panoramic™

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encompass

Model: HF100-Eagle

CLASSIFIED C UL US

USER'S MANUAL

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TABLE OF CONTENTS

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.

 **CAUTION**	**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:

Digital Panoramic Profiles
Digital Cephalometric Profiles

The digital machines use a CCD sensor with the traditional scintillator technologies and auto image processing that allow a speed up the diagnostic and improve the clinic workflow.

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.

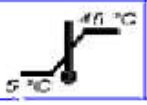
The user interface is composed of a control panel located close to the patient chin rest and an exposure switch. A remote exposure switch installed outside the radiation room is optional. The exposure switch is a dead-man type switch.

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.

	***"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.
	***"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.
	***"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.
	***"GND"*** Indicates the protection grounding terminals.
	***"Attention"*** Warning for reference to accompanying documents
	***"Type-B Applied Part"***
	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.
	***"Ionizing radiation"***
	***"Laser Diode Light Emitter"***
	***"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 storage	0ºC to +55ºC (+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.

 **ATTENTION**	**THE MANUFACTURER SHALL NOT BE LIABLE IN CASE:** • **THE X-RAY MACHINE IS USED FOR PURPOSES OTHER THAN THOSE FOR WHICH IT HAS BEEN DESIGNED.** • **DAMAGE CAUSED TO THE EQUIPMENT, THE OPERATOR AND/OR PATIENT AS A RESULT OF IMPROPER INSTALLATION AND MAINTENANCE PROCEDURES IN DISAGREEMENT WITH THE OPERATION INSTRUCTIONS ACCOMPANYING THE EQUIPMENT.** • **IMPROPER EQUIPMENT OPERATION.**

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.

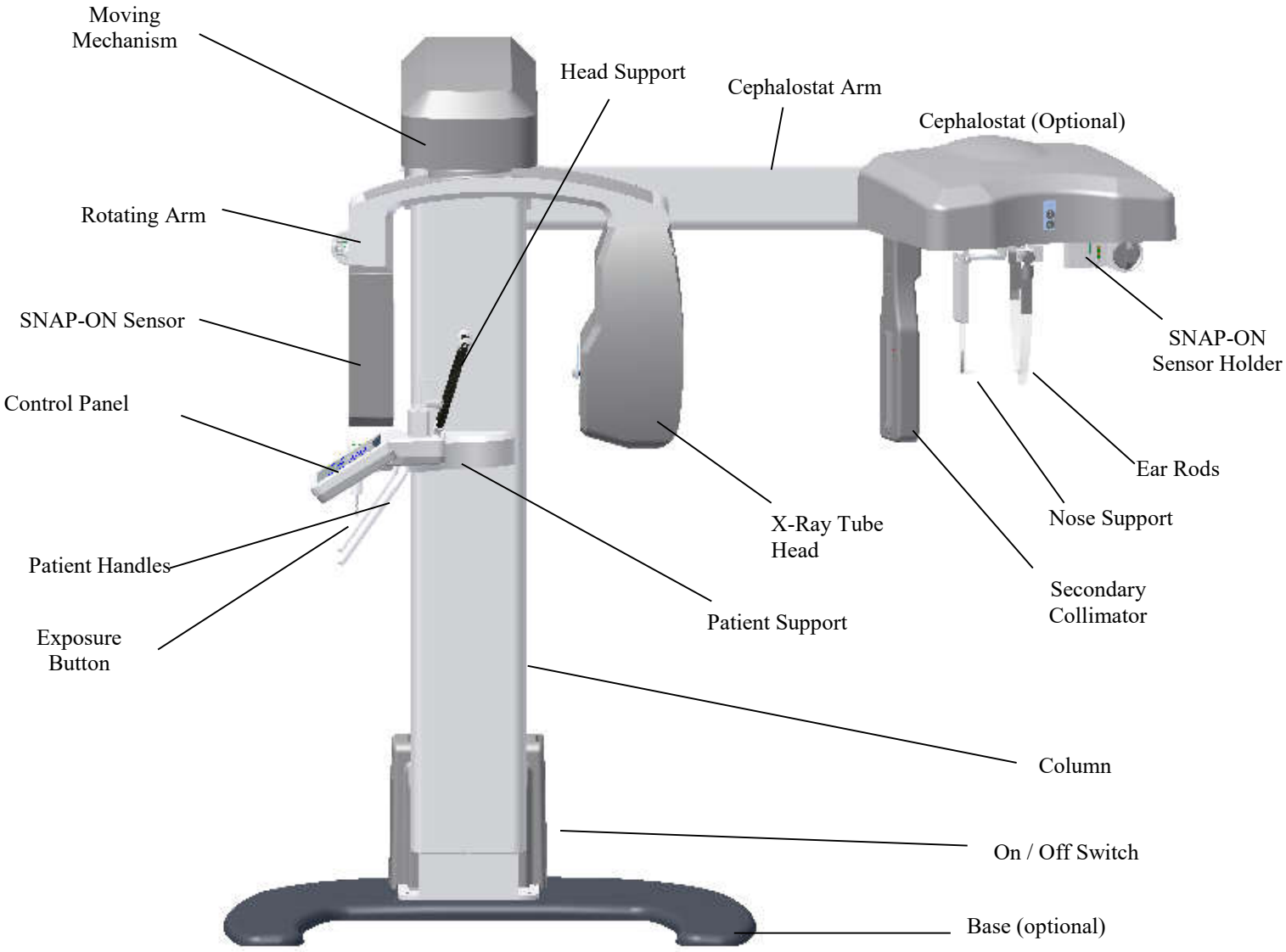
3.7. CAUTION IN CASE OF ABNORMAL EQUIPMENT FUNCTION

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

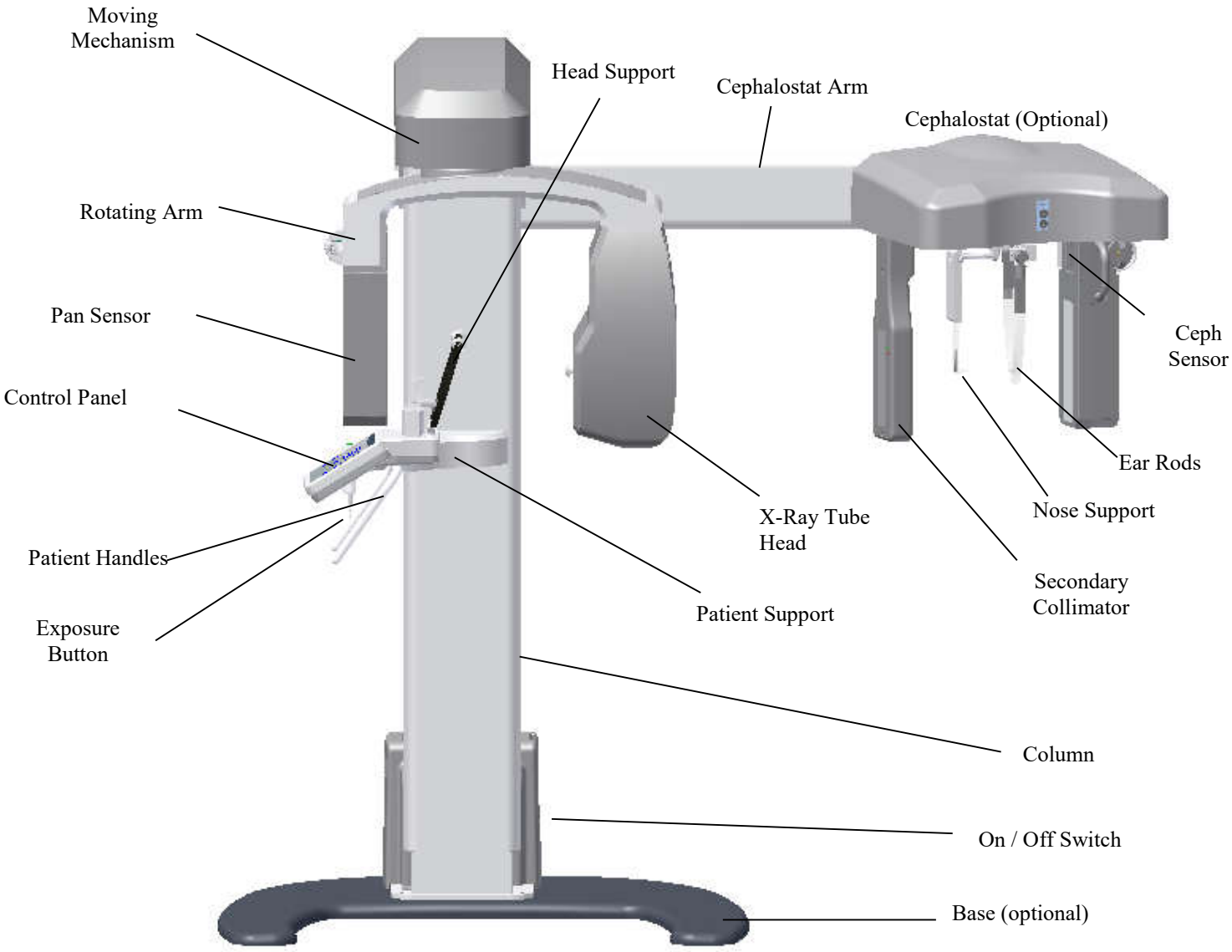
4.1. DIGITAL SNAP-ON SENSOR CONFIGURATION

The following image shows the whole system with optional Ceph arm mounted. This configuration has only one sensor movable between panoramic and cephalometric positions.



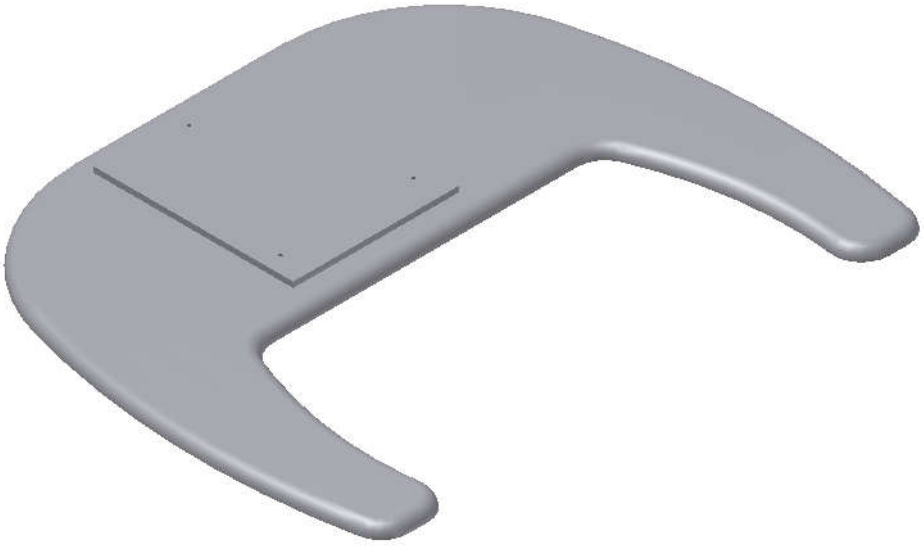
4.2. DIGITAL FIXED SENSOR CONFIGURATION

The following image shows the whole system with optional Ceph arm mounted. This configuration has one sensor fixed in the panoramic position and one sensor fixed in the cephalometric position.



4.3. 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. RECOMMENDED COMPUTER SYSTEM SPECIFICATIONS

It is imperative that this computer system be dedicated for the ENCOMPASS Panoramic X-Ray Machine.

