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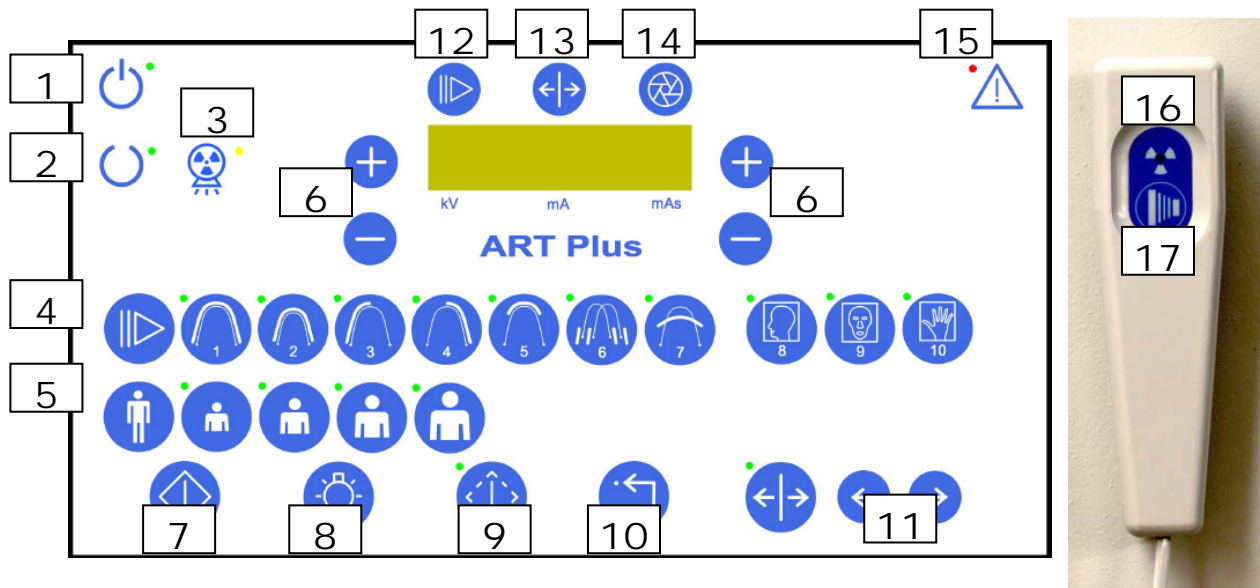
# **ART Plus**




















## **Dental Panoramic X-Ray**

### **Operator's Manual**

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## Symbols on Control Panels



1		Unit ON	10		Alarm Reset
2		Unit READY	11		Carriage shift left
3		X-ray indicator (ionizing radiation emission)	11		Carriage shift right
4		Program selection	12		Program selected 1 through 7 for Pan, 8 through 10 for Ceph
5		Patient size selection: small, medium, large, extra-large	13		Carriage displacement in mm
6	 	Increase/Decrease kV (left side) Increase/Decrease mA, mAs (right side)	14		Collimator selected (Not applicable)
7		Arm Sequential Movement	15		Alarm indication Error message on the display
8		Alignment lights 15 s	16		X-ray indicator (ionizing radiation emission)
9		TEST mode without radiation	17		Radiography push button



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ART Plus  
Dental Panoramic X-ray  
Operator’s Manual – English Edition

Version 2.0 February 2010

Printed 2/3/2010 8:33:00 AM  
Code 69 680 20110

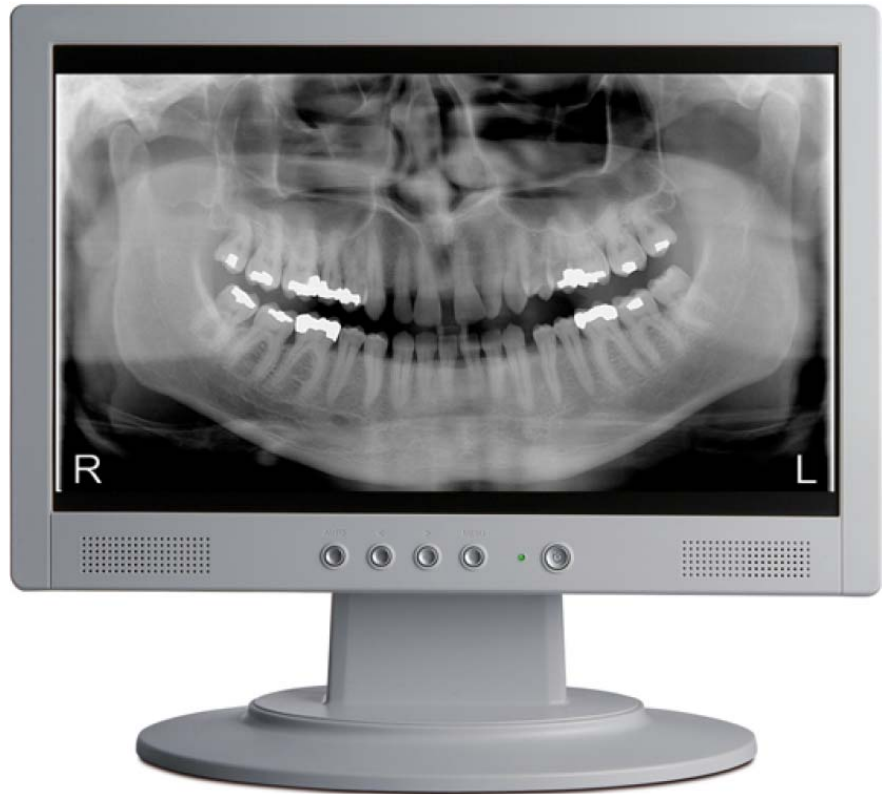
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## 1. INTRODUCTION

### 1.1 Purpose

ART Plus is a dental panoramic digital imaging system utilizing the latest CdTe-CMOS technology. ART Plus offers exceptional image quality and some advanced and unique features such as the ability to focus on different focal troughs, for optimal diagnostic result in the day to day routine. Units are manufactured under a Quality Control System that grants full compliance to specifications.



### 1.2 Product Documentation

The Operator’s Manual and the Service and Installation Manual supplied with the system are integral part of the product and must be kept with the product. The original language of the manuals is English.

Quick Reference Data is provided at the end of each manual

- Appendix A: Error Messages
- Appendix B: Icons
- Appendix C: Technical Data
- Appendix D: Labels
- Appendix E: Cooing Curves
- Appendix F: Fuse Table

### 1.3 Notice to installers

Obligations of the installer are:

- To make sure that the line voltage specified by the Manufacturer of the equipment is available and within the specified range.
- For safety reasons verify that a proper switch is available to disconnect the equipment from mains when needed during installation
- To install and test the equipment with due diligence according to the installation instructions from the Manufacturer.

### 1.4 Notice to Users

It is the responsibility of the User:

- To use the system following the instructions and recommendations contained in the Operator’s Manual.
- To maintain the equipment in compliance by following the manufacturer’s recommended maintenance schedule as described



in the Service & Installation Manual.  
Failure of the user to properly maintain the equipment may relieve the Manufacturer, or his Agent, from responsibility for any injury, damage, or non-compliance which may result.

- To report promptly to the Health Authority in charge and to the Manufacturer or to its Agent any accident involving this medical device or any alteration in features and/or performances which could cause death, injuries or health hazard to Patient and/or Operator.  
Important information to be gathered and to be included in the report to the Manufacturer are the type and serial numbers of the involved items which can be retrieved from the technical labels.

### 1.5 Warning

X-ray equipment produces ionizing radiation that may be harmful if not properly controlled. It is therefore recommended that the equipment be operated by trained personnel only, in accordance with existing law.



Even if compliant to specifications of electromagnetic compatibility, it is recommended not to use the equipment in presence of external electromagnetic fields, such as those generated by cellular phones, which might interfere with the electronic circuits of the system.

