PLANMECA

Planmeca ProScanner® 2.0

EN

user's manual

CE

30019182

The manufacturer, assembler and importer are responsible for the safety, reliability and performance of the unit only if:

- installation, calibration, modification and repairs are carried out by qualified authorised personnel
- electrical installations are carried out according to the appropriate requirements such as IEC 60364
- equipment is used according to the operating instructions.

Planmeca pursues a policy of continual product development. Although every effort is made to produce up-to-date product documentation this publication should not be regarded as an infallible guide to current specifications. We reserve the right to make changes without prior notice.

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1 Important information

1.1 About this document

This user's manual represents part of the unit.

If the instructions and information in this user's manual are not followed, Planmeca will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

NOTE

The English version of the manual is the original manual. All other languages are translations of the original instructions. These instructions for use apply to the following ProScanner 2.0:

- **Article number FE004607**
- **Article number FE004630**
- **Article number FE004631**

1.1.1 Warnings, cautions and notes

The warnings, cautions and notes in this manual are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning > Follow these measures to avoid the danger.

The signal word differentiates between the three levels of danger:

WARNING

Possible danger of severe injury or death.

CAUTION

Risk of minor injuries.

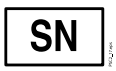
NOTE

Risk of extensive material/property damage.

1.1.2 Other symbols

The following symbols are used in the document and on or in the unit.

Order number



Serial number

Medical device

Lot / batch labelling


CE labelling

CE labelling with code of the Notified Body


Manufacturer


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


Electronic instructions for use


Instructions for use

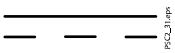

Comply with the operating instructions


Wear protective gloves

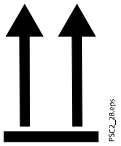

Switch off and de-energise the unit (e.g. unplug from mains)


Do not reuse

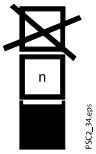
Health Industry Bar Code (HIBC)


Direct current (DC)


Non-ionizing electromagnetic radiation

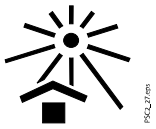

This way up / store and transport in an upright position


Keep dry

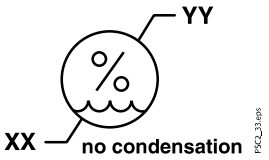


Stacking limits

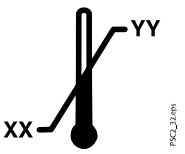
Fragile, handle with care



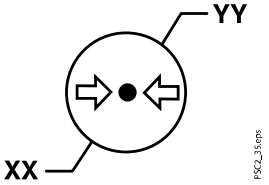
Keep away from sunlight



Lower and upper humidity limits



Lower and upper temperature limits



Lower and upper atmospheric pressure limits

1.1.3 Copyright information

1.2 Safety

The manufacturer has designed and constructed this unit so that when used properly and for the intended purpose it does not pose any danger to people or property. Nevertheless, the following residual risks may occur:

- Personal injury due to misuse
- Personal injury due to mechanical influences
- Personal injury due to electrical voltage
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects on the skin
- Personal injury due to lack of hygiene, for example, infection

You should therefore observe the safety information in the following sections.

1.2.1 Intended purpose

Planmeca ProScanner 2.0

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

Light protection cover

The functions of the light protection cover are as follows:

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

1.2.2 Intended use

Planmeca ProScanner 2.0

The unit may only be operated using accessories and optional articles manuctured by or branded with Dürr Dental.

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

Light protection cover

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

1.2.3 Improper use

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

Especially:

- The multiple use of this accessory and reprocessing contrary to the instructions of the manufacturer. The use of the accessory in combination with other than image plate scanners manufactured by or branded with Dürr Dental and image plates manufactured by or branded with Dürr Dental.

Planmeca ProScanner 2.0

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

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

Planmeca light protection cover

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

In particular:

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

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

1.2.4 General safety information

Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.

Check the function and condition of the unit prior to every use.

Do not convert or modify the unit.

Comply with the specifications of the user's manual.

The user's manual must be accessible to all operators of the unit at all times.

1.2.5 Qualified personnel

Operation

Unit operating personnel must ensure safe and correct handling based on their training and knowledge.

Instruct or have every user instructed in handling the unit.

Installation and repairs

Installation, readjustments, alterations, upgrades and repairs must be carried out by Planmeca or by qualified personnel specifically approved and authorised by Planmeca.

1.2.6 Electrical safety

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

Observe EMC rules concerning medical devices

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

NOTE

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

Use only Planmeca parts or accessories specifically approved by the manufacturer.

Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

NOTE

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

Do not stack the unit together with other devices.

If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

1.2.7 Essential performance characteristics

The Planmeca ProScanner 2.0 unit does not possess any significant performance characteristics as set out in IEC 60601-1 (EN 60601-1) section 4.3.

The unit complies with the requirements according to IEC 60601-1-2:2014.

Obligation to report serious incidents

The user or patient is obliged to report all serious incidents that have occurred in connection with the product to the manufacturer and the competent authority of the Member State in which the user or patient is located.

1.2.8 Only use original parts

Only use Planmeca parts or accessories and optional articles specifically approved by the manufacturer.

Only use only original wear parts and replacement parts.

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

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

1.2.9 Transport

The original packaging provides optimum protection for the unit during transport.

If required, original packaging for the unit can be ordered from Planmeca.

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

Only transport the unit in its original packaging.

Keep the packing materials out of the reach of children.

Do not expose the unit to any strong vibrations or shocks.

1.2.10 Disposal

NOTE

For an overview of the waste codes for Dürr Dental products, go to the Download section under www.duerrdental.com (document no. P007100155).

Unit

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

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

Image plate

The image plate contains barium compounds.

Dispose of the image plate properly in accordance with the locally applicable regulations.

In Europe, dispose of the image plate in accordance with waste code 090199 "Wastes not otherwise specified". Disposal as domestic waste is possible.

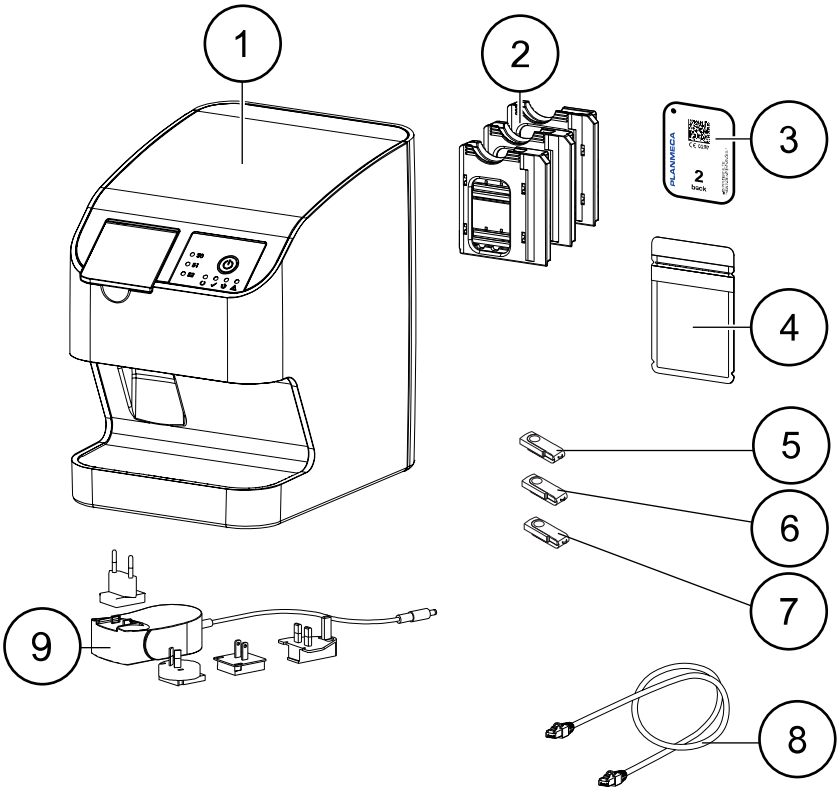
1.2.11 Protection from threats from the Internet

The unit is to be connected to a computer that can be connected to the Internet. Therefore, the system needs to be protected from threats from the Internet.

- Use antivirus software and update it regularly
- Look for evidence of possible virus infection and, if applicable, check with the antivirus software and remove the virus
- Perform regular data backups
- Restrict access to units to trustworthy users, e.g. via a user name and password
- Make sure that only trustworthy content is downloaded
- Only install software and firmware updates that have been authenticated by the manufacturer

2 Product description

2.1 Overview



1 Planmeca ProScanner 2.0 image plate scanner
2 Cartridge for image plates (S0 up to S2)
3 Planmeca imaging plate
4 Planmeca light protection cover
5 Romexis and imaging software USB stick
6 User's manual USB stick
7 Technical manual USB stick
8 Network cable (3 m)
9 Power supply unit with country-specific adapter

2.1.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

- ProScanner 2.0 Image Plate Scanner
- 2x Planmeca imaging plate Size 0
- 2x Planmeca imaging plate Size 1
- 4x Planmeca imaging plate Size 2
- 100x Planmeca light protection covers Size 0
- 100x Planmeca light protection covers Size 1
- 300x Planmeca light protection covers Size 2
- Cartridge for Image Plate, Size 0
- Cartridge for Image Plate, Size 1

- Cartridge for Image Plate, Size 2
- Image Plate storage box
- Power supply
- Power cable
- LAN cable RJ45

2.1.2 Accessories

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

Image plates

- Planmeca Imaging Plate, Size 0 (2pcs)
- Planmeca Imaging Plates, Size 1 (2pcs)
- Planmeca Imaging Plate, Size 2 (4pcs)
- Planmeca Imaging Plate, Size 2 (12pcs)

Light protection covers

- Planmeca Light Protection Cover, Size 0 (100 pcs)
- Planmeca Light Protection Cover, Size 1 (100 pcs)
- Planmeca Light Protection Cover, Size 2 (300 pcs)
- Planmeca Light Protection Cover, Size 2 (1000 pcs)

2.1.3 Optional articles

The following optional articles can be used with the unit:

- Wall mounting Plate for ProScanner 2.0
- ProScanner 2.0 Imaging Plate storage box
- Quart test phantom set for Planmeca ProSensor/ProScanner

2.1.4 Consumables

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

Cleaning and disinfection

- Image plate cleaning wipes (10 pcs.)
- FD 333 forte wipes for quick-acting disinfection
- FD 350 Classic disinfection wipes
- FD 333 rapid surface disinfection
- FD 322 rapid surface disinfection
- FD 366 rapid disinfectant for sensitive surfaces
- ID 213 instrument disinfection
- ID 212 instrument disinfection
- ID 212 forte instrument disinfection

Light protection covers

For more information, see section "Accessories" on page 9.

2.1.5 Wear parts and replacement parts

Cartridges

- Cartridge for Image Plate Size 0
- Cartridge for Image Plate Size 1
- Cartridge for Image Plate Size 2

Image plates

For more information on the image plates, see section "Accessories" on page 9.

For more information on wear parts and replacement parts, contact your local distributor through www.planmeca.com.

2.2 Technical data

2.2.1 Image plate scanner

Electrical data for the unit

Rated voltage	V DC	24
Max. current consumption	A	0.5
Max. power consumption	W	< 12
Protection class		II

Electrical data – power supply unit

Nominal input voltage	V AC	100 - 240
Frequency	Hz	50/60
Nominal output voltage	V DC	24
Max. output current	A	0.5

General technical data

Dimensions (W x H x D)	mm	167 x 231 x 216
Weight	kg	approx. 4
Duty cycle	%	100
Max. theoretical resolution	Line pairs / mm (Lp/mm)	approx. 16.7
Noise level during scanning	dB(A)	approx. 45

Network connection

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

Ambient conditions during operation

Temperature	°C	+10 to +35
Relative humidity	%	20 - 80
Air pressure	hPa	750 - 1060
Height above sea level	m	< 2000

Ambient conditions during storage and transport

Temperature	°C	-18 to +60
Humidity	%	10 - 95, non-condensing
Air pressure	hPa	500 - 1060
Height above sea level	m	< 16000

Classification

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

Laser class (unit) in accordance with EN 60825-1:2014: 1

Laser source

Laser class	3B acc. to IEC 60825-1:2014	
Wavelength	nm	635
Power	mW	<10

Technical data of the RFID Module

Frequency	MHz	13.56
Modulation		ASK
Max. power	mW	400

Electromagnetic compatibility (EMC) interference emission measurements

High-frequency emissions in accordance with CISPR 11 Group 1	Group 1, Class B
Interference voltage at the power supply connection CISPR 11:2009+A1:2010	Compliant
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Compliant

Electromagnetic compatibility (EMC) interference immunity measurements cover

Immunity to interference, discharge of static electricity IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant

Immunity to interference, high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010 3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	Compliant
Immunity to interference, near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 See immunity to interference table, near fields of wireless HF communication devices	Compliant

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

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

Electromagnetic compatibility (EMC) Interference immunity measurements supply input