Table 1 – Recommended Computer Specifications

Operating System	Windows 7 Professional – 64-bit
CPU	Intel ® Core ™ i5 or higher
HDD	500 GB or higher
RAM	4GB
PCI	PCI Express (PCIe) slot, full-height
NIC	Gigabit Ethernet dedicated

 **ATTENTION**	**AN EXCLUSIVE NETWORK ADAPTER IS SHIPPED WITH THE EQUIPMENT. THE HARDWARE MUST BE INSTALLED BY AN AUTHORIZED TECHNICIAN, OTHERWISE MAY RESULT IN A VOID OF WARRANTY.**

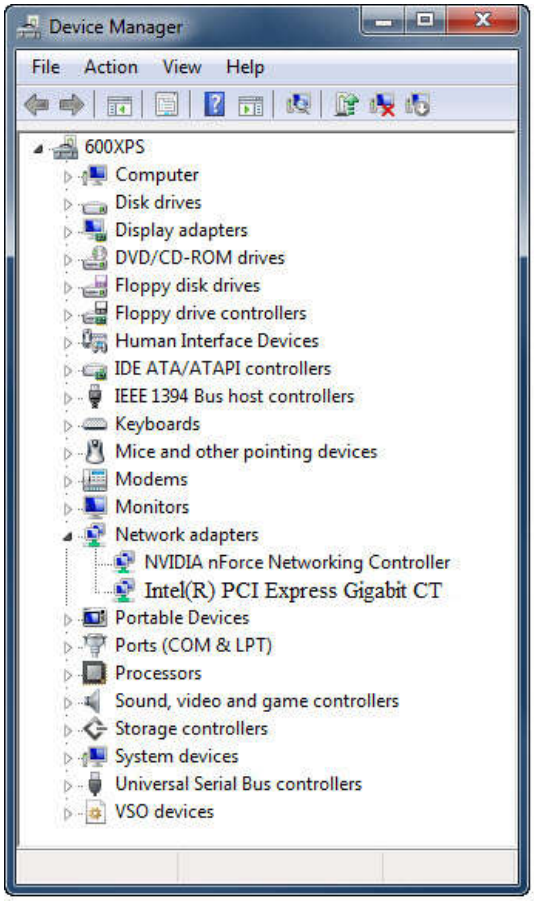
6. COMPUTER SYSTEM CONFIGURATION

6.1. 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 → All items → Control Panel → System → Device Manager → 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 → Network → Internet and Network Connections

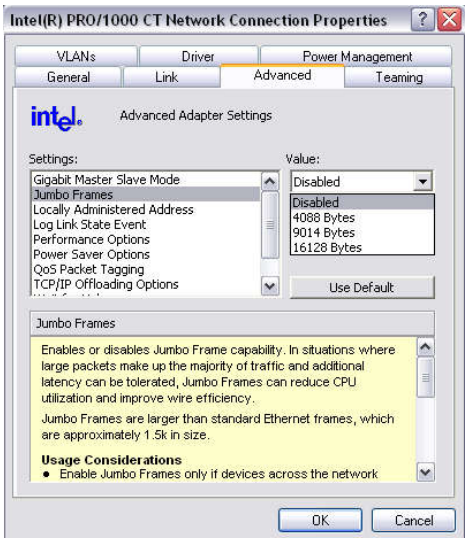
2 - Click the right mouse button on the connection DESKTOP Intel Gigabit CT, and visit the properties.

3 - Go to Settings → Advanced tab and search for item “Receive Buffer”
4 - Initially, this setting is disabled. Change the value to 2048 and then click OK.

5 - Go to Settings → Advanced tab and search for item “Transmit Buffer”
6 - Initially, this setting is disabled. Change the value to 2048 and then click OK.

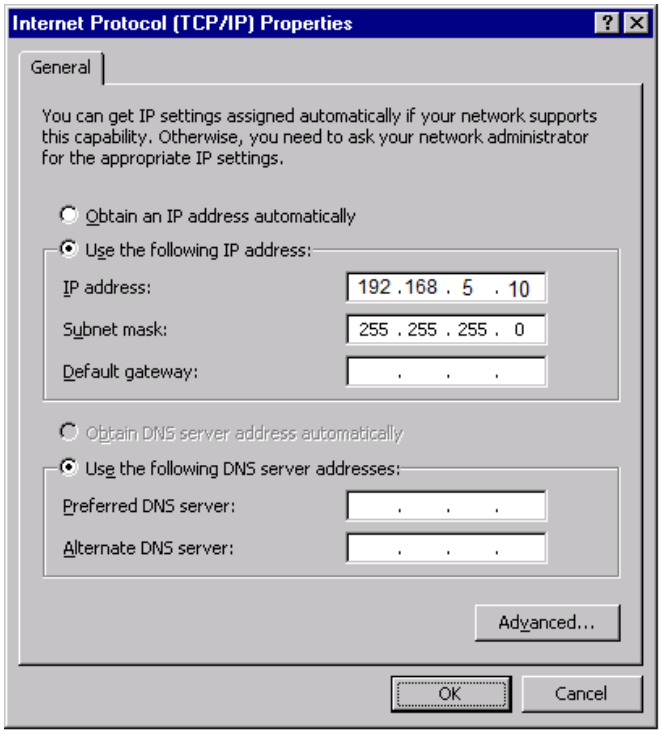
7 - Go to Settings → Advanced tab and search for item “Jumbo Frames”

8 - Initially, this setting is disabled. Change the value to 9014 bytes and then click OK.



9 - Go to Settings → Power Management tab and uncheck all items.

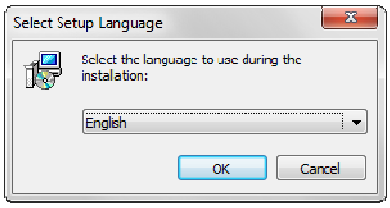
10 – Select Internet Protocol TCP/IP Version → Proprieties
11 – Define the IP address **192.168.5.10** and Subnet Mask **255.255.255.0**



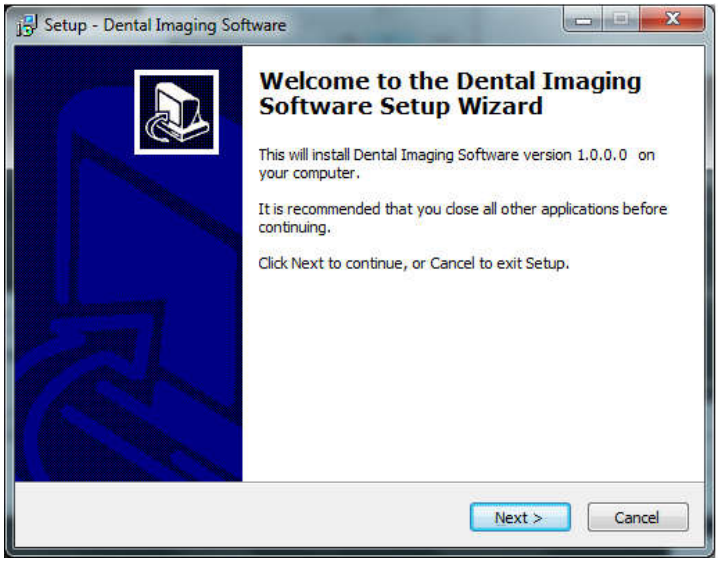
6.2. SOFTWARE INSTALLATION

Insert the accompanying media and execute the Setup.exe. The following screen should be displayed.

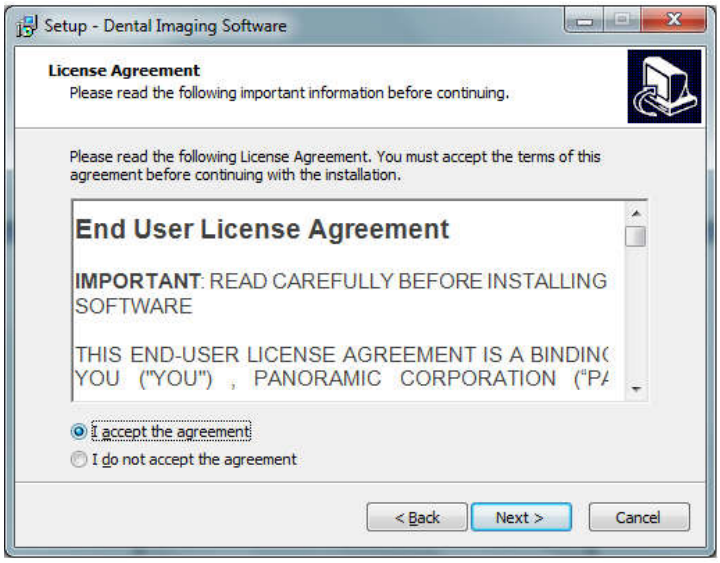
1 – Select the language



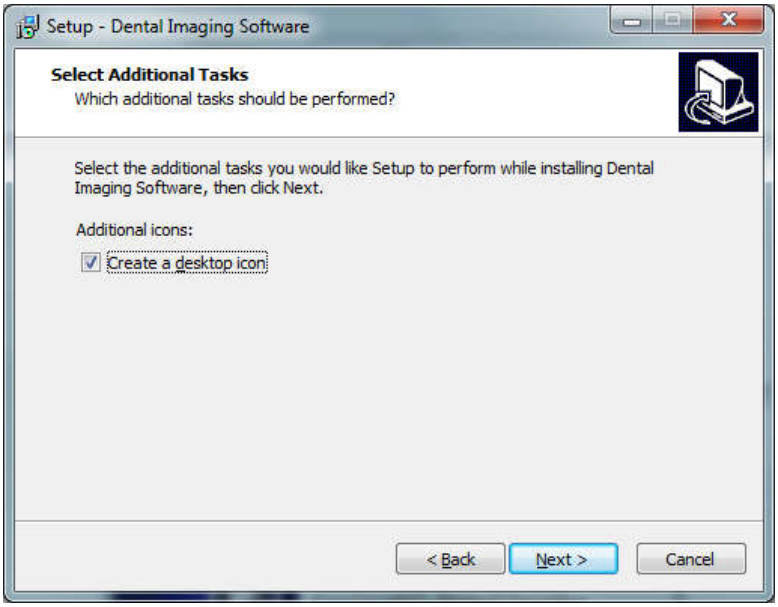
2 - Press NEXT:



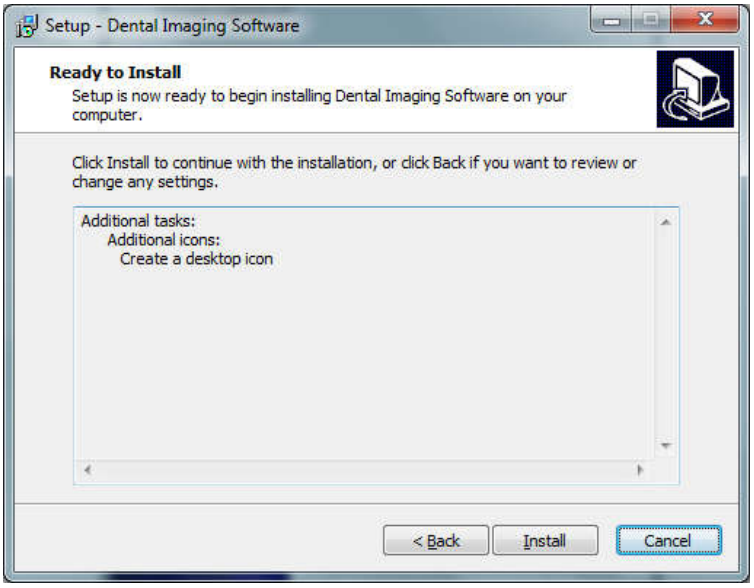
3 – Read carefully the EULA and if you agree select **" I accept the agreement"** and press NEXT



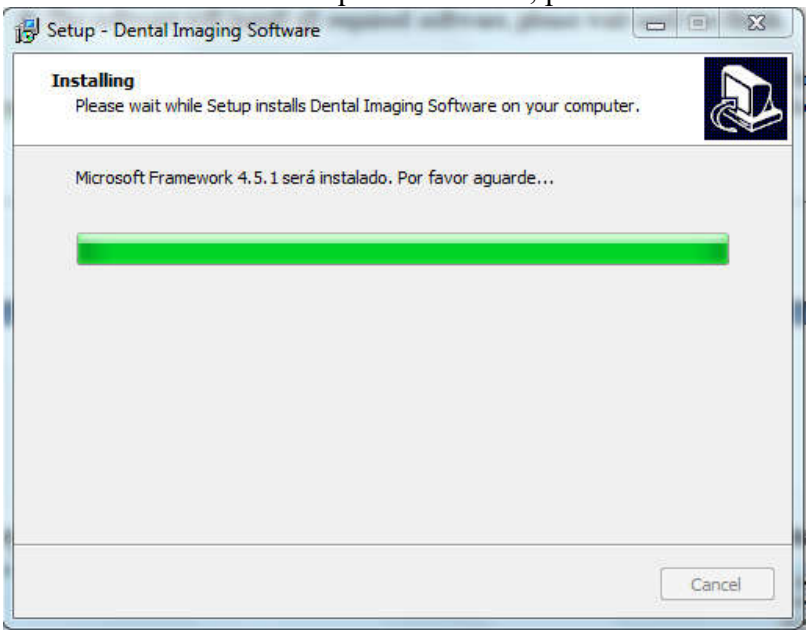
4 – Click on the Checkbox if you want create a desktop icon and Press NEXT



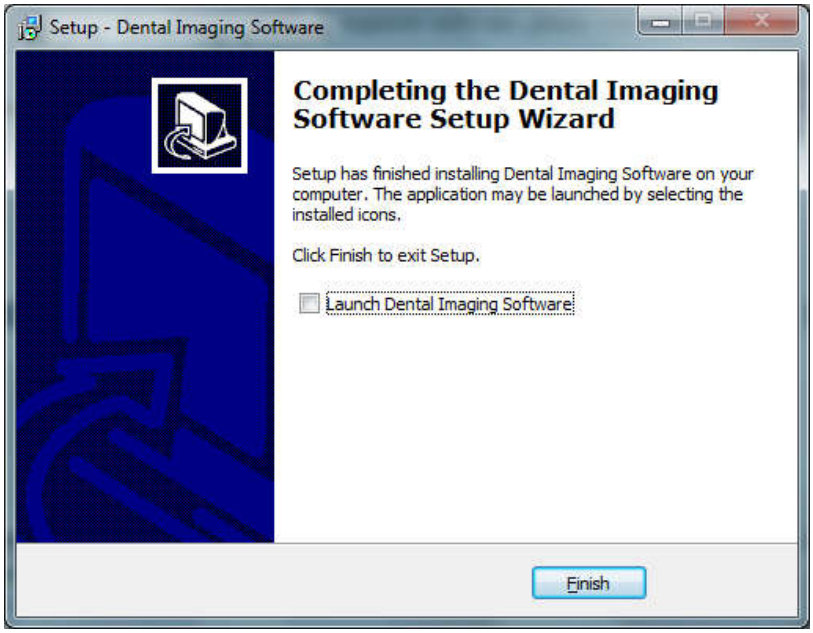
5 - Press INSTALL to start the installation.



