



EN

PLANMECA
ProSensor
Digital Radiography System

user's & installation manual

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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 authorized personnel
- electrical installations are carried out according to the appropriate requirements such as IEC364
- 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 INTRODUCTION

This manual describes how to use and install the Planmeca ProSensor Digital Radiography System. Please read this manual carefully before using and installing the system. See also Planmeca Intra X-ray unit user's manual.

NOTE The Planmeca Intra X-ray unit and Romexis software have separate user's manuals, which should be used in conjunction with this manual.

1.1 Symbols



Type BF equipment (Standard IEC 878).



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 Digital Radiography System is supplied with the UL Recognition mark.

1.2 Notes, cautions and warnings

NOTE The system should be installed and 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 Planmeca ProSensor Digital Radiography System 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 Planmeca Sensor near (3m or 10 ft) an electro-surgical knife.*



WARNING

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

1.3 Package contents for Ethernet / USB interface

1.3.1 Ethernet interface



- | | |
|---|----------------------------------|
| 1. Packing list | 6. Interconnection cable RJ45 |
| 2. Sensor holder package | 7. Interconnection cable RJ45 |
| 3. Romexis Software package | 8. ProSensor Ethernet ControlBox |
| 4. ProSensor User's/Installation Manual | 9. ProSensor with cable |
| 5. PoE port with power cable | 10. Sensor hanger |

1.3.2 USB interface



- | | |
|---|-----------------------------|
| 1. Romexis Software package | 5. ProSensor USB ControlBox |
| 2. Sensor holder package | 6. Packing list |
| 3. ProSensor User's/Installation Manual | 7. ProSensor with cable |
| 4. Sensor hanger | |

2 SYSTEM REQUIREMENTS

NOTE The PC and other equipment connected to the system must be:

- approved by local authorities: e.g. IEC-approved (CE marked), UL / CSA approved
- located outside the patient area (more than 2m (79 in.) from the X-ray unit)
- protectively earthed.

NOTE The connection of additional equipment to a multiple portable socket-outlet must only be possible by using a tool or be supplied via separating transformer.

NOTE The multiple portable socket-outlets shall not be placed on the floor.

NOTE Make sure that the system is protected with firewall and up to date anti-virus software. If possible, isolate the system from office network.

2.1 Planmeca Romexis computer requirements

	Planmeca Romexis client work station	Planmeca Romexis database server
Processor	1 GHZ	2 GHZ
RAM	1 GB	2 GB minimum
Hard disk space	40 GB or more	160 GB or more recommended
Graphics card	128 minimum memory	128 minimum memory
Monitor	1280 x 1024	1280 x 1024
Peripherals	CD-ROM drive	CD-ROM drive
Backup medium	None necessary	DAT or equivalent
Operating system	Windows XP, 2003, Vista, Mac OS X Linux Mac OS / Linux support subject to contract	Windows XP Pro, Windows 2003 Server, Vista
Other	Java platform (Java Virtual Machine 1.6 or later)	Java platform (Java Virtual Machine 1.6 or later)

3 PLANMECA PROSENSOR SYSTEM SETUP FOR ETHERNET & USB INTERFACE

3.1 Ethernet interface connection

The Planmeca ProSensor ControlBox must be installed so that the sensor can be easily placed in the the patient's mouth and that the input cable from the PoE (Power over Ethernet) port will reach the socket in the back of the PC.

NOTE The PoE port must comply with IEEE 802.3af standard

NOTE Only equipment complying with IEC/EN 60950 must be connected to the ethernet connector.

NOTE The ethernet cables must be connected to ethernet sockets only. Do not connect the cables to any other equipment.

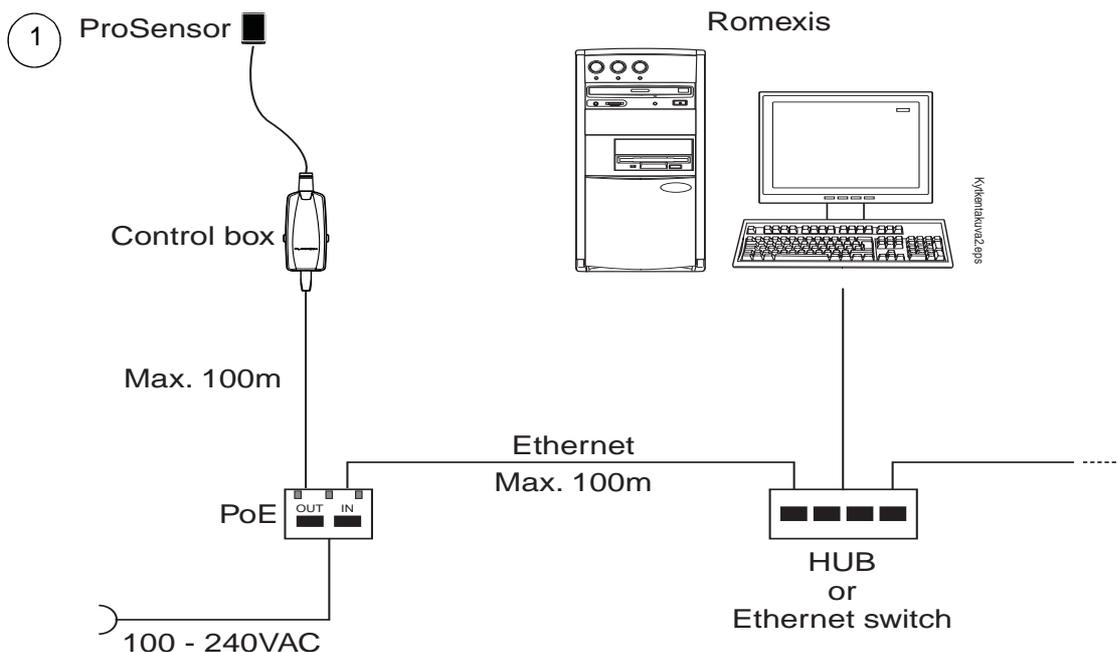
NOTE Ethernet connection has two LED indicator lights. Green light signifies "100 baseTx link on" and yellow "Communication active"

NOTE The distance between PoE port and ControlBox must not exceed 100 m.

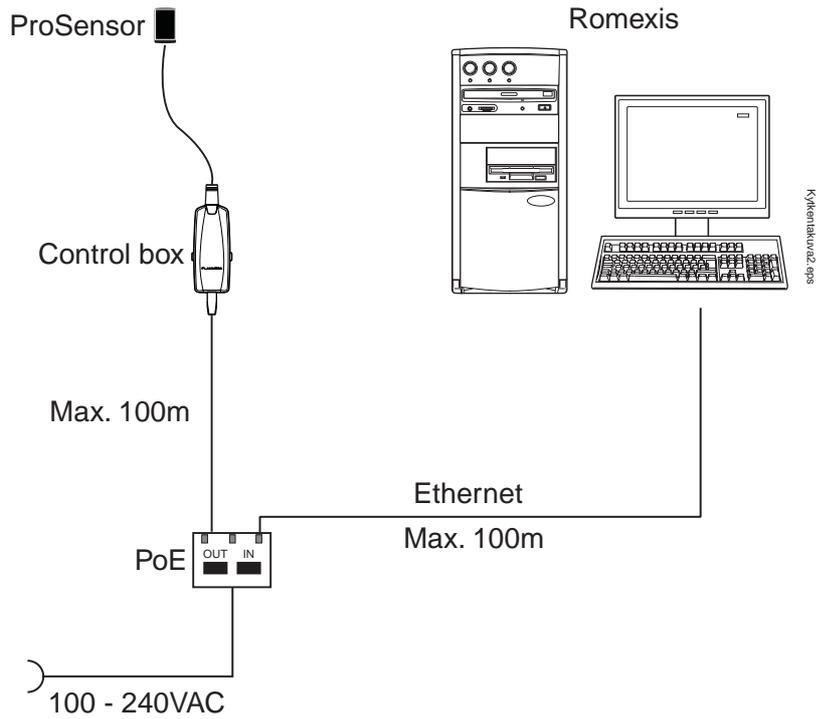
1. Connect the Ethernet cable from the PC / LAN network to the input socket of the PoE port. If necessary a hub can be connected between the PC and the PoE port.
2. Connect the Ethernet cable from the PoE output socket to the ControlBox).
3. Connect the ProSensor cable to the ControlBox. The PoE port can be installed in the same space with the Hub/ Ethernet switch or next to the ControlBox.

The control box must be installed so that no liquid will spill on it.

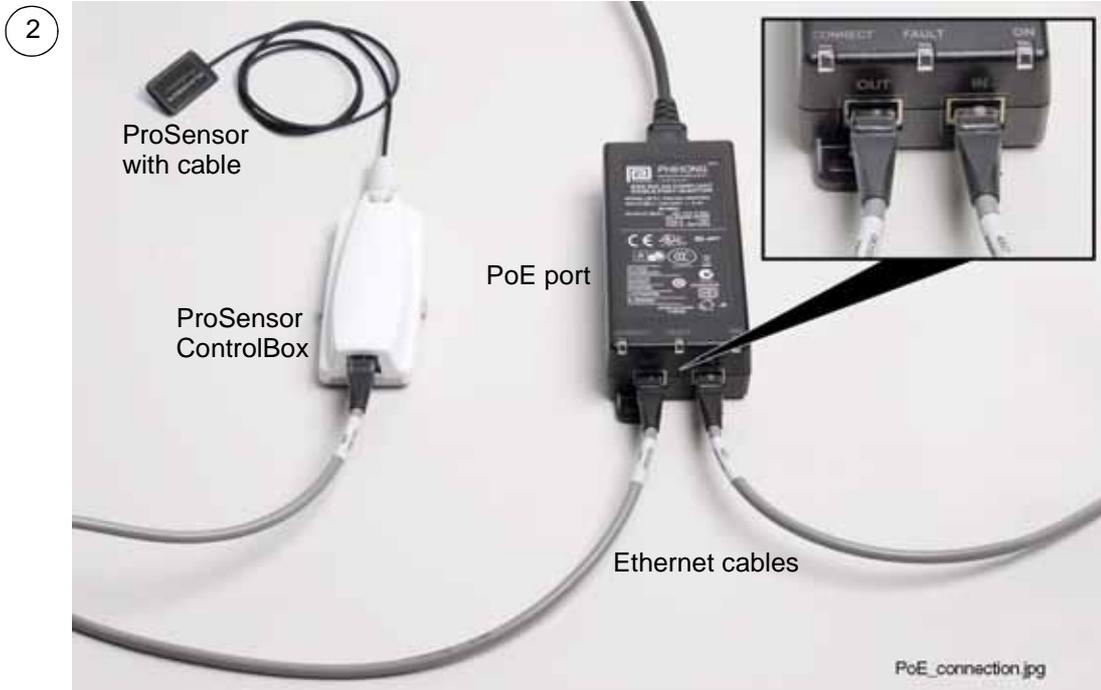
Typical network configuration



Typical standalone configuration



Connecting Planmeca ProSensor ControlBox to PoE (Power over Ethernet port)



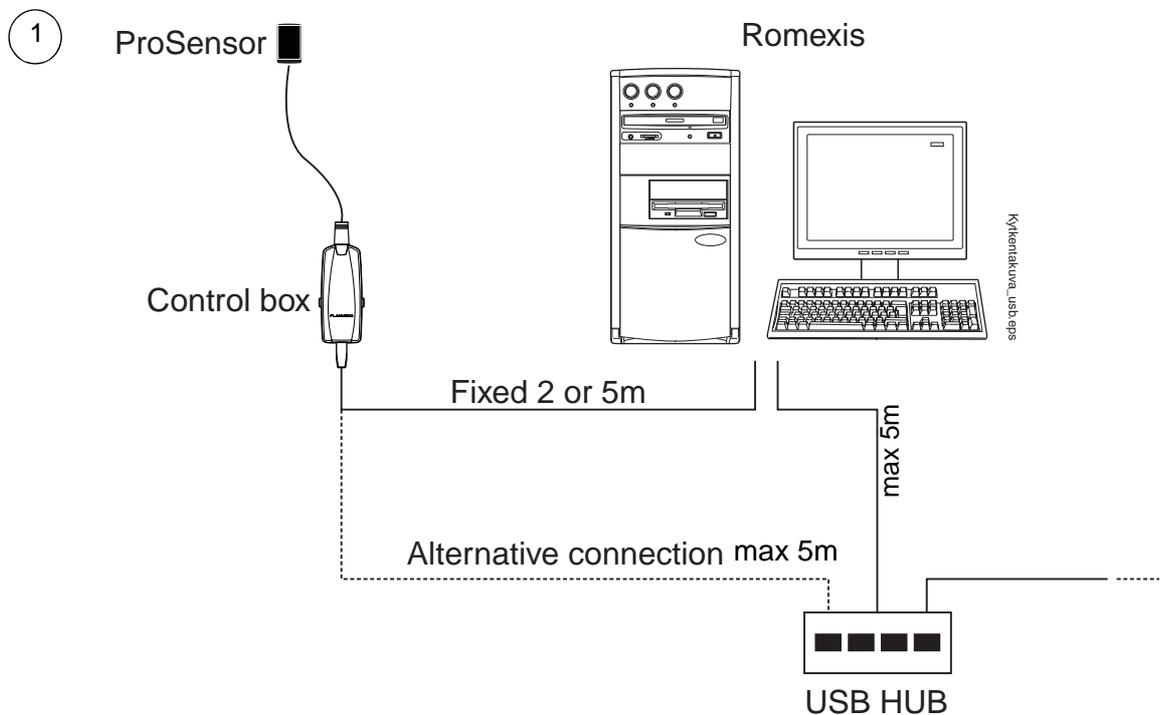
3.2 USB interface connection

The Planmeca ProSensor ControlBox must be installed so that the sensor can be easily placed in the patient's mouth and that the cable of the USB hub will reach the socket in the back of the PC.