Immunity to interference, rapid transient bursts – AC voltage grid IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition frequency	Compliant
Immunity to interference, surges IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Compliant
Immunity to interference, line-conducted disturbances induced by high-frequency fields – AC voltage grid IEC 61000-4-6:2013 3 V 0.15 - 80 MHz 6 V ISM frequency bands 0.15 - 80 MHz 80 % AM at 1 kHz	Compliant
Immunity to interference due to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP

Immunity to interference, discharge of static electricity IEC 61000-4-2:2008 ± 8 kV contact ± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to interference, rapid transient bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1 kV 100 kHz repetition frequency	Compliant

Immunity to interference, line-conducted disturbances induced by high-frequency fields – SIP/SOP ports IEC 61000-4-6:2013 3 V 0.15 - 80 MHz 6 V ISM frequency bands 0.15 - 80 MHz 80 % AM at 1 kHz	Compliant

2.2.2 Image plate

Classification

Medical Devices Directive (93/42/EEC) Class IIa

Ambient conditions during operation

Temperature °C 18 - 45

Relative humidity % < 80

Ambient conditions during storage and transport

Temperature °C < 33

Relative humidity % < 80

Dimensions of intraoral image plates

Size 0: 22 x 35 mm

Size 1: 24 x 40 mm

Size 2: 31 x 41 mm

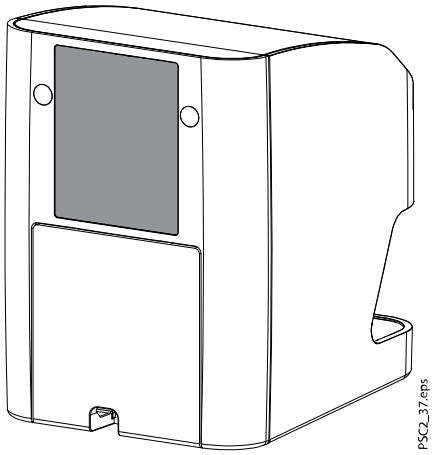
2.2.3 Light protection cover

Classification

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

2.2.4 Type plate

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



REF Order number

SN Serial number

2.2.5 Evaluation of conformity

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

Dürr Dental hereby declares that the radio system type "Planmeca ProScanner 2.0" conforms to directive 2014/53/EU.

The full text of the EU Declaration of Conformity is available at www.duerrdental.com.

2.2.6 Distributor and manufacturer

Distributor

Planmeca Oy, Asentajankatu 6, FIN-00880, Helsinki, Finland

Phone: +358 20 7795 500, Fax: +358 20 7795 555,
http://www.planmeca.com

Manufacturer

DÜRR DENTAL SE

Höpfigheimer Str. 17

74321 Bietigheim-Bissingen

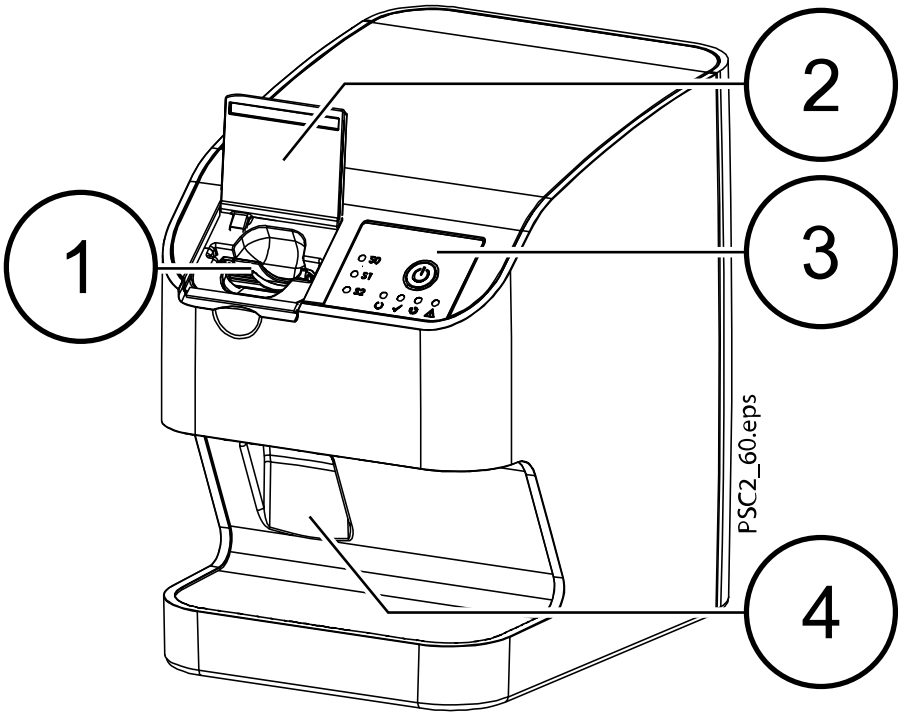
Germany

Phone: +49 7142 705-0
http://www.duerrdental.com

info@duerrdental.com

2.3 Operation

2.3.1 Image plate scanner



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

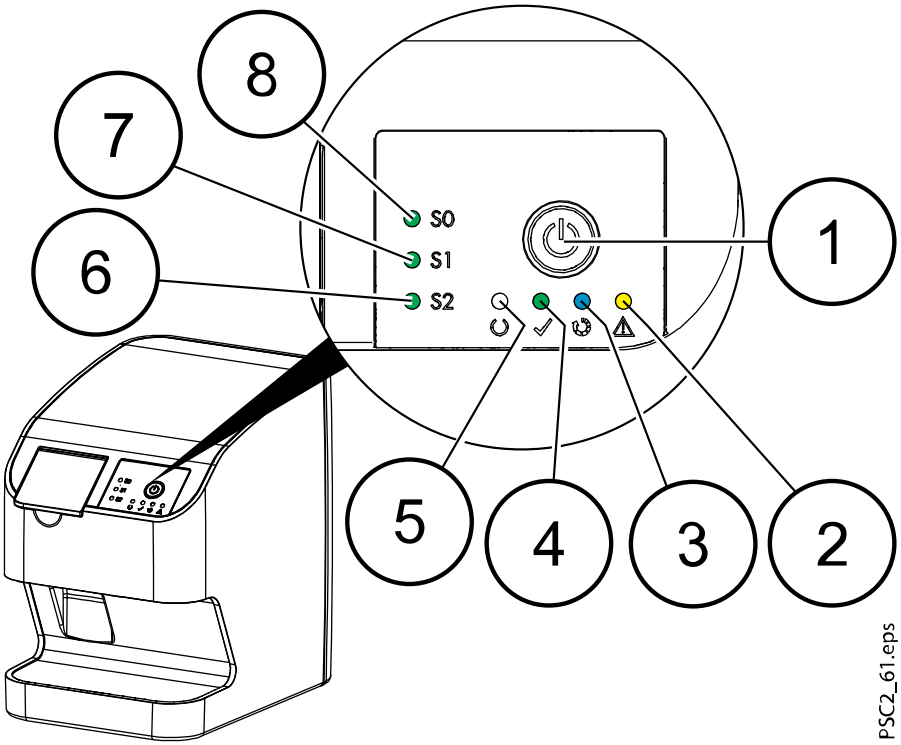
The image plate scanner is used to read image data stored on an image plate and to transfer the data to the imaging software (e.g. Planmeca Romexis) on a computer.

The transport mechanism guides the image plate through the device. The image plate is read using a laser inside the scanner unit. The scanned data is converted into a digital image and transferred to the imaging software.

After scanning, the image plate runs through the erasure unit. Image data still held on the image plate is erased with the aid of bright light.

The image plate is then ejected for re-use.

2.3.1.1 Operating elements



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

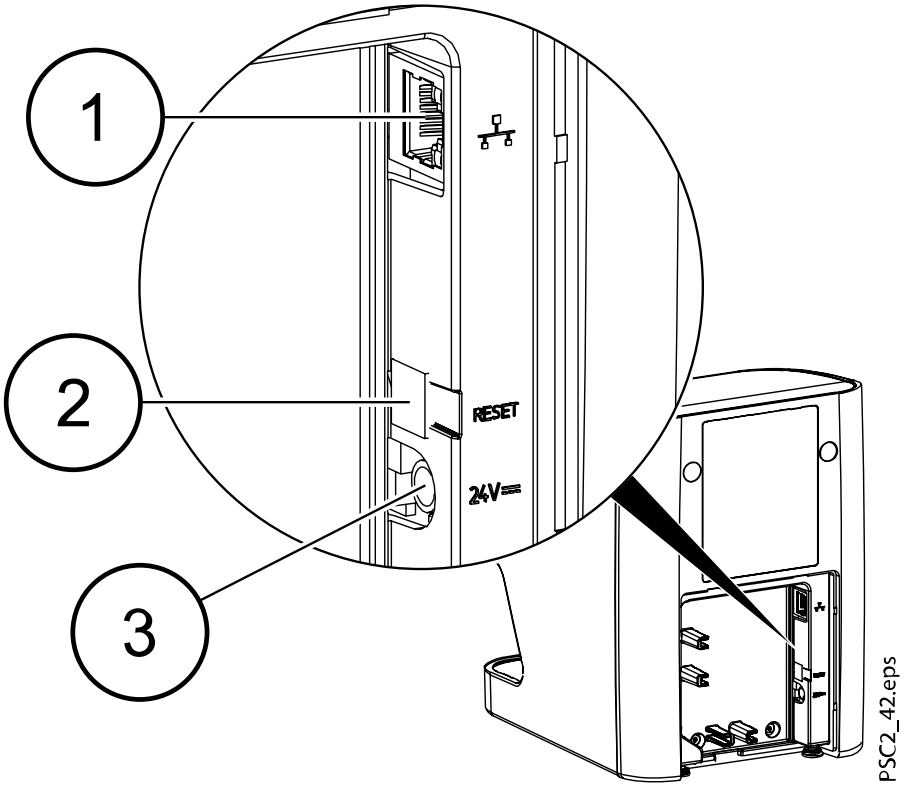
The status LEDs display the following status messages:

	Device starts
	Communication display Standby
	Ready to scan
	Image plate currently being processed
	Cartridge for image plate missing
	Error A message is displayed in the software

S0	S0 cartridge for S0 image plate is in the device
S1	S1 cartridge for S1 image plate is in the device
S2	S2 cartridge for S2 image plate is in the device
	Status LED flashing

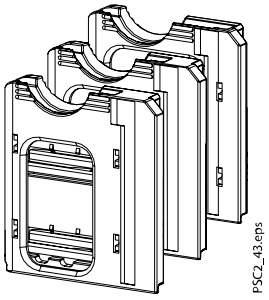
2.3.1.2 Connections

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



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

2.3.2 Cartridges (S0-S2)



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

2.3.3 Image plate

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

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

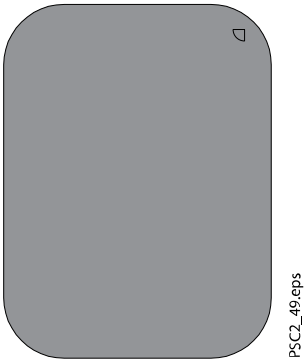
When used properly, image plates can be exposed, read and erased several hundred times provided there is no mechanical damage. The image plate must be replaced if there are any signs of damage, e.g. if the protective layer is damaged or there are visible scratches that could interfere with the diagnosis.

Intraoral

Inactive side:

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

Active side:



Light blue, with positioning aid:

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

NOTE

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

2.4 Light protection cover

The light protection cover protects the image plate against light.

3 Assembly

NOTE

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

3.1 Requirements

3.1.1 Installation/setup room

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

- Closed, dry, well-ventilated room
- It should not be a room made for another purpose (e.g. boiler room or wet cell)
- Max. light intensity 1000 Lux, no direct sunlight at the place of installation of the unit
- There should be no large fields of interference (e.g. strong magnetic fields) present that can interfere with the correct operation of the unit
- Refer to the requirements for environmental conditions in section "Technical data" on page 10

3.1.2 System requirements

NOTE

The system requirements for the computer systems can be found at www.planmeca.com/software/specifications/system-requirements.

3.1.3 Monitor

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

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

3.2 Installation

3.2.1 Setting up unit

WARNING

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

Do not expose the unit to any strong vibrations or shocks.

Do not move the unit during operation.

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

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

The unit can be set up as a tabletop unit (see section "Tabletop installation" on page 21) or mounted on a wall using the wall bracket (see section "Wall-mounted installation" on page 21).

