





USER'S MANUAL

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Attention

For greater safety:

- Read and understand all instructions written in this manual before installation or use of the equipment.
- This instruction manual should be read by all operators of the equipment.
- This instruction manual was originally written in Portuguese.

Intended Use

Intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures.



US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST OR PHYSICIAN.

Warning Statement

Only personnel authorized by Panoramic Corporation are qualified to install and service this equipment. Any attempt to install or service this equipment by anyone not so authorized will void the warranty.

It is imperative that this equipment be installed, serviced, and used by personnel familiar with the precautions required to prevent excessive exposure to both primary and secondary radiation. This equipment features protective designs for limiting both the primary and secondary radiation produced by the X-ray beam. However, design features cannot prevent carelessness, negligence, or lack of knowledge.

Panoramic Corporation requires anyone moving or transporting their machine to contact the Service Department at (800) 654-2027.

1. INTRODUCTION

The ENCOMPASS Panoramic X-Ray Machine is a complete system for dental imaging capable of:

Film Panoramic Profiles Film Cephalometric Profiles Digital Panoramic Profiles Digital Cephalometric Profiles

The digital machines use a sensor with CdTe/CMOS technology for imaging that allows for direct conversion between x-ray photons into voltage levels, making it less noisy than traditional scintillator technologies.

The equipment has three movement axes (two in orthogonal directions and one rotational) making it possible to execute elaborate imaging profiles.

It features a complex profile movement around the dental arch and radiographic emission compensation in the spinal region, when necessary reconstructing the dental arch into a plane image. Each individual profile prioritizes a set of characteristics improving diagnostic capabilities. For example, the standard panoramic prioritizes image layer width, constant vertical magnification and homogeneous exposure along the whole image. Likewise, the low dosage profile prioritizes the reduction of dosage (time and anodic current).

The profiles can be applied to a variety of patients: adult or child; small, medium or large. The equipment has predefined exposure parameters depending on patient type. However, the user can apply whatever is best for the situation.

The user interface is composed of a control panel located close to the patient chin rest and an exposure switch. A remote exposure switch installed outside the radiation room is optional. The exposure switch is a dead-man type switch.

Ease of patient positioning is complimented by the patient entry into the machine from the side. There are three lasers available for positioning: Mid-Saggital plane, Frankfurt Plane and Image Layer Plane (canine). These features make it possible for the user to precisely position the patient.

For patient comfort, a demonstration mode is also available making it possible to inform the patient of the procedure prior to exposure.

2. SYMBOLS

Use the icons below to identify the symbols on your equipment.

| 「 ⋓ っ | "Fragile" Located on the packaging side. It determines that the equipment must be carefully transported, thus preventing falls and shock. |
|-----------------------|--|
| [*] | "Protect against moisture" Located on the packaging side. It determines that the equipment must be protected against any type of moisture during transportation and storage |
| [∐] | "This side up" Located on the packaging side. It determines that it must always be handled with the arrow pointing upwards. |
| L B B L J | "Maximum piling" Located on the packaging side. It determines the maximum number of boxes that can be piled up during transportation and storage. |
| [/] | "Temperature limit" Located on the packaging side. It determines the temperature limits between which the packaging must be transported and stored. |
| [^{75%}] | "Humidity limit" Located on the packaging side. It determines the maximum relative humidity whitch the packaging must be transported and stored. |
| • | "Focal point" It indicates the exact position of the radiation-emitting center. |
| | "Operation temperature" It indicates the operation temperature limits |

| | "Radiation" It indicates that the equipment emits ionizing radiation. |
|---------------------|---|
| ٢ | "GND" Indicates the protection grounding terminals. |
| \triangle | "Attention" Warning for reference to accompanying documents |
| Ŕ | "Type-B Applied Part " |
| X | It indicates that the product must be taken to appropriate waste collection site equipment when it is no longer useble. It applies to the machine as well as to its accessories. |
| A , A | "lonizing radiation" |
| | "Laser Diode Light Emitter" |
| 4 | "High voltage symbol" |
| | "Manufacture" |

3. WARNINGS AND PRECAUTIONS

3.1. WARNINGS AND/OR CAUTION DURING TRANSPORTATION AND STORAGE

The equipment must be transported and stored by observing the following:

- Care should be taken to prevent falls and impact.
- The arrows must be pointing upwards.
- Do not stack.
- Protect against moisture, rainwater aspersion and wet ground.

This equipment must be unpacked and installed by an authorized technician. Premature unpacking does not generate safety risks, but leads to the equipment warranty voidance.

3.2. TRANSPORTATION OR STORAGE ENVIRONMENTAL CONDITIONS

| Environmental temperature range for transportation and | 0° C to $+55^{\circ}$ C |
|--|----------------------------------|
| storage | (+32°F to 131°F) |

3.3. INSTALLED EQUIPMENT CONDITIONS BETWEEN OPERATIONS

| Storage ambient temperature range | +5°C to +45°C (+41°F to 113°F) |
|---|--|
| Ambient temperature range recommended by manufacturer | +15°C a +30°C (+59°F to 86°F) |
| Storage relative humidity range | 30% to 75% (non- condensing) |
| Atmospheric pressure range | 700 hPa to 1060 hPa (525 mmHg to 795 mmHg) |

3.4. OPERATIONAL ENVIRONMENTAL CONDITIONS

| Operation ambient temperature range | +10°C to +35°C |
|---------------------------------------|------------------------|
| | (+50°F to 95°F) |
| Ambient temperature range recommended | +21°C a +26°C |
| | (69.8°F to 78.8°F) |
| Operation relative humidity range | 30% to 75% |
| | (non condensing) |
| Atmospheric pressure range | 700 hPa to 1060 hPa |
| | (525 mmHg to 795 mmHg) |

3.5. ADDITIONAL PROCEDURES PRIOR TO EQUIPMENT USE

Even prior to its first use, the equipment must be cleaned and disinfected; the same additional procedures must be followed for reuse, as described in chapter 11.

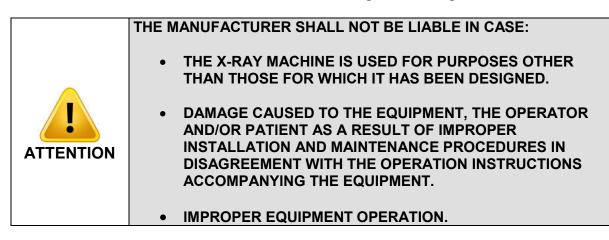
3.6. WARNINGS AND/OR CAUTION TO BE ADOPTED

3.6.1. WARNINGS AND/OR CAUTION DURING EQUIPMENT INSTALLATION

- The equipment must be installed only by service technicians authorized by the manufacturer.
- Place the equipment on a site where it will not be in contact with moisture or water.
- Install the unit on a site where it will not be damaged by pressure, temperature, moisture, direct sunlight, dust or salts.
- The equipment must not be submitted to inclination, excessive vibration or shock (including during transportation and handling).
- This equipment has not been designed for use in facilities where vapors, flammable anesthetic mixtures in contact with air, oxygen or nitrous oxide can be detected.
- Check the equipment's voltage when performing electric installation. Failure to do so may damage the equipment.
- The equipment must be properly grounded. Failure to do so may result in "Safety Hazard".
- Depending on local regulation the X-Ray emission control may require installation outside the facility where the equipment is placed, and the operator may need visual contact with the patient through a window with radiological glass or similar, since the operator must not lose visual contact with the patient.
- Mobile and portable RF communication equipment can affect the ENCOMPASS Panoramic X-Ray Machine.
- This equipment must be solely used by health care professionals as it may cause radio interference or interrupt the operation of nearby equipment. Mitigatory measures, such as equipment re-orientation or replacement and the facility's screening, may be necessary.

3.6.2.WARNING AND/OR CAUTION DURING EQUIPMENT USE

- The equipment must be operated only by qualified and trained professionals (dentists, radiology technicians, hygienists or engineers).
- Always observe the display messages, the equipment as a whole and the patient in order to detect any arising problems early.
- In case occasional maintenance is required, use only services provided by Authorized Service Technicians.
- The equipment has been designed to withstand continual and intermittent operation; therefore, follow the cycles described in these operation instructions.
- Since radiation exposure can cause damage to human cells, it is recommended that no one should remain in the radiographic examination room, unless the patient requires restraint. In this case, such individual must be properly protected against X-Ray emission.
- Although this equipment has been designed according to electromagnetic compatibility standards, it may, under very extreme conditions, interfere with other equipment. Do not use it with other devices that are sensitive to interference or with devices that create high electromagnetic disturbances.



3.6.3. WARNING AND/OR CAUTION AFTER EQUIPMENT USE/OPERATION

- Turn off the x-ray machine's master switch when it is not used for long periods of time.
- Always keep the equipment clean for its next operation.
- If the equipment is defective, do not try to fix it yourself, instead call for authorized technical assistance.
- Do not replace any equipment parts. Do not disconnect the cable or other connections unnecessarily.
- The ENCOMPASS Panoramic X-Ray Machine must be off when other equipment such as an electric scalpel or other similar devices are being used.
- After using the equipment, clean and disinfect all parts that may have been in contact with the patient.

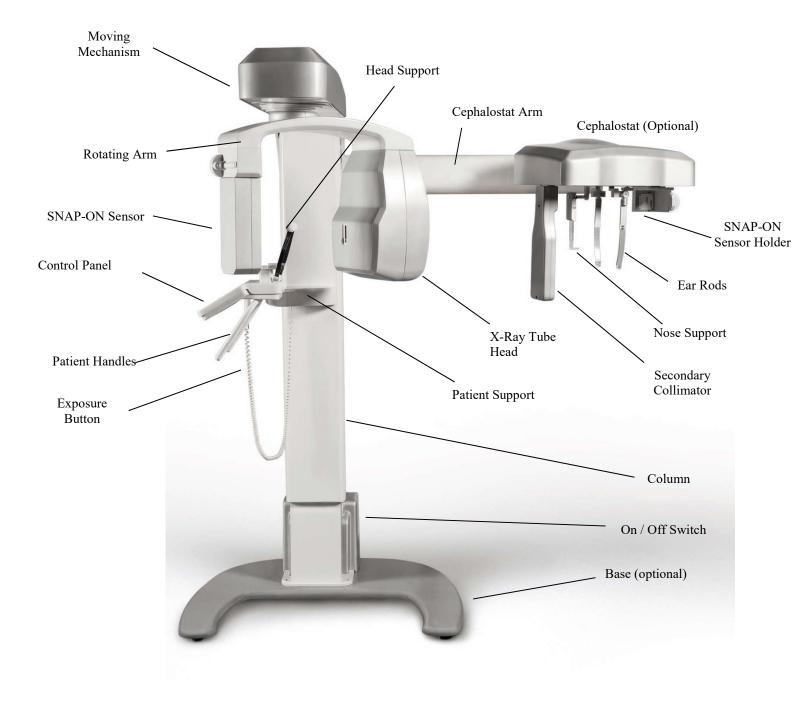
3.7. CAUTION IN CASE OF ABNORMAL EQUIPMENT FUNCTION

In case the equipment shows abnormal heating, noise or any other type of abnormality, check if the problem is related to any of the items listed in chapter 12. If the problem cannot be solved, turn off the equipment and call for Authorized Technical Assistance. Use the website http://www.pancorp.com or call the Panoramic Service Department at 1 (800) 654-2027.

