CRANEX Novus

Digital Panoramic X-ray Unit

User's Manual

Number 200409 ver. 2 (0612)

EN

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User's Manual

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0537
Medical Device Directive
93/42/EEC

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Contents

1. Introduction

1.1 CRANEX Novus X-ray unit

The **CRANEX Novus** is a digital panoramic dental x-ray unit designed to take:

- adult panoramic exposures,

- child panoramic exposures (reduced width),

- and TMJ exposures.

The unit uses a CCD sensor as the image receptor and a PC with suitable (MDD approved) dental imaging software, such as Digora for Windows (not in USA), for image aquisition and handling.

IMPORTANT NOTE:
Before using the unit for the first time, make sure that it is set up to your requirements. See section, **6. Unit Set up**.

1.2 About this manual

This manual describes how to use and set up the **CRANEX Novus** x-ray unit.

Please read these instructions carefully **before** operating the unit.

Before operating this unit read and observe the warnings and precautions that appear in section, **8. Warnings and Precautions**.

The status of indicator lights is shown as follows:

Light on

Light off

2. Unit description

2.1 Main parts

Column

NOTE
Tubehead + CCD sensor = Rotating Unit

Upper shelf

Vertical carriage

CCD sensor

Head support

Mirror

Frankfort light

Tubehead

Chin support

Midsaggital light

Patient handles

Emergency stop knob

Emergency stop
Emergen stop

- **Press to stop the unit,**
- **Rotate to release**

Ethernet cable

On / off switch
(rear of column)

PC with MDD approved
dental imaging software

2.2 Display and keys

Side control panel

Lights key

Up key

Down key

Return key

Display and main control panel

9.0 s

Display

Exposure warning light

Exposure ready light

PC

PC light
Green - system ready

60   70
kV

Yellow - image transfer

Red - no connection

T

7mA

kV key

Return key   **Test key**

TMJ key

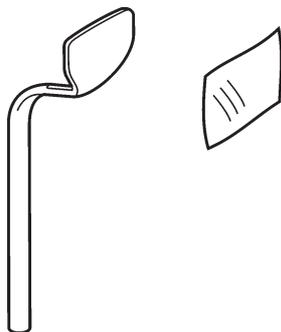**Panoramic key**
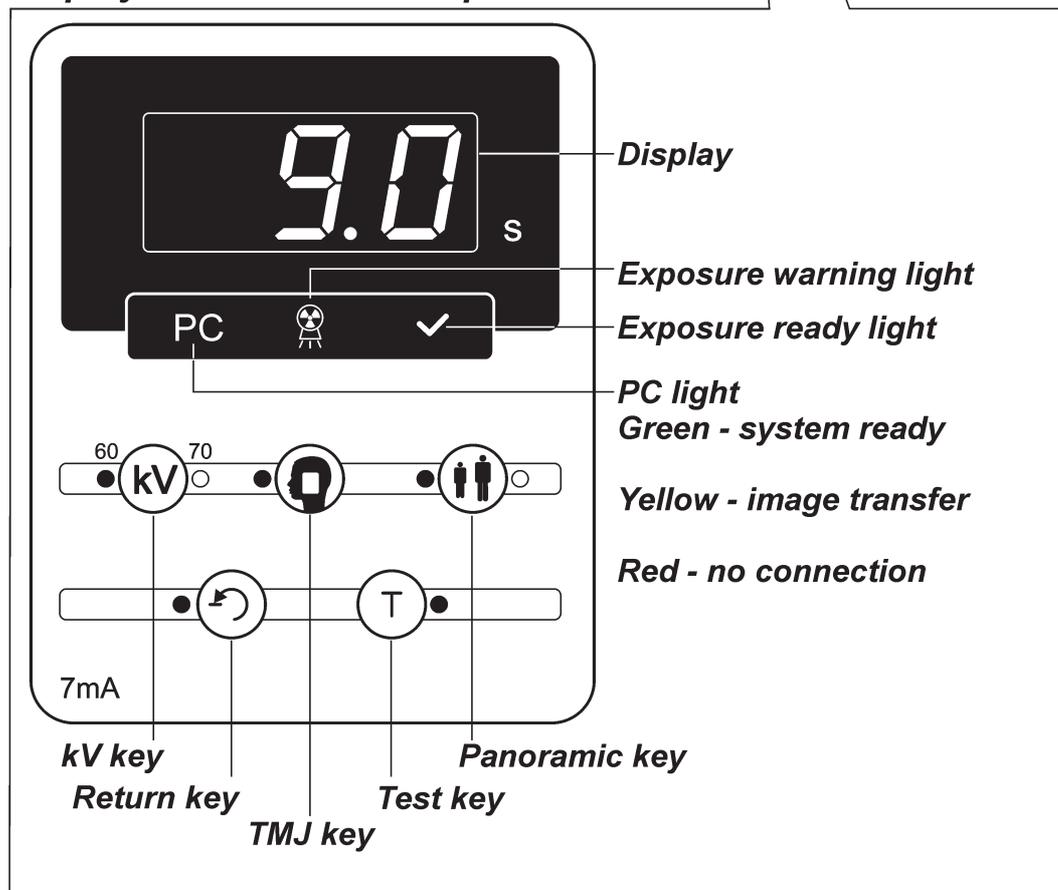
2.3 Accessories
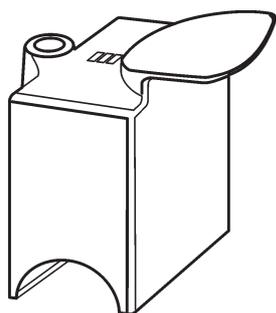
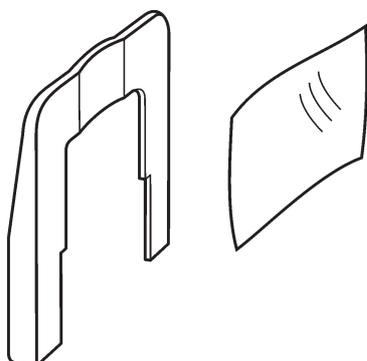Chin rest - 200682
Disposable cover - 6801140

Bite block - 200793
Disposable cover - 6801120

Rod short (62.5 mm) - 6809790
Rod long (72.5 mm) - 6809710

Lip holder - 6811870
Disposable cover - 6801130

Lip support - 6807870
Disposable cover - 6801130

3. Using the Unit

IMPORTANT NOTE:
If the unit is being used for the first time or if you are using the unit for the first time check thst it is set up to your requirements. See section, **6. Unit Set up**.

3.1 Preparing the Unit

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

2. Open the dental imaging software you are using, for example, Digora for Windows (not in USA) and then open a patient card.
   Refer to the instructions supplied with the dental imaging software for information on how to do this.

3. **UNIT:** Switch the unit on. The on/off switch is at the base of the column at the rear.
   The unit will carry out a self test. When the PC light turns green and the READY light comes on the unit is ready to take an exposure.
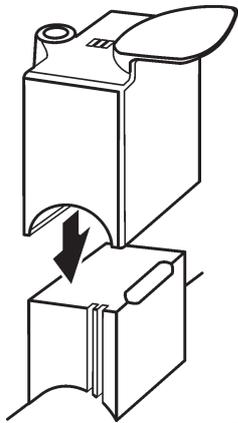   NOTE
   If the PC light turns RED it indicates that there is no connection to the PC.

4. Press the **Return** key to drive the rotating unit to the **P**atient **I**n/**O**ut (PIO) position.
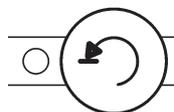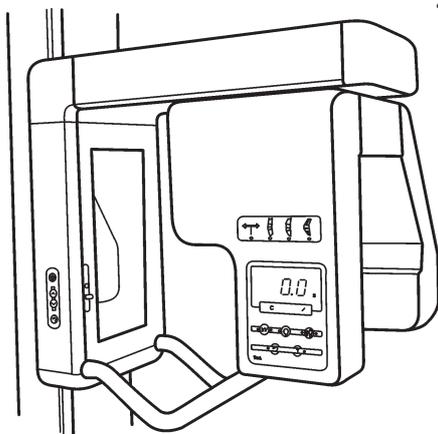
3.2 Taking Exposures

Panoramic - Adult or Child

1. Slide the chin rest on to the support holder.
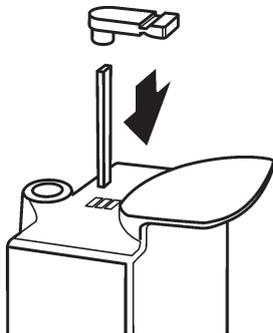
2. For dentate patients, attach the bite block to the rod and the insert the rod and bite block into the hole in the chin rest appropriate for the patient's occlusion.

