CRANEX D

Digital Panoramic and Cephalometric X-ray Unit

(Version 3)

User's Manual

Number 203371 rev. 1 (0812)

EN

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Digital Panoramic and Cephalometric X-ray Unit

(Version 3)

User's Manual

CE
0537

Medical Device Directive
93/42/EEC

Number 203371 rev. 1 (0812)
Original approved English language version

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Contents

1. Introduction

1.1 Cranex D digital X-ray unit

The **Cranex D** is a digital dental x-ray unit designed to take images of the dento-maxillo-facial complex of the human skull. It can be used to take:

- adult panoramic exposures,
- child panoramic exposures (reduced width and height),
- partial panoramic exposures
- sinus exposures,
- and TMJ exposures.

An optional cephalometric device allows ceph and carpus (not USA) exposures to be taken.

Both the unit and the cephalometric device use CCD sensors as the image receptor and a PC with the **User Interface** and suitable dental imaging software, such as Digora for Windows (not in USA), to handle the digital dental images.

1.2 About this manual

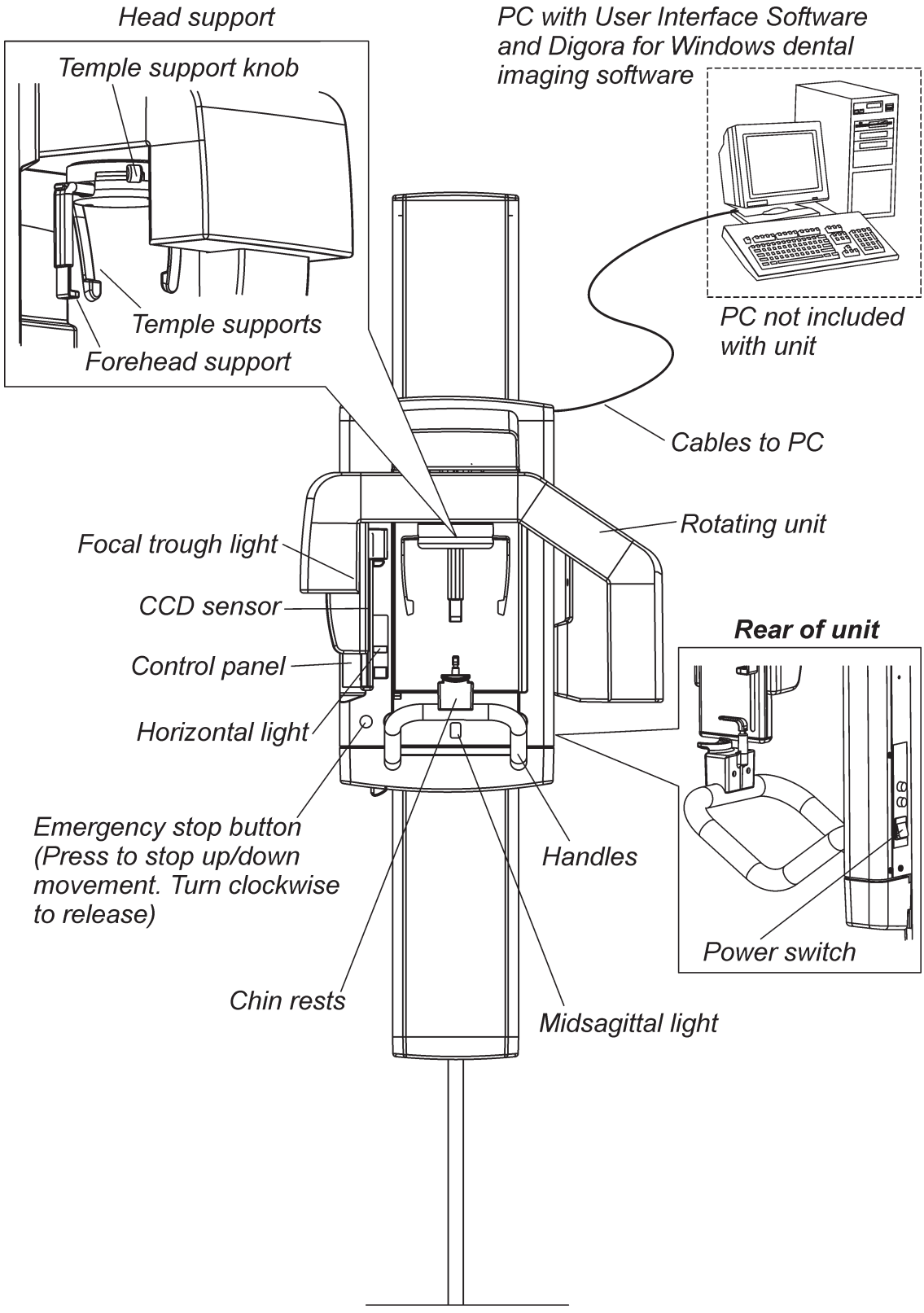
This manual describes how to use the **Cranex D** digital dental x-ray unit and the optional cephalometric device.

Please read these instructions and the Warnings and Precautions in section “11. Warnings and Precautions”, before operating the unit.

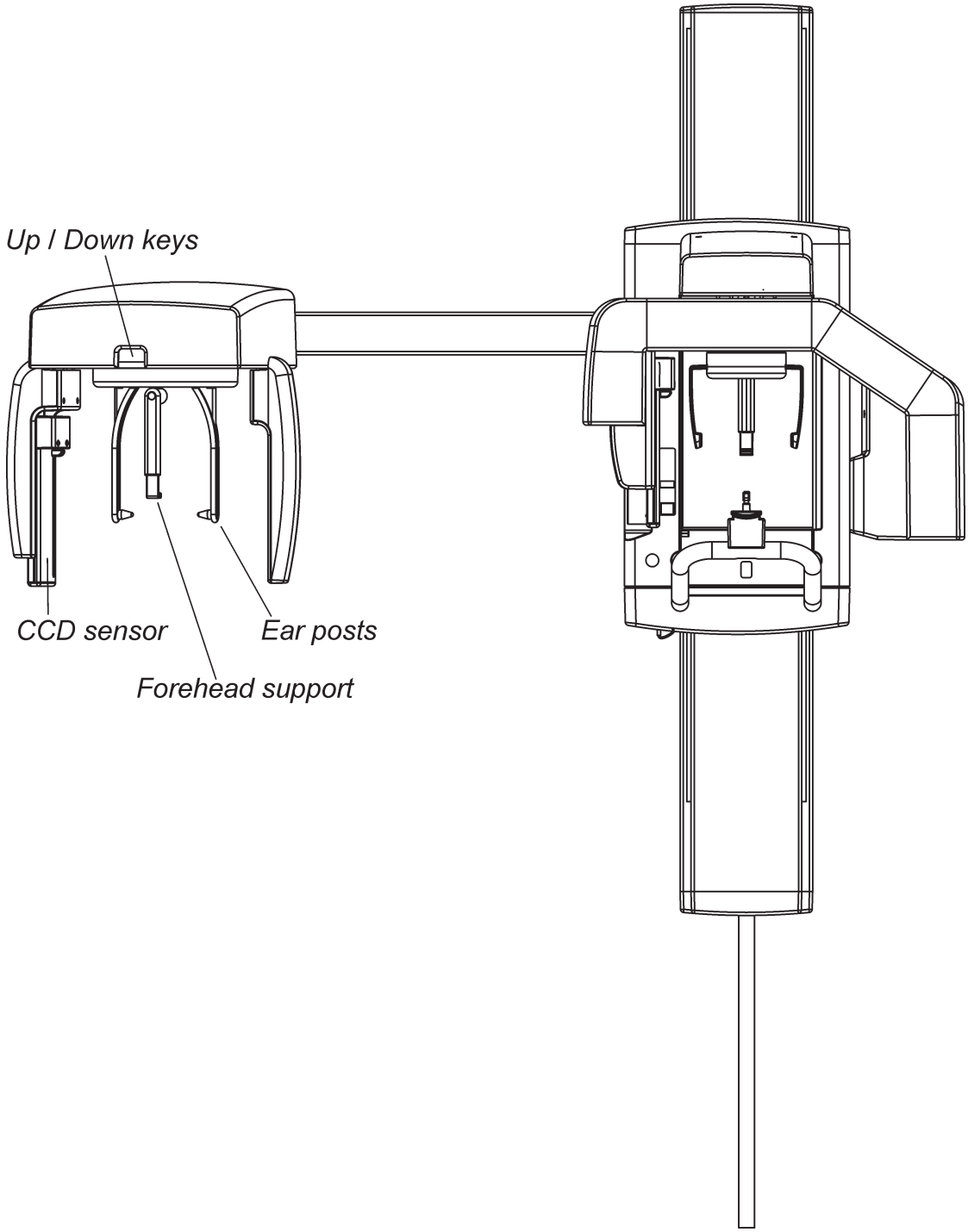
NOTE:
Instructions starting with **PC**: for example:
“1. **PC**: Open a patient card” indicate that the task is carried out from the PC.
Instructions NOT starting with PC: for example:
“3. Close the head supports” indicate that the task is carried out from the UNIT.