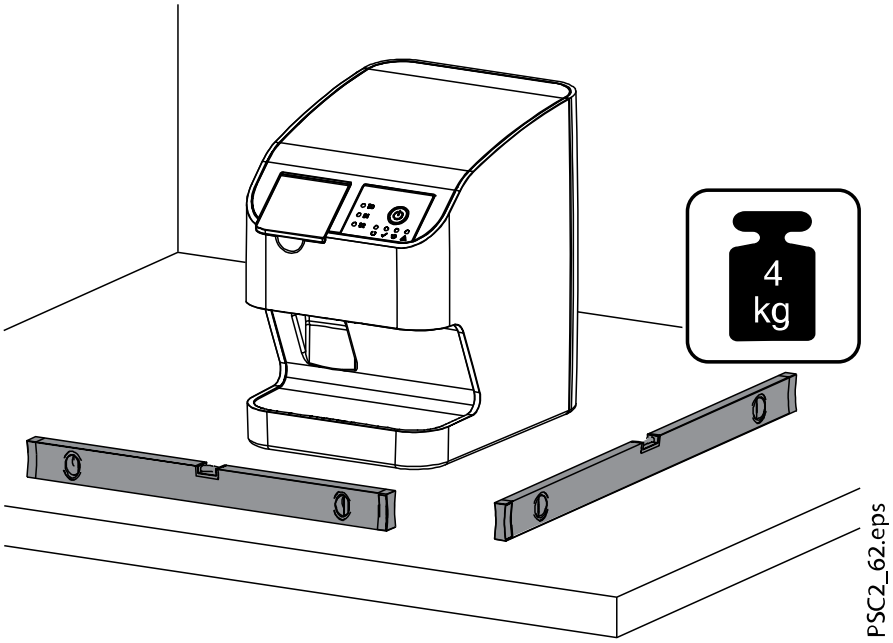
The load-bearing capacity of the table or wall must be suitable for the weight of the unit (see section "Technical data" on page 10).

3.2.1.1 Tabletop installation

NOTE

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

Place the unit on a firm, horizontal surface.



3.2.1.2 Wall-mounted installation

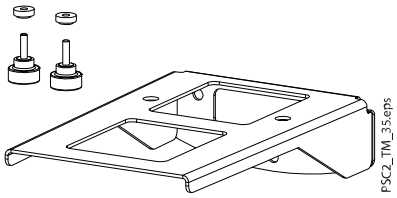
The unit can be mounted on a wall with the wall mounting bracket (optional article Wall mounting Plate for ProScanner 2.0).

The following information is supplementary to the device user's manual.

As a general rule, the user's manual for the device must also be observed. These instructions include important information such as safety instructions and information on the setup, electrical connections, disinfection process, cleaning process etc.

Scope of delivery

- Wall bracket
- Knurled screw (2x)
- Spacer (2x)



Tools required

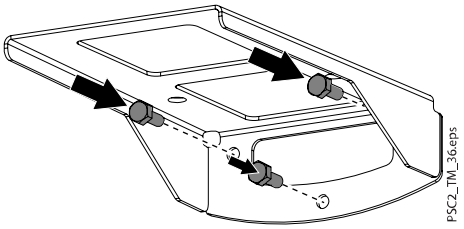
- Allen key size SW 2
- Allen key size SW 2.5
- Small slotted screwdriver

Installing unit on wall bracket

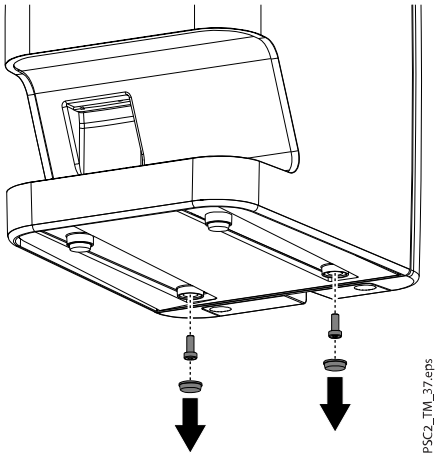
NOTE

The load rating of the wall and the fastening material must be suitable for a weight of approx. 5 kg (device + wall bracket).

1. Place the wall mounting bracket in place horizontally and secure using appropriate materials.

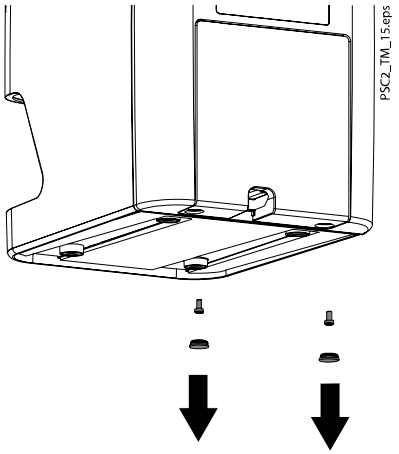


2. Remove rear rubber feet and the screws under them.

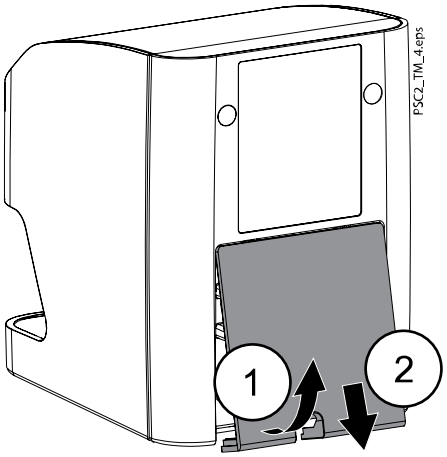


3. Remove the unit's rear side cover:

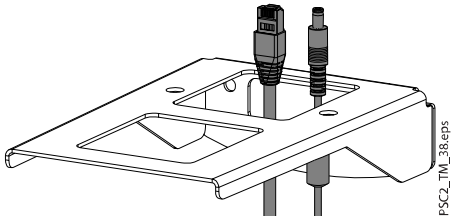
   Remove the cover plugs and the attachment screws under the edge of the rear side cover.

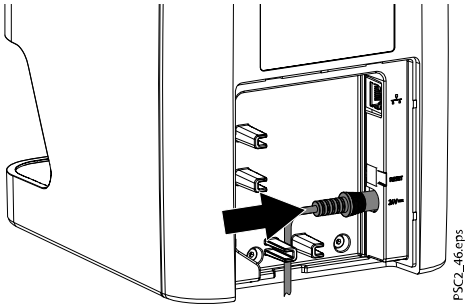


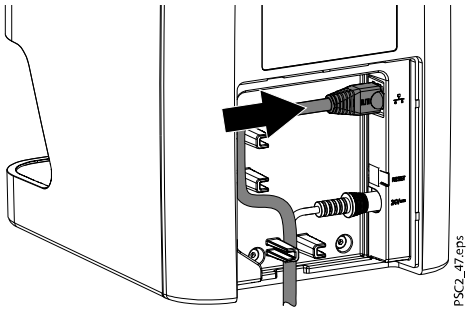
4. Pull the lower edge of the rear side cover out (**1**) and remove it downwards (**2**).



5. Lay the cables through the bracket and plug them into the unit.



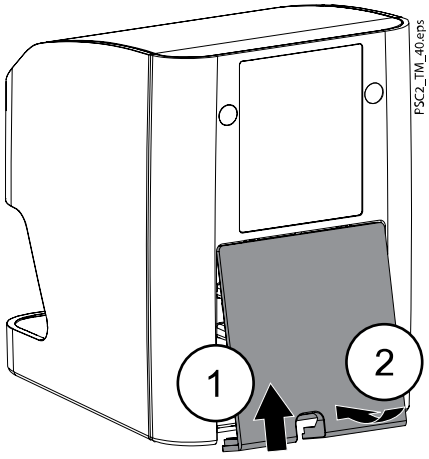




6. **NOTE**

When operating the device, the rear side cover must be mounted.

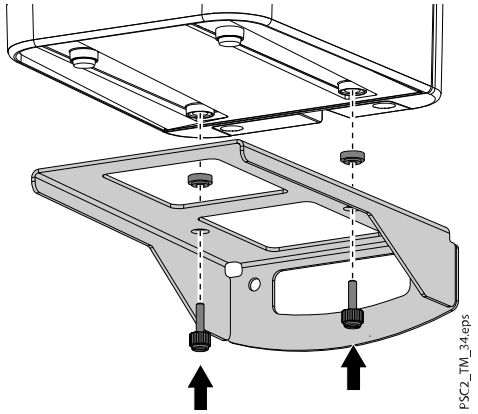
Mount cover by slotting the top edge into place (**1**), then closing the cover (**2**) and securing with screws. Make sure the cables are correctly fed through the bottom edge of the cover.



7. Put spacers into the holes of the wall brackets.

   Place the device onto the wall bracket and line up with the spacers.

   Use the knurled screws to secure the device onto the wall bracket.



3.2.2 Electrical connections

3.2.2.1 Safety when making electrical connections

- The device must only be connected to a correctly installed power outlet
- Do not place non-fixed multi-socket units on the floor; follow the requirements in section 16 of IEC 60601-1 (EN 60601-1)
- Do not operate any other systems using the same multiple socket
- Make sure that none of the electrical cables leading to the unit are under any mechanical tension
- Before initial start-up check that the mains supply voltage and the voltage stated on the type plate match (for more information, see section "Technical data" on page 10).

3.2.2.2 Connecting to mains supply

NOTE

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

Requirements

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

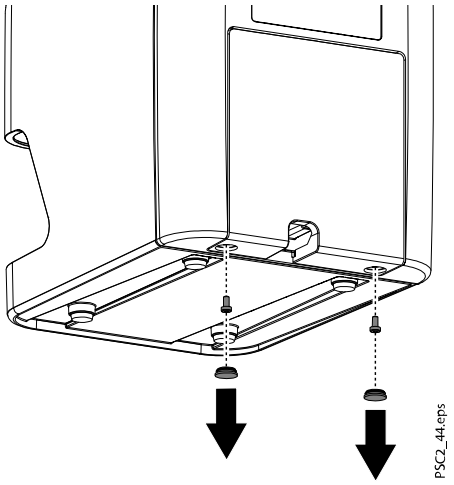
NOTE

Only the supplied power supply unit may be used.

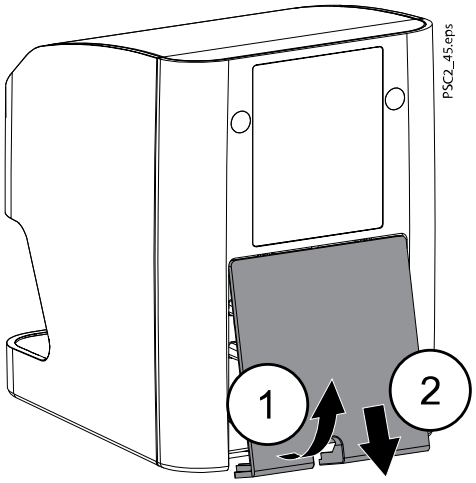
Connection

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

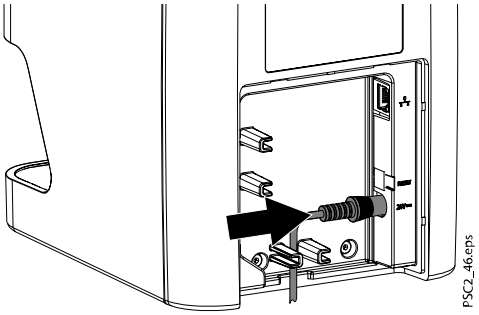
2. Remove the screw covers and screws from the bottom of the device.



3. Pull the cover back (**1**) and remove downwards from the rear of the device (**2**).



4. Plug in the connecting plug of the power supply unit into the socket connection of the device.



5. Plug the mains plug into the power outlet.
6. Refit the cover.

NOTE

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

3.2.3 Network connections

3.2.3.1 Purpose of network connection

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

- Display parameters
- Select operating modes
- Indicate messages and error situations
- Change unit settings
- Activate test functions
- Transmit data for archiving
- Provide documents concerning the units

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

3.2.3.2 Combining devices safely

- The overall safety of the unit and its main performance features are independent of the network
- Incorrect manual configuration can lead to significant network problems; the expert knowledge of a network administrator is required for configuration
- If, for example, the following changes are made to the network, new risks can arise that require further analysis:
  - Changes in the IT network configuration
  - Connecting additional elements to the IT network
  - Removing elements form the IT network
  - "Update" of devices that are connected to the IT network
  - "Upgrade" of devices that are connected to the IT network
- The data connection utilises part of the bandwidth of the network

  Interactions with other medical devices cannot be completely ruled out. Apply the IEC 80001-1 standard for risk assessment.
- The device is not suitable for direct connection to the public internet

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

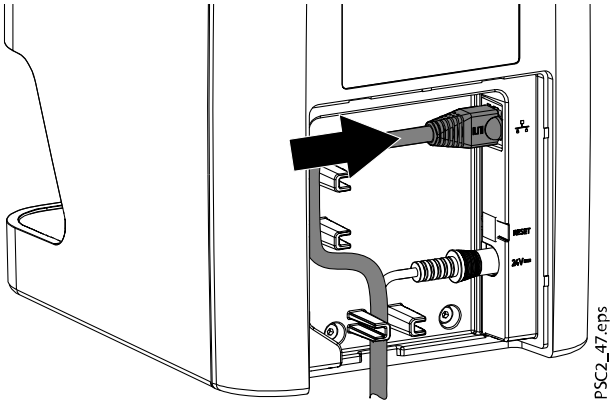
Only connect units when there can be no question of danger to operator or to patient.

- Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings
- If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe
- Observe the specifications of IEC 60601-1 (EN 60601-1) when connecting the appliance with other appliances, e.g. a PC system, both in and outside the patient environment
- Only connect peripheral units (such as computers, monitors or printers) that conform at least to the requirements set out in IEC 60950-1 (EN 60950-1)

- The connected computer must conform to EN 55032 (class B) and EN 55024

3.2.3.3 Connecting network cable

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



NOTE

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

3. Refit the cover.

3.3 Commissioning

CAUTION

Short circuit can occur due to build up of condensation.

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

The unit supports the following imaging programs:

- Planmeca Romexis

3.3.1 Network configuration

Various options are available for network configuration:

- Automatic configuration via DHCP
- Automatic configuration via Auto-IP for direct connection of unit and computer
- Manual configuration

Configure the network settings of the unit using the software or, if applicable, the touch screen.

Check the firewall and release the ports, if applicable.

3.3.2 Network protocols and ports

Port	Purpose	Service
45123 UDP, 45124 UDP	Unit recognition and configuration	

Port	Purpose	Service
2006 TCP	Unit data	
514[1)] UDP	Event protocol data	Syslog

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

NOTE

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

3.3.3 Configuring unit in Planmeca Device Tool

Configuration is performed using Planmeca Device Tool.

NOTE

The configuration with the Planmeca Device Tool should be performed by qualified service technician only.

For more detailed instructions, see *Planmeca ProScanner 2.0 technical manual* (publication number 30019806).

1. Start Planmeca Device Tool.
2. From the Device Tool launcher, select **ProScanner 2.0**.
3. Select the Planmeca ProScanner 2.0 unit from the left most device panel (if not yet selected).

   The connected ProScanner 2.0 should become visible in the Proscanner 2.0 devices list.
4. The unit name (designation) can be changed and information queried under the **General** tab.
5. An IP address can be entered manually and DHCP can be activated / deactivated under the **Connection** tab.

Entering a fixed IP address (recommended)

NOTE

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

The default settings are as follows:

- IP address: 192.168.1.100
- Subnet mask: 255.255.255.0
- DHCP activated.

1. Deactivate DHCP when you have selected a device from the list.
2. Enter the IP address, subnet mask and gateway.
3. Save the configuration by selecting **Apply**.

Testing device

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

1. Open Planmeca Romexis.
2. Create a test patient in Romexis (for example, patient ID: DEMO0001).

For more information see the *Romexis user's manual* (publication number 10014593)

3. Start ProScanner 2.0 image capturing.

   For more information see the *Romexis user's manual*, section **Image capturing with ProScanner 2.0**.

3.3.4 X-ray unit settings

NOTE

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

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

Intraoral X-ray units for an adult patient

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

DC emitter, 7 mA, Tube length 20 cm

	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	mGycm^2	60 kV	mGycm^2	60 kV	mGycm^2
Incisors	0.10 s	18.3	0.10 s	3.8	0.10 s	7.7
Premolars	0.14 s	25.6	0.14 s	5.4	0.14 s	10.8
Molars	0.19 s	34.8	0.19 s	7.3	0.19 s	14.7
Bite wing	0.21 s	38.4	0.21 s	8.1	0.20 s	15.5

DC emitter, 6 mA, Tube length 30 cm

	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	mGycm^2	60 kV	mGycm^2	60 kV	mGycm^2
Incisors	0.15 s	13.7	0.15 s	4.9	0.15 s	5.8
Premolars	0.20 s	18.2	0.20 s	3.8	0.20 s	7.7
Molars	0.27 s	24.6	0.27 s	5.2	0.27 s	10.4
Bite wing	0.28 s	25.5	0.29 s	5.6	0.28 s	10.8

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

Intraoral X-ray units for a child

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

DC emitter, 7 mA, Tube length 20 cm

	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	$mGycm^2$	60 kV	$mGycm^2$	60 kV	$mGycm^2$
Incisors	0.07 s	12.8	0.07 s	2.7	0.07 s	5.4
Premolars	0.09 s	16.4	0.09 s	3.4	0.09 s	6.9
Molars	0.13 s	23.8	0.13 s	5.0	0.13 s	10.1
Bite wing	0.15 s	27.4	0.13 s	5.0	0.13 s	10.1

DC emitter, 6 mA, Tube length 30 cm

	Without X-ray field limitation		X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	$mGycm^2$	60 kV	$mGycm^2$	60 kV	$mGycm^2$
Incisors	0.10 s	9.1	0.10 s	1.9	0.10 s	3.8
Premolars	0.13 s	11.8	0.13 s	2.5	0.13 s	5.0
Molars	0.16 s	14.8	0.16 s	3.1	0.16 s	6.2
Bite wing	0.16 s	14.8	0.16 s	3.1	0.16 s	6.2

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

3.3.5 Acceptance tests

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

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

Acceptance test

NOTE

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

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

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

For more information, see the Planmeca intraoral imaging system constancy tests manual (publication number 10009324).

Electrical safety checks

- Carry out the electrical safety check according to the national law (e. g. in accordance with IEC 62353)
- Document the results
- Instruct and hand over the device and document

NOTE

A sample template for a handover protocol is included in section "Sample handover protocol template" on page 61.

4 Usage

4.1 Correct use of image plates

WARNING

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

Do not use an image plate without a light protection cover.

Do not use the light protection cover more than once (disposable item).

CAUTION

The image data on the image plate is not permanent.

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

Read the image data within 30 minutes of exposure.

Never handle exposed image plates without the light protection cover.

Do not subject an exposed image plate to X-ray radiation before or after the scanning process.

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

CAUTION

Image plates are toxic

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

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

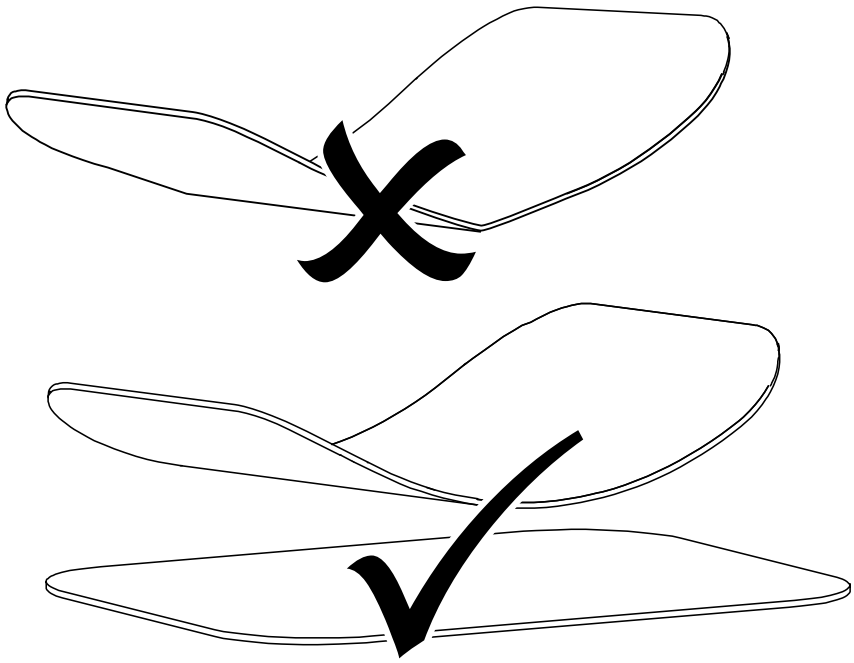
Do not swallow the image plate or parts of it.

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

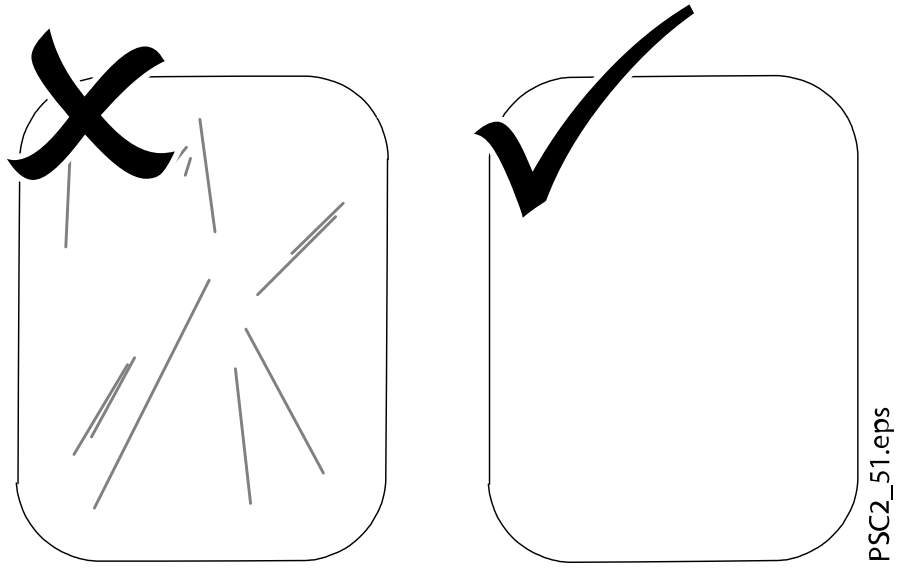
If the light protection cover has been damaged in the patient's mouth, rinse the mouth thoroughly with lots of water. Do not swallow the water in the process.

- Image plates must only be read using an image plate scanner that is approved by the manufacturer.

- Image plates are flexible like X-ray film. However, the image plates should not be bent.



- Do not scratch the image plates. Do not subject the image plates to pressure from hard or pointed objects.



- Do not soil the image plates.
- Protect the image plates against sunlight and ultraviolet light.
- Store image plates in a light protection cover or cartridge of the correct size.
- Image plates will be pre-exposed on exposure to natural radiation and stray X-ray radiation. Protect erased and exposed image plates from X-ray interference.
- If the image plate has been stored for longer than one week, erase the image plate prior to use.
- Do not store image plates under hot or moist conditions. Observe the correct ambient conditions (see section "Technical data" on page 10).

- When used properly, image plates can be exposed, read and erased several hundred times provided there is no mechanical damage.
- Replace the image plate if there are any signs of damage, e.g. if the protective layer is damaged or there are visible scratches that impair the quality of the diagnosis.
- Also replace the image plate if the RFID tag is damaged or becoming detached.
- Clean image plates properly (see section "Cleaning and disinfection" on page 48).

4.2 Operation

CAUTION

The image data on the image plate is not permanent.

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

Read the image data within 30 minutes of exposure.

Never handle exposed image plates without the light protection cover.

Do not subject an exposed image plate to X-ray radiation before or after the scanning process.

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

4.2.1 Changing input unit cartridge

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

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

CAUTION

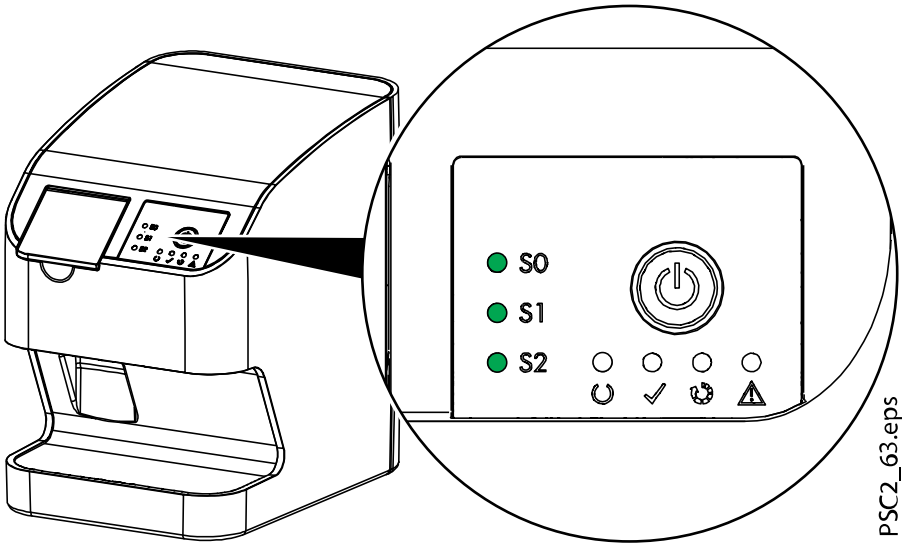
Loss of image information and equipment damage if an incorrect cartridge is used.

Always use the correct size of cartridge for the image plate being used.

Before each scanning process, compare the image plate size with the LED display on the control element.