## 1.6 Safety Issues

- Electrical.
  - Trained and qualified technicians only are authorized to remove covers and have access to power circuits.
  - Power supply lines must comply with safety legislation and have ground terminals for protective earth connection.
  - Switch the equipment off and possibly disconnect it from mains (room switch) before cleaning or disinfecting the unit.
  - Requirements for the hardware, like computers and other additional devices to be used for image acquisition, processing, and printing:
    - (a) it is recommended that such hardware be compliant with the requirements of the safety standard IEC EN 60601-1
    - (b) if not,
      - (b1) such hardware must stay outside the patient area, i.e. at an horizontal distance greater than 1.5 m from the patient or more than 2.5 m from the floor, when placed above the patient,
      - (b2) it is recommended that such hardware be compliant with the requirements of the standard IEC EN 60950
- Mechanical.
  - Make sure that fingers or other parts of the patient or of the operator are not pinched during the movement of the unit.
- Explosion.
  - The equipment cannot be used in presence of flammable gases or vapors.
- Radiation.
  - Trained and qualified personnel only are authorized to operate the equipment always complying with existing law for Radiation Protection.
  - Safety distance. The operator is invited to stay 3 meters from the column (in the designated significant zone of occupancy) or exit the room, always keeping an eye to the patient, ready to terminate the exposure in case of need.
  - Make sure that the equipment is not left unattended.
- Environmental.
  - The equipment contains components, which must be disposed-of following existing law.

## 2. GENERAL

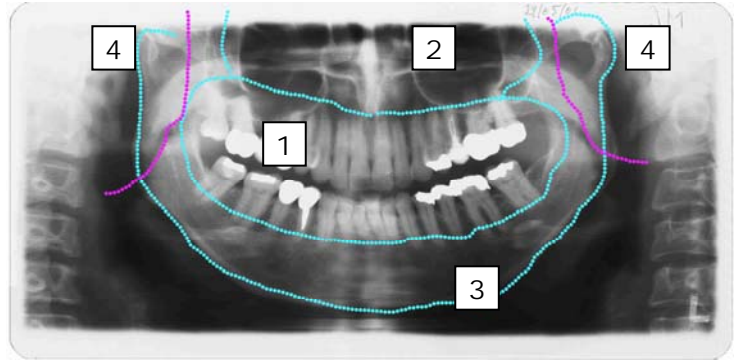
### 2.1 Indications for Use

The ART Plus digital imaging system is a diagnostic X-ray equipment to produce panoramic radiographs of the dento-maxillofacial area for diagnostic examination in any dental practice.

Panoramic imaging in dental X-ray is considered a routine procedure with which to perform a complete examination of the dental arch (1), of the maxillary (2) and mandibular (3) regions, and that of the TMJ (Temporo Mandibular Joints) (4).

Available panoramic examinations include:

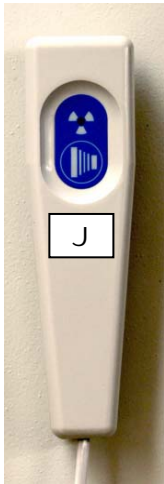
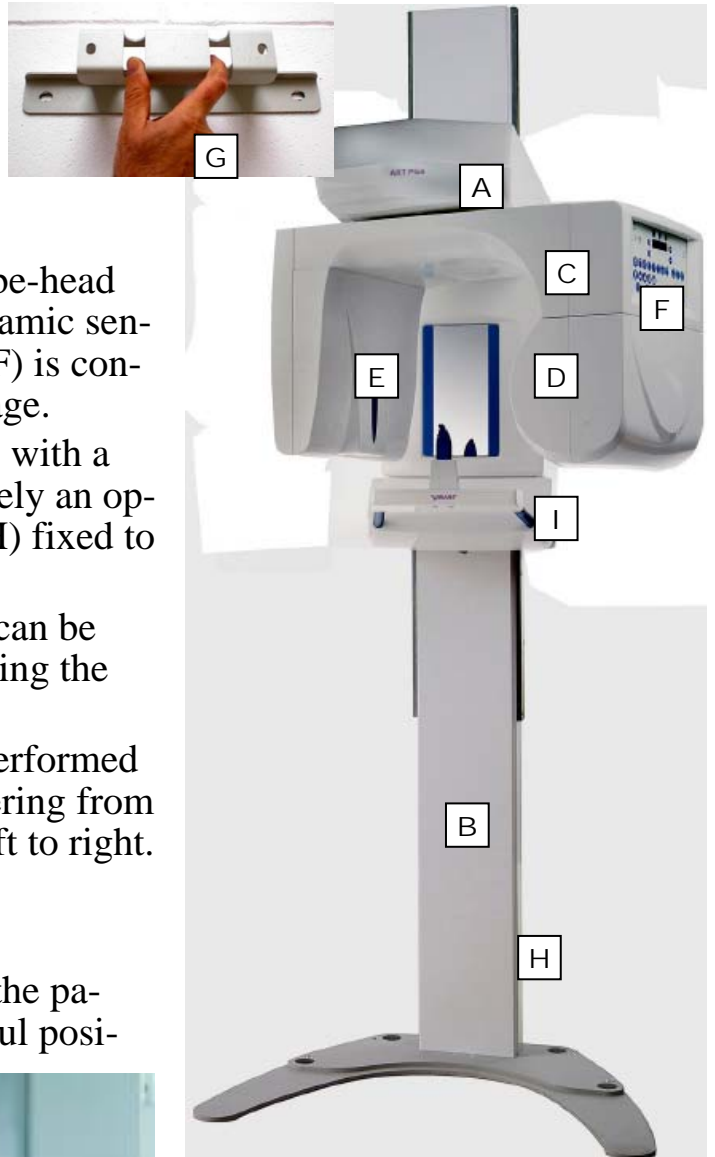
- panoramic for adults
- panoramic for children with reduced exposure,
- left side of dentition,
- right side of dentition
- anterior part of dentition
- TMJ, habitual occlusion and open at maximum extent.
- Anterior view of nasal (maxillary) sinuses





## 2.2 Theory of Operation

A vertical carriage (A), to which the power supply cord and the exposure hand-switch (J) are connected, can be moved vertically on the column (B).



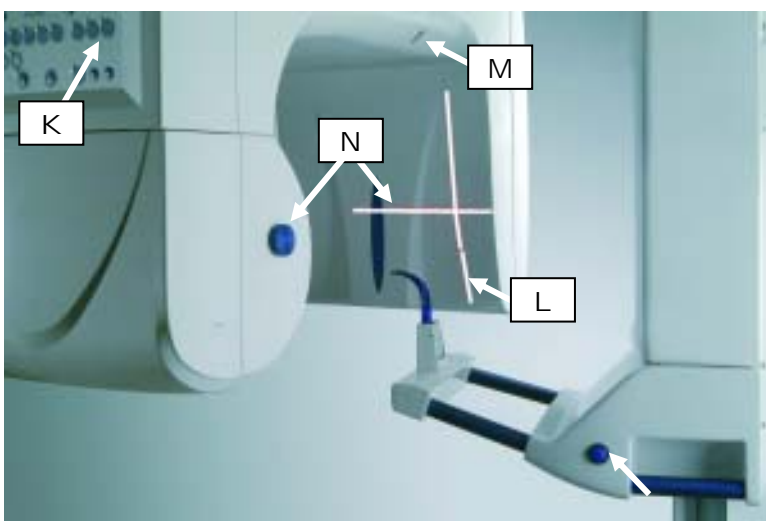
A rotating unit (C) with tube-head generator (D), digital panoramic sensor (E) and control panel (F) is connected to the vertical carriage.

The stand is fixed to a wall with a wall holder (G). Alternatively an optional self-standing base (H) fixed to the floor can be used.

The diagnostic equipment can be raised or lowered by releasing the electrical brake (I).

Panoramic picture of the dentition is performed by means of a narrow X-ray beam entering from the back of the patient and scanning left to right.

