1. Introduction

1.1 ORTHOPANTOMOGRAPH™ OP 2D

X-ray unit

The ORTHOPANTOMOGRAPH™ OP 2D (the unit) is a digital panoramic dental x-ray unit designed to take:

- Standard Panoramic exposures,
- Pediatric Panoramic exposures (reduced width)
- Segmented panoramic exposures (user selected segments)
- Bitewing exposures
- and TMJ exposures.

The unit uses a CCD sensor as the image receptor and a PC with suitable (Medical Device Directive 93/42/EEC compliant) dental imaging software, such as CLINIVIEW™ software, for image acquisition and handling.

The unit can be used in single or multiple user configurations. With the single user configuration, the unit is connected to a single PC. With the multiple user configuration (Easy Share activated), the unit is connected to a network where up to eight PCs can be connected to the unit. With the Easy Share configuration only one PC at a time can reserve and use the unit.

IMPORTANT NOTE:
Before using the unit for the first time, make sure that it is set up to your requirements. See section 5. Unit setup.

USA only
Caution:
Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.
1.2 About this manual

This manual describes how to use and set up the unit.

Please read these instructions carefully before operating the unit.

Before operating the unit, please read and observe the warnings and precautions that appear in section 8. Warnings and precautions.
2. Unit description

2.1 Main parts

1. Column
2. Upper shelf
3. Rotating unit
4. **Emergency stop button** - Press to stop, rotate to release.
5. On / off switch (rear of column)
6. **PC** with MDD compliant dental imaging software
2. Unit description

1. Exposure warning light
2. Midsagittal light
3. Mirror
4. Frankfort light and light positioning knob
5. Focal trough positioning knob
6. Patient support
7. Focal trough light
8. Patient support handles
9. Head support
2. Unit description

2.2 Unit controls

A. Side control panel
1. Lights key - switches the positioning lights on and off
2. Up key - drives the unit up
3. Down key - drives the unit down
4. Return key - drive the unit to the patient in/out position (PIO)

B. Main control panel
5. Program selection keys:
   - P1 = Standard Pan, P2 = Pediatric Pan, P3 = TMJ, BW = Bitewing
6. Patient Size selection keys:
   - Child, Juvenile, Adult, Large adult
7. Manual (M) mode selection key
8. kV and mA selection keys, manual mode only
9. Test key - operates the unit without x-rays
10. Exposure values
11. Service key
12. Patient Name -key (visible only if patient name display is supported by the dental imaging software)
13. Dose Area Product (DAP)
14. Unit status indicator
15. Segmented Panoramic program selection key
2. Unit description

2.3 Accessories

- Chin rest
- Bite block
- Bite fork
- Chin support
- Edentulous bite positioner
- Nose support long - for children
- Nose support short - for adults
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 that it is set up to your requirements. See section 5. Unit setup.

3.1 Preparing the Unit

The preparation steps below are for CLINIVIEW software. If you are using some other dental imaging software, refer to the documentation that is supplied with it.

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

2. **PC:** Open CLINIVIEW software or the dental imaging software you are using and enable image capture. Refer to the instructions supplied with the dental imaging software for information on how to do this.

3. Switch the unit on. The on/off switch is at the rear of the column near the base. The unit display will come on and the unit will carry out a self test.

When the self test is complete a question mark (?) will appear next to the unit status indicator. This indicates that you need to reserve the unit before you can take an exposure.

**Single user:**

**Multiple users:**
3. Taking an Exposure

**NOTICE:**
If the no connection symbol (X) appears next to the unit status indicator, it indicates that there is no connection between the unit and the PC. See section 6. Troubleshooting and Maintenance for more information.

4. **PC:** Press the device icon to reserve the unit and enable image capture.

**NOTICE:**
If a message appears stating that the unit is in use it indicates that the unit has been reserved by another user. Wait until the unit is free.

**INFORMATION:**
The status of the unit, available, ready or busy can be seen in the status field at the bottom of the PC display.

5. When the unit status indicator turns GREEN and the text **Ready** appears the unit is ready to take an exposure.

**Single users:**

```
[Ready]
```

**Multiple users:**

```
[Ready]
```
6. Press the **Return** key to drive the rotating unit to the **Patient In/Out (PIO)** position.

