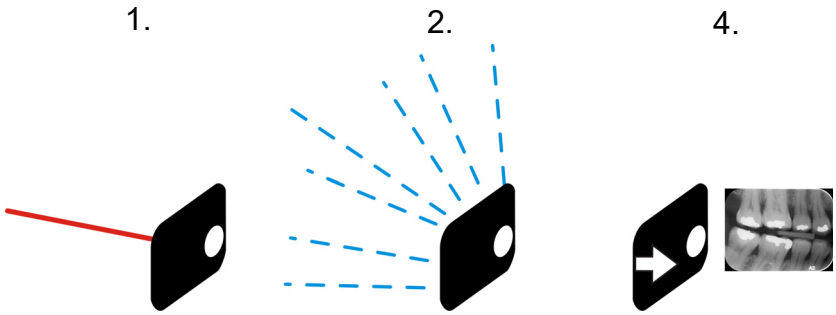
The hygiene bag should be disinfected after an exposure and **must** be disposed of after a single use.

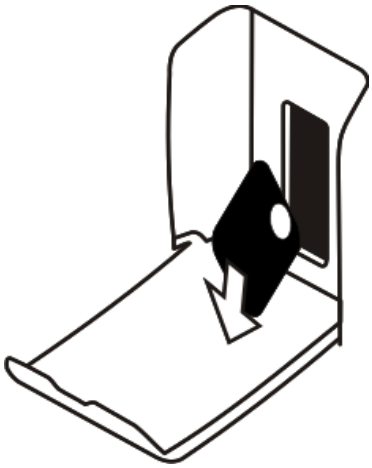
1. 2. 3.



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 photo-detector.
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.

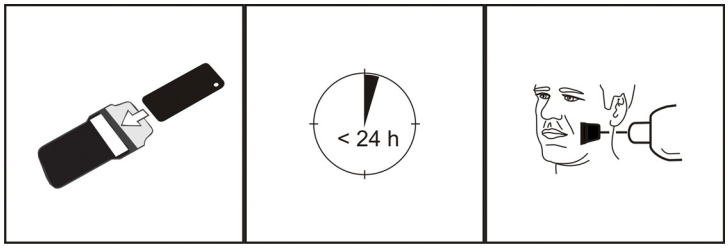
X-ray exposures and processing are not aging the imaging plate, so it is re-usable hundreds of times. In practice, mechanical wearing limits the service life of the plate.

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.

NOTICE! *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.

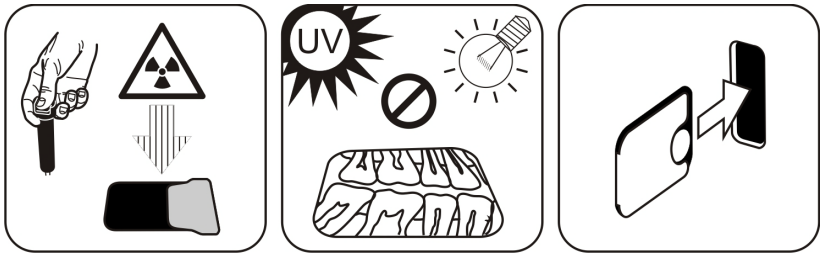
Imaging plates may gather radiation also during transportation from the manufacturer. Therefore it is recommended to perform initial erasing for the new plates. This means that all imaging plates should be processed once prior to use.

5.5 Light

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

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

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



6 Installation of the imaging plate system

Imaging plate system is formed of one or more workstation that connects the imaging plate scanner unit, software, accessories and consumables.