   For normal occlusion insert the rod into the middle rectangular hole.
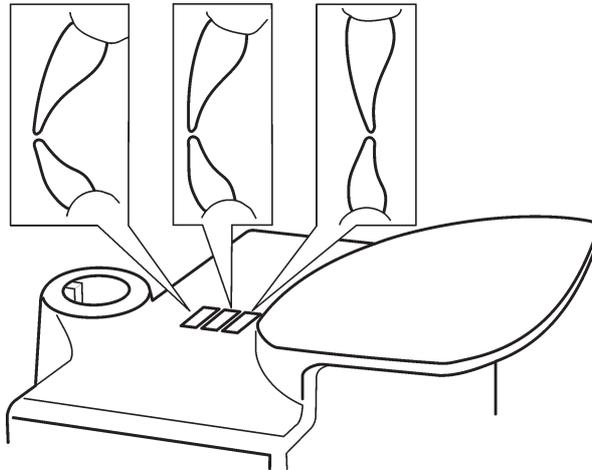
   If the patient's teeth protrude (angled outward), insert the rod into the rectangular hole nearest the column.

   If the patient's teeth retrude (angled inward), insert the rod into the rectangular hole furthest away from the column.

For edentulous patients use the lip holder and insert it into the round hole at the rear of the chin rest.
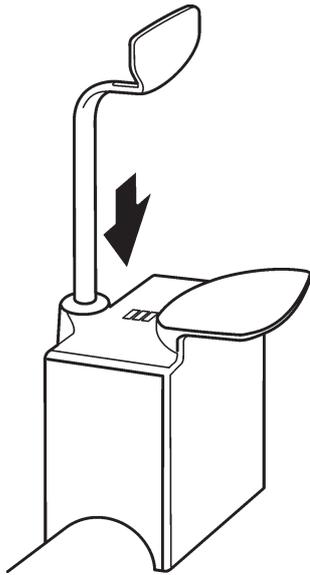
3. Place the appropriate disposable covers on the patient support you are using.
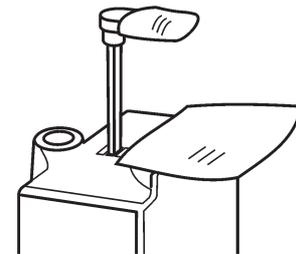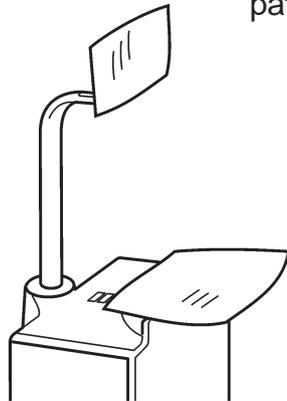
4. Press the **Panoramic** program key to select panoramic program you require, adult or child. The appropriate indicator light will come on. The magnification is 1.25.

Adult

Child

5. Select the **kV**, 70 kV for adults and 60kV for children.

60 70

kV

6. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Place a protective lead apron over the patient's shoulders.
    NOTE:
    If the patient is nervous, you can reassure them by demonstrating how the unit works before taking the exposure. See section 4.
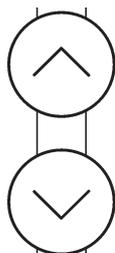
7. Press the **Up/Down** keys to adjust the height of the chin support so it is slightly higher than the patient's chin.
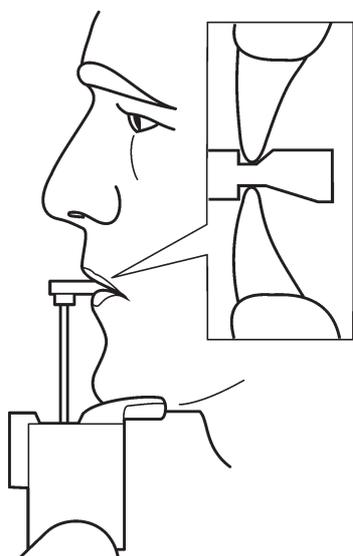
8. If the patient is dentate ask the patient to step into the unit, grasp the patient handles, place his/her chin on the chin rest and bite the notches in the bite block.

    If the patient is edentulous ask the patient to step into the unit, grasp the patient handles and press their top lip against the lip holder.
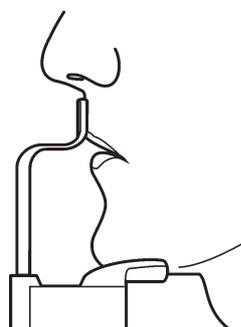
9. Press the mirror to open it so that you can see a reflection of the patient.
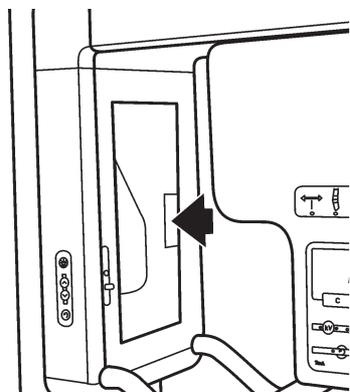
10. The patient positioning lights will automatically come on when one of the **Up/Down** keys is pressed or the mirror is opened. They will remain on for 30 seconds.
The Patient Positioning lights can also be switched on and off with the **Lights** key.
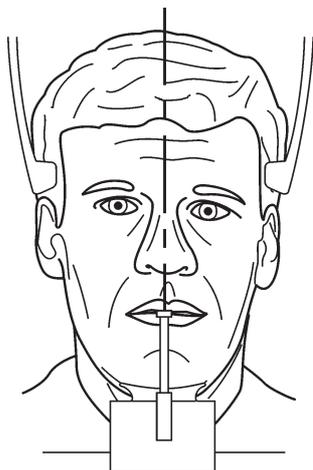
11. Look at the reflection of the patient in the mirror and position the **midsagittal plane** of the patient so that it coincides with the midsagittal plane light. Make sure that the patient is looking straight ahead and that the patient's head is not tilted or turned to one side.
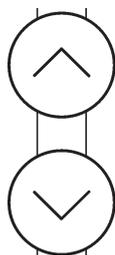
12. Press either **Up/Down** key to adjust the tilt of the patient's head until the patient's **Frankfort plane** coincides with, or is parallel to, the horizontal light.
CAUTION:
When pressing the **Up/Down** keys to adjust the tilt of the patient's head take care not to cause the patient any discomfort.
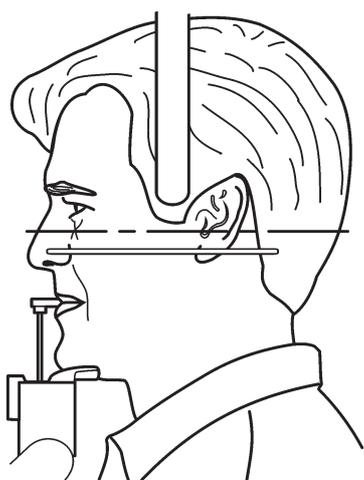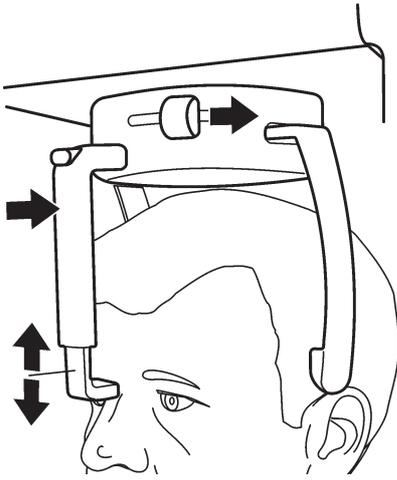
13. Close the temple supports by sliding the temple support knob to the right. Make sure that patient's neck is stretched and straight.
Carefully push the forehead support in until it touches the patient's forehead or nasion.