If the Patient Name key appears on the display, you can check the patient’s name by pressing the Patient Name key once. A dialog box showing the patient name opens for 5 seconds and then closes automatically. Re-press the Patient Name key if you wish to hide the name sooner.
3. Taking an Exposure

3.2 Exposure programs

Exposure programs can be selected using the unit’s main control panel. Before taking exposures, it is recommended to revise the need for the exposure and select the exposure program accordingly.

Illustrative sizes and locations of the exposed areas using different exposure programs:

Exposed areas of Standard Panoramic and Pediatric Panoramic programs
3. Taking an Exposure

Exposed segments of Segmented Panoramic program (1...5)

NOTICE:
Segment heights are the same, the differences shown are for illustrative purposes only.

Segment selection keys in segmented panoramic screen
3. Taking an Exposure

Exposed areas of Bitewing program

Exposed areas of TMJ program
3.3 Taking Exposures

**Standard Panoramic, Segmented panoramic, Pediatric Panoramic and Bitewing exposures**

1. Slide the chin rest on to the support holder.

2. **Dentate patients.** Attach the bite block to the bite fork and then insert the bite fork and bite block into the hole in the chin rest.

**Edentulous patients (panoramic standard and pediatric only).** Attach the chin support to the chin rest. If the patient is **partially edentulous** attach the edentulous bite positioner to a bite fork and then insert the bite fork and edentulous bite positioner into the hole in the chin rest.
3. Place the appropriate disposable covers on to the patient support you are using.

4. Select the panoramic program you require, **Standard Panoramic (P1)**, **Segmented Panoramic (P1+Segmented Pan. key)**, **Pediatric Panoramic (P2)**, or **Bitewing (BW)**. The magnification for these programs is 1.25.

5. Select the patient size, **Child**, **Juvenile or small adult**, **Adult** or **Large adult**.

Default kV and mA values for the selected patient size will be shown on the display.

The DAP value for the selected program and patient size will be shown on the display.

If you consider that the default kV and mA values are not correct for the patient being examined select different values based on the patient’s size, age and estimated bone density.

To select different kV and mA values press the **M** key. Plus (+) and Minus (−) keys will appear. These allow you to change the kV and mA values to suit the patient being examined.

The recommended values are:

- **Child**, 66kV
- **Juvenile/ small adult** 70kV
- **Adult**, 73kV
- **Large adult**, 77kV
6. If you wish to take a Segmented Panoramic exposure, press the Segmented Panoramic key.

**NOTICE:**
Segmented Panoramic key is available only if Standard Panoramic (P1) is selected first

The segmented panoramic screen will appear.

All segments are selected as default. Press the required segment selection keys to toggle between selected (blue) and unselected (white), until only the segments you wish to expose are selected.

If you decide to take other than Segmented Panoramic exposure and wish to return to main screen, press the Segmented Panoramic key again.

7. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Place a protective lead apron over the patient’s shoulders.

**NOTICE:**
If the patient is nervous, you can reassure him/her by demonstrating how the unit works before taking the exposure. See section 4. Operating the unit without generating X-rays.

8. Press the **Up/Down** keys to adjust the height of the chin rest so it is slightly higher than the patient’s chin so that the patient will have to stretch up to place their chin on the chin rest.
9. Ask the patient to step into the unit and grasp the patient handles.

If the patient is dentate, ask the patient to place his/her chin on the chin rest and bite gently thenotches in the bite guide.

If the patient is partially edentulous ask the patient to bite gently the edentulous bite positioner.

**NOTICE:**
Evaluate the condition of the patient’s dentition before using the bite block or edentulous bite positioner. Use chin support instead if there is a chance that biting the block could cause excess stress to the patient or their dentition.

If the patient is edentulous ask the patient press chin against the chin support.

10. Press the Lights key to switch the patient positioning lights on. They will remain on for two minutes.

**NOTICE:**
The patient positioning lights will automatically come on when either the **Up** or **Down** key is pressed.
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.

For a **Standard, Segmented** or **Pediatric** Panoramic exposure, position the patient so that the **Frankfort plane** coincides with, or is parallel to, the horizontal light.

For a **Bitewing** exposures position the patient so that the **Occlusal 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 make small adjustments only so as not to cause the patient any distress or discomfort.
13. The focal trough light indicates the center of the focal trough which is 10 mm wide at the front. Ask the patient to open their lips so that you can see the patient’s teeth.

