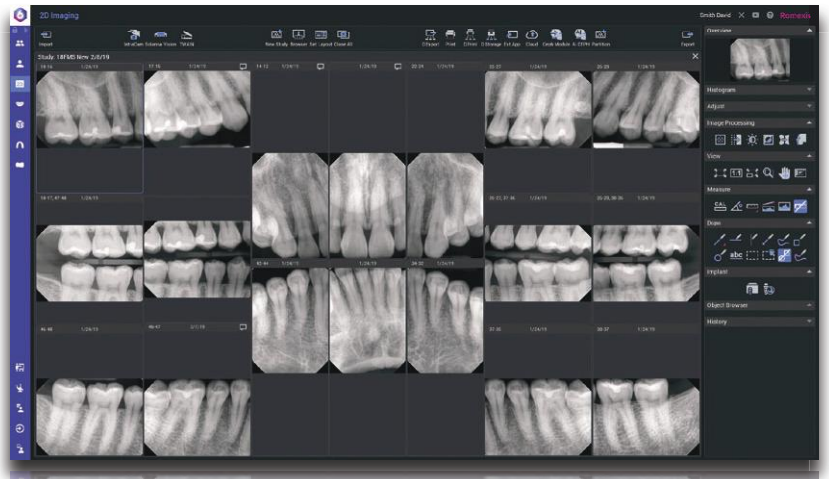
PLANMECA



Planmeca ProSensor® HD

EN

user's manual

Digitally signed by Chicu Natalia
Date: 2024.08.26 15:29:59 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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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Table of contents

1 Introduction

This manual describes how to use and install the Planmeca ProSensor HD sensor that is intended to be used for capturing digital intraoral X-ray images from patient's jaw, teeth, gums, roots and root canals by trained dental care professionals.

Please read this manual carefully before using the system.

Planmeca ProSensor automatically triggers and captures images to the start and end of the X-ray radiation so that any intraoral X-ray unit supporting exposure times and cones listed in chapter "Technical specifications" on page 21 can be used.

The Romexis imaging software or third party software stating compatibility with Planmeca ProSensor or software stating compatibility through TWAIN can be used for image capturing.

Planmeca ProSensor is connected to a computer using Ethernet or USB interface and it supports Windows and MAC operating systems, see details in section "Technical specifications" on page 21.

This manual is valid for following software versions:

- Planmeca ProSensor Ethernet software version **2.5.0.R** or later
- Planmeca ProSensor USB software version **2.5.1.R** or later
- Didapi software version **5.3.3.R** or later. The high resolution option for size 0 sensor requires version **5.5.1.R** or later.

CE 0598

Planmeca ProSensor HD sensor fulfils the requirements of Medical Device Regulation (EU) 2017/745, Class IIB and RoHS, REACH and WEEE.

BASIC UDI-DI (Global Model Number): 6430035420085T

1.1 Intended use

Planmeca ProSensor HD a digital intraoral X-ray sensor that is intended to be used together with an intraoral X-ray source. It is intended for taking intraoral X-ray images from patient's teeth, roots, root canals and other oral structures.

1.2 Intended patient population

Age	From infant to geriatric without any specific age limits
Sex	Not relevant
Weight	Not relevant
Height	Not relevant
Other	Patient must be in conscious state

1.3 Usage environment

This X-ray unit is intended to be used in a professional healthcare environment such as dental offices, clinics and similar environments.

2 Associated documentation

This manual should be used in conjunction with following manuals:

- Planmeca ProX User's manual
- Planmeca Romexis 6 User's manual

- Planmeca ProSensor HD Installation manual

3 Registering your sensor system

Before you start using your Planmeca ProSensor system, you must register it to activate the warranty.

To register:

Read the QR code on the package box with a QR code reader to enter the registration website.

OR

Navigate to the registration website www.planmeca.com/register/ in your Internet browser.

Follow the instructions on the website.

4 Symbols

CE 0598 — Fulfils the requirements of Medical Device Regulation (EU) 2017/745.

 Type BF equipment (Standard IEC 60601-1).

Medical Device (Standard ISO 15223-1).

 Manufacturer (Standard ISO 15223-1).

 Date of manufacture (Standard ISO 15223-1).

Serial number (Standard ISO 15223-1).

 Consult electronic instructions for use (Standard ISO 15223-1).

 Refer to instruction manual/booklet (Standard ISO 7010).

 The use of accessory equipment not complying with the equivalent requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the Patient Vicinity
- evidence that the safety certification of the accessory has been performed in accordance to appropriate IEC60601 and/or IEC60601-1-1 harmonized national standard.