4. ENCOMPASS PANORAMIC X-RAY SYSTEM OVERVIEW

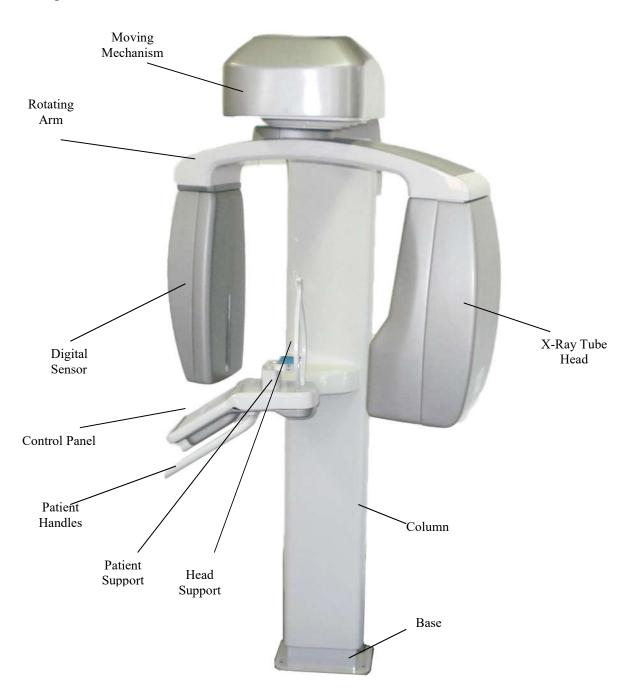
4.1. DIGITAL SNAP-ON CONFIGURATION

The following image shows the whole system with optional Ceph arm mounted.

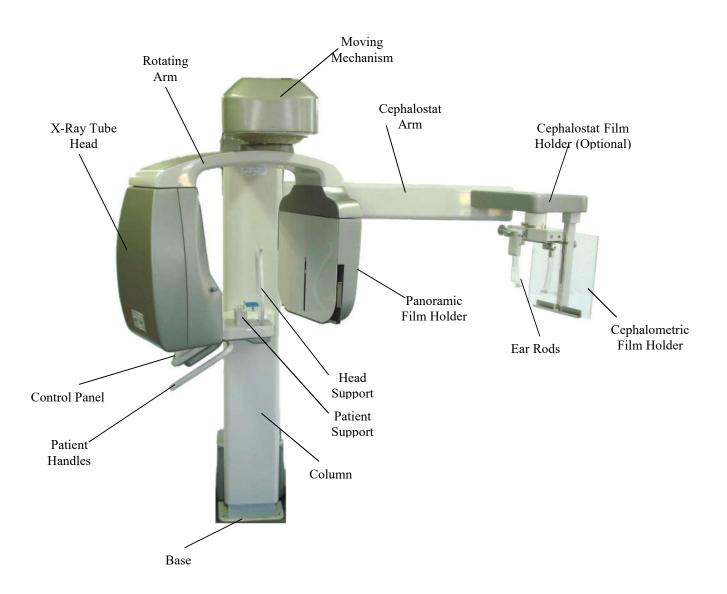


4.2. DIGITAL FIXED CONFIGURATION

The following image shows the whole system. No optional ceph arm is available in this configuration.



4.3. FILM CONFIGURATION



The following image shows the whole system with optional Ceph arm mounted.

4.4. FREE STANDING BASE (OPTIONAL)

The following image shows the optional Free Standing Base.



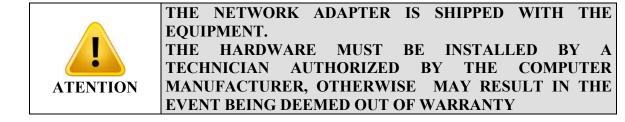
The equipment will be fixed to the base and wall by an authorized technician during installation.

5. COMPUTER SYSTEM REQUIREMENTS

It is imperative that this computer system have an EXCLUSIVE USE for EAGLE Panoramic X-Ray Machine. This system MUST fulfill the following requirements.

| Operating System | Windows XP professional SP3; Windows |
|------------------|--|
| | Vista Business; Windows 7 professional – |
| | (32 bit) |
| CPU | Intel Core 2 Due 3.0 Ghz ou higher |
| HDD | 10 GB of free disk space |
| RAM | 4GB DDR2 SDRAM |
| PCI | PCI Express (PCIe) slot, full-height |
| NIC | Gigabit Ethernet dedicated (32 bit) |

 Table 1 - Computer Requirements



6. NETWORK ADAPTER CONFIGURATION

To verify installation of the network card, follow the procedure:

1 – Verify the Windows system automatically installed the driver for the capture card.

Control Panel \rightarrow All items \rightarrow Control Panel \rightarrow System \rightarrow Device Manager \rightarrow Network Adapters



2 - Make sure the network adapter is installed. If not, install the network card drive using the CD shipped with the equipment.

3 - After installation restart the computer.

To configure the network card, follow the procedure:

1 - Go to Control Panel \rightarrow Network \rightarrow Internet and Network Connections

2 - Click the right mouse button on the connection DESKTOP Intel Gigabit CT, and visit the properties.

3 - Access the General tab and uncheck all items as shown below:

| 🕹 Local Area Connection Properties 🛛 😨 🔀 |
|---|
| General Advanced |
| Connect using: |
| Marcel (R) PCI Express Gigabit CT |
| This connection uses the following items: |
| Client for Microsoft Networks Client for Microsoft Networks Client for Microsoft Networks Client Scheduler Client Protocol (TCP/IP) |
| Install Properties Description |
| Show icon in notification area when connected Notify me when this connection has limited or no connectivity |
| OK Cancel |

4 - Go to Settings → Advanced tab and search for item "Jumbo Frames"
5 - Initially, this setting is disabled. Change the value to 9014 bytes and then click OK.

| VLANs | Driver | | Power Management | |
|--|---|------------------------------------|--|------------|
| General | Link | Advanced | | Teaming |
| ettings: | dvanced Adapter | - | /alue: | |
| Jumbo Frames .ocally Administer .og Link State Eve Performance Opti Power Saver Opti QoS Packet Taggi | ed Address ent ons ons ng | | Disabled 4088 Byt 9014 Byt 16128 By | es |
| CP/IP Offloading |) Options | ~ | Us | se Default |
| Enables or disak large packets m latency can be t utilization and im | oles Jumbo Frame ake up the majorit olerated, Jumbo F prove wire efficie | y of traffic rames can ency. | and additi reduce C | onal PU |
| are approximate | ire larger than sta ily 1.5k in size. erations | indard Ethe | rnet frame | es, which |

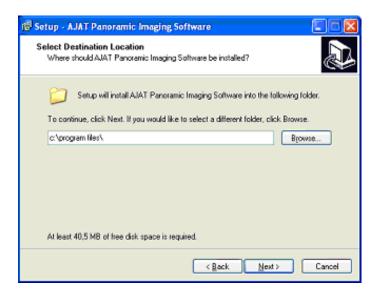
7. INSTALLING THE IMAGING SOFTWARE

Insert the accompanying CD into the CD-ROM drive of the personal computer. The following screen should be displayed. If Microsoft Windows Auto-Run functionality is disabled, open Windows Explorer and start the installation manually by opening the executable file on the root of the provided CD.

1 - Press NEXT:



2 - Select desired installation folder and press NEXT:



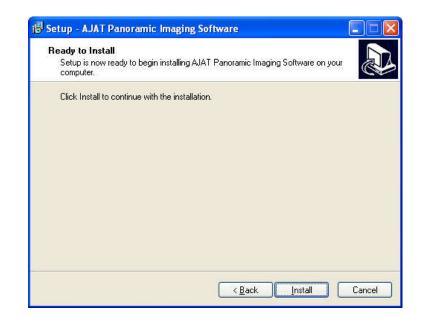
3 - Select desired Start Menu name and press NEXT:

| Select Star | t Menu Folder | | | |
|-------------|----------------------------|---------------------------|------------------------|-----------|
| Where she | ould Setup place the prog | gram's shortcuts? | | Ċ |
| i a | etup will create the prog | ram's shortcuts in the | following Start Men | u folder. |
| To continu | ie, click Next. If you wou | ld like to select a diffe | erent folder, click Br | owse. |
| Panorami | c Imaging Software | | | Browse |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

4 - Leave configuration as shown and press NEXT:

| Select Additional Tasks | | | | |
|-------------------------------------|-------------|-----------------|----------------|---|
| Which additional tasks should be pe | erformed? | | | Ċ |
| Select the additional tasks you wou | | erform while in | nstalling AJAT | |
| Panoramic Imaging Software, then o | click Next. | | | |
| Additional icons: | | | | |
| 🔽 Create a <u>d</u> esktop icon | | | | |
| File associations: | | | | |
| 🗹 Associate extension .DTZ | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

5 - Confirm the installation by pressing INSTALL:



6 - Restart the computer when prompted:

| 🕼 Setup - AJAT Panoramia | : Imaging Software |
|--------------------------|---|
| | Completing the AJAT Panoramic Imaging Software Setup Wizard To complete the installation of AJAT Panoramic Imaging Software, Setup must restart your computer. Would you like to restart now? • Yes, restart the computer now • Yes, restart the computer now |
| | <u> </u> |

7 - After restarting the computer click on Windows Start Menu / All Programs / Panoramic Imaging Software / AJAT Panoramic Imaging Software. The main software window should display as follows:

| 📲 AJAT Panoramic A | pplication - [Unsaved dataset] | | | |
|----------------------|---|---------------|----------------------------------|------------------------|
| | Image Iools <u>W</u> indow <u>H</u> elp | | | - 8 |
| System status | Histogram | Tools | Image | |
| Sensor Not connected | | | | Panoramic unit program |
| Action Idle (3) | | 🔍 🔍 🖉 | Enhance Focus Colors User DICOM | Undo Automatic |
| | | | Denoise Denoise Chargeon Count | |
| System not ready! | | High Light | Lownass Median Sharpen Equal -+- | New exposure |
| | | 4 | 3x3 3x3 Vertical | |
| | | | | Overview |
| | | | | |
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8. IMAGING PROGRAMS

The ENCOMPASS Panoramic X-Ray Machine contains a set of profiles for both analog and digital configurations.

