CRANEX D Digital Panoramic and Cephalometric X-ray Unit

User's Manual



Medical Device Directive 93/42/EEC

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1. Cranex D digital X-ray unit

1.1 Introduction

The **Cranex D** is a digital panoramic dental x-ray unit designed to take dental panoramic exposures. It can take:

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

An optional cephalometric device allows cephalometric 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 carefully **before** operating the unit.

Please read and observe the warnings and precautions that appear in this manual. See section "**10. Warnings and Precautions**".

2. Unit description

2.1 Cranex D



2.2 Optional cephalometric device



2.3 Unit operating keys

The keys on **User Interface** are for selecting the programs and exposure parameters. The keys on the unit display and control panel are for adjusting the height of the unit, positioning the focal trough and driving the rotating unit to the ready position.



2.4 Unit displays and indicator lights





3. Taking Panoramic Exposures

3.1 Preparing the PC



- 1. Switch on the PC that is connected to the unit.
- 2. Open Digora for Windows (DfW) software (not in USA) and then open a new or existing patient card for the patient. For information on how to do this refer to the Digora for Windows user's manual (not in USA).



Abort Capture

 Click the Image capture button (not in USA) on the patient card. The button text will change to Abort capture which indicates that DfW (not in USA) is ready to receive an image.



- 4. Click the **User Interface** icon to open the interface.
- 5. From the **User Interface**, click the appropriate program key or keys for the exposure you wish to take.

The programs are:



Adult panoramic - magnification 1.34

Child panoramic - magnification 1.34

Temporomandibular joint - magnification 1.34

3. Panoramic Exposures



Partial panoramic exposures - magnification 1.34

Select the Adult panoramic program. All the partial exposure indicator lights will come on.

Click the indicator light(s) for the area(s) that you DO NOT wish to expose, the indicator light(s) will go out.

The remaining "on" light(s) indicate the area(s) that will be exposed.

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

Click the uppermost left and right indicator lights so that the they go out.

The three remaining "on" light(s) indicate that the sinus area that will be exposed.

Cephalometric (Units with the ceph option only). See section "**4. Cephalometric exposures**".

The program lights on both the unit control panel and the **User Interface** will come on.



NOTE

If you wish the **User Interface** Window to always remain visible, click the "Always on top" key.

3.2 Preparing the Unit



1. If the CCD sensor is not attached to the sensor holder on the rotating unit, attach it.

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. If the READY light does not come on refer to section **9.1 Error messages**.

3.3 Panoramic exposures - adult, child and partial

Patient positioning for Panoramic 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 xrays**".

 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 focal trough is not 0, press either focal trough light adjusting keys to drive it to the 0 position.



7. 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.

- 8. 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.

9. 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.



Correct position







Incorrect - head turned



10. 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.





Focal

trough

light

5mm

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

12. 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).

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

If the patient is edentulous, press the focal trough adjustment key to position the focal trough light until it is approximately 5mm behind the lip holder.

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



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.





Check that the READY light is on. If it is not refer to section **9.1 Error messages**.



The kV value, based upon the size of the patient's head, will appear on the unit display.

IMPORTANT NOTE

ALWAYS press the RETURN key to drive the unit to the START position BEFORE you press the exposure button.

If you do not press the RETURN key first, the kV value will NOT be automatically selected. The kV value used will be the value on the control panel/User's Interface.

3. Panoramic Exposures



3. If you wish to change the kV, select a different value frm the **User Interface**.



- 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.

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

3.4 Temporomandibular Joint (TMJ) exposures

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 xrays**".

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.





- 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.



Т



70

Check that the READY light is on. If it is not refer to section **9.1 Error messages**.

The kV value, based upon the size of the patient's head, will appear on the unit display.

IMPORTANT NOTE ALWAYS press the RETURN key to drive the unit to the START position BEFORE you press the exposure button.

If you do not press the RETURN key first, the kV value will NOT be automatically selected. The kV value used will be the value on the control panel/ User Interface.



3. If you wish to change the kV, select a different value from the **User Interface**.





 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 the reflection of

Also ask the patient to look at the reflection of their nose 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.