Planmeca ProSensor is ETL classified and conforms to ANSI/AAMI ES60601-1 and is certified to CAN/CSA C22.2 No. 60601.1.

 Separate collection for electrical and electronic equipment according to Directive 2012/19/EU (WEEE).

5 Safety precautions

NOTE

The system should be operated by qualified personnel only.

NOTE

EMC requirements have to be considered, and the equipment must be installed and put into service according to the specific EMC information provided in the accompanying documents.

CAUTION

Handle the digital sensor according to the instructions given in this manual. Do not pinch the sensor or the cable. Do not to drop the sensor or pull strongly the sensor cable. Never cut, nick or sharply bend the sensor cable. Always advise the patient not to bite the sensor or the cable. The Planmeca limited warranty does not cover damage which is due to misuse, e.g. dropping the sensor, neglect, or any cause other than ordinary application.

CAUTION

Do not let the sensor cable run along the floor. Protect the cable from rolling over it with a chair or walking over it.

CAUTION

Do not store or use the digital sensor near (3m or 10 ft) an electrosurgical knife.

CAUTION

Do not unnecessarily touch the connector pins to keep them clean.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

No modification of this dental unit is allowed.

NOTE

Portable mobile devices and other high frequency electromagnetic energy emitting devices used close to the X-ray system may affect the system's performance. Diagnostic information of the X-ray image may be lost and unnecessary X-ray dose to the patient may result.

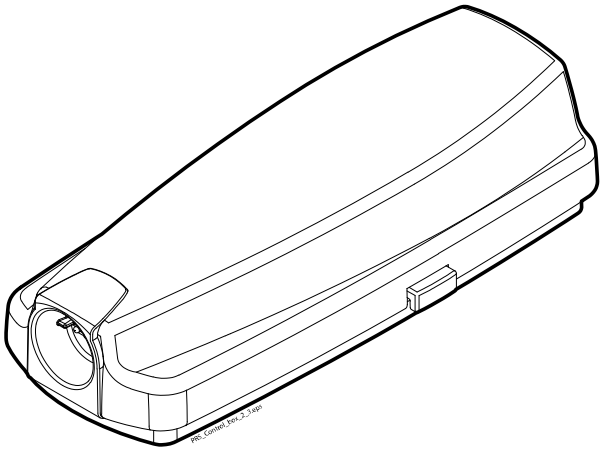
NOTE

Portable devices should be stored securely when not in use so that they cannot be stolen or damaged.

5.1 Reporting serious incidents

Serious incidents that have occurred in relation to the device must be reported to the manufacturer and the local competent authority.

6 Control box indicator light



Control box indicator light explanation

CONTROL BOX INDICATOR LIGHT	DIGITAL SENSOR STATUS
Off	Digital sensor system power off
Dim blue	Digital sensor system is off (not in intraoral exposure-mode and the cable is connected to the control box)
Bright blue	Digital sensor system is on (Imaging program communicates with the digital sensor system)
Slowly flashing blue	Waiting for Ready
Steady green	Waiting for Exposure
Rapidly flashing green	The exposure is taken and image is transferred from the sensor to the control box
Steady red	Error mode
Slowly flashing yellow	Service mode Uploading control box software
Slowly flashing blue, turns to slowly flashing dim blue, then to quickly flashing dim blue	Reading calibration files from the sensor
Flashing violet	Control box startup with back-up software
Flashing white	Sensor is being calibrated
Purple light at beginning when powering up the control box	Control box is running a factory software

NOTE

The exposure can only be taken when the control box indicator light is green and steady, not when the indicator light is flashing.

7 Before exposure

NOTE

Detailed instructions for using Planmeca ProX X-ray unit and Planmeca Romexis software are given in their User's manual, which should be used in conjunction with this manual.

NOTE

It is recommended to use a sensor holder. Select the correct sensor holder according to the type of exposure, refer to the sensor holder manual supplied with the sensor holder package.

NOTE

The sensor holders delivered with Planmeca ProSensor HD are not compatible with the older model Planmeca ProSensor sensors and vice versa.

NOTE

In case the environment temperature reaches 40°C the sensor surface warms up to its maximum temperature of 46°C and may feel warm. The surface temperature of the sensor cools off when in patient contact.

7.1 Positioning patient

Ask the patient to sit down. Place a protective lead apron over the patient's chest.

7.2 Preparing and positioning sensor

Before each use on a patient make sure the sensor has been appropriately disinfected. For detailed cleaning instructions see section "Sensors and cables" on page 17.

To avoid cross-contamination between patients during use, disposable hygienic sheaths must be used.