For **Standard and Segmented Panoramic (P1)** and **Pediatric Panoramic (P2)** panoramic exposures use the focal trough knob to position the patient so that the focal trough light is in the center of the patient’s upper and lower third teeth (canines).

The roots of the upper and lower front incisors must be located within the focal trough and be on the same vertical plane.

If the roots of the upper and lower front incisors are not on the same vertical plane adjust the tilt of the patient’s head until they are.
3. Taking an Exposure

For **bitewing (BW)** panoramic exposures position the chinrest on the BW line.

14. Close the temple supports by sliding the temple support knob to the right (**A**). Make sure that patient’s neck is stretched and straight. Adjust the position of the nasion support (**B**) and then carefully push the forehead support in until it touches the patient’s nasion (**C**).

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 ten seconds.
16. Ask the patient to step forward slightly so that they are out of balance and “hanging” onto the support handles. This will force the patient to stretch their neck as far as possible.

17. Make sure that the unit status indicator is still GREEN, indicating that the unit is ready to take an exposure. If the indicator is not GREEN the unit reservation time may have expired. Reserve the unit again, see section 3.1 Preparing the Unit.

18. Check once more that the patient has not moved and is still in the correct position.

19. 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.

20. Press and hold down the exposure button for the duration of the exposure. The exposure starts when you hear the exposure warning signal and the exposure warning indicator (control panel) and light (side of the unit) come on. The rotating unit will rotate around the patient’s head and take the exposure.

When the exposure warning signal and rotating unit stop, the exposure has been taken.

**NOTICE:**
After the exposure, a bar indicating the tubehead cooling time may appear on the display. A new exposure cannot be taken until the bar depletes, the exposure time reappears on the display and the unit status indicator comes on.
21. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transferred to the PC.

![Progress Bar](image)

22. Press the release button at the top of the forehead support (**A**) and then slide the forehead support away from the patient (**B**). Open the temple supports by sliding the temple support knob to the left (**C**). Guide the patient out of the unit.

![Headgear Diagram](image)

22. Press the **Return** key to drive the unit to the PIO position.
3. Taking an Exposure

**Temporomandibular Joint (TMJ)**

1. Slide the nose support into the support holder. Use the short version for adults and the long version for children.

2. Place a disposable cover on to the nose support.

3. Press the **TMJ** key (P3) to select TMJ program.
   The magnification is 1.25.

4. Select the patient size,
   - **Child**,
   - **Juvenile or small adult**,
   - **Adult**
   - or **Large adult**.

Default kV and mA values for the selected patient size will be shown on the display.

The appropriate DAP value will be shown on the display.

If you consider that the default kV and mA values are not correct for the patient being examined select different values based on the patient’s size, age and estimated bone density.
3. Taking an Exposure

To select different kV and mA values press the M key. Plus (+) and Minus (-) keys will appear. These allow you to change the kV and mA values to suit the patient being examined.

The recommended values are:

- **Child, 66kV**
- **Juvenile/ small adult 70kV**
- **Adult, 73kV**
- **Large adult, 77kV**

5. Use the focal trough knob and position the support holder so that it is -5 for an adult and 0 for a child.

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.
3. Taking an Exposure

**NOTICE:**
If the patient is nervous you can reassure him/her by demonstrating how the unit works before taking the exposure. See section 4. Operating the unit without generating X-rays.

7. Press the **Up/Down** keys to adjust the height of the nose support so that the top is level with the patient’s upper lip.

8. Ask the patient to step into the unit, grasp the patient handles and press their top lip against the top of the nose support.

9. Press the Lights key to switch the patient positioning lights on. They will remain on for two minutes.

**NOTICE:**
The patient positioning lights will automatically come on when either the **Up** or **Down** key is pressed.

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 make small adjustments only so as not to cause the patient any distress or discomfort.

12. Close the temple supports by sliding the temple support knob to the right (A). Make sure that patient’s neck is stretched and straight. Adjust the position of the nasion support (B) and then carefully push the forehead support in until it touches the patient’s nasion (C).

13. 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.
3. Taking an 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 ten seconds.

14. Make sure that the unit status indicator is still GREEN, indicating that the unit is ready to take an exposure. If the indicator is not GREEN the unit reservation time may have expired. Reserve the unit again, see section **3.1 Preparing the Unit**.

15. Check once more that the patient is positioned correctly and has not moved.

16. 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.