NOTE The USB cable must be connected to USB sockets only. Do not connect the cables to any other equipment.

NOTE If the distance between the Control box and the PC exceeds 5 m a HUB must be used.

1. Connect the ControlBox USB cable to the PC. Alternatively a hub can be connected between the PC and the ControlBox.
2. Connect the magnetic connector of the Planmeca ProSensor to the ControlBox.



4 CONFIGURING PLANMECA PROSENSOR DIGITAL RADIOGRAPHY SYSTEM

4.1 PC configuration

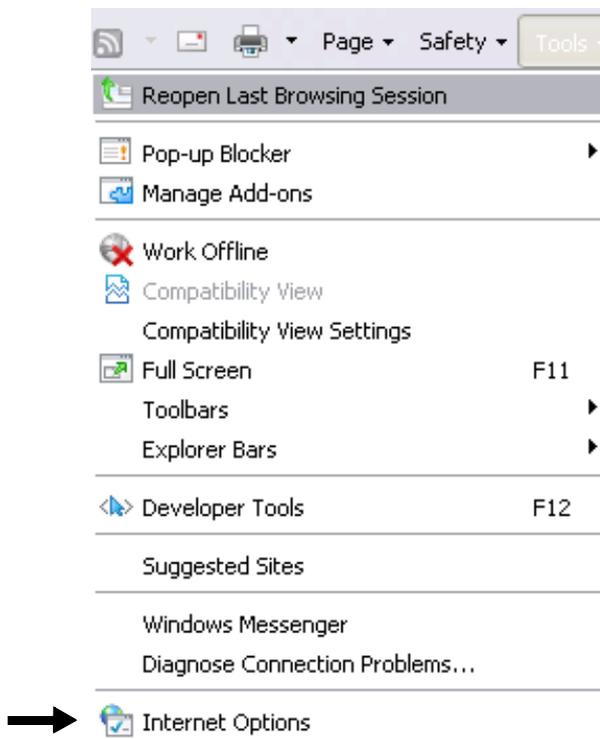
4.1.1 Disabling proxy server

The following example describes the configuration performed with the Internet Explorer 7 browser. However, configuration can be performed with any browser.

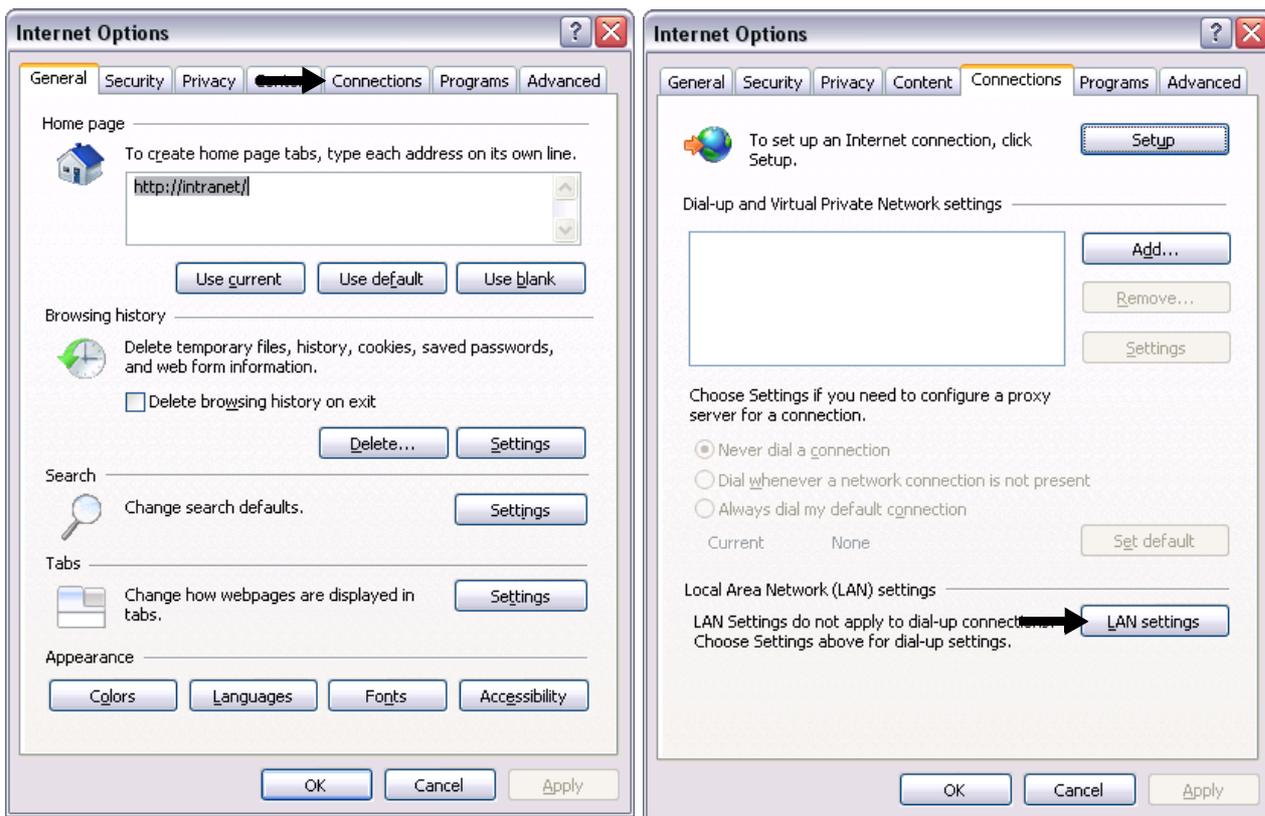
1. To access the ProxyServer settings click **Tools** on your browser window. .



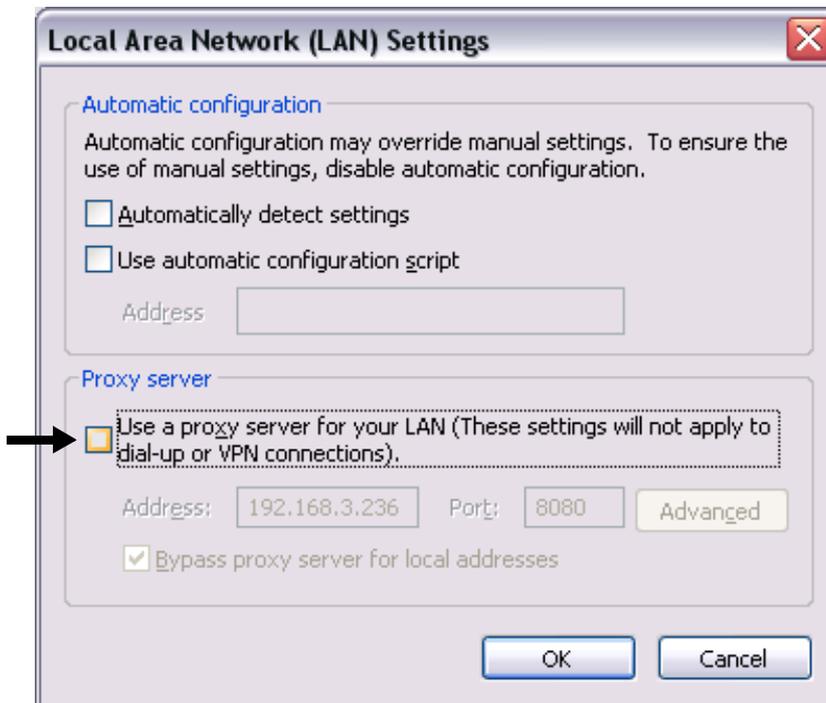
2. On the appearing menu select **Internet Options**.



3. On the *Connections* tab click **Lan Settings**.



4. The following window opens. Disable proxy server by unchecking the Proxy server tickbox. Click **OK**.



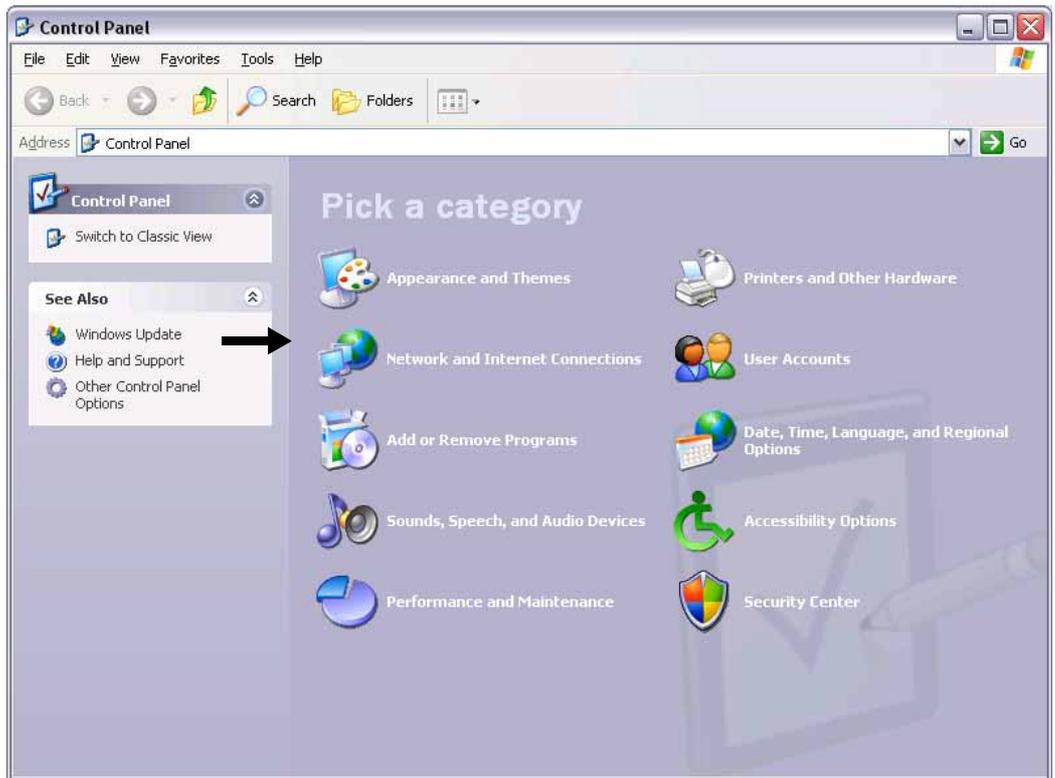
4.1.2 Changing the computer IP address

The PC IP address must be changed to the same IP space with the Control box so that the ControlBox can be configured.

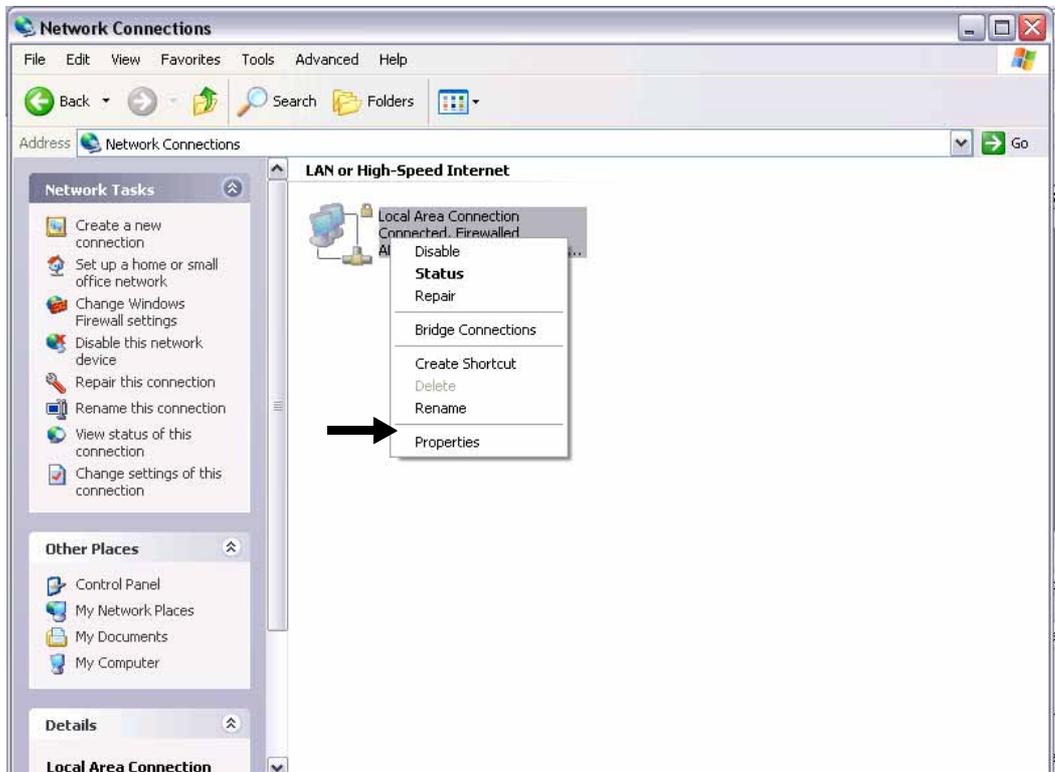
1. Click on windows **Start** menu and select **Control Panel**