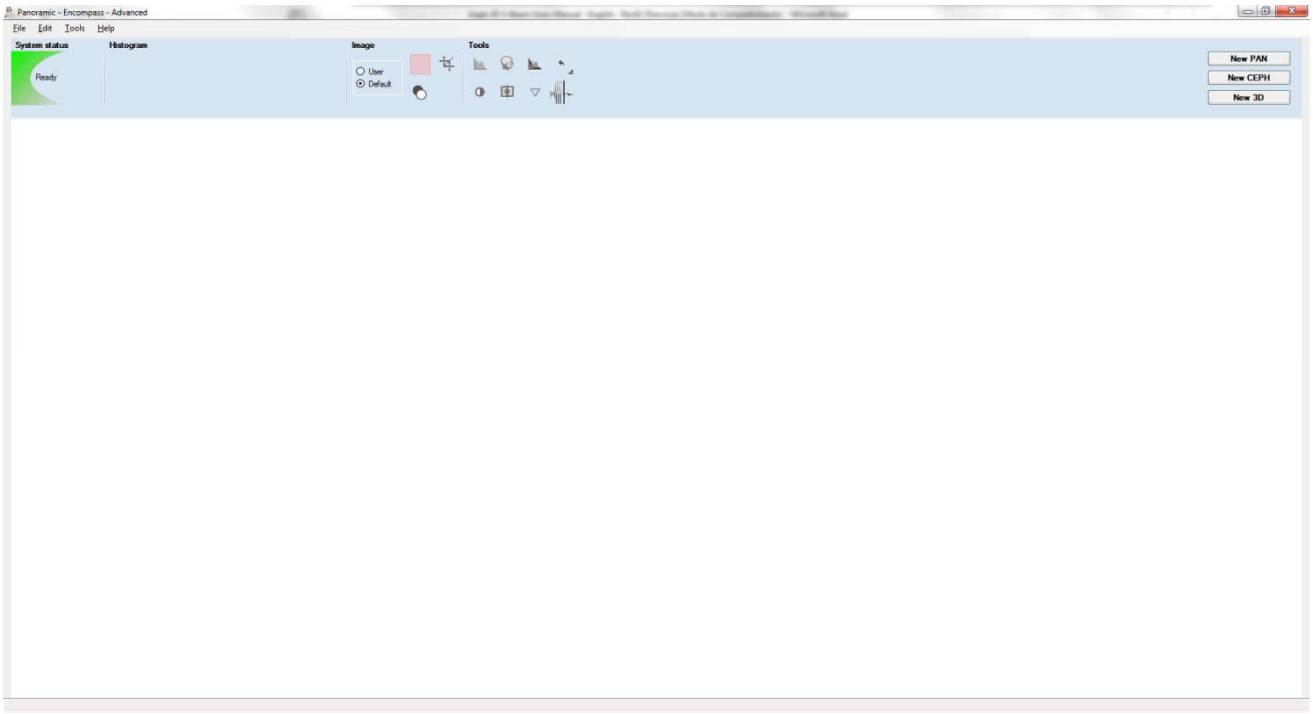
6- The software will install all required software, please wait until if finish.



7 - Press FINISH to close the setup.



8- After installation, access Windows Start Menu / All Programs / Dental Imaging Software/ Dental Imaging Software. The main software window should display as follows:



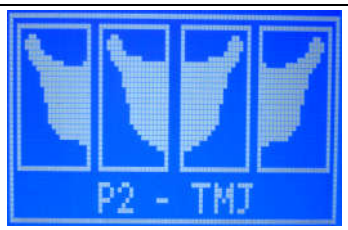
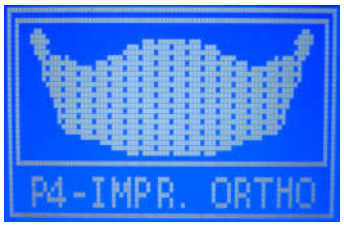
 **ATTENTION**	**A DIGITAL VERSION OF THE SOFTWARE USER MANUAL WILL BE AVAILABLE WITH TECHNICAL CHARACTERISTICS AND GUIDELINES ON THE SOFTWARE OPERATION.**

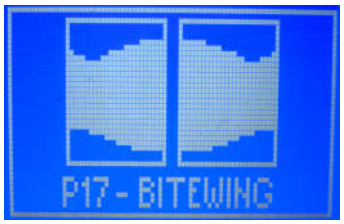
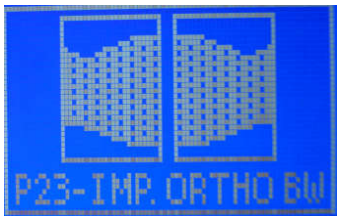
7. IMAGING PROGRAMS

The ENCOMPASS Panoramic X-Ray Machine contains a set of profiles.

7.1. PANORAMIC PROFILES:

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

Program		Description
P1		**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		**Temporomandibular Joint Exposure, TMJ:** This double exposure fits the condyle in both closed and open mouth configuration into a single image.
P3		**Sinus Exposure:** This exposure focuses on the maxillary sinus region.
P4		**Improved Orthogonally:** This exposure is the standard panoramic profile optimized for the beam to be more orthogonal in respect to the dental arch.
P5		**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		**Child Panoramic Exposure:** This exposure has a 15% size reduction with respect to the standard panoramic profile.
P17		**Bitewing Exposure:** This exposure is a bitewing-like image profile from premolar and molar area including parts of maxilla, mandible and rami.
P23		**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.

7.2. CEPHALOMETRIC PROFILES:

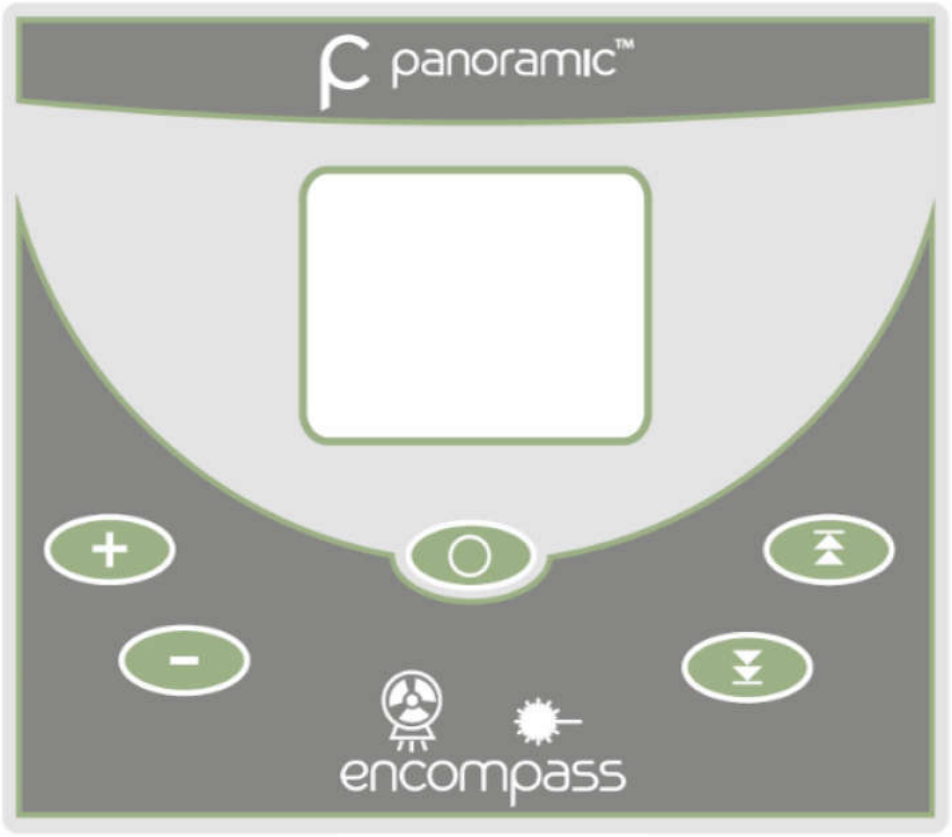
P8		**Digital Cephalometric profile:** With this profile it is possible to execute the following digital images: • PA: Posterior-Anterior • AP: Anterior-Posterior • 45º Degrees • Lateral • Carpal

P9		**Low Dosage Digital Cephalometric profile:** With this profile it is possible to execute a lateral ceph with a smaller exposure area resulting in a lower dose to the patient.

8. CONTROL PANEL

8.1. 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.

8.2. CONTROL PANEL KEYS

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

Plus Key:

Used to increase kV, 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, 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, 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.

8.3. 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.

8.4. 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

8.5. TURNING THE EQUIPMENT ON

ATTENTION	**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.**

ATTENTION	**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.

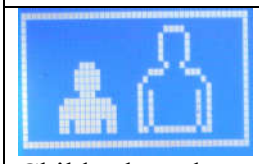
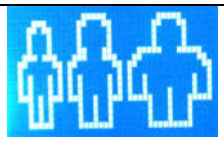
During the self-check, the following screen will be shown on the display:

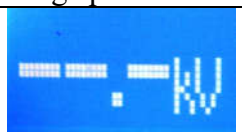
The machine can be configured to display an exposure counter that is displayed after the machine initialization and after each exposure.

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

8.6. 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.	 Equipment is not ready to expose x-rays. If exposure switch is pressed the equipment will operate in demonstration mode (no x-ray exposure).
		 Equipment is ready to expose x-rays.  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 order to assist the operator. This value is selected using PLUS/MINUS KEYS. Please be aware that the values of kV indicated are for reference only.	 No selection
		 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 PLUS/MINUS KEYS Please be aware that the values of kV indicated are for reference only.	 Size not selected
		 Small patient selected

		 Medium patient selected
		 Large patient selected
kV	This function is used to fine 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.  Example of kV selection: 75 kV.
mA	The anodic current is not user adjustable. The value indicated is optimum for image generation in each profile.	 Indication that current profile uses 8mA of anodic current.
TIME	In all profiles the value is not user adjustable.	 Value indicating that current profile has 14 seconds of x-ray exposure.
IMAGE LAYER POSITION	This function allows the user to adjust the image layer towards the back or front of the dental arch in panoramic profiles. The adjustment is made using the following keys: - **PLUS**: moves layer towards back of dental arch. - **MINUS:** moves layer	 The image layer positioning change commands are accepted when the image layer icon is selected on the screen.

	towards front of dental arch.	
PROFILE SELECTION	The image and text indicate the selected profile.	 Example with standard panoramic selected.

9. PREPARING FOR THE EXPOSURE

This section describes operations required for exposing images.

The type of radiography depends on machine type and the media (sensor snap or sensor fixed) position.

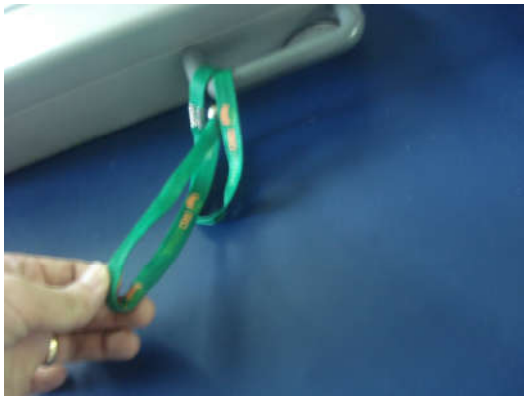
This section describes the steps required before positioning the patient on the machine.