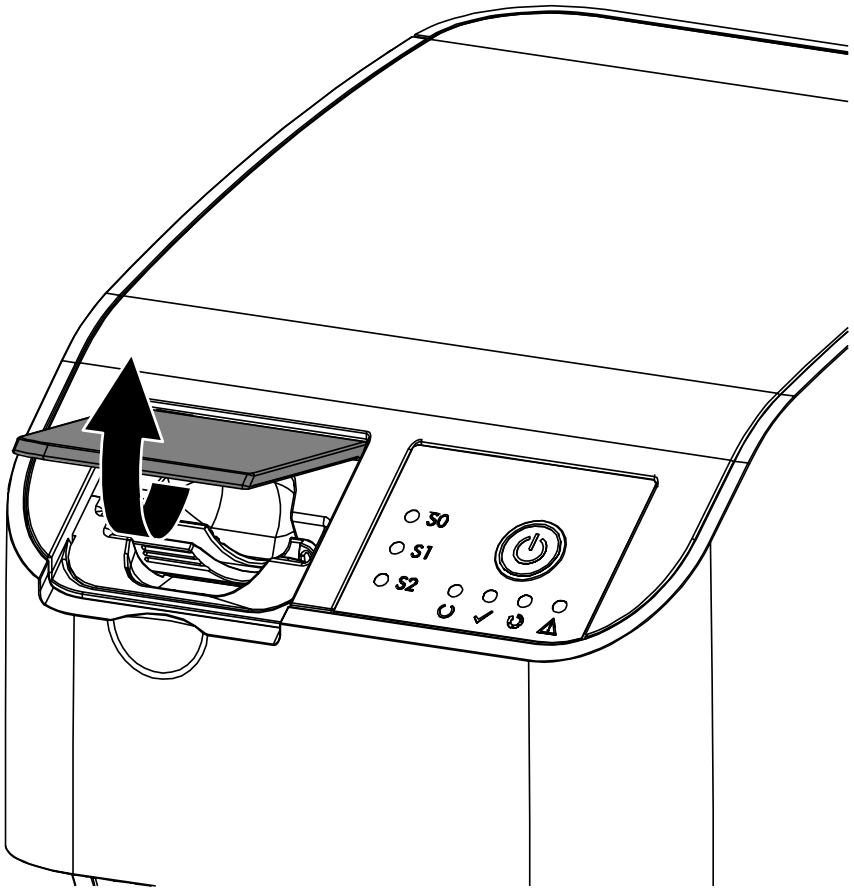
1. Check that the correct cartridge has been inserted with the display (S0, S1, S2).

   If the incorrect cartridge has been inserted, it must be removed and the correct cartridge inserted.



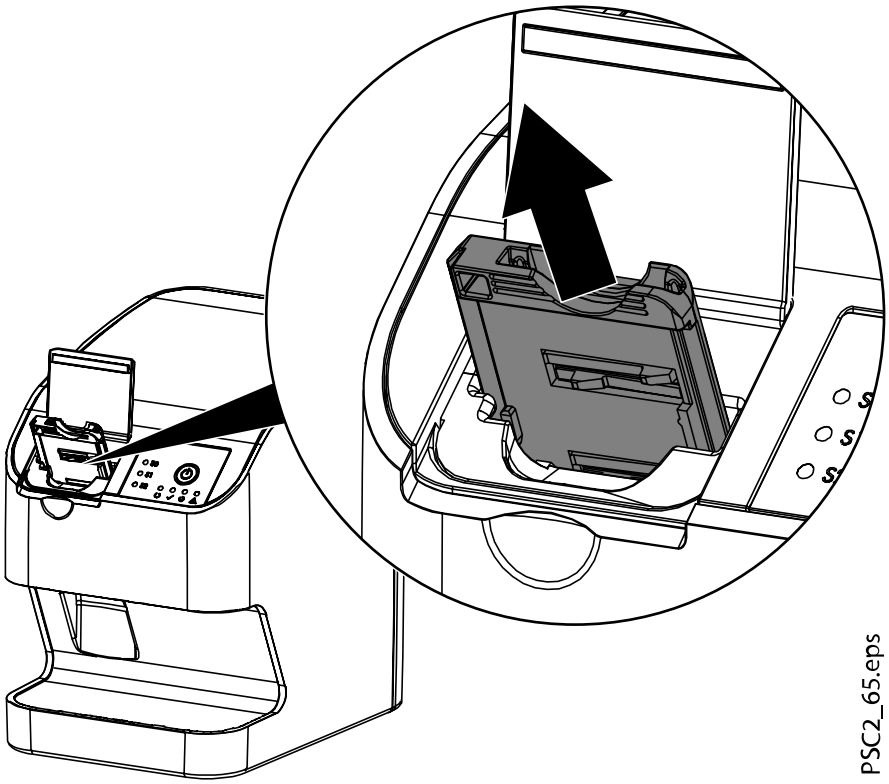
PSC2_63.eps

2. Open the cover.



PSC2_64.eps

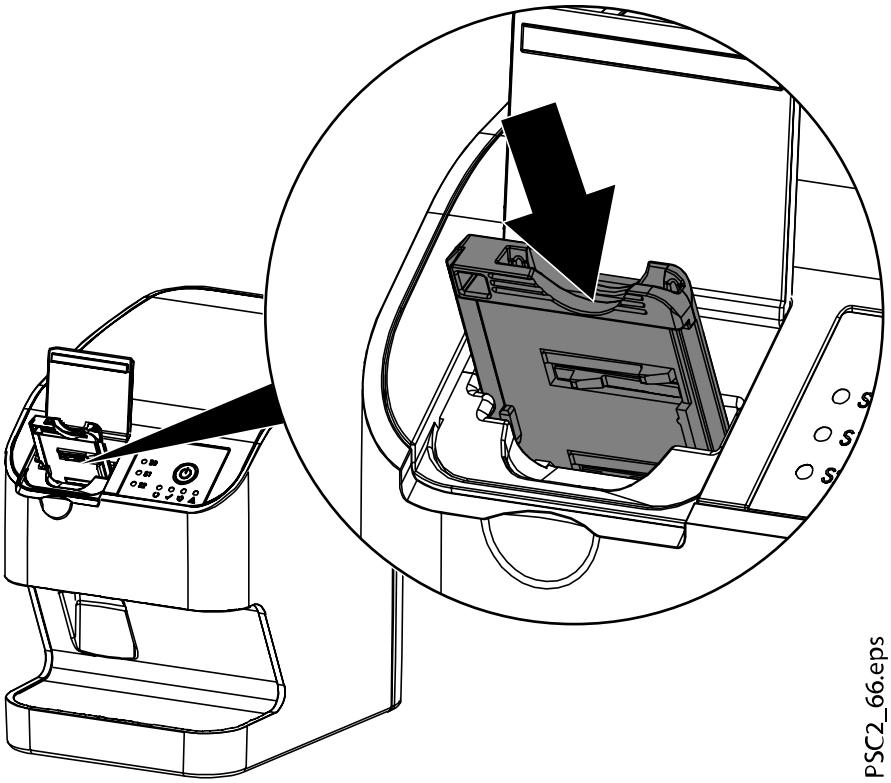
3. Remove cartridge.



PSC2_65.eps

The green cartridge display extinguishes. When the device is ready to scan, the green status LED flashes in addition.

4. Insert the appropriate cartridge.



The green status LED lights up. The green display for the corresponding cartridge lights up. The input unit is ready.

4.2.2 Capturing X-ray images

NOTE

The following procedure is described using a size 2 image plate as an example.

Required accessories

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

WARNING

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

Do not use an image plate without a light protection cover.

Do not use the light protection cover more than once (disposable item).

WARNING

Danger due to multiple use of products that are designed for single usage.

The disposable article is damaged after use and can no longer be used. Dispose of disposable items after a single use.

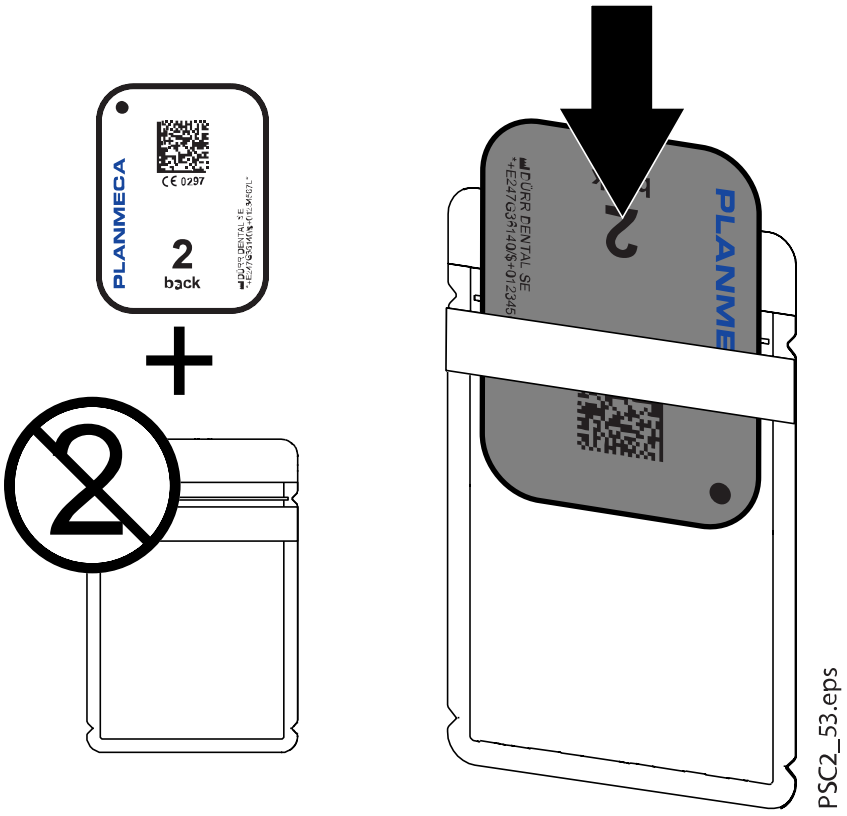
Preparing for taking X-ray image

Ensure that:

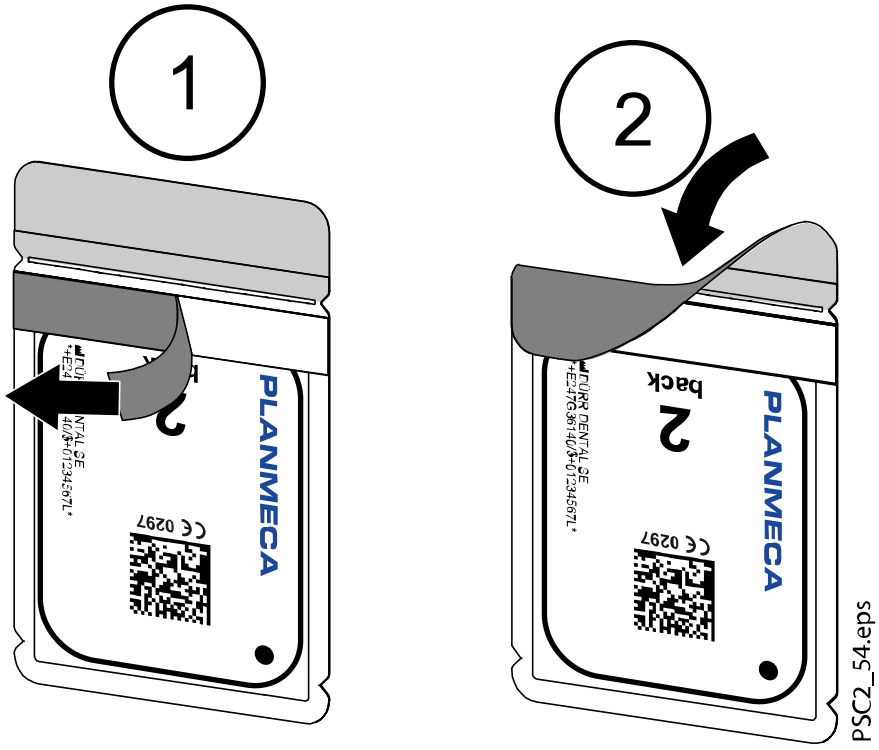
- The image plate has been cleaned
- The image plate is not damaged
- The RFID tag is attached to the image plate

  If the RFID tag peels off, replace the image plate.

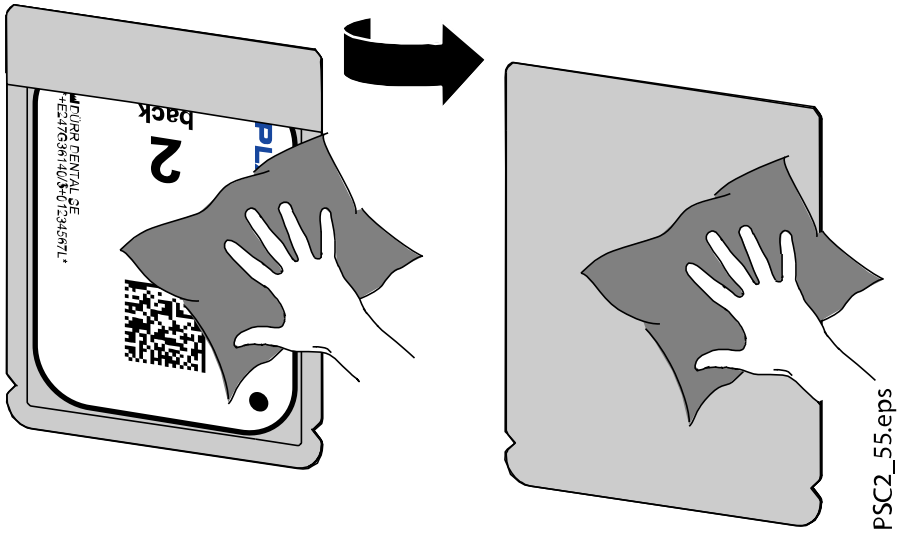
1. If using it for the first time or if it has been stored for over a week: erase the image plate (see section "Erasing image plate" on page 48).
2. Completely slide the image plate into the light protection cover. The black (inactive) side of the image plate must be visible.



