

# KaVo 3D eXam<sup>®</sup>

## Operators' Manual



Cone Beam Volumetric Tomography and  
Panoramic Dental Imaging System



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# *What's New in this Release*

<b>Change Description</b>	<b>Link to Topic</b>
Quality Control Frames added to help access quality of captured scan. First and last frames of a scan can be compared to determine if patient moved during the scan.	<a href="#">Using Quality Control Frames on page 7-3</a>
<b>Study Date</b> drop-down added to enable filtering by study dates.	<a href="#">Patient Information on page 5-1</a>
Two new options, <b>Reset Window/Level</b> and <b>Reset All Window/Levels</b> , added to reset brightness and contrast to original settings if they were changed.	<a href="#">Adjusting Brightness and Contrast on page 7-9</a>
Filter setting <b>Smooth</b> removed. New filter setting <b>Sharpen Mild</b> added.	<a href="#">Filter Settings on page 7-11</a>
Preview frames can be viewed for raw patient images.	<a href="#">Viewing and Reconstructing Raw Patient Scans on page 7-23</a>
<b>Level Up</b> menu option changed to <b>Screen</b> option. Screen option enables selection of any detail screen without having to access the Preview screen.	<a href="#">Preview Screen on page 8-1</a>
3D Model view added to the Implant Planning screen.	<a href="#">To Use the 3D Model View on page 8-6</a>
New feature added to enable marking of estimated nerve canal for left, right, or both canals.	<a href="#">Estimate the Nerve Canal on page 8-7</a>



Change Description	Link to Topic
Gridlines added to MPR screen.	<a href="#">MPR Screen on page 8-14</a>
Scroll wheel on mouse is activated to enable scrolling through slices on Implant Planning and MPR screens.	<a href="#">Implant Planning Screen on page 8-2</a> <a href="#">MPR Screen on page 8-14</a>
<b>Use Lossy Compression</b> option added to DICOM Export Properties and CD Burner Speed dialogs. This compression type can be used when exporting patient data across a network or when creating a CD.	<a href="#">Export DICOM on page 9-2</a> <a href="#">Create CD on page 9-3</a>
Networking support feature added to facilitate customer setup of networked VisionQ and Vision computers.	<a href="#">Networking Support Setup on page 14-1</a>
New features added to: 1) enable import of patient data from a DICOM worklist or Patient Management system, and 2) enable export of DICOM images to a remote system such as a Picture Archive and Communications System.	<a href="#">Remote System Import and Export on page 15-1</a>
Keyboard shortcuts added to access top-level menu items from the keyboard.	<a href="#">Keyboard Shortcuts on page C-2</a>
Calibration separated from VisionQ application and is accessed from Calibration icon on the desktop.	<a href="#">Calibration on page 10-1</a>



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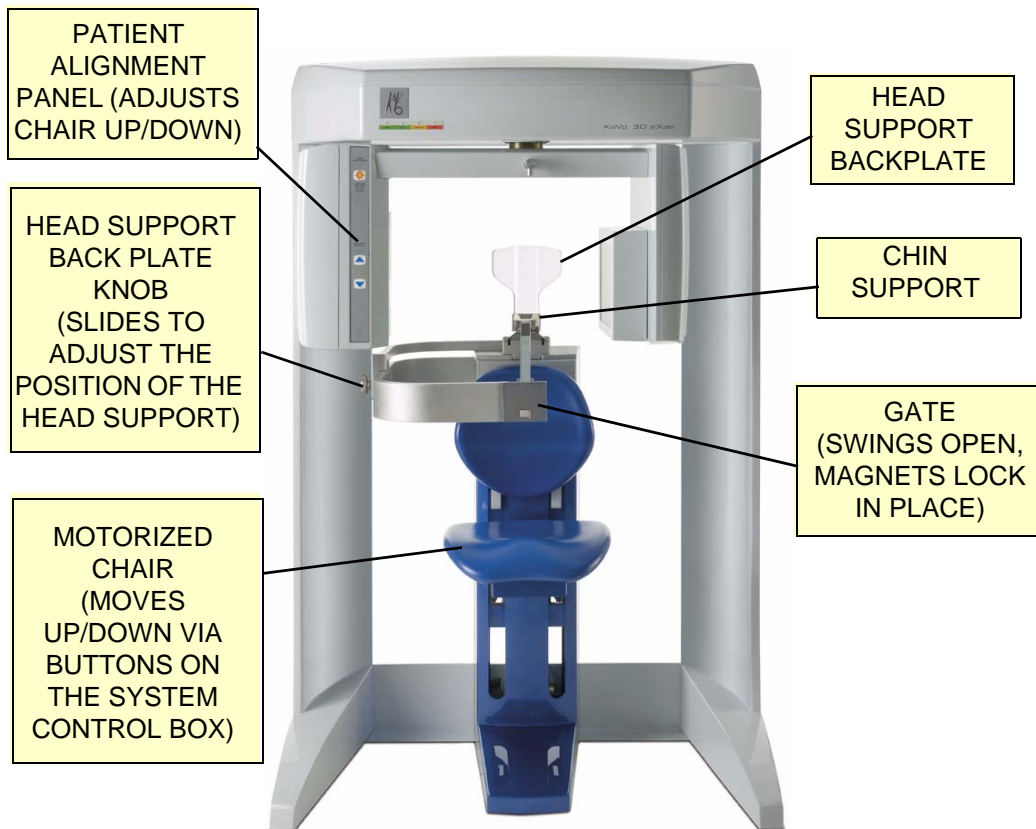


# Chapter **1** Introduction

## System Description

The system is a Cone Beam Volumetric Tomography and Panoramic X-ray device used for dental head and neck applications. The system consists of a Scanner and Computer Workstation which is suitable for an in-office environment.

This scanning device is an open design that allows Patients to sit upright during a procedure. An electric powered seat is built into the device for proper Patient positioning.



**KaVo 3D eXa<sup>®</sup> Imaging System**



The system consists of a Scanner and Computer Workstation. In order for the system to operate, both the Scanner and Computer Workstation must be turned ON.

The system captures data for 3D Skull Reconstruction for the following procedures:

- Implants
- TM Joints
- Reconstructed Panoramic
- Reconstructed Cephalometrics
- Airway / Sinus, etc.
- Nerve Canal
- PAN - Optional Conventional Digital Panoramic Feature

Cone Beam Volumetric Tomography is a medical imaging technique that uses X-rays to obtain cross-sectional images of the head or neck. Quality of the images depends on the level and amount of X-ray energy delivered to the tissue. Imaging displays both high-density tissue, such as bone, and soft tissue. When interpreted by a trained Physician, these images provide useful diagnostic information.

## ***Major System Items***

The system is comprised of the following major items:

- Scanner
- Computer Workstation
- Operator Control Box with 50 ft. (15.2m) Cable
- Patient Emergency Stop Box with 10 ft. (3m) Cable
- Interlock Jumper Cable, 8 inch (20cm)
- Interlock Cable 50 ft. (15.2m)
- Warning Light Cable 50 ft. (15.2m)
- Chair Connection Cable, 10 ft. (3m)
- Power Cable, 15 ft.(4.6m)
- CAT 5 Ethernet Cable, 50 ft. (15.2m)



## *About the Operators' Manual*

This documentation describes the safe and effective operation of the system. The information is intended to provide trained Technologists and Physicians the necessary guidance to operate the system in a safe and effective manner.

### *Conventions Used in the User Manual*

- Keyboard keys are represented in a **Bold** font.  
For example, “Press **Start**.”
- Menu items and button names on the user interface display are represented in a **Bold** font.  
For example, “At the Print window, click the **Print** button.”
- Keyboard entries are represented in **bold Courier font**.  
For example, “Type **QA Test** in the filename box.”



## *Standard Limited Warranty*

KaVo warrants the original purchaser that this hardware system will be free from defects for a period of one (1) year from the date of delivery. During the warranty period, KaVo will correct any defects in material or workmanship, at no charge for materials. Any replacement parts shall be new or serviceable used parts and are warranted for the remainder of the original warranty or thirty (30) days, whichever is longer. The warranty period is not extended as a result of purchasing any additional parts from KaVo. The original purchaser must promptly notify KaVo in writing if there is a defect in material or workmanship. Written notice in all events must be received by KaVo before expiration of the warranty period. This warranty is not transferable.

This One-Year Limited Warranty covers normal use. **KaVo does not warrant or cover:**

- Damage caused by impact with other objects, dropping, falls, spilled liquids or immersion in liquids
- Damage caused by a disaster such as fire, flood, wind, earthquake, or lightning
- Damage caused by unauthorized attachments, alterations, modifications or foreign objects
- Damage caused by peripherals
- Damage caused by failure to provide a suitable environment
- Damage caused by the use of the hardware system for purposes other than those for which it was designed
- Damage from improper maintenance
- Damage from improper electrical connection or supply
- Damage caused by any other abuse, misuse, mishandling, or misapplication
- Damage to acquisition computer, software, or operating system caused by;
  - o Unauthorized additions or changes
  - o Viruses, spyware, or gaming software
  - o Damage caused by Network or Operating Engineers
  - o Damage from the use of this machine or computer for any other purpose



- o Applications other than its intended use
- o Damage caused by third party software
- o Damage caused by unauthorized changes to the system software
- o Damage caused by unauthorized upgrades, additions or deletions
- o Damage caused by internet use, or any other unauthorized application.

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# Chapter 2 *Safety Items*

## *Important Safety Information*

KaVo designs its products to meet stringent safety standards. However, to maintain the safety of Operators and Patients, you must operate the equipment correctly and properly and ensure the equipment is properly maintained.

It is essential to follow all safety instructions, warnings, and cautions specified in this manual to ensure the safety of Patients and Operators. In addition, read and observe all danger and safety labelling on the system.

## *Warnings, Cautions, and Notes*

Before attempting to operate the equipment, it is recommended that you read this manual thoroughly including all cautions and warnings. This guide uses the following conventions to describe situations that are potential hazards to the Patient or Operator, potential loss of data, or potential damage to the equipment.



### **WARNING**

---

Warnings are intended to alert the user that failure to follow the procedure could cause fatal or serious injury to the user, Patient, or any other person, or result in a misdiagnosis.

---



### **CAUTION**

---

Cautions are intended to alert the user that failure to follow the procedure could cause damage to the equipment or cause loss of data.

---

**ADVISORY:** Advisories are used to defined information for the operator regarding advice towards use of the device or a process.

**NOTE:** Notes are used to highlight important or unusual points to be brought to the attention of the operator.

## *Safety Precautions*



### **WARNING**

The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.



### **WARNING**

Do not remove covers or cables on system. High voltage is present in the system. To avoid personal injury from electrical shock, do not operate the system with any covers open or cables removed.



### **WARNING**

Closing the Gate creates a pinch point. Keep hands and other body parts clear when closing Gate.

## *Electrical Fire Hazard*

Do not place any liquid or food on any part of the consoles or other modules of the system.

Observe all fire regulations. Fire extinguishers should be provided for both electrical and non-electrical fires. All operators should be fully trained in the use of fire extinguishers and other fire-fighting equipment and in local fire procedures.



### **WARNING**

In the event of an electrical fire, only use extinguishers that are labelled for that purpose. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.



### **WARNING**

In the event of an electrical fire, to reduce the risk of electrical shock, try to isolate the equipment from the electric source before attempting to extinguish the fire.

## ***Mechanical Hazards***



### **WARNING**

---

Do not operate the system with any covers open or removed. Operating the system with open or removed covers could expose mechanical operating systems that could cause serious or fatal personal injury to you or the Patient. Only qualified and authorized service personnel should remove covers from the system.

---

## ***Laser Beam Hazards***



### **WARNING**

---

Laser beams can cause optical damage. Close eyes when the laser beam is in use. Instruct the Patient to close eyes to avoid looking into the beam. The use of optical instruments such as eyeglasses with large diopter or mirrors, increase eye hazard with this product.

---

## ***Radiation Safety***

X-rays are dangerous to both operator and others in the vicinity unless established safe exposure procedures are strictly observed. Use the following safety measures to ensure safety to the Patient and Operator.

The useful and scattered beams can produce serious or fatal bodily injuries to Patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid or reduce exposure to the useful beam or to scattered radiation.

Operators are strongly urged to comply with the current recommendations of the International Commission on Radiological Protection and, in the United States, the US National Council for Radiological Protection.



---

## *System Safety Devices*

### *Emergency Stops*

This manual contains instructions for safe operation of this dental X-ray System. In the event of an emergency (any moving component collides with any parts of the equipment or items in the environment, or that could cause physical injury to the Patient), the Operator and/or Patient should utilize the **Emergency Stop buttons** to turn off the power to all moving parts in order for the Patient to be safely removed from the machine.

### *Warning System*

The System is equipped with provisions for warning lights and/or audible alarms when X-ray power is energized.

An externally powered Warning System can be connected to the cable provided which is capable of 250 volts, 50/60 hertz, and 2.5 amps. When X-ray power is energized the warning system is also energized.

### *Interlock System*

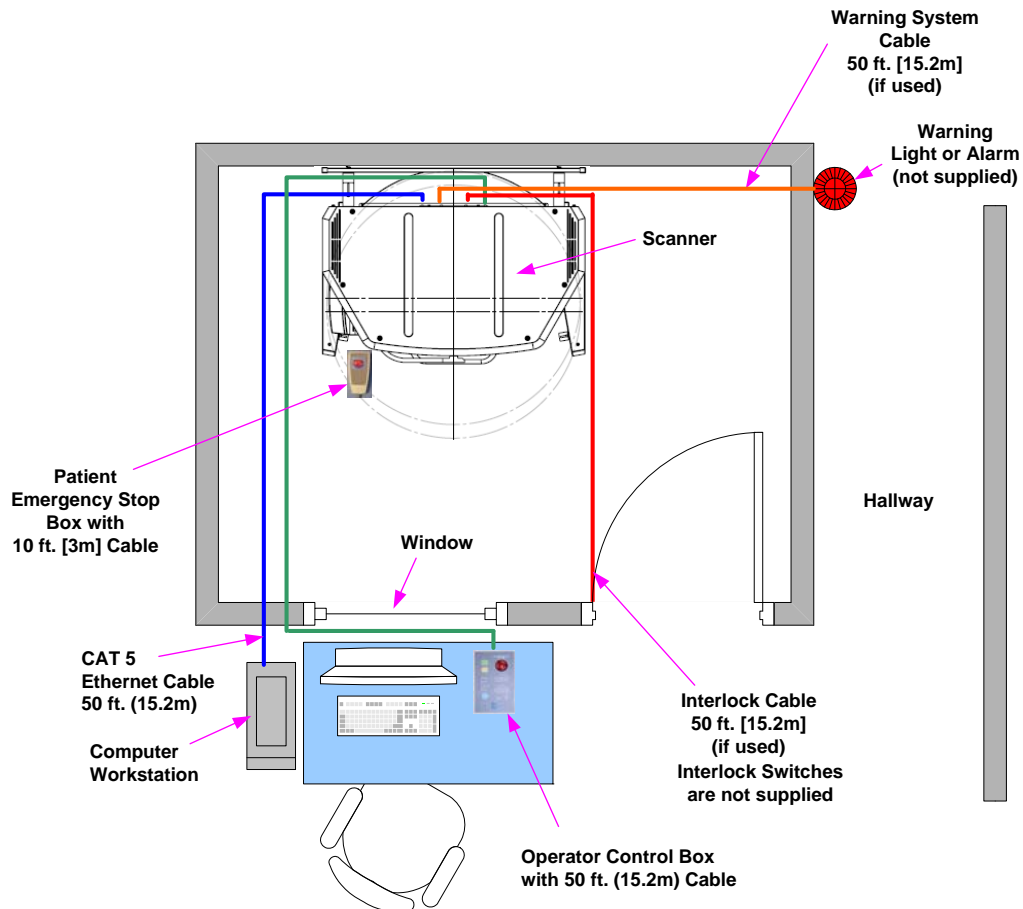
This System is equipped with provisions for an Interlock Circuit which, when opened, will turn off X-ray power. This is a low voltage circuit, 12 volts DC. To use the Interlock Circuit disconnect the factory installed Shorting Plug. Connect the supplied Interlock Cable to the scanner. Connect door switches (NO/COM terminals) and/or emergency stop switches (NC/COM terminals) in series between the other end of the Interlock Cable wires.

Multiple door switches and/or emergency stop switches can be connected as long as the devices are connected in series. The entire circuit must be a closed loop when all of the doors are closed and/or emergency stop switches are in their normally closed state.

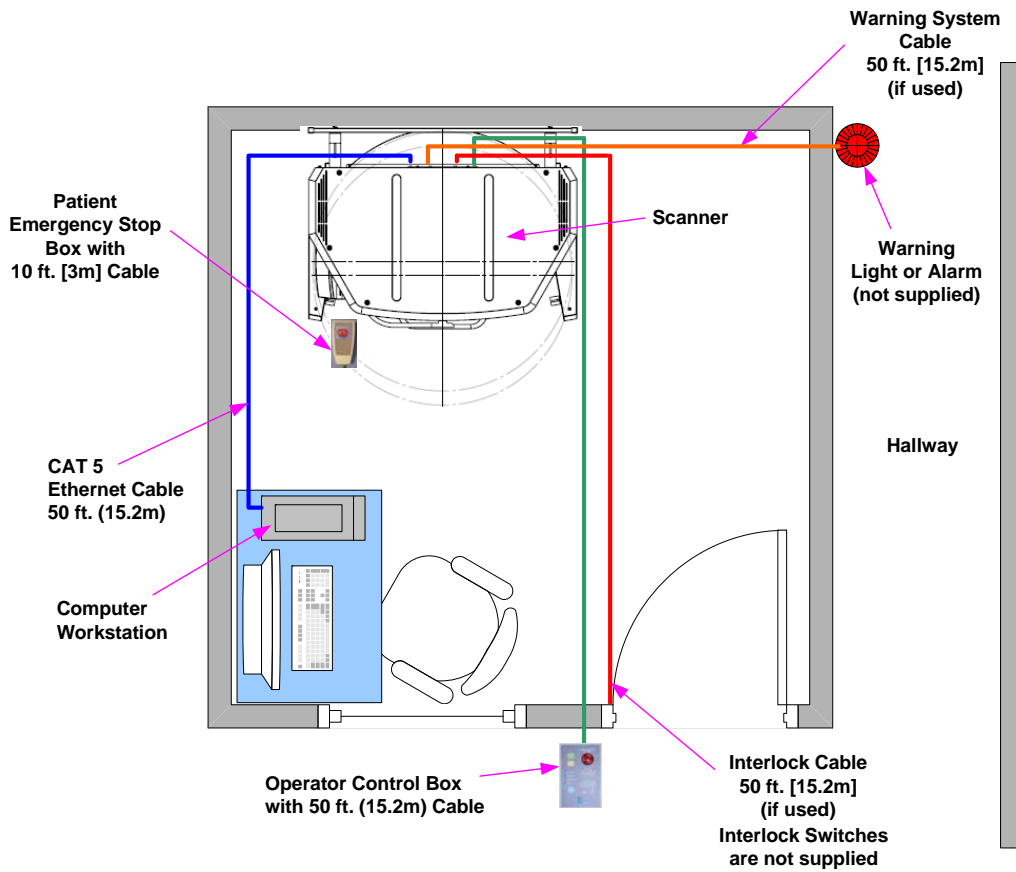
Whenever the door switch or switches are opened or emergency stop button(s) pressed the X-ray power will be turned off. X-ray power cannot be turned on when the interlock circuit is open.