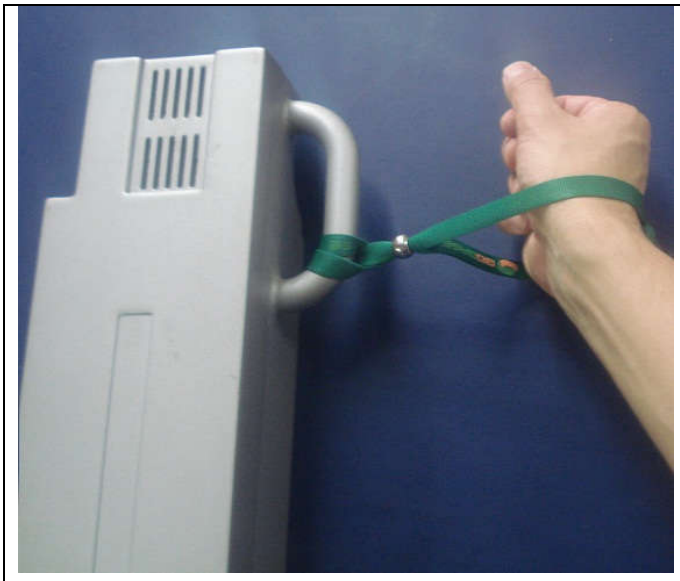
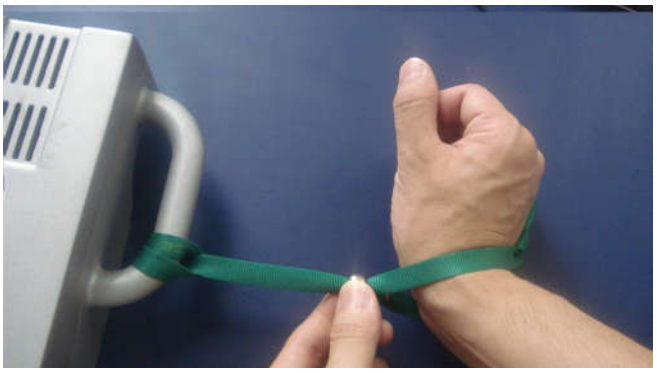
9.1. DIGITAL SNAP-ON SENSOR CONFIGURATION

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, anti-allergic material. The safety wrist strap is shown in the picture below.

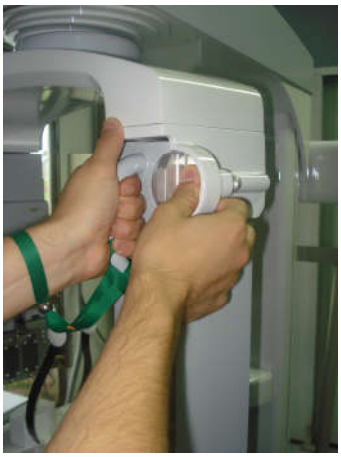
To use it, follow the procedure below.

	Pass the first strap loop inside the sensor handle.
	Pass the second strap loop inside the first one.
	Pull the strap until the sensor is tightly secured.

	Insert your hand into the strap loop.
	Adjust the safety strap to your wrist.

ATTENTION	**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.

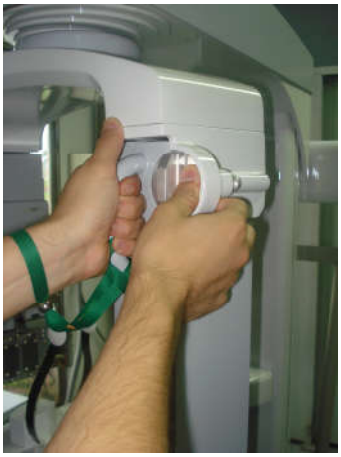


1. Hold the sensor tightly with your left hand and push the locking button with your right hand.

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

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

9.2. DIGITAL FIXED SENSOR CONFIGURATION

CHANGING FOR PANORAMIC OR CEPHALOMETRIC MODE

In order to change from Panoramic to Cephalometric mode, pull the locking button close to the panoramic sensor in C-arm. The equipment will automatically change the configuration to Cephalometric mode.

In order to change from Cephalometric to Panoramic mode, push the locking button close to the panoramic sensor in C-arm. The equipment will automatically change the configuration to Panoramic mode.

9.3. 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.

9.4. GETTING THE SOFTWARE READY

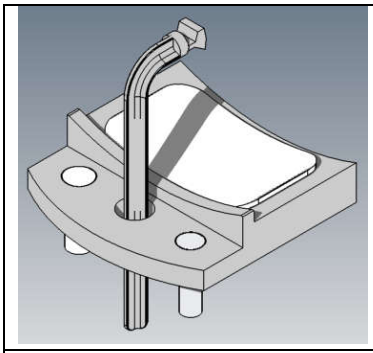
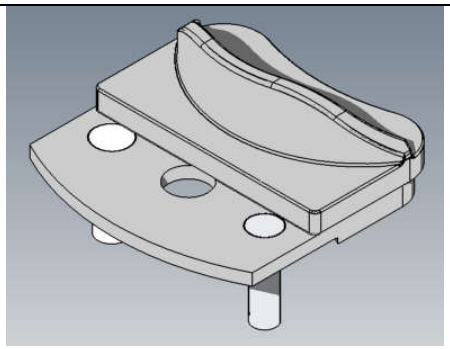
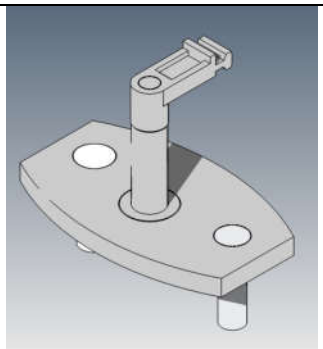
Open the Imaging software and press New Exposure. Make sure the green light is on before exposure.

10. 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.

		
Chin rest for patient with teeth	Chin rest for patient without teeth	Chin rest for Sinus and TMJ

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 Age	**kV**	
	Child	Adult
Small	60kV	70kV
Medium	65kV	75kV
Large	70kV	80kV

 ATTENTION	**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.**

10.1. GETTING THE SOFTWARE READY

Enter 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.

10.2. 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.

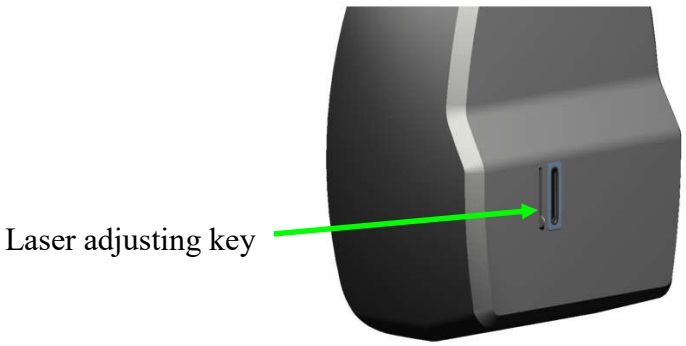
For a patient with teeth, ask them to step forward, grasp the patient handles, stretch up and bite the bite guide. The incisal edges of the maxillary and mandibular teeth must be in the groove of the bite guide.

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.

CAUTION	**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.

10.3. 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.

ATTENTION	**MAINTAIN AUDIAL AND VISUAL CONTACT WITH THE PATIENT AND UNIT DURING THE WHOLE EXPOSURE PROCESS. IF THE EXPOSURE OR MOVEMENT STOPS DURING THE PROCESS DUE TO AN INTERNAL ERROR, RELEASE THE SWITCH AND ASSIST 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 PROFILE (P2) ONLY	**TMJ PROFILE, P2, IS A DOUBLE EXPOSURE. AFTER THE FIRST EXPOSURE, POSITION THE PATIENT WITH OPEN MOUTH AND 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 software.

11. 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
- Waters PA
- AP
- Lateral
- Basal-Hirtz axial
- 45 degrees
- Carpal

 ATTENTION	**BEFORE START, OPEN THE HEAD POSITIONER AND REMOVE THE CHIN REST AND BITE GUIDE FROM THE PATIENT SUPPORT.**

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 Age	**kV – DIGITAL VERSION**	
	Child	Adult
Small	60kV	70kV
Medium	65kV	75kV
Large	70kV	80kV

 ATTENTION	**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.**

11.1. GETTING THE SOFTWARE READY

Enter 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 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, WATERS PA, CARPAL, BASAL-HIRTZ AXIAL, 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.

 CAUTION	**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.**

11.3. 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.

 ATTENTION	**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 software.

12. PROCEDURES FOR REUSE

12.1. 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.

 CAUTION	**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.**

12.2. DISINFECTION

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

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

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

 CAUTION	**FOR CLEANING, DO NOT USE MICRO ABRASIVE MATERIALS, STEEL WOOL, ORGANIC SOLVENTS OR SOLVENT-CONTAINING DETERGENTS, SUCH AS ETHER, STAIN REMOVER, GASOLINE, ETC.**

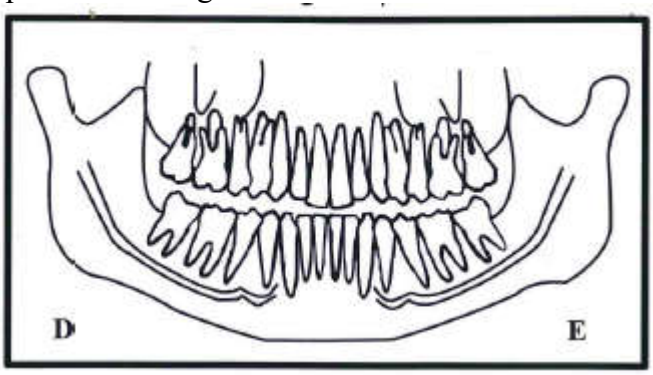
13. TROUBLESHOOTING GUIDE

13.1. UNIT OPERATION PROBLEM

Symptom	Possible Cause	Action required
Equipment does not turn on	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
	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
Digital image doesn't appear on the screen	Cable disconnected	Connect the cable
	Image acquisition software	Reinstall the software
	Acquisition button wasn´t selected	Select the acquisition button
Remote exposure button not actuating	Remote exposure cable disconnected	Connect remote exposure cable again

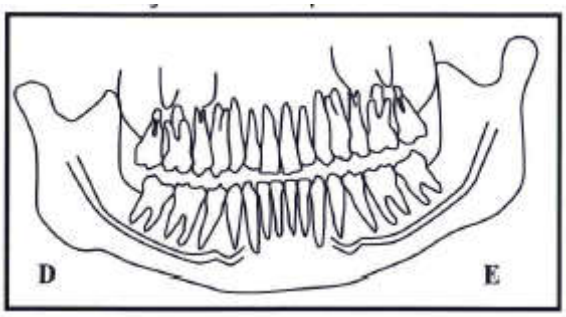
13.2. PATIENT POSITIONING PROBLEM[1]

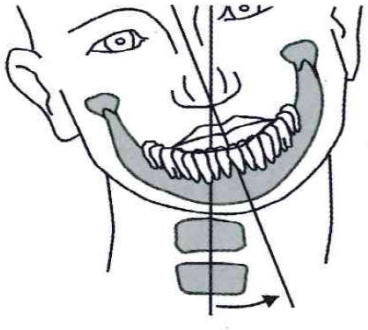
The standard panoramic image is showed below.



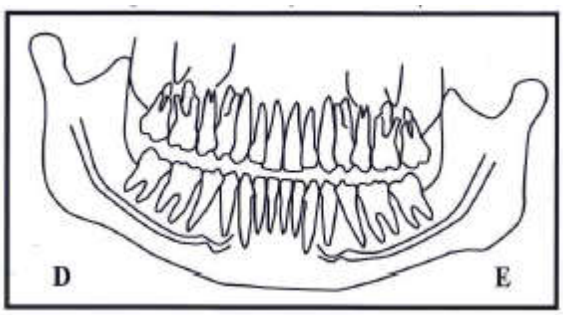
A error in the patient positioning may generate several failures in the image.