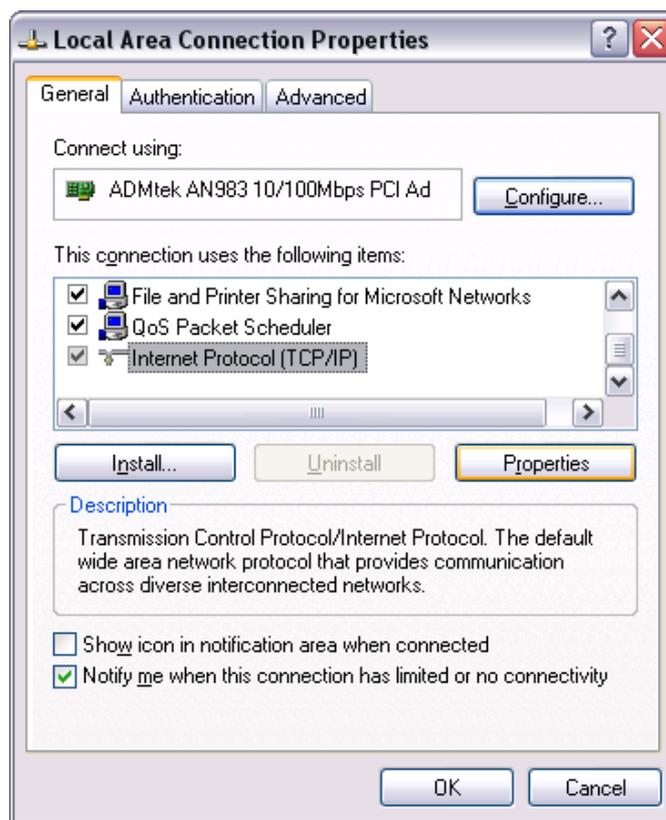
2. The Control Panel window opens. Click **Network and Internet connections**.



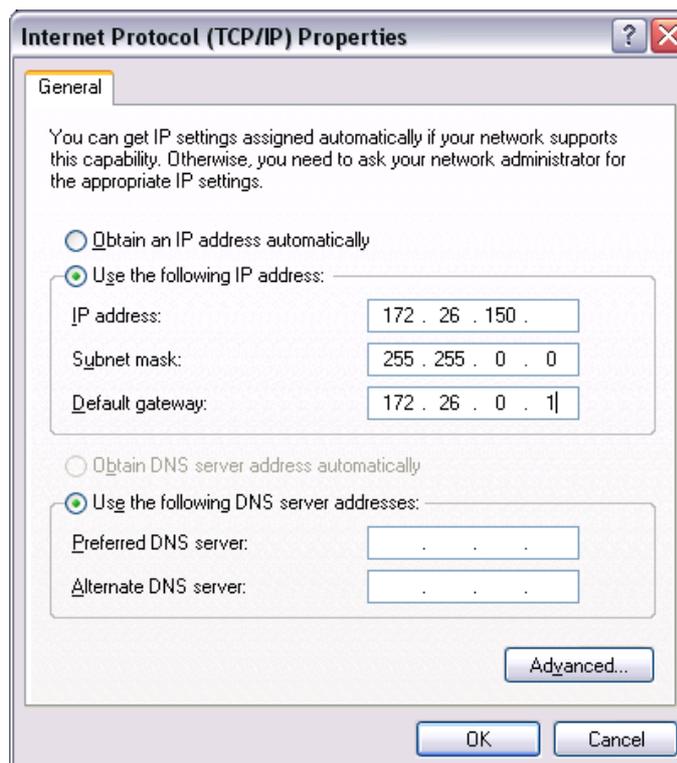
3. In the *Network Connections* window right-click the **Local Area connection** icon and select **Properties**.



4. Scroll down the menu and select **Internet Protocol (TCP/IP)**. Click **Properties**.



5. Select *Use the following IP address* and change your computer IP settings to same IP space with the default ControlBox IP address 172.26.150.150. The address must **not** be identical with the ControlBox IP address. Click **OK**.



4.2 Planmeca ProSensor configuration utilities

On the *Planmeca ProSensor* main page you will find utilities for:

- Changing the Planmeca ProSensor IP address
- Updating the ControlBox software

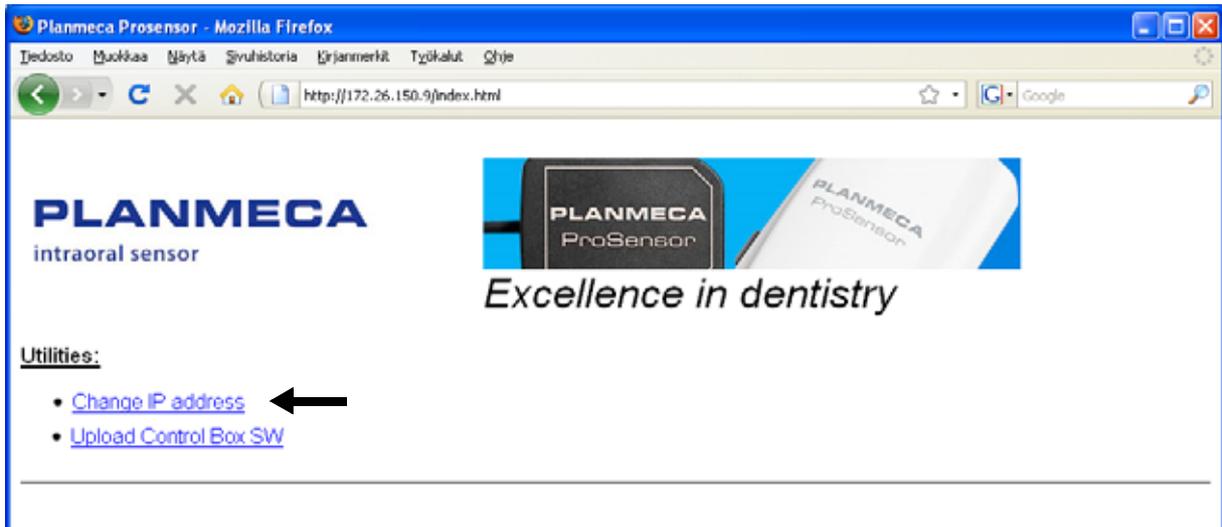
To access the Planmeca ProSensor main page:

1. Type the IP address of the controlbox and **/index.html** in the address field of the browser e.g. <http://172.26.150.150/index.html>. If the address has been modified it might be different from the address of this example. Make sure to type in the latest configured address of the control box.
2. The following window opens:



4.2.1 Changing the ControlBox IP-address

1. Click the link **Change IP-address**.



2. Browser goes to <http://172.26.150.150/netcfg.asp> and the following window opens.

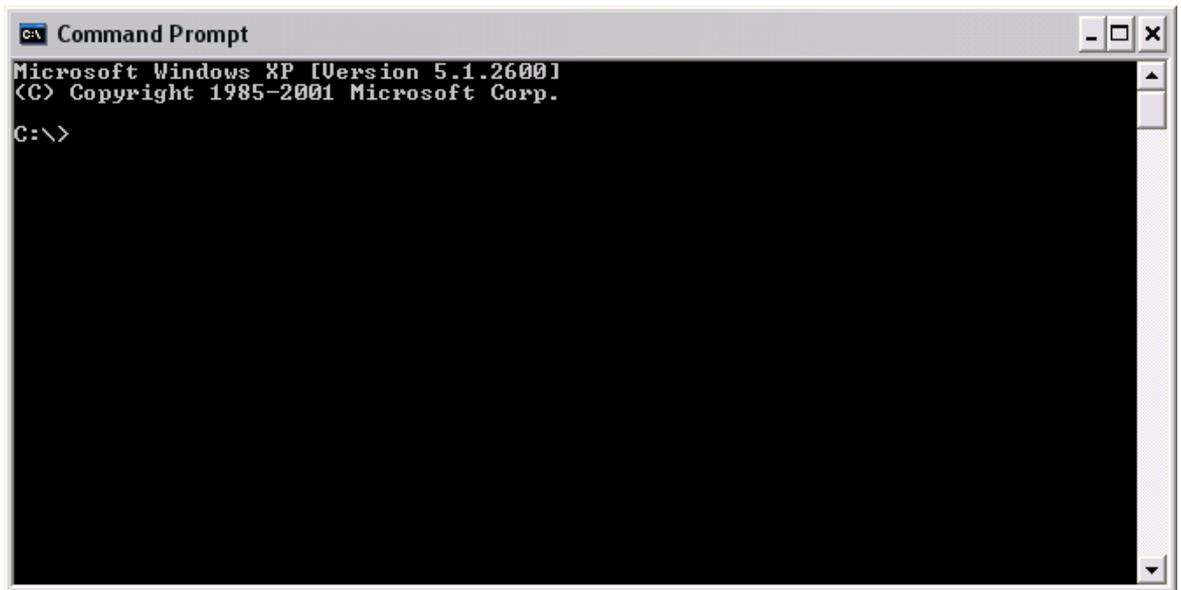


3. The default IP-address for each ControlBox is **172.26.150.150**. To change the ControlBox IP address type the new IP address, Subnet Mask and Default Gateway in the corresponding fields and click **Send**.
4. Wait until the ControlBox indicator light switches from yellow to blue.
5. Reboot the ControlBox by unplugging and replugging the ControlBox cable.
6. Change the computer IP address back to original (for more information see section "Changing the computer IP address" on page 10).

7. Change the new Controlbox IP to DidapiConfiguration (please see section “Configuring Planmecca ProSensor settings” on page 21”).

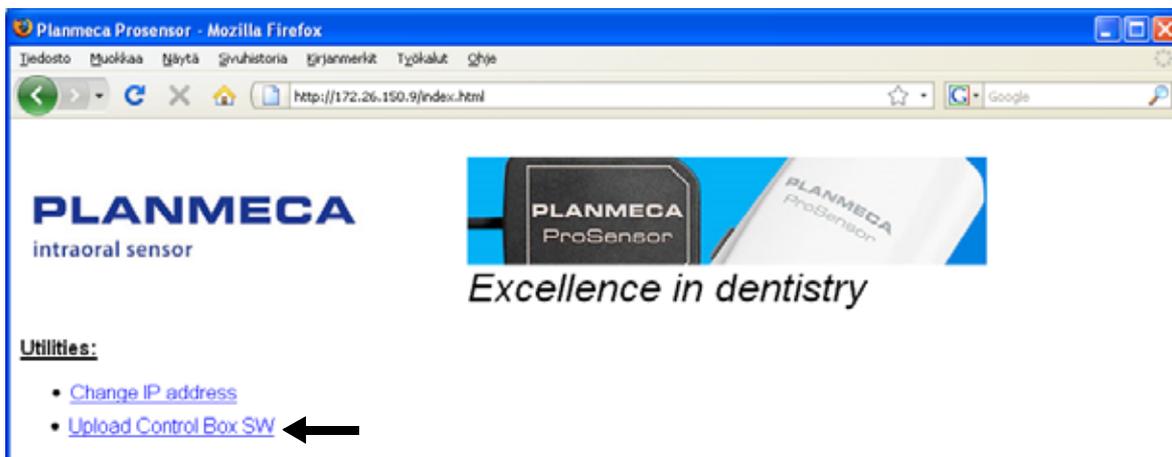
To test the ControlBox connection:

1. Open the Command Prompt window via Windows *Start* menu by selecting *All Programs > Accessories > Command Prompt*.
2. Type command **ping** and the new ControlBox IP address in the command prompt window.

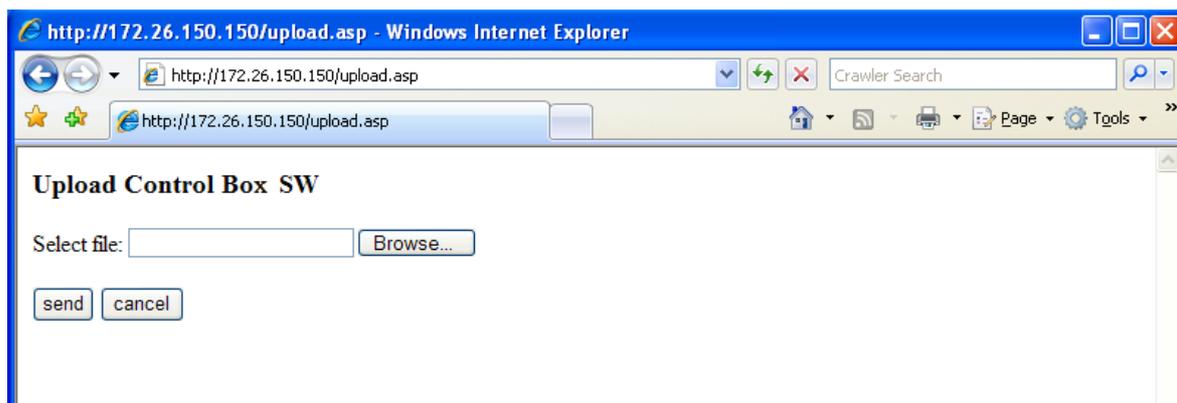


4.2.2 Updating the ControlBox software

1. Select **Upload ControlBox SW**.



2. Browser goes to <http://172.26.150.150/upload.asp>. To select a new software version click **Browse** and **Send**.



3. Wait until the ControlBox indicator light goes from yellow to blue and reboot the ControlBox.

4.3 Resetting the IP Address

NOTE The following procedure will reset the IP address, Subnet Mask and the Default Gateway only.