## Sample Site Plan

Below are two typical scanning room layouts that illustrate the system interconnect for the Warning System, Operator Control Box (Emergency Stop) and Interlock System which are all describe above.

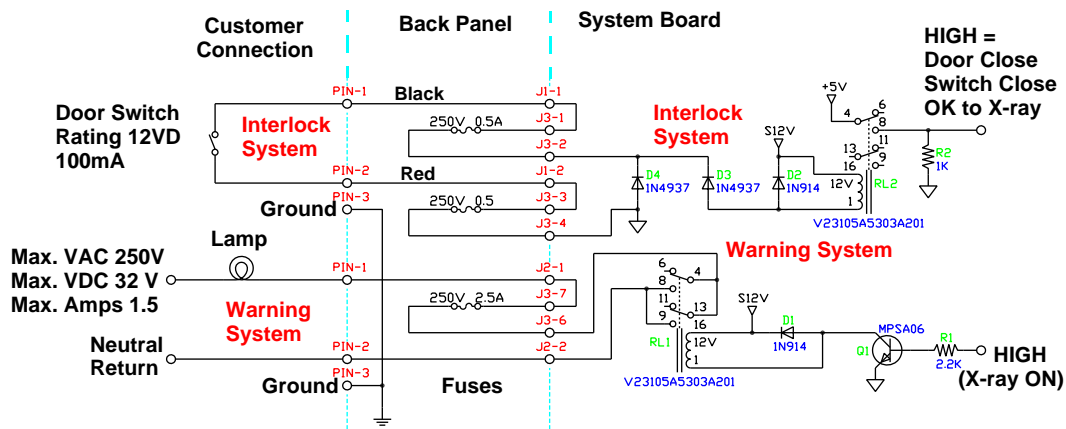


**Room Size**  
**6.5 x 8.5 feet [2 x 2.6 meters]**



Room Size  
8.5 x 8.5 feet [2.6 x 2.6 meters]

### Interlock and Warning System Schematic





## System Labels

The following labels are attached to the system.



<b>CAUTION</b>	<b>ATTENTION</b>
LASER RADIATION DO NOT STARE INTO BEAM	RAYONNEMENT DE LASER NE REGARDEZ PAS DANS LE FAISCEAU
3,5mW 635nm CLASS II LASER PRODUCT	3,5mW 635nm LASER DE CLASSE II

**CAUTION**

THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING PROCEDURE ARE OBSERVED. UNAUTHORIZED USE IS PROHIBITED.

**ATTENTION**

CETTE UNITÉ DE RAYON X PEUT ÊTRE DANREUSE POUR LES PATIENTS ET L'OPÉRATEUR À MOINS QU'ON OBSERVE À DES FACTEURS SÛRS D'EXPOSITION ET AUX MODES OPÉRATOIRES. L'UTILISATION NON AUTORISÉE EST INTERDITE

ALIGNMENT LIGHT

**CAUTION**  
DO NOT STARE INTO  
VISIBLE LIGHT BEAM

**ATTENTION**  
Ne pas regarder  
directement dans le  
faisceau lumineux  
visible. Présence de  
sortie



**X-RAY POWER SUPPLY**

INPUT VOLTAGE 115/230 VAC  
INPUT AMPS 10/5 A  
INPUT FREQUENCY 50/60 Hz  
COMPLIES WITH IEC 60951-2-7  
AND IEC 60951-2-2/8

**WARNING**  
PINCH POINT  
KEEP HANDS CLEAR

**AVERTISSEMENT**  
POINT DE RINCEMENT,  
TENIR LES MAINS À L'ÉCART.

**MAXIMUM LIFTING CAPACITY:**  
**CAPACITÉ MAXIMALES DE LEVAGE:**

SEAT NOT TO EXCEED 400 LBS (180 kg)	LA CHARGE DU FAUTEUIL NE DOIT PAS DÉPASSER 180 KG (400 LB)
---	--

**WARNING**

These capacitors may hold a lethal charge after the system is de-energized. Extreme caution needs to be exercised. Manually discharge capacitors before handling the unit.

**WARNING**

These capacitors may hold a lethal charge after the system is de-energized. Extreme caution needs to be exercised. Manually discharge capacitors before handling the unit.

**MAXIMUM LIFTING CAPACITY:**

SEAT  
NOT TO EXCEED  
400 LBS (180 kg)

**CAPACITÉ MAXIMALES DE LEVAGE:**

LA CHARGE DU FAUTEUIL  
NE DOIT PAS DÉPASSER  
180 KG (400 LB)



# Chapter 3 System Controls and Indicators

Controls and Indicators are found on the following system units:

- Operator Control Box
- Patient Alignment Panel
- Patient Emergency Stop Control
- System Status Indicators

## Operator Control Box

**ON** powers the Scanner and the POWER indicator lights to show that the device is ON.

**OFF** removes power from the device and the POWER indicators go OFF.

**EMERGENCY STOP** immediately halts all X-ray and scanning activities.

**SCAN** initiates Patient X-ray scanning. (This allows the Operator Control Box to be mounted in a location different from the Computer Workstation.) When scanning is occurring, the **X-RAY ON** indicator is lit.

**FAULT** indicator lights when a system error occurs (such as an X-ray exposure problem).



## Patient Emergency Stop Control

**PATIENT EMERGENCY STOP** allows the Patient to halt all X-ray and scanning activities by pressing the button.

The Emergency Stop Control can either be hung from the head support mechanism or held in the Patient's hand as desired.



## Patient Alignment Panel

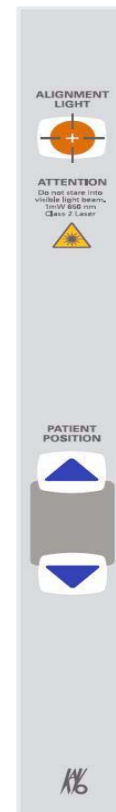


### WARNING

Laser beams can cause optical damage. Do not stare into the laser beam. Instruct the Patient to avoid looking into the beam. The use of optical instruments such as eyeglasses with large diopter or mirrors, increase eye hazard with this product.

**ALIGNMENT LIGHT** - pressing the button turns ON the laser alignment lights for three seconds. Press and hold the button for three seconds turns the laser lights ON permanently, until the button is again pressed to turn OFF the laser lights.

**PATIENT ALIGN** allows the Operator to move the Patient seat up and down to facilitate Patient alignment with the Chin Rest.



## System Status Indicators

The System Status Indicators are located on both the overhead unit and the Operator Control Box.

**POWER** indicator is lit when the scanner is ON.

**READY** indicator is lit when the software Acquire button is pressed to begin the scanning process.

**X-RAY ON** indicator is lit during the scanning process.

**FAULT** indicator lights when a system error occurs (such as an x-ray exposure problem).



# Chapter 4 *System Startup and Shutdown*

## *System Startup*

The System includes the Scanner and a Computer Workstation. Both units must be ON to function properly. To start the system, do the following:

1. **Power up the Scanner:** press the ON button on the Main Control Box. The POWER indicator on the Main Control Box and Scanner light.
2. **Power up Computer Workstation:** press the power button on the front of the Workstation. The computer boots and loads the operating system.
3. **Launch Vision Software:** double-click the **Vision** icon on Workstation desktop. The Vision software application is launched.



**NOTE:** Although the system is now ready to scan, the **Ready** indicator does not illuminate until the **Acquire** button is pressed to start a scan.

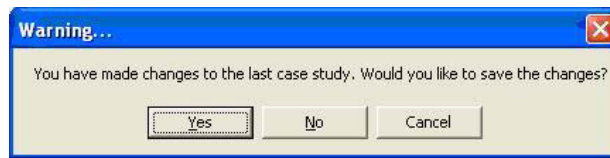
## *System Shutdown*

The Scanner and Computer Workstation are powered independently. Both units are powered OFF as described below.

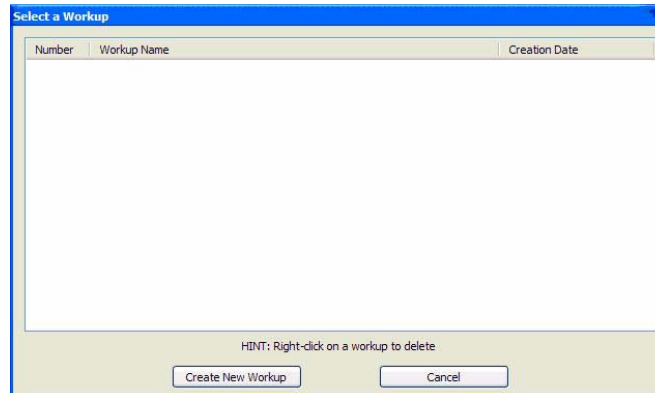
### **To shut down the system:**

1. From the Main menu on the Computer Workstation, select **File > Exit**. Vision closes but the Windows desktop remains ON.

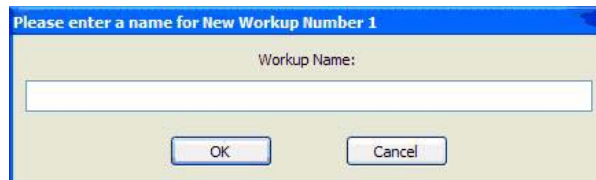
If changes were made to a case study, the following dialog box appears.



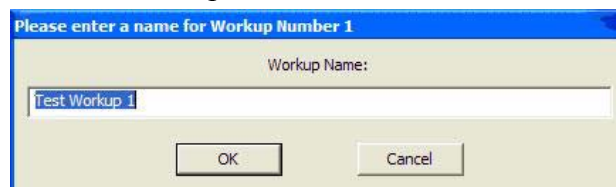
- a. Click **Yes**. The dialog box closes.



- b. Click **Create New Workup**.



- c. Enter a name for new Workup in the *Workup Name:* field.  
Click **OK**  
**or**  
Overwrite an existing Workup by clicking an existing Workup Name.



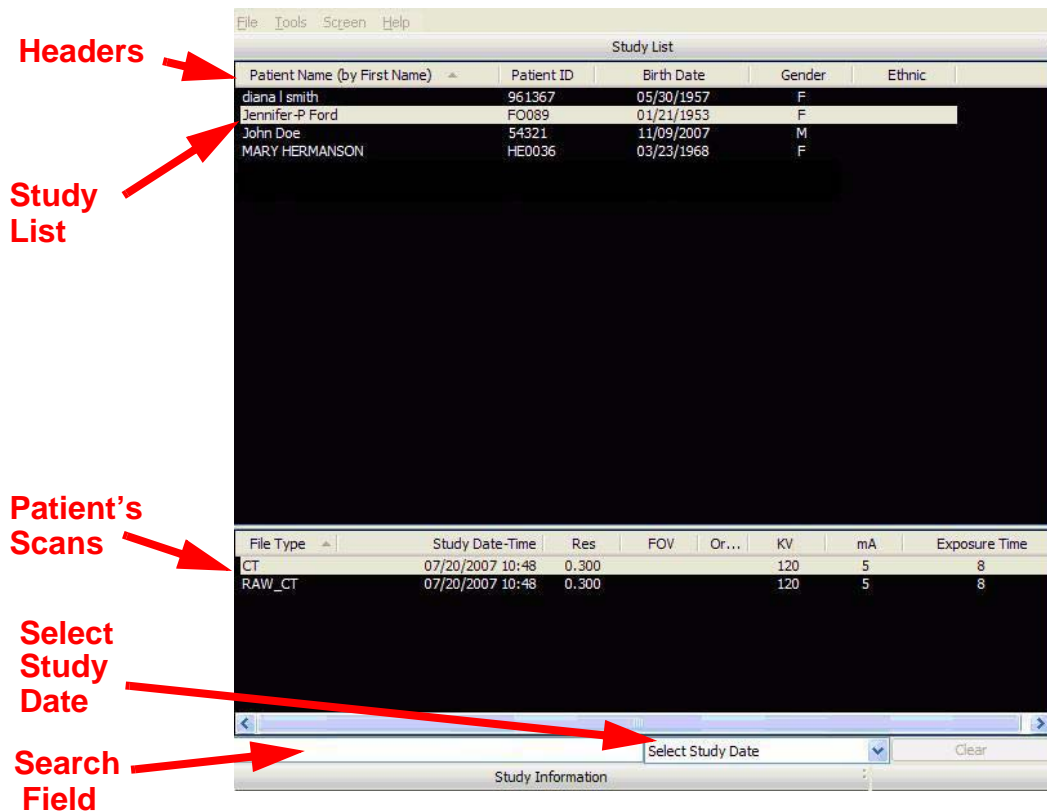
2. **Power OFF Scanner:** press the **OFF** button on the Main Control Box. The Scanner shuts down and the POWER indicators on the Main Control Box and Scanner go OFF.
3. **Power OFF Computer Workstation:** from the Windows desktop, select **Start > Shut Down** and then select **Shut Down** and press **OK**. The Computer shuts down and the POWER indicator on the Workstation goes OFF.



# Chapter 5 Managing Patient Data

## Patient Information

When Vision is launched, the Patient Information window is displayed. The Study List (shown below) lists all Patients that were entered into the database. When a Patient is selected (highlighted), that Patient's scanned images are listed in the window beneath the Study List.



The order in which patients are listed may be altered by clicking a header above the Study List. For example, clicking **Birth Date** changes the *Study List* to display numerically by birth dates, starting



from month 01 down to 12. Clicking **Birth Date** again reverses the order, displaying the 12th month first. This works with all headers for both the Patient and Scan Lists. Clicking **Patient Name** not only toggles the alphabetical order but can alter the listing to display the order of patients by *First Name* or by *Last Name*.

The **Search Field** enables entry of a character string (letters and/or numbers) for which to search the Patient Name and Patient ID columns to quickly locate a Patient by name or ID.

The **Select Study Date** displays only the Patients that were scanned within the selected time period. The drop-down list has the following selections:

- Today
- Two days
- Three days
- One week
- Two weeks
- Three weeks
- Four weeks

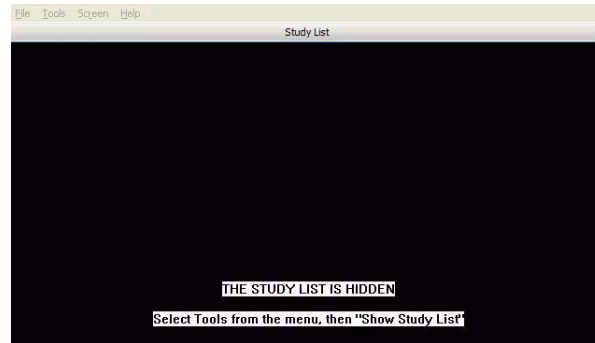
Clicking the **Clear** button returns the *Study List* to display all patients.

Patients can be added or deleted and Patient Data can be edited as desired. In addition, Patient Scans can be deleted, and the Study List can be hidden from view. These tasks are described below.



## Hide/Display Study List

The *Study List* can be hidden by selecting **Tools > Hide Study List** from the Main menu. When hidden, the Study List appears as shown below.



To display the Study List, select **Tools > Show Study List** from the Main menu.

## Delete Patient Scans

To delete a Patient dataset:

1. With a Patient selected in the Study List, right-click on the scan to be deleted and select **Delete**.

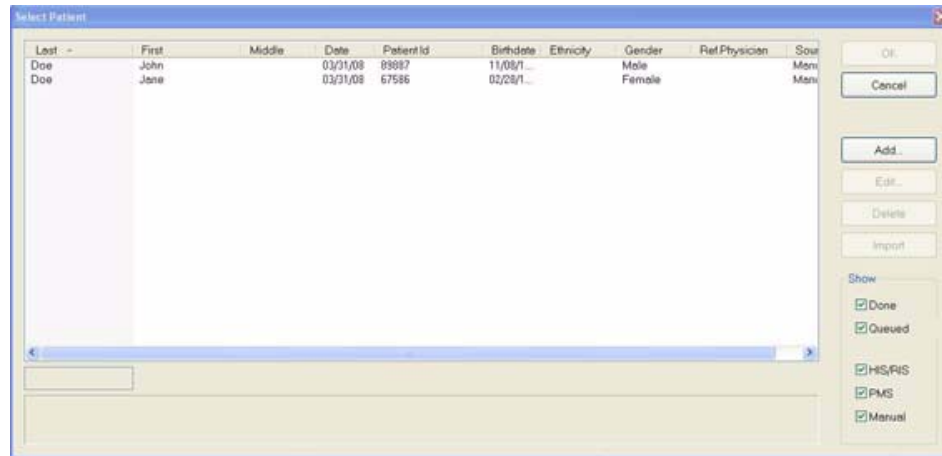
File Type	Study Date-Time	Res	FOV	Orientation	K'
CT	02/21/2008 15:56	0.200			12
CT	02/25/2008 09:41	0.200			12
CT	02/25/2008 09:53	0.200			12
CT	02/25/2008 10:03	0.200			12
CT	02/25/2008 10:12	0.200			12
CT	02/25/2008 10:19	0.200			12
CT	02/25/2008 11:07	0.200			12
CT	02/25/2008 11:33	0.200			12

2. Click **Yes** to confirm deletion of Patient Dataset, including all scans and workups. A second confirmation dialog is displayed.
3. Click **Yes** to confirm deletion.