2. Unit description

2.1 Cranex D

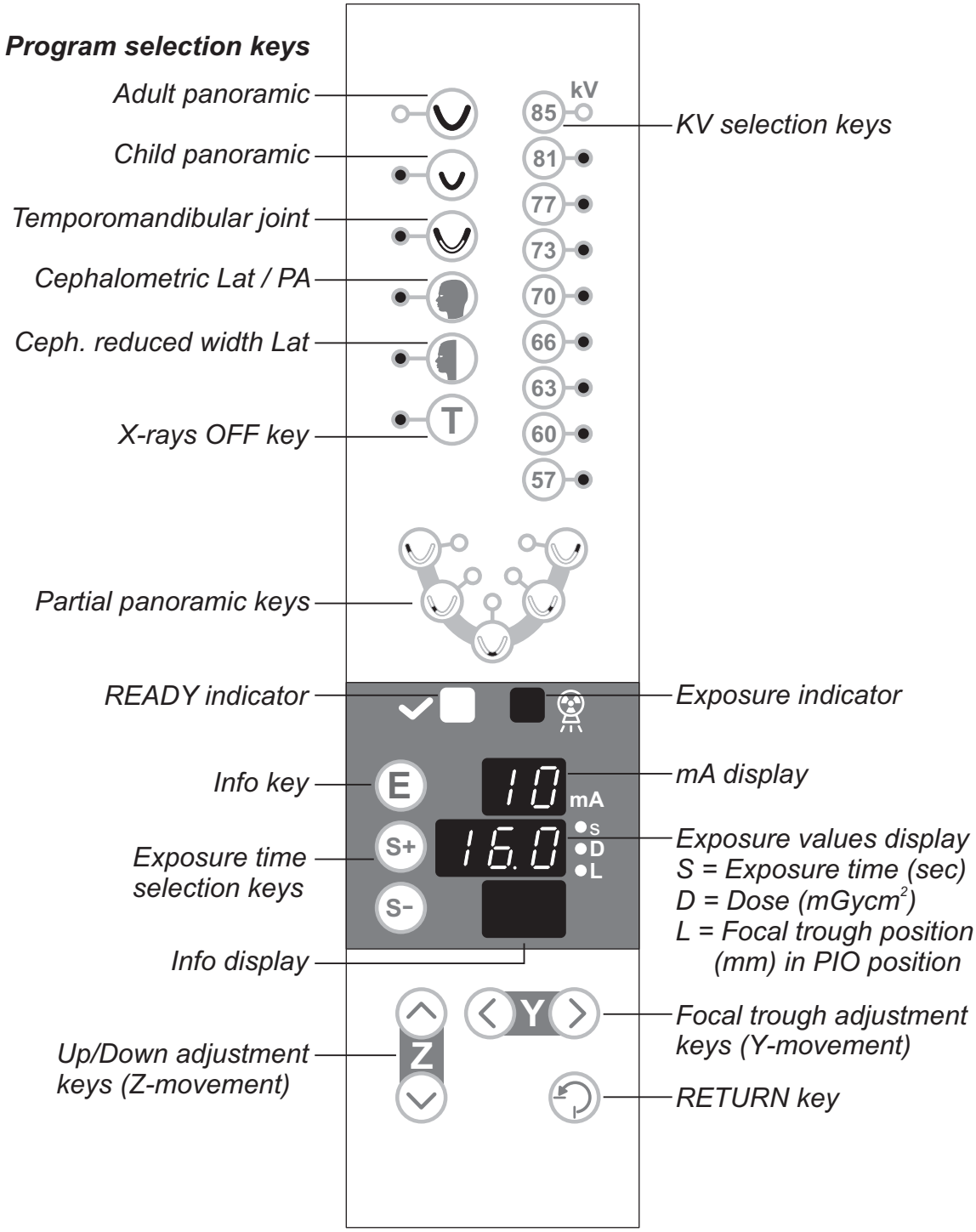


2.2 Optional cephalometric device

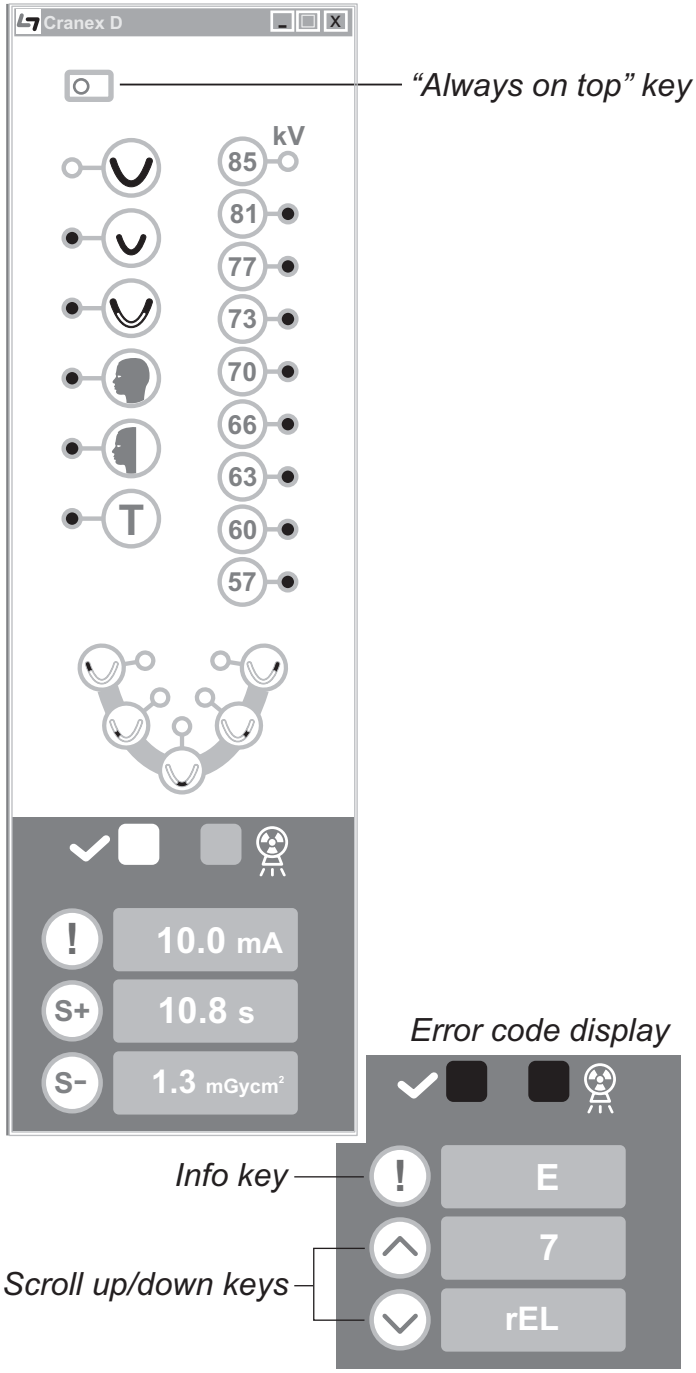


2.3 Control panel

Either the control panel or the user interface (2.4) can be used to select the imaging programs and exposure factors.

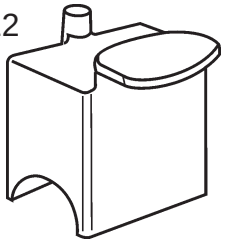


2.4 User interface



2.5 Accessories

Chin rest - 9802612

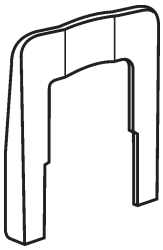


Disposable cover for chin rest - 6801140

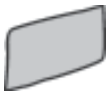
Bite block - 6811860

Disposable cover for bite block - 6801120

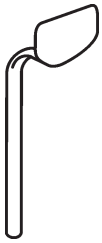
Lip support - 6811880



Disposable cover for lip support - 6801130



Lip holder - 6811870



Disposable covers for cephalometric ear cones - 6801150

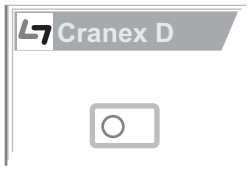
3. Taking Panoramic Exposures

3.1 Preparing the PC

1. **PC:** Switch on the PC that is connected to the unit.

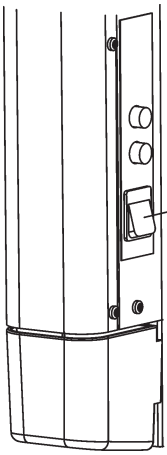
2. **PC:** Open the dental imaging software and then open a new or existing patient card for the patient. For information on how to do this refer to the user's guide supplied with the dental imaging software.

NOTE:
PC: If you wish to use the User Interface to select the program and exposure factors, click the CRANEX D Gui icon to open the User Interface.



PC: If you want the User Interface Window to remain visible, and always on top of other windows, click the "Always on top" key.

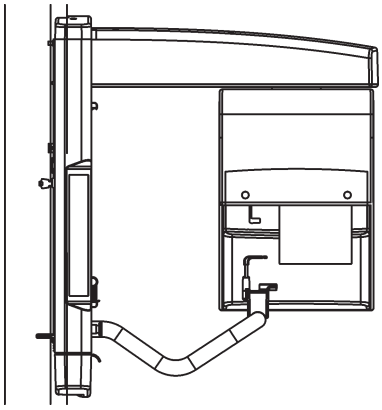
3.2 Preparing the Unit



1. Attach the CCD sensor to the sensor holder on the rotating unit if it is not already attached. For information on how to attach and remove the CCD sensor, see section "**7 Attaching and removing the CCD sensor**".

2. Press the ON / OFF switch, on the rear, right-hand side of the unit, to the on position (I) to switch the unit on. The unit will carry out a self test during which the display lights will come on.

3. Press the RETURN key to drive the rotating unit to the patient-in-out (PIO) position.



The READY light will come on and rotating unit will automatically move to the 0 mm focal trough position.

If the READY light does not come on refer to section "**10.1 Error messages**".

3.3 Taking a panoramic exposure

Selecting the panoramic program

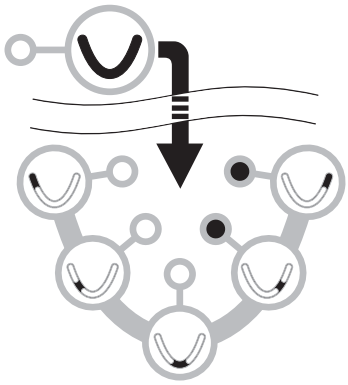
1. Select the exposure time you require.
   Press the **S+** key for the fast exposure time or the **S-** key for the standard exposure time. The selected exposure time will appear on the exposure values display.

   NOTE:
   When the unit is in the PIO position the exposure time will only appear briefly on the display when an S key is pressed.

2. Select the required panoramic program.
   The programs are:

Adult panoramic - magnification 1.34
Exposure time; standard 17.6 s or fast 11 s.

Child panoramic - magnification 1.34
Exposure time; standard 13.8 s or fast 8.6 s.



Partial panoramic exposures - magnification 1.34
Select the Adult panoramic program. All the partial panoramic indicator lights will come on.

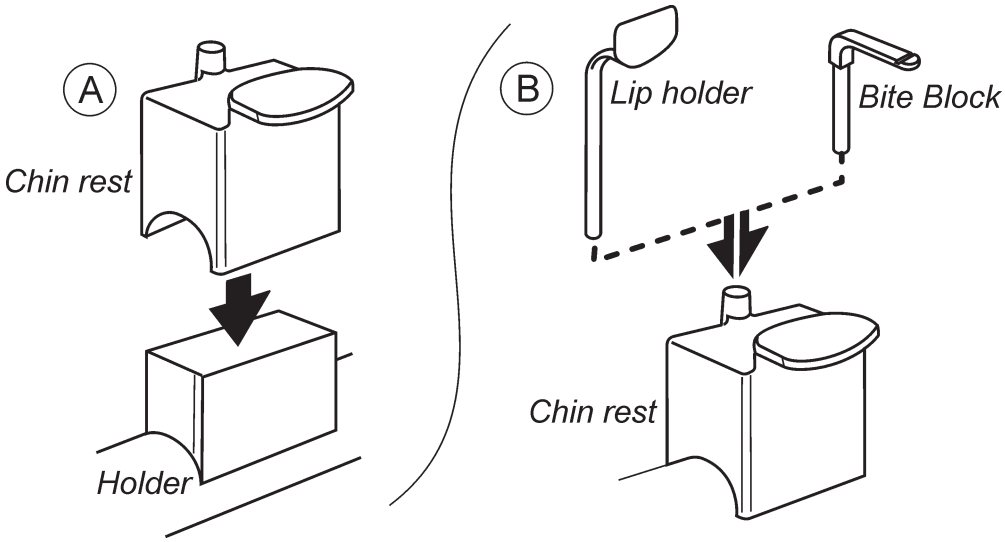
Select the first sector you wish to expose. The indicator light for this sector will stay on and all the other sector lights will go out. Select the other sectors you wish to expose.

Exposure times;
standard, 3.1 s - 4 s - 7.6 s - 4 s - 3.1 s
or fast, 1.9 s - 2.5 s - 4.8 s - 2.5 s - 1.9 s

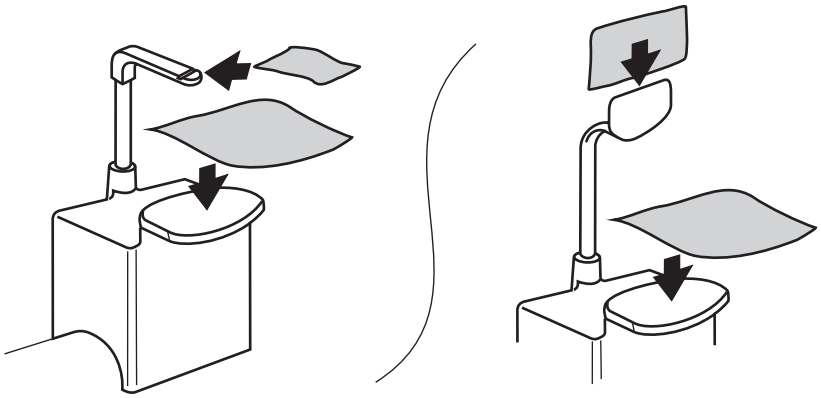
Positioning the patient for a panoramic exposure

NOTE:
If the patient appears nervous you may want to reassure the patient by demonstrating how the unit works. To do this see section "**6. Using the unit without x-rays**".

1. Slide the chin rest on to the holder at the front of the patient handles (A).
   If the patient is **DENTATE** slide the bite block into the chinrest (B). If the patient is **EDENTULOUS** slide the lip holder into the chin rest.