NOTE

Always use a new disposable hygienic sheath for every sensor usage.

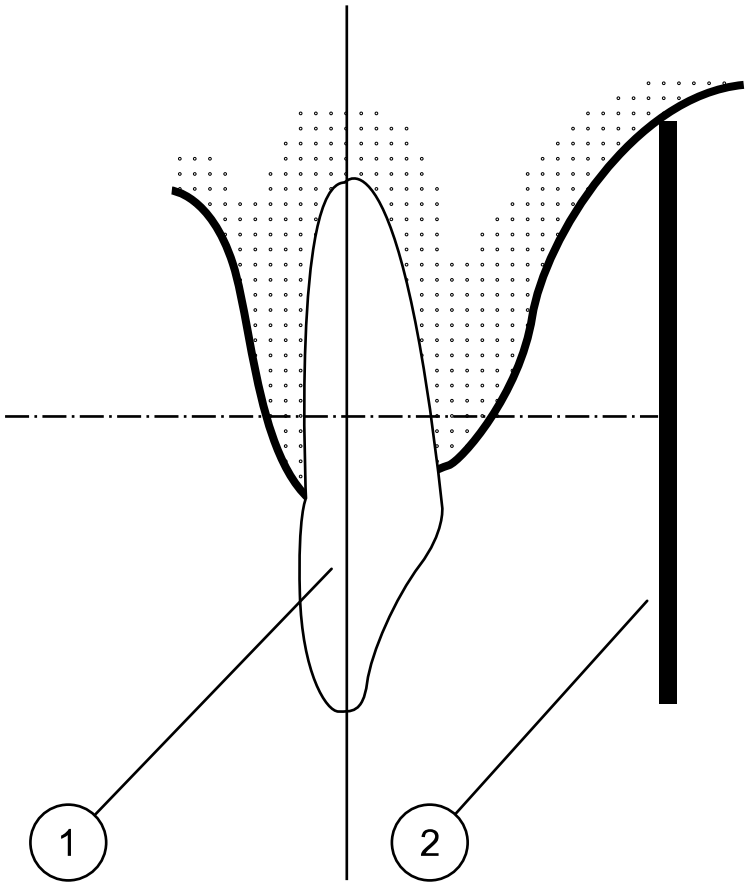
When using the sensor for the first time the message *Loading calibration files* will appear on the Romexis window.

NOTE

When connecting the same sensor to another workstation the calibration files will be reloaded.

Select the appropriate sensor and connect it to the control box.

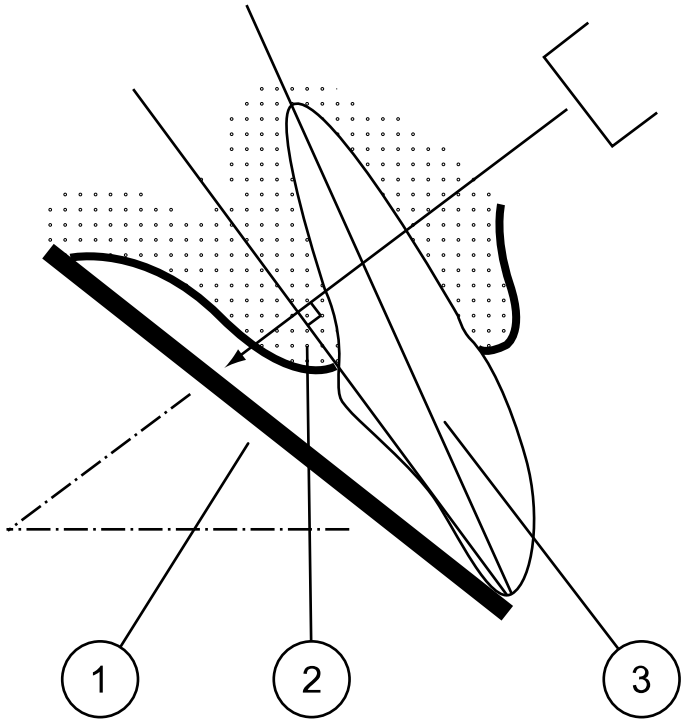
Paralleling technique (recommended)



Place the sensor (2) to a sensor holder and align the holder parallel to the long axis of the tooth (1).

Use a long cone for the paralleling technique.

Bisecting angle technique (optional)



The patient holds the sensor (1) in place with his finger. The X-ray beam is directed perpendicularly towards an imaginary line (2) which bisects the angle between the film plane and the long axis (3) of the tooth.

NOTE

Be very careful not to put excessive pressure on the sensor. Do not place a clamp on the sensor. Do not take occlusal exposures with the sensor, and advise the user not to bite the sensor.