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 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. The digital image will be transferred to the PC.

3.5 Sinus exposure

Positioning the patient for a Sinus exposure



- **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.





Check that the READY light is on. If it is not refer to section **9.1 Error messages**.



The kV value, based upon the size of the patient's head, will appear on the unit display.

IMPORTANT NOTE ALWAYS press the RETURN key to drive the unit to the START position BEFORE you press the exposure button.

If you do not press the RETURN key first, the kV value will NOT be automatically selected. The kV value used will be the value on the control panel/ User Interface.



3. If you wish to change the kV, select a different value from the **User Interface**.





- Before taking a Sinus exposure ask the patient to press their lips together.
 Also ask the patient to look at the reflection of their nose 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.



 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. The rotating unit will rotate around the patient's

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. The digital image will be transferred to the PC.

4. Cephalometric exposures (Ceph option)

4.1 Preparing the unit



- 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.







4. **REMOVE** the CHIN REST / LIP SUPPORT from the panoramic holder.



4.2 Preparing the PC user interface





 Click the Cephalometric program key. A window with 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.



5. If you plan to take a Lateral exposure two cephalometric keys will appear.

The left key indicates which lateral program is selected, full width or reduced width.



Reduced

Click the **right** key to change the lateral program, from full to reduced or from reduced to full.

If you plan to take a PA exposure one cephalometric key will appear.

The magnification of Cephalometric images is: - 1.15.

- The field sizes are:
- Lateral, full width 22cm high x 26cm wide,
- Lateral, reduced width 22cm high x 18cm wide,
- PA 22cm high x 20 cm wide .



4.3 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.



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.

4.4 Taking an exposure



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



 Press the RETURN key to drive the rotating unit to the ceph start position. The kV and exposure time will be automatically selected. NOTE
 When the unit is in the start position and the ready light is on, the unit cannot be driven up and down.



Check that the READY light is on. If it is not refer to section **9.1 Error messages**.



3. If you wish to change the kV or Exposure time, select different values from the **User Interface**.





- 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.

4.5 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. 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 on the User's Interface 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 pushing the locking lever forward.



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



4. 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 **9.1 Error messages**.

- 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.



Cranex D

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

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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. Troubleshooting and maintenance

9.1 Error messages



If the READY light does not come on and the INFO key appears on the User's Interface, it indicates that there is an error.

Press the RETURN key or the Exposure button. An error code (or codes) will appear on Unit Control Panel.

On the User's Interface, press the INFO key to display the error code. If there is more that one error code an arrow keys will appear that allow you to display the other error codes.

Correct the cause of the error and then press the **E** key on the Unit Control Panel to clear the error from the display.

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 you 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 you 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.

NOTE

Exposures of children can be taken with the adult panoramic program. Note ,however, that the height and width of the exposed area is not reduced.

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 or the User Interface are not on
- 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 (and press the capture image button) (not in USA) and the User Interface.
- 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 tube head has been activated because the unit has over heated because of extended continuous use.

SOLUTION

Wait at least one hour for the tube head 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 time will appear in seconds)

The mains voltage out of allowed tolerances.

C3 gEn

Tube fail signal activated. Tube head 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

Receptor 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 Ulb (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.

9.2 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.

10. 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 sure 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.

11. Technical Information

11.1 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)
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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 - 50 **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 AI @ 85 kV

OUTER SHELL TEMPERATURE

- +50°C (122°F) 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

- Normal 17.6 s (±15%)
- Child 16 s (±15%)
- Partial 1.9 s 3 s 9.2 s 3 s 1.9 s

Can be freely selected and combined, overlapping approx. 0.3 s.

- TMJ 3.3 + 3.3 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 22 cm for PA and AP projections
- Automatic filtration of soft tissues for lateral projections controlled by software.

Operating ambient conditions

- Operating temperature 10 40°C
- Relative humidity 0 85 RH%

Storage ambient conditions

- Storage temperature	0 - 40°C
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- 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)

COM 1 and COM 2 available (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

- only RS 232C interface cable and fibre cable, provided by the manufacturer, shall be used.