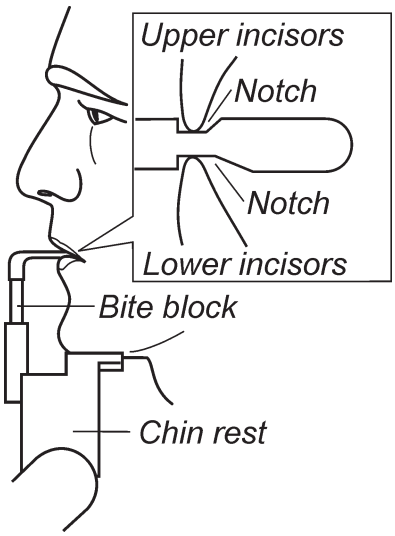
2. Place the appropriate disposable covers on the chin support you are using.



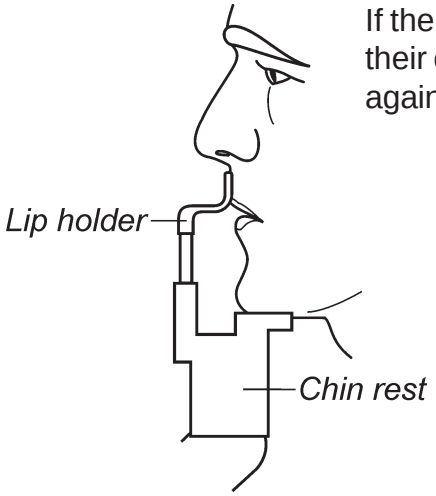
3. Ask the patient to remove any spectacles and false teeth and any jewellery or metal objects from their face, ears or neck. Also ask them to remove any hair clips or pins.

4. Place a protective lead apron over the patient's shoulders.

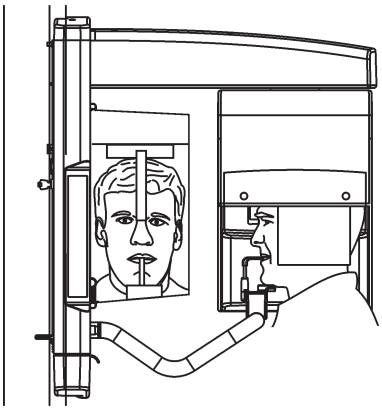
5. Press the height adjusting keys to adjust the height of the chin support until it is slightly higher than the patient's chin.



6. If the patient is **DENTATE** ask them to grasp the patient handles, place their chin on the chin rest and bite the bite block.
The biting edges of the patient's upper and lower incisors must be positioned in the respective notches in the top and bottom of the bite block.



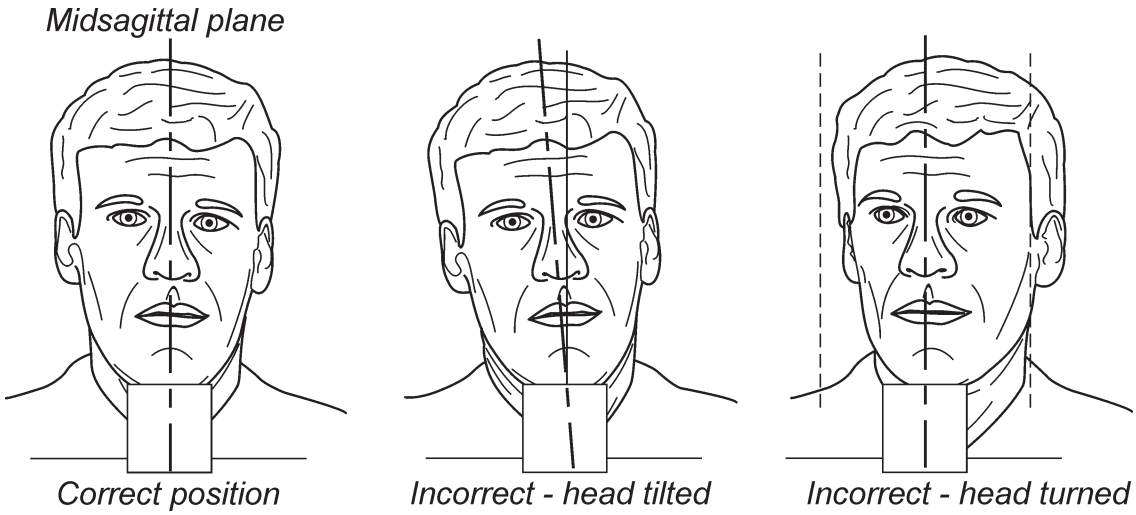
If the patient is **EDENTULOUS** ask them to place their chin on the chin rest and press their top lip against the lip holder.



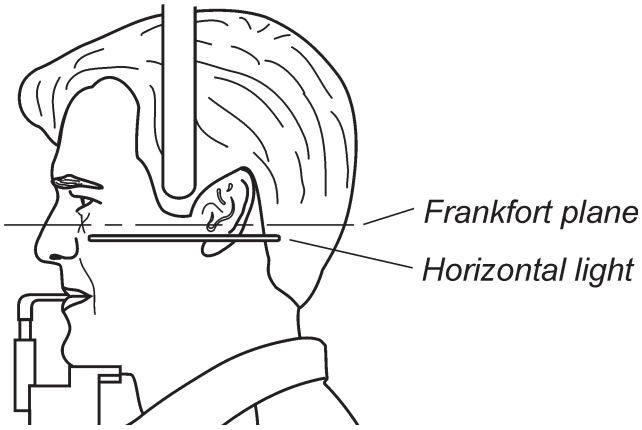
7. Open the mirror so that you can see a reflection of the patient in the mirror. The patient positioning lights will come on.

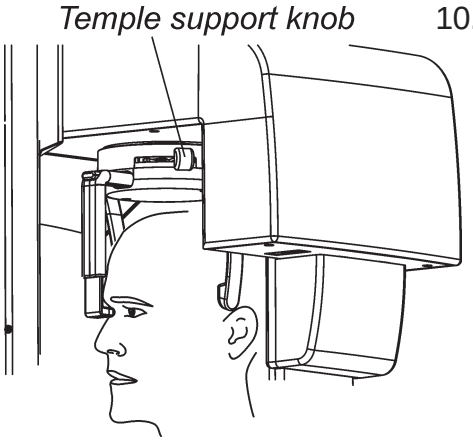
NOTE:
The lights will remain on for 30 seconds. If you need more time briefly press one of the focal trough light adjusting keys.

8. Look at the reflection of the patient in the mirror and position the **midsagittal plane** of the patient so that it coincides with the midsagittal plane light. The patient's head must be positioned symmetrically and the patient must be looking straight ahead.
The patient's head must NOT be tilted or turned to one side.

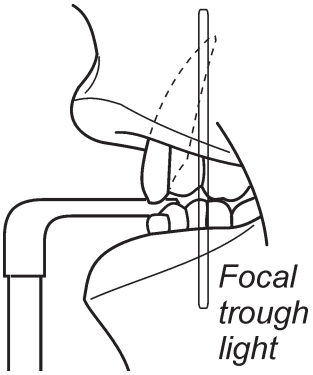


9. Press either height adjusting key to adjust the tilt of the patient's head until the patient's **Frankfort plane** coincides with, or is parallel to, the horizontal light.



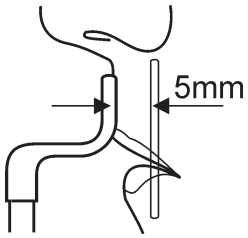


10. Close the temple supports by moving the temple support knob to the right. Make sure that patient's neck is stretched and straight.



11. The focal trough light indicates the **center** of the focal trough, which is 15 mm wide at the front. The root apices of the patient's central upper and lower front incisors must be within the focal trough.

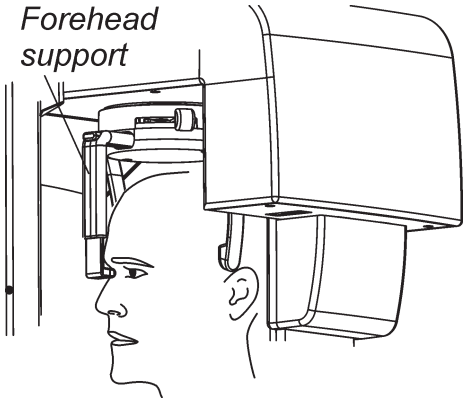
Ask the patient to open their lips so that you can see their teeth. The focal trough light should be positioned slightly in front of the root apices, which for most patients will be between the upper 2nd tooth (lateral incisor) and upper 3rd tooth (canine) when the focal trough position is 0 mm.



If the patient is edentulous the focal trough light should be approximately 5mm behind the lip holder when the focal trough position is 0 mm.

NOTE:
If the focal trough light is not positioned as described above, press the focal trough adjustment key(s) to move the focal trough light until it is positioned correctly.

12. Carefully push the forehead support in until it touches the patient's forehead or nasion.

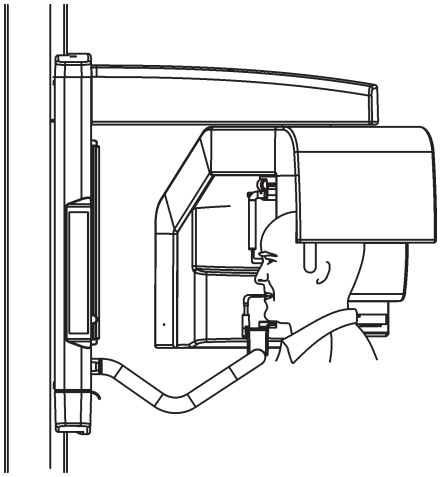


13. Close the mirror.

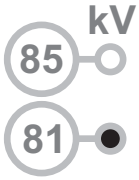
Taking a panoramic exposure

1. Check once more that the patient has not moved and is positioned correctly for a panoramic exposure.

2. Press the RETURN key to drive the rotating unit to the START position.

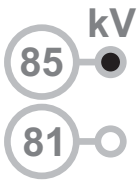


Make sure that the READY light is on. If it is not refer to section "**10.1 Error messages**".



The kV value, based upon the size of the patient's head, will be automatically selected.

IMPORTANT NOTE:
The rotating unit must be in the START position (press the RETURN key) for the kV value to be automatically selected.
If the rotating unit is not driven to the START position the kV value will NOT be automatically selected and the kV value that was used for the previous exposure will be selected.



3. If you wish to change the kV, select a different value.

4. Before taking a **panoramic** exposure ask the patient to press their lips together and press their tongue against the roof of their mouth.
   Also ask the patient to look at a fixed point in the mirror and to remain still for the duration of the exposure.

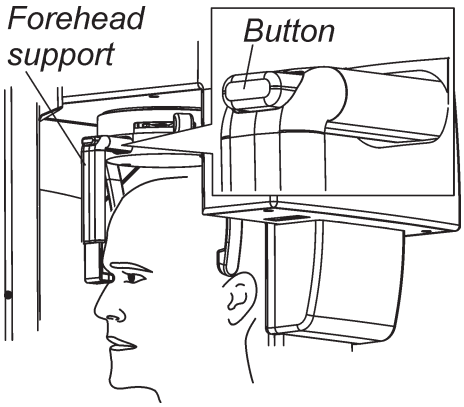
5. Move at least two metres from the unit and protect yourself from radiation. Make sure that you can see and hear the patient during the exposure.

6. Press and hold down the exposure button for the duration of the exposure. During the exposure you hear the audible signal and the radiation warning light on the display will come on.

   The rotating unit will rotate around the patient's head and then stop. When the rotating unit stops, the exposure has been taken.

After taking a panoramic exposure

1. Open the temple supports and press the button to release the forehead support.



2. Guide the patient out of the unit.

3. Press the RETURN key to drive the unit to the PIO position.

4. **PC:** The digital image can now be examined using Digora for Windows (not in USA).