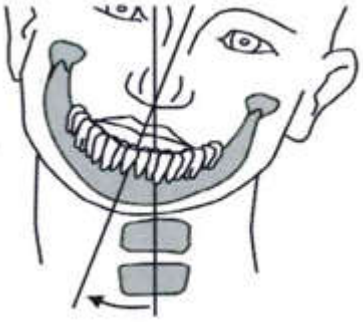
Symptom	Possible Cause	Action required
The teeth appear more amplified on one side and narrower on the other.	Head tilted patient. Patient position to tune in relation to the median sagittal plane	Check the position of the sagittal plane of the patient with the laser line





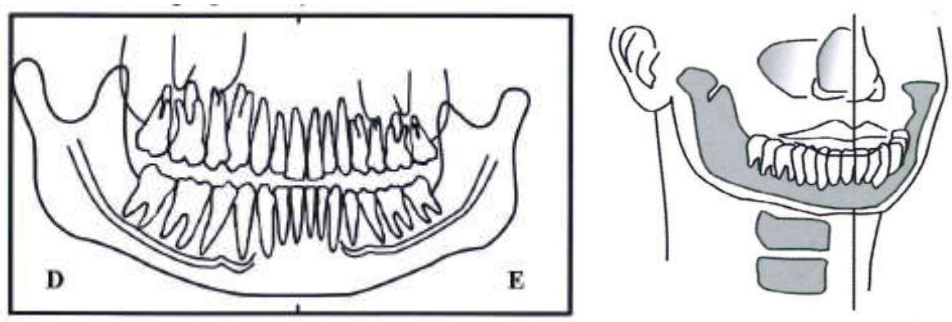
Head tilted to the right



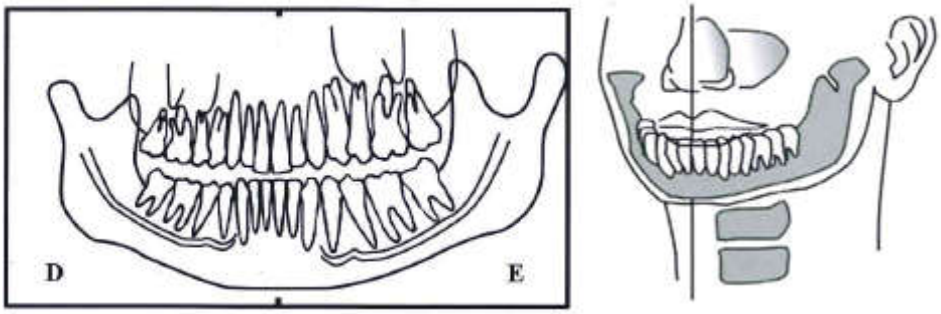


Head tilted to the left

Symptom	Possible Cause	Action required
The teeth appear more amplified on one side and narrower on the other.	The patient's head rotated. Patient position for posterior teeth in relation to the focal plane	Check the position of the sagittal plane of the patient with the laser line

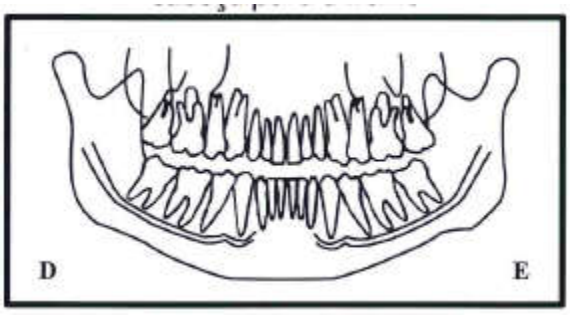


Head turned to the right

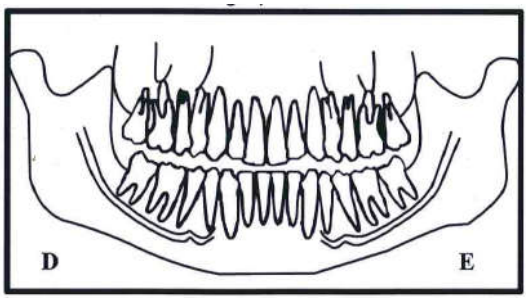


Head turned to the left

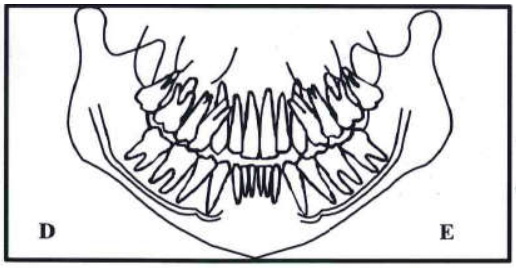
Symptom	Possible Cause	Action required
Incisors and canines narrow and unsharp.	Position of the arch is anterior of the focal plane.	Adjust the focal plane of the equipment by positioning the Canine red laser on the tooth Canine tooth.

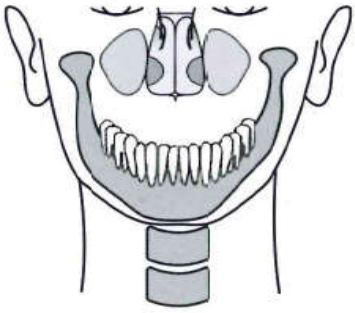


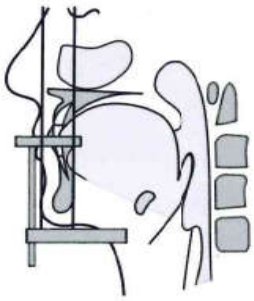
Symptom	Possible Cause	Action required
Incisors and canines wide and unsharp.	Position of the arch is posterior of the focal plane.	Adjust the focal plane of the equipment by positioning the Canine red laser on the tooth Canine tooth.



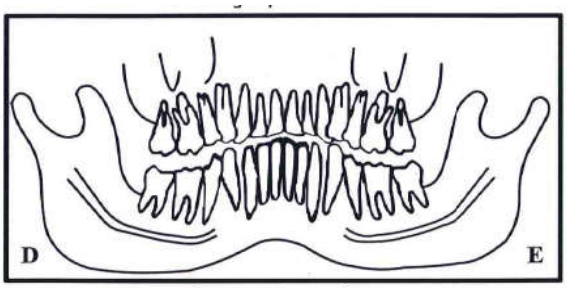
Symptom	Possible Cause	Action required
A row of teeth is bent upwards. The lower incisors are deformed. TMJ joints are very high and are often cut off from the image.	Patient's head is tilted forward	Reposition the patient relying on the Frankfurt plane laser

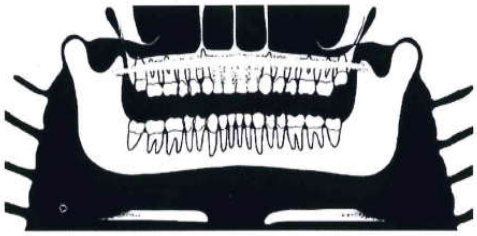


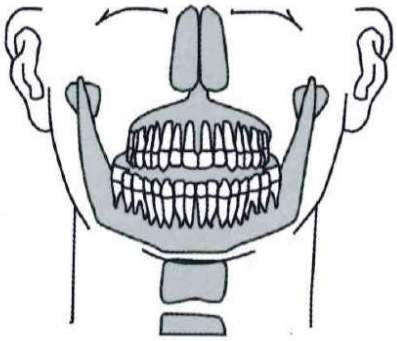


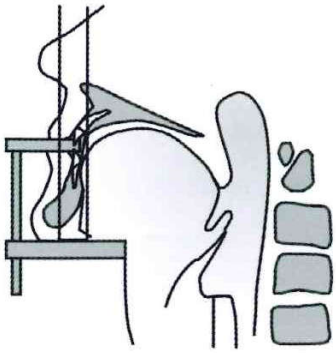


Symptom	Possible Cause	Action required
A row of flat teeth. Unable to see the roots of the upper teeth.	Patient's head is tilted back	Reposition the patient relying on the Frankfurt plane laser

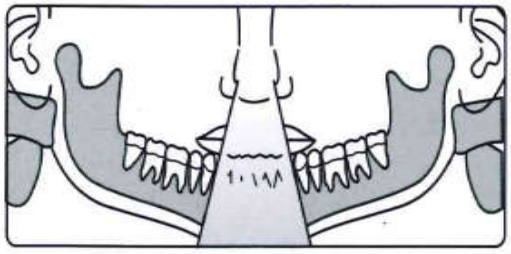


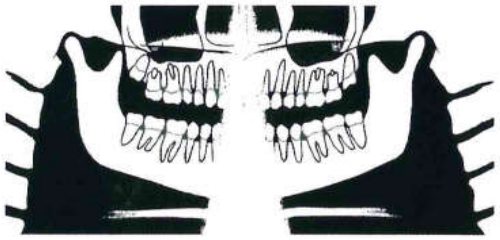


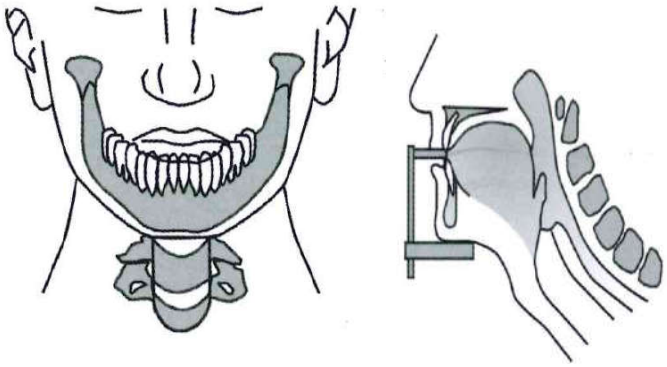




Symptom	Possible Cause	Action required
Central area of the image is very clear and deformed. Shadow of the column.	Patient neck is not stretched	Ask the patient to take a step forward and stretch your neck.
	Contrast and brightness setting is incorrect in software	Adjust the contrast and brightness in the software

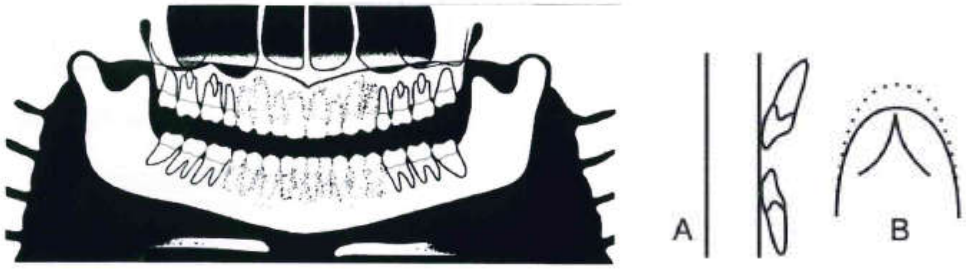






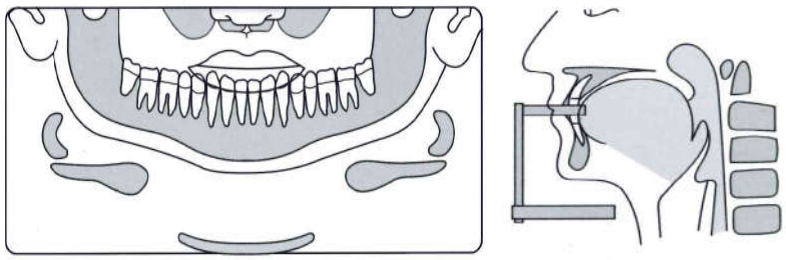
Symptom	Possible Cause	Action required
Incisors and canines teeth blurred.	Anterior teeth behind the focal plane	Adjust the focal plane by positioning the Canine red laser on Canine tooth.
	Anterior teeth ahead of the focal plane	

Anterior teeth behind the focal plane



Anterior teeth ahead of the focal plane

Symptom	Possible Cause	Action required
Upper arch outside the image area	chin is not leaning against chin rest	Ask the patient to rest his chin on the support.



Symptom	Possible Cause	Action required
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 nape of the patient touch the X-ray head	The inclination of the patient's head is not correct	Check the positioning of the patient head and reposition the patient
	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 cortical cross-sectional images.	The inclination of the patient's head is not correct	Reposition the patient
	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
Rows of teeth overexposed.	Tongue was not against the roof of palate	Ask patient to swallow and place tongue against the roof of palate
Artefact in the image	Patient did not remove the metal artifacts	Ask the patient to remove eyeglasses, hearing aids, dentures, and personal jewelry, such as earrings, necklaces and hooks.

14. DISPOSAL OF THE UNIT

14.1. 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 non-degradable plastic material.

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

15. EQUIPMENT INSTALLATION, CORRECTIVE MAINTENANCE AND CALIBRATION.

15.1. 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.

15.2. 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.

15.3. 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.