3. Pull off the adhesive strip (**1**), fold down the flap and close the light protection cover tightly by pressing together firmly (**2**).



4. The light protection cover must be disinfected using a suitable disinfectant wipe immediately before positioning it inside the patient's mouth (see section "Light protection cover" on page 50).



5. Allow the light protection cover to fully dry.

Taking X-ray image

CAUTION

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

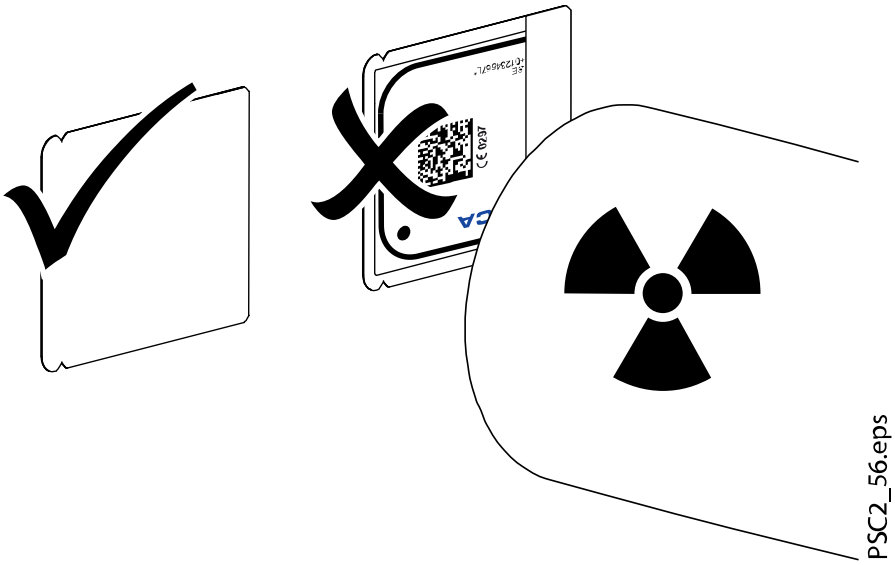
Only use holding systems that will not damage the light protection cover or the image plates in any way.

Do not use holding systems with sharp edges.

Wear protective gloves.

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

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



2. Set the exposure time and setting values on the X-ray unit (see section "X-ray unit settings" on page 30).
3. Record an X-ray image.

   The image data must be scanned within 30 minutes.

Preparing for scanning

CAUTION

Light erases the image data on the image plate

Never handle exposed image plates without the light protection cover.

Wear protective gloves.

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

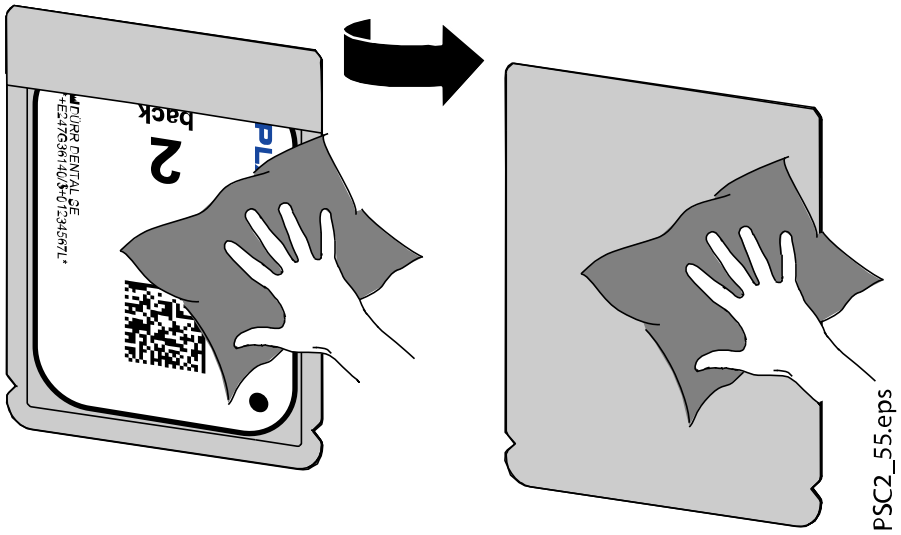
WARNING

Contamination of the unit

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

2. In the event of heavy soiling, e.g. from blood, dry clean the light protection cover and protective gloves, e.g. wipe with a clean cellulose cloth.

3. Disinfect the light protection cover and protective gloves with a suitable disinfection wipe (see section "Light protection cover" on page 50).



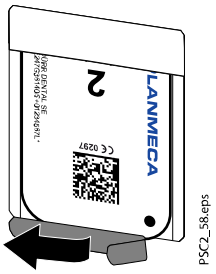
4. Allow the light protection cover to fully dry.
5. Pull off the protective gloves and disinfect the hands.

CAUTION

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

Completely clean all traces of the protective glove powder from your hands before handling the image plate.

6. Tear off the light protection cover.



4.2.3 Scanning image data

Starting image plate scanner and software

NOTE

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

For further information see the *Romexis user's manual*, section ProScanner 2.0 single image capturing.

1. Press the on / off switch to switch on the device.
2. Switch on the computer and monitor.
3. Start Planmeca Romexis.
4. Select the patient.
5. Select the ProScanner 2.0 image capturing button.

Recording starts directly.

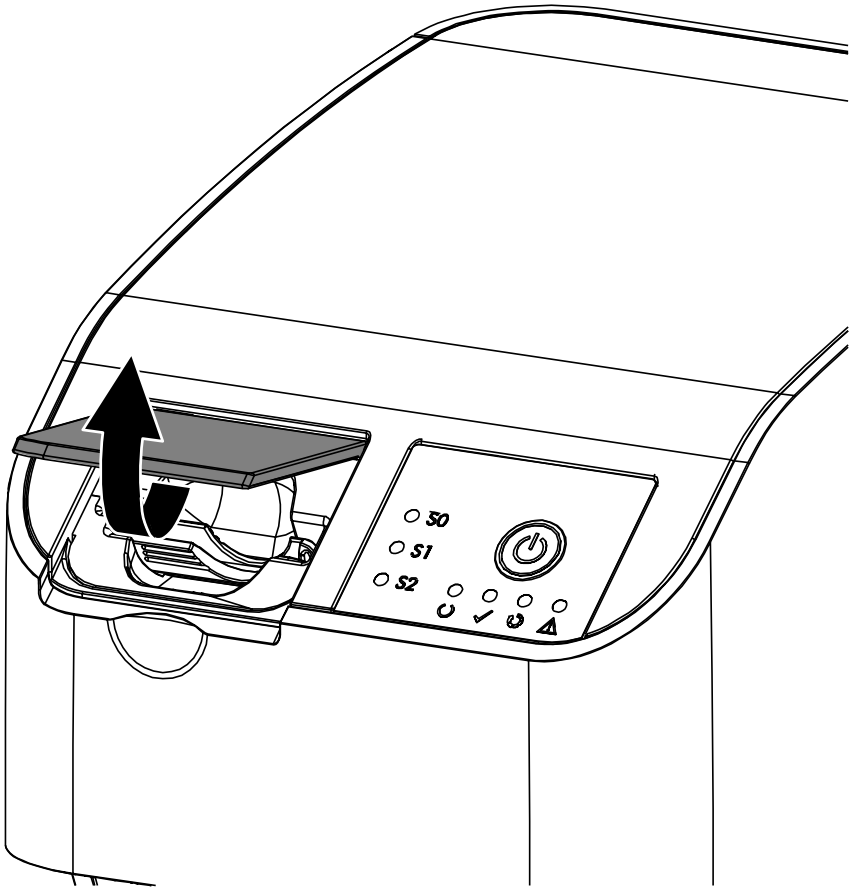
The green status LED lights up. Scan the image plate at this point (and not before).

Scanning image plate

NOTE

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

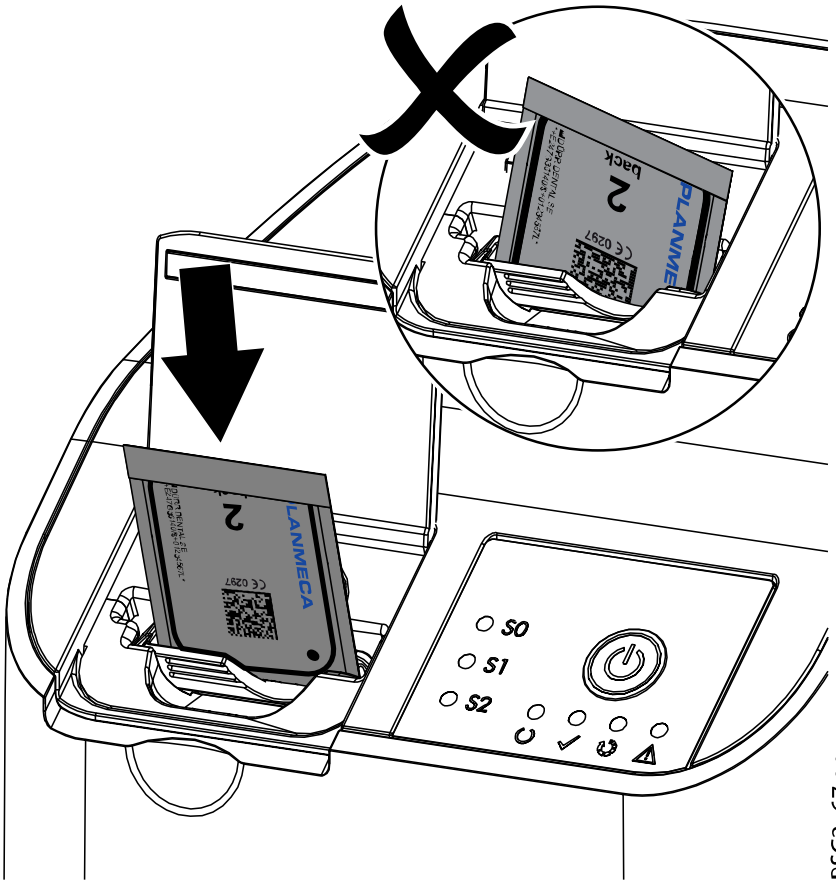
1. Open the cover.



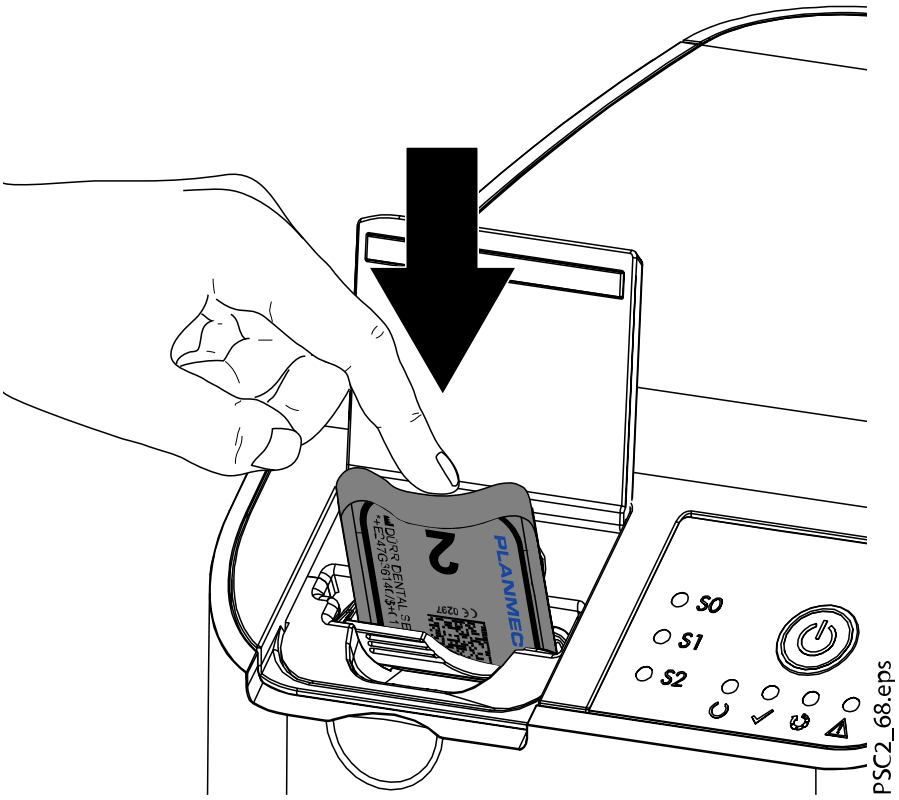
PSC2_64.eps

2. Place the light protection cover with the image plate centrally and straight onto the input unit. The torn-off side of the light protection cover faces down; the inactive (back) side of the image plate faces the operator.