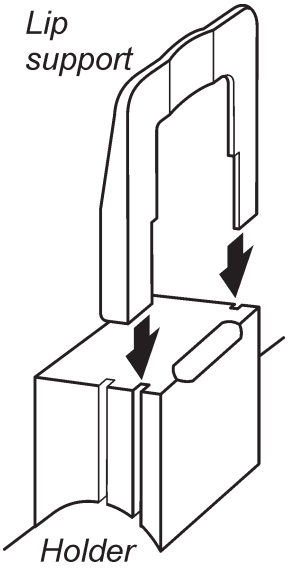
3.4 Taking a temporomandibular joint exposure

Selecting the TMJ program

1. Select the **Temporomandibular joint** program - magnification 1.34.

Positioning the patient for TMJ exposures

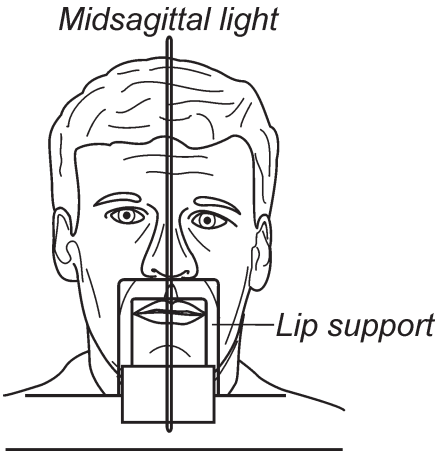
NOTE:
If the patient appears nervous you may want to reassure the patient by demonstrating how the unit works. To do this see section **"6. Using the unit without x-rays"**.



IMPORTANT NOTE:
You must take TWO separate exposures if you wish to have images of the TMJs with the mouth open and closed.

1. Slide the lip support on to the holder. Place a disposable cover on to the lip support.

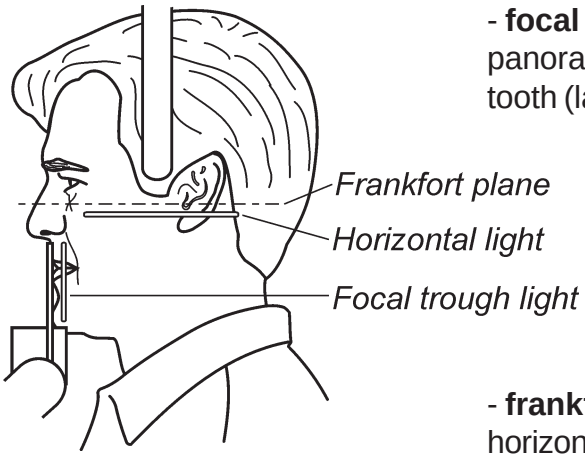
2. Prepare the patient in the same way as you would for a PANORAMIC exposure.



3. Open the mirror and position the patient as follows:

   - top lip pressed against the top of the lip support.

   - **midsagittal plane** coincides with the midsagittal plane light.



- **focal trough** light in the same position as for panoramic exposures, between the upper 2nd tooth (lateral incisor) and the 3rd tooth (canine).

- **frankfort plane** coincides or is parallel with the horizontal light.

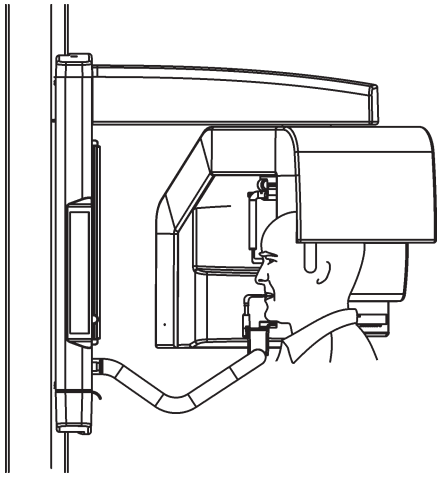
4. Close the temple supports by moving the temple support knob to the right, and carefully push the forehead support in until it touches the patient's forehead or nasion.

5. Close the mirror.

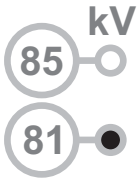
Taking TMJ exposures

1. Check once more that the patient has not moved and is positioned correctly for a TMJ exposure.

2. Press the RETURN key to drive the rotating unit to the START position.

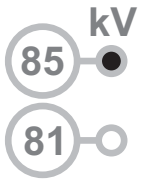


Make sure that the READY light is on. If it is not refer to section **10.1 Error messages**.

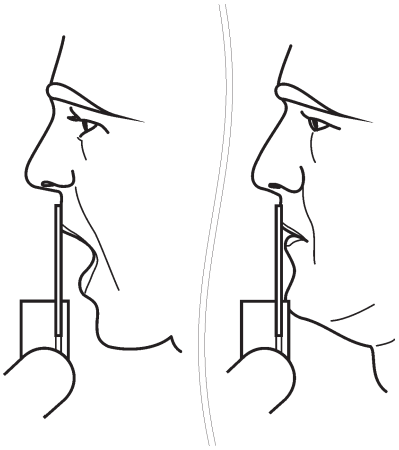


The kV value, based upon the size of the patient's head, will be automatically selected.

IMPORTANT NOTE:
The rotating unit must be in the START position (press the RETURN key) for the kV value to be automatically selected.
If the rotating unit is not driven to the START position the kV value will NOT be automatically selected and the kV value that was used for the previous exposure will be selected.



3. If you wish to change the kV, select a different value.



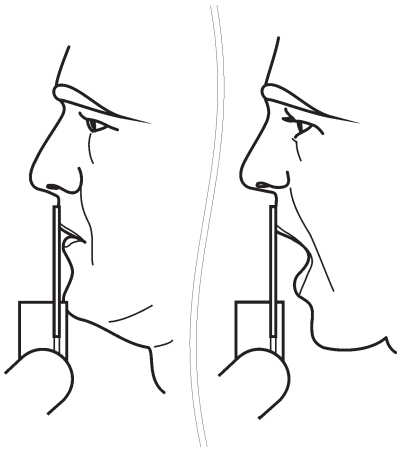
4. Before taking a **TMJ** exposure ask the patient to open their mouth (mouth open TMJ) or close their mouth and clench their back teeth together (mouth closed TMJ), depending on which TMJ exposure you wish to take first.
Also ask the patient to look at a fixed point in the mirror and to remain still for the duration of the exposure.

5. Move at least two metres from the unit and protect yourself from radiation. Make sure that you can see and hear the patient during the exposure.

6. Press and hold down the exposure button for the duration of the exposure. During the exposure you hear the audible signal and the radiation warning light on the display will come on.

The rotating unit will rotate around the patient's head and then stop. When the rotating unit stops, the exposure has been taken.

7. Press the RETURN key after you have taken the first pair of TMJ images to drive the rotating unit back to the PIO position.

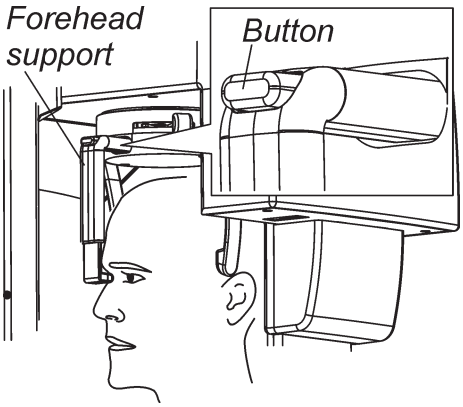


8. Reposition the patient for the second pair of images, mouth open or closed.

9. Press the RETURN key to drive the rotating unit to the START position and then take the second pair of TMJ images.

After taking TMJ exposures

1. Open the ear posts and press the button to release the forehead support.



2. Guide the patient out of the unit.

3. Press the RETURN key to drive the unit to the PIO position.

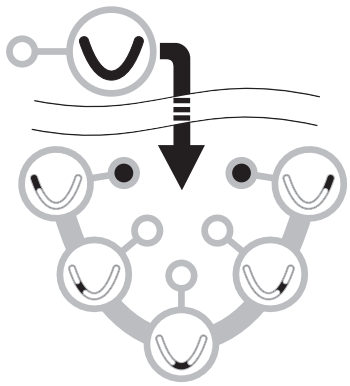
4. **PC:** The digital image can now be examined using Digora for Windows (not in USA).

3.5 Taking a sinus exposure

Selecting the sinus program

1. Select the exposure time you require.
   Press the **S+** key for the fast exposure time or the **S-** key for the standard exposure time.
   The selected exposure time will appear on the exposure values display.

   NOTE:
   When the unit is in the PIO position the exposure time will only appear briefly on the display when an S key is pressed.

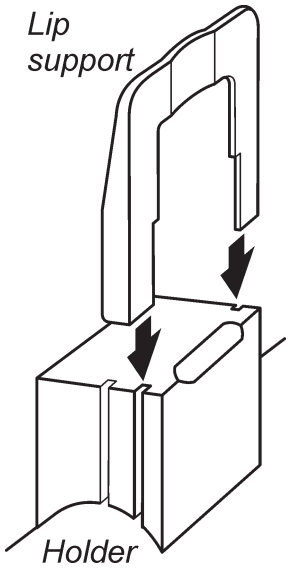


2. Select the Adult panoramic program. All the partial exposure indicator lights will come on.
   Select the lower three areas.
   After you select the first area the other indicator lights will go out. Select the other two areas.
   The magnification is 1.34.

   Exposure times;
   standard, 15.6 s
   fast 9.8 s

Positioning the patient for a Sinus exposure

NOTE:
If the patient appears nervous you may want to reassure the patient by demonstrating how the unit works. To do this see section "**6. Using the unit without x-rays**".



1. Slide the lip support on to the holder. Place a disposable cover on to the lip support.

2. Prepare the patient in the same way as you would for a PANORAMIC exposure.

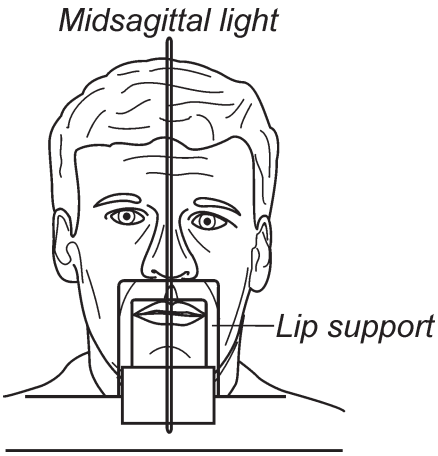
3. Open the mirror and position the patient as follows:

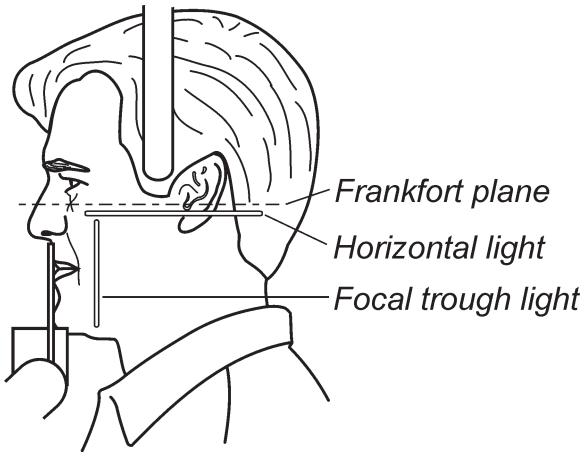
   - top lip pressed against the top of the lip support.

   - **midsagittal plane** coincides with the midsagittal plane light.

   - **focal trough** light as far backwards as possible (+20).

   - **frankfort plane** coincides with the horizontal plane light.