15.4. CALIBRATION

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

15.5. 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

16. TECHNICAL SPECIFICATIONS

16.1. REGULATORY INFORMATION

Manufactured for: Panoramic Corporation Phone Number: 1 (800) 654-2027 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 standard NBR IEC 60601-1	
Protection against electric shock	“Type-B” applied parts“ CLASS I (NBR IEC 60601-1)
Protection against harmful water penetration	Ordinary equipment - IPX0 (Sealed equipment without protection against water penetration)
Application safety level in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide	Unsuitable equipment
Operation mode	Operation Intermittent

16.2. 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
	Warning: pieces of the equipment may cause shock

16.3. 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 time/current	Standard – 14s – 8mA
	Improved orthogonally – 14s – 8mA
	Low dose –11s – 6mA
	Child – 10.5s – 8mA
Maxillary sinus	8s – 8mA

Open mouth + closed mouth TMJ exposure time (TMJ 1 + TMJ 2)	10s – 8mA
Bitewing	7.6s – 8mA
Mean magnification	1 : 1.22
Source to Image Distance SID	1.69 ft
Information Specific for Cephalometric Profiles	
Analog cephalometric exposure time/current	0,1 to 3s – 8mA
Complete digital cephalometric exposure time/current	10 or 16,5 – 8mA
Low Dosage digital cephalometric exposure time/current	6,6 or 11s – 8mA
Film dimension for analog cephalometric exposure	8” x 10”
Mean magnification	1:1.1
Source to Image Distance SID	5.41 ft
For this equipment proper patient positioning is required to produce a good quality image. The operator must stay away at least 9 feet from the equipment during exposure to minimize the amount of ionizing radiation risk.	

16.4. X-RAY GENERATOR

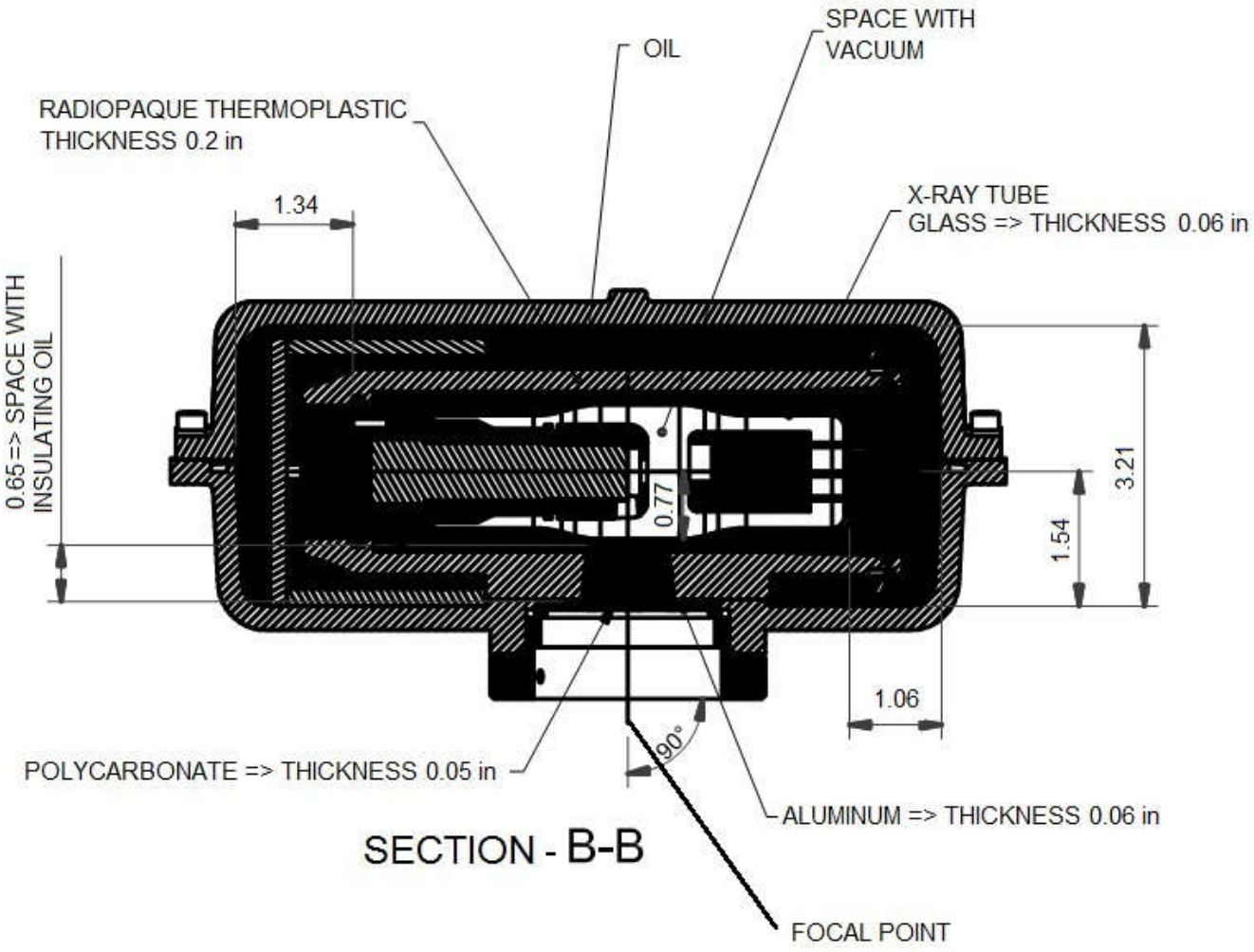
Generator type	High-frequency constant potential generator
Operating frequency	100 kHz
Maximum operation voltage	85 kVp
Heating and cooling curve	See Graphic on item 15.13 of this manual
Output power	680 W (85kV x 8mA)
Output power during 0,1s	680 W (85kV x 8mA)
Total filtration	0.01 ft Al eq. @ 85 kVp (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	

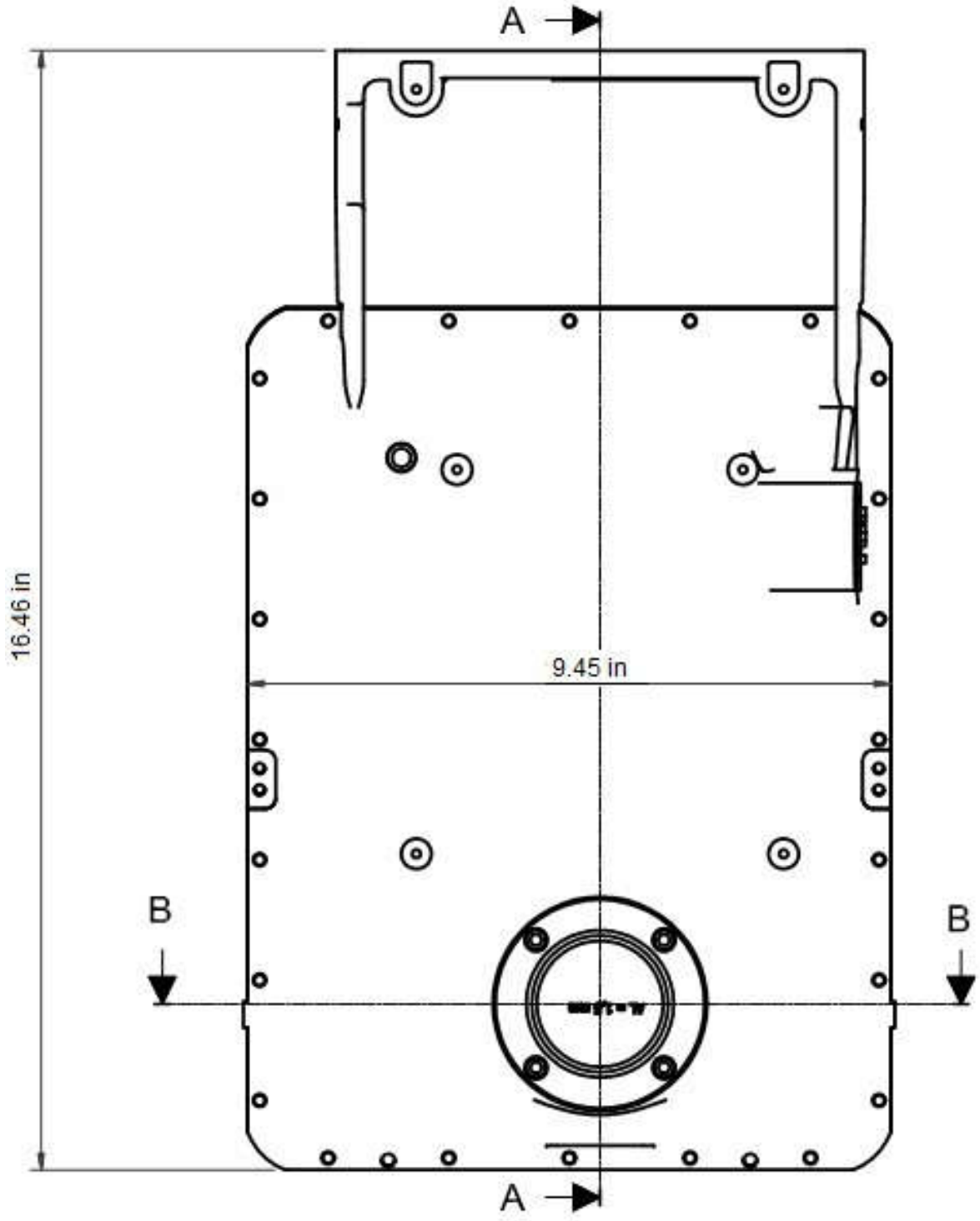
16.5. TESTED EQUIPMENT LAW NORM

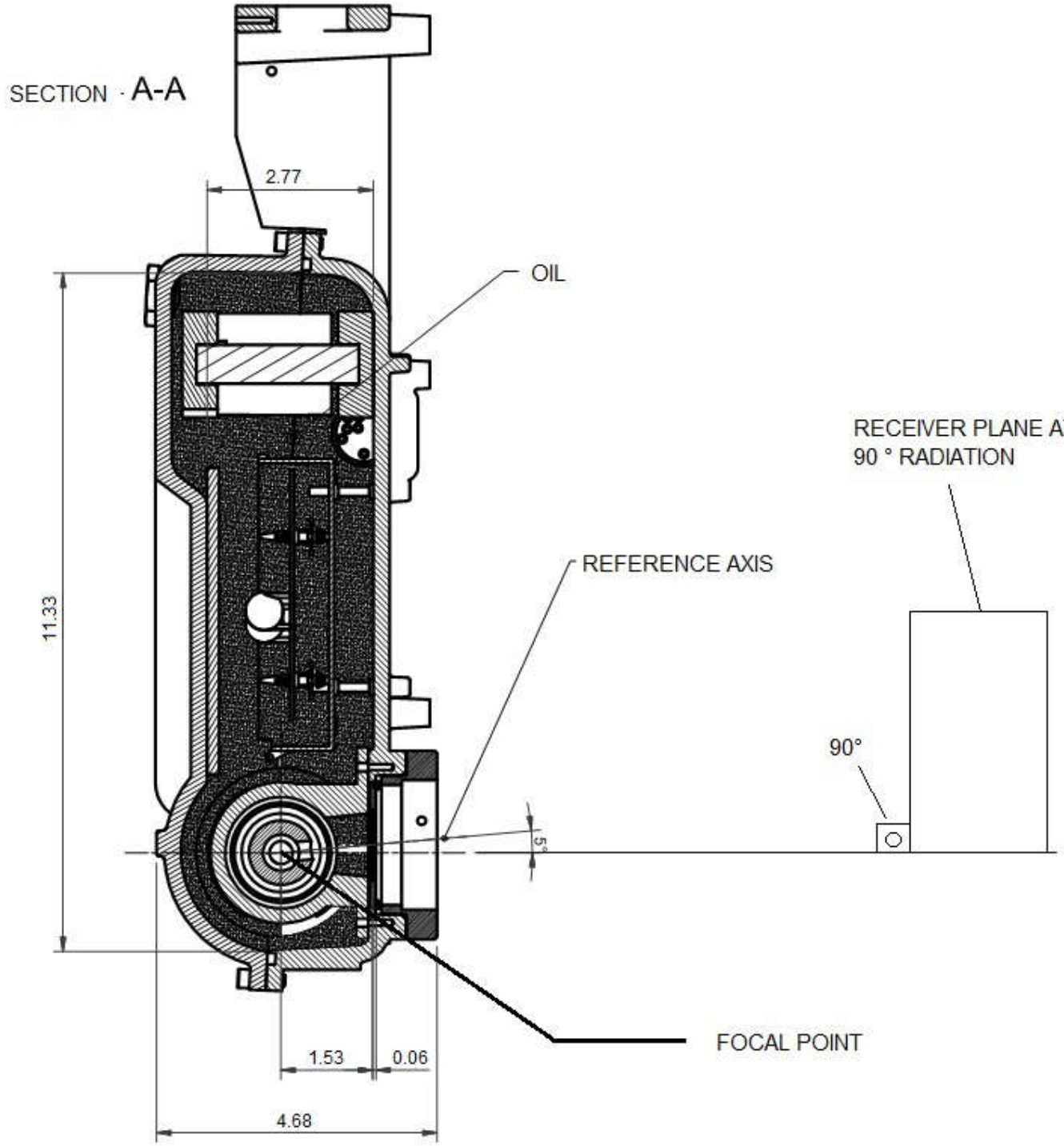
EN 60601-1 (1990);
Amendment 1 EN 60601-1 (1992);
Amendment 2 EN 60601-1 (1995);
Amendment13 EN 60601-1 (1995);
UL 60601-
60601-1-4-2004

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.