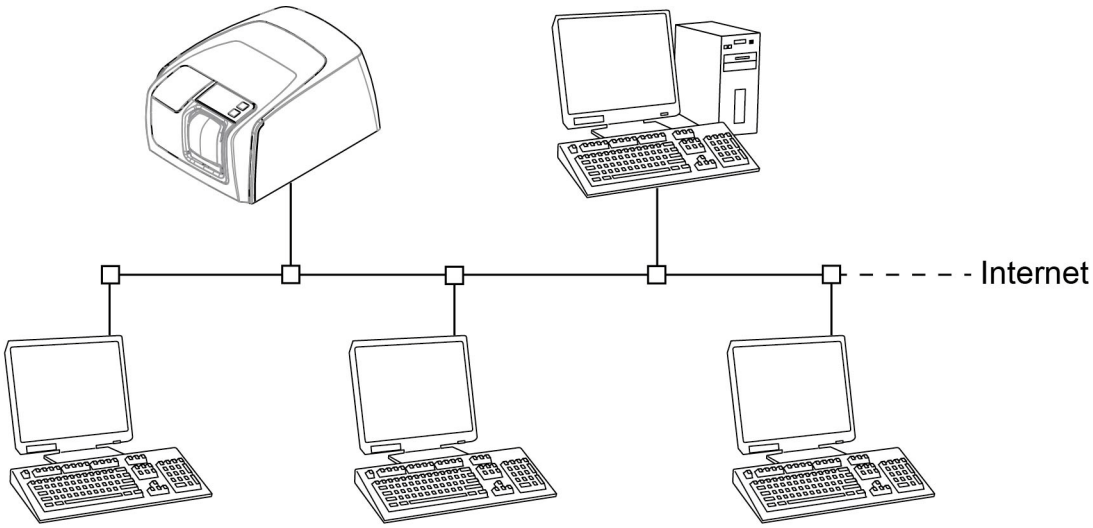
Electronic equipment that does not fulfill medical safety standards (office workstation, network connecting units etc.) must not be installed in the patient area. The definition of the patient area is 1,5 m in horizontal distance and 2.5 m in vertical distance to the patient. The Scan eXam™ One meets safety requirements of a medical electrical unit and it can be installed also in the patient area.

6.1 Positioning the unit

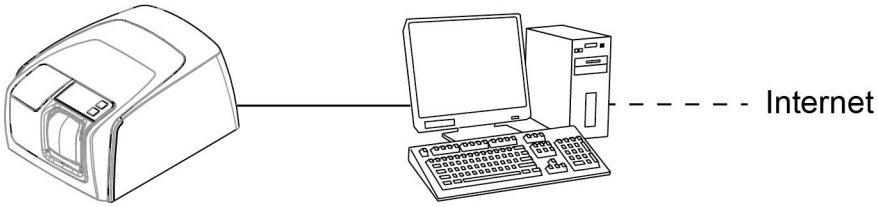
Position the unit on a stable flat surface so that any potential vibrations do not degrade the image quality. The unit must not be positioned so that it is touching other equipment. It must not be placed on top of or under other equipment.

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.

Typical location for a scanner unit in a shared use by multiple operators is somewhere in a common space for all users having an easy access to.



If the X-ray images are being captured and images scanned in a single location only (X-ray room or single user environments) it is most convenient to place the scanner unit near to the X-ray.



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

6.2 Connecting the unit to a network

The unit can be connected directly to a single workstation or several workstation using a wired local area network (LAN). It is recommended to use a LAN in all installations. Also any workstation used for managing an image capture should be connected to a wired LAN.

It is recommended to have an internet connection from the LAN. This makes registering potential software license easier.

Connect the Ethernet cable from the unit to the local area networking unit (router/switch). Consult a computer network specialist to build up a local area network if needed.

The unit can obtain an IP address automatically (DHCP) or it can be set manually (static IP).

The unit will show its IP number during the boot up sequence when powered on.

6.3 Install the Application software

To function with the scanner, the workstation must have:

- Client software (CLINIVIEW or DTX Studio with DTX Studio Core)
- DTX Studio Drivers

NOTICE! DTX Studio Drivers are automatically installed with CLINIVIEW but they must be separately installed for DTX Studio installation.

The imaging plate system is delivered with an software required to operate the system. In a functional system there are two main parts: a server for storing the patient data and images and client software for operating the system and the units. Both parts can be on the same computer but there must be only one computer acting as database server in a network. If the imaging plate system is operated and images are viewed from multiple workstation in a network install only the client software on the remaining other workstation. The workstation that is acting as a server must be powered at any times the system is used on any of the workstation.