NOTE

Never clamp the sensor package or cable with a hemostat or an unmodified "Snap-a-ray" holder.

Make sure the digital sensor system is ready for the exposure and communicates with Romexis (refer to section "Control box indicator light" on page 6.

On how to place the sensor into the patient's mouth refer to the sensor holder manual supplied with the digital sensor.

7.3 Selecting exposure values

The following tables show the recommended exposure values for Planmeca ProSensor HD.

Short cone 20 cm (8") exposure values

Jaw	mA	TIME	0.010s	0.012s	0.016s	0.020s	0.025s	0.032s	0.040s	0.050s	0.063s	0.080s	0.100s	0.125s	0.160s	0.200s	0.250s	0.320s	0.400s	0.500s	0.630s	0.800s
MAXI	8 mA	70 kV/ child						I	P	M												
MAND							I	P	M													

Short cone 20 cm (8”) exposure values

Jaw	mA	TIME	0.010s	0.012s	0.016s	0.020s	0.025s	0.032s	0.040s	0.050s	0.063s	0.080s	0.100s	0.125s	0.160s	0.200s	0.250s	0.320s	0.400s	0.500s	0.630s	0.800s
MAXI	8 mA	66 kV/ child							I	P	M											
MAND								I	P	M												
MAXI	8 mA	63 kV/ child								I	P	M										
MAND									I	P	M											
MAXI	8 mA	60 kV/ child									I	P	M									
MAND										I	P	M										
MAXI	8 mA	70 kV/ adult							I	P	M											
MAND								I	P	M												
MAXI	8 mA	66 kV/ adult								I	P	M										
MAND									I	P	M											
MAXI	8 mA	63 kV/ adult									I	P	M									
MAND										I	P	M										
MAXI	8 mA	60 kV/ adult										I	P	M								
MAND											I	P	M									

I = INCISORS, M = MOLARS, P = PREMOLARS AND CANINES

Long cone 30 cm (12”) exposure values

Jaw	mA	TIME	0.010s	0.012s	0.016s	0.020s	0.025s	0.032s	0.040s	0.050s	0.063s	0.080s	0.100s	0.125s	0.160s	0.200s	0.250s	0.320s	0.400s	0.500s	0.640s	0.800s
MAXI	8 mA	70 kV/ child									I	P	M									
MAND										I	P	M										
MAXI	8 mA	66 kV/ child										I	P	M								
MAND											I	P	M									
MAXI	8 mA	63 kV/ child											I	P	M							
MAND												I	P	M								
MAXI	8 mA	60 kV/ child												I	P	M						
MAND													I	P	M							
MAXI	8 mA	70 kV/ adult										I	P	M								
MAND											I	P	M									
MAXI	8 mA	66 kV/ adult											I	P	M							
MAND												I	P	M								
MAXI	8 mA	63 kV/ adult												I	P	M						
MAND													I	P	M							
MAXI	8 mA	60 kV/ adult													I	P	M					
MAND														I	P	M						

I = INCISORS, M = MOLARS, P = PREMOLARS AND CANINES

8 Capturing intraoral images

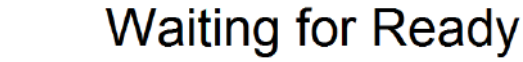
When connecting the sensor for the first time the message *Loading calibration files* appears on the Romexis window. Also, if you connect the same sensor to another workstation the files will be loaded again.

8.1 Capturing single intraoral images

Steps

1. Click the intraoral exposure button on the main page of the 2D module or on the top toolbar to initiate the intraoral image capture mode

   The *Intraoral Exposure* window appears.

   When the X-ray unit is getting ready for exposure, the message *Waiting for Ready* appears on top of the window.

2. Prepare the patient for exposure, select exposure parameters and position the intraoral X-ray unit as required, for more information refer to the unit's user's manual/Instructions for use.

   NOTE

   Inform the patient that the sensor may feel warm in the mouth.

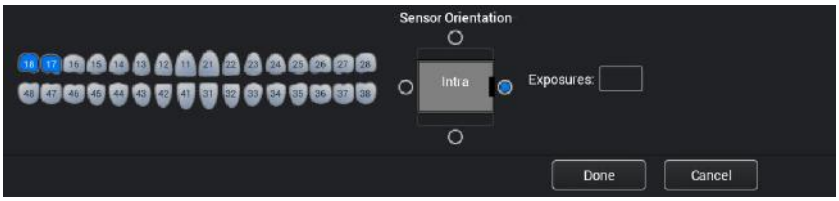
   

   When the intraoral sensor system is ready for exposure the message *Waiting for Exposure* appears on top of the window.