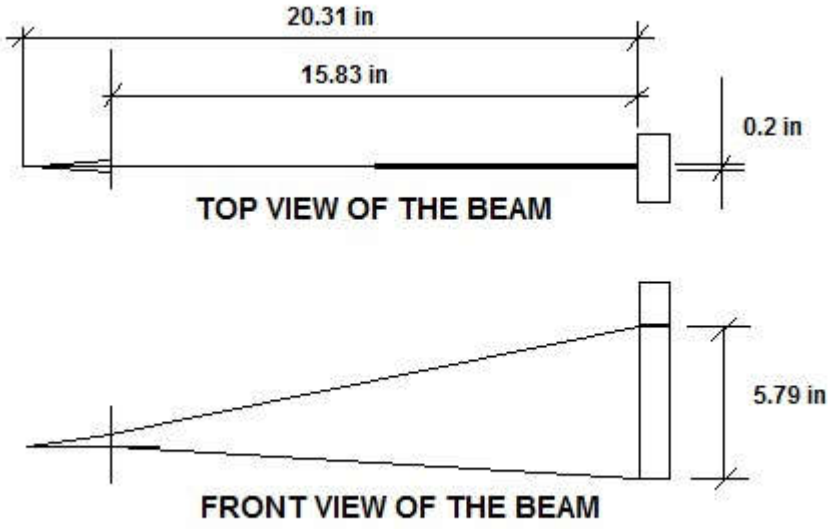
Reference axis between the target angle and the focal point of the X-ray tube:
90º With axis of anode and cathode, respective
Target angle with reference axis:
5º Reference axis angle between the target and the focal point of the x-ray generator mounted:
measurements of x-ray generator mounted:
318mm 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= ± 0.5mm (lateral)
Y= ± 0.5mm (depth)
Z= ± 0.5mm (height)


SPACE WITH
VACUUM
OIL
RADIOPAQUE THERMOPLASTIC
THICKNESS 0.2 in
X-RAY TUBE
GLASS => THICKNESS 0.06 in
1.34
0.65 => SPACE WITH
INSULATING OIL
0.77
3.21
1.54
1.06
90°
POLYCARBONATE => THICKNESS 0.05 in
ALUMINUM => THICKNESS 0.06 in
SECTION - B-B
FOCAL POINT

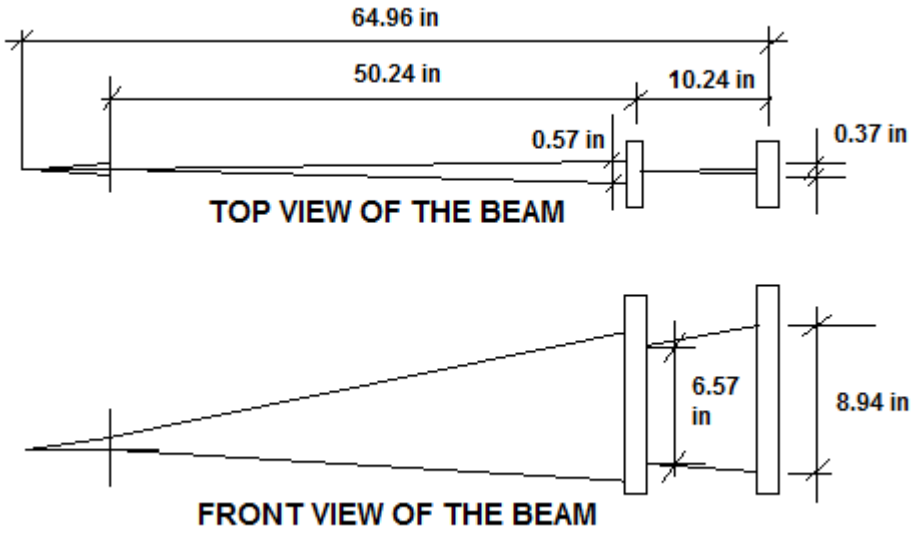

A
16.46 in
9.45 in
B
B
A


SECTION · A-A
2.77
OIL
RECEIVER PLANE AT
90 ° RADIATION
REFERENCE AXIS
11.33
90°
5°
FOCAL POINT
1.53
0.06
4.68

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



16.7. IRRADIATED FIELD SIZE – DIGITAL CEPH EXAM:



16.8. TUBE SPECIFICATIONS

Manufacturer	TOSHIBA
Model	D-054
Focus size	0.5 – IEC 60336
Equivalent filtration	0.003 ft Al equiv.
Anode angle	5 º
Anode material	Tungsten
Maximum voltage	105 kVp
Thermal capacity	30 kJ
Max thermal capacity and cooling time curve	See graphic thermal curve on item 15.13.
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

16.9. ELECTROMAGNETIC EMISSIONS

<table>
<tr><td colspan="3">Manufacturer’s guidelines and declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emission assays</td><td>Compliance</td><td>Electromagnetic Environment Guidelines</td></tr>
<tr><td>RF emissions ABNT NBR IEC CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions ABNT NBR IEC CISPR 11</td><td>Class A</td><td rowspan="3">The ENCOMPASS Panoramic X-Ray Machine is suitable for use in all types of facilities, including residential facilities and those directly connected to the public system of low -voltage electric power supply for residential buildings.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Emissions due to voltage/scintillation fluctuation IEC 61000-3-3</td><td>In compliance</td></tr>
<tr><td>RF emissions CISPR 15</td><td>In compliance</td><td>The ENCOMPASS Panoramic X-Ray Machine is not suitable for inter-connection with another piece of equipment.</td></tr>
</table>

16.10. ELECTROMAGNETIC IMMUNITY

Manufacturer's guidelines and declaration - electromagnetic immunity			
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	ABNT NBR IEC 60601 Assay Level	Compliance Level	Electromagnetic environment -Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by the air	± 6 kV by contact ± 8 kV by the air	Floors must be finished with wood, concrete or ceramics. In case the floor is covered with synthetic material, relative humidity must be at least 30%.
Fast electric transients /pulse train ("Burst") IEC 61000-4-4	± 2 kV on the mains supply line ± 1 kV on the input/output line	± 2 kV on the mains supply line ± 1 kV on the input/output line	The quality of power supply must be that of hospital facilities or of 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.			

Manufacturer's guidelines and declaration - electromagnetic immunity			
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 Level	Compliance Level	Electromagnetic environment - Guidelines
Conducted RF IEC 610004-6	3 Vrms 150 kHz up to 80MHz	3 Vrms	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. d = 1.2 √P d = 1.2 √P - 80 MHz up to 800 MHz d = 2.3 √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:
Radiated RF IEC 610004-3	3 V/m 80 MHz up to 2.5 GHz	3 V/m	
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 output power of the transmitter (W)	Separation distance according to the transmitter's frequency (m)		
	150 kHz up to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz up to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz up to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters 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.

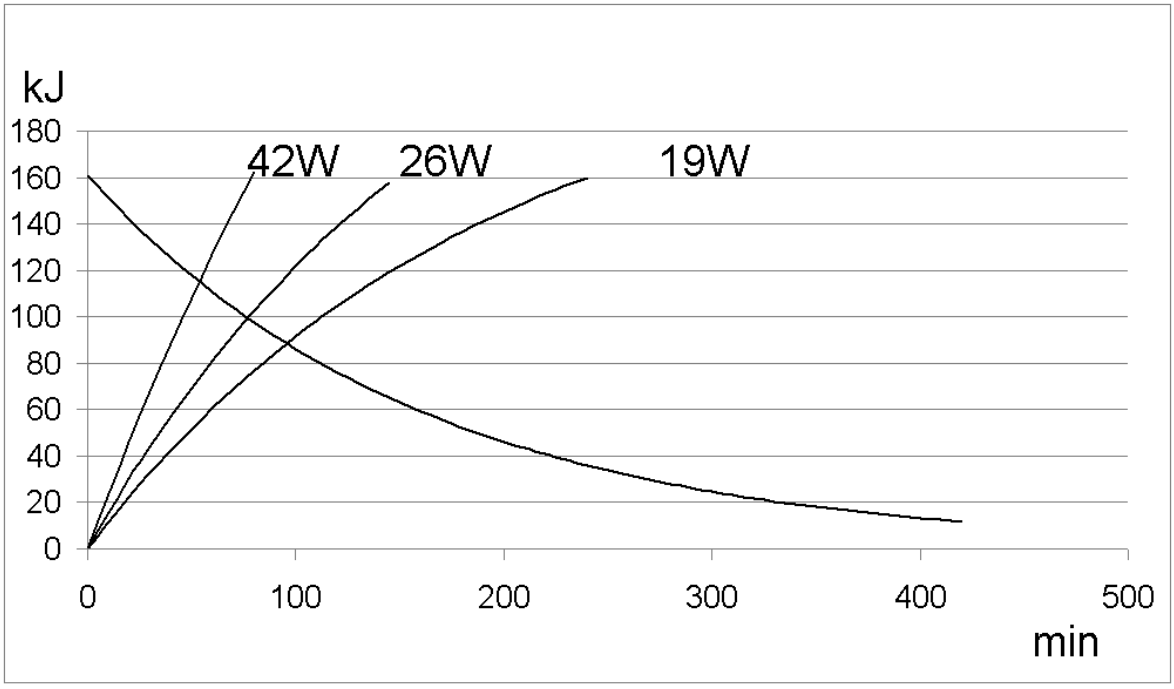
WARNING

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

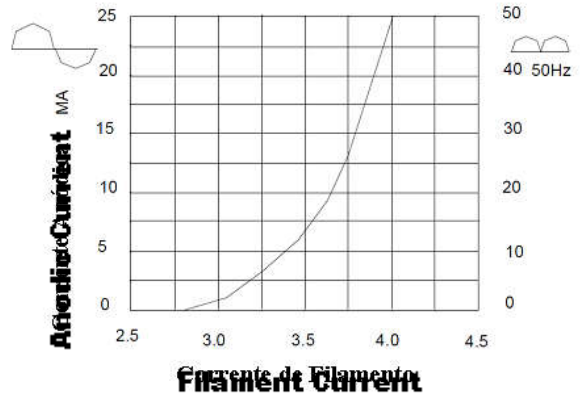
WARNING	**TO ENSURE SAFE OPERATION, THE OPERATOR MUST TURN AWAY FROM EQUIPMENT FOR SAFETY TO AVOID COLLISION WITH MOVING PARTS. THE PATIENT SHOULD BE INFORMED OF ALL MOVEMENTS THAT THE EQUIPMENT WILL PERFORM. THE PATIENT SHOULD ALSO BE TOLD NOT TO MOVE DURING THE EXPOSURE. IT IS THE RESPONSIBILITY OF 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.**

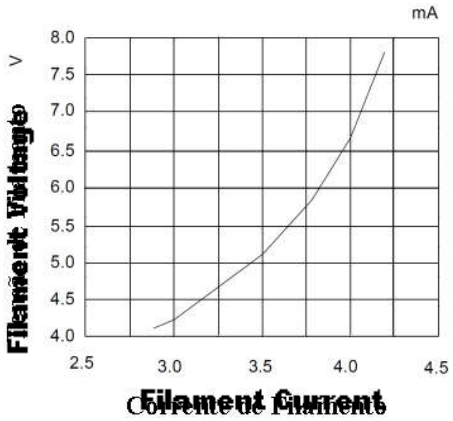
WARNING	**DO NOT USE ACCESSORIES, TRANSDUCERS, PARTS OF INTERNAL COMPONENTS AND CABLES OTHER THAN THOSE SPECIFIED AND PROVIDED BY THE MANUFACTURER. DOING SO CAN RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE ESE.**

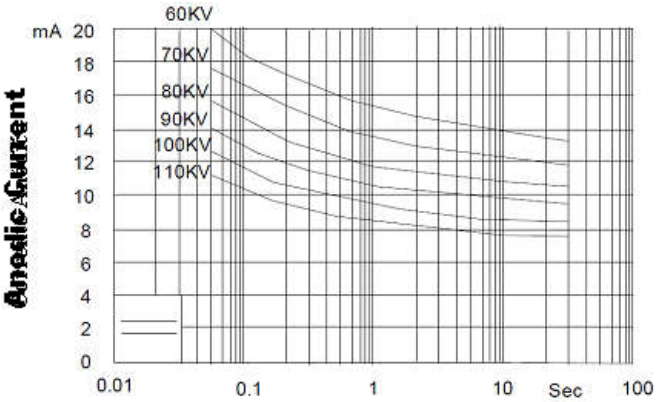
16.11. CHARACTERISTIC COOLING OF THE X-RAY GENERATOR