In order to make sure that the teeth of the patient fall into the “in focus layer” careful posi-

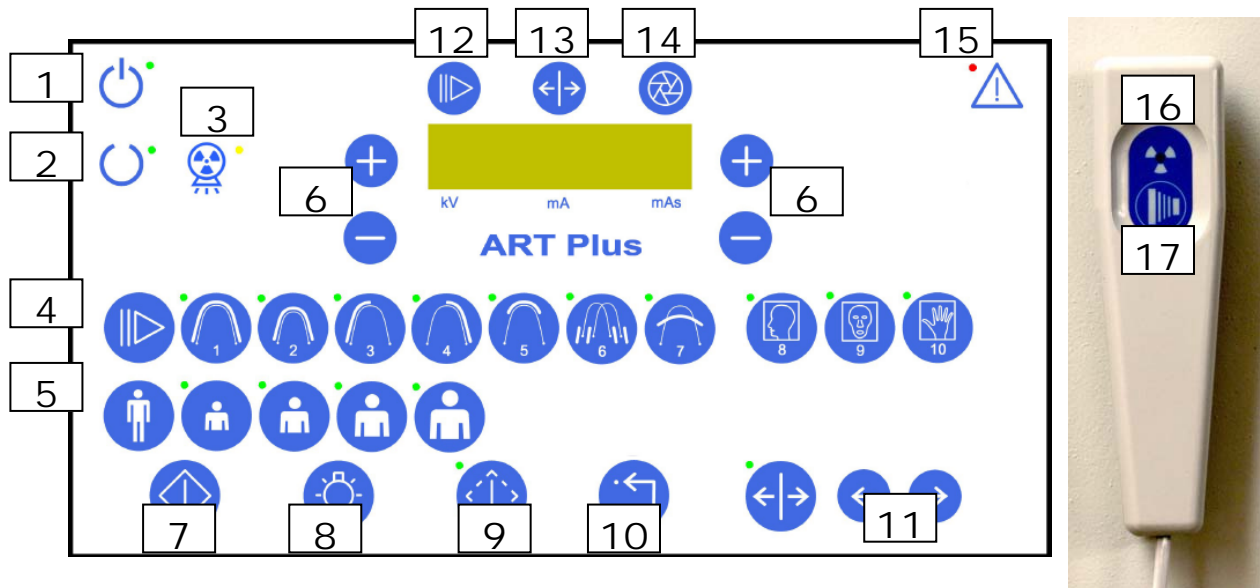





















tioning has to be done by properly shifting the rotating carriage either backward or forward as needed – using the displacement key (K) on control panel - with the help of the lateral light beam (L).

Midsagittal light (M) is available to check for side rotation of head.

Frankfurt plane can be adjusted (N) to verify backward or forward tilting of the head.


**2.3 Control panels**



1		Unit ON	10		Alarm Reset
2		Unit READY	11		Carriage shift left
3		X-ray indicator (ionizing radiation emission)	11		Carriage shift right
4		Program selection	12		Program selected 1 through 7 for Pan, 8 through 10 for Ceph
5		Patient size selection: small, medium, large, extra-large	13		Carriage displacement in mm
6	 	Increase/Decrease kV (left side) Increase/Decrease mA, mAs (right side)	14		Collimator selected (Not applicable)
7		Arm Sequential Movement	15		Alarm indication Error message on the display
8		Alignment lights 15 s	16		X-ray indicator (ionizing radiation emission)
9		TEST mode without radiation	17		Radiography push button


## 2.4 Functions

### A Switching Unit ON

Pressing the General Switch placed below the chin-rest, the unit is supplied and the green Led  turns ON.

Then the init function is started and after 30 s the message “DO RESET” appears.


### B Reset Function


By pressing the ARM MOVEMENT  key the rotation arm, and, in case, the cassette carriage, automatically locate the reference points and terminate in “PATIENT ENTRY” position (rotating carriage at 90°, with tube-head placed to the right of the patient, sensor to the left).




### C Panoramic Mode of Operation

The set of programs from 1 to 7 are available in panoramic mode and those from 8 to 10 for cephalometric mode are inhibited.



### D Examination Selection

By pressing key  of program selection the desired examination can be activated, with the relevant code reported on the display.

Patient size can be selected with the PATIENT key .

The applicable technique factors are thus selected. Should them be corrected manually, the plus  and minus  keys can be used to increase or decrease the proposed values. To step back to the automatically proposed values, the PATIENT key  can be pressed.

### E High Voltage Setting

In case the proposed value of kV level has to be corrected, it can be done with the plus  and minus  keys on the left side of the display.

The anodic voltage can be set from 61 to 85 kV in steps of 3 kV.

61	64	67	70	73	76	79	82	85
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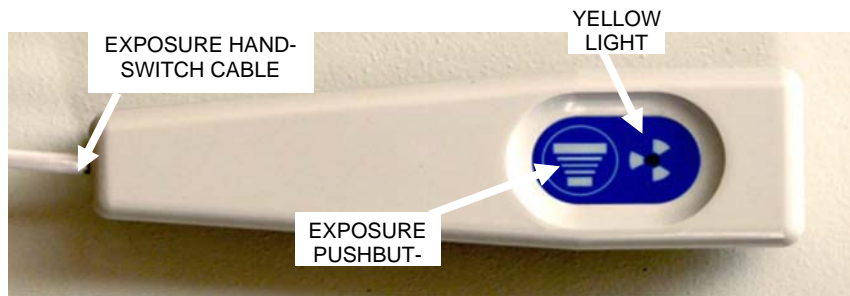
## F Anodic Current Setting

In case the proposed value of mA level has to be corrected, it can be done with the plus **+** and minus **-** keys on the right side of the display.

The anodic current can be set from 4 to 10 mA.


4.0	5.0	6.3	8.0	10
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## G Exposure control



The control unit takes care of both rotation and translation movements of the carriage together with X-ray generation during irradiation. A yellow light is emitted during irradiation and a sound buzzer is activated.

## H Error Handling

The ERROR number is shown on the display with the red light ON  (blinking).

To reset the error condition, the RETURN key  has to be pressed.


## 2.5 Panoramic Magnification Factor


The shown size of the teeth in the radiograph is different than actual size. The distance focus–sensor is of 513 mm, the one focus–object is of 404 mm. The magnification factor of panoramic radiography (MFpan) can be computed as follows:

$MF_{pan} = 513 / 404$  which is about 1.27, i.e. 27% magnification.


Magnification in panoramic is referred to the vertical size of incisor teeth.


## 2.6 Provisions for safety

Correct status of the unit and proper adjustment of movable parts are indicated by the READY light .

If system is not in the READY condition, press the ARM MOVEMENT key  to initialize the system.


After each exposure the unit enters a waiting period to cool down.

During the waiting time the READY indicator  blinks and exposures cannot be made. Count down register is displayed.

If a failure happens when system is switched ON or during exposure, the ERROR indicator  will light up.

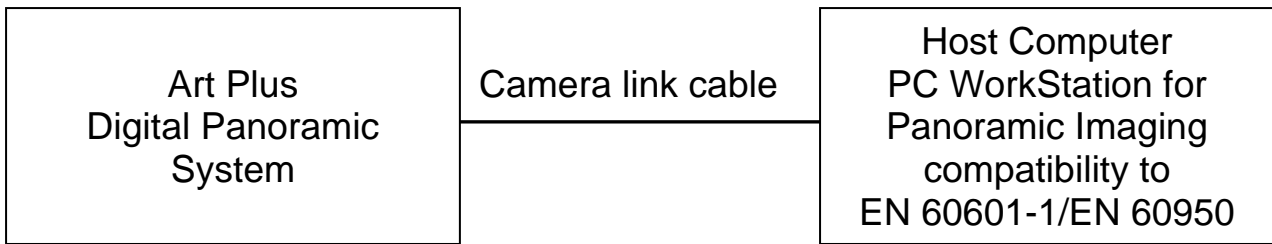
This indicator is also lit for incorrect operations (e.g. push-button released during exposure).

The number displayed represents the error code (see appendix A).

Press the ALARM RESET  key to acknowledge and cancel the error indication.

### **3. DIGITAL IMAGING**

#### **3.1 System Architecture**



The ART Plus radiographic system for panoramic radiology is connected to the PC Workstation through a camera link interface, made of a camera link cable and a frame grabber card PC2-Camlink on which the AJAT Panoramic Imaging application program is loaded.

#### **3.2 Computer Specifications**

The computer must fulfill the following requirements

- Safety standard: compatibility to EN 60601-1 or EN 60950
- CPU: SSE2 compatible processor with performance equal to or more than Intel Pentium 4 @ 3.2 GHz or Core 2 Duo 1.83 GHz
- Memory: 2 GB DDR-333 or higher
- Chipset: NVidia NForce or Intel chipset (VIA, SIS or ATI chipsets are not supported)
- Hard drive: 1 GB of free disk space for AJAT’s software.
- Operating system: Windows XP Professional with service pack 2 (Windows 2000 is not supported)
- PCI: One PCI 2.2 compatible 3v or 5v full height, half length, bus master capable slot
- Display adapter: AGP or PCI Express connection or integrated non-PCI connected. PCI display adapters are not supported unless approved by AJAT separately (high definition medical displays).
- Display (for AJAT’s application): Capable of resolution of at least 1024x768x16 bit
- Other software allowed simultaneously:
  - Basic Windows components. No virus scanners or software firewalls (not even Windows firewall) are allowed to be active.
  - The computer must not act as a network server or a server for any other purpose.

### 3.3 AJAT Panoramic Imaging

The application program is intended for image acquisition, processing and storage. Testing and servicing features are also included.