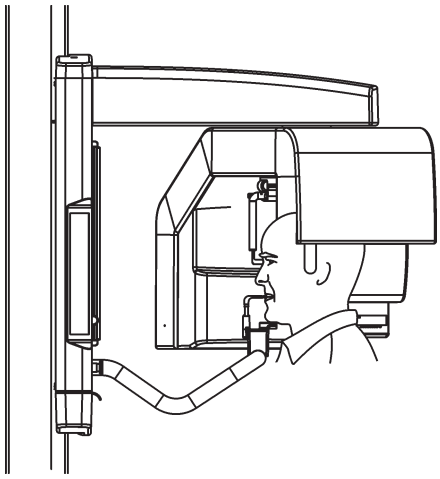
4. Close the temple supports by moving the temple support knob to the right, and carefully push the forehead support in until it touches the patient's forehead or nasion.

5. Close the mirror.

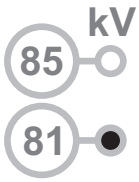
Taking a Sinus exposure

1. Check once more that the patient has not moved and is positioned correctly for a Sinus exposure.

2. Press the RETURN key to drive the rotating unit to the START position.

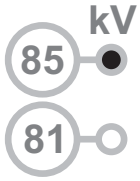


Make sure that the READY light is on. If it is not refer to section **10.1 Error messages**.



The kV value, based upon the size of the patient's head, will be automatically selected.

IMPORTANT NOTE:
The rotating unit must be in the START position (press the RETURN key) for the kV value to be automatically selected.
If the rotating unit is not driven to the START position the kV value will NOT be automatically selected and the kV value that was used for the previous exposure will be selected.



3. If you wish to change the kV, select a different value.

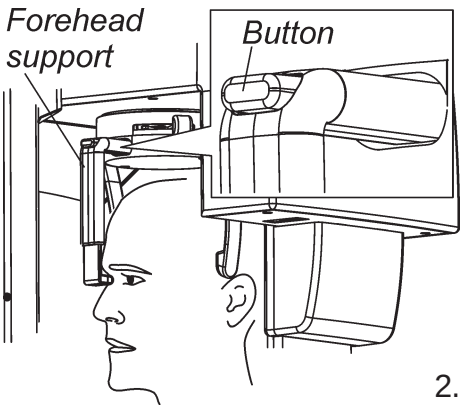
4. Before taking a **Sinus** exposure ask the patient to press their lips together.
   Also ask the patient to look at a fixed point in the mirror and to remain still for the duration of the exposure.

5. Move at least two metres from the unit and protect yourself from radiation. Make sure that you can see and hear the patient during the exposure.

6. Press and hold down the exposure button for the duration of the exposure. During the exposure you hear the audible signal and the radiation warning light on the display will come on.

The rotating unit will rotate around the patient's head and then stop. When the rotating unit stops, the exposure has been taken.

After taking a Sinus exposure



1. Open the temple supports and press the button to release the forehead support.

2. Guide the patient out of the unit.

3. Press the RETURN key to drive the unit to the PIO position.

4. **PC:** The digital image can now be examined using Digora for Windows (not in USA).

4. Taking cephalometric exposures (Ceph option)

4.1 Preparing the PC

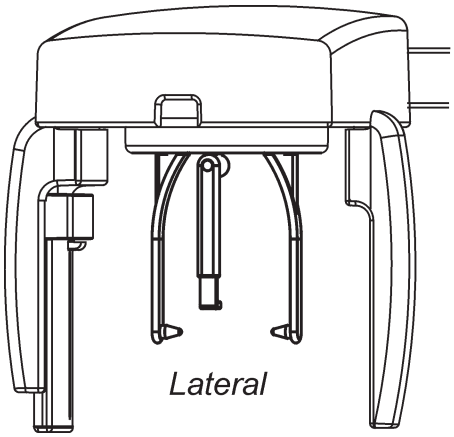
Prepare the PC in the same way as described in Taking panoramic exposures.

4.2 Preparing the unit

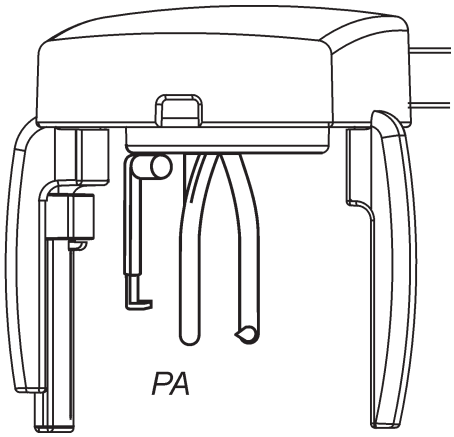
1. Attach the CCD sensor to the sensor holder on the ceph head, see section "**7. Attaching and removing the CCD sensor**".

2. Switch the unit on.

3. Rotate the cephalometric head support so that it is in the correct position (**Lateral** or **PA**) for the cephalometric exposure you wish to take.

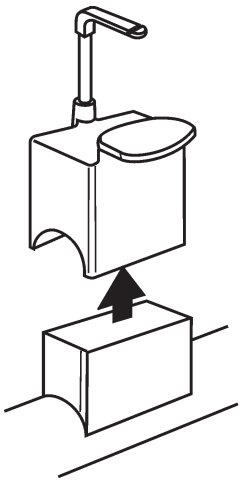


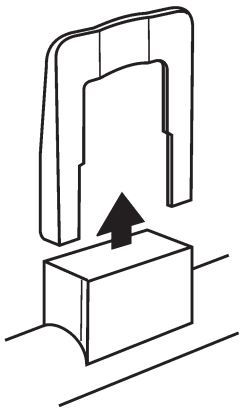
Lateral



PA

4. Remove any chin rest/support from the panoramic holder.





4.3 Taking a cephalometric exposure

Selecting the cephalometric program

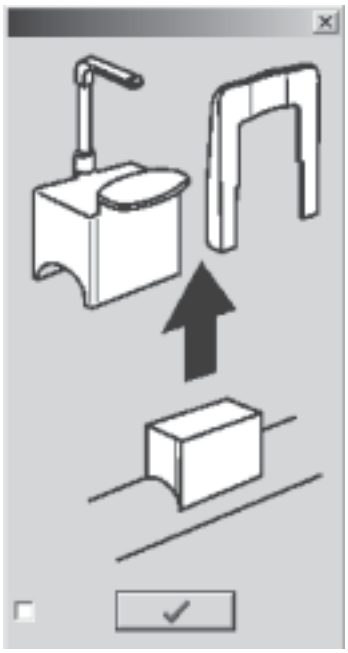
1. Select the required cephalometric program.

Full width Lateral or **Posterior Anterior (PA)**.
Magnification 1.15.
Field size:
- full width lateral 22 cm heigh x 26 cm wide
- PA 22 cm high x 20 cm wide.

NOTE:
The position of the ceph head support, lateral or PA, will automatically determine whether the lateral or PA program is selected.

Reduced width Lateral
Magnification 1.15
Field size:
- 22 cm high x 18 cm wide.

NOTE:
If the ceph head support is in the PA position the key is not active. Turn the ceph head support to the lateral position to activate the key.



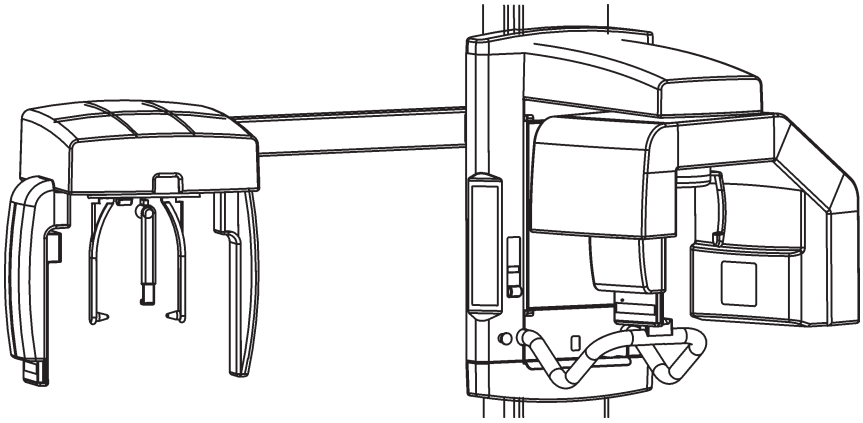
PC: A picture will appear reminding you to remove the chin rest / lip support before taking a cephalometric exposure.

Remove the chin rest / lip support if you have not already done so, and then click the tick button on the reminder picture. The picture window will disappear.

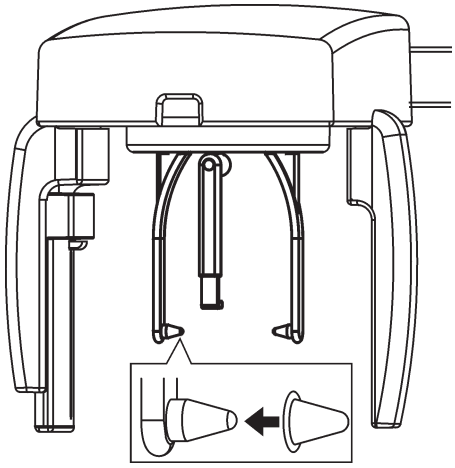
NOTE:
If you do not want the picture window to appear every time you click a cephalometric key, click the check box in the bottom left-hand corner of the picture window.

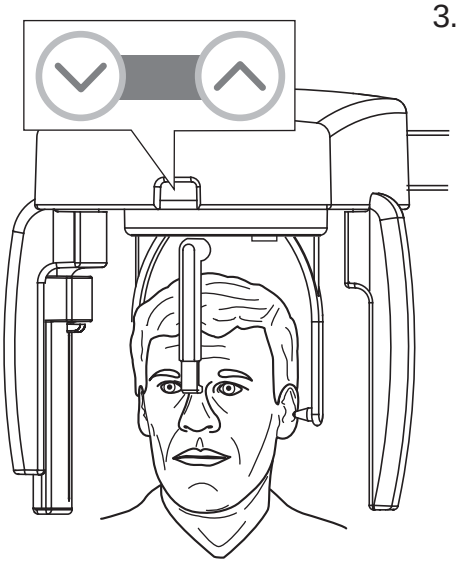
Positioning the patient

1. Press the RETURN key to drive the rotating unit to the ceph PIO position. The CCD sensor will also move to the PIO position.

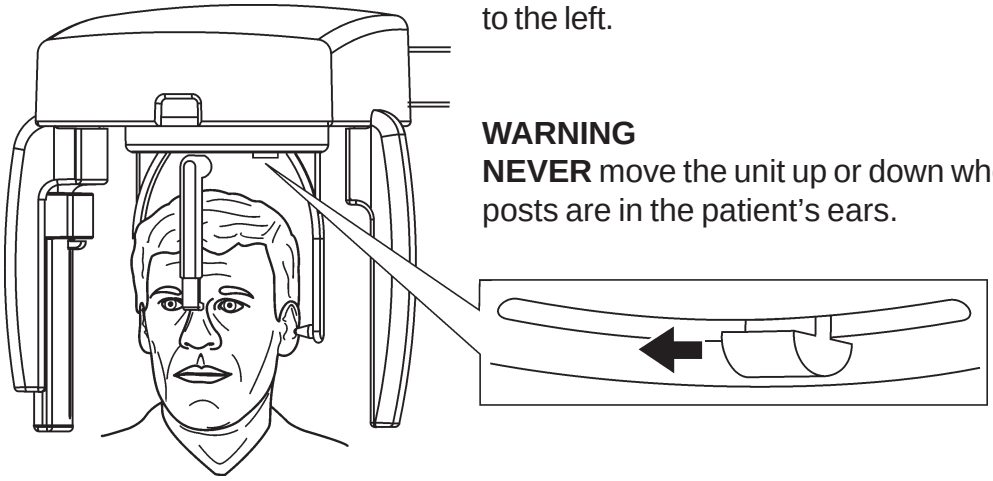


2. Place the protective disposable covers onto the ear cones.



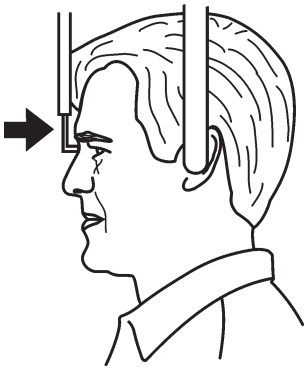


3. Ask the patient to stand between the open ear posts. Adjust the height of the unit so that the ear posts are level with the patients ears.
Position patient's head so that the Frankfort plane is horizontal.