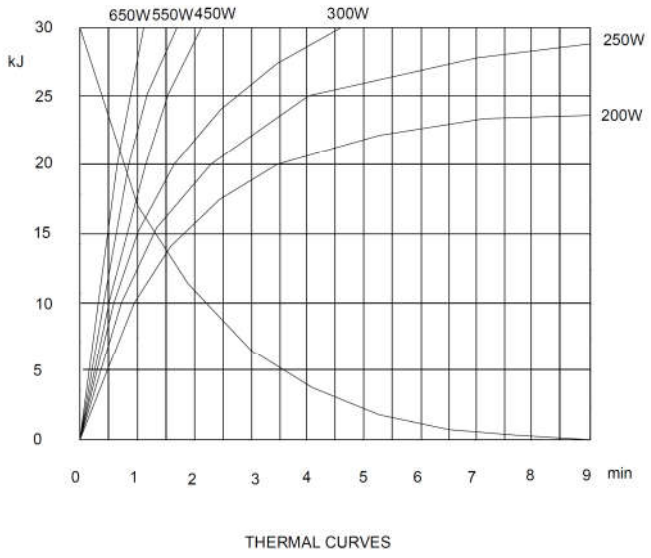


16.12. CHARACTERISTIC CURVES OF THE X-RAY TUBE.



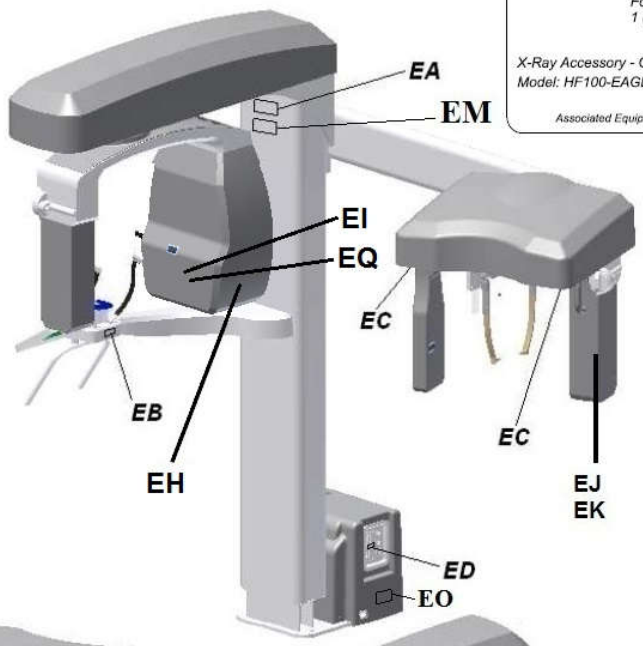






THERMAL CURVES

16.13. LABELS OF IDENTIFICATION



Manufactured for: Panoramic Corporation
4321 Goshen Road
Fort Wayne, Indiana 46818
1 (800) 654 - 2027

X-Ray Accessory - Cephalostat
Model: HF100-EAGLE

Serial N°

Associated Equipment (model HF100-EAGLE) - IEC 60601-2-32:2001

EL

Manufactured for: Panoramic Corporation
4321 Goshen Road
Fort Wayne, Indiana 46818
1 (800) 654 - 2027

X-Ray Accessory - Snap On
Model: HF100-EAGLE

Serial N°

Associated Equipment (model HF100-EAGLE) - IEC 60601-2-32:2001

CAUTION: HANDLE WITH CARE SENSITIVE EQUIPMENT

EJ

WARNING

"Do not remove the covers. High voltage inside. Danger of electrical shock. Repairs must be performed by authorized personnel only. Equipment require proper earthing. Disconnect mains before servicing. "

EG

THIS EQUIPMENT CAN NOT BE TILTED MORE THAN 5°. RISK OF TUMBLING.

EA

BE CAREFUL WHILE OPERATING THE EQUIPMENT, MOVING PARTS MAY BE DANGEROUS FOR YOUR FINGERS.

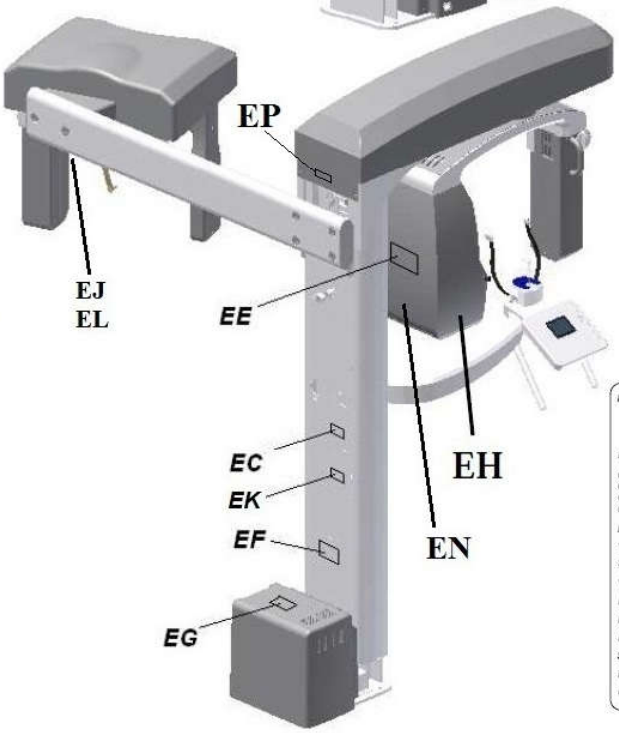
EC

Fuse (Time-Lag - Glass)
(20mm x 5mm)
F10 e F11: 110V~ 127 V~ = 10 A
F10 e F11: 220 V~ 240 V~ = 5 A

ED

EH

EI



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Fort Wayne, Indiana 46818
1 (800) 654 - 2027

X-Ray Generator
Model: HF100-EAGLE => IEC 60601-2-7:2001 => IEC 60601-1-1997
=> IEC 60601-1-3:2001 => IEC 60601-2-28:2001
=> IEC 60601-2-32:2001 => IEC 60601-1-4:2004

Serial N° X-Ray Tube: TOSHIBA

Nominal Tension of Tube	85 KVp ±10%
Output Power	0.68 kW
Output Current	8 mA ⎓ ±20%
Cooling Time	See Manual
Focal Point	0.5 x 0.5 mm IEC 60336
Total Filtration (aluminium equivalence)	3.52 mm Al (Toshiba)

Physiological Effects

EE

CAUTION

LASER RADIATION
DO NOT STARE INTO BEAM
POWER < 1 mW
WAVELENGTH 650nm
CLASS I LASER PRODUCT

EQ

Manufactured for: Panoramic Corporation
4321 Goshen Road
Fort Wayne, Indiana 46818
1 (800) 654 - 2027

Digital Panoramic X-Ray System Model: HF100-EAGLE Serial No.

Class I - Type B => IEC/UL 60601
Class II - Type B => DIRECTIVE 93/42/EEC
Ordinary Equipment - IPXO
Operation: Intermitent

	110V~ 127 V~	220 V~ 240 V~
Nominal Supply Voltage (Internal selection)		
Voltage Range	99 a 139 V~	198 a 250V~
Supply Net Apparent Resistance	0.17 Ohms	0.30 Ohms
Voltage Range Fluctuation	±3 V~	±3 V~
Input Current	10 A~	5 A~
Frequency	50/60 Hz	50/60 Hz
Power	1.25 kVA	1.25 kVA
Stand By Power	0.07 kVA	0.07 kVA
Fuse (Time-Lag - Glass)	10 A	5 A
Circuit Breaker	10 A	5 A

EF

WARNING

"This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

EM

The groundlng rellablllty can only be achleved when the equlpment ls connected to an equlvalent receptacle marked "Hosplta Grade",

EO

Maximum Load = 11 Lb

EB

CLASSIFIED C UL US

Digital Panoramic X-Ray System
Model: HF100-EAGLE
=> IEC 60601-2-7:2001
=> IEC 60601-1-3:2001
=> IEC 60601-2-32:2001
=> IEC 60601-1-1997
=> IEC 60601-2-28:2001
=> IEC 60601-1-4:2004
=> UL 60601-1
=> CAN/CS 22.2 Nº 601-1
Control Number: 4BZ4

EK

"WARNING"

For Contlnued Protectlon Agalnst Injury to Persons, to Repalr or the Rotatlng Arm Belt Replacement, Refer to Instructlons In the Servlce Manual Provlded Wlth the Equlpment.

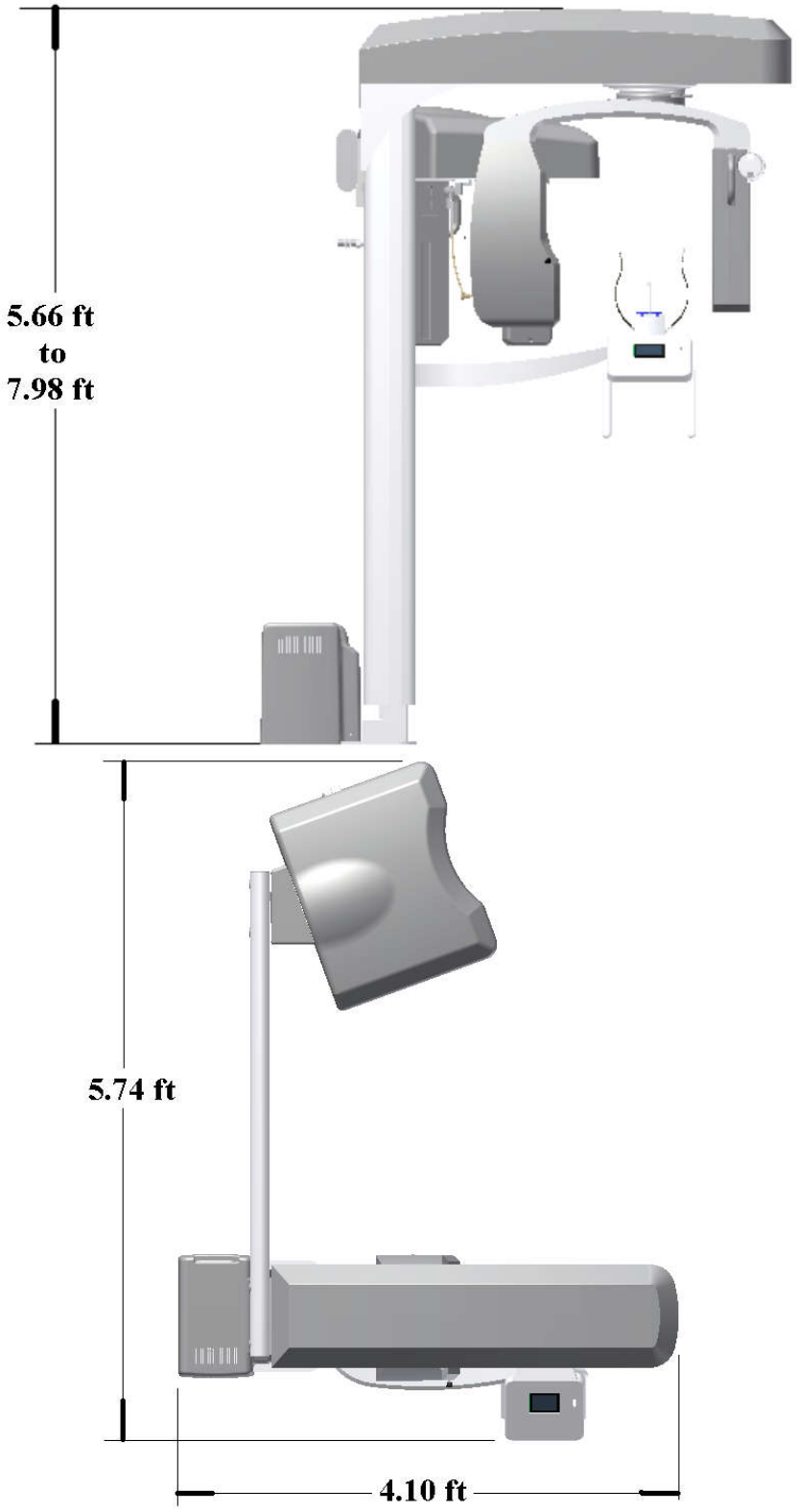
EP

This product conforms to DHHS radiation Standards of 21 CFR subchapter J as of the date of manufacture

Manufactured:

EN

16.14. EQUIPMENT DIMENSIONS



16.15. SERIAL NUMBER OF THE X-RAY TUBE

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