1. Switch on the power of the ControlBox
2. To access the reset button detach the bottom cover of the ControlBox by pushing the lock buttons on both sides of the ControlBox with your fingers.

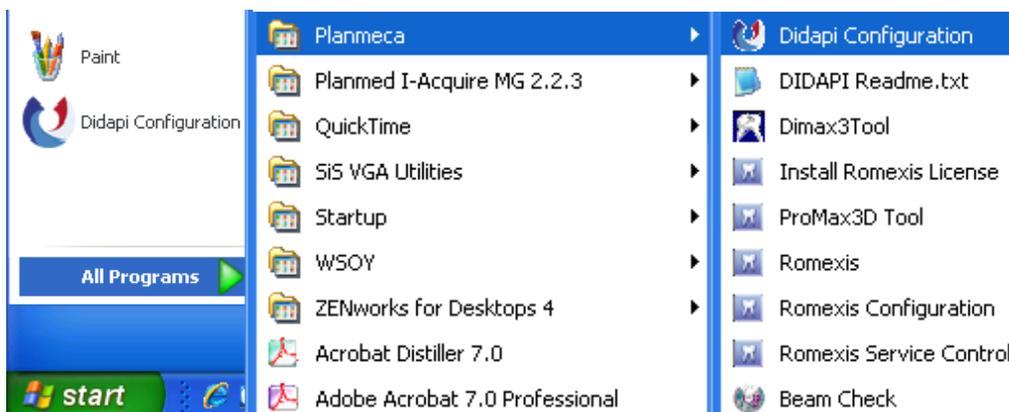


3. At the bottom of the ControlBox a small hole can be seen. To reset the default IP address insert an appropriate tool into the hole pushing it to the bottom.
4. The ControlBox indicator light starts to flash in yellow before switching to steady. Next, the steady green light comes on and switches to steady blue. This will take a few seconds.
5. Lift out the tool and reboot the ControlBox by unplugging and replugging the ControlBox cable.
6. Open the DidapiConfig software (see chapter 5 “USING THE DIDAPI CONFIGURATION SOFTWARE” on page 18).
7. Click **Open ProSensorEthernetConfig.txt** and enter the required information. By clicking the **Refresh** button the modifications will be updated in the address fields.

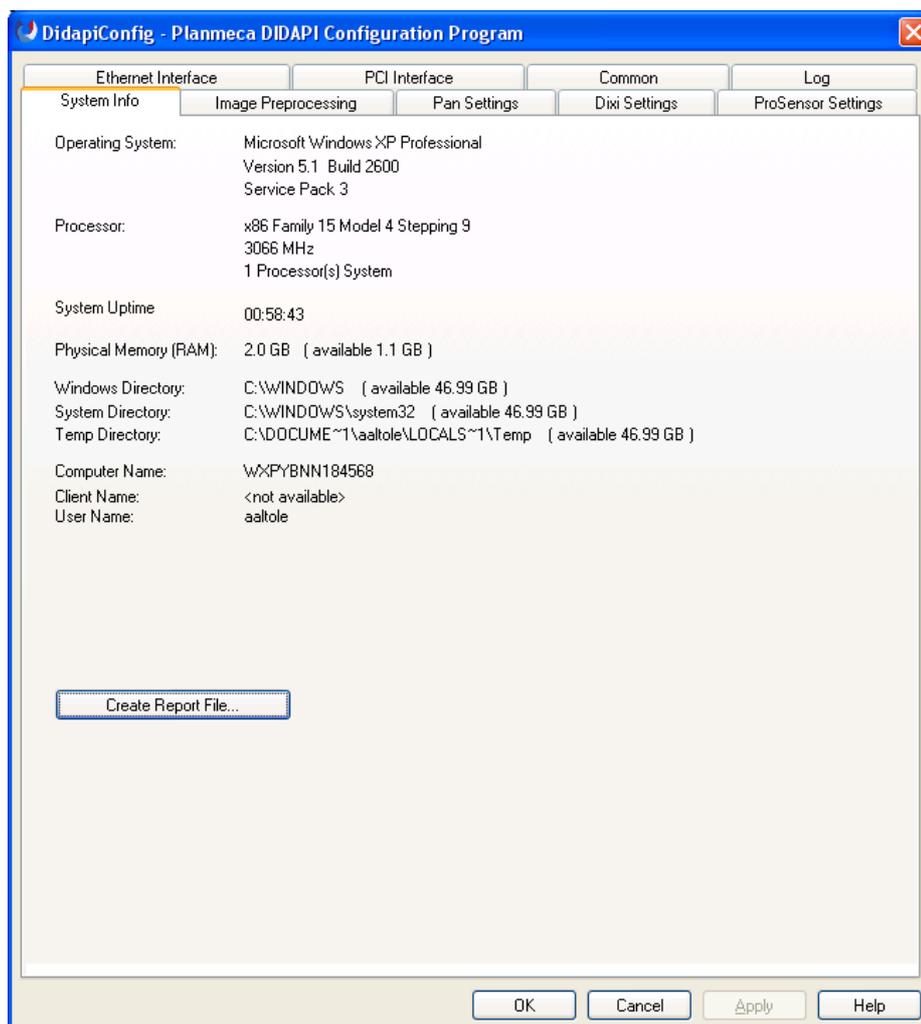
5 USING THE DIDAPI CONFIGURATION SOFTWARE

The Didapi Configuration is used to configure and monitor Planmeca device drivers. The DIDAPI Configuration software is automatically installed with the Romexis software.

1. Open the DIDAPI Configuration software by clicking *Start > Programs > Planmeca > Didapi Configuration*.



2. The **DIDAPI Configuration** tool will start and the *System Info* window appears.



5.1 Image Preprocessing

In this tab the parameters for intraoral images can be adjusted.

If the option *Auto Levels Enabled* is selected automatic adjustment is performed on the image when a new image is taken. In the *White(%)*(high) and *Black(%)*(low) fields percentage of the image tones to be cut in the ends of the histogram can be adjusted in order to gain reasonable contrast.

The *Midtones* value affects the gamma curve of the image. By adjusting the gamma value, you get an image that looks more like a conventional X-ray image.

By enabling the FMH filter an image can be filtered and sharpened.

For *Logarithmic Mapping* adjustment tick the respective checkbox and select the appropriate parameter from the drop-down menu. The logarithmic S-curves increases the contrast in the region of interest without clipping low or high values.

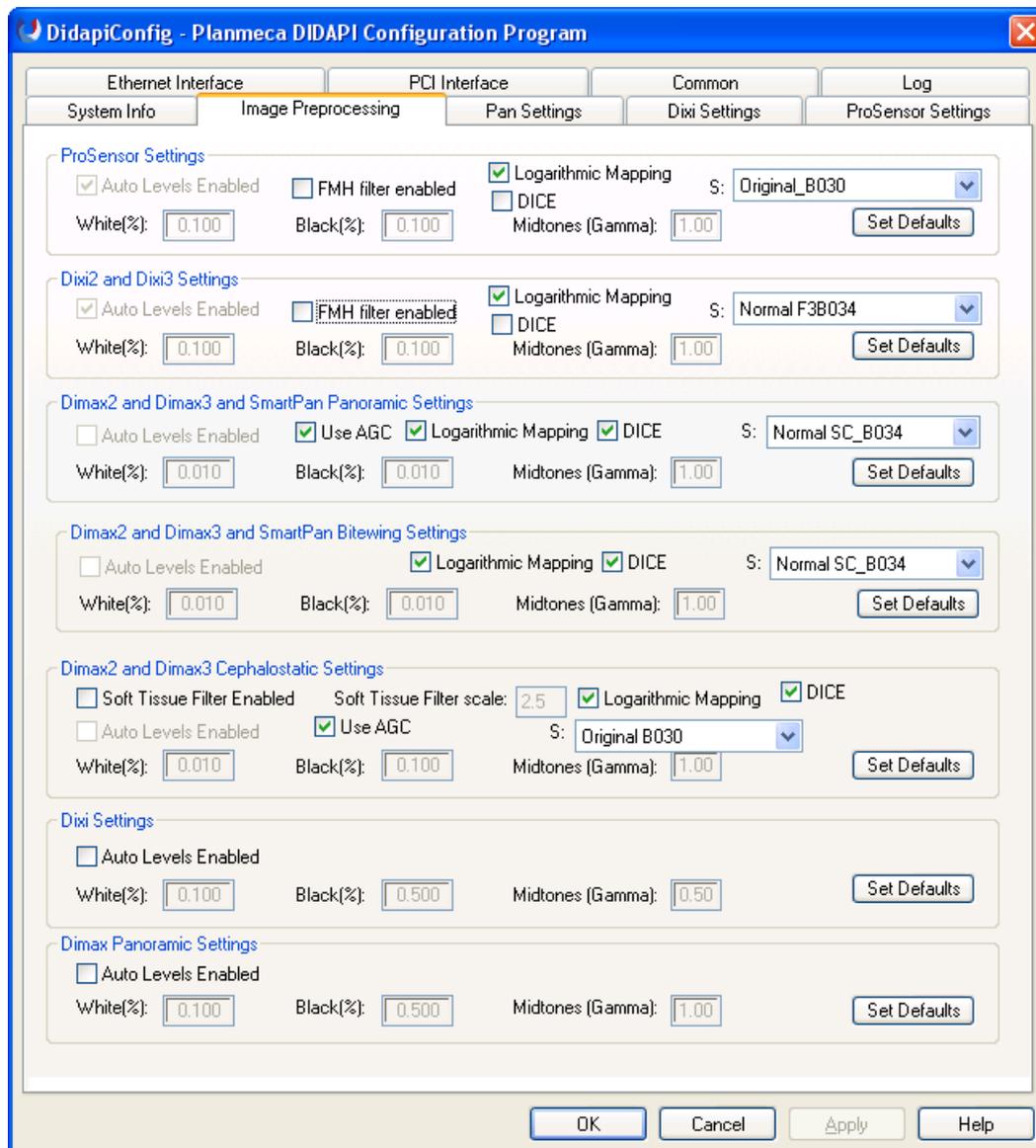
DICE (Dental Imaging Contrast Enhancement) is an image preprocessing method that suppresses low spatial frequencies in the image to bring out details in the image. You can set DICE on or off separately for different image modalities by checking the respective check box.

If the settings have been changed, the *Apply* button becomes active. To save the changed values click **Apply**. The recommended default settings can be restored by clicking the corresponding **Set Defaults** button.

Clicking *OK* quits the program and saves any changes made to the settings. Clicking *Cancel* quits the program without saving the changes.

USING THE DIDAPI CONFIGURATION SOFTWARE

The preprocessing performed by DIDAPI is permanent and can not be undone by Romexis. For more information on image preprocessing refer to Romexis Installation manual.