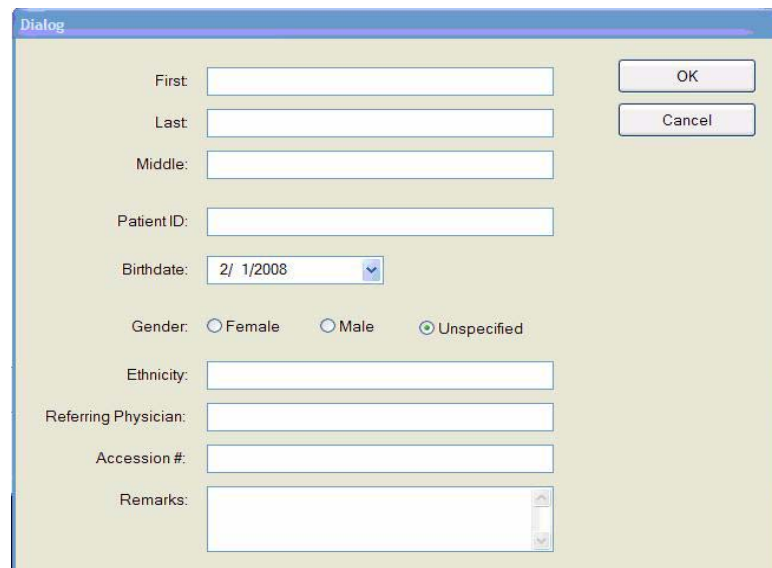
## Add New Patient

### To add a new Patient

1. From the Main menu, select **File > New Patient** or right click an existing image from Patient Study list and select **Acquire New Scan**.



2. Click **Add . . .** button.



3. Enter Patient data in the corresponding fields as applicable.
  - A unique **Patient ID** must be added, such as a Patient file number or social security number.

- Click the **Birthdate** drop-down to display the calendar tool.



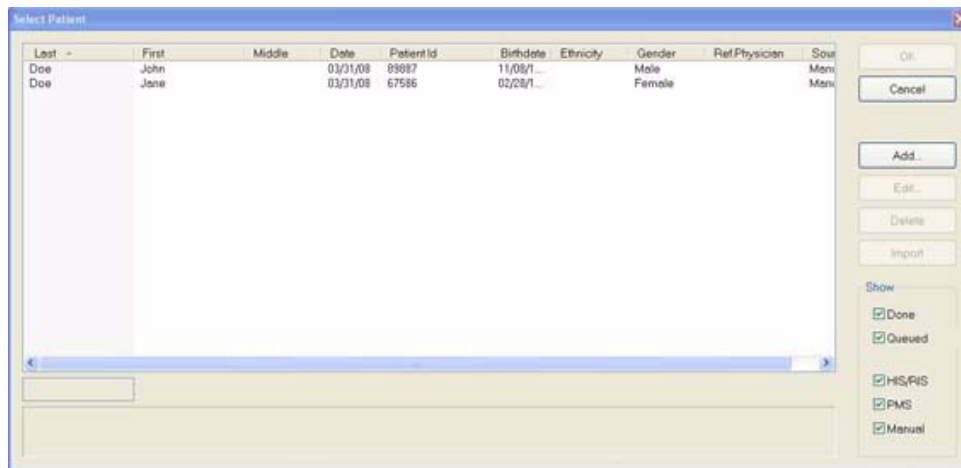
Although dates may be manually entered, it is recommended that the calendar tool be used in order to avoid data entry errors.

4. Click **OK** to add Patient data.
5. Click **Cancel** to close the dialog box or click **OK** to access the acquisition screen to start the patient scan.

## *Edit Patient Details*

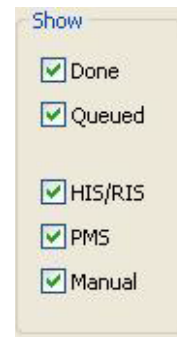
**To edit Patient details:**

1. From the Main menu, select **File > New Patient**.

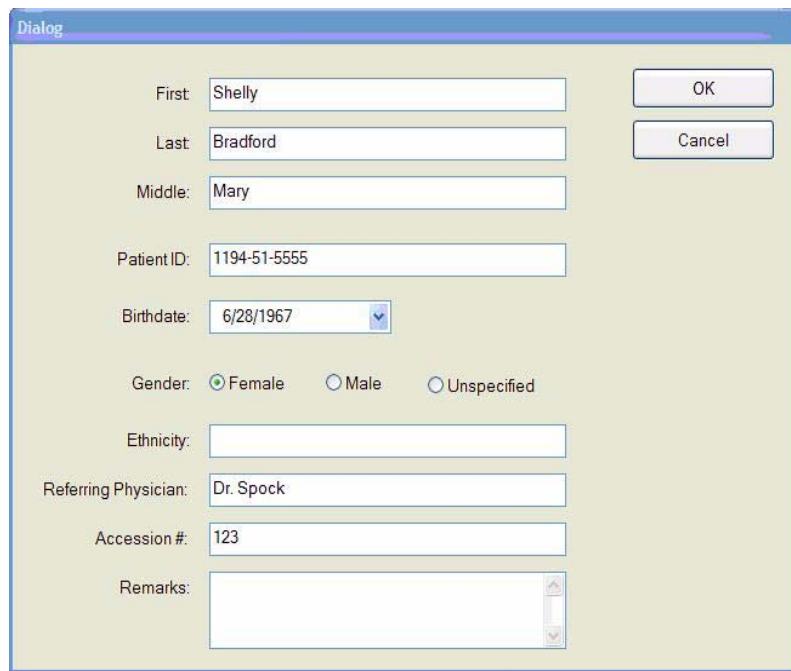


2. If desired, limit the number of Patients listed by using the check boxes in the Show area at the lower right side of the dialog box. Only Patients whose data matches the selected criteria are displayed.

- **Done** - Patient Data entered and scanned
  - **Queued** - Patient Data entered but not scanned
  - **HIS/RIS** - (Hospital Info System/Radiology Info System) imported Patient Data
  - **PMS** - (Practice Management System) imported Patient Data
  - **Manual** - Patient Data entered manually
3. Click (highlight) the Patient to modify.
  4. Click **Edit**.



Dialog box titled "Show" with five checked checkboxes: Done, Queued, HIS/RIS, PMS, and Manual.



Dialog box titled "Dialog" for editing patient information. Fields include:

- First: Shelly
- Last: Bradford
- Middle: Mary
- Patient ID: 1194-51-5555
- Birthdate: 6/28/1967
- Gender:  Female,  Male,  Unspecified
- Ethnicity: (empty)
- Referring Physician: Dr. Spock
- Accession #: 123
- Remarks: (empty text area)

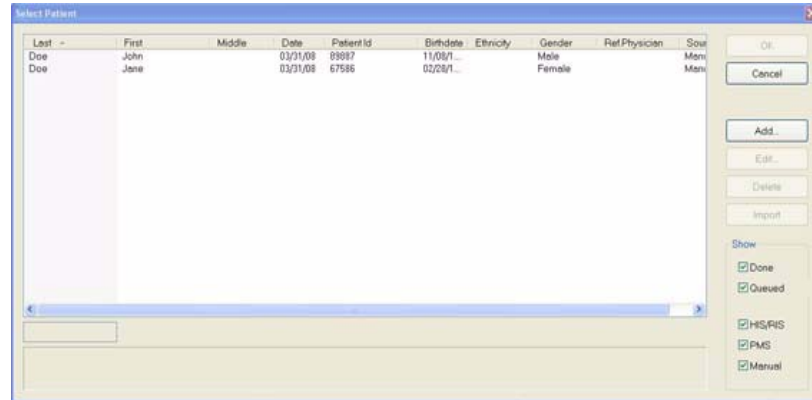
Buttons: OK, Cancel

5. Modify Patient data as desired.
6. Click **OK** to update Patient data.
7. Click **Cancel** to close the dialog box or click **OK** to access the acquisition screen to start the patient scan.

## Access Patient Data

### Access Patient Details to be Scanned:

1. From the Main menu, select **File > New Patient**.
2. Highlight the Patient to be scanned and click **OK** or just double click the patient line.



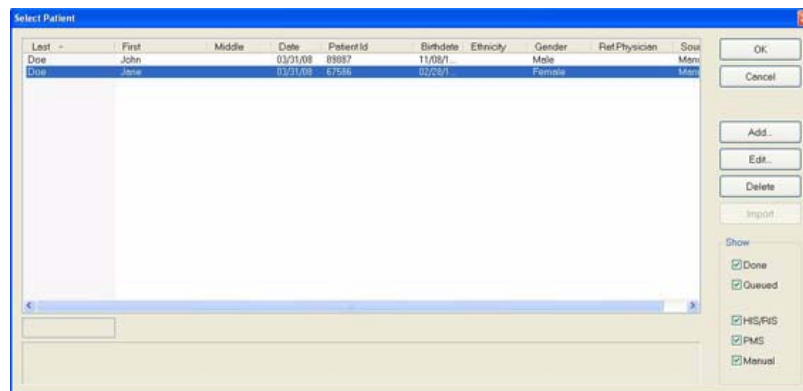
3. The Acquisition screen is displayed for the selected patient.

## Delete a Patient

### To delete an existing Patient:

**NOTE:** Deleting a Patient does not delete any of the Patient's scan data.

1. From the Main menu, select **File > New Patient**.
2. Click (highlight) the Patient to delete and click **Delete**.

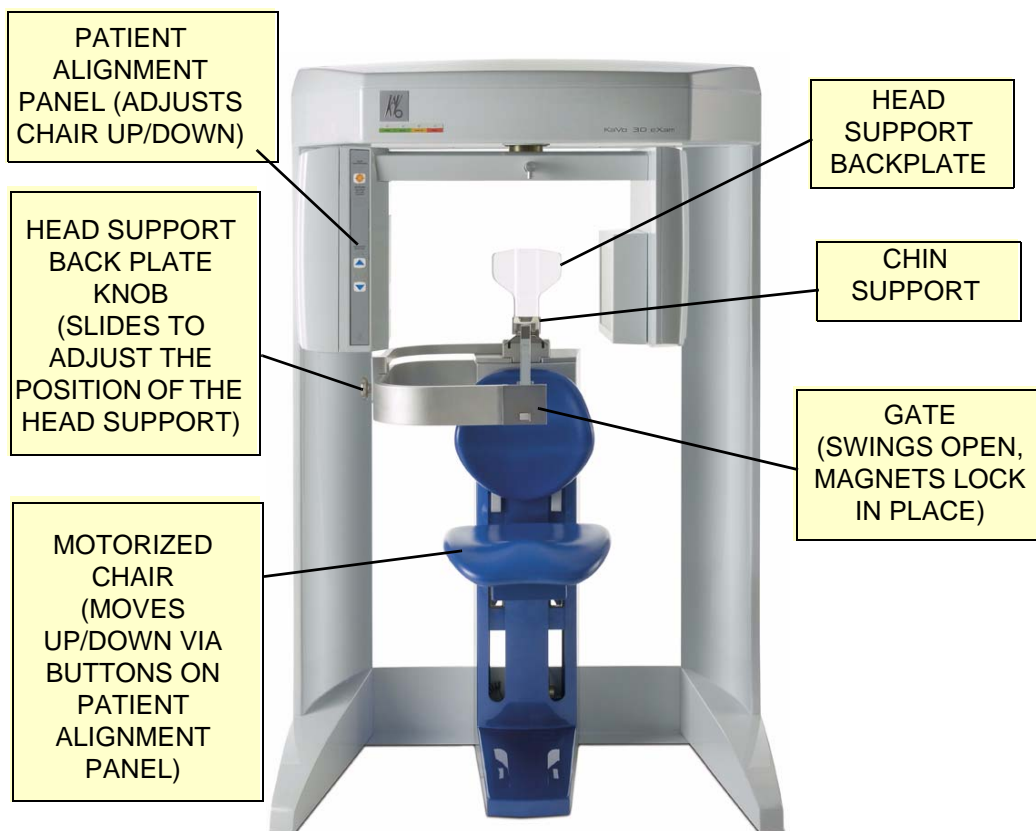


3. Click **Yes** to confirm deletion of Patient from database.
4. Click **Cancel** to close dialog box.



# Chapter 6 Acquisition (Scanning)

## Patient Positioning



### To position the Patient for scanning:

1. There are two sets of mounting slots for the chair. It is recommended to mount the chair in the lower slots for Patients that are taller than 4' 9".
2. With the gate opened, have the Patient seated in the chair, facing forward. The Patient should be seated comfortably with hands in lap.

3. Close Gate, making sure the magnet is secured in its locked position.
4. Use the **Patient ALIGN** buttons on the Patient Alignment Panel to adjust the Patient Chair height. These controls allow movement of the Patient chair, up ( $\Delta$ ) and down ( $\nabla$ ), to facilitate Patient alignment with the Chin Rest. When properly aligned, the Patient's chin is able to sit on the Chin Cup at the appropriate tilt (see illustration below).
5. Ensure the tilt of the Patient is such that the Occlusal Plane is Flat, which means Frankfort Horizontal is tilted up by about 5 degrees (see illustration below).



### WARNING

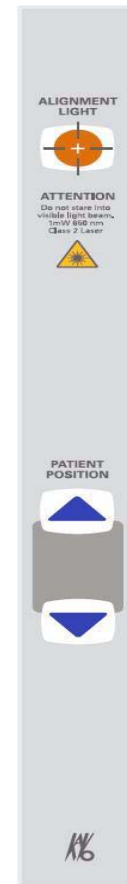
Laser beams can cause optical damage. Close eyes when the laser beam is in use. Instruct the Patient to close eyes to avoid looking into the beam. The use of optical instruments such as eyeglasses with large diopter or mirrors, increase eye hazard with this product.

6. **Alignment Light:** In general, the Alignment Light shall be positioned at the horizontal Occlusal Plane.
  - **Full Head Scan:** The Horizontal light should be at the Occlusal Plane between the lips (smile line).
  - **Clearance:** Make sure that the sensor side of the turret has enough clearance as to NOT brush the Patient's shoulders as it rotates. This may cause movement.

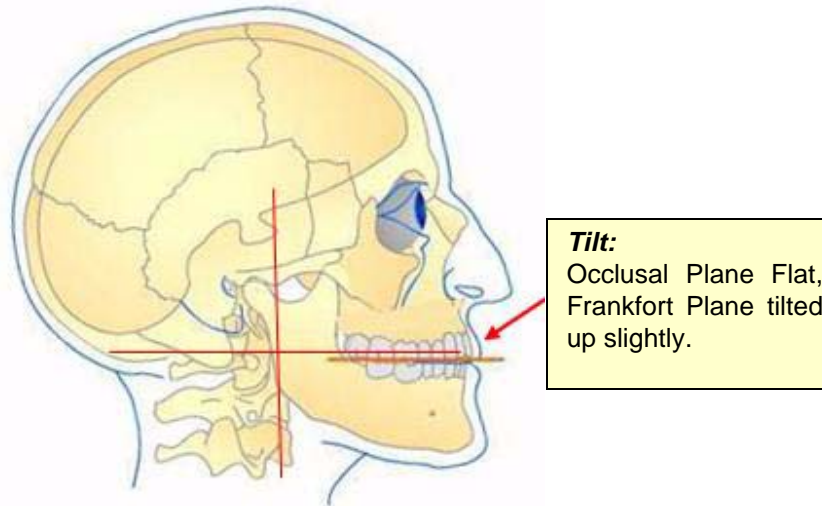


### CAUTION

The horizontal Alignment Light may vary slightly depending on the Patient position according to the selected height of scan desired, refer to taking a Preview, in the next paragraph, to ensure that the target area of interest is in the image.







**Position of Alignment Lights for Full Head Scan:**  
**Horizontal:** Occlusal plane between the lips.  
**Vertical:** 1.5 inches in front of condyle (chin support adjusted to acquisition position).

7. Make sure the Patient's chin is stabilized in the chin support.
8. Slide the head support forward for additional head stabilization.
9. Secure the head strap around the forehead.
10. For scans that are specific to TMJ or orthodontics, only the head support and head strap should be used. It is recommended that the chin support not be used because it can affect the Condular position in Fossa and interfere with soft tissue at the chin.

## Acquisitioning

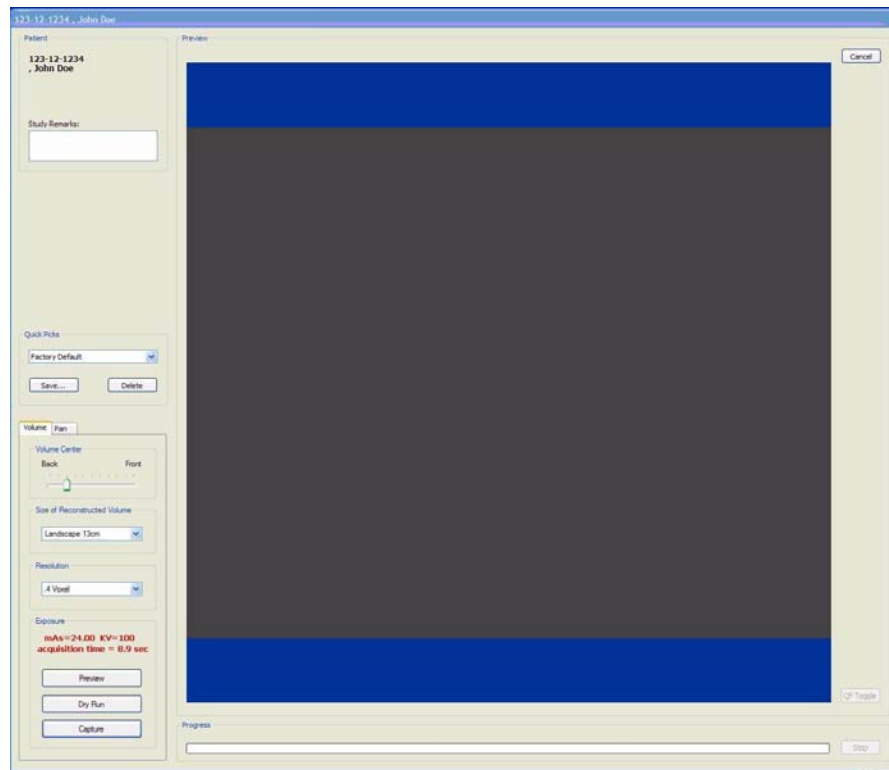
Once Patient data is entered and the Patient is properly positioned, acquisitioning can begin.

Acquire a new acquisition:

1. From the Main menu select **File > New Patient**.
2. In the *Select Patient* Pane, highlight patient and click **OK** or just double-click the patient to be scanned.

The Acquire window is displayed.

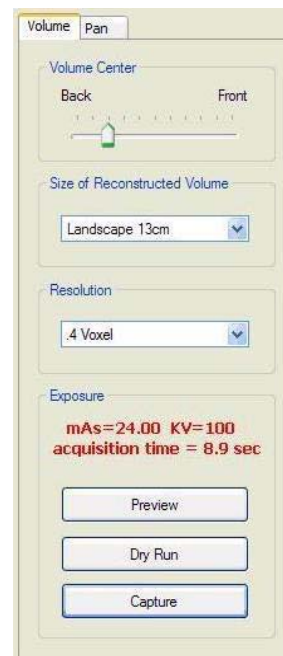
- If desired, enter any remarks in the *Study Remarks* text field.



- Select a **Resolution** from the drop-down list box.