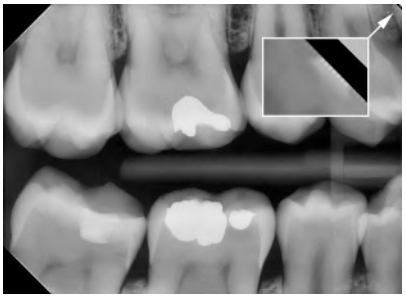
3. Take an exposure as usual.

   After the exposure the message Saving the image appears on the display and the image is automatically stored into the database.

4. Define the tooth numbers and sensor orientation.

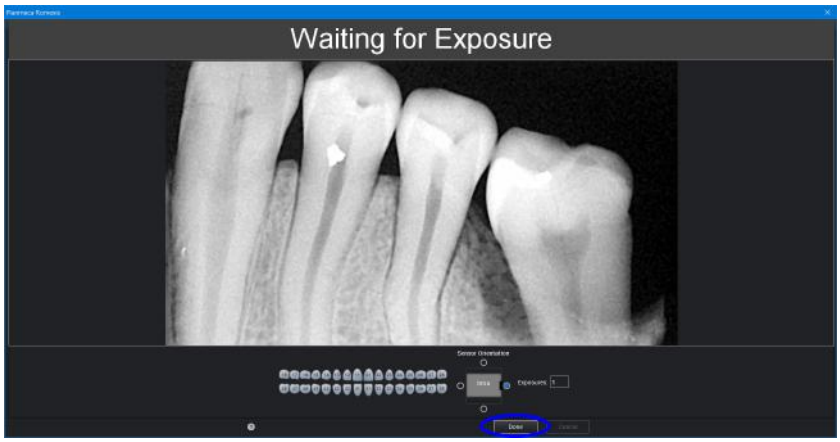
   

   The sensor orientation is indicated in the image by a grey triangle.

The triangle corresponds to the upper right corner of the sensor when positioned as illustrated with the cable running on the backside of the sensor.

5. Take the next exposure, or click **Done** to return to the **Imaging** module when all exposures have been captured.



NOTE

Remove the sensor from patient's mouth when all exposures have been taken.

8.2 Capturing images into study template

About this task

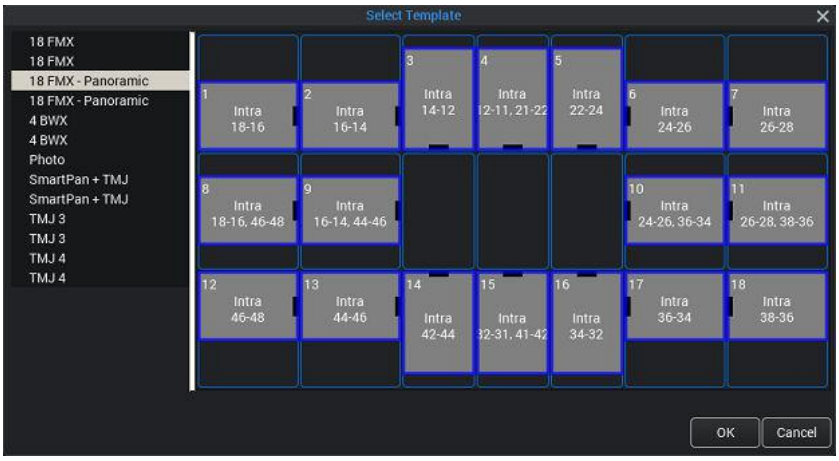
The images are captured into study templates containing a predefined set of multiple images.