8.1. PANORAMIC PROFILES:

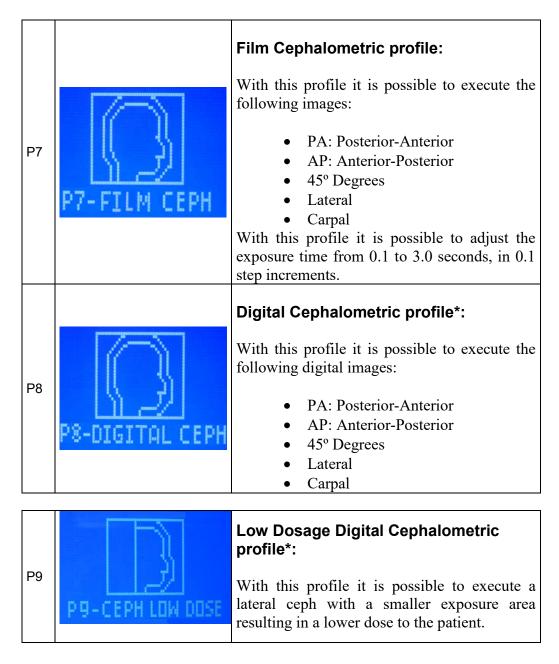
There are eight panoramic profiles available: from P1 to P6, P17 and P23:

| Program | | Description |
|---------|----------------|--|
| P1 | P1-STD PAN | Standard Panoramic: This exposure has constant vertical magnification of the dental arch region, optimal layer width, and prioritizes homogeneous exposure during the entire imaging. |
| P2 | P2 - TMJ | Temporomandibular Joint Exposure, TMJ: This double exposure fits the condyle in both closed and open mouth configuration into a single image. |
| P3 | P3 - | Sinus Exposure: This exposure focuses on the maxillary sinus region. |
| P4 | P4-IMPR. ORTHO | Improved Orthogonally*: This exposure is the standard panoramic profile optimized for the beam to be more orthogonal in respect to the dental arch. |
| P5 | P5-LOW DOSAGE | Low Dosage Panoramic Exposure*: This exposure is the standard panoramic profile with faster execution and lower dosage. The patient will receive less exposure, so as a result the overall image quality is decreased. |

| P6 | P6-CHILD PAN | Child Panoramic Exposure: This exposure has a 15% size reduction with respect to the standard panoramic profile. |
|-----|-------------------|---|
| P17 | P17 - BITEWING | Bitewing Exposure*: This exposure is a bitewing-like image profile from premolar and molar area including parts of maxilla, mandible and rami. |
| P23 | P23-IMP. ORTHO BW | Improved Orthogonally Bitewing*: This exposure is the bitewing-like image profile optimized for the beam to be more orthogonal in respect to the dental arch. |

* Only available for digital version

8.2. CEPHALOMETRIC PROFILES:

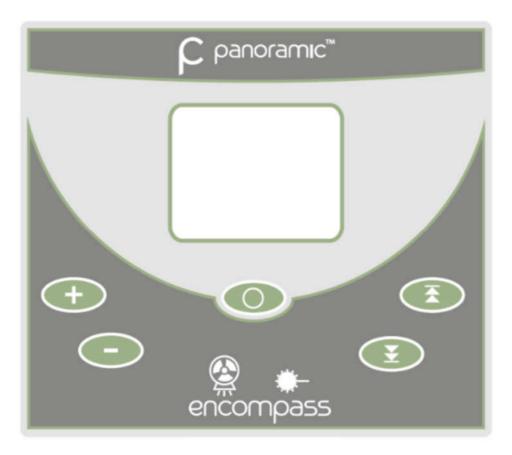


* Only available for digital version

9. CONTROL PANEL

9.1. INTRODUCTION

The equipment has a control panel with six buttons and an LCD display as follows:



The LCD display is graphical and has important information of the current status of the machine to help the user operate the unit.

The keys have multiple functionality depending on the current state of the machine. For instance, the PLUS key can increase the kV when in kV selection mode and the time when in analog ceph time selection.

9.2. CONTROL PANEL KEYS

The controls are shown and their functions on the main screen are shown below:



Plus Key:

Used to increase kV, exposure time (for analog ceph), select patient age (child and adult), size (small, medium and large) and radiography type (i.e. standard panoramic and low dosage).



Minus Key:

Used to decrease kV, exposure time (for analog ceph), select the patient age (child and adult), size (small, medium and large) and radiography type.



Select Key:

Used to change between adjustable functions: (patient size, biotype, kV, exposure time in analog ceph, image layer position (canine) and radiography type).



Laser key:

Used to turn on/off positioning lasers: Mid-Saggital, Frankfurt and Image layer Position (Canine).

Key Up:



Used to increase the column height. The equipment has a soft-start system that ramps up the column for 5 seconds until it reaches its cruise speed. The system stops automatically when it reaches the upper height limit.



Key Down:

Used to decrease the column height. The equipment has a soft-start system that ramps up the column for 5 seconds until it reaches its cruise speed. The system stops automatically when it reaches the lower height limit.

9.3. CONTROL PANEL INDICATING LIGHTS



Exposure-Signaling LED:

The LED at the center of the symbol will light up during x-ray exposure. An audible warning will also sound.

9.4. REMOTE EXPOSURE SWITCH (OPTIONAL)

A remote exposure switch installed outside of the radiation exposure room is available upon request or as required by state or country.

The remote exposure switch is a dead-man-like switch and illuminates during an exposure.

In order for the remote exposure switch to work properly the wall connector must have the proper cable (supplied) connected to the equipment. This is done during installation.



Wall remote exposure system connector



Wall remote exposure button

9.5. TURNING THE EQUIPMENT ON



THE UNIT IS CONFIGURED FOR A LINE VOLTAGE DURING INSTALLATION BY THE TECHNICIAN ONLY. THIS IS A TECHNICAL PROCEDURE AND CANNOT BE DONE BY THE USER.



BEFORE TURNING ON THE UNIT MAKE SURE THE UNIT IS CONNECTED TO THE CORRECT VOLTAGE.

To turn on or off the unit use the on/off switch on the base of the equipment.



When the main switch is turned on, the machine will perform a self-check. If everything is within specifications, the display will show the x-ray counter. During the self-check, the following screen will be shown on the display:

| | LOADI | ING | |
|----|-------|------|---|
| | | |) |
| P1 | ease | Wait | |

The machine can be configured to display an exposure counter that is displayed after the machine initialization and after each exposure.

| Coun | ter | |
|----------------|------------|----------------|
| Panor Ceph. | amic: : | 00053 00000 |
| CRC: | 00201 | ▶ OK |

Note: The exposure counter can be hidden by an authorized technician.

9.6. MAIN SCREEN

The main screen is shown below. To switch between functions use the SELECT key. Notice that only one item on the screen is selected each time. In the case shown below, the size is selected.



| FUNCTION | DESCRIPTION | DISPLAY INFORMATION AND EXPLANATION |
|------------------------------|---|--|
| INFO LINE | Displays current status of the machine. | Select the X Ray: Equipment is not ready to expose x-rays. If exposure switch is pressed the equipment will operate in demonstration mode (no x-ray exposure). |
| | | Ready to Expose Equipment is ready to expose x-rays. Cooline: 02:46 Equipment is cooling down. Wait until counter reaches zero. |
| ADULT / CHILD | Allows the user to select between adult and child. This function along with the small/medium/large function can be used to display predefined kV selections in | Ro selection |
| | order to assist the operator. This value is selected using PLUS/MINUS KEYS. | Child selected |
| | | Adult selected |
| SMALL / MEDIUM / LARGE | This function is used along with ADULT / CHILD function to pre-select the kV. This value is selected using | Size not selected |
| | PLUS/MINUS KEYS Please be aware that the values of kV indicated are for reference only. | Small patient selected |

| kV | This function is used to fine | Medium patient selected Image: Description of the selected Image: Description of the selected |
|----------------------------|--|--|
| | tune the kV after selecting the patient age and size or to directly select the kV. The range of kV is from 60kV to 85kV in increments of 2.5kV. This value is selected using PLUS/MINUS KEYS If the kV is left unchanged the equipment will be in demonstration mode. In this mode no x-ray is exposed. | No kV selected: Demonstration mode. |
| mA TIME | The anodic current is not user adjustable. The value indicated is optimum for image generation in each profile. The analog ceph mode allows the user to adjust the exposure time. This value ranges from 0.1s to 3.0s. This value is selected using | Indication that current profile uses 8mA of anodic current. Value indicating that current profile has 14 seconds of x-ray exposure. |
| IMAGE LAYER POSITION | PLUS/MINUS KEYS In all other profiles the value is not user adjustable. This function allows the user to adjust the image layer towards the back or front of the dental arch in panoramic profiles. | The image layer positioning change commands are accepted when the |

| | The adjustment is made using the following keys: PLUS: moves layer towards back of dental arch. MINUS: moves layer towards front of dental arch. | image layer icon is selected on the screen. |
|----------------------|--|--|
| PROFILE SELECTION | The image and text indicate the selected profile. | P1-STD PAN Example with standard panoramic selected. |

10. PREPARING FOR THE EXPOSURE

This section describes operations required for exposing images in both analog and digital configurations.

The type of radiography depends on machine type and the media (sensor or film) position. For example, if the sensor is placed in the panoramic position the machine will perform a panoramic profile exposure.

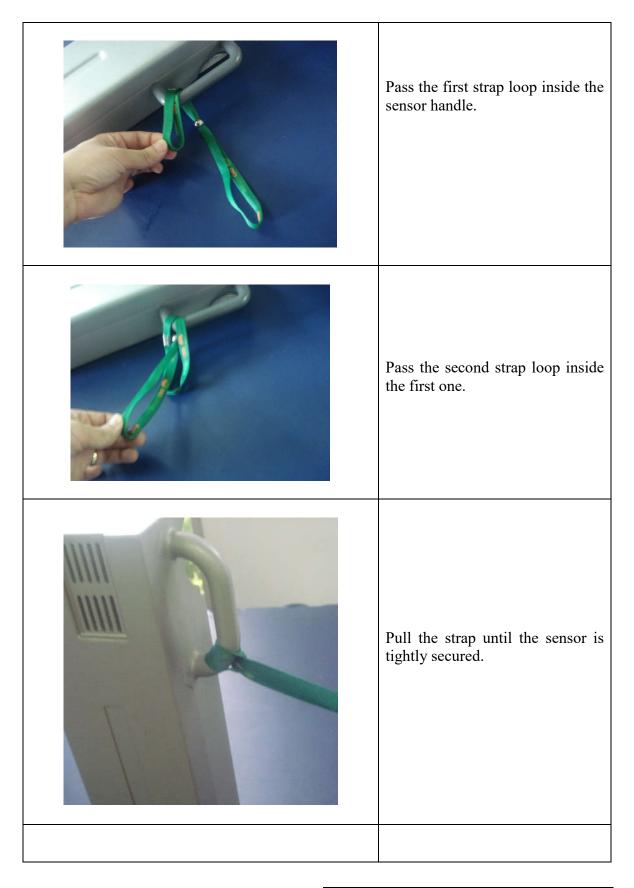
This section describes the steps required before positioning the patient on the machine.