In addition there can be a license server in the local area network to manage software licenses for multiple workstation.

Turn the unit on by pressing the power ON/OFF button before installing the software.

Insert the software installation media (DVD) and launch the software installer if it does not start automatically.

Read the software installation manual. Follow the instructions of the installation wizard to complete the software installation. Refer the software installation manual for details.

6.4 Accessing the unit from CLINIVIEW

In order to operate the scanner unit from a workstation the software needs to access the desired scanner unit in the network. There can be multiple scanners in one network. When using multiple scanners each unit can be assigned a unique call name by the user to separate the scanners in the network. By default the name of the scanner unit is “Scan eXam™ One”.

There are multiple ways of configuring the connection between the scanner unit and the operators software. The automatic connection is based on automatically detecting the scanner in the network. This is a preferred method.

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

NOTICE! It may not be possible to connect the unit to the workstation using the direct connection method if another device is al ready connected to the workstation 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 workstation(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 workstation(s) in the network.

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

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

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

6. **Workstation:** 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.

6.4.2 IP method (using the unit static address)

If your system does not allow the direct connection method to be used to connect the workstation(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. **Workstation:** From the Settings tab select IP based and then select the Enable changing IP address box.

   NOTICE! The workstation and the unit must be in the same subnet when setting the IP address of the unit.

3. **Workstation + 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 workstation is now sending the IP address the unit.

4. **Workstation:** Click **OK** to connect the workstation to the unit.

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

6.4.3 EXPRESS Share

1. **Workstation**: If the unit is to be used with several workstations select the Use Multiconnect check box and select a unique Workstation identifier number (between 1 and 4), for the workstation 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 workstation identifier number.

   NOTICE! If only one workstation 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 workstation before the workstation automatically released the unit so that it can be used by another workstation in the system (the scanner can be reserved in advance from another workstation). The default setting is 40 seconds. This can be changed by keying in a new value.

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

   NOTICE! An automatic technique automatically locates the unit within the local area network and connect the workstation.

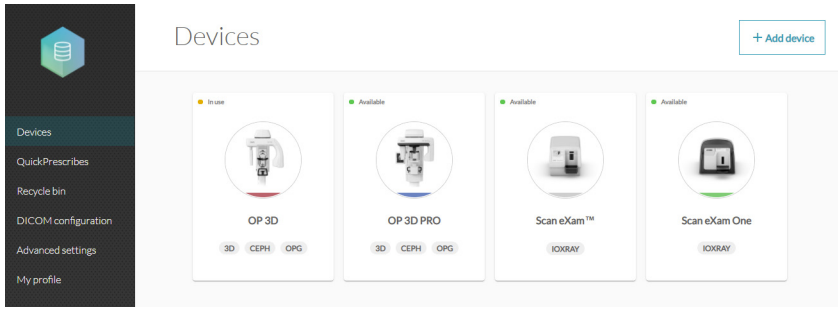
3. Repeat the above process for all the other workstations in the network. Make sure that you give each workstation a different Workstation identifier.

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

6.5 Accessing the unit from DTX Studio™ Core

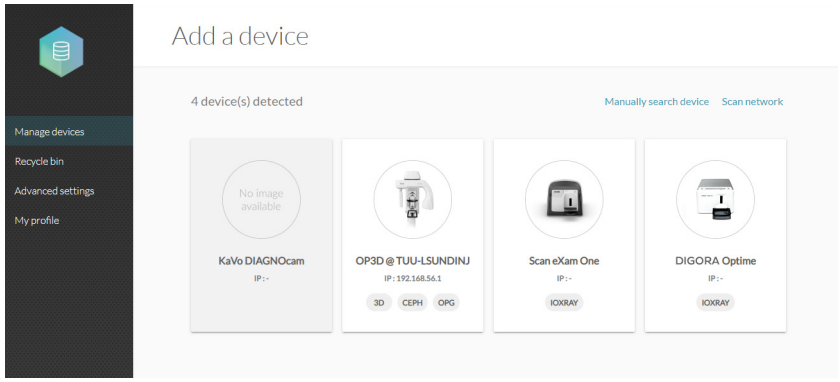
1. Sign into DTX Studio™ Core with the same user credentials as you use to login to DTX Studio™.