17. Press and hold down the exposure button for the duration of the exposure. The exposure starts when you hear the exposure warning signal and the exposure warning indicator (control panel) and light (side of the unit) come on. The rotating unit will rotate around the patient’s head and take the exposure.
3. Taking an Exposure

When the exposure warning signal and rotating unit stop, the exposure has been taken.

**NOTICE:**
After the exposure, a bar indicating the tubehead cooling time may appear on the display. A new exposure cannot be taken until the bar depletes, the exposure time reappears on the display and the unit status indicator comes on.

18. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transferred to the PC.

19. If you wish to take a second TMJ exposure, press the **Return** key to drive the unit back to the PIO position, enable image capture (PC) and then reposition the patient and take the second exposure, steps 13 -17.
20. Press the release button at the top of the forehead support (A) and then slide the forehead support away from the patient (B). Open the temple supports by sliding the temple support knob to the left (C). Guide the patient out of the unit.

21. Press the **Return** key to drive the unit to the PIO position.
4. Operating the unit without generating X-rays

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

Press the T key (Test), the exposure values on the display will clear. 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.

NOTICE:
After switching the unit off and then on again the unit returns to the normal (exposure) mode.
5. Unit setup

NOTICE:
Further unit configuration can be performed using the dental imaging software. Refer to the software user manual for more information about unit configuration.

5.1 Customizing patient size selection keys

It is possible to customize the kV and mA values of the patient size selection keys.

How to customise a patient size selection key

1. Press the M key to activate the manual mode. The edges of the key will appear.

2. Select the custom kV and mA values you require by pressing the + or - keys.

3. Press and hold the Patient Size key that you wish to assign the customized kV and mA values to. When the letter M appears on the key it indicates that the patient size has been customized.

4. Repeat the above procedure for any of the other patient size keys you wish to customize.
5. Unit setup

How to restore the default (factory) settings

1. Press the M key to activate the manual mode. The edges of the key will appear.

2. Press and hold the Patient Size key that you wish to restore the default settings to. When the letter M disappears from the patient size key it indicates that the default settings have now been restored to the patient size.

The default and recommended kV/mA settings are:

<table>
<thead>
<tr>
<th>Patient size</th>
<th>kV</th>
<th>mA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child</td>
<td>66</td>
<td>6</td>
</tr>
<tr>
<td>Juvenile/ small adult</td>
<td>70</td>
<td>7.5</td>
</tr>
<tr>
<td>Adult</td>
<td>73</td>
<td>9.6</td>
</tr>
<tr>
<td>Large adult</td>
<td>77</td>
<td>12</td>
</tr>
</tbody>
</table>
### 6. Troubleshooting and Maintenance

#### 6.1 Error messages and symbols

If the unit is not used correctly or the unit malfunctions an error message or symbol will appear on the unit display.

There are three groups of error message:

- **Error symbols**
  The symbol will clear when the problem is corrected.

- **H**, user errors

- **E** (Error), exposure errors, these occur during exposure.

These all appear on the unit display.

Touch the **CLEAR** key to clear the error message and return to the main screen.

**NOTICE:**
If the CLEAR key does not appear on the error message screen, you will have to wait for the error to clear automatically.
6. Troubleshooting and Maintenance

Error symbols

![Error symbols](image)

**REASON**

i. The PC connected to the unit is not on.
ii. The dental imaging software in the PC is not open.
iii. The cable connecting the unit to the PC is disconnected or damaged.
iv. The IP address is not set correctly.

**SOLUTION**

i. Switch the PC on.
ii. Open the dental imaging software and select a patient.
iii. Reconnect the cable. If damaged, contact service.
iv. Reconfigure the IP address.

![Emergency stop button](image)

**REASON**

The emergency stop button is pressed down in the STOP position.

**SOLUTION**

Rotate and release the emergency stop button. The error symbol will clear.
User errors

H1
REASON
The exposure button was released during an exposure.

SOLUTION
Clear the error message and 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

E4
REASON
Tubehead too hot or too cold.

SOLUTION
When the error message automatically clears the tubehead has reached the correct operating temperature. In normal conditions this will take about 30 minutes for the tubehead to reach the correct temperature. If the error message does not disappear within a reasonable amount of time, contact service.

E5
REASON
Line voltage not within limits.