In general, the lower the voxel size and the longer the scan time, the better the resolution and detail; however, a smaller voxel size and longer scan time creates a larger data set so the reconstruction time is longer. Also, these protocols are more sensitive to Patient movement, so it is critical to restrict Patient movement during the scan. Longer scan times also delivers a higher radiation dose.

Standard scans should be taken at *Full 13cm, 8.9 sec, 0.3 Voxel*. This captures the entire maxillofacial region from above the condyles down to below the lower jaw, at the most practical scan time (reducing chance of movement), at



a reduced radiation dose, with a voxel size that maximizes detail without the dataset being too large.

It is recommended to use a faster scan time (for example, 5 sec.) for children, some elderly Patients (if movement is a significant issue), or if you require only a quick PAN or TMJ Scan, or a secondary/follow-up scan (e.g. Open Jaw TMJ views, TMJ views with appliance/splint, etc.). Since it is a faster scan time, the radiation dose is the lowest, and the opportunity for Patient movement is less.

5. Select a **Size of Reconstructed Volume** from the drop-down list to indicate the portrait or landscape position of the X-ray sensor.
  - **2 arches/anchor, 8.9 sec, 0.3 Voxel** - recommended when data is exported to implant planning software systems such as Nobel or SimPlant.  
Please check with your service to determine the desired height of the scan. Please be aware that most 3rd party software currently requires the scan to be taken at 0.4 Voxel resolution and no smaller.
  - **Mandible or Maxilla...** - Protocols can be used if only 1 arch is required for an Implant case.
  - **High Resolution (0.2, 0.25, 26.9 sec.)** - recommended protocols for specialized cases such as 3rd molars, root canal relationships, small root fractures, supernumerary or impacted teeth, periodontal condition and other anatomy requiring detailed visualization.
  - **Portrait Mode** - should be used for adult Patients where cephalometric data is required.
6. Once the settings are made, you may perform a **Preview, Dry Run, and Capture** scan.

### *Preview, Dry Run, and Capture Scans*

After the acquisition is launched and the protocol is selected, a **Preview** of the Patient is recommended to verify Patient positioning.



#### **WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

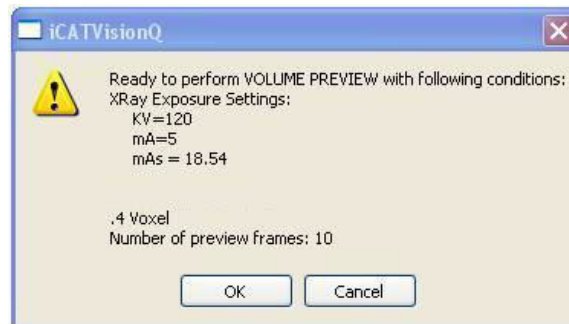
**Operation Guidelines:**

- A site review should have been performed by a qualified physicist prior to system installation to ensure proper equipment layout for safe operation of the system.
- If any changes are made to the equipment layout or occupancy of adjacent areas, or if there is a significant increase in patient workload after the original review, re-evaluation should be performed by a qualified physicist.
- Refer to the *Radiation Environment Survey* chapter for specific scatter beam measurements for your system.

1. Click the **Preview** button under *Exposure*.



The following dialog box is displayed.



2. Click **OK** to continue.
3. Press the **Scan** button on the Control Box when prompted to proceed with the Static Exposure.

An audible is sounded and the X-ray ON light is illuminated during radiation exposure.



If the Patient position appears to be correct, then proceed with the scan. To ensure good quality, the image should appear within a ¼ inch from the front border of the Preview screen.

Otherwise, re-position the Patient.

Access **Volume Center** to improve Front/Back positioning.

The **Volume Center** slide bar moves the X-ray sensor panel (Front/Back) which adjusts the vertical image positioning. Another Preview scan is recommended after repositioning the Patient.

4. **Dry Run** is used to give the Patient a demonstrate of the machine motion and also checks shoulder clearance without any radiation exposure. The Dry Run scan rotates the turret in the exact manner that is required for the selected protocol, but does not expose the Patient to any radiation. If desired, do a Dry Run by clicking the **Dry Run** button.





**NOTE:** It is critical that the Patient is instructed to hold still, swallow before the scan, take shallow breaths during the scan and may want to close his/her eyes so he/she won't be tempted to follow the turret with their eyes during the scan.



**WARNING**

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The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

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5. Click **Capture** to start the acquisition.
6. Ensure no one is in the immediate area, then click **OK**.
7. Press the **Scan** button on the Control Box when prompted to continue the scan process. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.

The turret rotates around the Patient's head. The exposure buzzer sounds for the duration of that rotation, although the true exposure time is much less because the exposure pulses on and off.

The progress of the scan is displayed on the *Progress* bar at the bottom of the Acquire window.

Once the acquisition is complete, the machine rewinds. **Wait until the machine rewinds before releasing the Patient from the machine.**

The software immediately begins reconstruction of the image data. The time required to reconstruct depends on the acquisition scan time and voxel size that was selected.

- The scan is ported to the Vision preview screen for anatomy reconstruction (shown below).



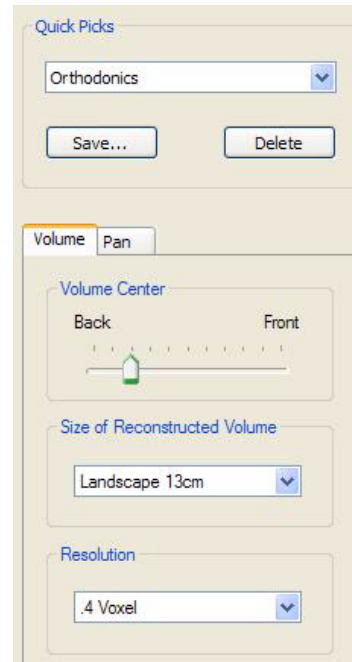
## Quick Picks

Quick Picks are created and named by the Operator. A Quick Pick captures and saves to memory the following settings: Exposure, Volume Center, Size of Reconstructed Volume, and Resolution. For convenience, speed, and accuracy, the Operator may create Quick Picks of commonly used scan settings.

### To add a Quick Pick:

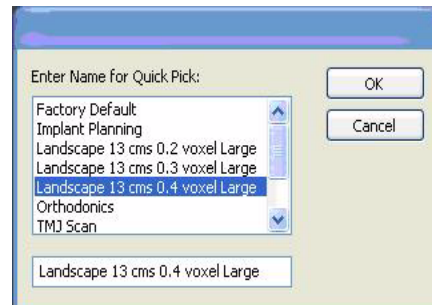
1. Select scan settings:
  - Exposure (if available)
  - Volume Center
  - Size of Reconstructed Volume
  - Resolution
2. Click **Save...** button, below the Quick Picks list box.

This saves the selected settings.



3. Enter a name for the new Quick Pick.
4. Click **OK**.

The newly created Quick Pick is now available from the Quick Picks drop-down list box.



### To delete a Quick Pick:

1. Select the Quick Pick to delete from the Quick Picks drop-down.
2. Click **Delete** button below the Quick Picks drop-down.
3. A confirmation box is displayed, click **Yes** to delete.



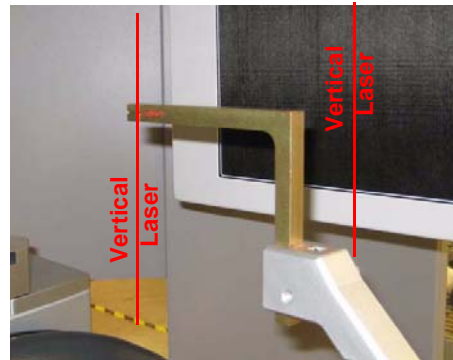
## PAN Scan (Optional)

A PAN scan is a scan mode that creates a Panoramic exposure that is a two dimensional image.

Patient positioning is critical for PAN scans. The device must also be properly aligned to ensure quality Patient images. Prior to performing a PAN scan, the Scanner alignment should be checked, to ensure optimal system performance. It is recommended to check the Scanner alignment monthly or if PAN image quality has degraded. Also, perform a PAN Phantom test described in the *Quality Assurance* chapter.

### To check Scanner alignment:

1. Replace the Chin Cup with the Chair Center Locator.
2. Ensure that the device is in the home position by closing and opening the device software.
3. Press the Alignment Light button on the device Front Panel to display lasers.



Lasers are available while the Volume tab is selected (not PAN).

4. **Ensure that the Vertical Laser intersects the notches on the Receptor Panel and the Chair Center Locator tool, as shown.**
5. If the Vertical Laser is in the correct position, then the device is ready to perform a PAN scan.

If the Vertical Laser is out of position, then adjust the chair foot, using a 1/4 inch nut driver.

- **Turn nut driver clockwise** - moves alignment tool towards rear of Scanner.
- **Turn nut driver counter-clockwise** - moves alignment tool towards front of Scanner.

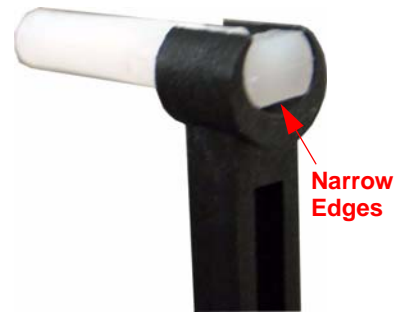


**NOTE:** Perform a PAN Phantom test, described in *Quality Assurance*, if image quality has degraded.

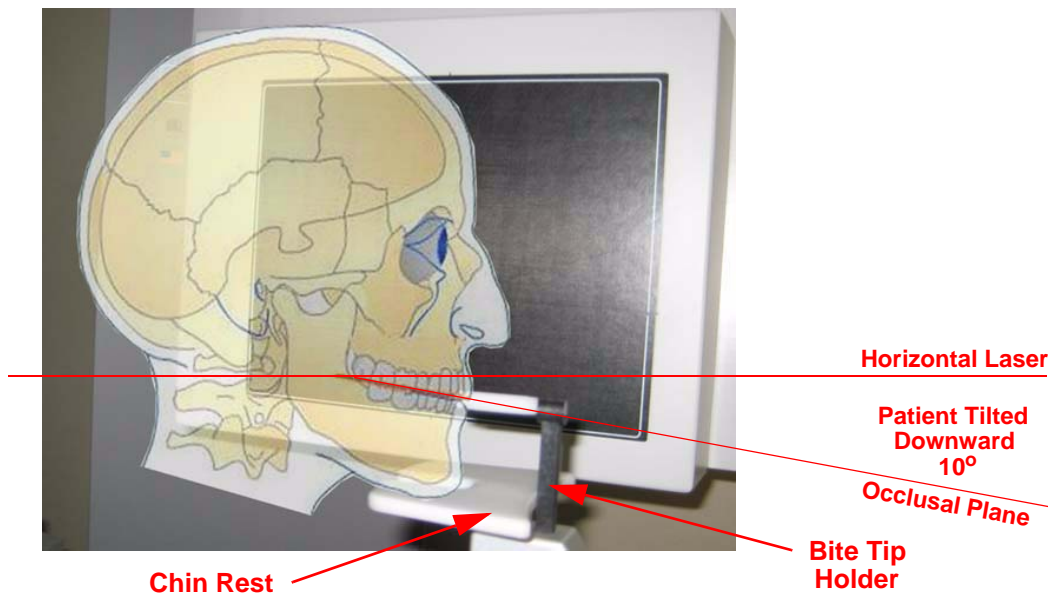
**To acquire a PAN scan:**

1. Place Chair in the upper slots so that chair back does not impede Patient's ability to sit with an Erect posture.
2. Seat the Patient in the chair with an Erect posture. Their neck must be as straight as possible to avoid the spine getting in the view.
3. Prepare the Bite Tip by inserting the narrow edges of white Bite Tip down into Bite Tip Holder uprights. Then turn the Bite Tip a 1/4 turn to lock into place.

The Patient will be biting on the groove of the white Bite Tip during the scan.



4. Insert the Chin Rest and Bite Tip Holder into the Positioning Block as shown below.



5. Adjust Patient height using the buttons on Patient Alignment Panel so that the Patient's chin is on the Chin Rest, but Erect posture is maintained.
6. Tilt the patient's head downward so that the occlusal plane forms roughly a 10° angle to the horizontal laser line.

**NOTE:** Patient positioning is critical for a quality image. Refer to the illustration above for a visual of tilting the Patient. Using the Sagittal Laser (front center laser), ensure that the Patient is centered and facing straight forward.

7. Patient must bite in the groove of the white bite tip to ensure proper front-to-back positioning.
8. From the Main menu select **File > New Patient**.
9. In the *Select Patient* Pane, highlight patient and click **OK** or just double-click the patient to be scanned.

The Acquire window is displayed.

10. If desired, enter any remarks in the *Study Remarks* text field.

11. Move Volume Center slider to the **Front** position.

12. On the Volume tab, set parameters as follows:

- Size of Reconstructed Volume: **Landscape 13 cm**
- Resolution: **0.4 Voxel**

13. Click the **Preview** button under *Exposure*. A dialog box is displayed.

14. Click **OK** to continue.

15. When prompted, press the **Scan** button on the Control Box.

An audible is sounded and the X-ray ON light is illuminated during radiation exposure.

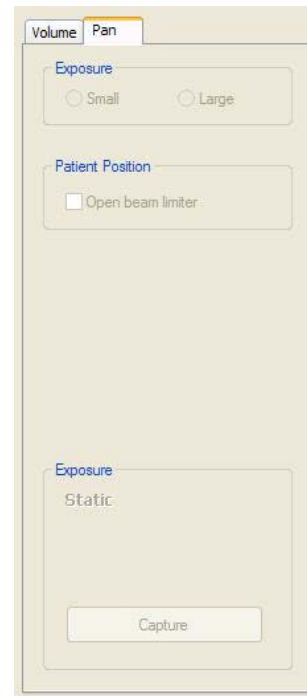


16. Check the Preview to ensure the following:

- The bottom of the mandible is at the bottom of the image.
- Overlay the iPAN visual aid (triangle with a  $10^{\circ}$  angle) over the preview image to verify patient's occlusal plane is positioned properly at a  $10^{\circ}$  angle. The bottom of the triangle should be parallel to the laser line, and the sloped side of the triangle should roughly align from the back of the smile line to the point where the patient is biting on the bite tip.
- If alignment is not correct, lower the chair to lower the degree of the angle or raise the chair to raise the degree of the angle. Perform another Preview scan to check positioning.



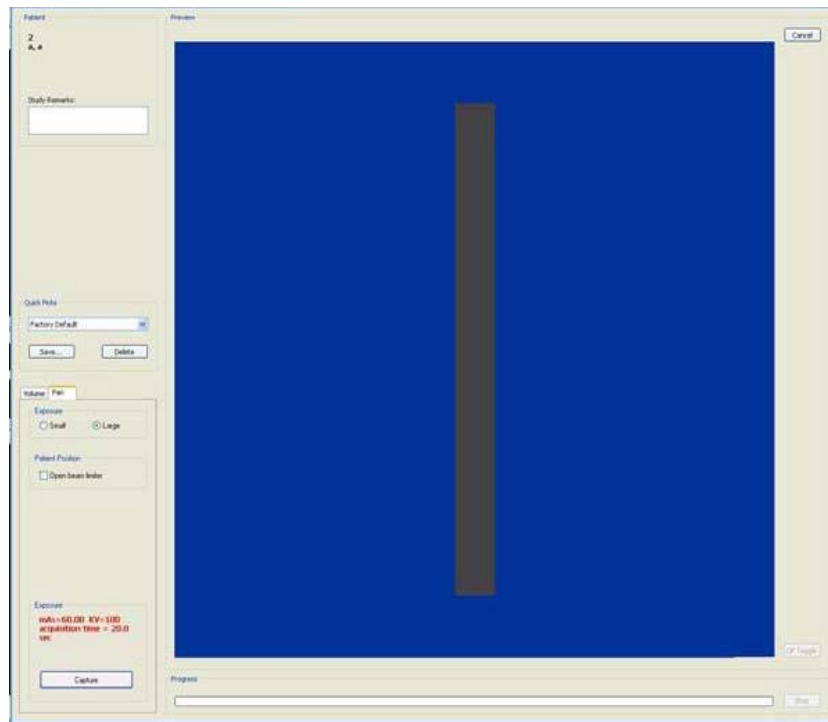
17. When Patient is properly positioned, click the **Pan** tab.
18. Make an *Exposure* selection by determining the Patient's head size.  
**Small** is normally selected for young children and small elderly females.  
**Large** is for a normal size adult or large child (head size).
19. Instruct the Patient to close lips around the bite tip as if using a straw.
20. Before capturing the image, instruct Patient to swallow and hold, putting the tongue to the roof of the mouth and holding for the duration of the exposure.



**WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

21. Click the **Capture** button to start the test.

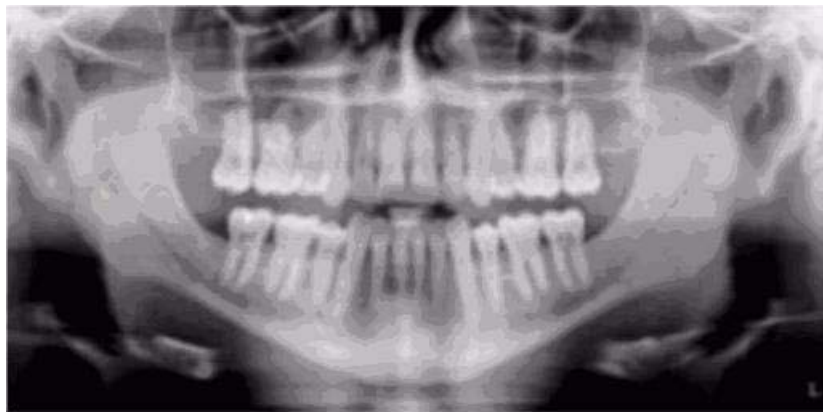


22. The system moves approximately 1/4 rotation to the Home Position and then displays the scan parameters.

23. Click **OK** to start the scan process.

24. Press the **Scan** button on the Control Box when prompted. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.

25. The PAN scan runs for about 20 seconds, and the reconstructed image displays in less than one minute.



26. Adjust the Brightness/Contrast by dragging the cursor across the image (vertical/horizontal).

# Chapter 7 *Reconstruction of Anatomy*

## *Preview Screen*

Once Patient data is acquired or data for a Patient is loaded, the software immediately reconstructs the Patient anatomy images. (User modified Patient data, referred to as a *Workup*, can also be loaded to the preview screen. While data loading is occurring, a preview window appears in the center of the screen.



At the bottom right side of the reconstruction window, the status of the data loading is displayed.