   The image plate must not be pulled out of the light protection cover before placement on the input unit. There is the risk of image information being erased by ambient light (see section "Correct use of image plates" on page 33).

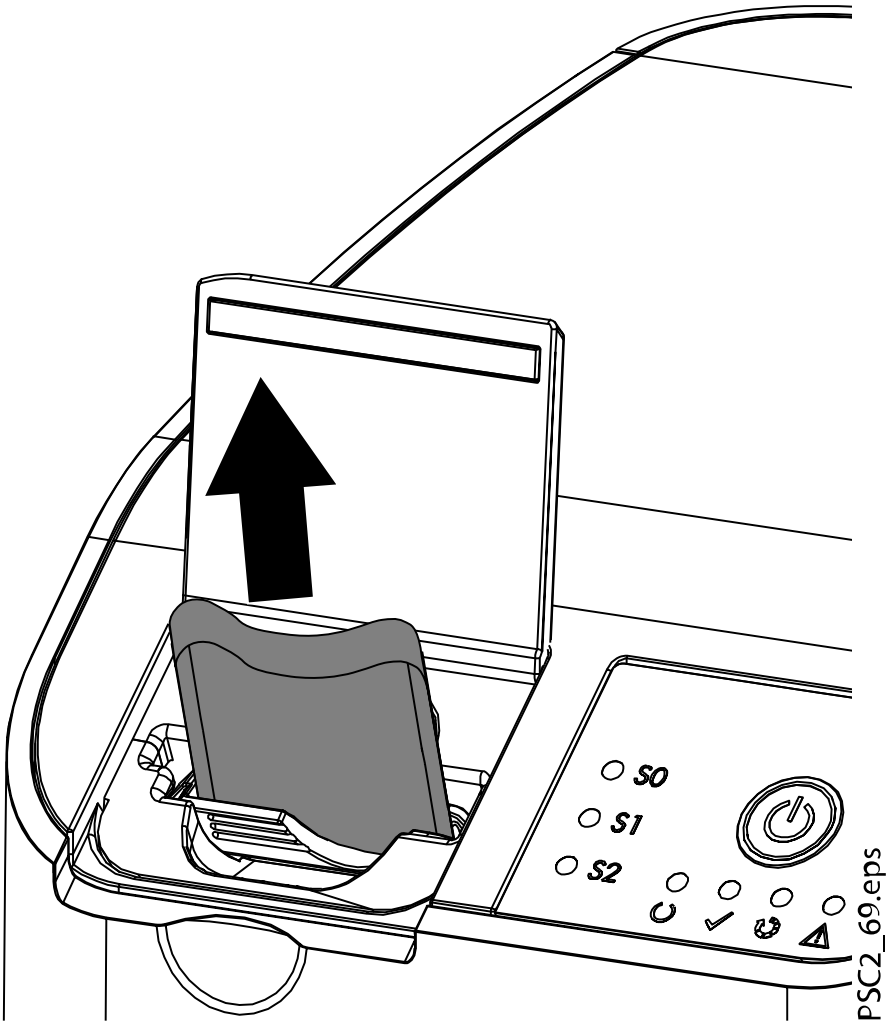


3. Slide the image plate out of the light protection cover downwards into the unit. The image plate must be inserted fully into the input unit.

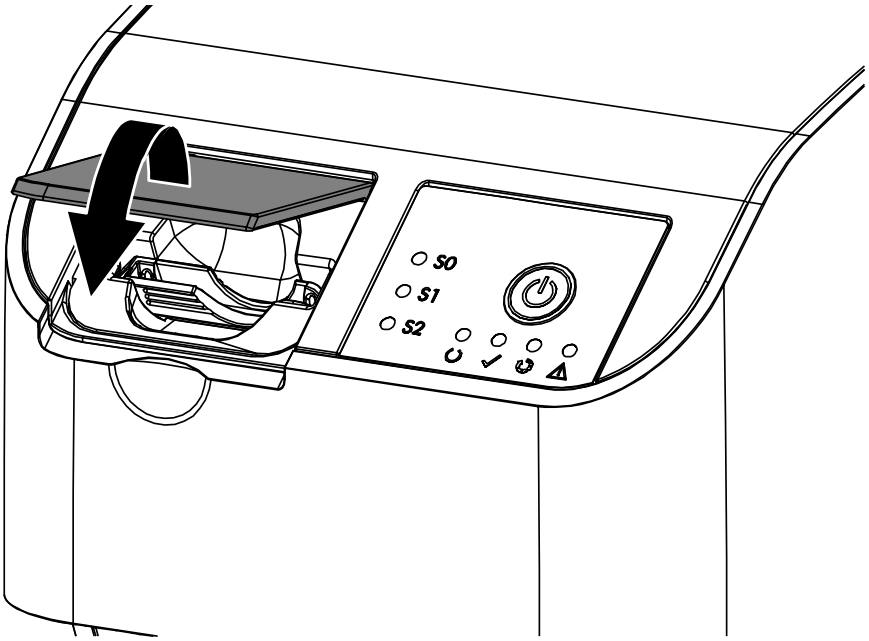


Make sure that only the image plate, and not the light protection cover, is inserted into the unit.

4. Remove the empty light protection cover.



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



PSC2_70.eps

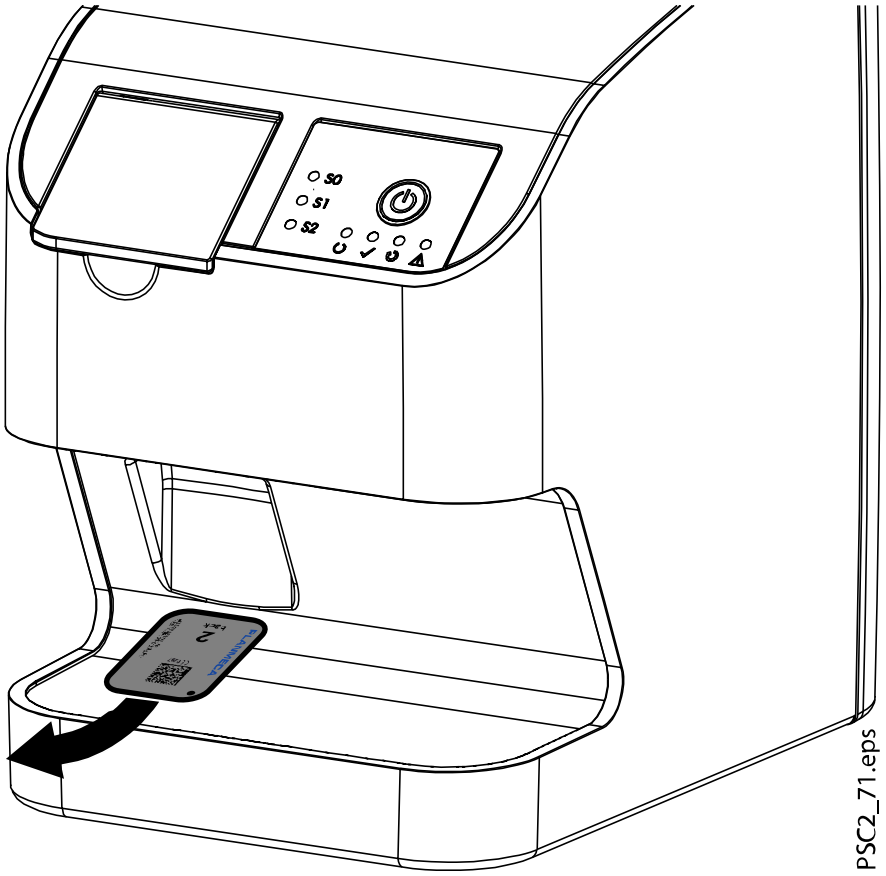
The blue status LED lights up.

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

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

1. When the green status LED lights up, the image is saved to Planmeca Romexis.

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



4.2.4 Erasing image plate

The image data is automatically erased after scanning. Beyond that, the image plate needs to be erased in the following cases:

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

As erasing of the image plate is always done by the ProScanner 2.0 after each scan of an image plate, for erasure of the image plate, please introduce the image plate to be erased unexposed by X-ray into the scanner as described in "Scanning image data" on page 42.

In this case the use of a light protection cover is not required. At step 4. do not use a real patient for erasing image plates, generate a dummy patient.

4.2.5 Switching off unit

1. Press the on/off switch for three seconds.
2. As soon as the unit has shut down it switches off completely.

   The LEDs go out.

4.3 Cleaning and disinfection

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

NOTE

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

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

- **The manufacturer recommends using disinfectants from the Dürr Dental product range; only the products specified in these instructions have been subjected to material compatibility testing by the manufacturer**
- **Read the operating instructions for the disinfectants**

Wear protective gloves.

4.3.1 Image plate scanner

Unit surfaces

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

The manufacturer recommends using the disinfectants FD 322, FD 333, FD 350 and FD 366 sensitive.

NOTE

Liquid can cause damage to the unit.

Do not spray the unit with cleaning and disinfectant agents.

Make sure that liquid does not get inside the unit.

- Remove any soiling with a soft, lint-free cloth that has been dampened with cold tap water
- Disinfect the surfaces using a disinfection wipe; alternatively, use disinfectant on a soft, lint-free cloth

Cartridges (S0-S2)

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

NOTE

Heat damages the cartridges.

Do not thermally disinfect or steam sterilise the cartridges.

- Remove any soiling from the cartridge with a soft, lint-free cloth that has been dampened with cold tap water
- Disinfect the cartridge using a disinfection wipe; alternatively, use disinfectant on a soft, lint-free cloth

  Comply with the operating instructions for the disinfectant when doing this.
- The manufacturer recommends ID 213, ID 212 or ID 212 forte instrument disinfectants for the cartridges if an immersion disinfection system is being used; these disinfectants have been subjected to material compatibility testing
- Allow the cartridges to completely dry before using them

4.3.2 Light protection cover

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

- Disinfect the light protection cover using a disinfectant before and after placement; the manufacturer recommends FD 333 forte wipes (virucidal), FD 350 (limited virucidal activity) and FD 322 premium wipes (limited virucidal activity)
- Allow the light protection cover to completely dry before using it

4.3.3 Image plate

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

Only use a cleaning agent that is compatible with the materials: the manufacturer recommends the image plate cleaning wipe (see section "Consumables" on page 9). Only this product has been subjected to material compatibility testing.

NOTE

Heat or humidity will damage the image plate.
Do not steam sterilise the image plate.
Do not immersion-disinfect the image plate.
Only use cleaning agents that are compatible with the materials.

- Soiling on both sides of the image plate should be cleaned off with a soft, lint-free wipe prior to every use
- Remove resistant or dried on dirt with the image plate cleaning wipe

  When doing this, observe the instructions for use for the cleaning wipe.
- Allow the image plate to completely dry before using it

4.3.4 Storage box with image plate storage tray

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

The manufacturer recommends the following disinfectant for the storage box:

- FD 366 sensitive

The manufacturer recommends the following disinfectants for the image plate storage tray:

- FD 350
- FD 366 sensitive

Observe the following cleaning and disinfection practices:

- Clean the surface of the storage box and the image plate storage tray with a soft, lint-free cloth that has been dampened with cold tap water
- Disinfect the storage box using a disinfection wipe; alternatively, use disinfectant on a soft, lint-free cloth
- Disinfect the image plate storage tray using a disinfection wipe
- Alternatively, the image plate storage tray can be treated in a thermal disinfector or steam steriliser

  Do not exceed a temperature of 134°C when doing this.

4.4 Maintenance

4.4.1 Recommended maintenance schedule

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

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

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

5 Troubleshooting

5.1 Tips for operators and service technicians

NOTE

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

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

5.1.1 Poor X-ray image

Instead of the X-ray image, software shows completely white image or no image

Possible cause	Remedy
Image plate not fed in straight and inactive side scanned	Scan the image plate again immediately, protecting it against ambient light and making sure you feed it in correctly in the process.
Image data on the image plate has been erased, e.g. by ambient light	Always scan the image data of the image plate as quickly as possible.
Fault on the unit	Inform a Service Technician.
No image data on image plate, image plate not exposed or not sufficiently exposed	X-ray tubes / check unit settings Expose the image plate.
X-ray unit is faulty	Inform a Service Technician.
Incorrect cartridge, light protection cover was also pushed into the unit	Use the correct cartridge for the size of image plate being used.

Image plate falls out of unit and no image appears on monitor

Possible cause	Remedy
Correct image plate not used	Only use Planmeca imaging plates.

X-ray image too dark

Possible cause	Remedy
X-ray dose too high	Check X-ray parameters.
Incorrect brightness/contrast settings in the software	Adjust the brightness of the X-ray image in the software.