Refer to the AJAT Panoramic X-ray Imaging manual for detailed information on installation and use. The following functions are available

#### **A System Status (box)**

- Red and Green light for acquisition mode

#### **B Image Control (box)**

Histogram and grey level control

#### **C Tools (box)**

- Magnification
- Image move
- High light
- Focus
- Image process
- User image process
- Undo

#### **D Panoramic unit program (box)**

- Automatic
- New exposure

#### **E File (toolbar)**

- Open Image File
- Open dataset
- Reopen
- Save image as
- Save dataset as
- Save image as TWAIN
- Close image
- Close dataset

#### **F Patient (toolbar)**

- Show patient information

#### **G View (toolbar)**

- Show mean frame signal level
- Diagnostics
- Data repository
- Show overview image
- Show temperature plot

#### **H Tools (toolbar)**

- Settings: General, Panoramic unit, TWAIN, Image, Files and saving, Advanced
- Mechanical alignment
- Calibrate
- Apply auto-levelling
- Send error report
- Data set tools

#### **I Windows (toolbar)**








- Tile horizontally
- Tile vertically
- Tile square
- Cascade
- Dataset image

#### **J Help (on toolbar)**



- About. Provides version of running application.

## 4. PANORAMIC RADIOLOGY

### 4.1 Panoramic Programs

Icon	Program	Exposure time
	Standard Adult	15 s
	Child	13 s
	Half Panoramic Left	8 s
	Half panoramic Right	8 s
	Frontal Dentition	7 s
	TMJ Projections	4 x 2.5 s
	Maxillary Sinus	13 s

### 4.2 Trial Session

- A trial session without irradiation can be started by pressing the TEST key  push-button (9).
- By pressing the exposure hand-switch under the TEST condition the unit performs normally, but X-rays are not generated.
- To exit the TEST mode press again the TEST  key.
- After the execution of a trial exposure without radiation, the rotating carriage moves to the “patient entry” position, and automatically exits from the “test mode” condition.



### 4.3 Technique Factors

Default values are reported in the tables below for film-screen combination of speed 400. The proposed technique factors can be manually changed according need.

- Increase of technique factors lead to darker radiographs.
- Decrease of technique factors lead to lighter radiographs.

Technique Factors		Patient Size		
Anodic Voltage (kV)	Anodic Current (mA)	Child Panoramic	Adult Panoramic & partial views	Adult TMJ & Sinus
61	6.3	Small		
64	6.3	Medium		
67	6.3	Large		
70	6.3	Extra large	Small	Small
73	6.3		Medium	Medium
76	6.3		Large	Large
79	6.3		Extra large	Extra large
82	6.3			
85	6.3			

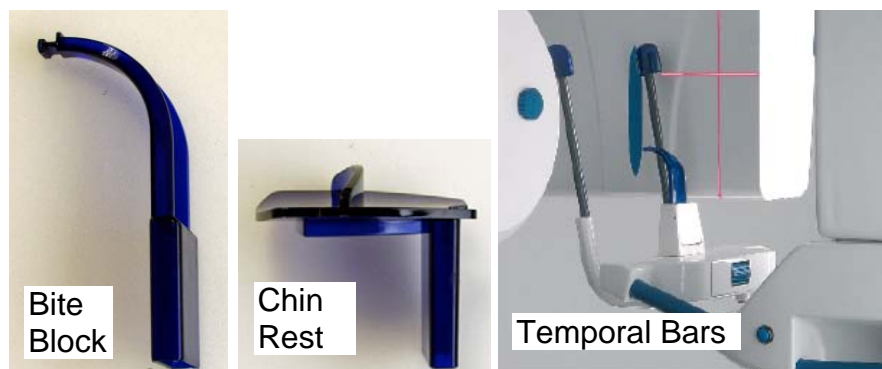
Values of kV and mA are automatically set and indicated on the display upon selection of type of examination and patient size. In case a change is needed the relevant parameter can be corrected on the control panel.

The kV level is related to penetration of X-ray, i.e. the ability to go through the anatomical structures and build the image information: the bigger the patient the higher the kV level has to be.

### 4.4 Positioning Accessories

A bite block and a chin rest for edentulous patients are available as positioning devices.

Temporal resting bars can be added as an option.



## 4.5 The Aiming Lights

The unit is equipped with a set of LASER lights for the three alignment planes:

- Median Sagittal. It divides the head of the patient in left and right side. Check to be done for the light beam to fall in the middle of the face.
- Frankfurt Horizontal Plane. This beam source can be moved up and down to align just above the ear hole and allow the operator to check for correct orientation of the head (forward or backward tilting of the head).
- Lateral Vertical Plane. It defines the center of the focal trough for the frontal teeth (incisors), i.e. the correct position of the carriage (backward or forward displacement of the rotating carriage) to have the teeth structures falling into the focal trough.



The laser light beams are activated with ALIGNMENT LIGHTS  key on the control panel and stay on for 15 s.



The laser aiming system is a Class I laser product.

Avoid during patient positioning unnecessary exposure of the eyes of the patient or of the operator to the laser radiation.

Also pay attention that the laser beams are not intercepted by any optical device.



## 4.6 Resetting Carriage in Patient Entry Position

- The carriage is in PATIENT ENTRY position when the tube housing assembly is on the right. The laser lights can be switched on and the alignment of patient performed. In case of different position:
  - push briefly the X-ray pushbutton or the ARM MOVEMENT  key on the control panel to rotate forward
  - keep pressed briefly the RETURN  key until it starts for backward rotation, from the READY position to PATIENT ENTRY position.

## 4.7 Patient Positioning

- Remove from the patient any metal item such as provisional denture, earrings, necklaces, which might cause ghost images on the radiograph (side picture).



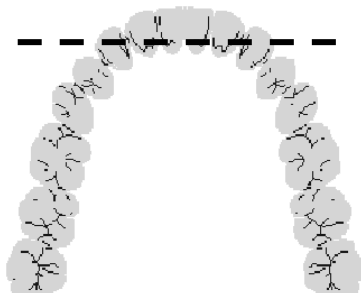
- In case a protective apron is used leave the neck free not to interfere with the X-ray beam (radiation enters from sides and from back).
- With the carriage in “entry” position, place the patient facing the mirror and make sure he is holding firmly the handles.
- The patient must stay with lowered shoulders with advanced feet (almost close to the column) to stretch the spine at cervical level for a better beam penetration.

- Start with the unit slightly higher. Ask the patient to tilt the head backward and bite the reference block. Then press the brake pushbutton to release the carriage and lower the unit at the same time asking the patient to tilt the head forward following the lowering of the carriage. Stop when the Frankfurt plane is horizontal, then lock the carriage by releasing the brake push-button.



Same procedure in case the chin rest is used.



- Use the angled mirror to see the face of the patient and correct any side rotation of the head.
- Ask patient to open the lips and teeth are visible. By biting the thin block, mouth is closed and teeth are not superimposed. Use of cotton roll allows for same condition in case the chin rest is used instead.



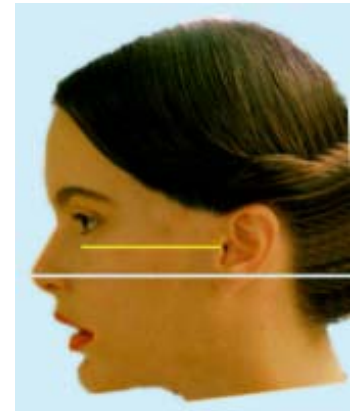
- Switch the positioning lights ON to properly locate the in-focus layer on frontal teeth by

pressing the ALIGNMENT LIGHTS  key.

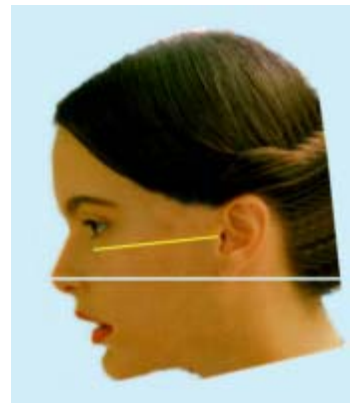
- Correction of the side position of the carriage is not required for patients with normal occlusion
- In case of patient with overjet for class II or class III malocclusion, using the the relevant

displacement key  left or  right, the rotating carriage is shifted forward or backward until the lateral light beam falls over the canine (the corresponding shift in mm is displayed). In this position the roots of the frontal teeth are positioned into the in-focus layer.