14. Check once more that the patient is positioned correctly and has not moved. Close the mirror.

15. Ask the patient to press their lips together and press their tongue against the roof of their mouth. Then ask the patient to look at a fixed point in the mirror and to remain still for the duration of the exposure.
The exposure takes approximately 12 seconds.

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

17. Press and hold down the exposure button for the duration of the exposure. During the exposure you will hear an audible signal and the exposure warning light on the control panel 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.

18. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transfered to the PC.
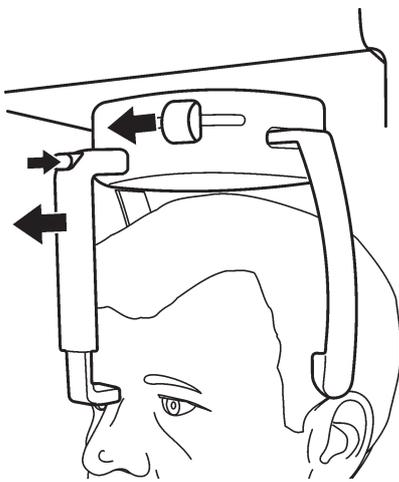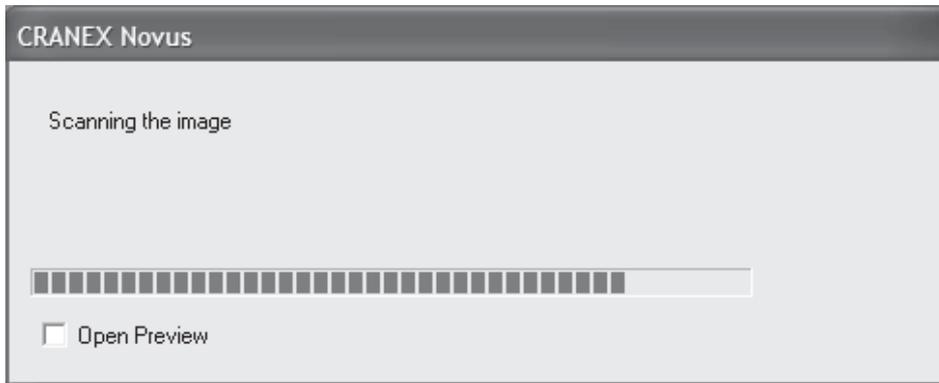
19. **UNIT:** Press the release button at the top of the forehead support and then slide the forehead support away from the patient.
Open the temple supports by sliding the temple support knob to the left.
Guide the patient out of the unit.
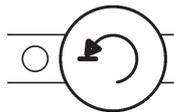
20. Press the **Return** key to drive the unit to the PIO position.
NOTE:
After the exposure, a timer indicating the tubehead cooling time will appear on the display. A new exposure cannot be taken until the counter reaches zero and the exposure time reappears on the display, and the ready light comes on.

Temporomandibular Joint (TMJ)
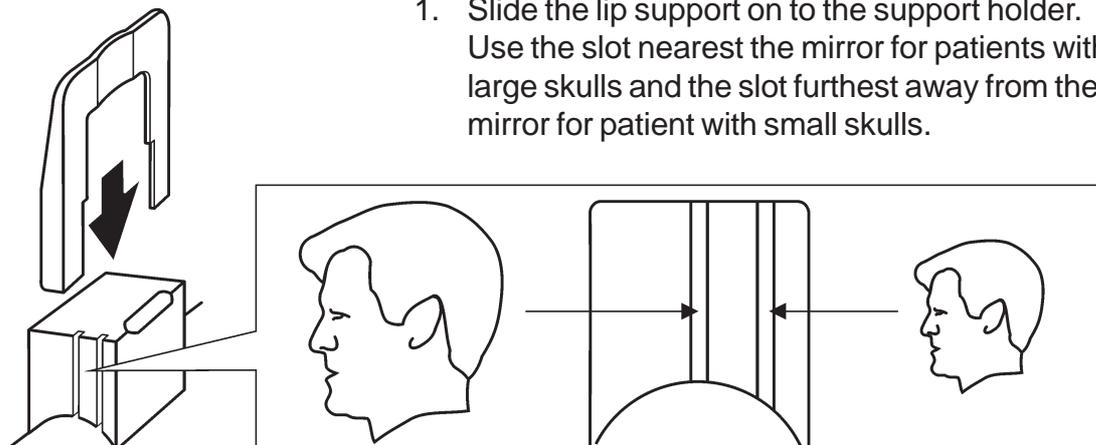
1. Slide the lip support on to the support holder.
    Use the slot nearest the mirror for patients with
    large skulls and the slot furthest away from the
    mirror for patient with small skulls.

2. Place the disposable cover on the lip support.

3. Press the **TMJ** key to select TMJ program. The
    indicator light will come on.
    The magnification is 1.25.

4. Select the **kV**, 70 kV for adults and 60kV for
    children.

5. Ask the patient to remove any spectacles, false
    teeth, jewellery and hair clips and pins.
    Place a protective lead apron over the patient's
    shoulders.
    NOTE:
    If the patient is nervous you can reassure them by
    demonstrating how the unit works before taking
    the exposure. See section 4.
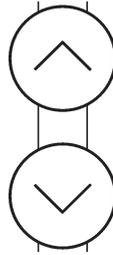
6. Press the **Up/Down** keys to adjust the height of the lip support so it is level with the patient's upper lip.
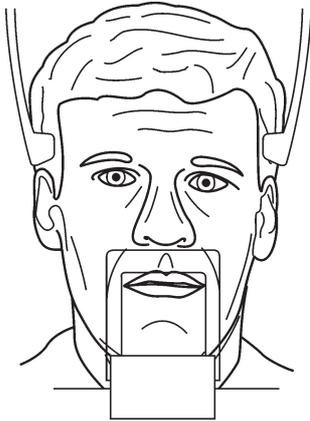
7. Ask the patient to step into the unit, grasp the patient handles and press their top lip against the top of the lip support.
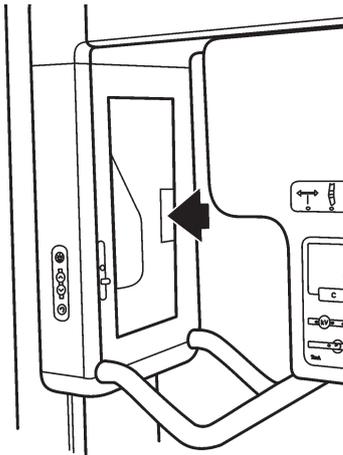
8. Press the mirror to open it so that you can see a reflection of the patient.