SOLUTION
If the error message reappears it indicates that the voltage is not within limits. The error message will automatically clear when the voltage returns to the correct level. If the error message keeps on appearing or does not disappear within a reasonable amount of time, contact service.
6. Troubleshooting and Maintenance

**E16**

**REASON**
Z-motor has overheated.

**SOLUTION**
Wait until the Z-motor, driving the unit up and down, has cooled down. The error message clears automatically when the motor has cooled down to the appropriate level. If the error message keeps on appearing or does not disappear within a reasonable amount of time, contact service.

**E19**

**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.

**Exx** (all other E errors except E4, E5, E16 and E19 (above).

**SOLUTION**
Clear the error message and try to take an exposure **without a patient**. If the error message reappears, switch the unit off, wait for half a minute and then switch the unit on again. If the error message reappears contact service.
6. Troubleshooting and Maintenance

6.2 Care and Maintenance

Cleaning and disinfecting the unit

Warning
Switch the unit off before cleaning it.

**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.

**Unit surfaces**
Use a soft cloth dampened with a mild detergent/disinfectant to clean unit surface. DO NOT use abrasive cleaning agents or polishes on the unit.

**Positioning mirror and light lenses**
The positioning mirror is made of glass and the focal trough positioning light cover is made of plastic. Use a soft cloth dampened with a mild detergent. NOT use abrasive cleaning agents or polishes on these parts.

**Touch screen control panel**
If the surface of the control panel becomes soiled, clean it with absorbent cotton or other soft cloth.
Remove any drops of liquid from the control panel surface immediately. Prolonged contact with liquid may cause the surface of the control panel to discolor or spots to appear.
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.
6. Troubleshooting and Maintenance

**Yearly maintenance**

Once a year an authorized service technician must carry out a full inspection of the unit. The following tests and checks must be carried out:

- a kV/mA test
- a beam alignment test
- check that the safety ground is connected
- check that the positioning lights operate
- check that no oil is leaking from the tube head
- check that the power lead is not damaged in any way.
- check that all covers and mechanical parts are correctly secured and have not come loose.
- check that any vents in the covers are not blocked with dust and that no dust has accumulated inside the unit.

A full description of all the tests and checks is described in the Service Manual.
7. Quality Assurance

Additional Quality Assurance (QA) exposures can be taken after installation and periodically to ensure that the image quality remains stable. The QA exposures can be taken using special QA program.

To take QA images you need an additional Cu (Copper) filter and Digital Test Tool (Prüfkörper test tool) that need to be ordered separately.

There are different thicknesses of the Cu-filters, select the correct one depending on the national requirements.

The unit provides two different QA program selections (QA1 and QA2):

- QA1 is intended for use with 0.8mm thick Cu filter (in accordance to IEC61223-3-4)
- QA2 is intended for use with 1.8mm thick Cu filter.
7. Quality Assurance

Taking a QA exposure:

1. **PC:** Prepare the unit for an exposure.

2. Attach the Ball and Pin Phantom to the Chin rest.

3. Then attach the Digital Test Tool (Prüfkörper test tool) to the Ball and Pin Phantom.

4. Attach the additional filter (Cu filter) to the center line of the tubehead inner cover as shown below. The filter has suction cups.

5. Set the chin rest to the zero (0) position.

6. Touch the service key on the main control panel of the unit to open the configuration screen.
7. Select **QA**.

8. The QA program screen appears. Here the user can select from two preset programs which to use for the QA exposure.

   **QA 1** for use with 0.8mm thick Cu filter
   
   **QA 2** for use with 1.8mm thick Cu filter

9. Select the QA program to be used

10. Move at least two meters away from the unit and protect yourself from radiation.

11. Press and hold down the exposure button for the duration of the exposure. The exposure starts when you hear the exposure warning signal and the exposure warning indicator (control panel) and light (side of the unit) come on. The rotating unit will rotate around the test phantom and take the exposure.

   When the exposure warning signal and rotating unit stop, the exposure has been taken.
7. Quality Assurance

12. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transferred to the PC.

13. Press the **Return** key to drive the unit to the PIO position.

14. **PC:** Visually evaluate the result using the dental imaging software.