5.2 Configuring Planmeca ProSensor settings

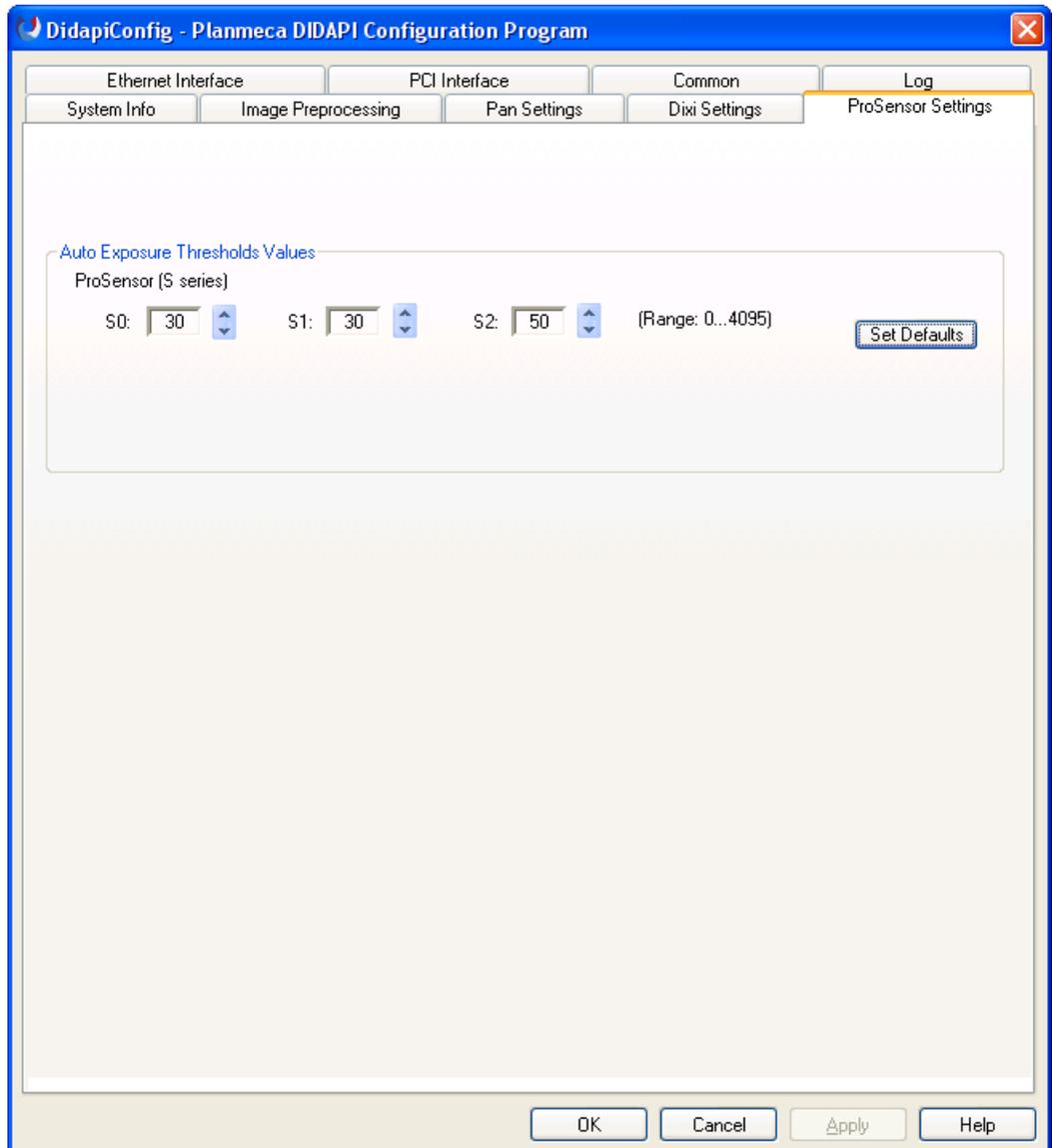
5.2.1 Auto exposure threshold values (Ethernet interface)

If the Planmeca ProSensor Digital Radiography System is used with some other intra oral X-ray unit than Planmeca Intra the sensor threshold values can be adjusted for the used X-ray unit. Change these values only if necessary.

The threshold value affects the detection sensitivity of the the start of exposure. Increase the threshold value if the sensor appears to be too sensitive, i.e. it triggers and takes exposures without radiation. Decrease the value if the sensor fails to detect an exposure.

If the settings have been changed, the *Apply* button becomes active. To save the new values click *Apply*. The factory default values can be restored by clicking the respective *Set Defaults* button.

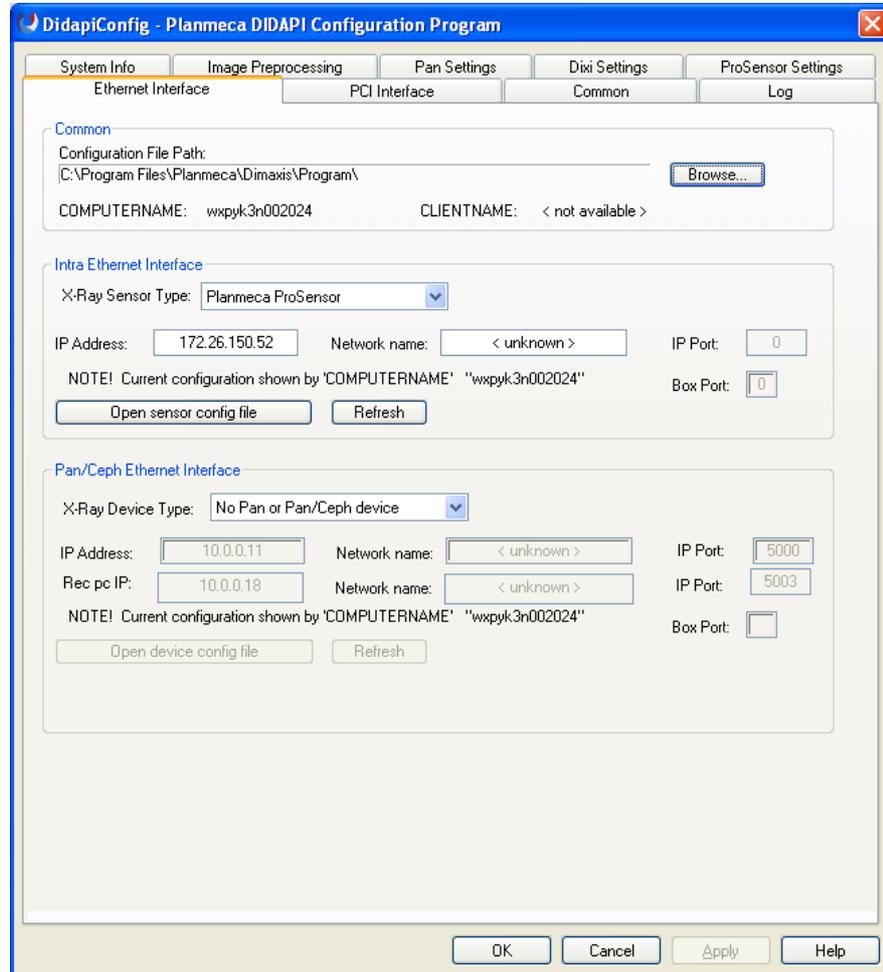
Clicking *OK* quits the program and saves any changes made to the settings. Clicking *Cancel* quits the program without saving any changes.



5.3 Configuring ProSensor ethernet interface

The ProSensor Ethernet Interface can be configured in the *Ethernet Interface* tab .

NOTE Make sure that the configuration file path is defined as *C:\Program Files\Planmeca\Dimaxis\Program*. If not, click *Browse* to select the correct path.



To perform the configuration:

1. Enter the ControlBox IP Address in the correct field and click **Apply**.
2. The default IP address is **172.26.150.150**, see also paragraphs 4.2.1 “Changing the ControlBox IP-address” on page 14 and 4.3 “Resetting the IP Address” on page 17.
3. Alternatively you can leave the *IP Address* field empty and enter the network name in the *Network name* field. It is not necessary to enter the IP address as well as the network name; by entering the IP address you will obtain the network name, and vice versa. All IP addresses do not necessarily have a network name.

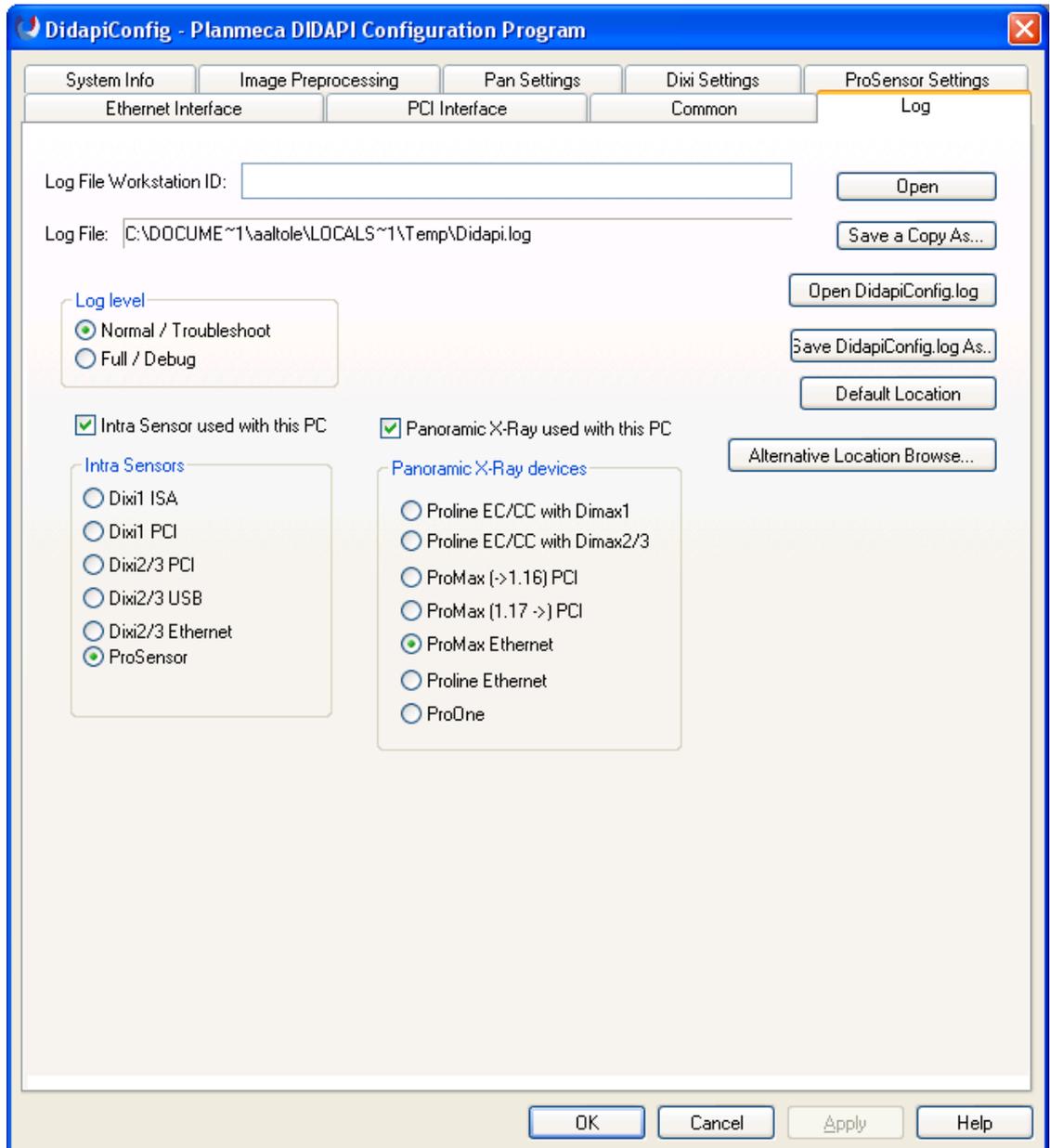
NOTE When using Planmeca ProSensor in the same PC with *Dixi PCI* or *USB* interface, imaging is performed with the Dixi sensor even though the Planmeca ProSensor has been configured. Choosing Dixi Ethernet will affect imaging only if *Dixi Ethernet* interface is being used.

5.4 Log

From the *Log* window the Didapi Log can be accessed and a copy of the log can be saved to the desired location. *Log File Workstation ID* sets the name of the current workstation's DIDAPI log file.

NOTE Check that the log file path has been defined.

The log file location can be changed from *Alternative Location Browser*. *Default Location* restores the default log file path.



The *Log level* setting determines how much information will be written to the log file. The *Log level* should be set to *Normal*. If set to *Full* it might be hard to find relevant information for troubleshooting.

If intraoral images are taken with this PC, check the option *Intra Sensor used with this PC* and select the *ProSensor Ethernet* intraoral sensor.

6 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.

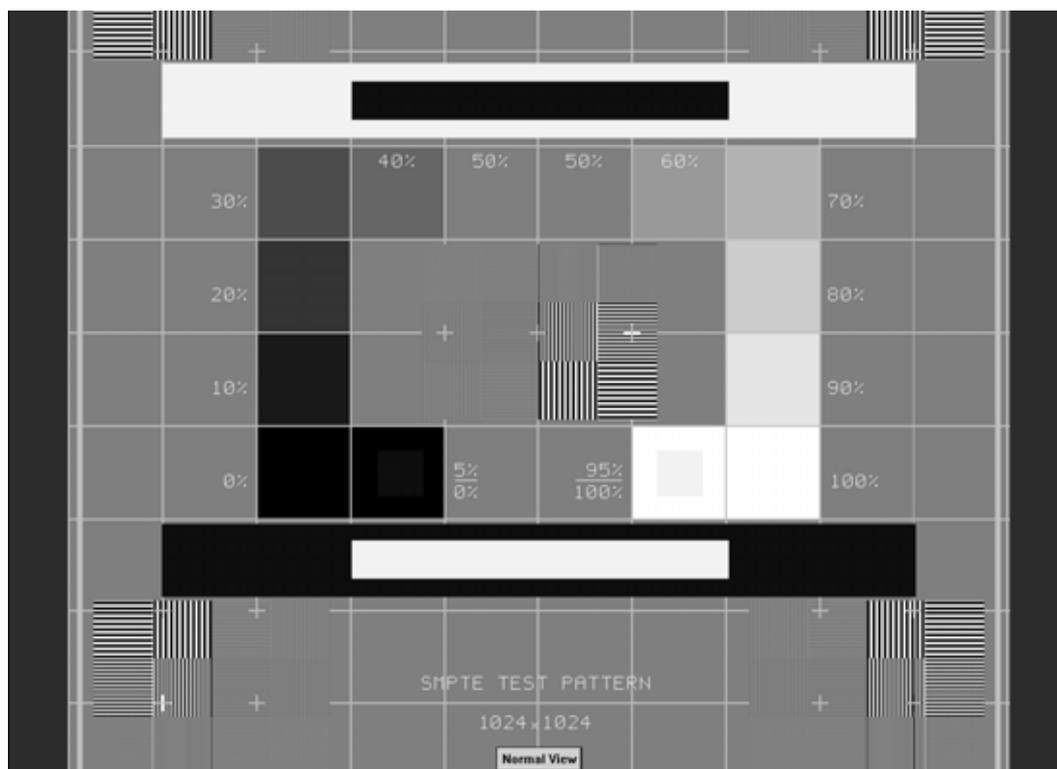
It is recommended to regularly monitor the image quality using the same phantom according to the requirements of local authorities.