9. The patient positiong lights will automatically come on when one of the **Up/Down** keys is pressed or the mirror is opened. They will remain on for 30 seconds.
    The Patient Positioning lights can also be switched on and off with the **Lights** key.
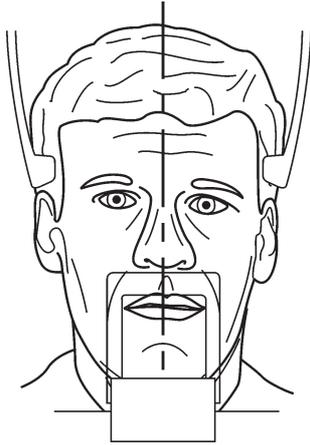
10. Look at the reflection of the patient in the mirror and position the **midsagittal plane** of the patient so that it coincides with the midsagittal plane light. Make sure that the patient is looking straight ahead and that the patient's head is not tilted or turned to one side.
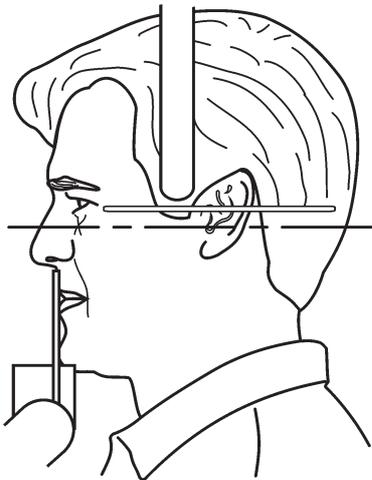
11. Press either **Up/Down** key to adjust the tilt of the patient's head until the patient's **Frankfort plane** coincides with, or is parallel to, the horizontal light. CAUTION:
When pressing the **Up/Down** keys to adjust the tilt of the patient's head take care not to cause the patient any discomfort.
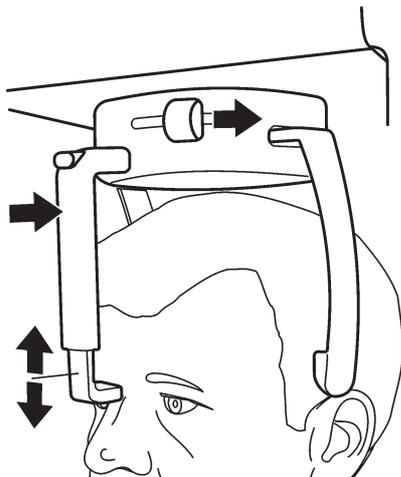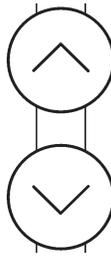
12. Close the temple supports by sliding the temple support knob to the right. Make sure that patient's neck is stretched and straight.
Carefully push the forehead support in until it touches the patient's forehead or nasion.

13. Check once more that the patient is positioned correctly and has not moved. Close the mirror.
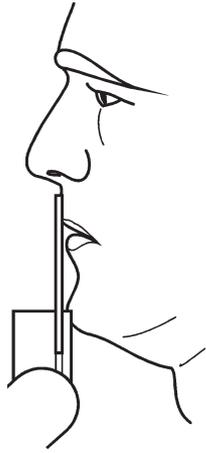
14. If you are taking a TMJ exposure with the patient's **mouth closed** ask the patient to clench their back teeth together, look at a fixed point in the mirror and to remain still for the duration of the exposure.
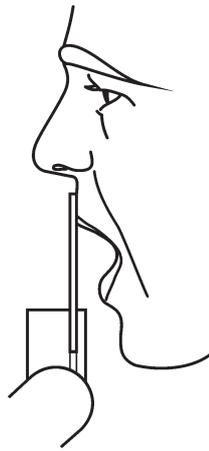
    If you are taking a TMJ exposure with the patient's **mouth open**, ask the patient to open their mouth, look at a fixed point in the mirror and to remain still for the duration of the exposure.

    The exposure takes approximately 12 seconds.

15. 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.

16. Press and hold down the exposure button for the duration of the exposure. During the exposure you will hear an audible signal and the exposure warning light on the control panel 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.

17. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transfered to the PC.
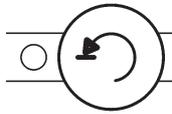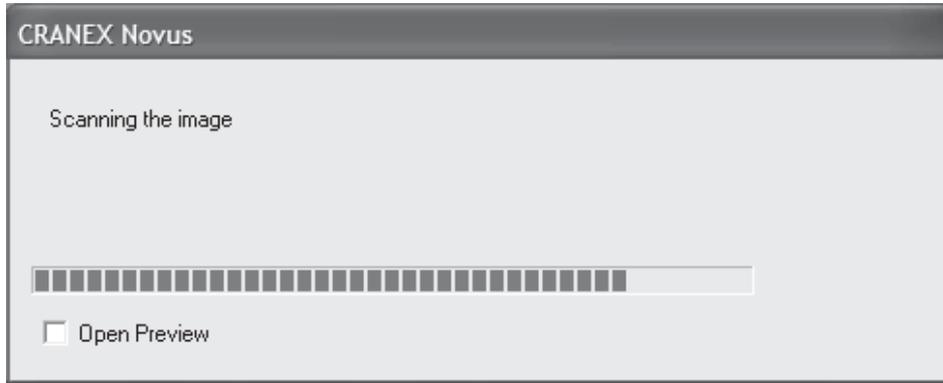
18. **UNIT:** If you wish to take a second TMJ exposure, press the **Return** key to drive the unit back to the PIO position, reposition the patient, step 13, and then take the second exposure steps 14 -15.
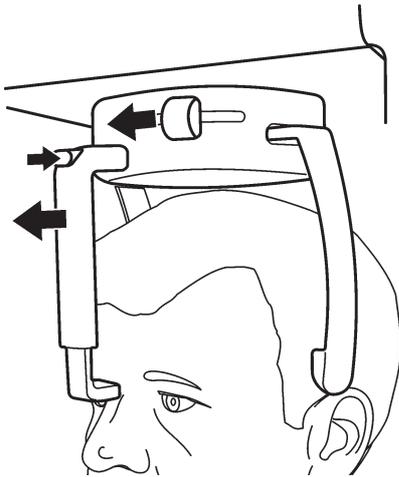
19. Press the release button at the top of the forehead support and then slide the forehead support away from the patient.
Open the temple supports by sliding the temple support knob to the left.
Guide the patient out of the unit.
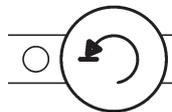
20. Press the **Return** key to drive the unit to the PIO position.

4. Operating 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 an exposure.

Press the **T** key (Test), 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 **T** key a second time to return to the normal exposure mode.

NOTE:
After switching the unit off and then on again the unit returns to the normal (non test) mode.

5. Exposure switch lock

The exposure switch locks the exposure switch so that unauthorized people cannot take exposures even if the unit is switched on.
The exposure switch lock is located at the rear of the unit near the base.

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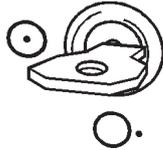
Insert the key and turn it clockwise to the horizontal position to unlock the exposure switch.

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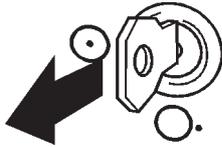
Turn the key anticlockwise to the vertical position and remove the key. The exposure switch is locked.

6. Unit Set up

Various set-up options allow the unit to be customized to your specific requirements

6.1 Set up options

1. **PC:** Open DFW or the dental imaging software you are using:

2. Select **Options** and then click **CRANEX Novus Setup**.
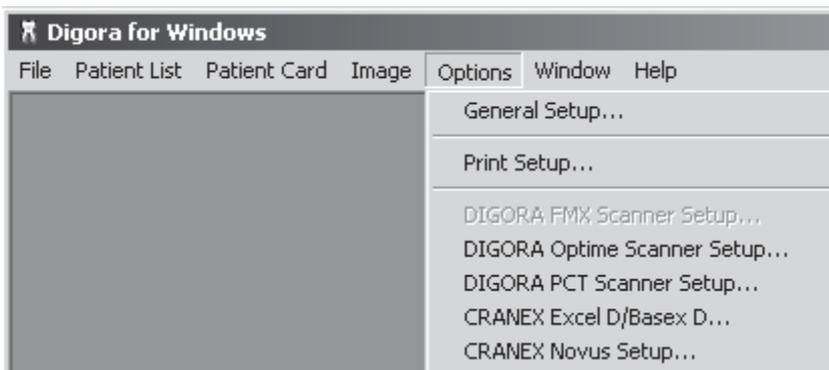
3. The **CRANEX Novus Setup** window will appear.
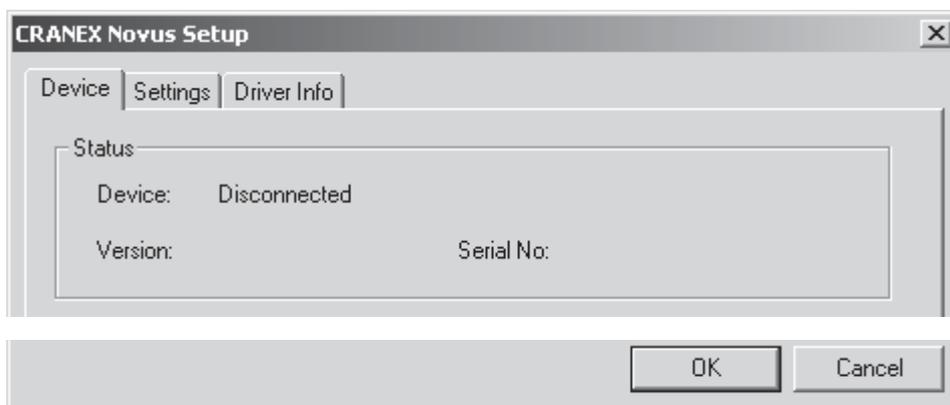
The **Status** field.
Device indicates whether the unit is connected to the PC. **Version:** shows the software version of the unit and **Serial No:** the serial number of the unit.