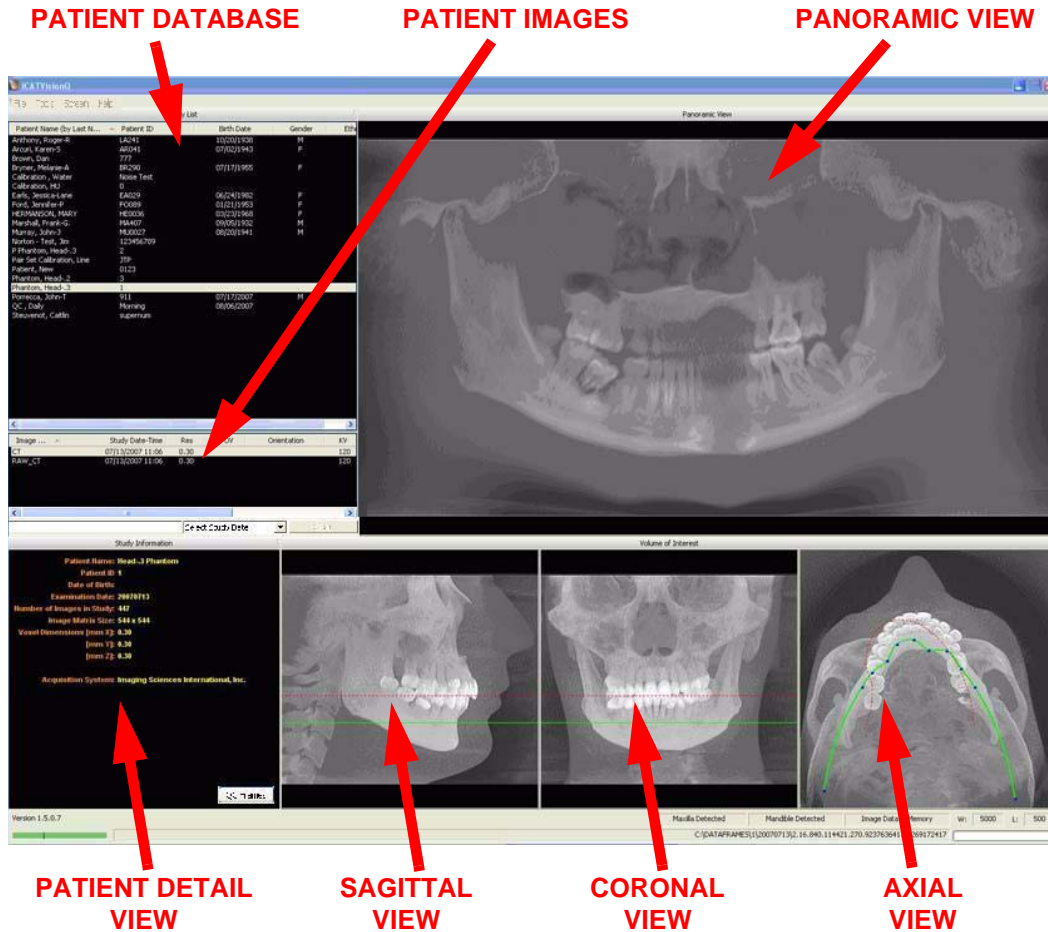


### **CAUTION**

DO NOT do anything in a Patient study until the status bar located at the bottom right of the window indicates that the Patient data is fully loaded. Wait until the status bar reads "Image Data in Memory" prior to performing any tasks. Otherwise, data loss may occur.



Once data is successfully reconstructed, the Preview screen appears as shown below, showing the Panoramic, Sagittal, Coronal, and Axial views of the skull through midline.



The Preview Screen is divided into seven views:

- Patients in Database
- Patient Images
- Patient Detail View
- Panoramic View
- Sagittal View
- Coronal View
- Axial View

**Patients in Database** lists all Patients and their data who are entered into the database.



**Patient Images** lists all images that pertain to the selected (highlighted) Patient from the *Patients in Database* list.

**Patient Detail View** shows detailed Patient data, including acquisition details for the currently selected Patient workup that is highlighted in the *Patients in Database* list.

**Panoramic View** shows a wide detail view of the selected points on the Axial View. Distance and Hounsfield Unit measurements can be taken on this view. Double-clicking the Panoramic View brings up the Implant Planning Screen.

**Sagittal View** displays the Maxilla and Mandible contour lines. Distance and Hounsfield Unit measurements can be taken on this view. Double-clicking on the Sagittal View brings up the Ceph Screen.

**Coronal View** also displays the Maxilla and Mandible contour lines. Distance and Hounsfield Unit measurements can be taken on this view. Double-clicking on the Coronal View brings up the MPR Screen.

**Axial View** controls the image displayed in the Panoramic View. Distance and Hounsfield Unit measurements are taken on this view. Double-clicking the Axial View brings up the TMJ Screen.

See the remainder of this chapter for details on taking measurements, modifying the displayed information, and changing filter settings etc.

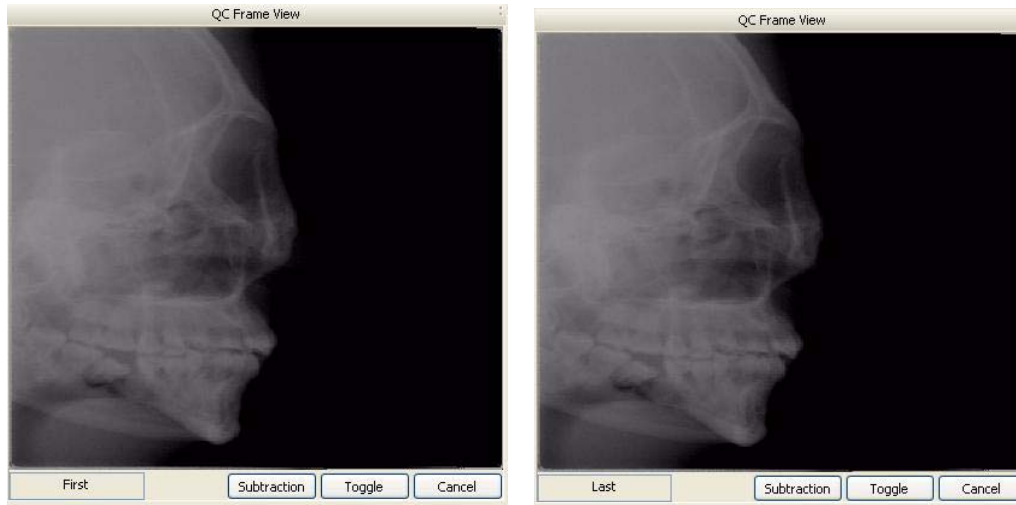
## ***Using Quality Control Frames***

QC frames can be used to help detect patient movement during a scan.

### **To use QC Frames:**

1. With a study selected, click **QC Frames** on the Patient Detail view. The first image of the selected scan is displayed.

2. Click **Toggle** to display the last image of the scan. Toggle as needed to compare first and last frames. Frames should look identical if patient did not move.



3. Click **Subtraction**. Values for motion factor (Mf) and brightness density (Bd) are displayed.
  - The Mf and Bd values are intended to be used by Technical Support to help diagnose image quality issues.
  - In general, Mf values below 80 indicate no visible motion between the first and last scan. However, values above 80 do not mean a rescan is required. Use your professional judgement as to whether the scan is acceptable.
  - Bd values are not as important for motion assessment, but values below 50 are generally good.



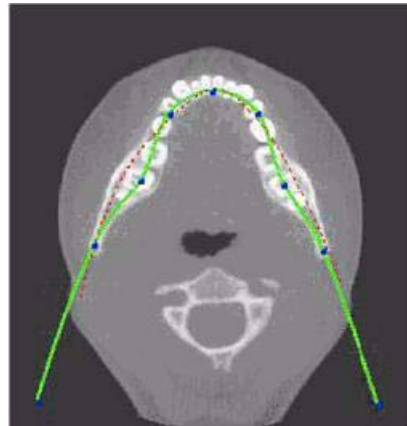
4. Click **Cancel** to exit QC Frames.

## *Adjusting the Panoramic View*

The Axial View is used to adjust the displayed image in the Panoramic View.

### **To adjust the Panoramic View:**

1. Select whether the Maxilla or Mandible Contour Line is used as the Panoramic View adjustment reference by clicking on the desired contour line in the Sagittal or Coronal View. The selected Contour Line is shown as a solid line; the line which is not currently selected is shown as a dotted line. The displayed line in the Axial View matches the color of the selected Contour Line in the Sagittal and Coronal Views.
2. Center the anterior point at midline.
3. Move the next two points up closer to the anterior point on each side. Place them a few teeth away from anterior center.
4. Then move the next two points closer to the molars. See the example below.

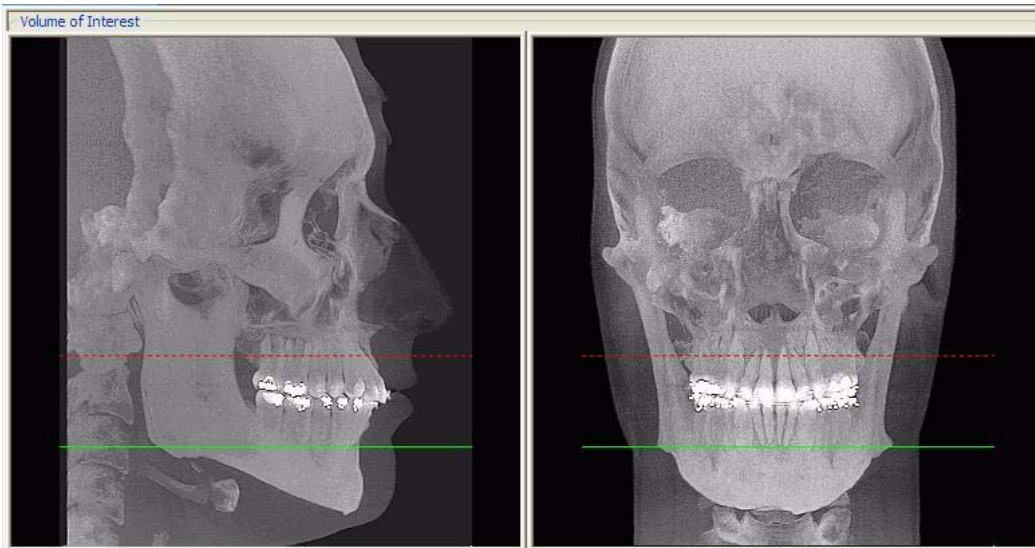


All changes are reflected in the Panoramic View.

## *Contourline Setup*

Contourlines are used to mark the Maxilla and Mandible in the Sagittal and Coronal Views on the preview screen.

- **Maxilla** is a **red** line
- **Mandible** is a **green** line.



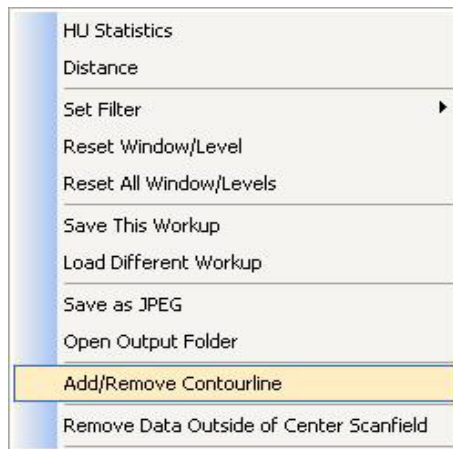
Both the Maxilla and Mandible Contourlines can be repositioned with a click and drag to the desired location.



Clicking a Contour Line selects that line for use in adjusting the Panoramic View via the Axial View.

One or both Contourlines can be added/removed from the Sagittal and Coronal Views on the preview screen. To do this, do the following:

1. On an image view on the Preview screen, right-click and select **Add/Remove Contourline**.



2. Click check boxes to add or remove Contourlines.



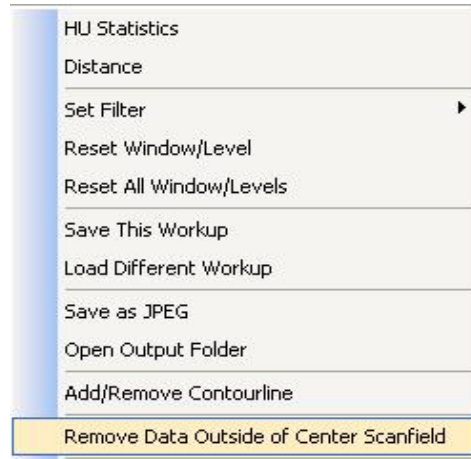
3. Click **OK**. The dialog box closes and the selected settings are used for the Sagittal, Coronal, and Axial views.



### ***Removing Circumference Artifacts***

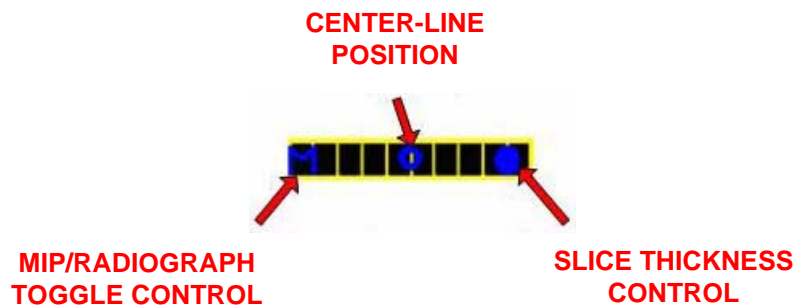
Circumference Artifacts are displayed in the Preview Screen as horizontal lines in the Coronal and Sagittal views and a white partial circle around the Axial View.

This artifact can be removed from the dataset by right clicking the Preview Screen and selecting **Remove Data Outside of Center Scanfield**. The data is recalculated without the artifact.



## Adjusting MIP, Centerline and Image Type

The following slice control bar is found in various views and positions throughout the system software.



- **Center-Line Position** - click and drag the *Center-Line Position* tool moves the displayed centerline of the selected image. This changes the selected position of subordinate images.
- **MIP/Radiograph Toggle Control** - clicking the *MIP/Radiograph Toggle Control* toggles the images displayed between MIP and Radiograph.
- **Slice Thickness Control** - click and drag the *Slice Thickness Control* right/left increases/decreases slice thickness and spacing (respectively).

**NOTE:** The Slice Thickness of each view is at the Voxel size originally scanned. For example, if scanned at a 0.3 Voxel size, the slice thickness is 0.3. If scanned at a Voxel size of 0.4, the slice thickness is 0.4

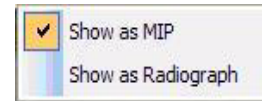
## Selecting MIP or Radiograph Display

The system software enables displaying images as MIP or Radiograph.



**To select the type of image displayed:**

1. Move cursor to the top right of any of the image views on the preview screen. The cursor becomes an **M**.
2. Click mouse while cursor is an **M** and the following popup window appears.
3. Click the menu item corresponding to the desired image type. (The currently selected image type is denoted with a checkmark.)



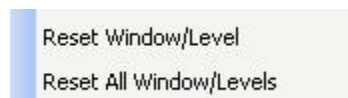
## Adjusting Brightness and Contrast

All views include a window level Brightness/Contrast cursor tool. By default, this cursor is displayed. When cursor appears as shown, click and drag up/down and left/right to adjust brightness and contrast.



- **Brightness** - left and right.
- **Contrast** - up and down.

**NOTE:** If brightness and contrast are changed, they can be reset for the specific window/level, or for all window/levels that were affected, using the reset options on the pop up menu.



## ***Pan Feature***

Most views allow panning left, right, up, or down in order to view a desired portion of the displayed image.



### **To use the pan feature:**

1. Move the cursor to the bottom left of the image where the pan function is to be used. The pan cursor tool appears.
2. Click and drag up/down and left/right to pan to the desired portion of the displayed image.

## ***Rotation Feature***

The Sagittal, Coronal and/or Axial views can be rotated.

### **To use rotate feature:**

1. Hover the cursor over the lower right corner of the desired view. The cursor changes to the rotation tool.
2. Using the rotation tool, click and drag to rotate the selected image. A grid appears over the selected image to provide a reference for rotation.



## ***Zoom Feature***

Most views allow zooming in and out to view more or less detail for the displayed image.



### **To use the zoom feature:**

1. Move the cursor to the bottom right of the image where the zoom function is to be used. The zoom cursor tool appears.
2. Click and drag up and down to zoom in and out, respectively.

## ***Back Tool***

When viewing one of the detail screens, the X cursor can be used to return to the preview screen.



### **To exit the detail screen and return to the preview screen:**

1. Move cursor to the top left corner of the screen until the cursor becomes an **X**.



2. While the cursor is an **X**, click mouse to return to the preview screen.

This can also be performed by clicking **Screen>Preview Screen** on menu bar.

## *Filter Settings*

Filtering is provided for all image views. Images can be softened/ sharpened as desired by selecting one of five filter settings (**Normal**, **Sharpen Mild**, **Hard**, **Sharp** or **Very Sharp**).

Default filter values are selected for all screens as follows:

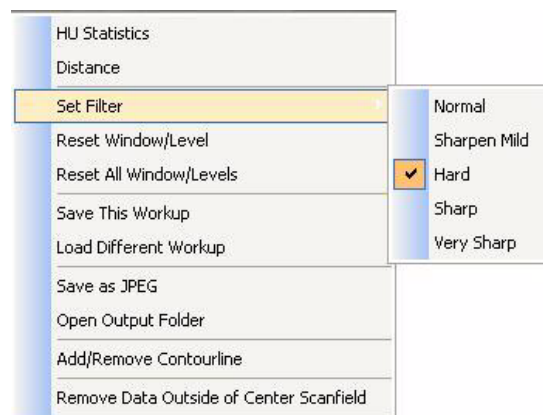
- Preview Screen: **Hard** on Panoramic and **Sharpen Mild** for all others.
- Implant Screen: **Sharpen Mild** on Axial Slice and Cross Sections - **Hard** on Panoramic Map.
- TMJ Screen: **Hard** for top row images and **Sharpen Mild** for Condyle Ceph Images.
- MPR Screen: **Sharpen Mild** all images.
- Ceph Screen: **Sharp** for Upper Left Right Lateral and **Hard** for all others.

These defaults can always be changed by using one of the methods described below.