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

6.1 Quality check using SMPTE test pattern

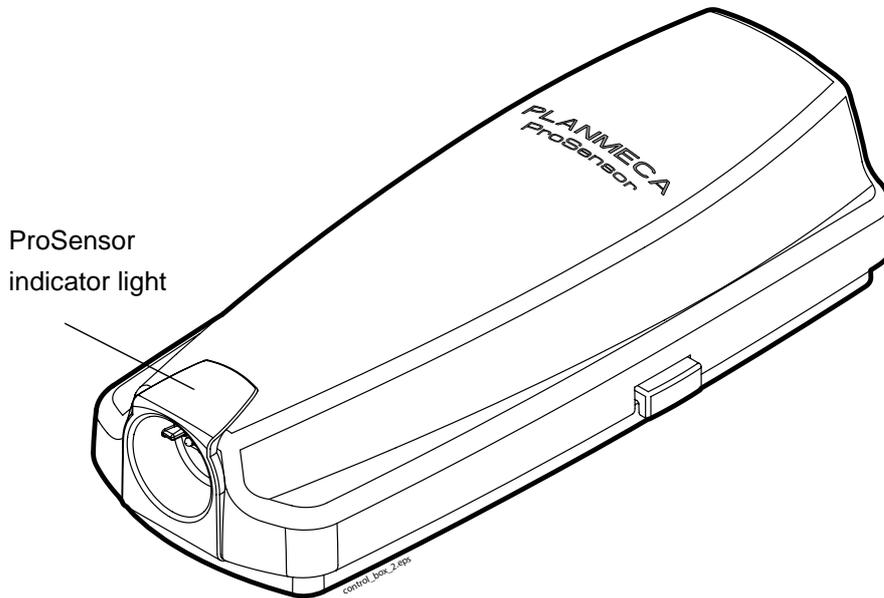
The test image is specified by the Society of Motion Picture and Television Engineers (www.smpte.org), and follows the SMPTE Recommended Practise RP 133-1991 Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras. This image should be used for 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 center must be visible, the vertical and horizontal lines must form undistorted squares and the homogenous gray background must not be coloured.



7 USING THE PLANMECA PROSENSOR SYSTEM

7.1 Planmeca ProSensor ControlBox



7.1.1 Planmeca ProSensor ControlBox indicator light

PLANMECA PROSENSOR STATUS	
Planmeca ProSensor system power off	controlbox indicator light is off
Planmeca ProSensor system is off (not in intraoral exposure-mode and the cable is connected to the ControlBox)	controlbox indicator light is dim blue
Planmeca ProSensor system is on (Imaging program communicates with the Planmeca ProSensor system)	controlbox indicator light is bright blue
Waiting for Ready	controlbox indicator light is blue and flashing slowly
Waiting for Exposure	controlbox indicator light is green and steady
The exposure is taken and image is transferred from the sensor to the ControlBox	controlbox indicator light is green and flashing rapidly
Error-mode	controlbox indicator light is red and steady
Service mode <i>Uploading ControlBox software</i>	controlbox indicator light is yellow and flashing slowly

NOTE The exposure can only be taken when the indicator light on the Planmeca ProSensor ControlBox is green and steady, not when the indicator light is flashing.

7.2 Image acquisition (Planmeca Intra X-ray unit with Romexis)

7.2.1 Preparing an intraoral exposure

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

1. Select the desired CMOS-sensor and connect it to the Planmeca ProSensor ControlBox.
2. Prepare and position the X-ray unit as specified in the user's manual. Select the exposure parameters according to the instructions specified in section 7.3 on page 32.

It is recommended to use a sensor holder, refer to the sensor holder manual supplied with the sensor holder package.

3. Select the correct sensor holder according to the exposure.

7.2.2 Capturing Intraoral Images

Intraoral images can be captured either as *single images* or into *study templates* containing a predefined set of multiple images.

Single images

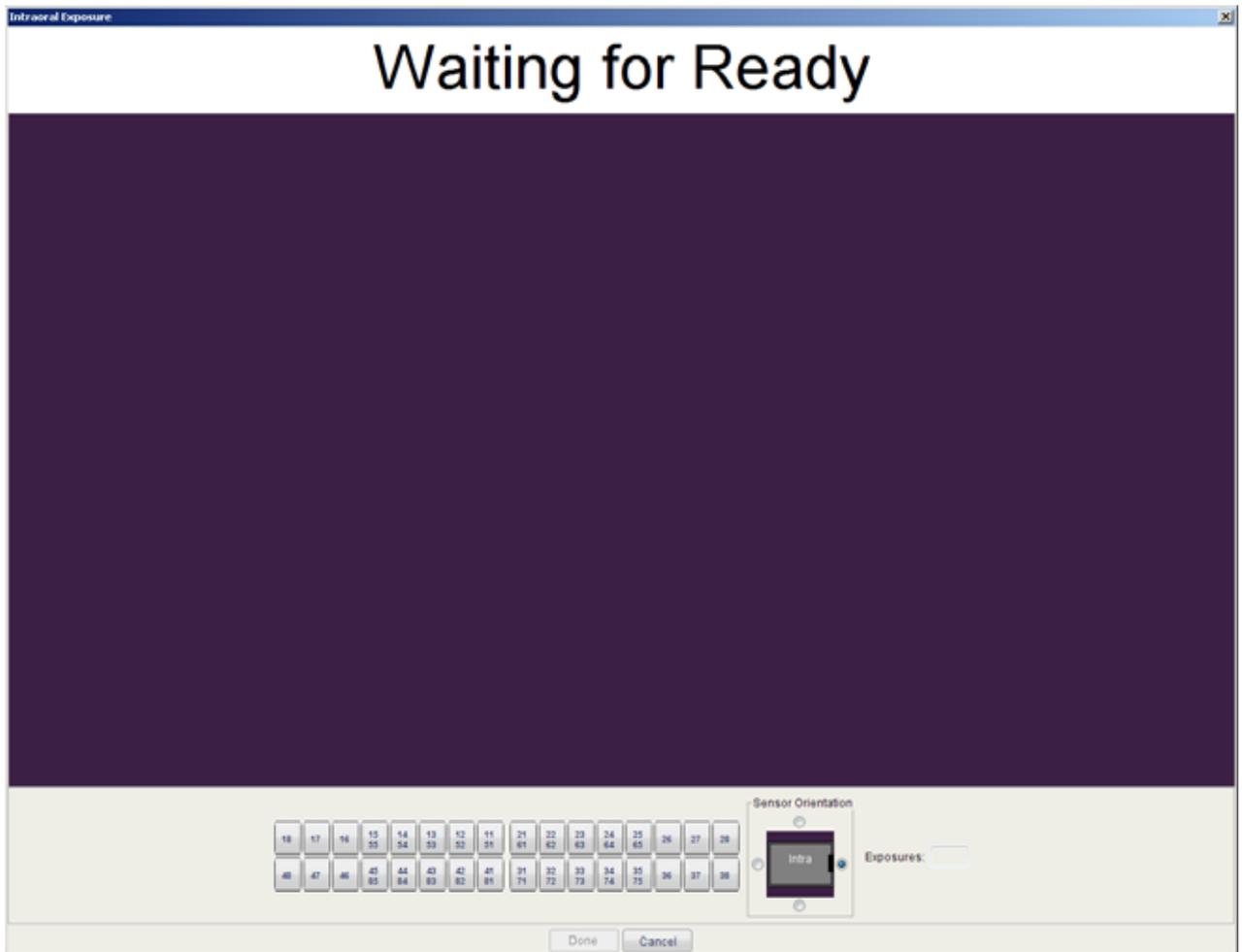
1. To capture an intraoral image click the *Intraoral Exposure* button on the upper toolbar to initiate the intraoral image capture mode.



Intraoral Exposure

2. The *Intraoral Exposure* window appears.

3. When the X-ray unit is in ready state a message *Waiting for Ready* appears on top of the window.



4. Prepare the patient for exposure, select exposure parameters and position Planmeca Intra as required, for more information refer to Planmeca Intra user's manual.
When the Planmeca ProSensor system is ready for exposure the message *Waiting for Exposure* appears on top of the window. You can now expose the X-ray as usual. After the exposure a message stating *Saving the image* appears on the display and the image is automatically stored into the database.
5. Define the tooth numbers and sensor orientation and take the next exposure, or click *Done* to return to the **Imaging module** when all exposures have been captured.

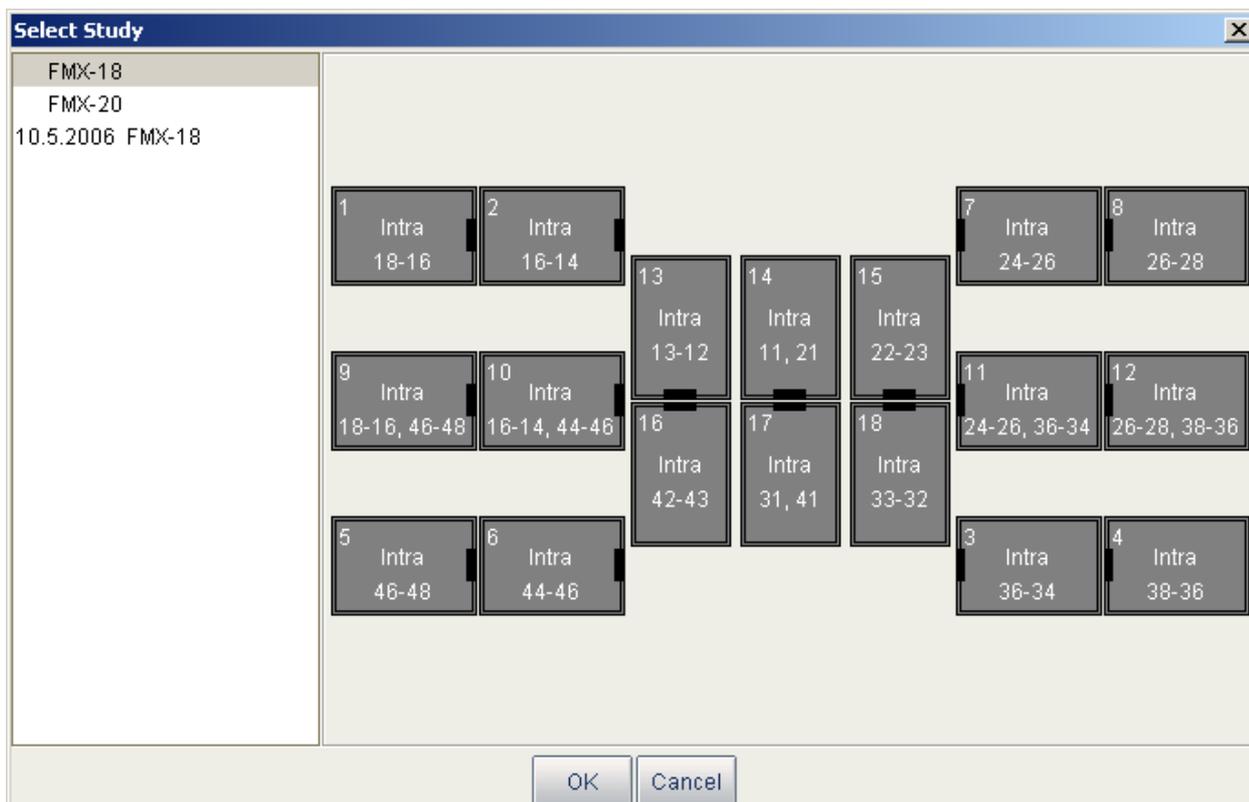
Template images



To capture intraoral images into a study template click this button.