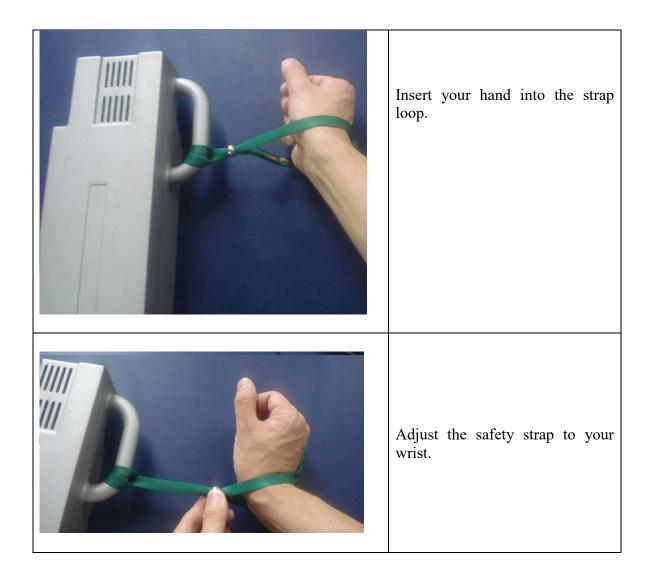
10.1. INSERTING/REMOVING THE SNAP-ON SENSOR FOR PANORAMIC OR CEPHALOMETRIC POSITION

A safety wrist strap is provided with the snap-on sensor and should be used to avoid dropping and consequent loss of warranty. The safety wrist strap is made of a flexible, antiallergic material. The safety wrist strap is shown in the picture below.



To use it, follow the procedure below.







THE SENSOR IS FRAGILE. WHILE REMOVING, HANDLING OR INSERTING THE SENSOR HOLD IT TIGHTLY AND WITH APPROPRIATE CARE. WARRANTY WILL BE VOIDED IF THE SENSOR IS DROPPED.

In order to remove the SNAP-ON Sensor from the Holder (cephalostat or C-arm) proceed as indicated in the instructions below.





and push the locking button with your right release the sensor. hand.

1. Hold the sensor tightly with your left hand 2. Rotate the knob 180 degrees until you



3. Remove the sensor carefully.

In order to insert the sensor follow the steps below.



1. Insert the sensor carefully.



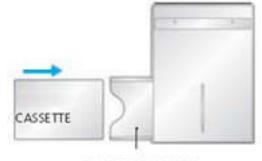
2. Rotate the knob 180 degrees until you lock the sensor



3. Hold the sensor tightly with your left hand and push the locking button with your right hand

10.2. INSERTING THE FILM IN THE PANORAMIC FILM HOLDER

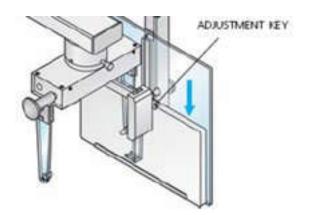
Locate the film holder and push the film until it reaches its limit. To remove the cassette, pull it from the cassette holder.



CASSETTE HOLDER

10.3. INSERTING/REMOVING THE FILM IN CEPHALOMETIC POSITION

To insert the film in the analog ceph arm release the adjustment key using the knob on the back of the ceph arm and move the lock up. Insert the film using the direction indicated on the plastic markers and according to cassette manufacturer's instructions. Move the adjustment key down and lock it with the knob. To remove the film do the reverse process.



10.4. BEFORE POSITIONING THE PATIENT

Ask the patient to remove any glasses, hearing aids, dentures, and personal jewelry such as earrings, necklaces, and hairpins.

If required, place a protective lead apron over the patient's body. Always follow local regulation.

10.5. GETTING THE SOFTWARE READY (FOR DIGITAL VERSION)

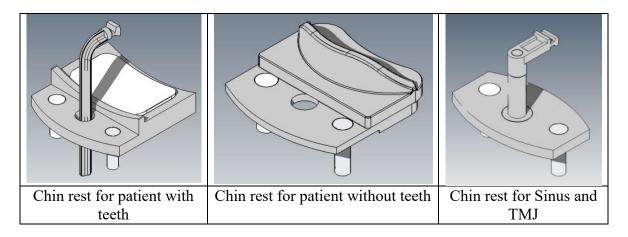
Open the AJAT Imaging software using Start / All Programs / AJAT Imaging Software / AJAT Imaging Software. Make sure the green light is on before exposure.

11. PANORAMIC EXPOSURES

This section uses operation concepts described on previous sections. Please refer to those sections when needed.

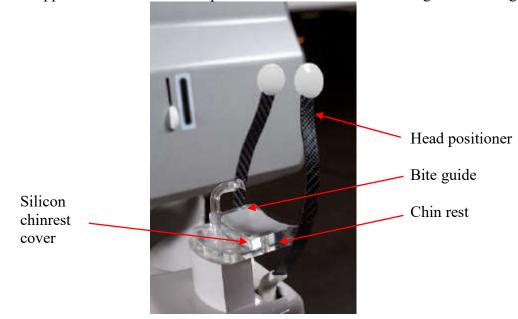
This procedure will produce a full size panoramic exposure. If the child program is selected, the width and height of the exposed area will be slightly reduced.

For this procedure it is necessary to use a chin rest. There are three different type of chin rest, as you can see in the picture below.



The first one is used for a patient with teeth and it has three parts (bite guide, chin rest and a silicon chinrest cover). The second is used for a patient without teeth and it has two parts (chin rest support and a plastic chin rest). The third is used for both kinds of patients (with or without teeth) for only the Sinus and TMJ profiles.

Insert the appropriated chin rest into the adapter. Insert the adapter into the holes on the patient support table. Please see the picture below for reference to usage of the bite guide.



Before positioning the patient, completely open the head support.

Select the required panoramic profile (from P1 to P23).

Select the correct exposure parameters in accordance with the patient characteristics. The table below gives the suggested parameters. Please use these values as a reference only. If necessary, change the values according to your needs.

| Patient Size and | k | V |
|------------------|-------|-------|
| Age | Child | Adult |
| Small | 60kV | 70kV |
| Medium | 65kV | 75kV |
| Large | 70kV | 80kV |



IF THE REQUIRED DIAGNOSTIC VALUE CAN BE REACHED WITH LOWER VALUES THAN THE ABOVE TABLE INDICATES, YOU SHOULD USE THOSE LOWER VALUES. ALWAYS TRY TO MINIMIZE THE RADIATION DOSAGE TO THE PATIENT.

11.1. GETTING THE SOFTWARE READY (DIGITAL VERSION ONLY)

Enter AJAT Imaging Software and be sure that the green light is on indicating that the sensor is ready. Refer to previous sections for assistance if required.

11.2. POSITIONING THE PATIENT

Guide the patient to the unit in front of the chin rest. If necessary, adjust the height of the unit using the Up and Down keys of the control panel.

For a patient with teeth, ask them to step forward, grasp the patient handles, stretch up and bite the bite guide. The incisal edges of the maxillary and mandibular teeth must be in the groove of the bite guide.



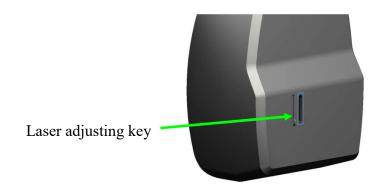
For a patient without teeth use the specific chin rest that doesn't have a bite guide. Ask patient to lean his/her chin against it.



Press the laser key to operate the patient positioning laser lights in order to assist with proper patient positioning. The laser diodes will automatically switch off after a period of time, or if the exposure button has been pressed. If the laser diodes turn off before you complete the patient positioning, press the laser key again.

Use the laser to position the Mid-Saggital plane, the Frankfurt plane and adjust the Image layer position.

If required adjust the Frankfurt laser position using the indicated adjusting key on the tubehead.

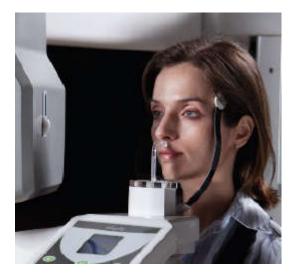


If required, adjust the image layer position using the plus and minus key while in layer positioning mode on the main screen.



THE LASERS USED ON THE EQUIPMENT ARE CLASS I LASERS INDICATING THAT THE POWER OUTPUT IS MINIMAL. HOWEVER, AS GOOD PRACTICE, AVOID INTENTIONALLY EXPOSING USER AND PATIENT EYES TO THE LASER BEAM.

For Sinus and TMJ profiles you need to use a specific chin rest. This chin rest has a nose support and the patient needs to lean his/her nose against it.



11.3. TAKING A PANORAMIC EXPOSURE

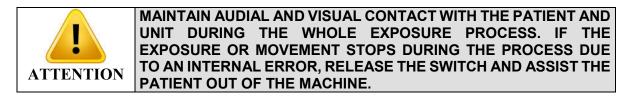
When "Ready to Expose" is shown on the display the system is ready to take an exposure. Ask the patient to close their lips on the bite guide, swallow, place their tongue flat against the roof of their mouth, breathe normally, and stand as still as possible.

Move to a protected area without losing direct eye contact to the patient.

Press and hold down the exposure button. The machine will first move to the start position and then it will proceed with the exposure. During exposure, a visual LED and audible beeping will indicate the presence of x-ray emission.

The exposure switch is a dead-man like switch. If released, the x-ray exposure will stop immediately. Otherwise, after the rotation has completed and audible beeping stops you may release the exposure switch.

Upon completion of the exposure, the arm will rotate to the patient exit position. At this point, you may guide the patient out of the machine.



In order to reset the rotating arm for the next patient, press the SELECT button on the control panel.

| FOR TMJ | TMJ PROFILE, P2, IS A DOUBLE EXPOSURE. AFTER THE FIRST |
|--------------|--|
| PROFILE (P2) | EXPOSURE, POSITION THE PATIENT WITH OPEN MOUTH AND |
| ONLY | PROCEED WITH THE SECOND EXPOSURE. |

The machine will enter a cool down process to setup for the next exposure. The display will indicate the status of the machine. Cool down time will vary based on the type of exposure taken last.

For digital machines you may save the image as required using the File/Save menu in the AJAT software.

12. CEPHALOMETRIC EXPOSURE

This section will occasionally use procedures described in previous sections. Please refer to those sections when needed.