Steps

1. Click the intraoral exposure with study button on the main page of the 2D module or on the top toolbar.

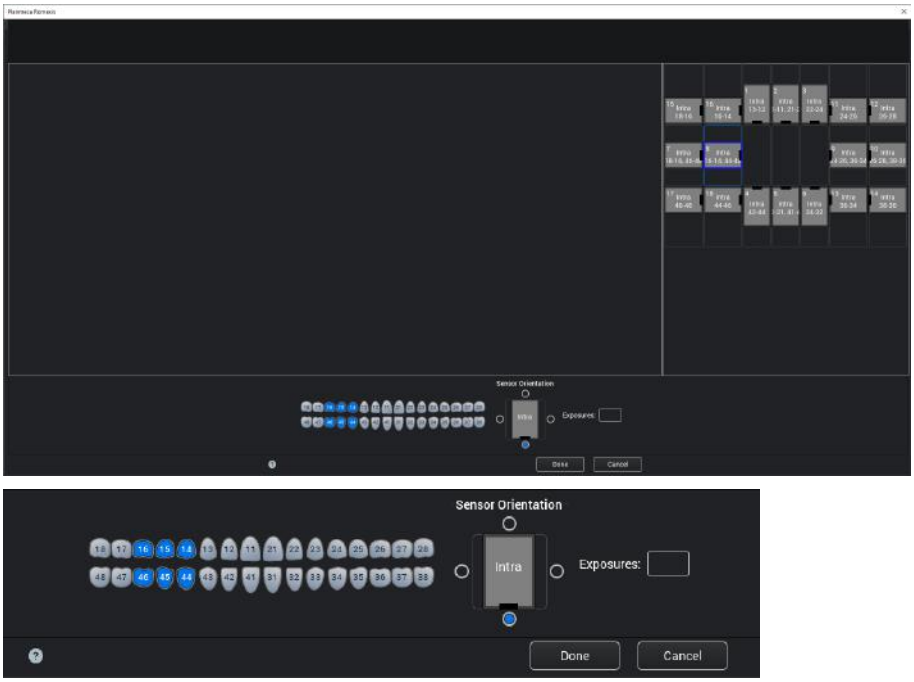
2. Select the desired study template from the list.

   At the beginning of the list there are empty templates and at the bottom of the list there are studies with dates that already include images captured earlier for the selected patient.



While capturing images using a template, Romexis navigates through the template in a predefined order, denoting the current image to be captured by a blue border around the slot.

3. Follow the tooth numbering and sensor orientation as shown on the image and predefined in the template.



4. Prepare the patient for exposure, select exposure parameters and position intraoral X-ray unit as required, for more information refer to unit's user's manual / Instructions for use.

NOTE

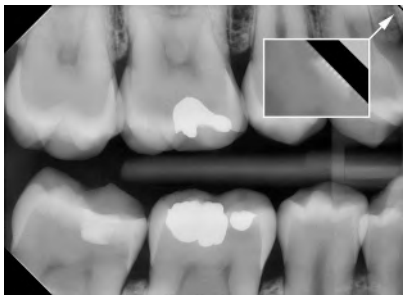
Inform the patient that the sensor may feel warm in the mouth.

When the sensor system is ready for exposure the message *Waiting for Exposure* appears on top of the window. You can now take exposures as usual.

After the exposure the message *Saving the image* appears on the display and the image is automatically stored into the database.

5. Define the tooth numbers and sensor orientation.

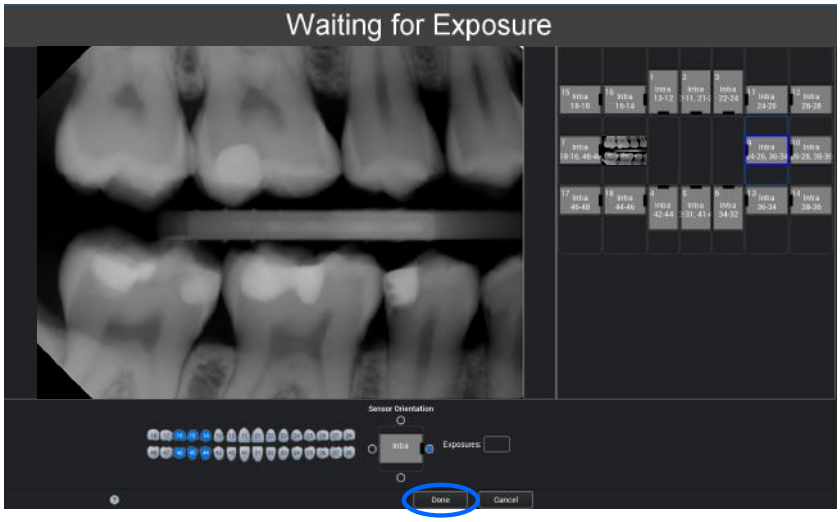
   The sensor orientation is indicated in the image by a grey triangle.



   The triangle corresponds to the upper right corner of the sensor when positioned as illustrated with the cable running on the backside of the sensor.

   To cancel the process click Cancel. The captured images are saved and the incomplete study is preserved for later use.

6. Once all images have been captured click Done.



9 Planmeca ProSensor HD in Planmeca Romexis Clinic Management module

NOTE

The Planmeca Romexis Clinic management is supported only with Planmeca ProSensor HD Ethernet Control box using software version 2.5.8 or later.

Planmeca Romexis Clinic Management module allows time stamped recording and real-time monitoring and control of most activities performed using Planmeca ProSensor intraoral sensor. The features and the gathered data can be used for remote assistance, service and maintenance, as well as preventive maintenance planning.