## *Setting Filters for a Single Image*

**To change the filter setting for an individual image:**

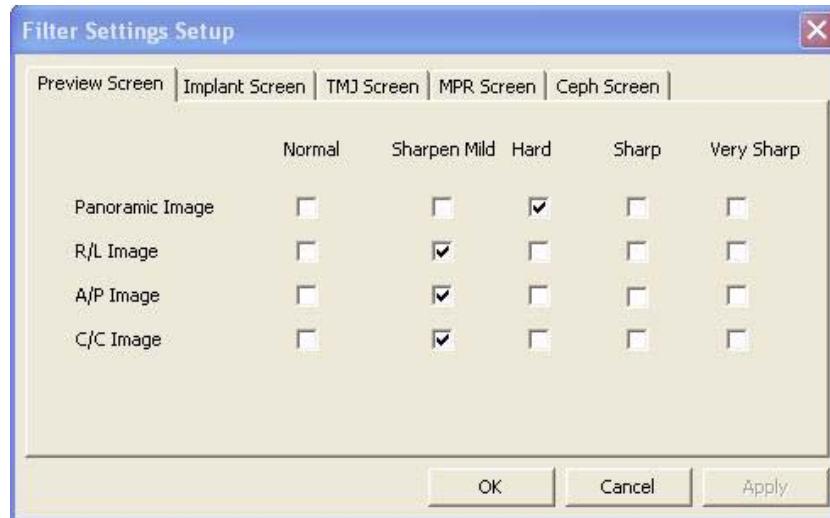
1. Right-click image and select **Set Filter >** and select filter setting. The selected filter setting is applied.



## Setting Filters for One or More Image Types

To change the filter setting for one or more image types:

1. From the Main menu, select **Tools > Filter Settings > Set Filters**



2. Select a tab at the top of the dialog box which contains the screen to change the filter setting.
3. Select check boxes to change the filter settings.
4. Click **OK**. The dialog box closes and the selected filter settings are applied.

## Resetting all Filters to the Default Values

To reset filters to the default values:

1. From the Main menu, select **Tools > Filter Settings > Reset To Default**.



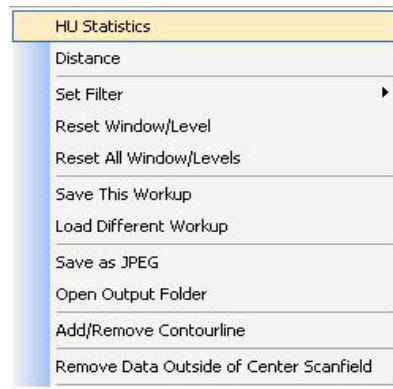
2. Click **Yes**. The dialog box closes and all filter settings are set to the default.

## Taking Measurements

### Hounsfield Units

The system software allows making measurements in Hounsfield Units (Shape Region) for all image views. These measurements calculate and display the average (Mean) grayscale level of the area enclosed from -1000 to 3000 (where 0 equals the density of water). The Standard Deviation is also calculated, where the smaller the number, the closer each shade of gray is in density to the others in the enclosed area.

1. To make an HU measurement, right click image and select **HU Statistics**.



The menu closes and the cursor changes to the **hu** measurement symbol.



2. Click, drag, and click to define an area. Measurement statistics appear in the upper right corner of the image.



- Repeat steps 2 and 3 to take additional measurements. A maximum of four HU measurements can be taken at a time in a normal view and two in a cross section view. Additional measurements are displayed in varying colors so that they can be easily associated with the selected image area.



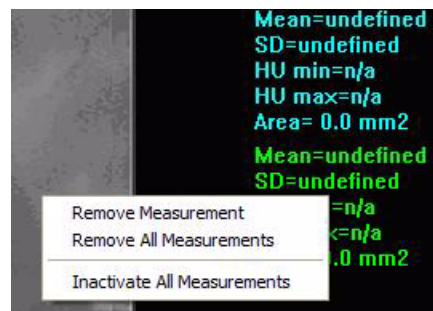
**To switch off the hu cursor:**

- Right click the image. A popup window appears.
- Click **HU Statistics** on the popup menu. The menu closes and the cursor reverts to the default cursor.

Measurements can be selectively removed from a view as desired. All measurements can also be deactivated/reactivated for a view.

**To remove a specific measurement:**

- Right-click the measurement that is to be removed.
- Select **Remove Measurement** from the popup menu.



**Remove All Measurements** - removes all measurements from selected view.

**Inactivate All Measurements** - grays out all measurement indicators and removes the measurements from the selected view. When this is done, the *Reactivate All Measurements* becomes available.

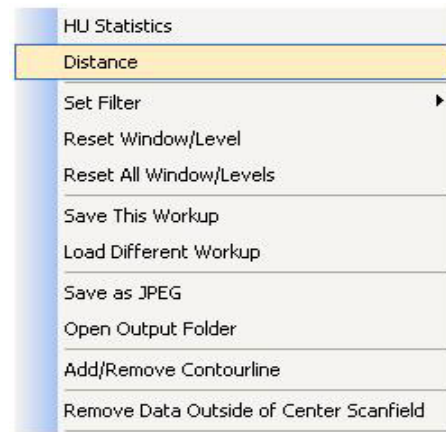
**Reactivate All Measurements** - restores all of the inactivated measurements to the selected view.

## *Distance*

The system software allows making distance (linear) measurements for all image views. These measurements calculate and display the average (Mean) grayscale level of the area enclosed from -1000 to 3000 (where 0 equals the density of water). The Standard Deviation is also calculated, where the smaller the number, the closer each shade of gray is in density to the others in the enclosed area.

**To make a linear (distance) measurement:**

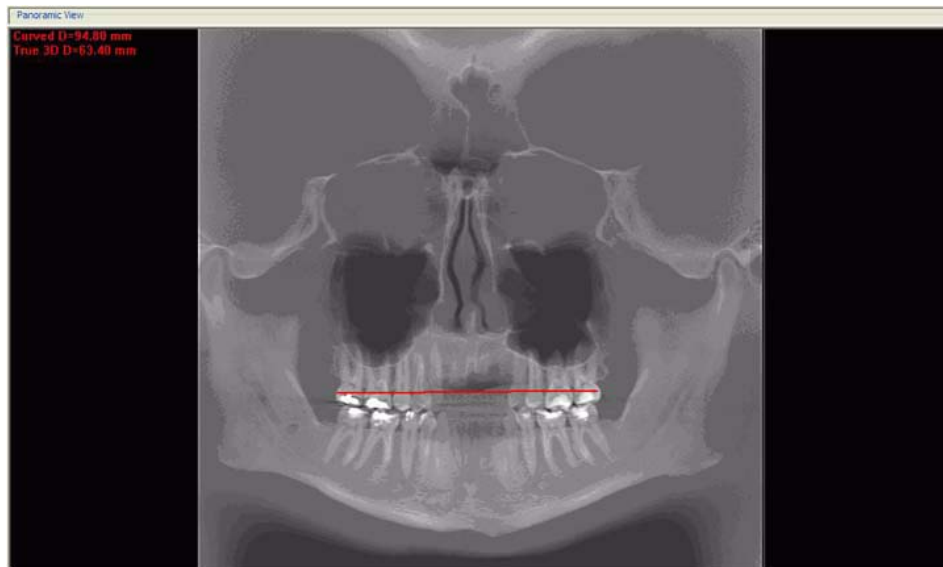
1. To make a measurement, right click image and select **Distance**.



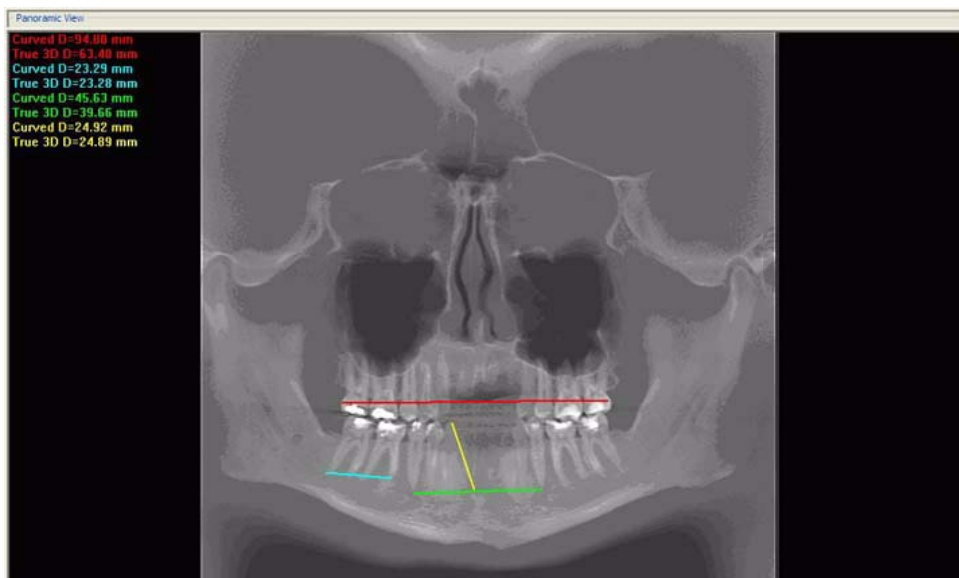
The menu closes and the cursor changes to the distance measurement symbol.



2. Click, drag, and click to define the measurement. Measurement statistics appear in the upper left corner of the image.



3. Repeat steps 2 and 3 to take additional measurements. A maximum of nine distance measurements can be taken at a time in a normal view and four in a cross section view. Additional measurements are displayed in varying colors so that they can be easily associated with the selected measurement.



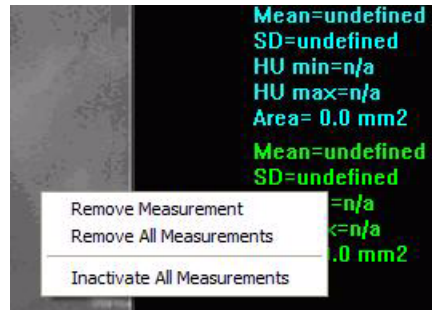
**To switch off the distance cursor:**

1. Right click the image and select **Distance**. The cursor reverts to the default cursor.

To remove a specific measurement:

Measurements can be selectively removed from a view as desired. All measurements can also be deactivated/reactivated for a view.

1. Right-click the measurement to be removed and select **Remove Measurement**.



**Remove All Measurements** - removes all measurements from selected view.


**Inactivate All Measurements** - grays out all measurement indicators and removes the measurements from the selected view. When this is done, the *Reactivate All Measurements* becomes available.

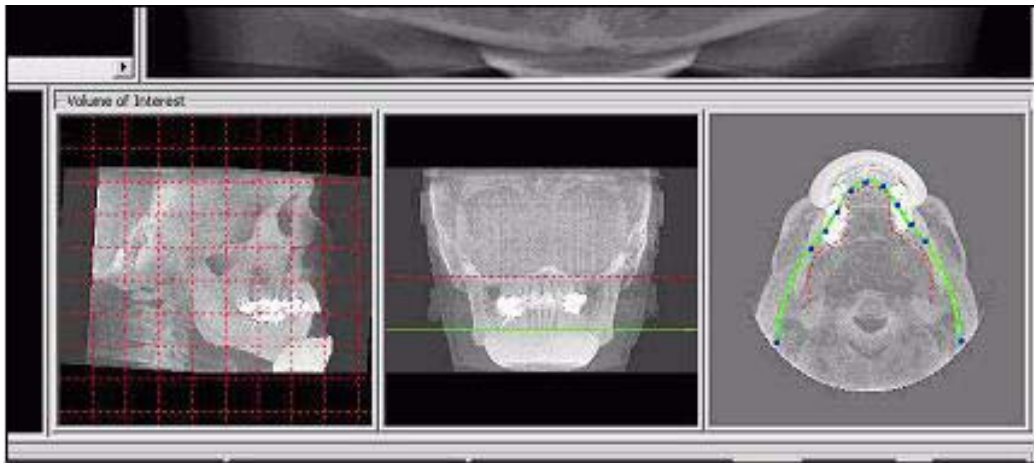
**Reactivate All Measurements** - restores all of the inactivated measurements to the selected view.

## Rotating Views

The Sagittal, Coronal and/or Axial views can be rotated.

### To rotate a view:

1. Hover the cursor over the lower right corner of the desired view. The cursor changes to the rotation tool. 
2. Using the rotation tool, click and drag to rotate the selected image. A grid appears over the selected image to provide a reference for rotation.

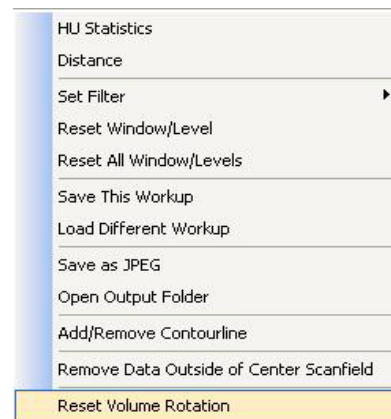


3. After the selected image is rotated, release the mouse. All views adjust to the new position and the grid is no longer present.

### To return to the original rotation orientation:

4. Right click image and select **Reset Volume Rotation**.

The menu closes and the software recalculates the original rotation in all views.





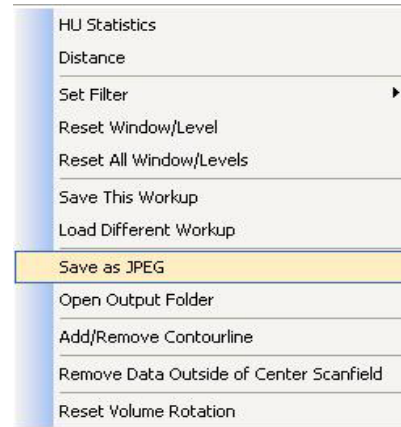
## Saving Views as JPEG Image Files

Data in any view in Vision can be saved as a JPEG image file.

### To save view as a JPEG Image File:

1. Right click image and select **Save as JPEG**.

The file is named and saved into a customized directory based on the type of image currently selected, Patient name, and other details.



### To open directory where image was saved:

2. Right click image and select **Open Output Folder**.

Microsoft Internet Explorer opens to the selected directory.

## Saving and Loading Workups

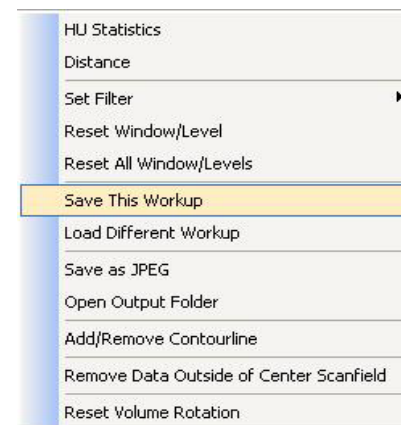
Modifications made to reconstructed Patient data (Case Studies), are named and saved as a *Workup*.

Workups allow the retrieval of various modifications, markups, measurements, etc. made to previously modified *Detail Screens*.

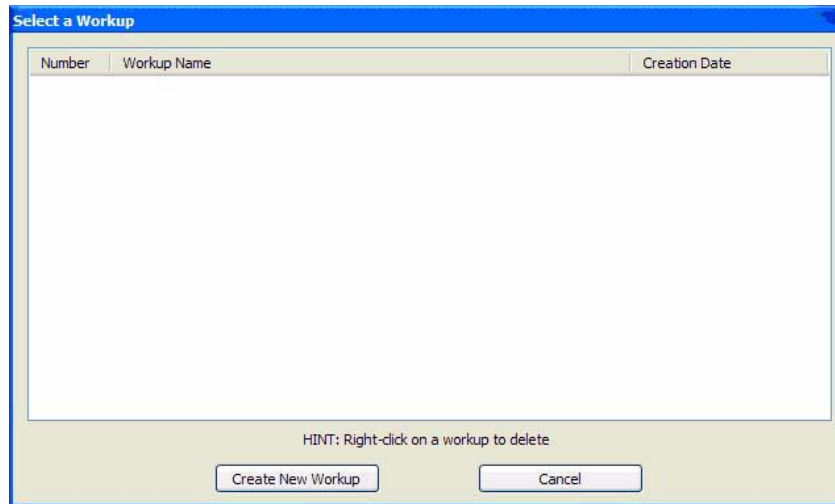
### Save a Workup

#### To save the currently displayed data (Case Study) as a Workup:

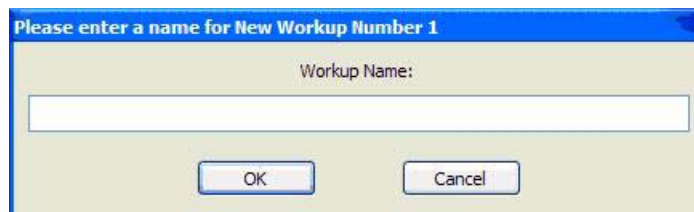
1. Right-click any image on the Preview screen and select **Save This Workup**.



2. Then do one of the following:



a. Click **Create New Workup**.

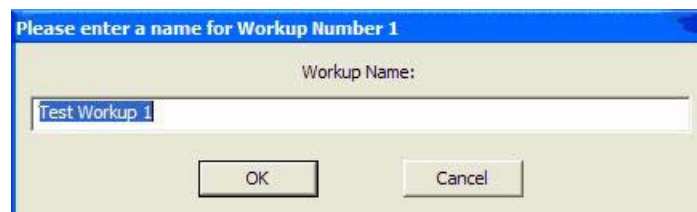


b. Enter a name for the new workup in the *Workup Name:* field.

c. Click **OK**. The dialog box closes and the new workup is displayed on the *Select a Workup* dialog box.

- or -

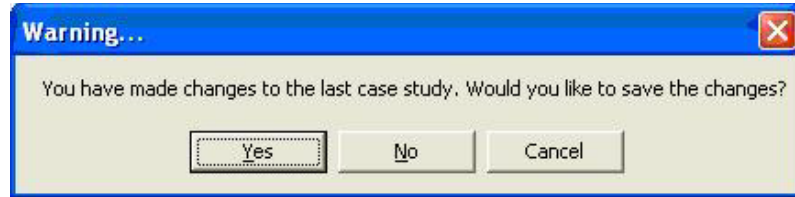
a. Overwrite an existing workup by clicking an existing Workup Name.



b. Click **OK**. The dialog box closes and the new workup is displayed on the *Select a Workup* dialog box.

3. Click **Cancel** to close the *Select a Workup* dialog box.

If a workup was made or changed and an attempt is made to close the Vision software or switch to a different Patient, the following dialog box appears.