The **Image Scanning** field.

CRANEX Novus Setup   ✕

Device | Settings | Driver Info

Image Scanning

☑ Show Image Preview

Operation: ● Normal   ○ Calibrate
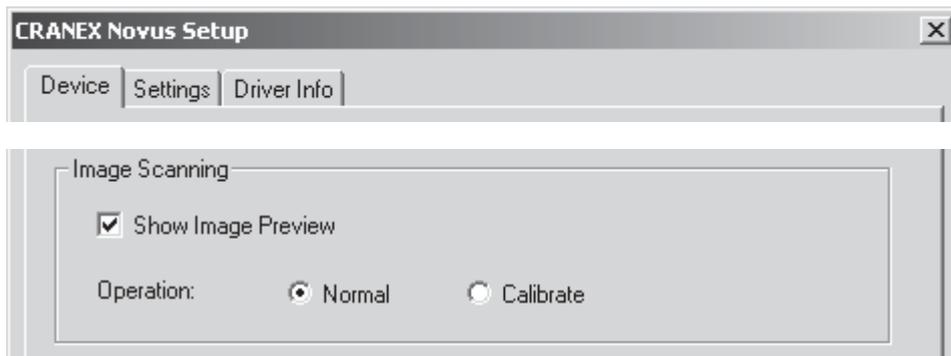
The **Show Image Preview** check box, see section **6.2 Image Preview**.
The **Operation** radio buttons, the **Normal** option is selected in normal use.

The **Image Processing** field

CRANEX Novus Setup   ✕

Device | Settings | Driver Info

Image Processing
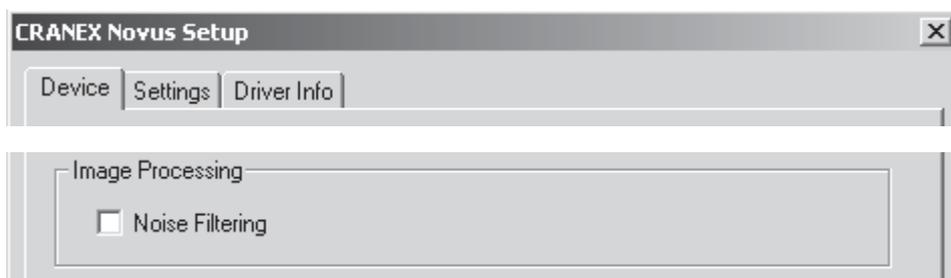
☐ Noise Filtering

The **Noise Filtering** check box should normally be selected. Noise filtering make images smoother when they are taken at low doses.

The **Retrieve Last Image** field

CRANEX Novus Setup   ✕

Device | Settings | Driver Info

Retrieve Last Image

☐ Must be activated every time an image needs to be retrieved
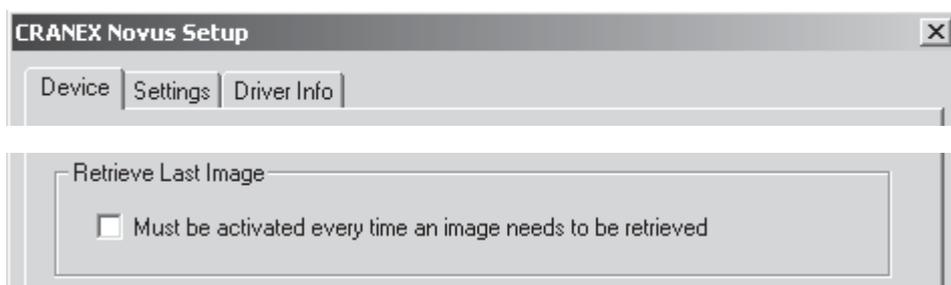
If the last image read is not transferred to the PC because of a network, PC or software failure, the image can be retrieved.

IMPORTANT NOTE
The last read image can only be retrieved if the unit has been left connected to the power supply. If the unit has been disconnected the image will be lost.
To retrieve the last image:

i. Correct the problem that caused the network failure, and then reopen the patient card.

ii. The last scanned image should automatically be transferred.
If it is not, click the check box in the **Retrieve Last Image** field to retrieve the last read image.

iii. Click **OK** to close the **CRANEX Novus Setup** window.
The last image taken will appear on the patient card.

Device Serial Number field
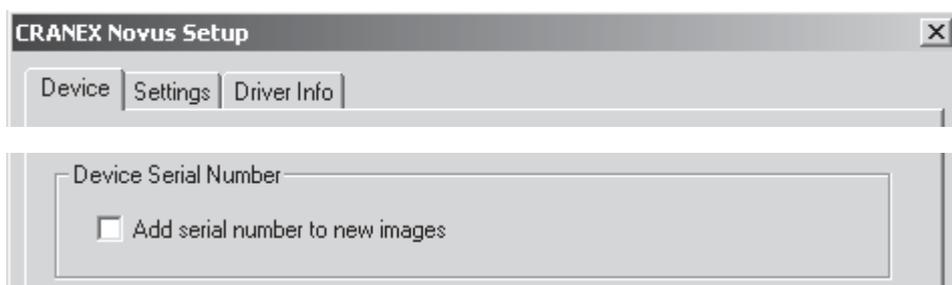
Click the **Add serial number ...** check box and the serial number of the unit will be added to all new images. The serial number will appear in the top left-hand corner and the bottom right-hand corner of the image.
NOTE:
If you select **Enable image marking** in DFW (**General Setup / Image / Image marking**) do not select the left top or right botton options as the image marking text will appear on top of the serial number.

6.2 Image Preview

The Image Preview feature allows grayscale adjustments to be made to an image BEFORE it is saved. The adjustments can be applied to the open image only or ALL subsequent images.
CAUTION:
Grayscale adjustments made to images CANNOT be undone after the adjustments have been saved.

1. Click the **Show Image Preview** check box if you want an image preview to appear.
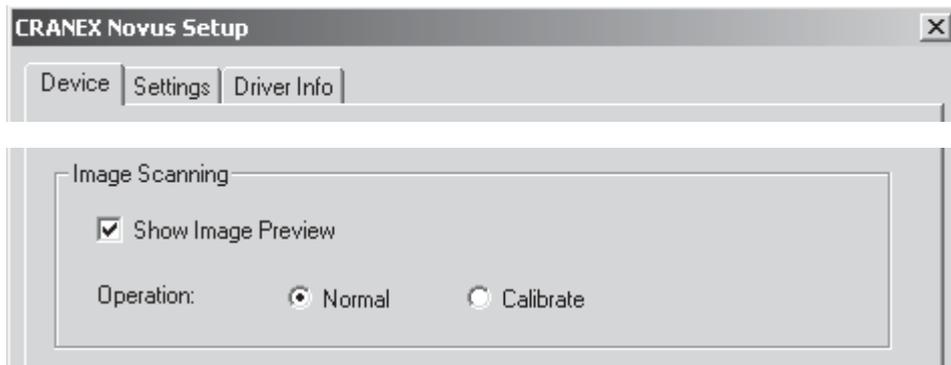
After taking an exposure the **Image Preview** window will appear.

2. In **Grayscale Controls** field at the bottom of the window the **Speed**, **Contrast** and **Enhancement** slide controls allow the image to be adjusted.