1. Select the desired study template from the list.

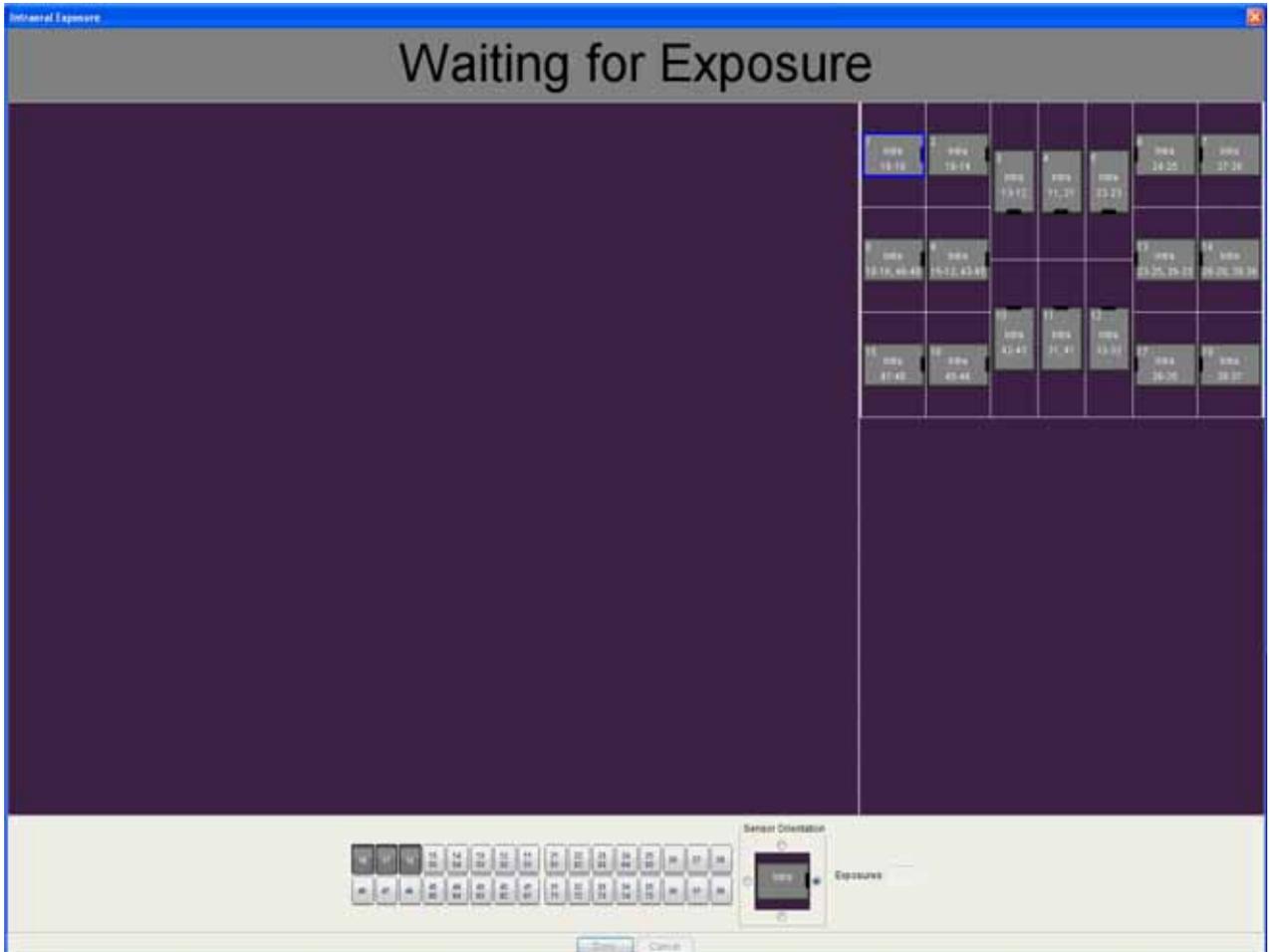
At the beginning of the list there are empty templates and at the bottom of the list there are studies with dates that already include images captured earlier.



USING THE PLANMECA PROSENSOR SYSTEM

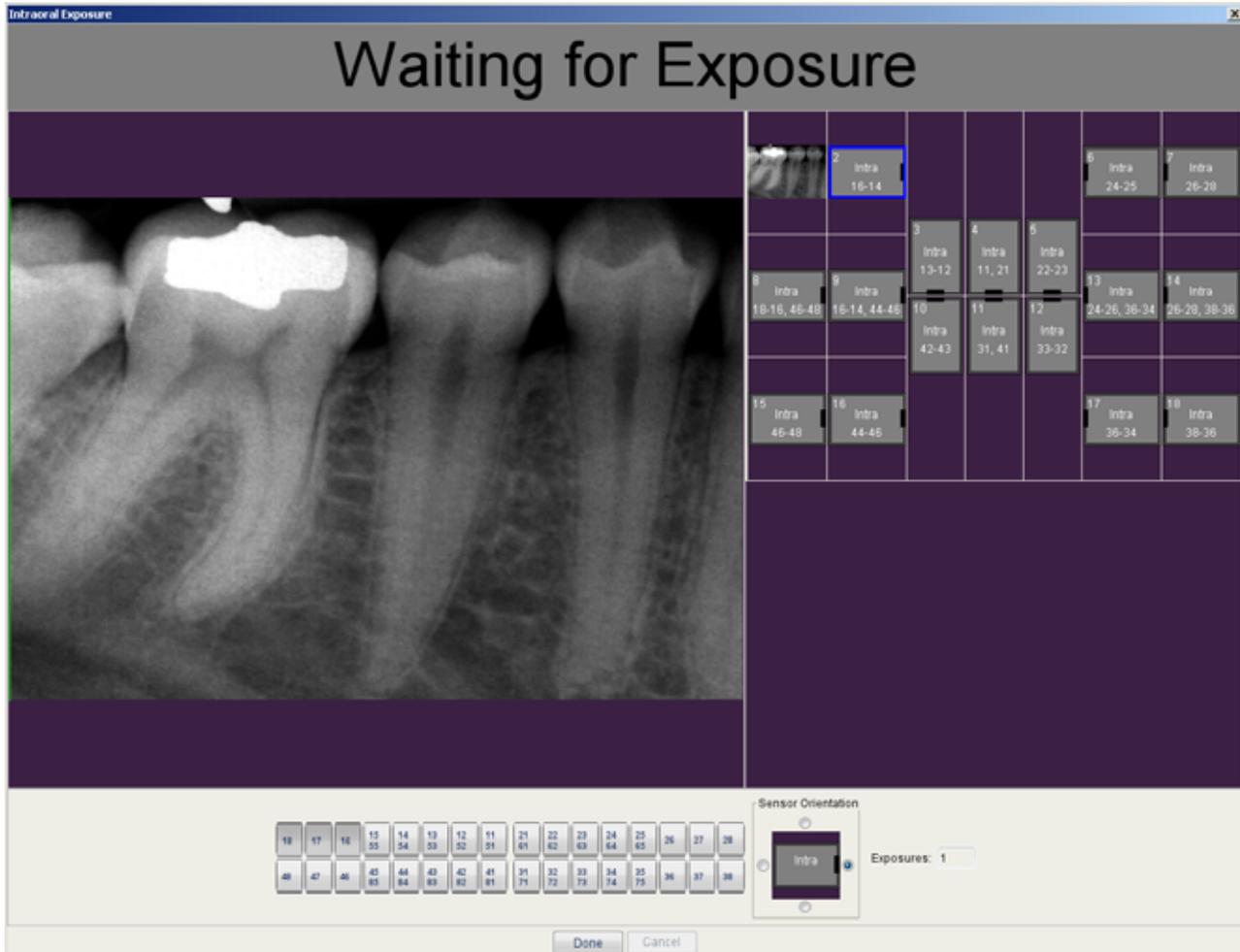
While capturing images using a study, Romexis navigates through the template in a predefined order, denoting the current image to be captured by a blue border around the slot.

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



USING THE PLANMECA PROSENSOR SYSTEM

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



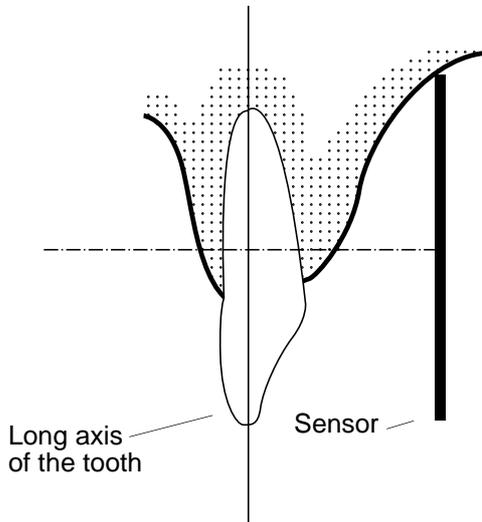
3. Once all images have been captured click *Done*.

7.2.3 Patient positioning

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

7.2.4 Positioning the sensor

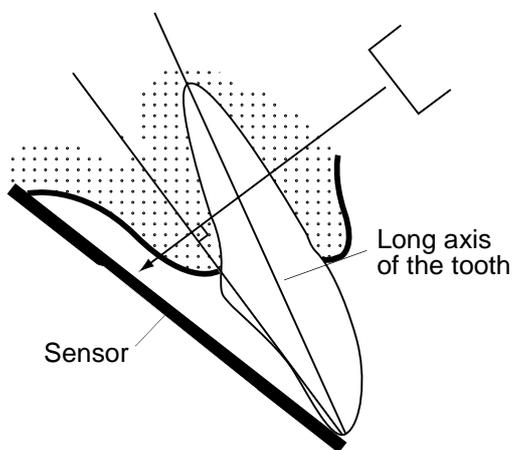
Paralleling technique (recommended)



The sensor is placed to a sensor holder which is used to align the sensor parallel to the long axis of the tooth.

Use a long cone for the paralleling technique.

Bisecting angle technique (optional)



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

The use of the plastic cover is not necessary because the sensor can be sterilized with liquid. The sterilization must be done after each patient.

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 Planmeca ProSensor system is ready for the exposure and communicates with Romexis (refer to section 7.1 "Planmeca ProSensor ControlBox" on page 25.

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

7.3 Exposure values for Planmeca ProSensor sensors

Select the digital imaging mode of the unit or adjust the exposure time according to the table.

NOTE In the digital imaging mode the highest time value that can be selected is 0.80 seconds.

Exposure values for ProSensor sensors with 20 cm (8") cones

TIME	0.01s	0.02s	0.03s	0.04s	0.05s	0.06s	0.08s	0.10s	0.12s	0.16s	0.20s	0.25s	0.32s	0.40s	0.50s	0.64s	0.80s
70 kV/ child		I	P	M	maxilla												
	I	P	M	mandible													
66 kV/ child			I	P	M	maxilla											
		I	P	M	mandible												
63 kV/ child			I	P	M	maxilla											
			I	P	M	mandible											
60 kV/ child				I	P	M	maxilla										
				I	P	M	mandible										
57 kV/ child					I	P	M	maxilla									
					I	P	M	mandible									
55 kV/ child						I	P	M	maxilla								
						I	P	M	mandible								
52 kV/ child							I	P	M	maxilla							
							I	P	M	mandible							
50 kV/ child								I	P	M	maxilla						
								I	P	M	mandible						
70 kV/ adult				I	P	M	maxilla										
				I	P	M	mandible										
66 kV/ adult					I	P	M	maxilla									
					I	P	M	mandible									
63 kV/ adult					I	P	M	maxilla									
					I	P	M	mandible									
60 kV/ adult						I	P	M	maxilla								
						I	P	M	mandible								
57 kV/ adult							I	P	M	maxilla							
							I	P	M	mandible							
55 kV/ adult								I	P	M	maxilla						
								I	P	M	mandible						
52 kV/ adult									I	P	M	maxilla					
									I	P	M	mandible					
50 kV/ adult										I	P	M	maxilla				
										I	P	M	mandible				

I INCISORS
P PREMOLARS AND CANINES
M MOLARS

Exposure values for Planmeca ProSensor sensors with 30 cm (12") cones

TIME	0.01s	0.02s	0.03s	0.04s	0.05s	0.06s	0.08s	0.10s	0.12s	0.16s	0.20s	0.25s	0.32s	0.40s	0.50s	0.64s	0.80s	
70 kV/ child					I	P	M	maxilla										
				I	P	M		mandible										
66 kV/ child					I	P	M	maxilla										
					I	P	M		mandible									
63 kV/ child							I	P	M	maxilla								
						I	P	M		mandible								
60 kV/ child								I	P	M	maxilla							
							I	P	M		mandible							
57 kV/ child									I	P	M	maxilla						
								I	P	M		mandible						
55 kV/ child										I	P	M	maxilla					
									I	P	M		mandible					
52 kV/ child											I	P	M	maxilla				
										I	P	M		mandible				
50 kV/ child												I	P	M	maxilla			
											I	P	M		mandible			
70 kV/ adult							I	P	M	maxilla								
						I	P	M		mandible								
66 kV/ adult								I	P	M	maxilla							
							I	P	M		mandible							
63 kV/ adult									I	P	M	maxilla						
								I	P	M		mandible						
60 kV/ adult										I	P	M	maxilla					
									I	P	M		mandible					
57 kV/ adult											I	P	M	maxilla				
										I	P	M		mandible				
55 kV/ adult												I	P	M	maxilla			
											I	P	M		mandible			
52 kV/ adult										maxilla				I	P	M		
										mandible			I	P	M			
50 kV/ adult										maxilla				I	P	M		
										mandible			I	P	M			

I INCISORS
P PREMOLARS AND CANINES
M MOLARS

8 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.

9 CLEANING

NOTE Before cleaning the system, always check that the X-ray unit and the Planmeca ProSensor system are off (Planmeca ProSensor ControlBox indicator light is off).

9.1 Surfaces

The surfaces can be cleaned with a soft cloth dampd in a mild cleaning solution.

Stronger cleaning agents can be used for disinfecting the surfaces. We recommend Dürr System-hygiene FD 333 or respective disinfecting solution.

9.2 Sensors and cables

Planmeca ProSensor sensors allow enhanced infection control in the surgery.

As the sensor casing is hermetically sealed the sensors can be immersed in disinfectant solution.

NOTE Always use appropriate instruments for cleaning the sensors.

NOTE It is mandatory to carefully follow the disinfecting and cleaning recommendations in order to not damage the sensors.