   Subjects to be evaluated:

   1. Exposed area; Smoothness of the exposed area. Non-exposed area surrounds the whole image.

   2. Line Pair Resolution; minimum 2.5 LP/mm must be distinguishable.

   3. Low contrast resolution; Minimum two low contrast resolution holes must be visible.
NOTICE:
Some adjustments may be required to be made to the default image processing settings in the dental imaging software, when evaluating the QA image. Write down the used settings, so that the same settings can be used when taking the control images later on.
8. Warnings and precautions

8.1 General warnings

- 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 must only be used by personnel qualified and experienced in the use and operation of digital panoramic dental x-ray devices.

- If this device will be used with 3rd party imaging application software not supplied by Instrumentarium Dental, 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 Instrumentarium Dental.

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

- The unit should not be used adjacent to or stacked with other equipment.

- This unit can interfere with other devices due to its EMC characteristics and other devices can interfere with this unit due to their EMC characteristics. Refer to the EMC Declaration (A4) in Appendix A for more information.
8.2 User / patient warnings

- 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.

- 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 user to decide if the x-ray exposure is necessary.

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

- Always use suitable hygienic barriers on parts of the unit that the patient has contact with.

- Always evaluate the condition of the patient’s dentition before using any biteable positioners.

- Avoid taking x-ray exposures of pregnant women.

- If the patient is using a pacemaker, consult the manufacturer of the pacemaker to confirm that the x-ray unit will not interfere with the operation of the pacemaker before taking an exposure.
8. Warnings and precautions

- The user of the unit must stand at least two meters away from the unit AND protect him/herself from radiation when taking exposures. It is recommended that a moveable radiation protection screen is used to protect the user. The radiation protection screen should be located so that the user is able to see the control panel and patient from behind the radiation protection screen (the protected area or control zone).

The radiation protection screen must be large enough to fully protect the user from radiation. The radiation protection area must be at least 60 cm wide, 60 cm deep and 200 cm high. The radiation protection screen must include lead shielding with a minimum thickness 0.5 mm and the screen must conform to all national regulations concerning radiation shielding of dental/medical devices.
8. Warnings and precautions

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

- The user must be positioned so that he/she can see the exposure warning light/indicator and hear the audio exposure warning signal during the exposure. If the unit is installed in such a place where the exposure warning light/indicator cannot be seen or the audio exposure warning signal cannot be heard, then a separate exposure warning light/indicator device should be used. Please contact your local service for help.

- Disinfect all the surfaces that the patient is in contact with after every patient.

- 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 your local service for help.

- If the unit will not be used for a long time, switch the unit off in order to prevent unauthorized people using the unit.

- Do not use the unit if any of its covers or parts are damaged, loose or have been removed. Contact a service person approved by Instrumentarium Dental and get them to repair or replace any damaged, loose or removed covers or parts before reusing the unit.

- When touching the patient do not touch any electrical or Ethernet connectors at the same time.

- Do not touch or operate the unit if the unit is being serviced or if the covers have been removed for any reason.
9. Disposal

At the end of useful service life of the device, its spare parts, its replacement parts and its accessories make sure that you follow all local, national and international regulations regarding the correct and safe disposal and/or recycling of the device, its spare parts, its replacement parts and its accessories.

The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Hazardous materials and parts that are made of or contain these materials:

**LEAD:**
- Tubehead housing, collimator, CCD sensor, circuit boards.

**TUBEHEAD OIL**
- Inside tubehead

**CAESIUM IODIDE (CsI)**
- CCD sensor

For more information on these parts contact your dealer.
Appendix A. Technical Information

A.1 Technical specifications

Type
OP30-2

Classification
Complies with
- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-3
- IEC 60601-1-4
- IEC 60601-2-7
- IEC 60601-2-28
- IEC 60601-2-32
- UL 60601-1
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 - IP20
Disinfection methods:
  - mild soapy water (non-abrasive)
  - non-alcohol based disinfectant for the chin rest
  - disposable plastic covers for bite piece, chin rest and lip support
For use in environments where no flammable anaesthetics nor flammable cleaning agents are present
Mode of operation - continuous operation/intermittent loading

Unit description
A dental panoramic x-ray unit 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
  Toshiba D-052 SB or D-054 SB or CEI 105/5
TUBEHEAD HOUSING ASSEMBLY
  THA-M-X (where X is the version number)
FOCAL SPOT
  0.5 mm (according to IEC 60336/2005)
FOCAL SPOT ACCURACY
The accuracy is 10 mm from the marking on the tubehead cover.