2. Select **Manage devices** menu.



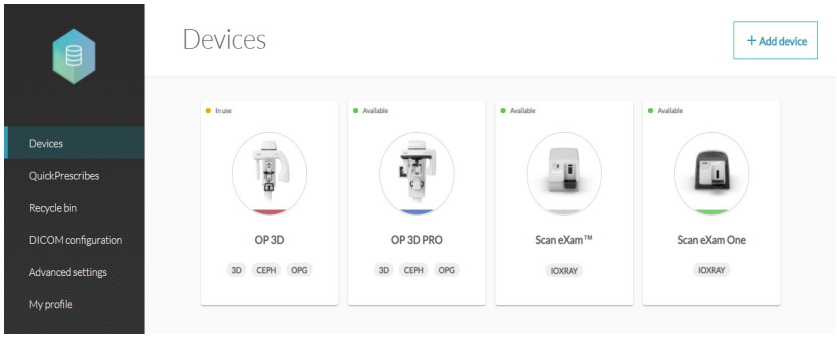
3. Click **Add device**.

4. Devices connected to the network are automatically listed on the device manager view.



- If the device does not appear on the list, click **Scan network**.
- If the device still does not appear on the list, add the device manually by clicking **Manually search device** and fill the prompted device information fields.

5. Select the device from the list.



6.6 Other devices

DO NOT connect any other devices to the unit or the workstation 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.

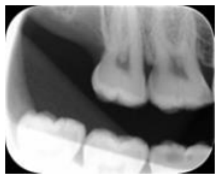
The workstation connected to the unit should not be used in the patient environment. The minimum horizontal distance between the patient and the workstation is 1.5 m (4.5 ft). The minimum vertical distance between the patient and the workstation is 2.5 m (6.5 ft).

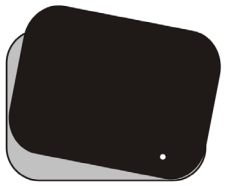
7 Troubleshooting

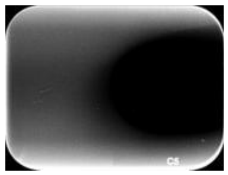
7.1 Error images

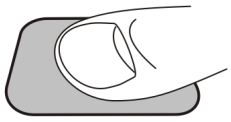
7.1.1 Improper use of the hygiene accessories and imaging plates

Decreased contrast, shadows or shading, ghost images



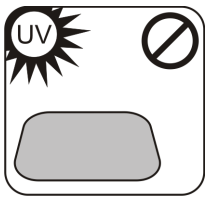






Shows a “ghost image” (having shape of the plate or other object). Plate not properly shielded from light between exposure and process. Part of the image erased by ambient light.

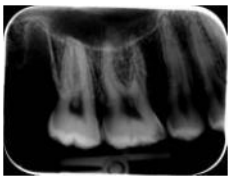
- Protective cover misused or not used at all.
- Hygiene bag not sealed properly.
- Improper, non-genuine hygiene accessories use.



- 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.

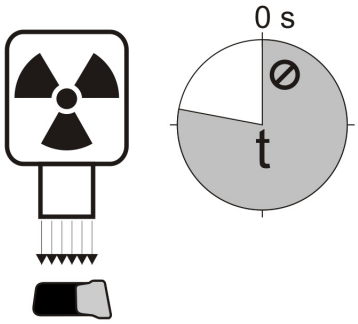
7.1.2 Application errors

Improper x-ray settings used



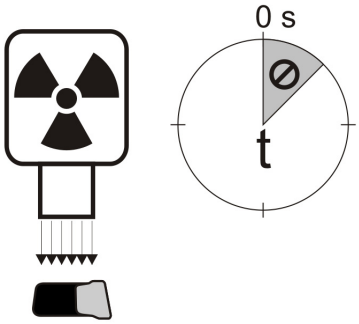
Too dark image. Some areas showing uniform “black”. Decreased diagnostic value.