3. **No adjustments**
   i. If you do not wish to make any grayscale adjustments DO NOT move any of the sliders just click the **OK** button.
   NOTE:
   If you moved the sliders and do not wish to save the new settings refer to **Retrieving the factory defaults** at the end of this section.
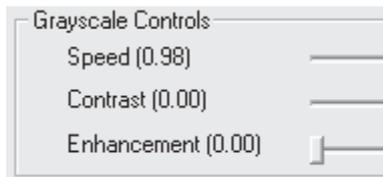
Adjust ONE image only
i. If you want to make grayscale adjustments to the image in the Image Preview window only, use the grayscale sliders to adjust the image to your preference.

ii. Click the **OK** button to apply adjustments to the image in the Image Preview window only.
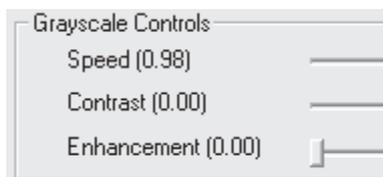
Adjust ALL future images
i. If you want apply grayscale adjustments to ALL subsequent images, use the grayscale sliders to adjust the image to you preference.

ii. Click the **Edit Quality Presets** button.

iii. The **Set Image Quality Presets** window will appear.

Click the **Get from Preview window** radio button to activate it and then click **OK**.

Set new control values
⦿ Get from Preview window (0.01/-0.24/0.00)
○ Panoramic factory defaults (1.00/0.00/0.00)

[OK]   [Cancel]
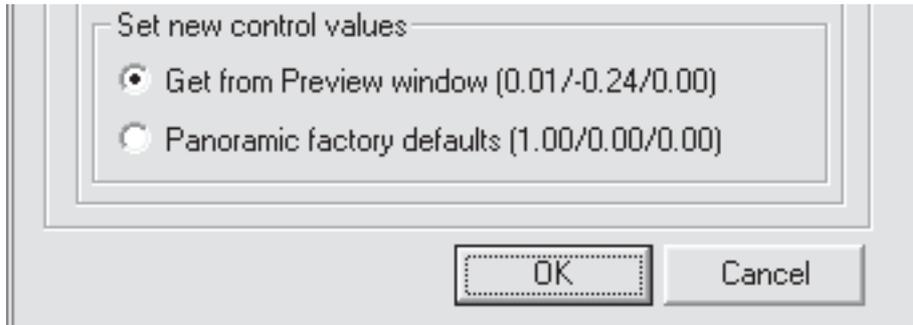
iv. The **Image Preview** window will reappear.

Image Preview

Click **OK** to apply adjustments to the image in the Image Preview window and ALL subsequent images.

Retrieving the factory defaults
If you made some grayscale adjustments but do not wish to save them click the **Panoramic factory defaults radio** button in the **Set Image Quality Presets** window to retrieve the factor settings.

⦿ Panoramic factory defaults (1.00/0.00/0.00)

Framing

Text

A

4. The **Framing** and **Text** tools in the top right-hand corner allow the image to be rotated and manipulated, and text to be added to the image.
NOTE:
Framing and text changes are only saved with one image, the image in the Image Preview window.

7. Troubleshooting and Maintenance

7.1 Information messages

Information messages are grouped into two categories:
- user errors, these begin with the letter H
- and system errors, these begin with the letter E.
To clear an information message from the display, press any key on the main control panel (NOT the side control panel).

User errors

H 1 (flashes alternatively with the exposure time)

REASON
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, contact service.

System errors

E 0

REASON
Tube arcing.
SOLUTION
Switch the unit off and then on again. If the message reappears contact service.

E 1

REASON
Tube kV out of limits
SOLUTION
Switch the unit off and then on again. If the message reappears contact service.

E 2

REASON
Tube current (mA) out f limits.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 3

REASON
Preheat failure.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 4

REASON
Tubehead too hot or too cold.
SOLUTION
Wait for the tubehead to reach the right temperature, approximately 30 minutes.

E 5

REASON
Line voltage out of limits.
SOLUTION
The error code will clear when the voltage stabilizes. If the error does not clear within a reasonable time, contact service.

E 6

REASON
Exposure timeout error, exposure more than 10 seconds.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 7

REASON
Optosensor failure.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 8

REASON
Z-motor running timeout, runs for more than 30 seconds.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 9

REASON
Rotating motor running timeout, runs for more than 30 seconds.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 10

REASON
CCD error, configuration.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 11

REASON
CCD error, power failure.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 12

REASON
CCD error, line failure.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 13

REASON
CCD error, DMA failure.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 16

REASON
Control panel keys suck down.
SOLUTION
Switch the unit off, press the keys and then switch the unit on again. If the message reappears, contact service.

E 18

REASON
Display not connected.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

E 19

REASON
Exposure switch stuck down during unit start.
SOLUTION
Switch the unit off and check that the exposure switch is not stuck in the exposure position. Switch the unit on again. If the message reappears, contact service.

E 20

REASON
Flash check error.
SOLUTION
Switch the unit off and then on again. If the message reappears, contact service.

7.2 Care and Maintenance

Cleaning and disinfecting the unit

Warning
Switch the unit off before cleaning it.

Surfaces

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent. DO NOT 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 these parts.

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 on the display 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.

Every week check that the power supply cable is in good order (not damaged in any way) and that the unit operates correctly in accordance with the instructions in this manual.
Make sure that the unit cannot be driven up/down when the emergency stop button has been pressed down.

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 that the safety ground is connected
– a check that the positioning lights operate
– a check that oil is not leaking from the tube head
– a check 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.

8. 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.

- The user must stand at least two meters from the unit when taking exposures protect him/herself from radiation when taking exposures. It is recommended that a moveable radiation protection screen be used.

- The user must be able to see and hear the patient during an exposure.

- The user must see the radiation warning light and/or 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 should 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 exposure switch, in order to prevent unauthorized people using the unit.

- Disinfect all the surfaces that the patient is in 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.

- Do not connect any device to the unit that has not been supplied with the unit or that is not recommended by SOREDEX.

- If the patient is using a pacemaker, consult the manufactuer of the pacemaker to confirm that the x-ray unit will not interfer with the operation of the pacemaker before taking an exposure.

Appendix A. Technical Information

A.1 Technical specifications

Type

CRA-1

Classification

Complies with IEC 60601-1/1995, IEC 60601-2-7/1998, IEC 60601-2-28/1993 and IEC 60601-2-32/1994, IEC 878

UL 2601-11/2006 (for products with the UL Classification Mark) and EN 55011 standards

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

Safety according to IEC 60601-1

Protection against electric shock - Class 1

Degree of protection - Type B applied with no conductive connection to the patient

Protection against the ingress of liquids - IPX 0

Disinfection methods:

      - mild soapy water (non-abrasive)

      - non-alcohol based disinfectant for the the chin rest

      - disposable plastic covers for bite piece, chin rest and lip support

For use in environments where no flammable anaesthics nor flammable cleaning agents are present

Mode of operation - continuous operation/intermittent loading

Unit description

A dental panoramic x-ray units with a high frequency switching mode x-ray generator. The unit takes panoramic exposures.

The unit uses a CCD sensor as an image receptor.