4. Close the ear posts by sliding the ear post knob to the left.

WARNING
NEVER move the unit up or down when the ear posts are in the patient's ears.



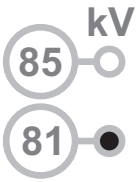
5. If you are taking a **lateral** exposure push the frontal support in carefully until it touches the patient's nasion.
The frontal support will automatically select the correct amount of soft tissue filtering.
If you are taking a **PA** exposure turn the frontal support sideways to the horizontal position.

Taking an exposure

1. Check once more that the patient is positioned correctly for the exposure you plan to take and has not moved.

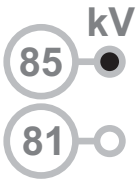
2. Press the RETURN key to drive the rotating unit to the ceph start position.

Make sure that the READY light is on. If it is not refer to section **10.1 Error messages**.
NOTE:
When the unit is in the ceph start position and the ready light is on, the unit cannot be driven up and down.



The kV value and exposure time, based upon the size of the patient's head, will be automatically selected.

IMPORTANT NOTE:
The unit must be in the ceph START position (press the RETURN key) for the kV value and exposure time to be automatically selected.
If the unit is not driven to the ceph START position the kV value and exposure time will NOT be automatically selected and the values that were used for the previous ceph exposure will be selected.



3. If you wish to change the kV or exposure time, select different values.

4. Ask the patient to bite their teeth together normally.

5. Move at least two metres from the unit and protect yourself from radiation. Make sure that you can see the patient during the exposure.

6. Press and hold down the exposure button for the duration of the exposure. During the exposure you hear the audible signal and the radiation warning light on the display.

After exposure

1. Open the ear posts and the forehead support.

2. Guide the patient out of the unit. The front head support can be turned to make it easier for the patient to get out.

3. **PC**: The digital image can now be examined using Digora for Windows (not in USA).

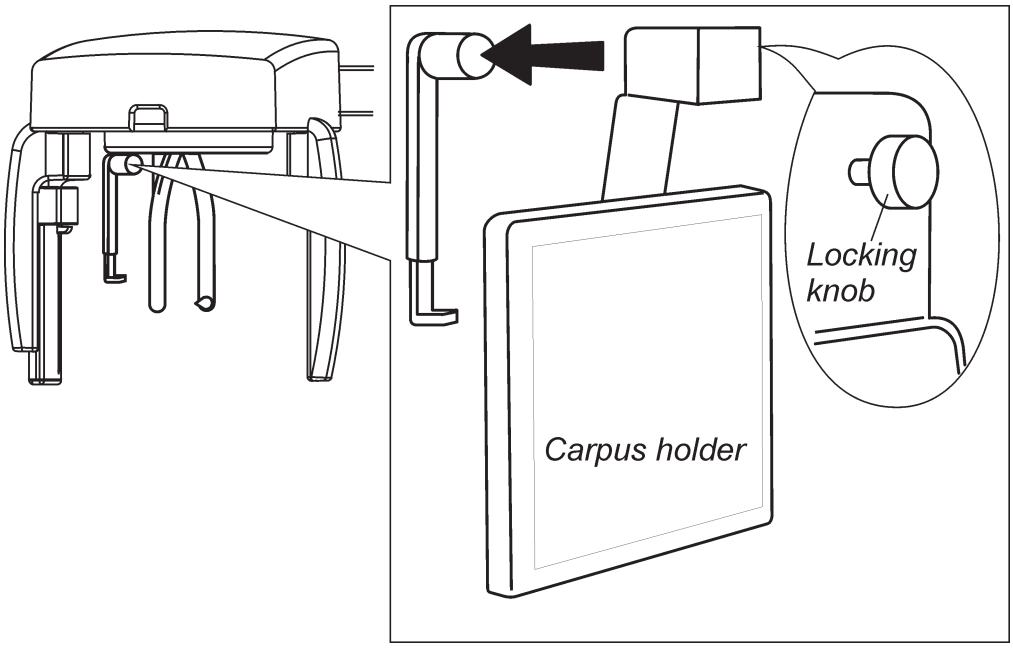
4. Press the return key and the unit is now ready to take another ceph exposure.

   If you wish to take a panoramic exposure, click the appropriate panoramic exposure key and then press the RETURN key. The rotating unit will return to the panoramic PIO position.

5. Carpus exposures (Not in USA)

1. Prepare the unit to take a PA cephalometric exposure.

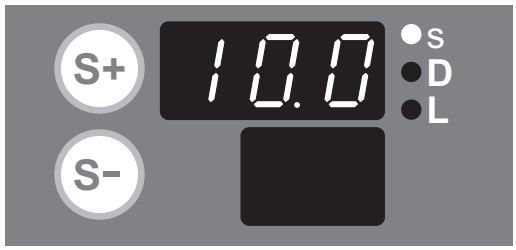
2. Slide the carpus holder on to the forehead support and then lock the carpus holder in position by turning the locking knob.



3. Press the RETURN key to drive the rotating unit to the ceph start position.

   Check that the READY light is on. If it is not refer to section **10.1 Error messages**.

4. Select a kV value of 60 and an exposure time of 10 sec.



5. Place the patient's hand on the carpus holder.

6. Move at least two metres from the unit and protect yourself from radiation. Make sure that you can see the patient during the exposure.

7. Press and hold down the exposure button for the duration of the exposure.
During the exposure you hear the audible signal and the radiation warning light on the display will come on.

6. Using the unit without x-rays

In some situations, for example with nervous patients or patients with unusual anatomy, you may wish to operate the unit without x-rays before taking a proper exposure.

To do this, press the TEST (T) key, the indicator light will come on. The exposure switch can now be pressed to demonstrate how the unit operates without x-rays being generated.

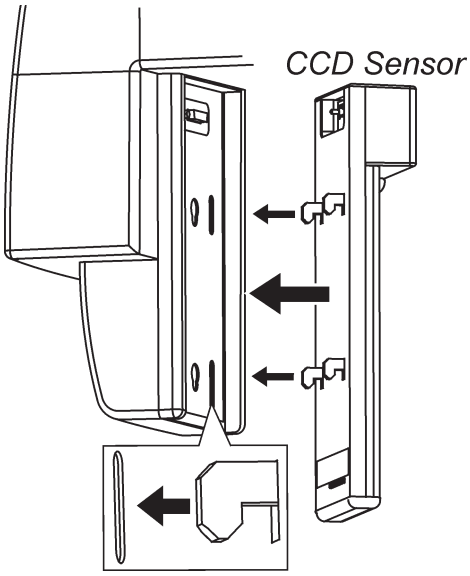
Press the TEST (T) key a second time to return to the normal exposure mode.

7. Attaching and removing the CCD sensor

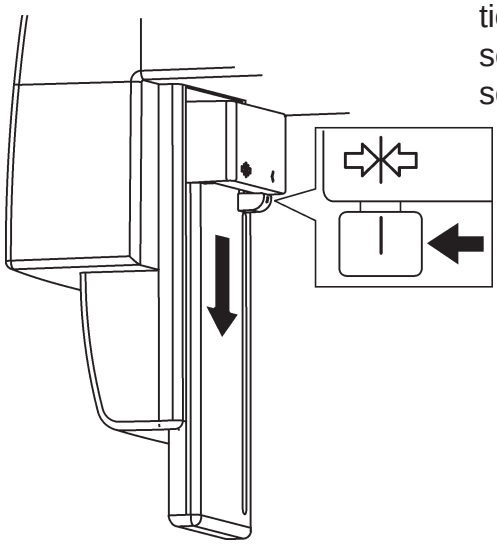
IMPORTANT NOTE:
Handle the CCD sensor with care and do not drop it.

7.1 Attaching the sensor

1. Insert the four hooks, on the rear of the CCD sensor, into the four slots in the sensor holder.

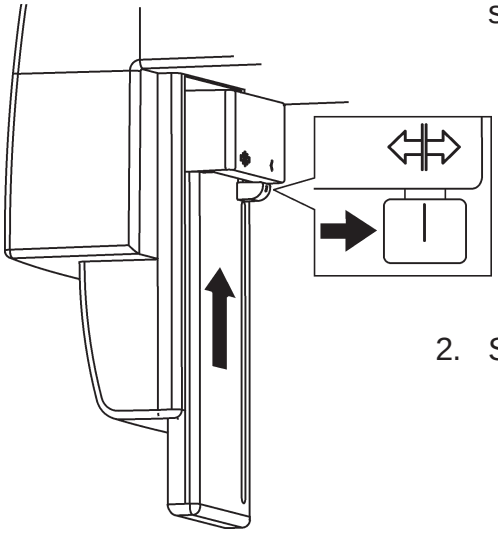


2. Slide the CCD sensor down until it stops and then slide the locking knob on the front of the CCD sensor to the left to lock the CCD sensor in position. The GREEN light on the rear of the CCD sensor will come on. This indicates that the CCD sensor is ready.



NOTE:
If the light is RED it indicates that the CCD sensor is not functioning correctly. Switch the unit off and then on again. If the light is still RED, contact you dealer for assistance.

7.2 Removing the sensor



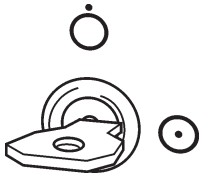
1. Slide the locking knob on the front of the CCD sensor to the right to unlock the CCD sensor.

2. Slide the CCD sensor up and remove it.

8. Exposure switch lock

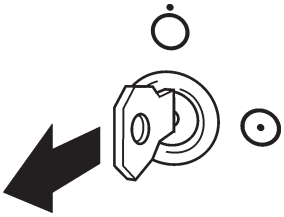
The exposure switch lock allows the exposure switch to be locked. This prevents unauthorized people from taking exposures even if the unit is switched on. The exposure switch lock is located on the side of the unit.

8.1 Unlocking the exposure switch



Insert the key and turn it clockwise to the horizontal position to unlock the exposure switch.

8.2 Locking the exposure switch



Turn the key anticlockwise to the vertical position and remove the key. The exposure switch is locked.

9. Unit setup

Various setup options allow the unit to be customized to your specific requirements

9.1 Setup options

1. **PC**: Open DfW (not in the USA) or the dental imaging software you are using.

2. **PC**: Select **Options** and then click **CRANEX D Setup**.
   The **CRANEX D Setup** window will appear.

   The **Device Status** field
   Shows the statuses of the **Pan device** or **Ceph device** (Pan/Ceph) device.
   The statuses are:
   - Ok, the device is ready for image capture
   - Connected, the device is connected to the PC.
   - Disconnected, the unit is switched off or the there is no connection between the unit and the PC.
   - No Camera, the CCD sensor is not connected to the unit.
   - Not Enabled, device not enabled.
   - Not Enabled (no gain file), device not enabled because the gain file is missing.

   The **Versions** field
   Shows the software and driver versions.

   The **Image Processing** field
   The **Show image preview** check box, see section **9.2 Image Preview**.

   The **Automatic Density Adjust** check box.
   Select to automatically optimize the image density.

The **Apply Enhancement** check box.
Select to sharpen the image. The enhancement value must be entered in the **Matrix size** edit box. The recommended value is between 7 and 11. The maximum value is 25 (maximum sharpening) and 1 is the minimum (minimum sharpening).

The **Retrieve Last Image** field
If you wish to recover an image after a system failure or are dissatisfied with any automatic or manual changes made to the the image, click the **Must be ..... retrieved** check box to retrieve the original image.

The **Device Serial Number** field
The **Add serial number ...** check box. Select, and then enter the serial number of the unit into the **Serial number** edit box to add the serial to the images. The serial number will appear in the top left-hand corner and the bottom right-hand corner of all new images.