For detailed information see Planmeca Romexis user's manual.

10 Image quality control

Verify the image quality after installing the software and before patient exposure. Perform quality control check according to the requirements of local authorities, using for example Quart phantom or similar.

It is recommended to regularly monitor the image quality using the same phantom according to the requirements of local authorities. See also the Constancy test manual for Planmeca Digital Intraoral X-ray System.

Before performing phantom exposures verify that the brightness and contrast settings of the monitor are accurate by using a SMPTE test pattern or similar.

10.1 Quality check using SMPTE test pattern

The test image is specified by the Society of Motion Picture and Television Engineers (www.smpte.org), and follows the SMPTE Recommended Practise RP 133-1991 Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras. This image should be used for monitor setting and quality checks performed:

- Before every working day: The 5% gray field inside the 0% field and the 95% gray field inside the 100% field should be visible. If not, adjust the brightness and contrast of the monitor.
- Every month: The line raster in the corners and in the centre must be visible, the vertical and horizontal lines must form undistorted squares and the homogeneous grey background must not be coloured.

11 Sensor holders

The sensor holders provide an easy way to position the sensor for different anatomical and diagnostic needs. For instructions how to use the sensor holders, please refer to the manual supplied with the sensor holder package.

12 Cleaning and disinfection

NOTE

Before cleaning the system, always check that the X-ray unit and the digital sensor system are off (the control box indicator light is off).

Recommended disinfectants

For disinfection manufacturer recommends the following disinfectants for wiping:

- CaviWipes (Metrex Research, USA)
- Dürr FD 322 (Dürr Dental AG, Orochemie GmbH)
- Dürr FD 333 (Dürr Dental AG, Orochemie GmbH
- Cidex Opa (Johnson & Johnson)

All recommended disinfecting agents have been tested and found to be harmless to the surfaces.

12.1 Sensors and cables

The sensors allow enhanced infection control in surgery.

NOTE

Always use appropriate instruments for cleaning the sensors.

NOTE

It is mandatory to carefully follow the cleaning and disinfection recommendations for not to damage the sensors.

CAUTION

The sensors cannot be sterilized in autoclave or UV oven.

Wipe the sensor surface with a soft cloth damped into a disinfectant solution.

The recommended disinfectant solutions are Dürr System Hygiene FD 322 or FD 333 or similar product.

If more effective disinfection or cold sterilization is preferred for cleaning, we recommend the Johnson & Johnson Cidex Opa high level disinfectant.

NOTE

Follow carefully the manufacturer's recommendations on disinfectant liquids.

Use a new disposable hygienic sheath for every sensor usage.

NOTE

The sensor connector can be cleaned using a soft cloth.

12.2 Sensor holders

For cleaning the sensor holders refer to the manual supplied with the sensor holder package.

12.3 Control box

The control box can be cleaned with a soft cloth damped in a mild cleaning solution.

CAUTION

Switch off the unit before cleaning.

NOTE

Do not disinfect the unit.

CAUTION

Never detach the control box ethernet cable without releasing the latch on the cable connector. Forcefully detaching the cable will damage the control box.

13 Service

All cyber security software updates listed in a technical bulletin must be installed on the X-ray unit.

14 Disposal

In order to reduce the environmental load over the product's entire lifecycle, Planmeca's products are designed to be as safe as possible to manufacture, use and dispose of.

Parts which can be recycled should always be taken to the appropriate processing centres, after hazardous waste has been removed. Disposal of obsolete systems is the responsibility of the waste possessor.

All parts and components containing hazardous materials must be disposed of in accordance with waste legislation and instructions issued by the environmental authorities. The risks involved and the necessary precautions must be taken into account when handling waste products.

Part	Main material for disposal	Recyclable material	Waste disposal site	Hazardous waste (separate collection)
ControlBox				
• metal	stainless steel	X		
• plastic	ASA + PC	X		
	POM	X		
	PC		X	
	PU		X	
Cables	copper	X		
	TPE/PU		X	
Packing	cardboard,	X		
	paper,	X		
	PE foam	X		
Sensors	Return the sensors to Planmeca.			
Other parts	PoE		X	

NOTE

If the component boards cannot be recycled handle them as electronic scrap, i.e. according to the local legislation.