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

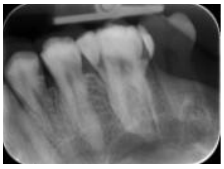


Too light, noisy image with decreased diagnostic value. Showing only part of the image.
Showing wrong size of the image (Image smaller than imaging plate).

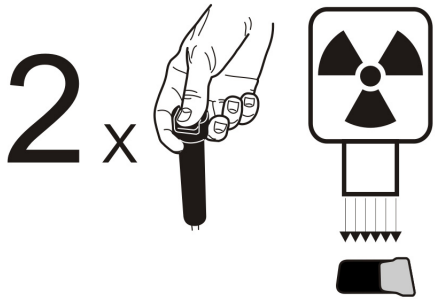
- Too short exposure time / Too low X-ray dose.



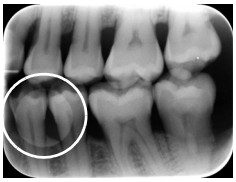
Ghost images, shadows



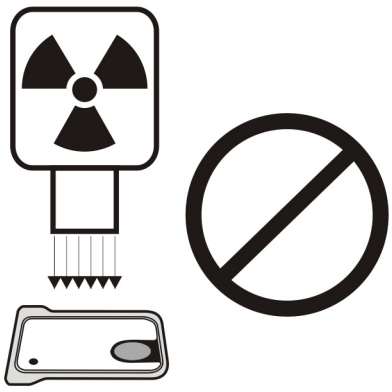
- Imaging plate has been exposed twice without processing in
  between.
- More than one image exposed to the same plate.
- Imaging plate has not been erased properly after processing.
- Unit erasing leds are monitored during normal operation. If leds are defected, application SW shows warning.



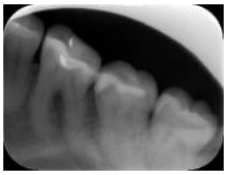
Circular shape on the image

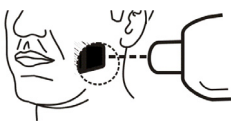


Imaging plate has been exposed from the wrong side, which shows the phantom of the metal disc on the rear side of the plate.



Cone cut

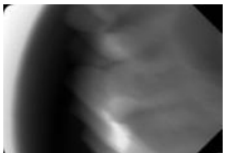


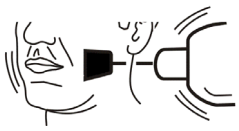


X-ray beam has exposed only part of the imaging plate surface. Image may show on different (smaller) size than the imaging plate used.

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

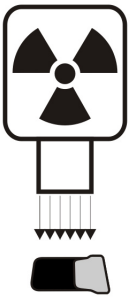
Unsharp or blurred images, motion artefact

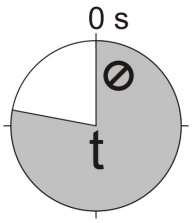




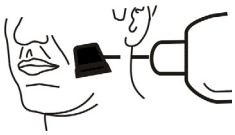
Patient or X-ray cone has moved during the exposure.

- 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).





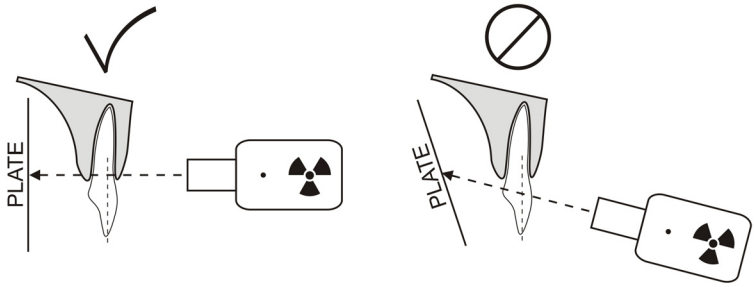
Geometry distortion



Improper patient positioning.

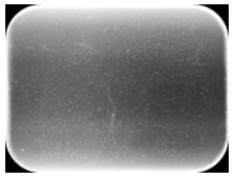
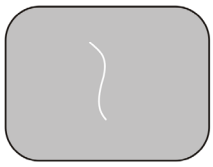
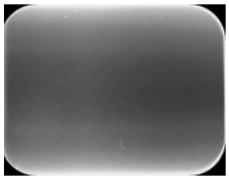
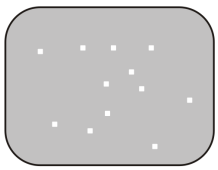
- Use proper holders to avoid this.