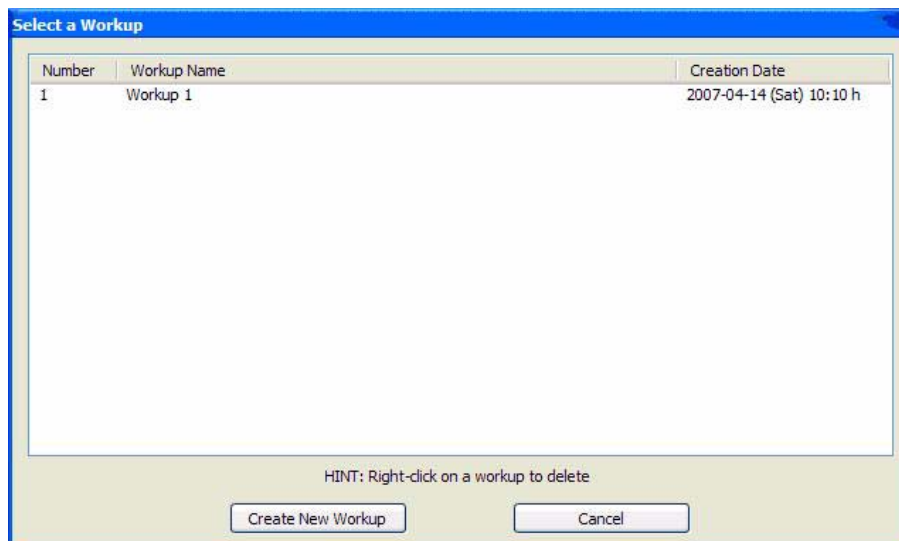
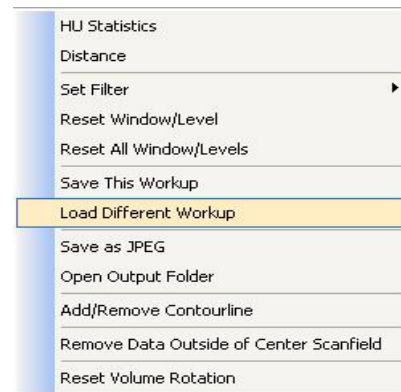


To save the changes made, click **Yes**. The Select a Workup dialog box appears. Continue the save procedure as described above.

### *Load an Existing Workup*

**To load an existing workup for a Patient with multiple workups:**

1. Right-click any image on Preview screen and select **Load Different Workup**.

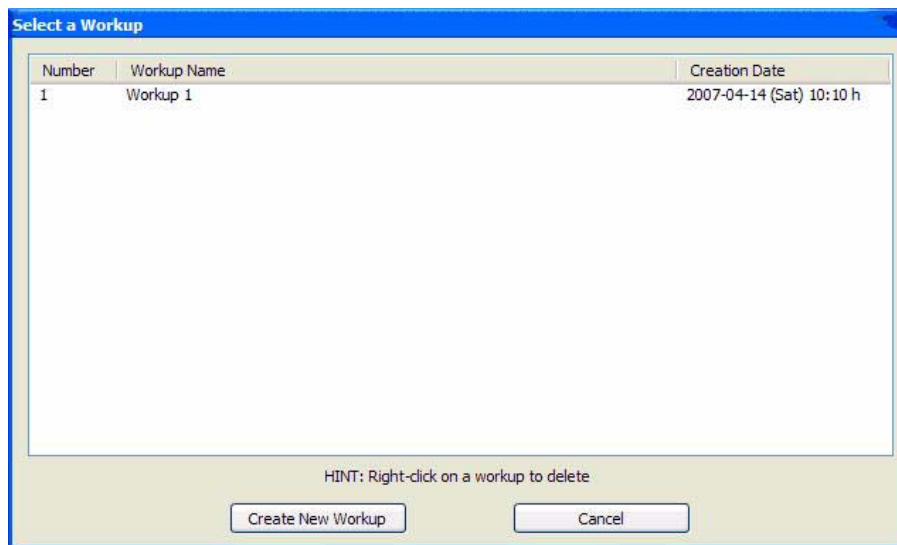
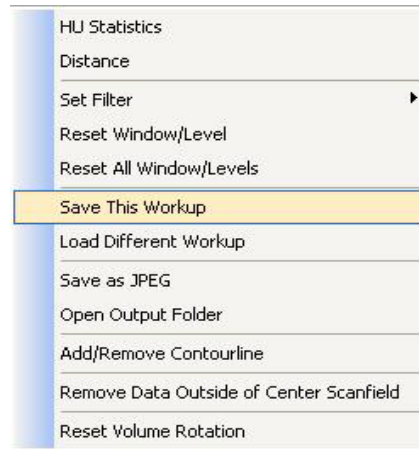


2. Double-click Workup Name. The dialog box closes and the existing workup is loaded.

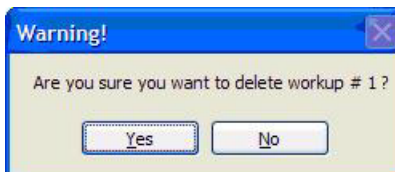
## Delete an Existing Workup

To delete an existing workup:

1. Right-click any image on Preview screen and select **Save This Workup**.



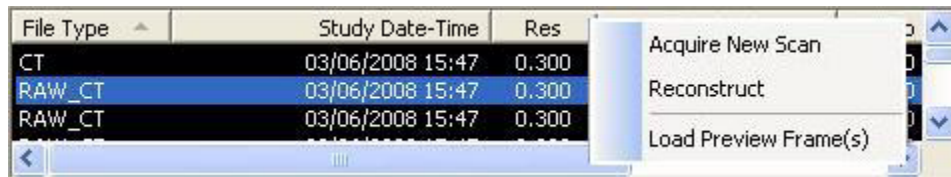
2. Right-click the Workup to delete.



3. Click **Yes**. The dialog box closes and the selected Workup is deleted.
4. Click **Cancel** to close.

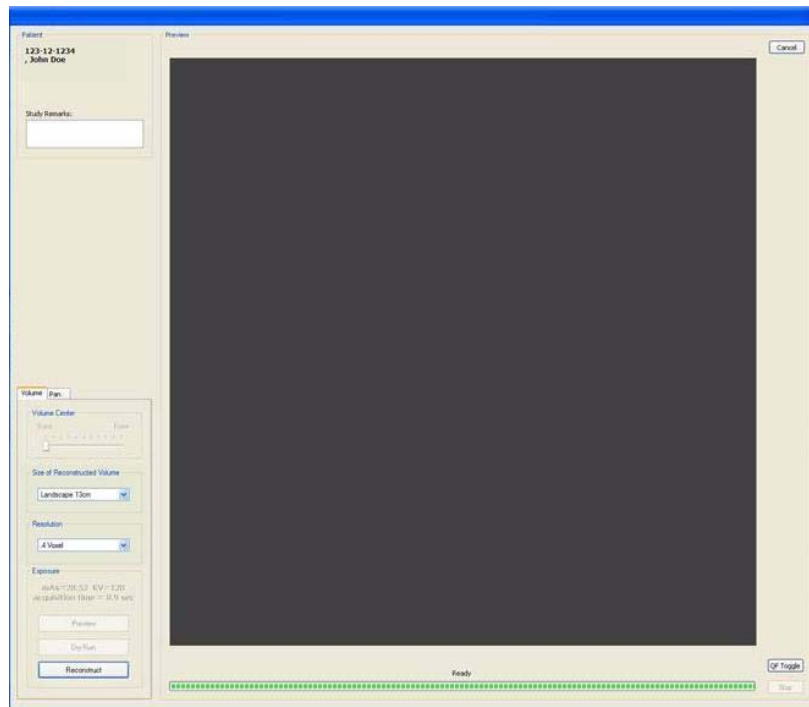
## Viewing and Reconstructing Raw Patient Scans

Raw scan data that is displayed in the Patient Images section can be reconstructed using different volume and resolution parameters, and preview scans can be viewed and manipulated.



### To Reconstruct Raw Images:

1. Right-click on Raw scan and select **Reconstruct**. Reconstruct screen is displayed

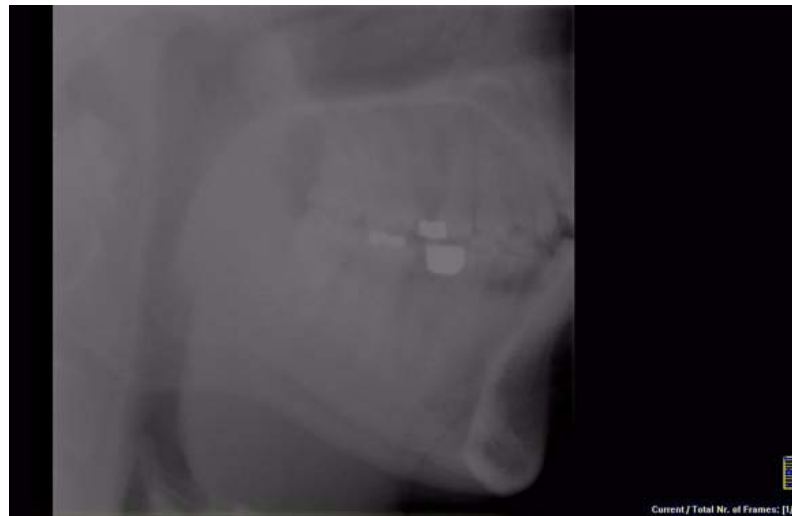


2. Select the Size of Reconstruction Volume from the drop-down menu. Sizes available for selection are limited based on the field of view captured in the original scan.
3. Select a Resolution from the drop-down menu. Resolutions available for selection are limited as follows:
  - Scans taken at 0.3 or 0.4 can be reconstructed at 0.3 or 0.4.

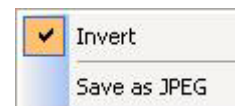
- Scans taken at 0.2 or 0.25 can be reconstructed at 0.2 or 0.25.
4. Click **Reconstruct**. The raw DICOM images are reconstructed as specified.

**To Load Preview Frames:**

1. Right-click on Raw scan and select **Load Preview Frame(s)**. Preview screen is displayed.



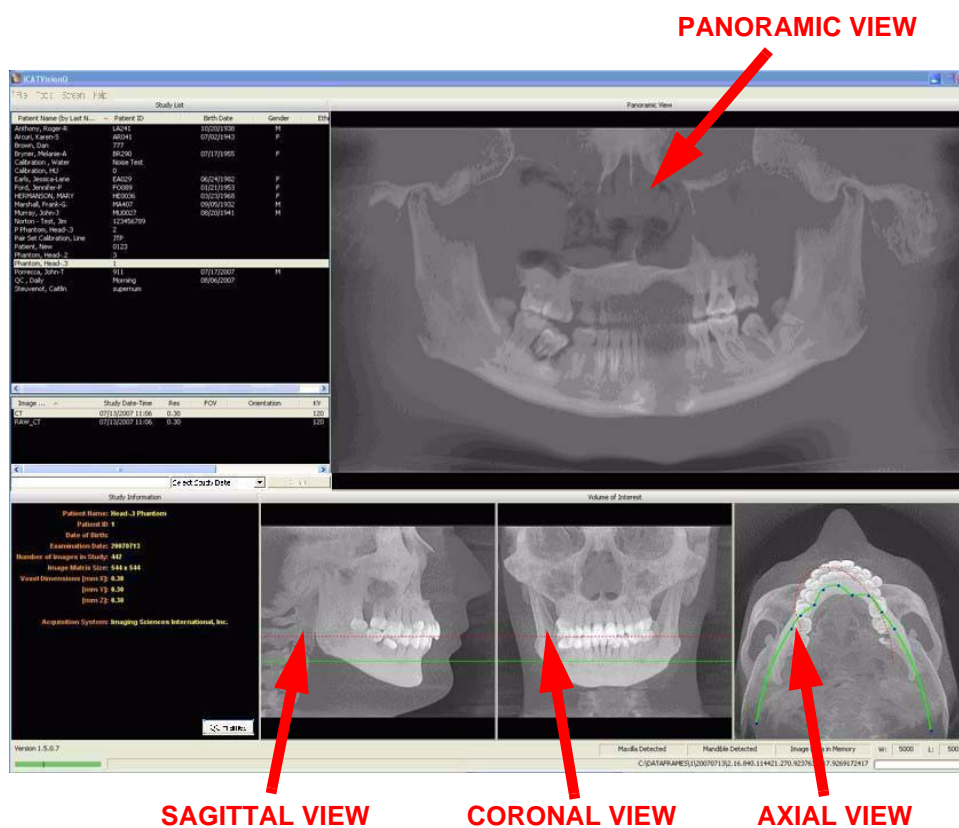
2. Image can be manipulated as follows using the features described earlier in this chapter:
  - Adjust brightness and contrast
  - Zoom
  - Pan
  - Scroll between first and last frame
3. Right-click on the image to:
  - **Invert** - Toggle between MIP and Radiograph.
  - **Save as JPEG** - Select a location on the computer to save the image as a JPEG file.
4. To return to the Preview screen, click **Screen > Preview Screen**.



# Chapter 8 Detail Screens

## Preview Screen

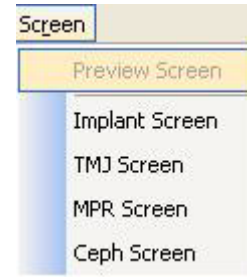
All Detail Screens are accessed by double-clicking a corresponding view on the Preview Screen. To correlate the mouse position on the Preview screen to the Sagittal, Coronal, and Axial views, hold down the **C** key on keyboard and move the mouse. A yellow mark shows the correlated positions on the other views.



- **Panoramic View** - double-click displays the Implant Planning Screen.
- **Sagittal View** - double-click displays the Ceph Screen.

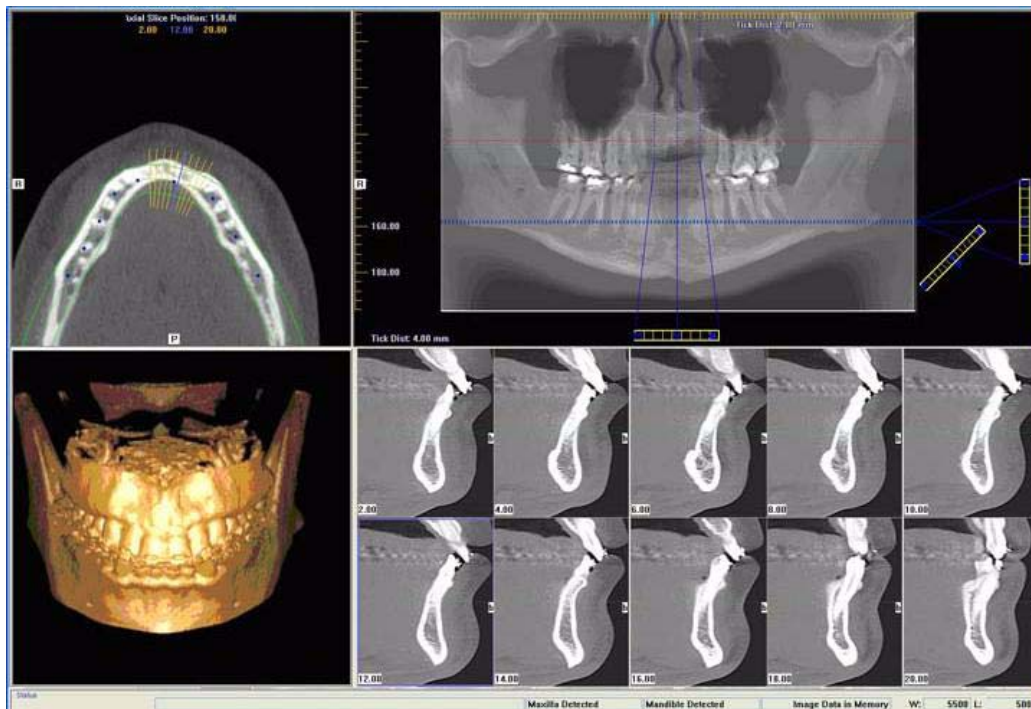
- **Coronal View** - double-click displays the MPR Screen.
- **Axial View** - double-click displays the TMJ Screen.

Detail screens can also be selected from the Screen menu accessed from the top menu bar. This enables movement from one detail screen to another without having to access the Preview screen.



## Implant Planning Screen

Double-clicking the Panoramic View on the Preview Screen displays the Implant Planning Screen.



The Implant Planning Screen is divided into four viewing areas:

- **Axial Slice Position View (upper left)** used to adjust the panoramic map view (upper right). The mouse scroll wheel is active to scroll through the slices.
- **Panoramic Map View (upper right)** used to modify the position of the axial views (which are represented on the



axial slice position view) and modify the criteria used to generate the axial views (lower right).

- **3D Model View (lower left)** shows a three-dimensional representation of the anatomy of interest displayed on the Implant Panning Screen. Dragging the cursor across the image rotates the 3D image in the direction of the cursor. Double right click-and-hold the mouse button horizontally rotates the image. The mouse scroll wheel is active to scroll through the slices.
- **Cross Section Views (lower right)** shows cross section details of the anatomy of interest as specified on the axial slice position view and the panoramic map view. The mouse scroll wheel is active to scroll through the slices.

Patient position indicators are used on the Implant Planning Screen to indicate the orientation of the displayed data. These are:

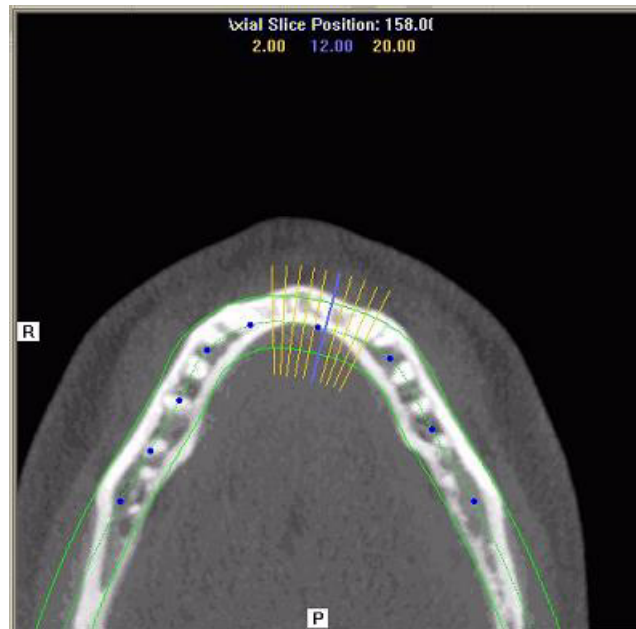
**R** = Right Side

**P** = Posterior

**B** = Buccal

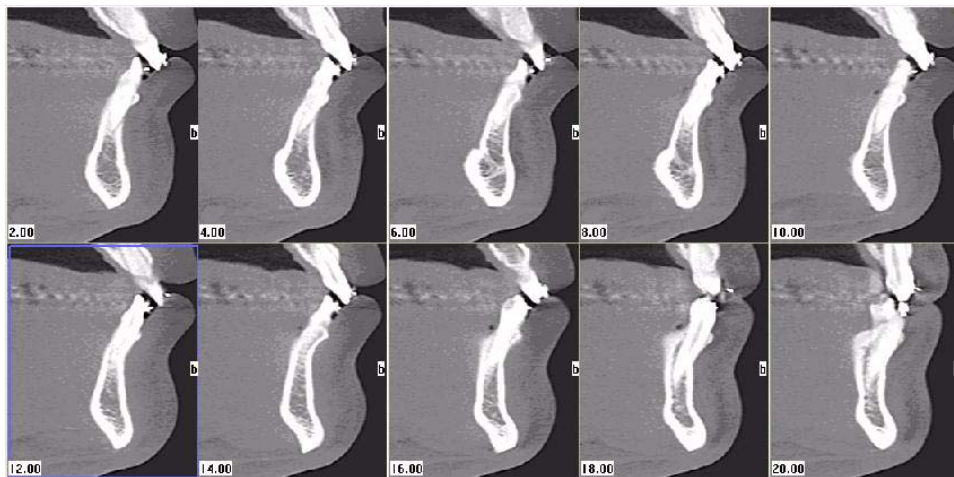
**To use the Implant Planning Screen:**

1. Click and drag the blue dots on the axial slice position view to adjust the image displayed on the panoramic map view.