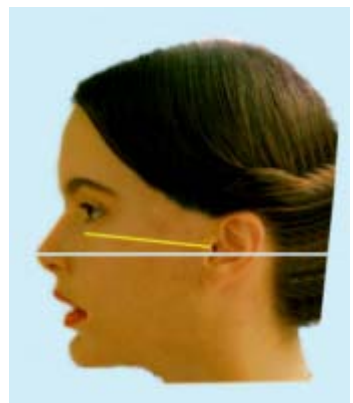
- Ask the patient to swallow and keep the tongue lightly pressed to the palate, then recommend to stay calm and firm, avoiding movements, till the end of the exposure.



a) Correct position, Frankfurt plane is horizontal

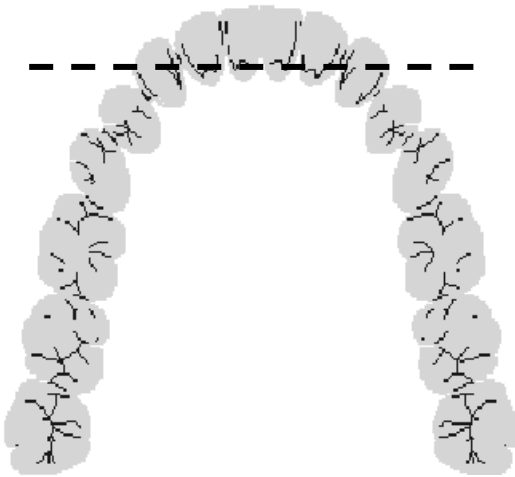


b) Wrong position, head tilted forward, V shaped dental arch



c) Wrong position; head tilted backward, flat dental arch

## 4.8 Adjustment of displayed layer

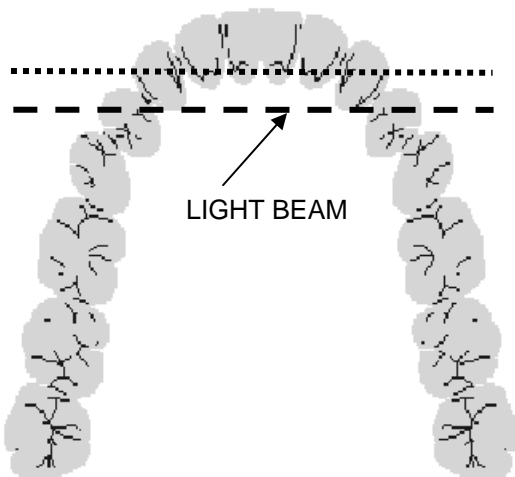


- Focal trough set correctly

The light beam is lined up on the canine.

The roots of the incisors are exactly in the center of the focal trough.

Front teeth are displayed sharply.

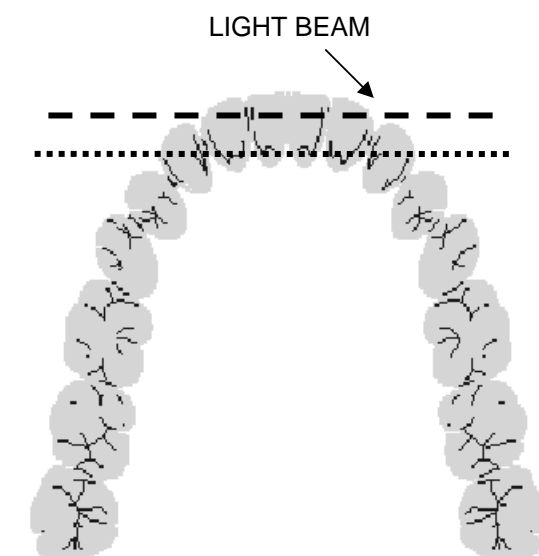


- The light beam (dash line) is posterior to the canine (dotted line).

The roots of the incisors fall outside the focal trough.

The front teeth appear blurred and proportionally narrower (reduction).

Move the carriage forward (towards the column) to correct.



- The light beam (dash line) is anterior to the canine (dotted line).

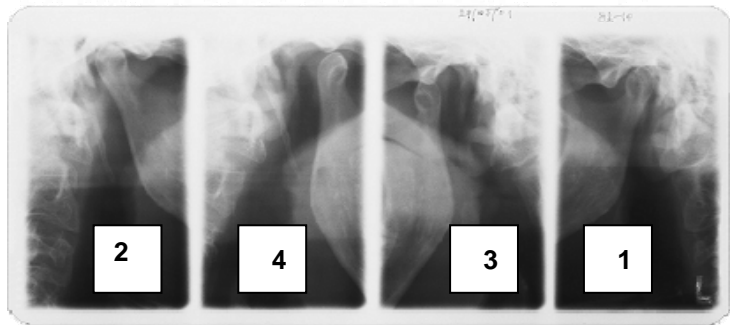
The roots of the incisors fall outside the focal trough.

The front teeth appear blurred and proportionally wider (magnification).

Move the carriage backward (away from the column) to correct.

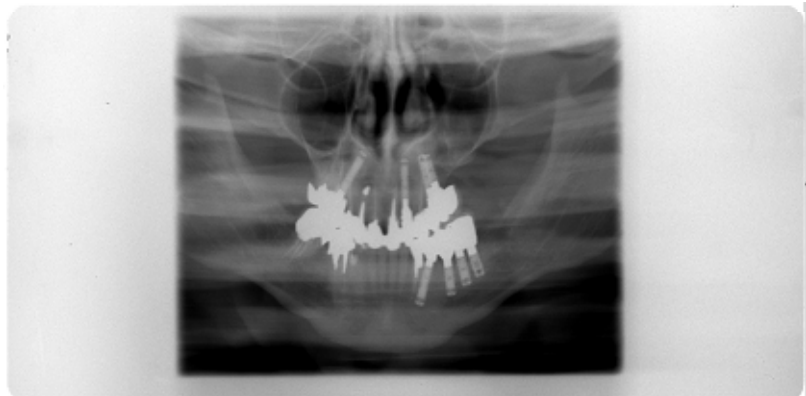
## 4.9 TMJ projections

- Two exposures are usually taken with closed and open mouth.
- Patient is positioned with bite block under the nose.
- The lateral light is set on canine as for standard panoramic.
- Once taken the first set of two images, return the unit.
- A set of two exposures open mouth can be taken immediately.







## 4.10 Maxillary Sinuses

- Patient is positioned using chin rest.
- The lateral light is set on canine as for standard panoramic.



## 4.11 Panoramic Exposure

- Activate on computer the AJAT Panoramic Imaging application and make sure the Green Light on System Status Box is turned ON.
- The READY light  on the control panel has to be ON too.
- The operator is invited to stay behind the patient, three meters from the column, always keeping an eye to the patient, ready to terminate the exposure in case of need, at any time.
- Press the exposure hand-switch and hold it down during the whole cycle until the acoustical and optical alarms are terminated and the rotating carriage and the cassette holder stop.
- Press the hand switch or the ARM MOVEMENT  key. The rotating unit performs the first part of return function to make it easier for the patient to exit.
- Press the hand switch or the ARM MOVEMENT  key to return to the initial position for patient entry.  
Last used data are stored and appear on the display: Program number, patient size, carriage shift, used collimator, kV level, mA value.
- Press the hand switch to have the rotating arm moving to the START position.  
In case the patient is not properly positioned, the rotating arm can be brought to the PATIENT ENTRY position by pressing for few second the ALARM RESET  key.
- Error messages to be handled by the operator:
  - 11 - Exposure Aborted During Irradiation.
  - 12 - Exposure Aborted Before Irradiation.
  - 20 - Exposure aborted after irradiation.
  - 29 - Data Acquisition System Not Ready. The AJAT Panoramic Imaging program on computer has to be started first to make sure data acquisition will be performed during radiographic exposure.

## 5. MAINTENANCE

### 5.1 Cleaning

Switch the equipment off and possibly disconnect it from mains (room switch) before cleaning or disinfecting the unit.

Use a mild soap to remove finger or other dirty marks paying attention not to have liquid substances enter into the equipment.

Plastic covers can be wiped with a soft cloth and light detergent.

### 5.2 Disinfecting

Parts which can come in touch with the patient must be cleaned with a detergent (such as 2% solution of ammonia) and then disinfected making sure solvents or corrosive disinfectants are NOT used.

The bite block can be sterilized at 121°C.

### 5.3 Servicing

It is the responsibility of the User to maintain the equipment in compliance with the standard. Failure of the User to properly maintain the equipment may relieve the Manufacturer, or its Agent, from responsibility for any injury, damage or non compliance which may result.