Generator

TUBE

      - KL40-0.5-70, or equivalent

FOCAL SPOT

      - 0.5 mm (IEC 60336/1993)

TARGET ANGLE

      - 12º

TARGET MATERIAL

      - Tungsten

OPERATING TUBE POTENTIAL

      - Panoramic imaging 60 and 70 kV (±5 kV)
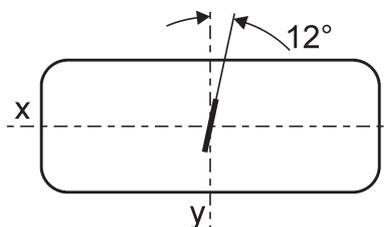
OPERATING TUBE CURRENT
- 7 mA (±1 mA)
NOMINAL ANODE INPUT POWER
- 490 W nominal at 70 kV, 7 mA
MAXIMUM TUBE CURRENT
- 7 mA
MAXIMUM ANODE OUTPUT POWER
- 600 W nominal nominal at 75 kV, 8 mA, 0.1 s
REFERENCE TIME PRODUCT
- 7 mAs at 60 kV, 7 mA, 1.0 s
FILTRATION
- inherent filtration minimum 0.8 mm Al at 50 kV (IEC 60522/1999)
- additional filtration 1 mm Al
- patient support attenuation equivalent less than 0.2 mm Al
- total fltration 2 mm Al at 70 kV
BEAM QUALITY
- HVL over 2.0 mm Al at 70 kV
PRIMARY PROTECTIVE SHIELDING
- minimum 0.5 mm Pb or equivalent
OUTER SHELL TEMPERATURE
- +50ºC (122ºF) maximum
DUTY CYCLE
- controlled by the software of the unit

Power requirements

INPUT VOLTAGE
- 115/230 VAC (±10%), 50/60 Hz single phase, grounded socket
LINE CURRENT
115 VAC
- long term: 1.6 A (cont) at 70 kV/7 mA, 115 VAC mains)
- momentary: 8 A at 70 kV/7 mA, 115 VAC mains)
230 VAC
- long term: 1 A (cont) at 70 kV/7 mA, 230 VAC mains)
- momentary: 5 A at 70 kV/7 mA, 230 VAC mains)
MAXIMUM LINE RESISTANCE
- 1 ohm
MAXIMUM LINE FUSING
- 10 A /16A slow at 230/115 VAC (main fuse 5 A/8 A 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) 500 mm (±10 mm)
- Magnification factor 1.25

WEIGHT
- 100 kg

DIMENSIONS
- (H x W x D) 2316 x 835 x 1070 mm

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

Digital image receptor (CCD)

PIXEL SIZE
- 96 microns

ACTIVE SENSOR SURFACE
- 147.5 x 6.1mm

Timer

EXPOSURE TIMES
- Normal   9.0 s (±15%)
- Child   7.5 s (±15%)
- TMJ   1.8 + 1.8 s (±15%)

SINGLE LOAD RATING
70 kV, 7 mA, 9 s, panoramic

BACK-UP TIMER
- 12 s (±15%)

Leakage technique factors

PANORAMIC
- 70 kV, 1200 mAs/h (70 kV, 7 mA, duty cycle 1:20, for example a normal exposure per 3 minutes cool-down period)

Measurement bases

The kV is measured by monitoring differentially the current flowing through 450 Mohm, 1% feedback resistor connected between the tube anode and ground.
The mA is measured by monitoring current in the HT return line, which equals the tube current.

Collimator

PRIMARY SLIT
- Adult panoramic slit only. For child panoramic the exposure time is reduced to give a reduced length image.

PRIMARY SLIT SIZE
- 0.6 x 38 mm

Z-motor

DUTY-CYCLE
-Intermediate use: 6.25%, 25s ON, 400s OFF

Environmental data

OPERATING
- ambient temperature from $+10^oC$ to $+40^oC$
- relative humidity 10 - 90% no condensation

STORAGE/TRANSPORTATION
- ambient temperature from -20^oC to $+50^oC$
- relative humidity 5 - 85% no condensation
- atmospheric pressure 500 - 1080 mbar

PC requirements

- The PC must meet the IEC 60950 standard (minimum requirements).
- Windows XP Professional, SP1 or SP2 or Windows 2000 Professional SP4
- 512 MB RAM, >20 GB HDD
- 32 MB Video RAM
- Pentium 4 or equivalent
- one Ethernet 10/100 Mbit/s NIC
- 19" CRT or 17" TFT LCD (min. resolution 1024 x 768 pixels with DfW)

System requirements and connections

- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to it's own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.

- Position the PC and any other external device at least 1.5 m (60") from the x-ray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed with liquids.
- Clean the PC in accordance with the manufacturer's instructions.

X-ray system - to IEC 60601-1-1
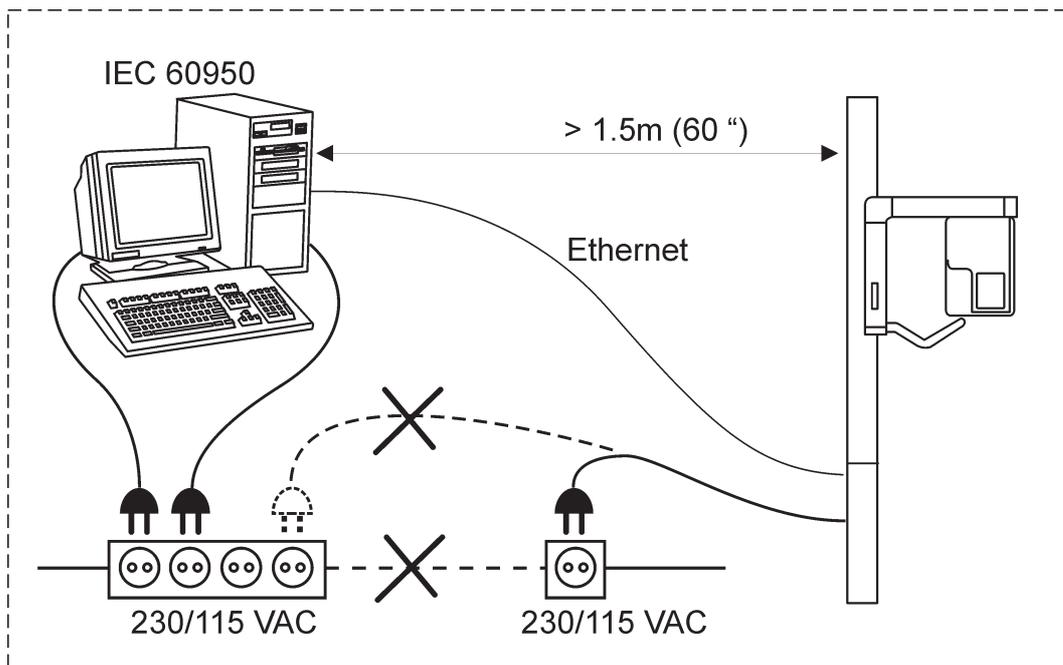
Tube housing assembly cooling/heating characteristics
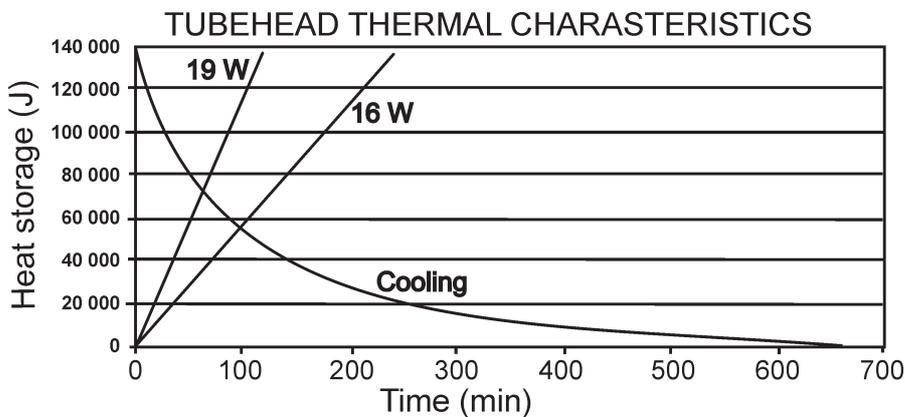
Tube rating chart KL40-0.5-70

Maximum Rating Charts
(Absolute maximum rating charts)