CAUTION *The sensors cannot be sterilized in autoclave or UV oven.*

Wipe up the sensor surface with a soft cloth damped into a disinfectant solution. The sensors can be soaked in a disinfection solution as long as there are no nicks in the cable.

The recommendable disinfectant solutions are Dürr System Hygiene FD 322 or FD 333 or similar product. The immersion time with the Dürr disinfectants is 2 minutes.

If more effective disinfection or cold sterilization is preferred for cleaning, we recommend the Johnson&Johnson Cidex Opa high level disinfectant at a minimum temperature of 20° C with maximum immersion time of 8 minutes for a reuse period not to exceed 14 days.

NOTE Follow carefully the manufacturer's recommendations on immersion time and recommended disinfectant liquids.

Do not leave the sensor in the disinfection solution overnight. The magnetic connector of the sensor cable should not be soaked.

CLEANING

- Use a new disposable protection cap for every sensor usage.
- Wipe up the sensor surface with a compress moisten into a sterile solution.

NOTE The sensor connector can be cleaned using a soft cloth.

9.3 Sensor holders

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

9.4 Planmeca ProSensor ControlBox

The ControlBox 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.

10 DISPOSAL OF THE PLANMECA PROSENSOR SYSTEM

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 materials 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.

11 TECHNICAL SPECIFICATIONS

Sensor

Sensor type	CMOS with scintillator	
Sensor dimensions:		
Size 0	overall	33.6 x 23.4 mm (1.33 x 0.92 in.)
	active area	25.5 x 18.9 mm (1,00 x 0,74 in.)
	number of pixels	850 x 629
	view delay	<5 sec.
Size 1	overall	39.7 x 25.05 (1.56 x 0.99 in.)
	active area	31.5 x 20.7 (1.24 x 0.81 in.)
	number of pixels	1050 x 690
	view delay	<5 sec.
Size 2	overall	44.1 x 30.4 mm (1,74 x 1.2 in.)
	active area	36 x 26.1 mm (1,74 x 1,2 in.)
	number of pixels	1200 x 870
	view delay	<5 sec.
Resolution	17 lp/mm	
Theoretical resolution	33 lp/mm	
Cable length	0.86 m (33.9 in.) or 2.0 m (78.7 in.)	

Ethernet ControlBox

Dimensions	112 x 46 x 24 mm (4.41 x 1.81 x 0.94 in.)
Power supply	48 V DC 65 mA

Cables

ControlBox to PoE	RJ45 10m OR 15m
PoE to LAN	RJ45 10m OR 15m
Power supply	Phihong Single Port Injector Type: PSA16U-480 (POE) Input voltage 100-240 VAC (50-60 Hz) Output voltage 48VDC Max. output current 0.35 A Insulation voltage Primary-secondary 3000VDC

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 or 5m (6.6 or 16.4 ft)

Operating environment

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 %.

Transportation and Storage Environment

Transportation and storage temperature -5°C - +60°C.

Relative humidity during transportation and storage should not exceed 60 %.

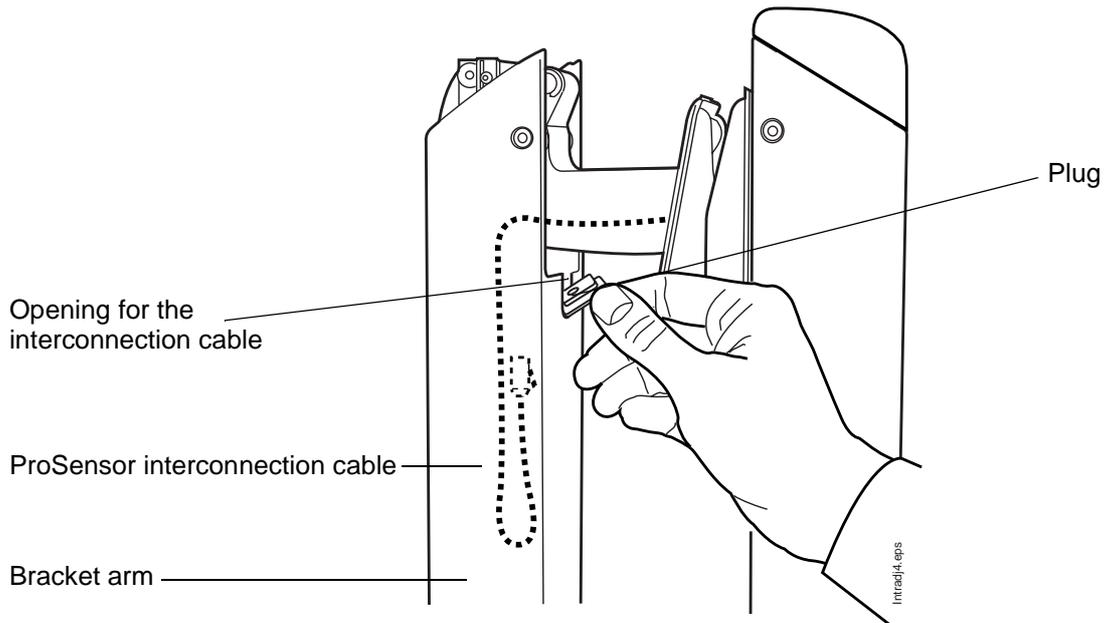
APPENDIX A: INSTALLING PLANMECA PROSENSOR SYSTEM TO PLANMECA INTRA X-RAY UNIT

1.1 Installing the ControlBox to the bracket arm

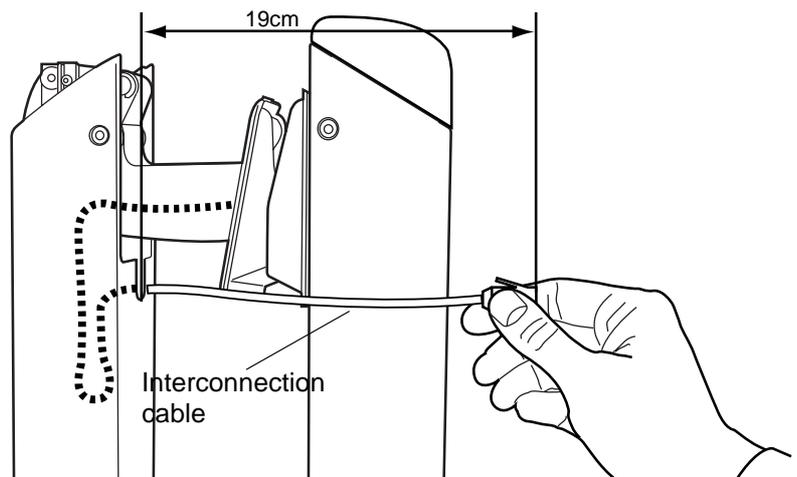
NOTE These instructions apply for Ethernet installation.

The ProSensor interconnection cable is routed into the Planmeca Intra bracket arm at the factory.

1. Remove the cable opening plug on the bracket arm.



2. Pull out the interconnection cable for approx. 19 cm (7.5 in.) as shown in the figure below.

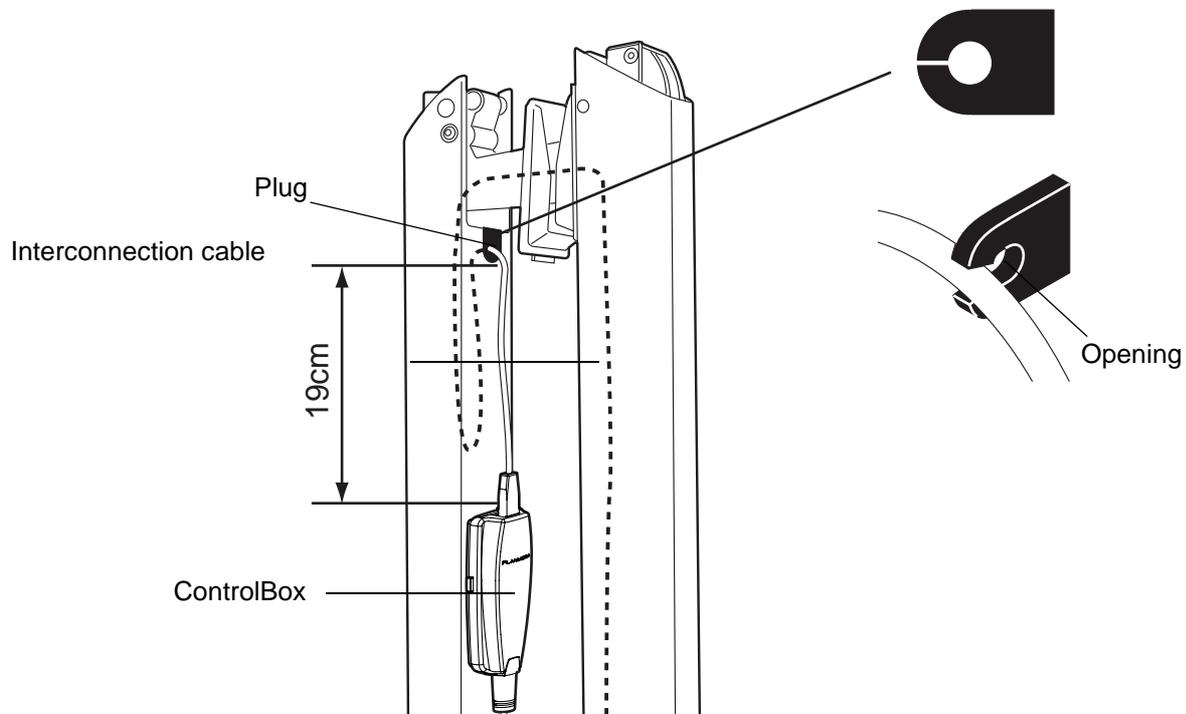


3. To ensure that the interconnection cable moves freely as the bracket arm moves, route the cable through the bracket arm as shown in the following figure.
4. Cut the plug and attach it to the cable. Reattach the plug to the bracket arm opening.

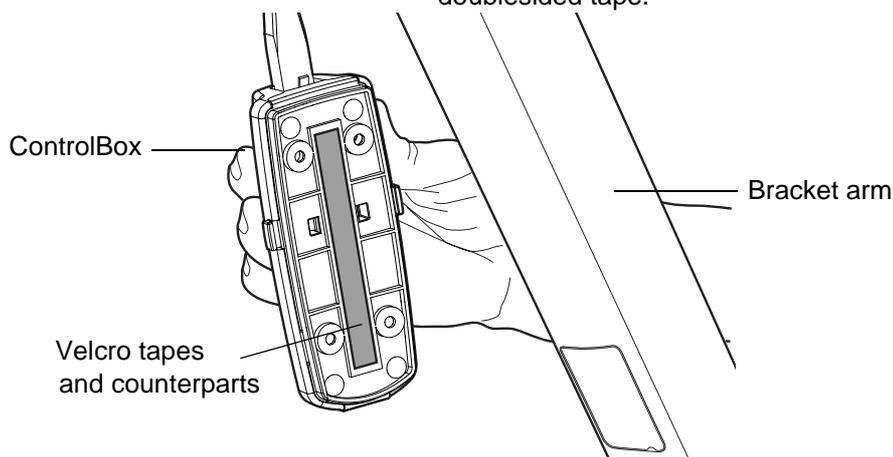
INSTALLING PLANMECA PROSENSOR SYSTEM TO PLANMECA INTRA X-RAY UNIT

NOTE The plug is cut on the rounded end. Remove the cap from the opening before assembling the plug to the cable.

5. Attach the velcro tapes under the ControlBox.
6. Clean the bracket arm properly with pure alcohol.
7. Connect the interconnection cable and attach the ControlBox to the arm.



8. Connect the sensor cable to the ControlBox and attach the sensor holder to the tube head support with doublesided tape.



1.2 Connecting the interconnection cable (Planmeca Intra X-ray Unit)

The interconnection cable is routed through the Planmeca Intra extension arm and out from the generator box, single stud adapter, ceiling arm or through the Planmeca Compact dental unit. For more information see *Planmeca Intra X-ray unit installation manual*, publication number 10006030.

APPENDIX B: EMC INFORMATION



WARNING

Use of any accessories and cables other than those specified in ProSensor Digital Radiography System documentation, with exception of cables sold by Planmeca as replacement parts for internal components, may result in increased emission or decreased immunity of the system



WARNING

ProSensor Digital Radiography System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ProSensor Digital Radiography System should be observed to verify normal operation in configuration which it will be used.

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

EMC INFORMATION

Guidance and manufacturer's declaration - electromagnetic immunity			
ProSensor Digital Radiography System is intended for use in the electromagnetic environment specified below. The customer or the user of ProSensor Digital Radiography System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Not Applicable Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of ProSensor Digital Radiography System requires continued operation during power mains interruptions, it is recommended that ProSensor Digital Radiography System be powered from an uninterruptible power supply.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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

Recommended separation distances between portable and mobile RF communications equipment and ProSensor Digital Radiography System			
<p>ProSensor Digital Radiography System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ProSensor Digital Radiography System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ProSensor Digital Radiography System as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.2	0.2	0.3
0.1	0.4	0.4	0.7
1	1.2	1.2	2.4
10	4.0	4.0	8.0
100	12.0	12.0	24.0

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