This procedure will produce a cephalometric exposure as selected:

- PA
- AP
- Lateral
- 45 degrees
- Carpal

Select the correct exposure parameters in accordance with the patient characteristics. The table below gives the suggested parameters. Please use these values for reference only. If necessary, adjust the values according to your needs.

| Patient Size and | kV – DIGITAL VERSION | |
|------------------|----------------------|-------|
| Age | Child | Adult |
| Small | 60kV | 70kV |
| Medium | 65kV | 75kV |
| Large | 70kV | 80kV |

| Patient Size and | kV/TIME – ANALOG VERSION | |
|------------------|-----------------------------|-----------|
| Age | Child | Adult |
| Small | 60kV/0.7s | 70kV/1.5s |
| Medium | 65kV/1.2s | 75kV/2.0s |
| Large | 70kV/1.5s | 80kV/2.5s |



IF THE REQUIRED DIAGNOSTIC VALUE CAN BE REACHED WITH LOWER VALUES THAN THE ABOVE TABLE INDICATES, YOU SHOULD USE THOSE LOWER VALUES. ALWAYS TRY TO MINIMIZE THE RADIATION DOSE TO THE PATIENT.

12.1. GETTING THE SOFTWARE READY (DIGITAL VERSION ONLY)

Enter AJAT Imaging Software and be sure that the green light is on indicating that the sensor is ready. Refer to previous sections for assistance if required.

12.2. POSITIONING THE PATIENT

Guide the patient to the unit in front of the ceph arm rest. Adjust the height of the unit using the UP and DOWN keys on the control panel or ceph head as necessary.

Ask the patient to step forward and hold still while you prepare the ceph head.

Rotate the ceph head into the desired position (PA/AP/CARPAL, LATERAL or 45 degree).

Open the ear holders using the appropriate knob. Position the patient and rotate the knob so that the patient will be securely positioned using the ear holders.

Press the light key to turn the patient positioning laser lights on in order to properly align the patient's head. The laser diodes will automatically switch off after a period of time, or if the exposure button has been pressed. If the laser diodes turn off during patient positioning, press the light key again.

Use the laser to position the Frankfurt plane.



THE LASERS USED ON THE EQUIPMENT ARE CLASS I LASERS INDICATING THAT THE POWER OUTPUT IS MINIMAL. HOWEVER, AS GOOD PRACTICE, AVOID INTENTIONALLY EXPOSING USER AND PATIENT EYES TO THE LASER BEAM.

12.3. TAKING A CEPHALOMETRIC EXPOSURE

When "Ready to Expose" is shown on the display the system is ready to take an exposure.

Move to a protected area without losing direct eye contact with the patient.



KEEP CONSTANT EYE CONTACT WITH THE PATIENT AND ASSURE HE/SHE HAS BOTH HANDS DOWN DURING THE PROCESS. IN DIGITAL CEPH THIS IS ESPECIALLY IMPORTANT SINCE THE MECHANISM IS AUTOMATIC. IF THE PATIENT BEHAVES UNEXPECTEDLY STOP THE EXPOSURE AT ONCE.

Press and hold down the exposure button. The rotating arm will first move to the start position and then begin exposure. During this period, an audible beeping and visual LED will indicate the presence of x-rays.

The exposure switch is a dead-man like switch. If released, the x-ray exposure will stop immediately. Otherwise, after the rotation has completed and audible beeping stops you may release the exposure switch.

Upon completion of the exposure, the arm will rotate to the patient exit position. At this point, you may guide the patient out of the machine.

The machine will enter a cool down process to setup for the next exposure. The display will indicate the status of the machine. Cool down time will vary based on the type of exposure taken last.

For digital machines you may save the image as required using the File/Save menu in the AJAT software.

13. PROCEDURES FOR REUSE

13.1. CLEANING

- Using a clean moist cloth product, clean the equipment's surface such as the head positioner, patient handles, nose support, silicon chin rest cover, chin rest, ear rods, temple stabilizers on a regular basis.
- It is recommended to use a moist cloth product with the following chemical properties: corrosion inhibitor, humectant effect, flotator; high tension-active power, anti-static effect, biodegradable, non-toxic, non-flammable.
- The use of other chemical products is not recommended as it may damage the equipment.



DO NOT USE ORGANIC SOLVENTS, SUCH AS THINNER, TO CLEAN THE EQUIPMENT. IN CASE THE DEVELOPING SOLUTION IS SPILLED ON THE PANEL, CLEAN IT IMMEDIATELY, SINCE SUCH SOLUTIONS MAY DISCOLOR IT.

13.2. DISINFECTION

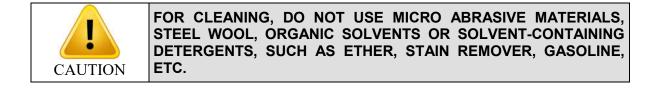
• To ensure the prevention of cross-contamination, the operator must dispose of the bite guide after each usage.



ALWAYS TURN OFF THE MAIN SWITCH BEFORE PERFORMING DAILY MAINTENANCE PROCEDURES.



AVOID SPILLING WATER OR OTHER SOLUTIONS INSIDE THE EQUIPMENT, AS IT COULD CAUSE SHORT CIRCUITS.



14. TROUBLESHOOTING GUIDE

14.1. UNIT OPERATION PROBLEM

| Symptom | Possible Cause | Action required |
|--------------------------------------|--|---|
| | Mains voltage not available | Wait for mains voltage to be available. |
| | Power supply cable is unplugged from back of equipment | Plug it into the equipment |
| Equipment does not turn on | Power supply cable is unplugged from wall socket | Plug it into the wall socket |
| | Unit circuit breaker turned off | Turn on unit circuit breaker |
| | Main ON/OFF switch turned off | Turn on main ON/OFF switch. |
| | Blown fuse | Replace the fuse |
| | Cable disconnected | Connect the cable |
| Digital image doesn't appear | Image acquisition software | Reinstall the software |
| on the screen | Acquisition button wasn't selected | Select the acquisition button |
| Remote exposure button not actuating | Remote exposure cable disconnected | Connect remote exposure cable again |

14.2. IMAGE QUALITY PROBLEM

| Symptom | Possible Cause | Action required |
|----------------------|--|--|
| Film over-exposed or | The value adjustment of KV is not suitable for the size of | Check the development system and repeat the test by |
| underexposed | the patient. | varying the value of KV. If |
| 1 | Possible errors during film development | this solution fails, call for assistance. |
| White film | The film received light or accidental radiation | Check the closing of the dark room and keep new films far away from radiation or light sources. |
| Fogged film | The border of the film is not printed out and the dental arch is not perfectly transparent, causing failures in the whole film | Check if the film is not expired and if the storage conditions specified by the manufacturer are being followed. Check if the lamp of the dark room is correct. |
| Film with strips | The film may have suffered consecutive wipes packing box and accumulated electrostatic charges or | Avoid rubbing the films in the box and clean the screens with anti-static liquid |

| | screens reinforcement weren't treated with a anti- static liquid. | |
|---|---|---|
| Films with smeared details and good contrast. | The film isn't correctly pressed between the screens | Change the cassette |
| Film with dark bands | Dark room with light penetration | Keep the dark room away from sunlight and excess lighting |
| Film totally dark | Excessive print processing time | In the heat, print processing should be faster |

14.3. PATIENT POSITIONING PROBLEM

| Symptom | Possible Cause | Action required |
|---|---|--|
| Incisors and canines narrow and unsharp | Patient position incorrect | Check patient positioning with laser |
| The patient's shoulders touch the X-ray head or digital sensor / cassette holder. | Patient is too large for the unit | Reverse the patient's hands on the patient handles: Left on the right side and vice- versa |
| | The inclination of the patient's head is not correct | Check the positioning of the patient head and reposition the patient |
| The nape of the patient touch the X-ray head | Patient is too large for the unit | Ask for the patient to more forward bite and adjust the equipment using the canine laser to reposition the equipment |
| You can not see the bottom edge of the jaw in the | The inclination of the patient's head is not correct | Reposition the patient |
| cortical cross-sectional images. | Patient without teeth (molar- premolar) in the molar plate | Use cotton rolls and take a new exposure. |
| You can not see the cortical bone cross-sectional images. | The patient wasn't placed correctly. The patient's position is oblique to the image layer. | Reposition the patient |
| Teeth appear wider on one side and narrower on the | Patient's head not in center position | Check that patient's head is centered |
| opposite. | Midsagittal plane not obeyed | Check patient's mid sagittal plane with laser line |

| Rows of teeth are curved upwards. Mandibular incisors are unsharp. TMJ joints exposed high and are often cut off from the image. | Patient head tilted forward | Check Frankfurt plane |
|--|-----------------------------|----------------------------|
| | Patient's neck was | Ask the patient to stretch |
| Middle area of the image | not stretched | his/her neck |
| too bright and unsharp. | Wrong software | Adjust contrast |
| Spine shadow. | contrast and | and brightness on the |
| | brightness settings | software |
| | | Ask patient to swallow |
| Rows of teeth overexposed. | Tongue was not against | and place tongue |
| Rows of teeth overexposed. | the roof of palate | against the roof of |
| | | palate |

15. DISPOSAL OF THE UNIT

15.1. ENVIRONMENTAL CONTAMINATION

In order to prevent environmental contamination or improper disposal of the ENCOMPASS Panoramic X-Ray Machine, the equipment must be disposed of (according to local, state, or federal regulations) at an appropriate site.

The equipment contains materials and solutions listed below which, upon completion of its useful life, must be disposed of at the appropriate sites.

In particular, the equipment contains the following materials and/or components:

- Tubehead: non-conductive oil, lead, copper, iron, aluminum, glass, tungsten.
- Control panel and shooter: iron, copper, aluminum, glass resin, non-biodegradable plastic material.
- Column, rotating arm and extensions: iron, lead, aluminum, copper, glass resin and nondegradable plastic material.

The manufacturer and/or its distributors are not responsible for improper disposal by the buyer.

16. EQUIPMENT INSTALLATION, CORRECTIVE MAINTENANCE AND CALIBRATION.

16.1. INSTALLATION OF THE EQUIPMENT

This equipment must be installed by authorized service technicians from Panoramic Corporation because only he/she has the tools, information, and training needed to perform this task.

16.2. CORRECTIVE MAINTENANCE

All instructions to use the equipment as intended are provided in this user manual. If problems are detected and cannot be corrected with the instructions in the troubleshooting section, contact the Panoramic Corporation Service Department.

Note: Do not open the equipment or try fix to it yourself or with the help of someone without training/authorization. This could worsen the problem or produce a failure that could endanger the safety of the equipment.

Warranty will be voided if original parts are removed/replaced by non-authorized Service technicians.

16.3. PREVENTIVE MAINTENANCE

Panoramic Corporation strongly recommends a preventive maintenance be performed on your equipment at least every two years. All service requests must be submitted through Panoramic Corporation's Service Department by calling our toll-free number at (800) 654-2027.

Panoramic has an extensive network of independent installation and service organizations throughout the U.S. and Canada to install and service our products. The Independent Representatives have been specifically trained by our organization in the service and installation of Panoramic products. We strongly recommend that you use one of our Independent Representatives to service Panoramic products. To the extent you use third parties other than Independent Representatives to service Panoramic products, we cannot accept responsibility or liability for any work performed by those third parties and any resulting damages or liability attributable thereto. In no event shall Panoramic be liable to you or any other third party for any direct, indirect, punitive, incidental, consequential or special damages or lost profits arising from, relating to or connected with, the installation of or repair of a Panoramic product by someone other than an Independent Representative.