Focus Spot: 0.5 mm

Anode thermal characteristics
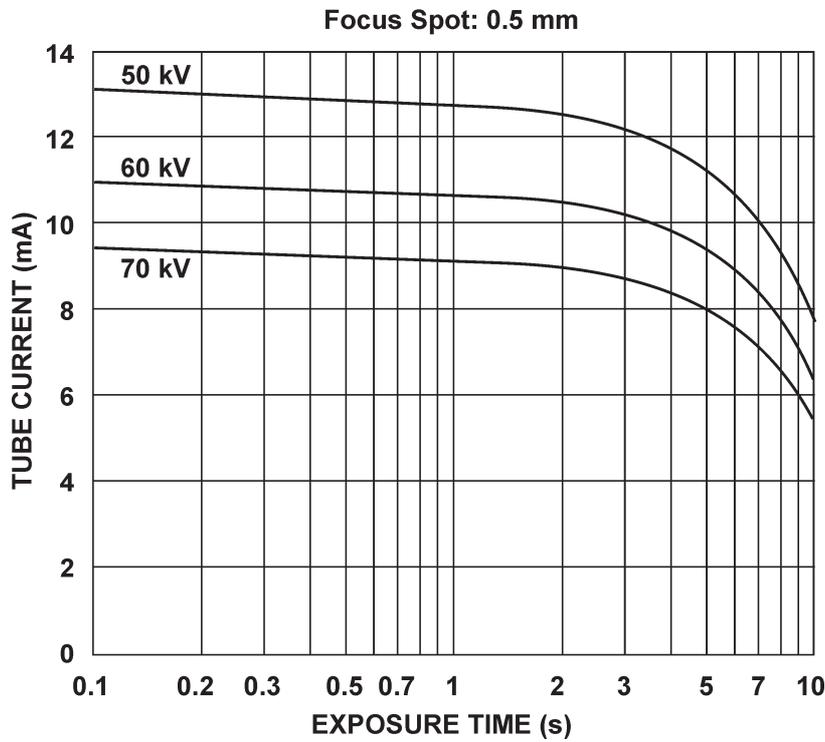
Anode Thermal Characteristics

A.2 Unit dimensions

2316 mm
(91.2 in)

950 - 1750 mm
(27 in - 80 in)

150 mm
(6 in)

1070 mm
(42 in)

835 mm
(39 in)
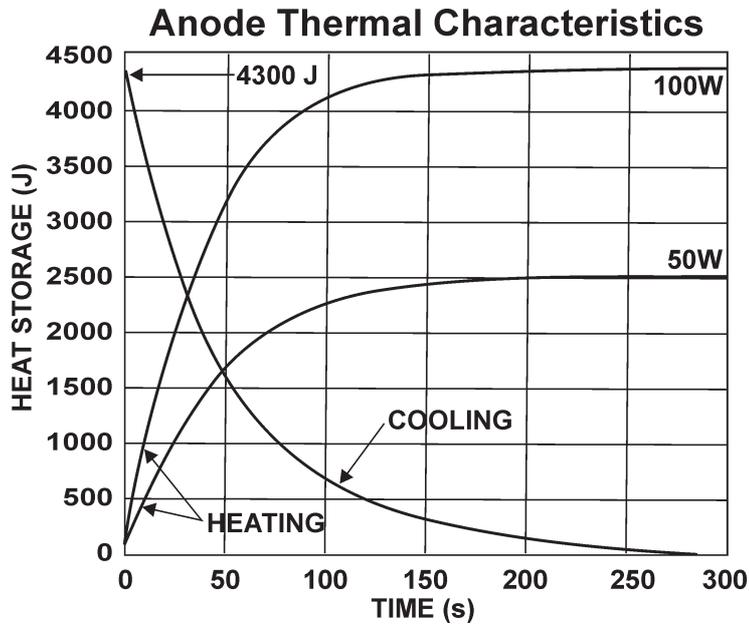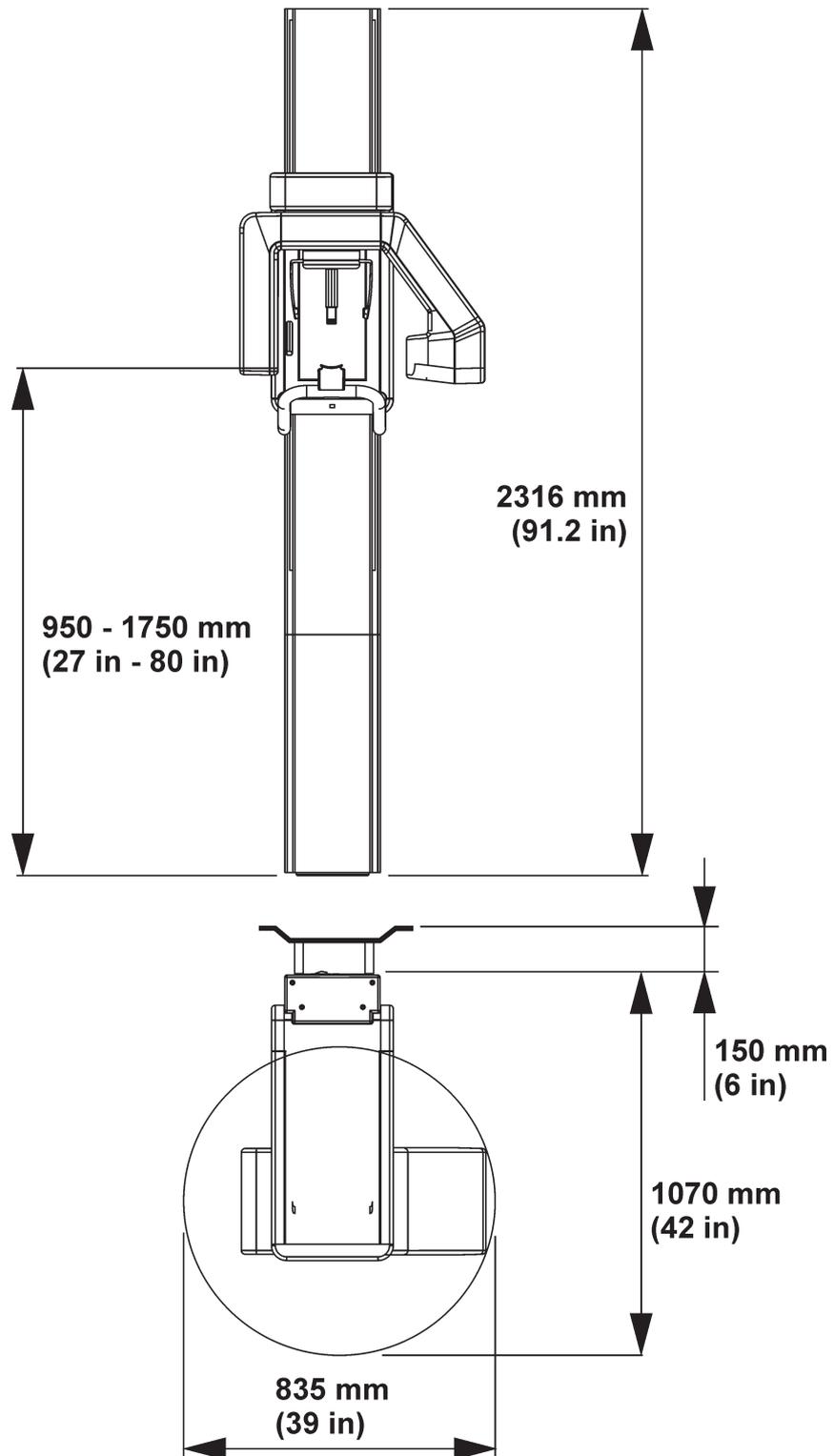
A.3 Symbols that appear on the unit

Radiation warning

Dangerous voltage

On or enabled

Off or disabled

Unlocked (exposure switch)

Locked (exposure switch)

Exposure switch

Connector for Ethernet RJ44

Connector for exposure switch

Connector for external exposure light

Attention, consult accompanying documents

⏚ Ground (Functional)

Protective ground

CLASS 1 LASER PRODUCT

EN 60 825-1/A2:2001

Laser class label
(Patient positioning lights)

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.

Type B equipment

C€
0537

CE (0537) symbol
MDD 93/42/EEC

UL Classification and CSA classification

A.4 Electromagnetic declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The CRA-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the CRA-1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The CRA-1 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 CRA-1 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 CRA-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the CRA-1 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 CRA-1 requires continued operation during power mains interruptions, it is recommended that the CRA-1 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The CRA-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the CRA-1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the CRA-1, 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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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: $\left(\left(\left(\cdot\right)\right)\right)$
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.			
[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 CRA-1 is used exceeds the applicable RF compliance level above, the CRA-1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the CRA-1. [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 CRA-1.			
The CRA-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CRA-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CRA-1 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.			