NOTE:
If you select **Enable image marking** in DFW (**General Setup / Image / Image marking**) do NOT select the left top or right bottom options as the image marking text will appear on top of the serial number.

9.2 Image Preview

The Image Preview feature allows an image to be adjusted BEFORE it is saved. The adjustments be applied to the open image only or to ALL subsequent images.

CAUTION:
Adjustments made to images CANNOT be undone after the adjustments have been saved. If you wish to "undo" the adjustments retrieve the original image click **Retrieve Last Image**.

1. **PC**: In the **CRANEX D Setup** window click the **Show Image Preview** check box.

2. Take an exposure.

3. **PC**: The **Image Preview** window will automatically appear.
   To activate image adjustment, click the **Density Adjustment** and **Sharpen filter** check boxes.
   The **Image Quality Controls** will become active and the image can be adjusted.

   CURRENT IMAGE ONLY
   Click **OK** to apply the adjustments to the image in the Image Preview window ONLY.

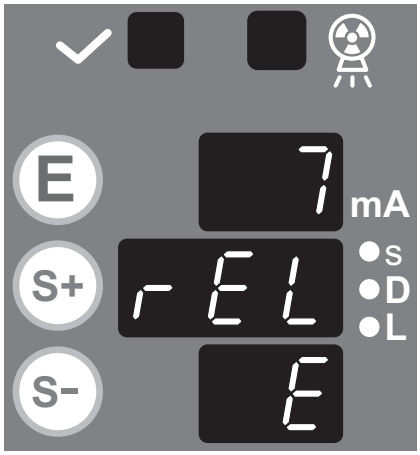
   CURRENT AND ALL SUBSEQUENT IMAGES
   Click the **Edit Quality Presets** button.
   The **Set Image Quality Presets** window will appear. The **Get from Preview window** radio button will be active. Click **OK** to accept the image adjustments you have made.
   The **Image Preview** window will reappear. Click **OK** to apply adjustments to the current image and ALL subsequent images.

   NOTE:
   If you wish to have the factory default settings click the **Factory defaults** radio button.

The **Marking** field
These tools allow you to add text and numbers to an image.

10. Troubleshooting and maintenance

10.1 Error messages



If the READY light does not come on and an error message appears on the screen it indicates that there is a problem with the unit.
Correct the cause of the error and then press the **E** key to clear the error from the display.
If another error message appears after you have cleared the first it indicates that there is another problem with the unit.

PC: On the user's interface the info key will turn red and the error message will appear. The scroll up/ down keys allow you to scroll through errors.

User Errors

PC1 NC (only on the User's Interface)

PROBLEM
X-ray unit not switched on or there is no connection between the PC and the Unit.

SOLUTION
Switch the unit on and/or check that the cable between the PC and the UNIT is connected properly.

E3 CoL (Pan/Ceph units only)

PROBLEM
The primary slot has not moved to the correct position. Ceph primary slot has been selected for a panoramic program exposure.

SOLUTION
Contact your dealer.

E4 CoL (Pan/Ceph units only)

PROBLEM
The primary slot has not moved to the correct position. Panoramic primary slot has been selected for a ceph exposure.

SOLUTION
Contact your dealer.

E7 rEL

PROBLEM
The exposure button was released during an exposure.

SOLUTION
Check if the attempted exposure is sufficient for the diagnostic task. If it is not, take a new exposure.
If the exposure failed while the exposure button was still being pressed, check the exposure switch by taking a test exposure without patient to see if the exposure button is defective or not. If the same problem occurs again, call service.

E8 MoE

PROBLEM
The exposure button was pressed when one of the Y/Z keys was being pressed.

SOLUTION
Do not press the exposure button while the Y/Z buttons are being pressed.

E9 (*******) (the WAIT time will appear in seconds)

PROBLEM
The WAIT time (cooling time between exposures) has not yet elapsed.

SOLUTION
Wait until the WAIT time elapses.

E10 dor

PROBLEM
The patient positioning mirror is open.

SOLUTION
Close the mirror.

E12 cCo

PROBLEM
The primary collimator has not changed to the child panoramic size.

SOLUTION
Press the E key to clear the error message. Then press the RETURN key to drive the unit to the PIO position, and then press the key again to drive it to the START position. If the error message reappears, call service.

E16 PoS

PROBLEM
i. The rotating unit is not in the PIO or START position.

ii The mirror is open.

SOLUTION
i. Press the E key to clear the error and then press the RETURN key to drive the rotating unit to the right position.

ii. Close the mirror.

E18 dCh

PROBLEM

i. There is no connection to the PC

ii. or DfW (not in USA), or the dental imaging software you are using is not open

iii. or the CCD sensor is not attached to the sensor holder

iv. or the CCD sensor is attached to the wrong sensor holder (pan/ceph units only)

v. or the CCD sensor is not fully locked in position

SOLUTION

i. Switch the PC on and start DfW (not in USA), or the dental imaging software you are using and start the User Interface program

ii. Start DfW (not in USA) or the dental imaging software you are using.

iii. Attach the CCD sensor to the sensor holder.

iv. Attach the CCD sensor to the correct pan or ceph sensor holder.

v. Make sure that the CCD sensor locking lever is pushed fully to the left, the locked position.

Unit Errors

If any of the following errors appear, switch the unit off and then on again. If the error message reappears call service for help.

C1 HHo

PROBLEM
The thermal switch in the tubehead has been activated because the unit has over heated because of extended continuous use.

SOLUTION
Wait at least one hour for the tubehead to cool down. Note that you will not be able to clear the error message until the tube head has cooled to the correct temperature. If the error message appears even if the unit has not been used a lot, switch the unit off and then on again. If the error message reappears call service for help.

C2 (*******) (the mains voltage is displayed)
The mains voltage out of allowed tolerances.

C3 gEn
Tube fail signal activated. Tubehead or generator defected.

C4 Inu
Inverter defect. The voltage of the tube does not increase during an exposure.

C5 FIL
Filament defect. mA does not increase during exposure.

C6 EEP
EEPROM defect.

C7 Por

R movement error.

C8 PoC

Collimator movement error.

C9 PoL

Linear (Y) movement error.

C10 PoU

Z movement error.

C11 Poc

Cephalo movement error.

C12 SEn

CCD sensor base frequency failing.

C13 (*******) (the wait time will appear in seconds)

Stepping motors over heated.

C14 Cba

Cephalo beam misaligned.

C15nPC

No connection to PC or PC does not acknowledge the image identification data.
SOLUTION: Check that the cables between the PC and unit are connected.

C19LbL

The PC acknowledges the image identification data, but the data is corrupted.
SOLUTION: Check that the cables between the PC and unit are connected.

C40 rAM

RAM defect.

C41 roM

EPROM defect.

C42 Lin

Mains voltage selector in wrong position.

C43 FIL

Preheat circuit not functioning/preheat not calibrated on the Filament Board.

C44 InP

A key is held or stuck down

C46 cPu

CPU defect.

C51 UIb (Only PC user's interface)

X-ray unit is in the "service" mode. Reset error codes from control panel.

Other operating problems

The unit does not become READY for an exposure.

CAUSE

Wrong collimator, CCD sensor not installed or no connection to the PC.

SOLUTION

Press the exposure or info button. On the kV and mA displays there appears an error code, which indicates the reason, why the unit is not ready for exposure. Clear the error code by pressing the E key. Rectify the reason. If the error appears, although the detail is in order, please call service.

The unit does not move to the start position (START).

CAUSE

The unit is not ready for exposure (READY).

SOLUTION

Find out why the unit is not ready for exposure by pressing the exposure button. Rectify the problem and try again.

Red error Indicator light on the CCD sensor comes on.

CAUSE

If the GREEN led on the rear of the CCD sensor turns RED, it indicates that there is a problem with the CCD sensor imaging chain.

SOLUTION

Switch the power off from the Cranex D unit for few seconds and switch it on again.

10.2 Care and Maintenance

Cleaning and disinfecting the unit

Warning
Switch the unit off before cleaning it.

Enamelled surfaces

All enamelled surfaces can be wiped clean with a soft cloth dampened with a mild detergent. NEVER use abrasive cleaning agents or polishes on this equipment.

Positioning mirror and light lenses

The positioning mirror and positioning light lenses are made of glass. Use a soft cloth dampened with a mild detergent. NEVER use abrasive cleaning agents or polishes on this equipment.

Surfaces that the patient touches

All surfaces and parts that the patient touches or comes into contact with must be disinfected after each patient. Use a disinfectant that is formulated specifically for disinfecting dental equipment and use the disinfectant in accordance with the manufacturer's instructions.

Correct operation of the unit

If any of the unit's controls, displays or functions fail to operate or do not operate in the way described in this manual, switch the unit off, wait 30 seconds and then switch the unit on again. If the unit still does not operate correctly contact your service technician for help.

If you hear the exposure warning tone but the exposure warning light does not come on when an exposure is taken, stop using the unit and contact your service technician for help.

If you do not hear the exposure warning tone when an exposure is taken, stop using the unit and contact your service technician for help.

Check weekly that the mains cable of the unit is in proper order and that all the unit operates. Make sure that the unit does not move up/down if the safety switch is pressed.

Yearly maintenance

Once a year an authorized service technician must carry out a full inspection of the unit. During the inspection the following tests will be carried out:
– a kV/mA test
– a beam alignment test
– a ball/pin test
– a check to see that the safety ground is connected
– a check to see that the positioning lights operate
– a check to see that the tube head is not leaking
– a check to see that all covers and mechanical parts are correctly secured and have not come loose.
A full description of all the tests and checks is described in the Service Manual.

Disposal

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

11. Warnings and precautions

- The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take an x-ray exposure that the unit is not designed to take.

- The unit or its parts must not be changed or modified in any way without approval and instructions from Soredex.

- The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.

- Always use the lowest suitable x-ray dose to obtain the desired level of image quality.

- Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.

- It is the responsibility of the doctor to decide if the x-ray exposure is necessary.

- Avoid taking x-ray exposures of pregnant women.

- Never press the up/down height adjustment button (Z-movement) when the patient is positioned in the cephalometric head holder.

- The user must protect him/herself from radiation when taking exposures. The user must stand at least two meters from the patient when taking exposures.

- The user must be able to see and hear the patient at all times.

- The user must see the radiation warning light and hear the audio warning signal during the exposure. If the unit is installed in such a place where the warning light cannot be seen, a separate warning light must be used. Please contact the local service for help.

- If the unit does not appear to be working correctly, switch the unit off and release the patient. Make sure that the unit operates correctly before you continue using it. If you are not sure whether the unit is operating correctly, please contact the local service.

- If the unit will not be used for a long time, switch the unit off and lock the key switch, in order to prevent unauthorized exposures.

- Disinfect all the surface that the patient has contact with after every patient.

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

Appendix A - Technical Information

A.1 Technical specifications

Model

PP1

Classification

IEC class I, type B, IP20
Conforms with the standards EN 60601-1, EN60601-1-3, EN 60601-2-7 and EN 60601-1-2 (Group 1, class B)

Conforms with the regulations of DHHS Radiation Performance Standard, 21CFR Subchapter J.

The unit must be installed within a protected clinical area.

Unit description

Dental panoramic and panoramic/cephalometric x-ray units with a high frequency switching mode x-ray generator. The panoramic version takes panoramic exposures. The panoramic/cephalometric version takes panoramic and cephalometric exposures. The unit uses a CCD sensor as image receptor.