TARGET ANGLE
5°

TARGET MATERIAL
Tungsten

NOMINAL X-RAY TUBE VOLTAGE WITH THE HIGHEST X-RAY TUBE CURRENT

- **100 V~**: 81 kV at 7.5 mA
- **120 V~**: 81 kV at 9.6 mA
- **220-240 V~**: 81 kV at 12 mA

X-RAY TUBE VOLTAGE accuracy is ± 4 kV.

HIGHEST X-RAY TUBE CURRENT WITH THE HIGHEST X-RAY TUBE VOLTAGE

- **100 V~**: 7.5 mA at 81 kV
- **120 V~**: 9.6 mA at 81 kV
- **220-240 V~**: 12 mA at 81 kV

X-RAY TUBE CURRENT accuracy is ± 1 mA.

NOMINAL ANODE INPUT POWER AND NOMINAL ELECTRIC POWER

- **100 V~**: 607 W at 81 kV, 7.5 mA, 10 s
- **120 V~**: 778 W nominal at 81 kV, 9.6 mA, 10 s
- **220-240 V~**: 972 W nominal at 81 kV, 12 mA, 10 s

X-RAY TUBE VOLTAGE STEPS

- **100 V~**: 63, 66, 70, 73, 77 and 81 kV
- **120 V~**: 63, 66, 70, 73, 77 and 81 kV
- **220-240 V~**: 63, 66, 70, 73, 77 and 81 kV

X-RAY TUBE VOLTAGE accuracy is ± 4 kV.

X-RAY TUBE CURRENT STEPS

- **100 V~**: 6 and 7.5 mA
- **120 V~**: 6, 7.5 and 9.6 mA
- **220-240 V~**: 6, 7.5, 9.6 and 12 mA

X-RAY TUBE CURRENT accuracy is ± 1 mA.

FILTRATION

- Inherent filtration minimum 0.6 mm Al at 50 kV (IEC60522/1999)
- Additional filtration minimum 2 mm Al
- Patient support attenuation equivalent less than 0.2 mm Al
- Attenuation equivalent of plastic cover, approximately 0.25 mm Al
- Total filtration minimum 2.6 mm Al at 77 kV
Appendix A. Technical Information

BEAM QUALITY
HVL over 2.77 mm Al at 77 kV

DAP (Dose Area Product) accuracy of displayed value better than 25%

PRIMARY PROTECTIVE SHIELDING
Minimum 0.5 mm Pb or equivalent

OUTER SHELL TEMPERATURE
+50ºC (122ºF) maximum

DUTY CYCLE
1:8, at maximum technique factors.
(Example: an 81 kV, 12 mA, 10 s exposure will have a 85 s cool-down period)

Power requirements

OPERATING LINE VOLTAGE
100 - 120 V~ or 220 - 240 V~, 50/60Hz

INPUT POWER
Standby: 26 W, maximum: 1300 W

MAXIMUM LINE IMPEDANCE
Apparent resistance of supply mains 0.5 ohm

MAXIMUM LINE FUSING
100-120 V~ 16A
220-240 V~ 10 A

MAIN FUSE
T-10A-H-250V

LINE SAFETY SWITCH (when required)
100 - 120 V~ Approved type, min. 16 A 250 V~
220 - 240 V~ Approved type, min. 10 A 250 V~

EARTH LEAKAGE CIRCUIT BREAKER (when required)
100 - 120 V~ Approved type, min. 16 A 250 V~
220 - 240 V~ Approved type, min. 10 A 250 V~,
breaker activation leakage current in accordance with local regulations.
Appendix A. Technical Information

Mechanical parameters

PANORAMIC
- Source to Image layer Distance (SID) 500 mm (±10 mm)
- Magnification factor 1.25
- Focus to skin distance, minimum 154 mm

WEIGHT
- 120 kg

DIMENSIONS
- (H x W x D) 2340 x 835 x 715 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 10.0 s
- Child 8.8 s
- Bitewing 2.5 + 2.5 s
- TMJ 3.1 + 3.1 s
- Segmented 2.2 - 10.0 s

Accuracy for the displayed exposure times ± 5%

SINGLE LOAD RATING
- **100 V~** 81 kV, 7.5 mA, 10 s, panoramic
- **120 V~** 81 kV, 9.6 mA, 10 s, panoramic
- **220-240 V~** 81 kV, 12 mA, 10 s, panoramic