Tube housing assembly cooling characteristics

TUBE HOUSING ASSEMBLY COOLING CHARACTERISTICS



OPX/105 and KL5



11.2 Unit dimensions











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.

User's Manual 8201083

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	
Harmonic emissions IEC 61000-3-2	Class A	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

Guidance and manufacturer's declaration – electromagnetic immunity			
The PP1 is intende	d for use in the electromage	gnetic environment spec	ified below. The customer
or the user of the F	P1 should assure that it is	used in such an enviror	nment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic
			environment - guidance
Electrostatic	±6 kV contact	±6 kV contact	Floors should be wood,
discharge (ESD)			concrete or ceramic tile.
IEC 61000-4-2	±8 kV air	±8 kV air	If floors are covered with
			synthetic material, the
			relative humidity should
			be at least 30 %.
Electrical fast	± 2 kV for power supply	±2 kV for power	Mains power quality
transients/bursts	lines	supply lines	should be that of a
IEC 61000-4-4	$\pm 1 \text{ kV}$ for input/output	±1 kV for	
0	lines	input/output lines	nospital environment.
Surge	±1 kV differential mode	±1 kV differential	Mains power quality
IEC 61000-4-5	±2 kV common mode	mode	should be that of a
		±2 kV common	
	5.04.14		nospital environment.
Voltage dips,	$<5\% U_{\rm T}$	$<5\% U_{\rm T}$	Mains power quality
snort	$(>95\%$ dip in $U_{\rm T})$	$(>95\%$ dip in $U_{\rm T})$	should be that of a
	10 % 11	10 % 11	user of the PP1 requires
	(60% din in 1/L)	(60% din in /L)	continued operation
IFC 61000-4-11	for 5 cycles	for 5 cycles	during power mains
			interruptions it is
	70%//	70%//	recommended that the
	$(30\% \text{ dip in } U_{\rm T})$	$(30\% \text{ dip in } U_{\rm T})$	PP1 be powered from
	for 25 cycles	for 25 cycles	an uninterruptible power
			supply or a battery.
	<5 % U⊤	<5 % UT	
	(>95 % dip in $U_{\rm T}$)	$(>95\%$ dip in $U_{\rm T})$	
	for 5 sec	for 5 sec	
Power frequency	3 A/m	3 A/m	Power frequency
(50/60 Hz)			magnetic field should be
magnetic field			at levels characteristic
IEC 61000-4-8			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.			

Guidance and manufacturer's declaration – electromagnetic immunity				
The PP1 is in	tended for use in th	ne electromagne	tic environment specified below. The customer	
or the user of the PP1 should assure that it is used in such an environment.				
Immunity	IEC 60601 test	Compliance	Electromagnetic environment - guidance	
test	level	level		
			Portable and mobile RF communications	
			part of the PP1, including cables, than the	
			recommended separation distance calculated	
			from the equation applicable to the frequency	
			of the transmitter.	
	a.).(a.).(Recommended separation distance	
Conducted	3 Vrms	3 V	$d = 1.2 \sqrt{P}$	
4-6	00 1011 12		$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz	
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz	
Radiated	3 V/m	3 V/m	where <i>P</i> is the maximum output power rating	
RF	80 MHz to		of the transmitter in watts (W) according to the	
1EC 61000-	2.5 GHZ		transmitter manufacturer and d is the	
4-5			recommended separation distance in	
			metres (m).	
			Field strengths from fixed RF transmitters, as	
			^a should be less than the compliance level in	
			each frequency range	
		Interference may occur in the vicinity of		
			equipment marked with the following symbol:	
			$(((\bullet)))$	
NOTE 1 At 8	0 MHz and 800 MF	l Iz the higher fre		
NOTE 2 The	se quidelines may	not apply in all s	ituations. Electromagnetic propagation is	
affected by absorption and reflection from structures, objects and people.				
^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				
producast cannot be predicated theoretically with accuracy. To assess the electromagnetic				
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.				

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	Separation distance according to frequency of transmitter m		
output power of	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
transmitter W	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
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.