Any defect or malfunction should be corrected immediately by qualified personnel with adequate training.

To be performed regularly:

- Cleaning and disinfecting of the parts in touch of the patient.
- Checking the condition of the cables for the vertical movement of the carriage. If even only one wire of the strands of the steel rope is broken, the steel rope must be replaced immediately.

**WARNING.** Any defective item affecting a safe use must be repaired or replaced. Maintenance to the equipment must be performed **at least once a year** by qualified personnel.



The following actions to be done:

- Complete check of system performance (kV, mA, mAs, s)
- Check for proper working condition of all mechanical and electrical safety features.
- Lubrication of accessible parts. Specific lubrication of movable parts has to be done by Technical Service at least every two years.



## 5.4 Disposing of Obsolete Equipment

A radiological system is made of different materials which include many kinds of metals (iron, aluminum, lead, copper and others), plastic materials, electronic components and dielectric oil in the tank of the X-ray tube.



The "crossed-out wheeled bin" symbol on the product indicates that the product at the end of its useful life must not be disposed of as unsorted municipal waste but has to be collected separately and delivered to specialized operators for recycling or disposal of waste of electrical and electronic equipment (WEEE), in compliance with existing laws.

By doing in this way possible negative effects on human health and environment are prevented, and recycling of the component materials is promoted. Penalties are applicable to illicit disposal.

Oy AJAT Ltd and its local Dealers commit to fulfill obligations related to the management of WEEE of professional nature, according to the provisions of the European directives 2002/96/EC and 2003/108/EC.

## 6. CLASSIFICATION

- IEC: ART Plus is a Class I, type B equipment
- IEC: ART Plus includes Class I lasers as aiming lights for patient positioning (IEC 60825-1).

















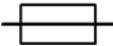


























ART Plus complies with the following standards.

IEC 601-1	General requirements for safety
IEC 601-1-2	Electromagnetic compatibility
IEC 601-1-3	General requirements for radiation protection in diagnostic X-ray equipment
IEC 601-2-7	Particular requirements for the safety of high voltage generators of diagnostic X-ray generators
IEC 601-2-28	Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
21CFR1020.30	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic X-ray Systems and their major Components
21CFR1020.31	Performance Standards for Ionizing Radiation Emitting Products: Radiographic Equipment
21CFR1040.10	Performance Standard for Light Emitting Products: Laser products
IEC 60825-1	Safety of laser products. Part 1: Equipment classification, requirements and user’s guide

## Appendix A Error Messages

Num	Description
1	kV reference signal out of range
2	mA reference signal out of range
3	Carriage rotation encoder failure
4	Carriage displacement encoder failure
5	Carriage rotation sensor failure
6	Carriage displacement sensor failure
7	Cassette displacement sensor failure
11	Exposure aborted during irradiation
12	Exposure aborted before irradiation
13	38 V DC supply out of range
14	24 V DC supply out of range
15	15 V DC supply out of range
16	5 V DC supply out of range
17	High voltage failure
19	Exposure time exceeded
20	Exposure aborted after irradiation
21	No tube current
23	Filament current out of range
25	Carriage rotation motor over-current
26	Carriage displacement motor over-current
27	Cassette displacement motor over-current
29	Data Acquisition system not ready
32	Control unit fault

## Appendix B Icons

	IEC Type B Equipment		Compliance to European Community Requirements		See the Annexed Documentation
	The unit is ON		The unit is READY		X-ray indicator (ionizing radiation emission)
	Radiation Emission Light		Radiography Push Button		
	Program selection panoramic and cephalometric		Program selected 1 through 7 for Pan, 8 through 10 for Ceph		OFF (disconnected from mains supply)
	Patient size selection: small, medium, large extralarge		Standard panoramic		ON (connected to mains supply)
	Increase parameter kV level mA or mAs level		Child Panoramic		Fuse
	Decrease parameter kV level mA or mAs level		Half Panoramic Left		Alternate Current
	Carriage shift right for patient positioning		Half Panoramic Right		Protective Earth
	Carriage shift left for patient positioning		Anterior Dentition		Inherent Filtration
	Entity of carriage displacement in mm		TMJ Open and Closed Mouth		Dispose properly Do not abandon in the environment
	Type of collimator selected (Pan, Child, AP, LLA, LLB, APXL)		Maxillary Sinus		Fragile, Handle With Care
	Arm Sequential Movement		Ceph Latero Lateral		Fear of Humidity
	Patient alignment laser beams (15 s ON)		Ceph Antero Posterior		Up, Do Not Overturn
	Test mode without radiation emission		Wrist		Stacking Limit Number
	Alarm Reset		Size Adult/Child: small, medium, large extralarge		

## **Appendix C Technical Data**

### **EXTRAORAL RADIOGRAPHIC SYSTEM**

IEC Classification: Class I, type B

Power Supply: 230 V  $\pm$  10%, 50/60 Hz, 8 A, slow fuse  
115 V  $\pm$  10%, 50/60 Hz, 16 A, slow fuse

Mains Resistance: < 2 ohm at 230 V, < 1 ohm at 115 V

X-ray generator: Multipulse at 40/80 kHz

Anode Voltage: 61 - 85 kV  $\pm$  10%, constant potential

Anode Current: 4 - 10 mA  $\pm$  10%, direct current (DC)

Focus size: 0.5 IEC 336

Inherent Filtration > 2.5 mm Al @ 85 kV

Leakage Radiation < 50 mR/h (0.43 mGy/h) @ 100 cm, 85 kV, 10 mA

Column Height 220 cm/87"

Displacement 86 cm/34", from 90 to 176 cm (35 to 69")

Vertical Movement Manual adjustment with electrical brake

Patient Positioning Motorized displacement

Centering Light 3 lasers: Lateral, Median sagittal, Frankfurt

Centering Reference Bite block and chin rest for edentulous, tunable  
temporal resting bars (option)

Source Image Distance Pan 51.3 cm/20.2"

Vertical Magnification Pan 27%

Panoramic Projections: Adult standard with constant vertical magnification  
on dental arch (15 s), Child at reduced dose (13 s),  
Half Dentition Left (8 s), Half Dentition Right (8 s),  
Anterior Teeth (7 s), TMJ habitual occlusion and  
opened at maximum extent (4 x 2.5 s), Frontal View  
of Maxillary Sinuses (13 s)

Cooling pause: Automatically controlled, 7 min maximum

Weight: 220 kg/485 lb

### **DIGITAL SENSORS**

Sensor Area 145 mm x 5.6 mm

Pixel Size 100 microm x 100 microm

Detector Material 0.75 mm thick CdTe

Image Size Pan 15x30 cm, 2800 x 1400 pixels

A/D Conversion 12 bits @ 3ms integration (300 frames/s)

Frame Grabber CameraLink PC2 CamLink

### **LASER LIGHTS**

FDA Classification Class I

Wavelength 650 nm

Output Power < 0.12 mW  $\pm$  10% @ 100 mm

## Appendix D Labels

**ART Plus**  
PANORAMIC DENTAL  
DIGITAL X-RAY SYSTEM

Oy AJAT Ltd Tietotie 3  
FIN-02150 ESPOO FINLAND

CERTIFICATION Product complies with radiation performance standards under the Federal Food, Drug, and Cosmetic act.

PN 8468007000  
Serial Number 2406AJ0001  
Manufactured December 2007

Input Voltage Requirements  
Maximum Momentary Rating  
16 A @ 115 V ~ 50/60 Hz  
8 A @ 230 V ~ 50/60 Hz

CE 0051

MANUFACTURED BY BLUE X IMAGING SRL  
VIA IDIOMI 1/8-33 20090 ASSAGO ITALY

**ART Plus**  
PANORAMIC DENTAL  
DIGITAL X-RAY SYSTEM

Oy AJAT Ltd Tietotie 3  
FIN-02150 ESPOO FINLAND

**WARNING**  
THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS ARE OBSERVED

Input Line 50/60 Hz  
Voltage Fuse

<input type="checkbox"/> ~ 115 V	<input type="checkbox"/> T16A
<input type="checkbox"/> ~ 230 V	<input type="checkbox"/> T8A

BLUE X IMAGING SRL  
VIA IDIOMI 1/8-33  
20090 ASSAGO ITALY

**HIGH VOLTAGE GENERATOR  
TUBE HOUSING ASSEMBLY**

PN 78 680 00500  
Serial Number 2312KY0001  
Manufactured December 2007

Output 85 kV 10 mA  
Focal Spot 0.5 IEC 336  
Insert OPX/105  
Inherent filtration ≥2.5 Al/86

CERTIFICATION Product complies with radiation performance standards under the Federal Food, Drug, and Cosmetic act.