BACK-UP TIMER
- 15 - 17 s (±15%)
Leakage technique factors

**PANORAMIC**

**100V~:** 4329 mAs/h, exposure with maximum values (81 kV, 7.5 mA, 10 s) according to the 1:5 duty cycle

**120V~:** 4486 mAs/h, exposure with maximum values (81 kV, 9.6 mA, 10 s) according to the 1:7 duty cycle

**220-240V~:** 4606 mAs/h, exposure with maximum values (81 kV, 12 mA, 10 s) according to the 1:8 duty cycle

**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**

**TYPE**
BLD-M-1

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

**PRIMARY SLIT SIZE**
0.7 - 0.75 x 38 mm

**Z-motor**

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

**Environmental data**

**OPERATING**
Ambient temperature from +10ºC to +40ºC
Relative humidity 10 - 90%, no condensation
Atmospheric pressure 700 - 1060 mbar

**STORAGE/TRANSPORTATION**
Ambient temperature from -20ºC to +50ºC
Relative humidity 0 - 85% no condensation
Atmospheric pressure 500 - 1080 mbar
Appendix A. Technical Information

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 its 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 1.85 m (73”) 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
Appendix A. Technical Information

Tube housing assembly cooling/heating characteristics

Tube rating chart Toshiba D-052 SB

Maximum Rating Charts
(Absolute maximum rating charts)

Focus Spot: 0.5 mm

TUBE CURRENT (mA)

EXPOSURE TIME (s)
Anode thermal characteristics

![Graph showing anode thermal characteristics with curves for 315W, 225W, and 175W power levels. The graph plots heat storage (kJ) against time (min). The curves indicate heating and cooling phases.]
A.2 Unit dimensions

- **Standard column leg**
  - 2340 mm (92.1")
  - 965 - 1740 mm (38 - 68.5")

- **Short column leg**
  - 2250 mm (88.6")
  - 875 - 1650 mm (34.5 - 65")

- **Exhibition stand**
  - 790 mm (31")
  - 225 mm (8.9")

The height of the unit on the exhibition stand is the same as the height of the unit with the standard column leg 2340 mm (92.1")
A.3 Symbols that may appear on the unit

Manufacturer name and address

Serial number

Reference number

Radiation warning (yellow label)

Dangerous voltage

On or enabled

Off or disabled

Exposure switch

Connector for Ethernet RJ45

Connector for exposure switch

Connector for external exposure light

Operating instructions
Refer to operating instructions for more information.
The operating instructions can be supplied electronically or in paper format.
Electrostatic discharge (ESD) warning symbol (yellow label)

Type B Applied part

Ground (functional)

Protective ground

Warning, Laser radiation (yellow label)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed of 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.

Recyclable

Do not reuse

CE (0537) symbol
MDD 93/42/EEC

ETL symbol

GOST-R symbol
A.4 EMC declaration for the OP 2D

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The device 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The device 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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
## Guidance and manufacturer’s declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td></td>
<td></td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td></td>
</tr>
<tr>
<td></td>
<td>±8 kV air</td>
<td>±8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transients/bursts</td>
<td>±2 kV for power</td>
<td>±2 kV for power</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>supply lines</td>
<td>supply lines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode</td>
<td>±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>±2 kV common mode</td>
<td>±2 kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply lines</td>
<td>&lt;5 % (U_T) (&gt;95 % dip in (U_T)) for 0.5 cycle</td>
<td>&lt;5 % (U_T) (&gt;95 % dip in (U_T)) for 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40 % (U_T) (60 % dip in (U_T)) for 5 cycles</td>
<td>40 % (U_T) (60 % dip in (U_T)) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70 % (U_T) (30 % dip in (U_T)) for 25 cycles</td>
<td>70 % (U_T) (30 % dip in (U_T)) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 % (U_T) (&gt;95 % dip in (U_T)) for 5 sec</td>
<td>&lt;5 % (U_T) (&gt;95 % dip in (U_T)) for 5 sec</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE**: \(U_T\) is the a.c. mains voltage prior to application of the test level.
Appendix A. Technical Information

### Guidance and manufacturer’s declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>Recommended separation distance $d = 1.2 \sqrt{P}$&lt;br&gt;$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz&lt;br&gt;$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**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.

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*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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.*

*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 device.

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>( d = 1.2 \sqrt{P} )</td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.