15 Technical specifications

15.1 Sensor

Sensor type	CMOS with scintillator
Pixel size	15 µm x 15 µm
Sensor dimensions	
Size 0	
overall	33.6 x 23.4 mm (1.32 x 0.92 in.)
active area	25.5 x 18.9 mm (1.00 x 0.74 in.)
pixel matrix	1700 x 1258
number of pixels	2.14 M
Size 1	
overall	39.7 x 25.05 mm (1.56 x 0.99 in.)
active area	30.6 x 20.7 mm (1.20 x 0.82 in.)
pixel matrix	2040 x 1380
number of pixels	2.82 M
Size 2	
overall	44.1 x 30.4 mm (1.74 x 1.2 in.)
active area	36 x 26.1 mm (1.42 x 1.03 in.)
pixel matrix	2400 x 1740
number of pixels	4.18 M
Image sizes	
Size 0	850 x 629 (0.5 MP)/ 1700 x 1258 (2.14 MP)* * High resolution mode with size 0 requires Didapi software version 5.5.1.R or later.
Size 1	1020 x 690 (0.7 MP)/ 2040 x 1380 (2.82 MP)
Size 2	1200 x 870 (1.0 MP)/ 2400 x 1740 (4.18 MP)
Image format	16-bit
Resolution	
Normal	17 lp/mm
High	20+ lp/mm
Theoretical resolution	33 lp/mm
Cable length	1.0 m (39.4 in.) or 2.0 m (78.7 in.)
Expected service life	10 years / 100 000 exposure cycles

15.2 Ethernet ControlBox

Dimensions	112 x 46 x 24 mm (4.41 x 1.81 x 0.94 in.)
Power input	48 V DC 65 mA
Cables	
ControlBox to PoE	RJ45 10m OR 15m

PoE to LAN	RJ45 10m OR 15m

PoE power supply

Phihong Single Port Injector

Type	**PSA16U-480 (POE)**	**POE15M-1AF/ POE15M-1AFE-R**
Input voltage	100-240 VAC (50-60 Hz)	100-240 VAC (50-60 Hz)
Output voltage	48 VDC	56 VDC
Max. output current	0.32 A	0.275 A
Insulation voltage primary-secondary	3000 VAC	3000 VAC

15.3 USB ControlBox

Dimensions	112 x 46 x 24 mm (4.41 x 1.81 x 0.94 in.)
Cables	Fixed USB 2.0 power supply cable 2 m (6.6 ft)
Power input	2.5 W

15.4 Supported operating systems

- Windows OS (64 bit)
- Mac OS X

15.5 Operating environment

For indoor use only. The equipment is installed on the wall or on/under the table. The user moves the sensor into the operation position by hand.

The room and operation must comply with the X-ray safety shielding requirements according to radiation safety regulation in the country.

The system is used by dental care professionals.

Prior to installation of the system check that the local conditions are compatible with the appliance design.

The temperature of the operating environment should be between + 15°C and + 40°C.

The relative humidity of the operating environment should not exceed 60%.

Atmospheric pressure range should be between 700 hPa - 1060 hPa.

15.6 Transportation and storage environment

Transportation and storage temperature -10°C - +60°C.

The relative humidity during transportation and storage should not exceed 95%.

Atmospheric pressure range should be between 700 hPa - 1060 hPa.

Appendix A: Exposure value tables for Planmeca ProX

A.1 Default exposure values

The following table shows the default exposure values for Planmeca ProSensor with no target selected.

	Short cone				Long cone		
	kV	mA	s		kV	mA	s
Adult	63	8	0,1	Adult	63	8	0,2
Child	60	8	0,08	Child	60	8	0,16

A.2 Preprogrammed settings values

Short cone 20 cm (8”)

		INCISORS			PREMOLARS AND CANINES			MOLARS		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	60	8	0.080	63	8	0.1	63	8	0.125
	Mandible			0.063			0.08			0.1
Child	Maxilla	60	8	0.063	60	8	0.08	60	8	0.1
	Mandible			0.050			0.063			0.08

		OCCLUSAL			ENDODONTIC			BITE-WING		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	70	8	0.08	60	8	0.08	60	8	0.125
	Mandible									
Child	Maxilla	66	8	0.063	60	8	0.063	60	8	0.1
	Mandible									

Long cone 30 cm (12”)

		INCISORS			PREMOLARS AND CANINES			MOLARS		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	60	8	0.16	63	8	0.2	63	8	0.25
	Mandible			0.125			0.16			0.2
Child	Maxilla	60	8	0.125	60	8	0.16	60	8	0.2
	Mandible			0.1			0.125			0.16

		OCCLUSAL			ENDODONTIC			BITE-WING		
		kV	mA	time	kV	mA	time	kV	mA	time
Adult	Maxilla	70	8	0,16	60	8	0.16	60	8	0.25
	Mandible									
Child	Maxilla	66	8	0,125	60	8	0.125	60	8	0.2
	Mandible									

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