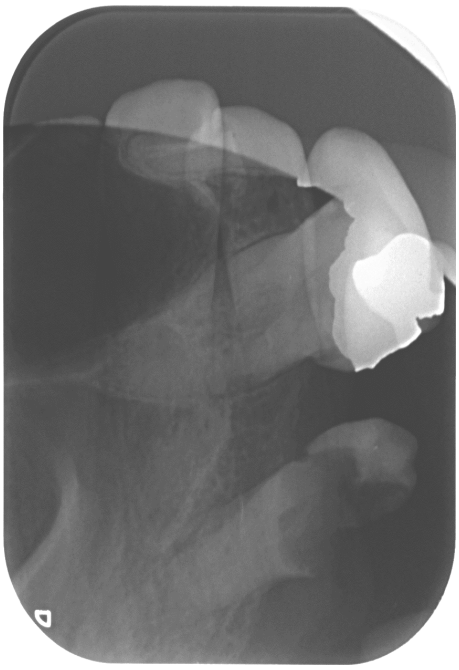
X-ray image too bright

Possible cause	Remedy
Exposed image plate has been exposed to ambient light	Always scan the image data of the image plate as quickly as possible.
X-ray dose too low	Check X-ray parameters.
Incorrect brightness/contrast settings in the software	Adjust the brightness of the X-ray image in the software.

X-ray image only shadowy

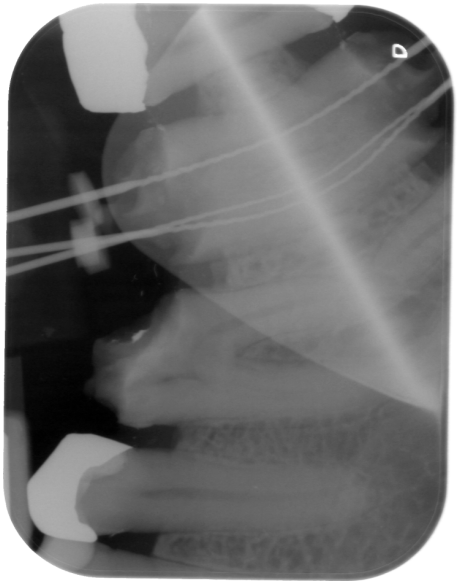
Possible cause	Remedy
The X-ray dose on the image plate was insufficient	Increase X-ray dose.

Ghosting or double exposure on X-ray image



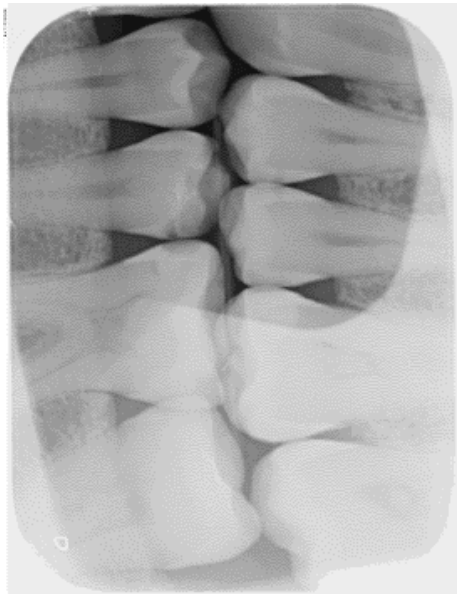
Possible cause	Remedy
Image plate exposed twice	Only expose the image plate once.
Image plate not sufficiently erased	Check the erasure unit is working correctly. Inform a service technician if the problem persists.

X-ray image mirrored in one corner



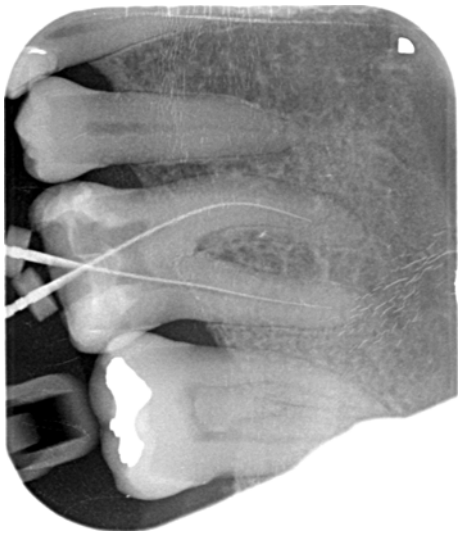
Possible cause	Remedy
Image plate bent during X-ray exposure	Do not bend the image plate.

Shadow on X-ray image



Possible cause	Remedy
Image plate removed from the light protection cover before scanning	Do not handle image plates without a light protection cover. Store the image plate in a light protection cover.

X-ray image cut off, part missing

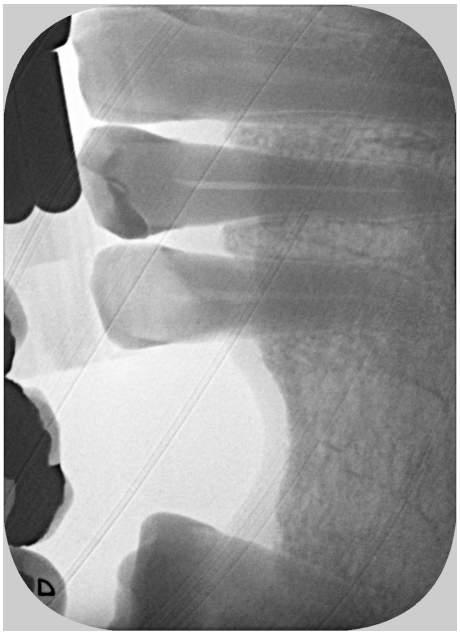


Possible cause	Remedy
The metal part of the X-ray tube is in front of the X-ray beam	When taking an X-ray image, make sure there are no metal parts between the X-ray tube and the patient. Check X-ray tube.

Software unable to combine the data to make complete image

Possible cause	Remedy
The X-ray dose on the image plate was insufficient	Increase X-ray dose.

X-ray image has strips on image



Possible cause	Remedy
Image plate has been pre-exposed, e.g. by natural radiation or stray X-ray radiation	If the image plate has been stored for longer than one week, erase the image plate prior to use.
Parts of image plate exposed to light during handling	Do not expose used image plates to bright light. Scan image data within half an hour after the exposure.
Image plate dirty or scratched	Clean the image plate. Replace scratched image plates.
Unit was shaken by impact or light protection cover closed during scanning process	Set up the unit so that it cannot be shaken. Prevent the unit from being touched during the scanning process.

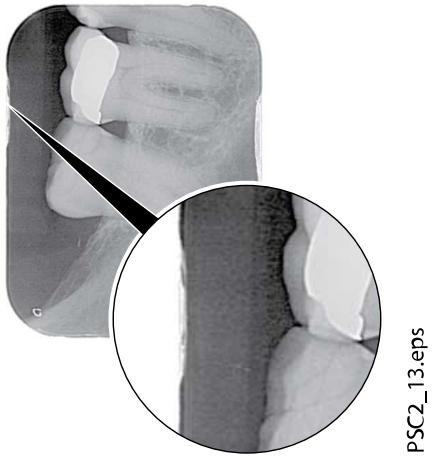
Light strips in CaptureUI

Possible cause	Remedy
Too much incident ambient light during the scanning process	Darken the room. Turn the unit so that the light does not fall directly onto the input unit.

X-ray image with small bright spots or clouding

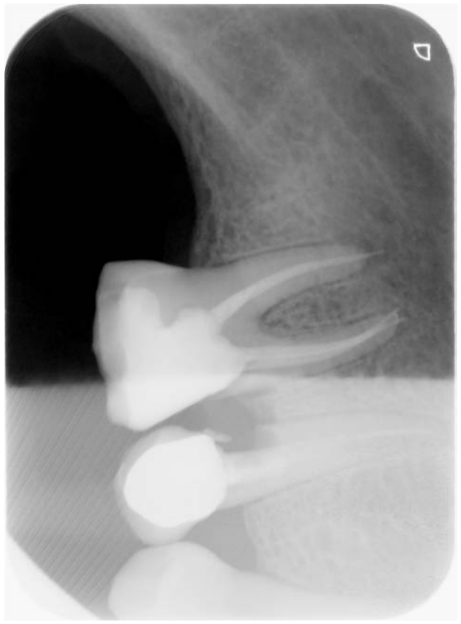
Possible cause	Remedy
Micro scratches on the image plate	Replace the image plate.

Lamination of image plate becoming detached at edge



Possible cause	Remedy
Incorrect retainer system used	Only use original image plates and film retainer systems.
Image plate handled incorrectly	Use the image plate correctly. Observe the operating instructions for the image plates and film retainer systems.

X-ray image shows pre-erasure at one end



Possible cause	Remedy
After the light protection cover has been torn off and before pushing into the input unit, the image plate is pushed out of the light protection cover	Do not push out the image plate until the torn-off light protection cover has been placed on the input unit.

5.1.2 Software errors

Fault	Probable cause	Solution
"Too much ambient light E10000"	Unit exposed to too much light	Darken the room. Turn the unit so that no light can fall directly into the entry slot.
"Temperature of the device is high E10008"	Laser or erasure unit too hot	Switch off the unit and allow it to cool.
"Erasure unit fault"	LED defective	Inform a Service Technician.
Imaging software does not recognise the unit	Unit not switched on	Switch on the unit.
	Connecting cable between device and computer not correctly connected	Check the connecting cable.
	Computer does not detect any connection to the unit	Check the connecting cable. Check the network settings (IP address and subnet mask).
	Hardware fault	Inform a Service Technician.
	The IP address of the device is being used by another unit	Check the network settings (IP address and subnet mask) and assign a unique IP address to every device. Inform a service technician if the problem persists.
"Connection to scanner lost E2490"	The connection to the unit was interrupted while the software was still attempting to communicate with the unit	Restore the connection to the unit. Repeat the process.
Error during data transmission between unit and computer. Error message "CRC error timeout"	Connecting cable used is incorrect or too long	Only use original cables.
"Image plate might be exposed from wrong side H30000"	The image plate was exposed on the back (inactive) side while the X-ray image was being taken	When diagnosing the X-ray image, note that the X-ray image might be displayed mirror inverted. You can flip the image horizontally in Romexis image properties.

5.1.3 Unit faults

Fault	Probable cause	Solution
Unit not shown in the imaging software	Network cable not installed	Install the network cable.
	No DHCP server connected	It may take some time for the imaging software to detect the unit. Update the unit list.
	Network configuration incorrect	Configure the network correctly.

Fault	Probable cause	Solution
Unit does not switch on	No mains voltage	Check the mains cable and plug connection and replace if necessary. Check the power supply unit. If the green status LED does not light up, replace the power supply unit. Check the mains fuse in the building.
	On / off switch is defective	Inform a Service Technician.
Unit switches back off after a short time	Mains cable or power supply unit plug not inserted correctly	Check the mains cable and plug connections.
	Hardware fault	Inform a Service Technician.
	Mains supply voltage too low	Check the mains voltage.
Unit is on but none of the indicator LEDs are lit up (status, error or operating LEDs)	Display defective	Inform a Service Technician.
Unit not responding	The unit has not yet completed the startup procedure	After switching on, wait 20 - 30 seconds until the startup procedure has finished.
	Unit is blocked by the firewall	Enable the ports for the unit in the firewall settings.
Image plate does not fit into the intake slot	Incorrect cartridge used	Use the correct cartridge for the size of image plate being used.
Light protection cover slips into intake slot together with image plate	Incorrect cartridge used (too large)	Use the correct cartridge for the size of image plate being used.
Cartridge display does not light up	Cartridge not inserted correctly	Insert the cartridge correctly.
Network connection has been disconnected	Connecting cable between device and computer not correctly connected	Check the connecting cable.
	The IP address of the device is being used by another unit	Check the network settings (IP address and subnet mask) and assign a unique IP address to every device. Inform a service technician if the problem persists.
Unit ejects the image plate without the image data being transmitted to the imaging software. "Incorrect image plate type E10025"	Correct image plate not used	Only use Planmeca imaging plates. The ejected image plate can be imported on a suitable image plate scanner (e.g. Planmeca ProScanner). Make sure that the image plate is protected against ambient light.

Appendix A: Resolution data

A.1 Scanning times

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

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

For technical reasons, the surface of the largest size of image plate (size 2) is always scanned. As a result, the scan times are the same for all sizes of image plate.

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

A.2 File sizes (uncompressed)

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

Suitable compression methods can considerably reduce the file size without loss of data.

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

A.3 Contact information

Distributor

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http://www.planmeca.com

Manufacturer

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Höpfigheimer Str. 17

74321 Bietigheim-Bissingen

Germany

Phone: +49 7142 705-0
http://www.duerrdental.com

info@duerrdental.com

A.4 Sample handover protocol template

Handover protocol

This document confirms the qualified handover and provision of instructions for the medical device from Dürr Dental. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

- ☐ Visual inspection of the packaging for any damage
- ☐ Unpacking the medical device and checking for damage
- ☐ Confirmation of the completeness of the delivery
- ☐ Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction: Signature:

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

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

PLANMECA

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