NOTICE! 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

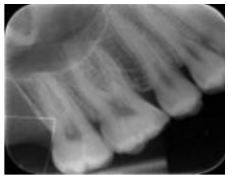
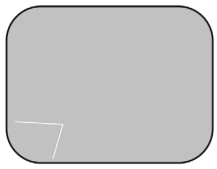
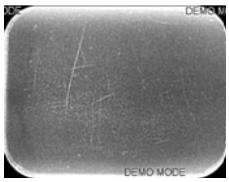





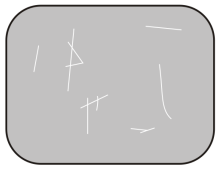
- Dust or stains on the imaging plates.
- Any extra particle on top of the active sensitive surface of the plate is visible on the image.

- 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

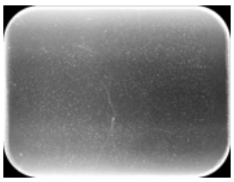
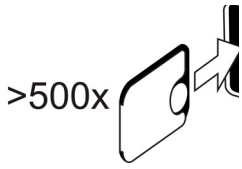
Scratches

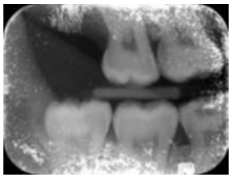
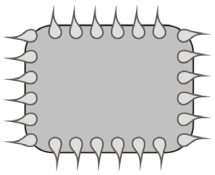






- Clean the plate(s).
- Replace if cleaning does not help.
- Pay attention on handling, storing and maintenance. Ensure that only the genuine hygiene accessories are used.

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

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 “Exposure level” 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 SP00267 (Intra digi QC IEC phantom w. instructions).

8.2 Unit 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 Unit cleaning

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

- cool or lukewarm water
- soapy water
- mild detergent
- isopropyl alcohol
- ethanol (ethyl alcohol) 70 - 96%
- 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 Unit

Product name	Scan eXam™ One
Model	eXam6
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 unit to sale by or on the order of a dentist or other qualified professional.
Manufacturer	PaloDEx Group Oy, Nahkelantie 160 FI-04300 Tuusula, FINLAND
Quality system	In accordance with ISO13485
Environmental management system	In accordance with ISO14001 standard
Conformity to standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60825-1 • ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 • CAN/CSA –C22.2 No. 601-1-M90 This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. The device is in conformity with the provisions of Council Directive 93/42/EEC as amended by the Directive 2007/47/EC concerning medical devices.
eXam6 Classification IEC60601-1	- CLASS II equipment - No applied part - Continuous operation - IPX0 (enclosed equipment without protection against ingress of liquids

Laser Safety Classification	CLASS 1 LASER PRODUCT, IEC 60825-1
Dimensions (H x W x D)	168 mm x 233 mm x 328 mm (6.6 x 9.2 x 12.9 inches)
Weight	3,7 kg (8.2 lb)
Power supply unit (PSU)	Delta MDS-030AAC24
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	1.0 or higher
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 workstation, network adapter and network switch	
Workstation 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
Network cyber security requirements	• The device must be connected to a private, firewall protected local area network to ensure proper data security. All connections from outside of the local area network to the device must be blocked. Connections between the device and the workstation in the local area network shall be allowed. • Network elements used for IT-network must not use their default passwords. • The workstation connected to the device must use an antivirus software and have individual password protected user accounts to prevent unauthorized access to patient data.
Use	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 workstation with imaging application software to same subnet in LAN.