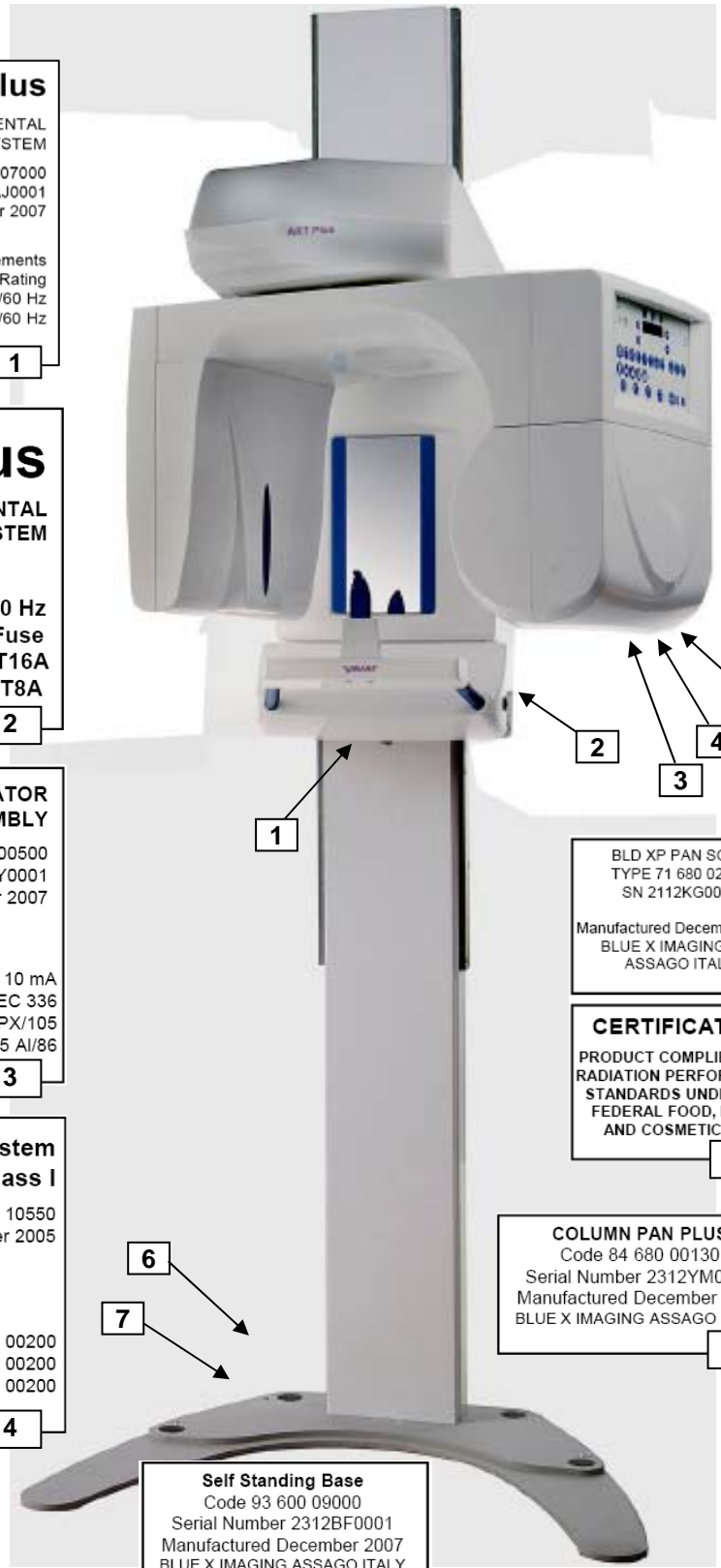
BLUE X IMAGING SRL  
20090 ASAGO ITALY  
MANUFACTURED FOR  
OY AJAT LTD TIETOTIE 3  
FIN-02150 ESPOO FINLAND

**Alignment System  
Laser FDA Class I**

Code 86 680 10550  
Manufactured December 2005

COMPLIES WITH FDA PERFORMANCE STANDARDS FOR LASER PRODUCTS CODE OF FEDERAL REGULATIONS CHAPTER 21 PARTS 1040.10 AND 1040.11

Lateral Source PN 42 680 00200  
Median Source PN 42 680 00200  
FrankfurtLSource PN 42 680 00200



BLD XP PAN SOLO  
TYPE 71 680 02200  
SN 2112KG0001

Manufactured December 2005  
BLUE X IMAGING SRL  
ASSAGO ITALY

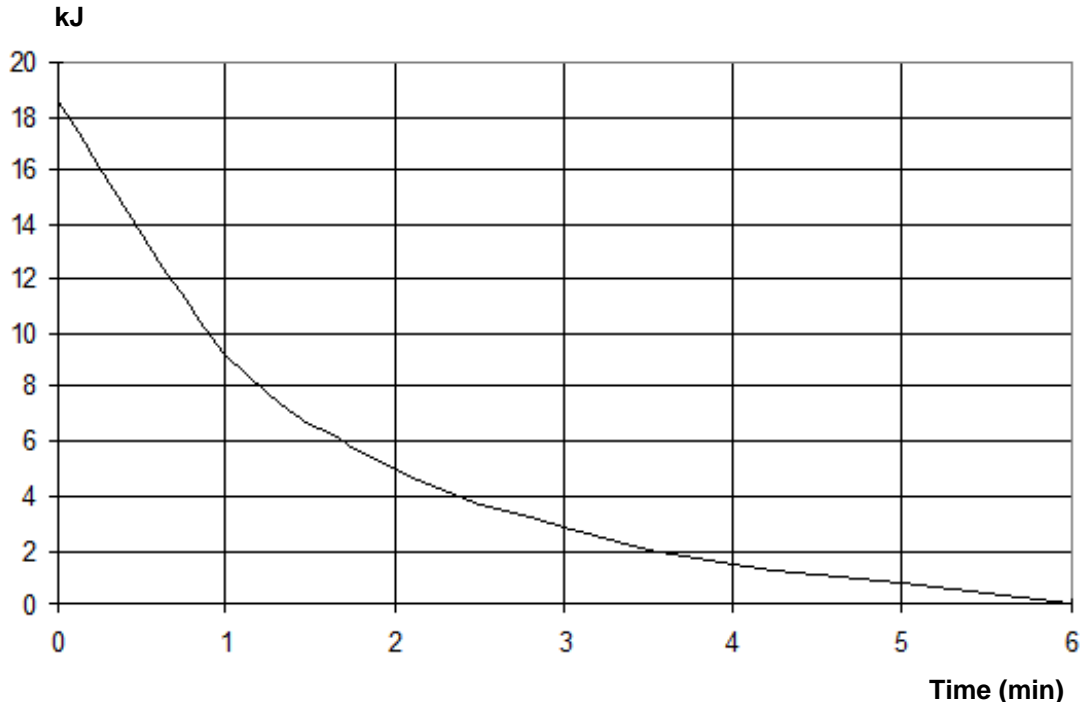
**CERTIFICATION**  
PRODUCT COMPLIES WITH RADIATION PERFORMANCE STANDARDS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

**COLUMN PAN PLUS**  
Code 84 680 00130  
Serial Number 2312YM0001  
Manufactured December 2007  
BLUE X IMAGING ASSAGO ITALY