X-ray generator

TUBE
- OPX/105, or equivalent

FOCAL SPOT
- 0.5 mm IEC 336

TARGET ANGLE
- 5º

TARGET MATERIAL
- Tungsten

OPERATING TUBE POTENTIAL
- Panoramic imaging 57 - 85 kV (±4 kV)
- Cephalometric imaging 60 - 85 kV (±4 kV)

OPERATING TUBE CURRENT
- 10 mA (±1 mA) at 0.5 FS

MAXIMUM TUBE CURRENT
- 11 mA

MAXIMUM OUTPUT POWER
- 945 W nominal

FILTRATION
- minimum filtration 2.7 mm Al

BEAM QUALITY
- HVL over 2.5 mm Al @ 85 kV

OUTER SHELL TEMPERATURE
- +50ºC (122ºF) maximum

DUTY CYCLE
- controlled by the software of the unit

Power requirements

INPUT VOLTAGE
- 230 or 115 VAC (±10%), 50/60 Hz, single phase, grounded socket

MAXIMUM LINE CURRENT
- 7 A (@85 kV/10mA, 230 VAC mains)

MAXIMUM LINE RESISTANCE
- 1 ohm

MAXIMUM LINE FUSING
- 10 A /20A slow @ 230/115 VAC (main fuse 8A/16A slow in the device)

LINE SAFETY SWITCH (when required)
- Approved type, min. 10 A 250 VAC

EARTH LEAKAGE CIRCUIT BREAKER (when required)
- Approved type, min. 16 A 250 VAC, breaker activation leakage current in accordance with local regulations.

Mechanical parameters

PANORAMIC
- Source to Image layer Distance (SID) 520 mm (±10 mm)
- Magnification factor 1.34

CEPHALOMETRIC
- Source to Image layer Distance (SID) 1721 mm ±20 mm
- Source to Object Distance (SOD) 1500mm
- Magnification factor 1.15

WEIGHT
- Panoramic unit 120 kg
- Panoramic/cepahlometric unit 165 kg

DIMENSIONS
- Panoramic unit (H x W x D) 2320 x 1200 x 1000 mm
- Panoramic/cephalometric unit (H x W x D) 2320 x 1200 x 1900 mm

VERTICAL HEIGHT OF CHIN REST
- 950 - 1750 mm (+- 10 mm)

Digital image receptor

Only the CCD sensors specifically designed for Cranex D unit can be used.
PIXEL SIZE

- 96 micrometres

Timer

PANORAMIC EXPOSURE TIMES

- Adult normal 17.6 s (±15%), fast 11 s (±15%)
- Child normal 13.8 s (±15%), fast 8.6 s (±15%)
- Partial normal 3.1 s - 4 s - 7.6 s - 4 s - 3.1 s,
  fast 1.9 s - 2.5 s - 4.8 s - 2.5 s - 1.9 s
  Can be freely selected and combined, overlap approx. 0.3 s.
- TMJ 3.2 + 3.2 s (±15%)
  Max 240 mAs

CEPHALOMETRIC EXPOSURE TIMES

- 8 - 20 s scanning times, 5 steps according to R'10 series (ISO)

BACK-UP TIMER

- 23.5 s (±1.5s)

Leakage technique factors

PANORAMIC

- 85 kV, 2400 mAs/h (85 kV, 10 mA, duty cycle 1:15)

CEPHALOMETRIC

- 85 kV, 1800 mAs/h (85 kV, 10 mA, duty cycle 1:20)

Measurement bases

kV and mA values can be verified with a specified digital multimeter according to separate measurement instructions. The exposure times can be measured as the duration of radiation in the primary radiation beam.

Exposed field size in cephalometry

- 22 x 26 cm for lateral projections
- 22 x 20 cm for PA and AP projections
- Automatic filtration of soft tissues for lateral projections controlled by software.

Operating ambient conditions

- Operating temperature 10 - 40ºC
- Relative humidity 0 - 85 RH%

Storage ambient conditions

- Storage temperature 0 - 40ºC
- Relative humidity 0 - 85 RH%

Minimum computer requirements

The values in (brackets) are recommended values.

OPERATING SYSTEM
- Windows XP Professional / Home / SP1 or SP2
- Windows 2000 Professional / SP4

CPU
- Pentium 4 or Athlon XP or equivalent (1.5 GHz or better recommended)

RAM
- 256 MB (512 MB recommended)

HDD
- 20 GB (single user)

VIDEO RAM
- 16 MB (or more)

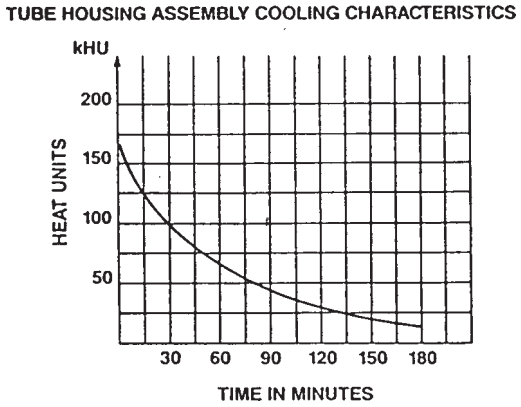
NETWORK CONNECTION
- 10/100 Mbit/s Ethernet NIC

DISPLAY
- 1280 x 1024 x 24-bit Tru Color, 85Hz display
  (19" CRT or 17" TFT LCD recommended)

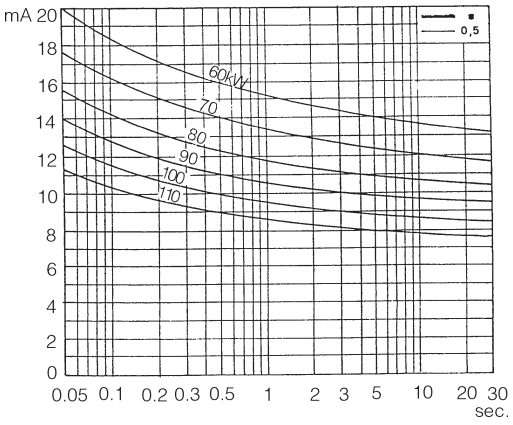
PCI slot
- 1 free

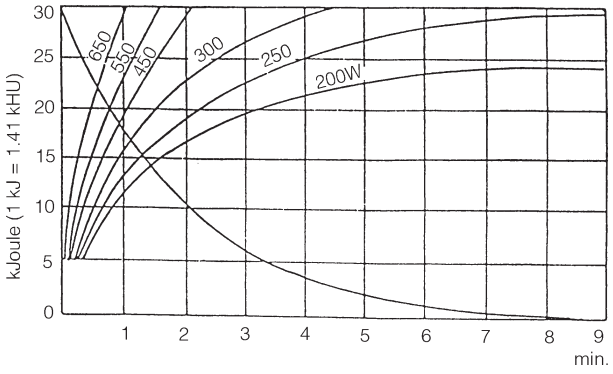
Connection to the PC must meet EN60601-1 requirements.
The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
- use of the accessory in the PATIENT VICINITY
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard
- the fibre optic cable, provided by the manufacturer, shall be used.

Tube housing assembly cooling characteristics

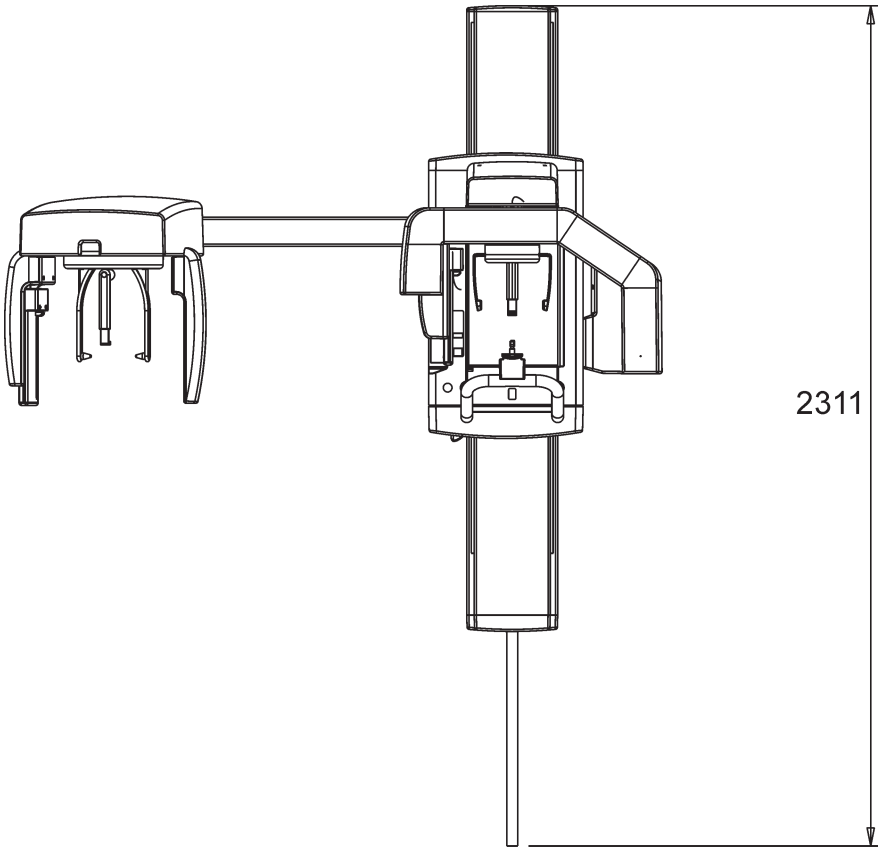


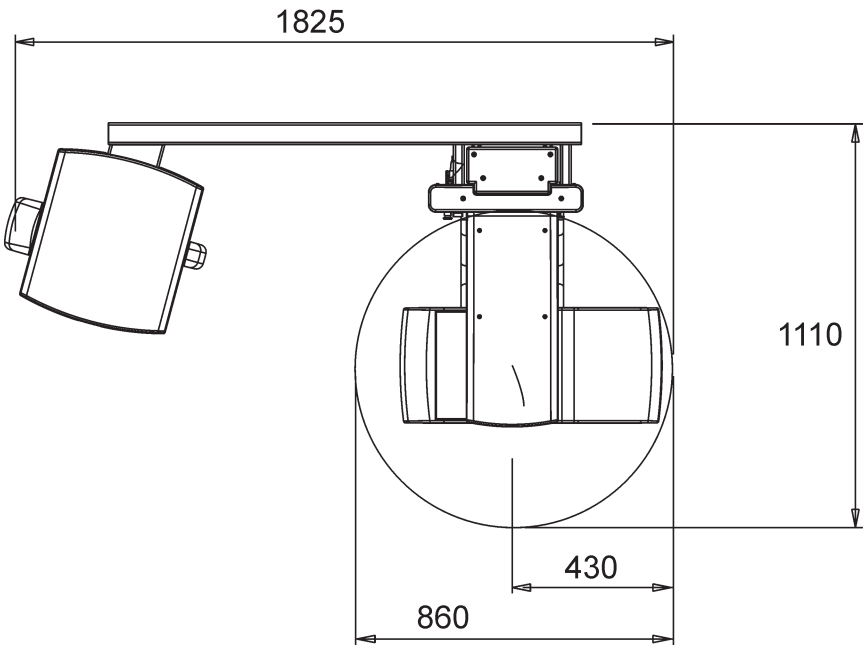
OPX/105 and KL5





A.2 Unit dimensions





A.3 Symbols that appear on the unit


Exposure switch locked


Exposure switch


Exposure switch unlocked


Ready

On or enabled


Off or disabled


Radiation warning


Attention, consult accompanying documents


X-ray source assembly: emitting


Dangerous voltage


Protective earth (ground)


Ground (Functional)


CE (0537) symbol
MDD 93/42/EEC


UL Classification and CSA classification


Type B equipment

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The PP1 is intended for use in the electromagnetic environment specified below. The customer or the user of the PP1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PP1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PP1 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The PP1 is intended for use in the electromagnetic environment specified below. The customer or the user of the PP1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If user of the PP1 requires continued operation during power mains interruptions, it is recommended that the PP1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The PP1 is intended for use in the electromagnetic environment specified below. The customer or the user of the PP1 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the PP1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PP1 is used exceeds the applicable RF compliance level above, the PP1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the PP1.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the PP1.

The PP1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PP1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PP1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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