NOTICE! *Image is not transferred from device to workstation imaging application software in case of connection lost during image processing. Image is stored in unit memory until it has been transferred to workstation. 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
Environmental conditions	Storage and transportation	-10°C … +33 °C / max 80% RH / NO UV radiation				
	Use	+18°C …+45 °C / max 80% RH				
Material		Layer of small photo-stimulable particles (that exhibit the phenomenom 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 edges. 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 hygiene accessories (protective covers and hygiene bags) will extend the service life of the imaging plates.				
Disposal		Imaging plates contain small amount of Barium and should be considered hazardous or special waste. At the end of the useful working life, make sure to follow the national and local regulations regarding disposal of the imaging plates. 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.  **Single use only. Do not reuse.**
Disposal	Observe relevant national requirements. 

9.5 Electromagnetic Compatibility (EMC) tables

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

IEC60601-1-2 ed4 testing has verified that electromagnetic interference stimulus has no effect to safety critical functionality of the device. This includes image readout and erasing.

If abnormal performance is observed, such as degradation of essential performance in form of reduction of line pair resolution, additional measures may be necessary, such as re-orienting or relocating the device.

The device is suitable for use in both at professional healthcare (hospitals/large clinics) facility environment and home healthcare (clinics in domestic establishments and those directly connected to the public low-voltage power supply) environment.

Exceptions for professional healthcare facility environment: Not to be used or installed near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

Table 1: Electromagnetic emissions IEC 60601-1-2 Ed4

The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the device should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Radio-Frequency Emissions CISPR11	Group 1	The device uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	The device is suitable for use in both at professional healthcare (hospitals/large clinics) facility environment and home healthcare (clinics in domestic establishments and those directly connected to the public low-voltage power supply) environment. Exceptions for professional healthcare facility environment: Not to be used or installed near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
Harmonic emissions IEC61000-3-2	IEC61000-3-2 Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Table 2: Electromagnetic immunity IEC 60601-1-2 Ed4

The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the device should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV for contact discharge ±2, 4, 8, 15 kV for air discharge	± 8 kV for contact discharge ±2, 4, 8, 15 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines (100 kHz) ±1 kV for input/ output lines (100kHz)	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 0.5, 1 kV differential mode ± 0.5, 1, 2 kV common mode	± 0.5, 1 kV differential mode	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	-0% U mains; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° -0% U mains; 1 cycle, At 0°-70% U mains; 25/30 cycles At 0° -0% U mains; 250/300 cycle At 0°	-0% U mains; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° -0% U mains; 1 cycle, At 0°-70% U mains; 25/30 cycles At 0° -0% U mains; 250/300 cycle At 0°	Mains power quality is that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply.
Power frequency (50/ 60Hz) magnetic field IEC 61000-4-8	30A/m	30 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/ or hospital environment. The device shall not be used closer than 15cm to sources of 50/60Hz magnetic field.
NOTICE! *UT is the a.c. mains voltage prior to application of the test level.*			

Table 3: RF immunity of non-life-support equipment or system IEC 60601-1-2 ed.4

The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the device should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Conducted RF IEC 61000-4-6	3V 150kHz to 80 MHz, 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz according to table 60601-1-2. Ed4. Table 5/8.	3V 150kHz to 80 MHz, 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz according to table 60601-1-2. Ed4. Table 5/8.	Portable and mobile RF communications equipment are used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = 2\sqrt{P}$ 150kHz-80MHz $d = 0,6\sqrt{P}$ 80MHz to 800 MHz $d = 0,6\sqrt{P}$ 800 MHz to 2,7 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz Immunity to proximity fields from RF wireless communication equipment, levels according to table 60601-1-2 ed4 table 9.	10 V/m 80 MHz to 2,7 GHz Immunity to proximity fields from RF wireless communication equipment, levels according to table 60601-1-2 ed4 table 9.	