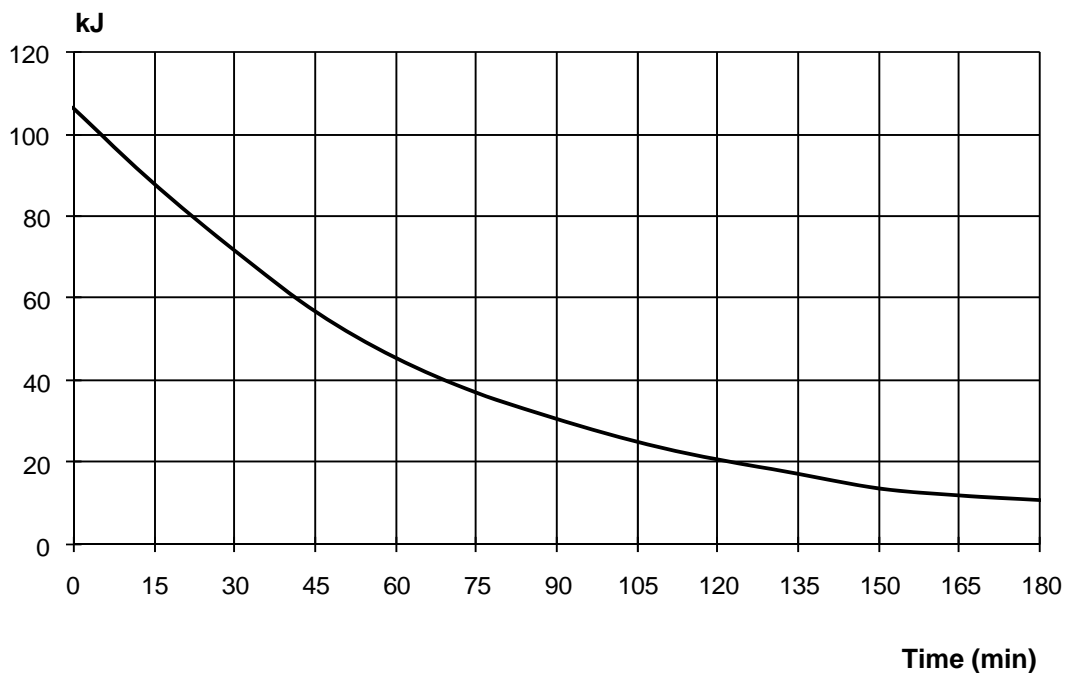
**Self Standing Base**  
Code 93 600 09000  
Serial Number 2312BF0001  
Manufactured December 2007  
BLUE X IMAGING ASSAGO ITALY

## Appendix E Cooling Curves

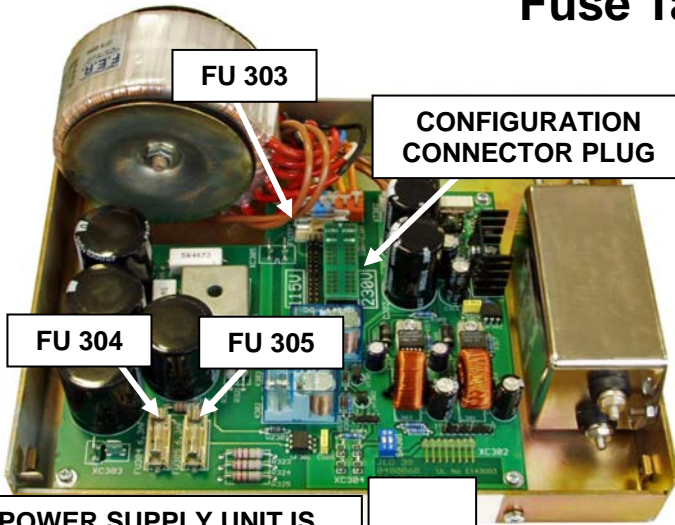
**COOLING CURVE OF X-RAY TUBE**



**COOLING CURVE OF TUBE HOUSING ASSEMBLY**



## Appendix F Fuse Table



	230 V	115 V
F 501	T 8 A 5x20	T 16 A 6.3x32
FU 303	T 1.6 A 5x20	T 3.15 A 5x20
FU 304	F 6.3 A 5x20	F 6.3 A 5x20
FU 305	F 6.3 A 5x20	F 6.3 A 5x20

POWER SUPPLY UNIT IS AT TOP OF VERTICAL CARRIAGE

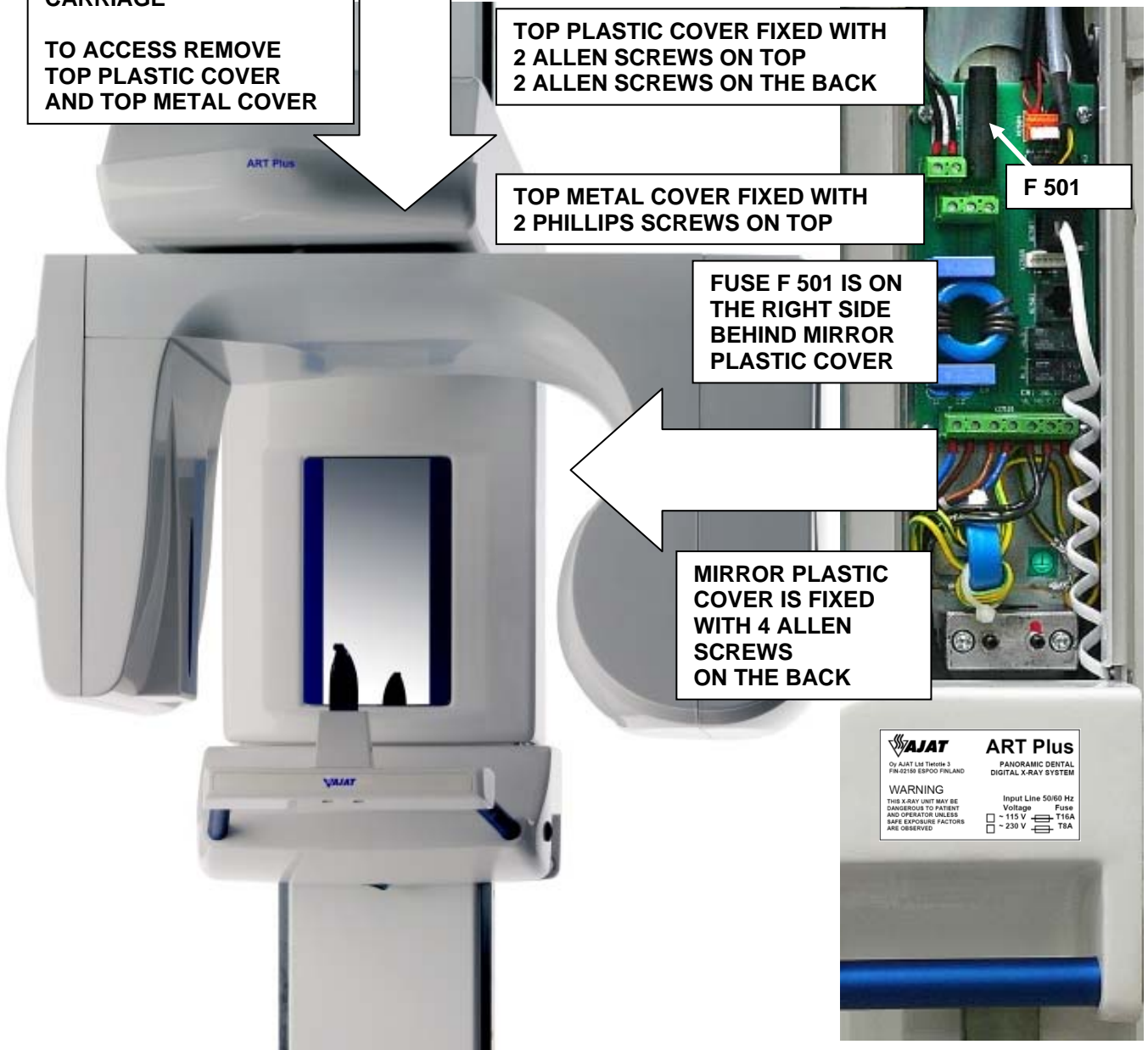
TO ACCESS REMOVE TOP PLASTIC COVER AND TOP METAL COVER

TOP PLASTIC COVER FIXED WITH 2 ALLEN SCREWS ON TOP  
2 ALLEN SCREWS ON THE BACK

TOP METAL COVER FIXED WITH 2 PHILLIPS SCREWS ON TOP

FUSE F 501 IS ON THE RIGHT SIDE BEHIND MIRROR PLASTIC COVER

MIRROR PLASTIC COVER IS FIXED WITH 4 ALLEN SCREWS ON THE BACK



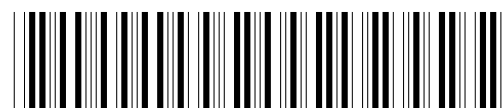
**AJAT**  
OY AJAT LHM TIEHIN-3  
FIN-02160 ESPOO FINLAND

**WARNING**  
THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS ARE OBSERVED

**ART Plus**  
PANORAMIC DENTAL  
DIGITAL X-RAY SYSTEM

Input Line 50/60 Hz  
Voltage Fuse  
~ 115 V T16A  
~ 230 V T8A

**ART Plus**  
Dental Panoramic X-Ray  
Operator's Manual  
English Edition  
Version 2.0



\* 6 9 6 8 0 2 0 1 1 0 \*