Always refer to your state and local regulations to determine how often to perform a preventive maintenance on your equipment as the regulations may supersede manufacturers' recommendation.

Owners of Panoramic Corporation X-Ray machines must call Panoramic Corporation Service Department for all reasons listed below but not limited to:

- Preventive maintenance at least every two years
- Physical relocation of machine
- Changing the power source to a different power source from original installation
- Questions/Help related to compliance with your state, and local regulations regarding radiological equipment
- Corrective Maintenance
- Physical damage that may affect radiation safety
- Interrupted movement, unusual noises, leaks, etc.

To schedule a preventive maintenance on your equipment contact the Service Department by dialing our toll-free number at (800) 654-2027.

16.4. CALIBRATION

The equipment calibration must be performed by an authorized service technician during installation and during corrective or preventative maintenance

16.5. NETWORK OF AUTHORIZED SERVICE TECHNICIANS

The installation and all services performed on Panoramic Corporation equipment/products should be done by technicians authorized by Panoramic Corporation, otherwise, warranty will be voided.

To request electrical schematics, or component specifications not found in this manual, call the Panoramic Corporation service department.

Phone Number: 1 (800) 654-2027 E-Mail: tech-support@pancorp.com Address: 4321 Goshen Rd., Fort Wayne, Indiana 46818

17. TECHNICAL SPECIFICATIONS

17.1. REGULATORY INFORMATION

| Manufactured for: Panoramic Corporation | | |
|---|---|--|
| Phone Number: 1 (800) 654-2027 | Phone Number: 1 (800) 654-2027 | |
| Address: 4321 Goshen Rd., Fort Wayne, In | Address: 4321 Goshen Rd., Fort Wayne, Indiana 46818 | |
| Reference type X-Ray Panoramic | | |
| Model HF100-EAGLE | | |
| Equipment classification according to FDA | | |

| Classification class (risk class) | CLASS II |
|---|--|
| Equipment classification according to stand | ard NBR IEC 60601-1 |
| Protection against electric shock | "Type-B" applied parts" |
| | CLASS I (NBR IEC 60601-1) |
| Protection against harmful water | Ordinary equipment - IPX0 |
| penetration | (Sealed equipment without protection against |
| | water penetration) |
| Application safety level in the presence of | Unsuitable equipment |
| a flammable anesthetic mixture with air, | |
| oxygen or nitrous oxide | |
| Operation mode | Operation Intermittent |

17.2. GENERAL INFORMATION

| Mains power voltage | 110/127/220 or 240 V |
|-------------------------------------|--|
| Number of phases | 1 or 2 |
| Current type | AC (alternating current) |
| Mains power frequency | 50 or 60 Hz |
| Delay fuses | 10A -110/127V 5A -220/240A |
| Power consumption | 1.25 kVA |
| Stand by consumption | 0.070 kVA |
| Net weight without a cephalostat | 253.5 lb |
| Net weight with a cephalostat | 335.1 lb |
| Net weight of X-Ray generator | 34.2 lb |
| Column height adjustment | 2.30 ft |
| Minimum room sizes for installation | 5.90 x 8.20 ft |
| 4 | Warning: pieces of the equipment may cause shock |

17.3. RADIOLOGICAL INFORMATION

| General Information | |
|---|--|
| Exposure time accuracy | ±10 % |
| Maximum operation factor | 1 : 25s |
| Tube voltage (kVp) | Adjustable from 60 to 85 kVp, 2.5 steps. |
| Accuracy at the kVp value | ± 10 % |
| Accuracy at the anodic current value | ± 20 % |
| Maximum energy accumulated in 1 hour | 1120 mAs |
| Cassette type | Flat |
| Information Specific for Panoramic Profiles | |
| Complete panoramic exposure | Standard – 14s – 8mA |
| time/current | Improved orthogonally – 14s – 8mA |
| | Low dose –11s – 6mA |
| | Child – 10.5s – 8mA |
| Maxillary sinus | 8s – 8mA |

| Open mouth + closed mouth TMJ | 10s – 8mA | |
|--|----------------|--|
| exposure time (TMJ 1 + TMJ 2) | | |
| Bitewing | 7.6s – 8mA | |
| Panoramic film size | 0.49 x 0.98 ft | |
| Mean magnification | 1:1.2 | |
| Source to Image Distance SID | 1.69 ft | |
| Information Specific for Cephalometric Pro | files | |
| Analog Ceph Exposure Time/mA | From 0.1 to 3s | |
| Analog Ceph Exposure Anodic Current | 8mA | |
| Digital Ceph Exposure Time | 10.5s | |
| Digital Ceph Exposure Anodic Current | 8mA | |
| Analog Ceph Size | 0.66 x 0.82 ft | |
| Mean enlargement | 1.1 | |
| Focus-film distance | 5.41 ft | |
| For this equipment proper patient positioning is required to produce a good quality image. | | |
| The energiest must stay away at least 0 fast from the equipment during experience to | | |

The operator must stay away at least 9 feet from the equipment during exposure to minimize the amount of ionizing radiation risk.

17.4. X-RAY GENERATOR

| Generator type | High-frequency constant potential generator | | |
|---|---|--|--|
| Operating frequency | 100 kHz | | |
| Maximum operation voltage | 85 kVp | | |
| Heating and cooling curve | See Graphic on item 15.13 of this manual | | |
| Output power | 680 W (85kV x 8mA) | | |
| Output power during 0,1s | 680 W (85kV x 8mA) | | |
| Total filtration | 0.01 ft Al eq. @ 85 kVp (This value takes all | | |
| | mitigating circumstances that exist from the | | |
| | emission source to the output of equipment) | | |
| Radiation escape | < 1.00mGy/h at 85kV / 8mA | | |
| Equipment | CLASS I - Type-B applied part | | |
| | When submitted in charge the equipment | | |
| emits ionizing radiation. | | | |
| - | | | |
| Operation mode | Intermittent | | |
| The X-Ray Generator is mounted by the manufacturer. | | | |
| X-Ray machine with radiologic protection according to NBR IEC 60601-1-3:2001. | | | |
| X-Ray generator ENCOMPASS NBR IEC 60601-2-7:1998 | | | |
| X-Radiation-emitting set ENCOMPASS NBR IEC 60601-2-28:2001 | | | |
| Radiological equipment associated ENCOMPASS NBRIEC60601-2-32:2001 | | | |

17.5. TESTED EQUIPMENT LAW NORM

EN 60601-1 (1990); Amendment 1 EN 60601-1 (1992); Amendment 2 EN 60601-1 (1995); Amendment13 EN 60601-1 (1995);

UL 60601-60601-1-4-2004 EN 60601-1-3 (2001); EN 60601-2-7 (2001); EN 60601-2-28 (2001); EN 60601-2-32 (2001); IEC 60601-1; Emenda 1 IEC 601-1; IEC 60601-1-2; CISPR 11, edição 3.1 (1999); IEC 61000-4-2 (1999); IEC 61000-4-3 (1998); IEC 61000-4-4 (1995); IEC 61000-4-5 (1995); IEC 61000-4-6 (1996); IEC 61000-4-11 (1996); IEC series 60601-1 Medical Electrical Equipment - Part 1: General requirements for safety; EN 980:2003 (Ed. 2) - Graphical symbols for use in the labeling of medical devices; ISO 14971 - Medical devices - application of risk management medical devices; ISO 9687: 1993 - Dental equipment - graphical symbols; ISO 7494 - Norma dental units; ISO 13485-2 - Quality systems - medical devices; ISO 780 - Packaging - pictorial marking for handling goods; ISO 11144 - Norma dental equipment - connections for supply and waste lines.

Reference axis between the target angle and the focal point of the X-ray tube:

90° With axis of anode and cathode, respective

Target angle with reference axis:

5° Reference axis angle between the target and the focal point of the x-ray generator mounted:

measurements of x-ray generator mounted:

318mm x 440mm x 212mm

weight of X-ray generator mounted:

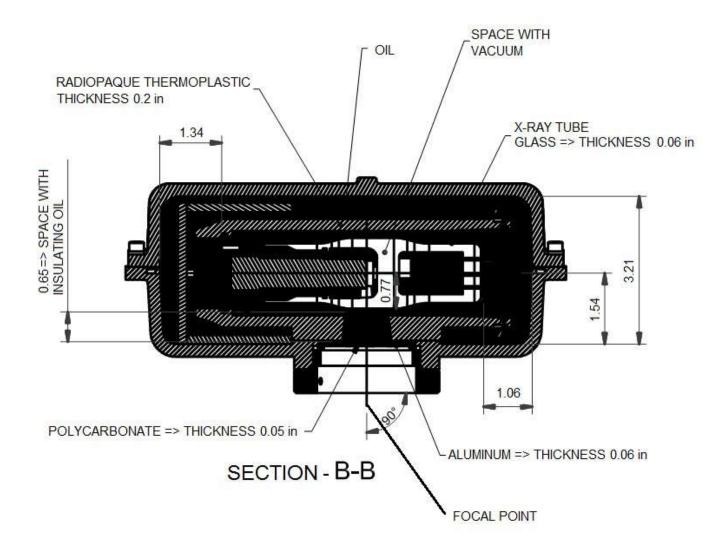
34.6 lb.

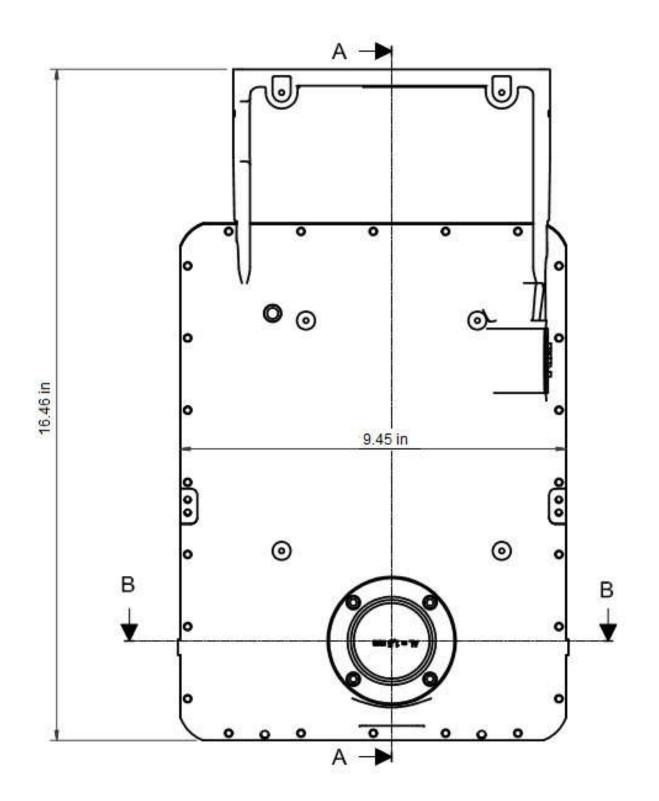
Tolerances of the focal point in relation in relation to the axes of reference:

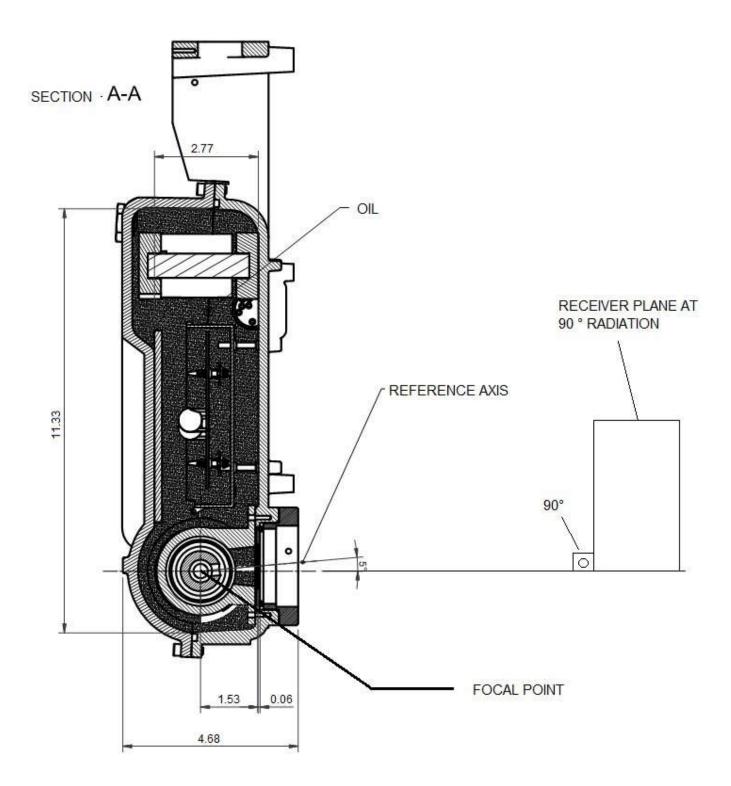
 $X=\pm 0.5$ mm (lateral)

 $Y = \pm 0.5 mm$ (depth)

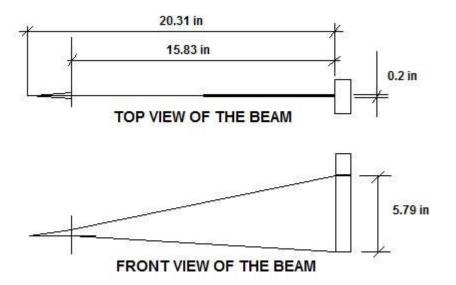
 $Z=\pm 0.5$ mm (height)



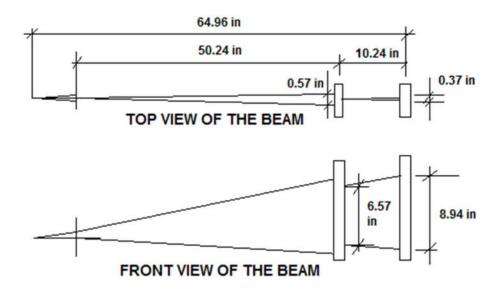




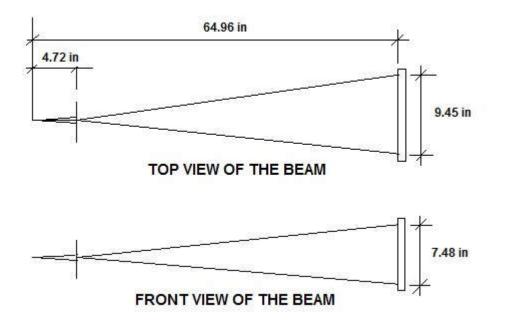
17.6. IRRADIATED FIELD SIZE - ANALOG AND DIGITAL PANORAMIC EXAM (PAN: ADULT AND CHILD – TMJ – MAXILLARY SINUS)



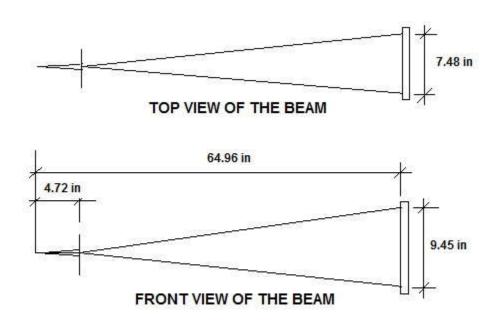
17.7. IRRADIATED FIELD SIZE – DIGITAL CEPH EXAM:



17.8. IRRADIATED FIELD SIZE – ANALOG CEPH EXAM (LATERAL AND LATERAL SIDE 45°)



17.9. IRRADIATED FIELD SIZE – ANALOG CEPH EXAM (POSTERIOR AND ANTERIOR)



17.10. TUBE SPECIFICATIONS

| Manufacturer | TOSHIBA |
|---------------------------------------|--|
| Model | D-054 |
| Focus size | 0.5 – IEC 60336 |
| Equivalent filtration | 0.003 ft Al equiv. |
| Anode angle | 5 ° |
| Anode material | Tungsten |
| Maximum voltage | 105 kVp |
| Thermal capacity | 30 kJ |
| Max thermal capacity and cooling time | See graphic thermal curve on item 15.13. |
| curve | |
| Maximum current | 24mA rectified by half or whole wave and |
| | 20mA constant potential |
| Maximum filament current | 4.0A / 8.0V |
| Frequency | DC |
| Maximum exposure time | 20s |
| Max anodic power | 680kW |

17.11. COOLING TIME BY TECHNIQUE USED

| kV Utilized | MA Utilized | Cooling time corresponding to each of the second issue |
|-------------|-------------|--|
| 60kV | 6.3mA | 13.2 sec. |
| 62.5kV | 6.3mA | 13.8 sec. |
| 65kV | 6.3mA | 14.3 sec. |
| 67.5kV | 6.3mA | 14.9 sec. |
| 70kV | 6.3mA | 15.4 sec. |
| 72.5kV | 6.3mA | 16 sec. |
| 75kV | 6.3mA | 16.5 sec. |
| 77.5kV | 6.3mA | 17.1 sec. |
| 80kV | 6.3mA | 17.6 sec. |
| 82.5kV | 6.3mA | 18.2 sec. |
| 85kV | 6.3mA | 18.8 sec. |
| 60kV | 8mA | 17.6 sec. |
| 62.5kV | 8mA | 18.4 sec. |
| 65kV | 8mA | 19.1 sec. |
| 67.5kV | 8mA | 19.9 sec. |
| 70kV | 8mA | 20.6 sec. |
| 72.5kV | 8mA | 21.3 sec. |
| 75kV | 8mA | 22.1 sec. |
| 77.5kV | 8mA | 22.8 sec. |
| 80kV | 8mA | 23.5 sec. |
| 82.5kV | 8mA | 24.3 sec. |
| 85kV | 8mA | 25 sec. |

17.12. ELECTROMAGNETIC EMISSIONS

| Manufacturer's guidelines and declaration - electromagnetic emissions | | | | |
|--|--|---|--|--|
| | The ENCOMPASS Panoramic X-Ray Machine has been designed for use in electromagnetic | | | |
| | | client or X-Ray Machine operator must | | |
| ensure that the equipment is | s used in such type of environr | ment. | | |
| Emission assays | Compliance | Electromagnetic Environment Guidelines | | |
| RF emissions ABNT NBR IEC CISPR 11 | Group 1 | The ENCOMPASS Panoramic X- Ray uses RF energy only for its internal functions. However, RF emissions are very low and are not likely to cause any interference with electronic equipment nearby. | | |
| RF emissions ABNT NBR IEC CISPR 11 | Class A | The ENCOMPASS Panoramic X- Ray Machine is suitable for use in | | |
| Harmonic emissions IEC 61000-3-2 | Class A | all types of facilities, including residential facilities and those directly connected to the public | | |
| Emissions due to voltage/scintillation fluctuation IEC 61000-3-3 | In compliance | system of low -voltage electric power supply for residential buildings. | | |
| RF emissions CISPR 15 | In compliance | The ENCOMPASS Panoramic X- Ray Machine is not suitable for inter-connection with another piece of equipment. | | |

17.13. ELECTROMAGNETIC IMMUNITY

| Manufacturer's guidelines and declaration - electromagnetic immunity | | | | | | | |
|--|---|---|------------------------------|--|--|--|--|
| The ENCOMPASS Panoramic X-Ray Machine has been designed for use in electromagnetic | | | | | | | |
| | | | Ray Machine operator must | | | | |
| ensure that the equip | oment is used in such typ | e of environment. | | | | | |
| Immunity Assays | Assays ABNT NBR IEC 60601 Compliance Level Electromagnetic | | | | | | |
| | Assay Level | | environment -Guidelines | | | | |
| Electrostatic | ± 6 kV by contact | ± 6 kV by contact ± 6 kV by contact Floors must be finished | | | | | |
| discharge (ESD) | ± 8 kV by the air | ± 8 kV by the air | with wood, concrete or | | | | |
| IEC 61000-4-2 | | | ceramics. In case the | | | | |
| floor is covered with | | | | | | | |
| | | | synthetic material, relative | | | | |
| | | | humidity must be at least | | | | |
| 30%. | | | | | | | |
| Fast electric | ± 2 kV on the mains | ± 2 kV on the mains | The quality of power | | | | |
| transients /pulse | supply line | supply line | supply must be that of | | | | |
| train ("Burst") | ± 1 kV on the ± 1 kV on the hospital facilities or of | | | | | | |
| IEC 61000-4-4 | input/output line | input/output line | typical business facilities. | | | | |

| Impulses IEC 61000-4-5 | ±1 kV - differential mode ± 2 kV - regular mode | ±1 kV - differential mode ± 2 kV regular mode | The quality of power supply must be that of hospital facilities or of typical business facilities. | |
|--|--|---|---|--|
| Voltage drops, short interruptions and voltage variations on the mains supply input lines IEC 61000-4-11 | < 5% Ut (>95% of voltage drop in Ut) per 0.5 cycle 40% Ut (60% of voltage drop in Ut) per 5 cycles 70% Ut (30% of voltage drop in Ut) per 25 cycles <5% Ut (>95% of voltage drop in Ut) per 5 seconds | < 5% Ut (>95% of voltage drop in Ut) per 0.5 cycle 40% Ut 60% of voltage drop in Ut) per 5 cycles 70% Ut (30% of voltage drop in Ut) per 25 cycles <5% Ut (>95% of voltage drop in Ut) per 5 seconds | The quality of power supply must be that of hospital facilities or of typical business facilities. In case the user of the ENCOMPASS Panoramic X-Ray Machine required continuing operation during power supply interruption, the equipment should be supplied by an uninterrupted source or battery. | |
| Magnetic field in the mains supply frequency (50/60 Hz) IEC 61000-4-8 | 3A/m | 3A/m | Magnetic fields in the mains supply frequency should be in similar levels to those of a typical hospital or business facility. | |
| Note: Ut is the mains supply AC voltage prior to the application of the assay level. | | | | |