The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the device should assure that it is used in an electromagnetic environment as described below:
* Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe the device to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. Guidance for actions taken can be found from AAMI TIR 18:2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities. **NOTICE!** Precautions to take if the use location is near (e.g. less than 1,5 km from) AM, FM or TV broadcast antennas. ** Over the frequency range 150 kHz to 80 MHz, field strengths are less than 3 V/m. **The Recommended Separation Distances are listed in the next table**. **NOTICE!** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTICE! *RF communications equipment can effect medical electrical equipment.*

Table 4: Separation distances

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Frequency of Transmitter Equation Rated Maximum Output Power of Transmitter (watts)	150 kHz to 80 MHz $d = 2\sqrt{P}$ Separation Distance (meters)	80 MHz to 800 MHz $d = 0,6\sqrt{P}$ Separation Distance (meters)	800 MHz to 2.7 GHz $d = 0,6\sqrt{P}$ Separation Distance (meters)
0,01	0,20***	0,06***	0,06***
0,1	0,63	0,19***	0,19***
1	2	0,6	0,6
10	6,32	1,90	1,90
100	20	6	6
For transmitters rated at 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. **NOTICE!** At 80 MHz, the separation distance for the higher frequency range applies. **NOTICE!** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. **WARNING!** *** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12") to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.			

USE LIMITATION:

External components

WARNING! Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

INSTALLATION REQUIREMENTS & ENVIRONMENT CONTROL:

In order to minimize interference risks, the following requirements shall apply.

Cables shielding & grounding

All interconnect cables to peripheral devices must meet the requirements given in Technical specifications. Use of incorrect cables may result in the device causing radio frequency interference.

Electrostatic discharges environment & recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor should be installed to prevent charge accumulation.

- The dissipative floor material must be connected to the system reference ground, if applicable.
- Relative humidity must be maintained above 30 percent.

Stacked components & equipment

WARNING! *The device should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.*

Interference may occur in the vicinity of equipment marked with the following symbol:

10 Symbols and labeling

10.1 Symbols that may appear on the device or its parts

Name and address of the manufacturer

Date of manufacture

Medical device

Serial number

Reference number

Lot number

Caution

Do not reuse (Single use)

Recyclable

Operating instructions
Refer to operating instructions for more information. The operating instructions can be supplied electronically or in paper format

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

UKCA (UK Conformity Assessed) marking

Swiss authorised representative

Caution: Federal law restricts this to sale by or on the order of a licensed healthcare practitioner.

ETL symbol

GOST-R symbol

Importer

This symbol indicates that the waste of electrical and electronic equipment must not be disposed of 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.

China RoHS. Environment friendly use period (EFUP) of 10 years.

Ingress protection (IP) code.

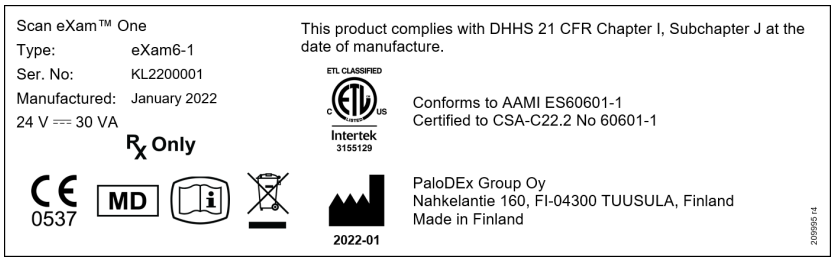
Power Supply efficiency level.

10.2 Device labels

The device labels are located at the rear of the device

Type label:

NOTICE! *The type label shown below is for reference only. The texts may be different in the actual label.*



CLASS 1 Laser product warning label:

10.3 Warnings and precautions

THE UNIT IS A CLASS 1 LASER PRODUCT

NOTICE! *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 re-manufactured 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 workstation / 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.

- Connecting the device to an IT-network that includes other equipment or changing the IT-network configuration can cause unknown safety or security risks to patients or operators. It is the responsibility of the organization controlling the IT-network to identify, analyze, evaluate and control these possible risks.

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

- The workstation 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 workstation where it could be splashed with liquids.

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

- Image is not transferred from unit to workstation imaging application software in case of connection lost during image processing. Image is stored in unit memory until it has been transferred to workstation. 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.

- Due to Occlusal 4C projection imaging geometry and imaging plate positioning, accurate distance and angle measurements cannot be taken from occlusal projection images.

- If imaging plates show any signs of deterioration affecting image quality, do not use them.

- Report any incident, related to the use of this device, having a serious effect on the health of a patient, user or other person to the manufacturer and the local competent authority.

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