The ENCOMPASS Panoramic X-Ray Machine has been designed for use in electromagnetic environments according to the specifications below. The client or X-Ray Machine operator must ensure that the equipment is used in such type of environment.

| Immunity Assays | IEC 60601 Assay | Compliance | Electromagnetic environment - |
|------------------------------|----------------------------------|------------|--|
| | Level | Level | Guidelines |
| | | | Portable and movable RF communication equipment must not be used near any of the parts of the ENCOMPASS Panoramic X-Ray Machine, including cables, with a shorter separation distance than recommended, calculated from the equation applicable to the transmitter's frequency. Recommended Separation Distance. |
| Conducted RF IEC 610004-6 | 3 Vrms 150 kHz up to 80MHz | 3 Vrms | d = 1.2 √P |

| Radiated RF IEC 610004-3 | 3 V/m 80 MHz up to 2.5 GHz | 3 V/m | d = $1.2 \sqrt{P} - 80$ MHz up to 800 MHz d = $2.3 \sqrt{P} - 800$ MHz up to 2.5 GHz, where P is the transmitter's maximum nominal output power in watts (W), according to the transmitter's manufacturer, and d is the recommended separation distance in meters (m). It is recommended that the field intensity established by the RF transmitter, as determined by an electromagnetic | | |
|---|---|-------|--|--|--|
| | | | inspection on the site, ^a should be less than the compliance level in each frequency range. ^b Interference may occur around the equipment marked by the following symbol: | | |
| | NOTE 1: In 80 MHz and 800MHz, the higher frequency range is applied. NOTA 2: These guidelines may not be applicable in all situations. Electromagnetic propagation | | | | |
| | is affected by absorption and reflection by structures, objects and people. | | | | |
| ^a Field intensities established by fixed transmitters, such as stations for base radio, telephone | | | | | |
| (cellular/wireless), mobile ground radios, amateur radio, AM and FM radio transmission and TV | | | | | |
| broadcast cannot be theoretically predicted accurately. In order to evaluate the electromagnetic environment due to fixed RF transmitters, an electromagnetic inspection of the site is | | | | | |
| recommended. If the measurement of the field intensity on the site where the ENCOMPASS | | | | | |
| Panoramic X-Ray Machine is used exceeds the applicable RF compliance level described above, | | | | | |
| the equipment's operation should be checked in order to ensure it is within normal standards. In | | | | | |
| case abnormal performance is observed, additional procedures, such as re-orientation and replacement of the ENCOMPASS Panoramic X-Ray Machine may be required. | | | | | |
| | | | | | |

^b It is recommended that field intensity should be lower than 3 V/m above the frequency range of 150 kHz to 80 MHz.

Recommended separation distances between portable and mobile RF communication equipment and the ENCOMPASS Panoramic X-Ray Machine

The ENCOMPASS Panoramic X-Ray Machine has been designed for use in electromagnetic environments where RF radiated perturbations are controlled. The client or user of the ENCOMPASS Panoramic X-Ray Machine can help prevent electromagnetic interference by keeping a minimum distance between portable and movable RF communication equipment (transmitters) and the ENCOMPASS Panoramic X-Ray Machine, as recommended below, according to the maximum output power of the communication equipment.

| Maximum nominal | Separation distance according to the transmitter's frequency (m) | | | | | |
|---------------------|--|------------|------|--|--|--|
| output power of the | 150 kHz up to 80 MHz 80 MHz up to 800 800 MHz up to 2.5 GHz | | | | | |
| transmitter (W) | $d = 1.2 \sqrt{P}$ MHz $d = 2.3 \sqrt{P}$ | | | | | |
| | | d = 1.2 √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 with maximum nominal output powers that are not listed above, the recommended separation distance d in meters (m) can be determined by using the equation applicable for the transmitter's frequency, where P is the transmitter's maximum nominal output power in watts (W) according to the transmitter's manufacturer.

NOTE 1: In 80 MHz and 800MHz, the separation distance for the higher frequency range is applied.

NOTA 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

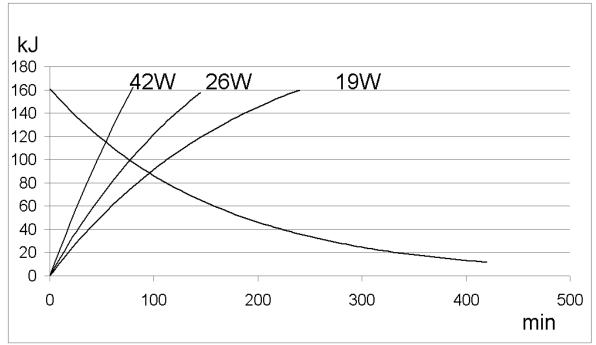


THE EQUIPMENT SHOULD NOT BE USED ADJACENT TO OR STACKED ON OTHER EQUIPMENT, RECOMMENDATIONS OF THIS MANUAL MUST BE FOLLOWED.

TO ENSURE SAFE OPERATION, THE OPERATOR MUST TURN AWAY FROM EQUIPMENT FOR SAFETY TO AVOID **COLLISION WITH MOVING PARTS. THE PATIENT SHOULD BE INFORMED OF ALL MOVEMENTS THAT THE EQUIPMENT** WILL PERFORM. THE PATIENT SHOULD ALSO BE TOLD NOT MOVE DURING THE **EXPOSURE.** IT THE TO IS WARNING **RESPONSIBILITY OF THE OPERATOR TO WATCH THE** PATIENT AND INTERRUPT THE EXPOSURE IN SUCH **EVENTS. IMPORTANT: THE STRENGTH OF THE MOVEMENT** IS NOT ENOUGH TO HARM THE OPERATOR OR PATIENT.

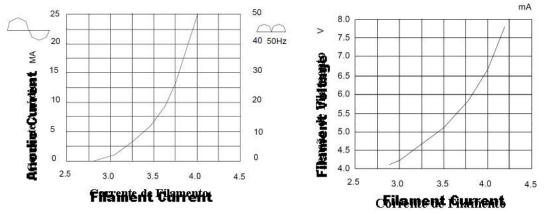


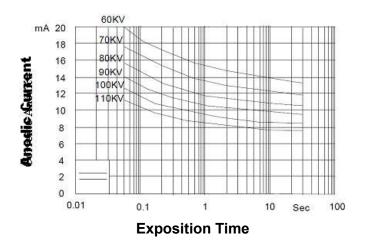
DO NOT USE ACCESSORIES, TRANSDUCERS, PARTS OF INTERNAL COMPONENTS AND CABLES OTHER THAN THOSE SPECIFIED AND PROVIDED BY THE MANUFACTURER. DOING SO CAN RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE ESE.

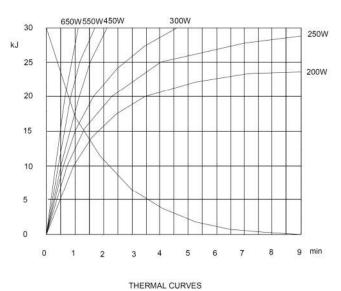


17.14. CHARACTERISTIC COOLING OF THE X-RAY GENERATOR

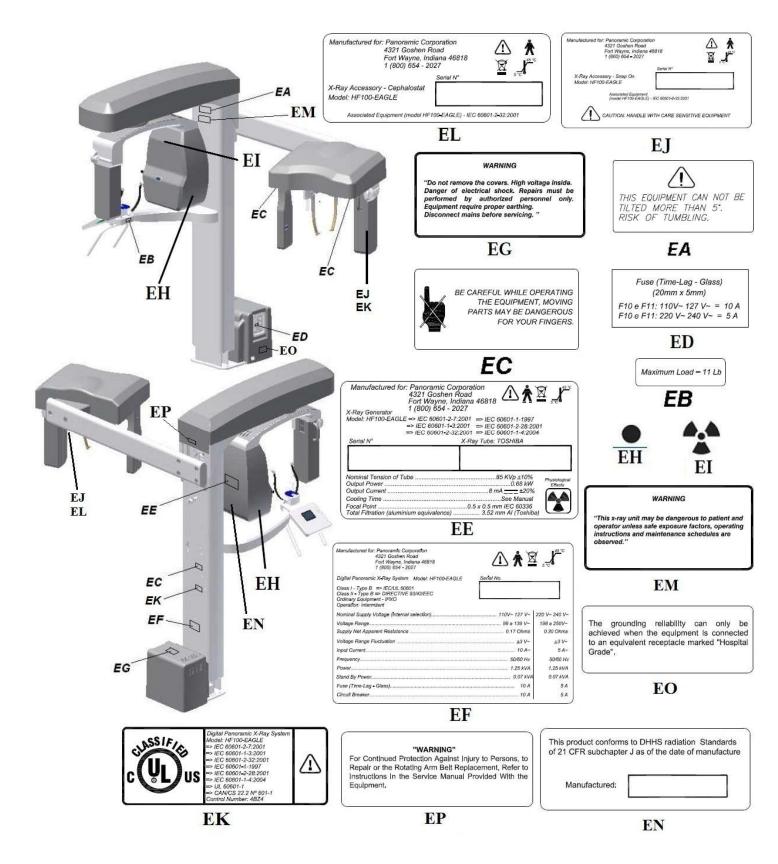
17.15. CHARACTERISTIC CURVES OF THE X-RAY TUBE.



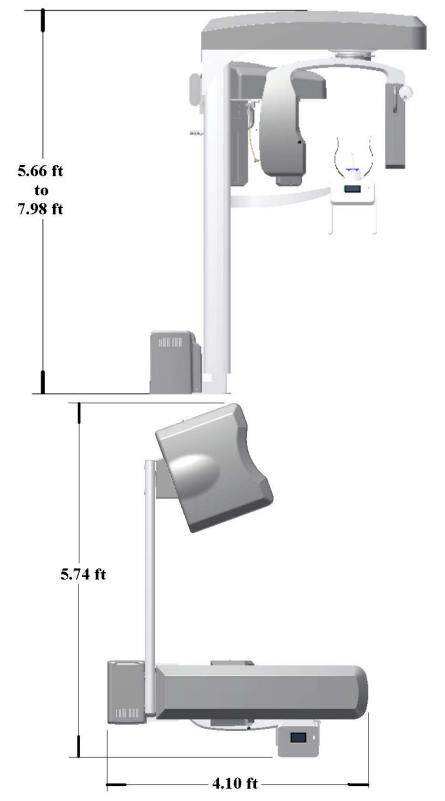




17.16. LABELS OF IDENTIFICATION



17.17. EQUIPMENT DIMENSIONS



17.18. SERIAL NUMBER OF THE X-RAY TUBE

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Responsible Author: Daniel R. de Camargo Approved by: Marco Candolo