To correlate the mouse position on the axial slice position view to the panoramic map view, hold down the **C** key on keyboard and move the mouse. A yellow mark shows the correlated position.

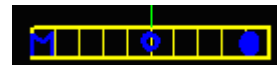
The blue hash mark represents the center line of the axial slices displayed on the cross section views. (The corresponding center cross section slice is displayed with a blue frame in the cross section views.) The orange hash marks represent the other axial slices displayed on the cross section views. At the top of the axial slice position view, the positions of the rightmost axial cross section, center cross section, and leftmost cross section are displayed.

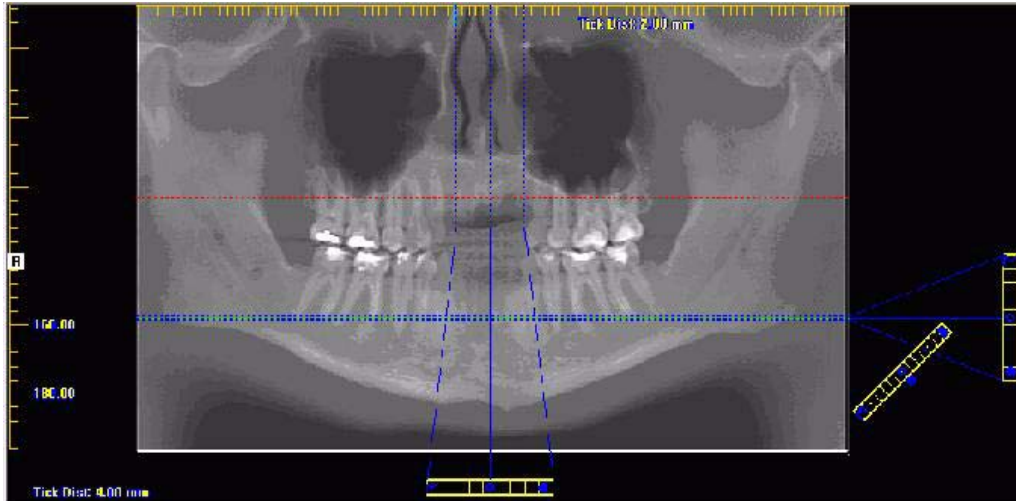


The cross section views are located as indicated by the hash marks displayed in the axial slice position view. If the 0.00 position is displayed, it is outlined in red. All slices to the patient's right side are displayed as negative numbers. All slices to the patient's left side are displayed as positive numbers.

2. Use the panoramic map view to modify the position of the cross section views (which are represented on the axial slice position view) and modify the criteria used to generate the cross section views (at the lower right of the Implant Planning Screen):

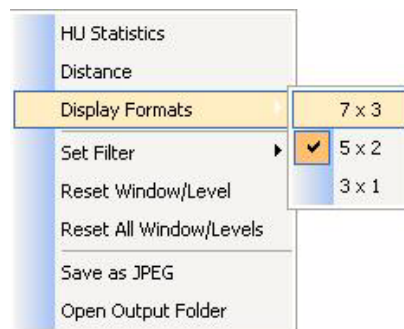
- a. Drag the **O** in the center of the horizontal toolbar (bottom of view) left or right to change the location of the center axial cross section. Changes made here are reflected on the axial slice position view and the cross section views.





- b. Drag the solid dot on the right side of the diagonal toolbar (bottom right) to adjust the slice thickness displayed on the panoramic map view.
  - c. Drag the **O** in the center of the diagonal toolbar to adjust the pan focal trough.
  - d. Drag the **O** in the center of the vertical toolbar (right side of view) up or down to change the height of anatomy viewed in the cross section views. Changes made here are reflected on the axial slice position view and the cross section views.
  - e. Drag the solid dot on the right side of the vertical toolbar to adjust the slice thickness displayed on the cross section views. Changes made here are reflected on the cross section views.
3. Individual cross section images can be zoomed in by double-clicking them. Double-clicking again returns the image to normal zoom.

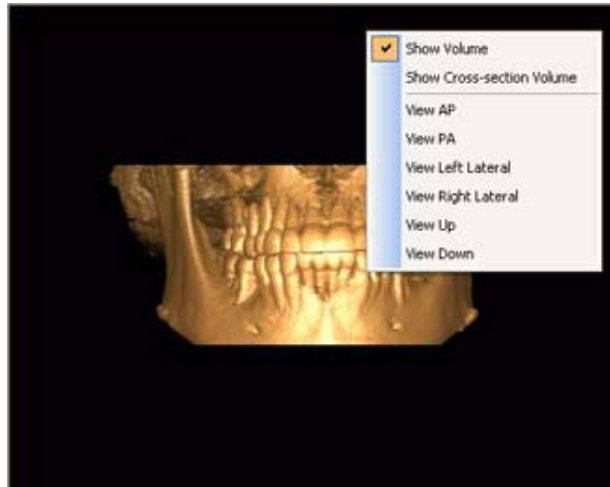
4. Right-clicking on a cross section brings up a popup menu. Selecting one of the submenu items from the Display Formats menu item changes the number of displayed cross sections to correspond to the selected submenu item. For example, selecting the 3 x 1 menu item



causes the Implant Planning Screen to include three cross section images in a single row.

### To Use the 3D Model View

1. Right-click in the 3D Model view to display a popup menu.



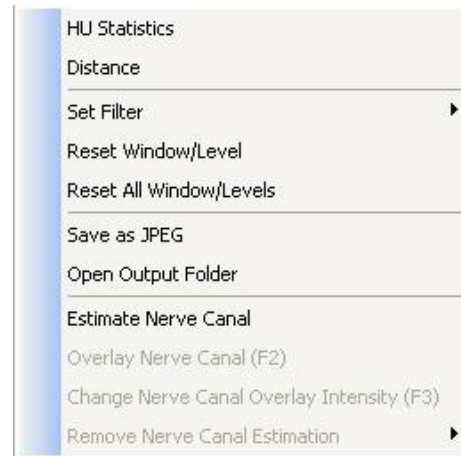
2. Select desired option to change the view.
  - Show Volume - Displays a full 3D volume model of the image area displayed between the red and green lines on the Panoramic Map View. To change the view, adjust the lines and select Show Volume option.
  - Show Cross-section Volume - Displays a cross-section of the 3D volume model for the cross section that is selected on the Panoramic Map View. To change the view, adjust the cross section and select Show Cross-section Volume option.

The remaining options change the view as follows for either the full volume or cross-section model.

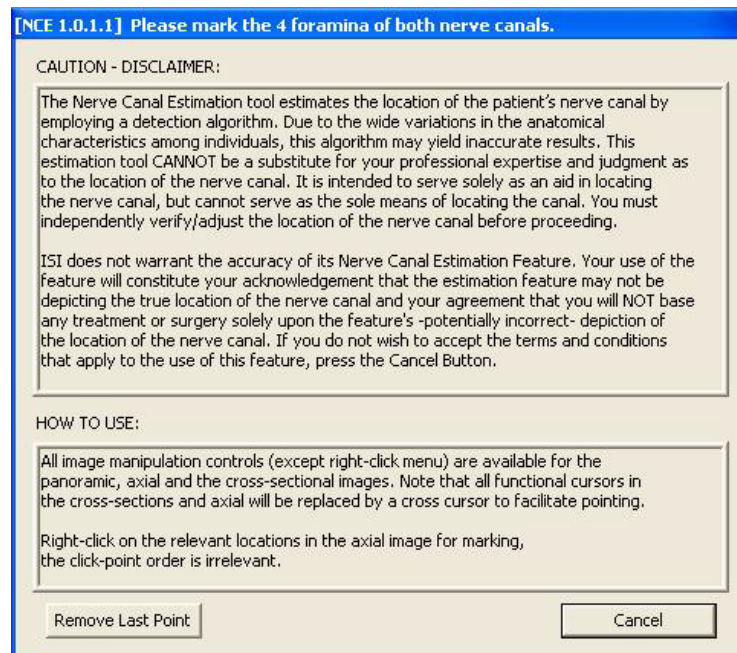
- View AP - Displays view from anterior to posterior.
  - View PA - Displays view from posterior to anterior.
  - View Left Lateral - Displays lateral view of model from left.
  - View Right Lateral - Displays lateral view of model from right.
  - View Up - Displays model from the bottom looking up.
  - View Down - Displays model from the top looking down.
3. To rotate any of the views, click on the view and drag in any direction.

## Estimate the Nerve Canal

1. From the Implant Planning view, right-click to select **Estimate Nerve Canal**.

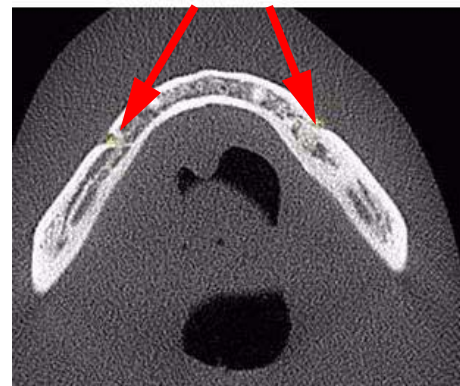
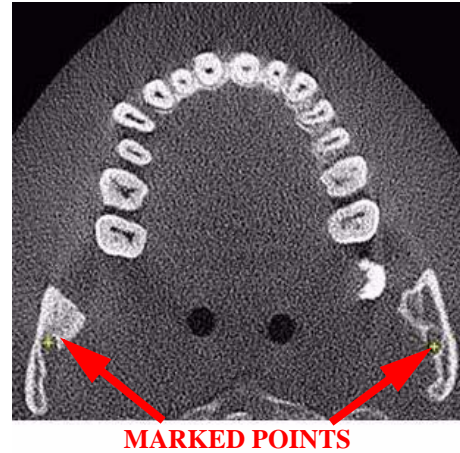


The nerve canal dialog is displayed.



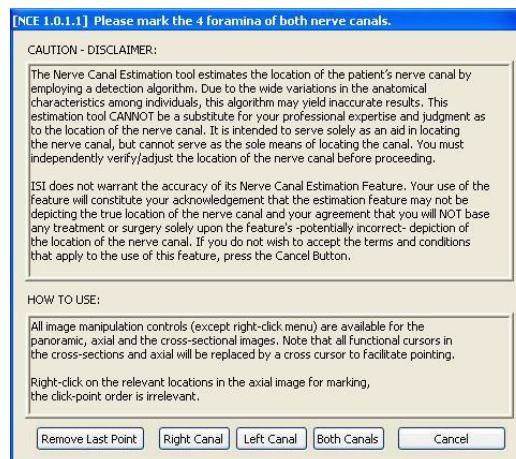


2. Manipulate the axial view to locate the anterior left and right nerve canals.
3. Right-click to mark the relevant points on the axial view. The click and point order is irrelevant. A cross is displayed marking each point selected on both the axial and panoramic map view.
4. To remove a point, click **Remove Last Point**. Points are removed in last-created to first-created order.
5. Repeat steps 2 through 4 to mark the posterior left and right nerve canals.



**NOTE:** To quickly move from anterior to posterior foramina, hold down the **Ctrl** key and scroll the mouse wheel 2 to 3 times. From there, fine tune the position with the mouse wheel.

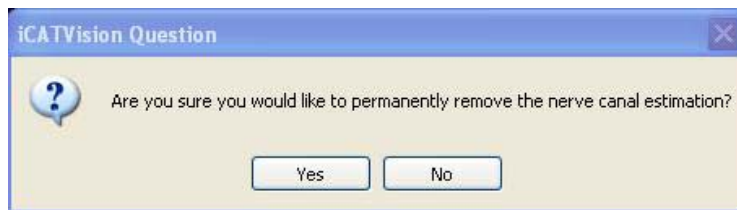
6. When all points are selected for right, left or both canals, one or all of the following buttons are displayed. Click desired button to confirm the marking of the selected nerve canal(s). The canals are calculated and displayed on the panoramic map view.



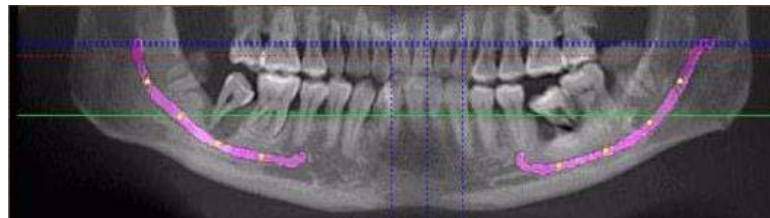
7. If there is an error calculating either of the nerve canals, a dialog is displayed. Click **OK** on dialog..



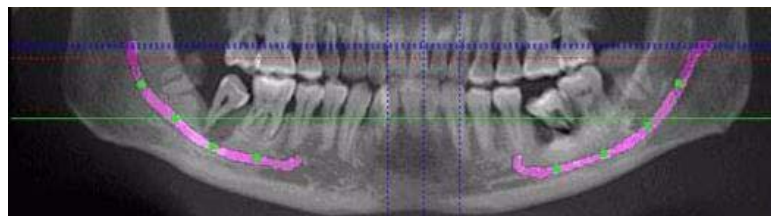
- a. To begin the entire canal estimation again, click **Cancel**. On the resulting dialog, click **Yes** to remove the estimation..



- b. If one of the canal estimations was calculated, and you want to confirm it, continue with next step.
8. On the panoramic map view, click the yellow circles to verify the nerve canal estimation. Each circle turns green when verified.

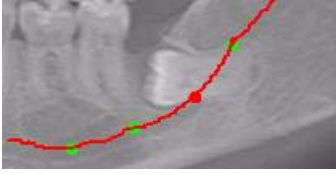


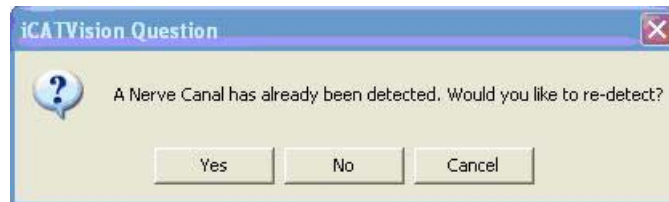
**BEFORE POSITIONS ARE VERIFIED**



**AFTER POSITIONS ARE VERIFIED**

**NOTE:** The canal location should be visually verified along the length of the canal. It is recommended that the overlay is removed, and the pan contour line is adjusted if necessary to clearly visualize the canal. Once the canal is distinctly visualized, the accuracy of the estimated path can be confirmed, or adjusted if necessary.

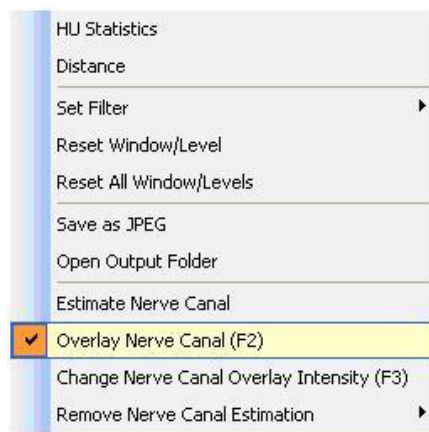
9. To adjust the path, click and drag circles to the desired locations. A red line is displayed to highlight the new canal estimation.
 
10. To reset any adjustments to the nerve canal estimation, click **Reset**. The panoramic map view is reset to the state before positions were verified.
11. To confirm a nerve canal estimate after position of circles are verified, click **Confirm**. The marked canals can be viewed on the axial, panoramic map and cross section views.
12. To save the workup:
  - a. Click **Screen** and select **Preview Screen**.
  - b. On Preview screen, right-click to select **Save this Workup**.
13. If a nerve canal is detected by the system when the Estimate Nerve Canal option is selected, a dialog is displayed:



- Click **Yes** to remove current estimation and begin nerve canal estimation from scratch.
- Click **No** or **Cancel** to cancel the action.

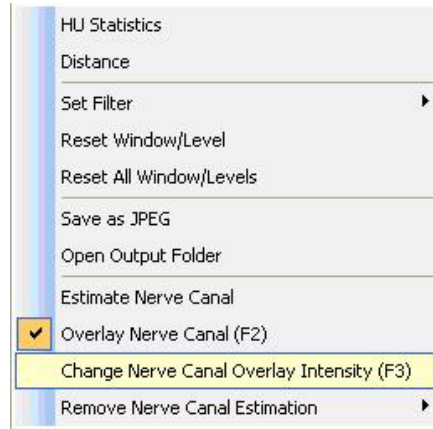
#### To overlay the nerve canal:

1. Right-click and select **Overlay Nerve Canal**, or press **F2** key. Nerve canal is overlaid in pink.



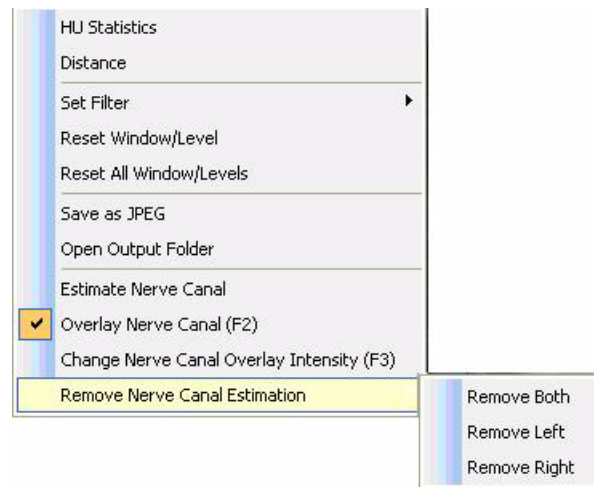


2. To change the intensity of the overlay, right-click and select **Change Nerve Canal Overlay Intensity**, or press **F3** key. Selecting this option in succession toggles the overlay intensity brighter or dimmer.



**To remove a nerve canal estimation:**

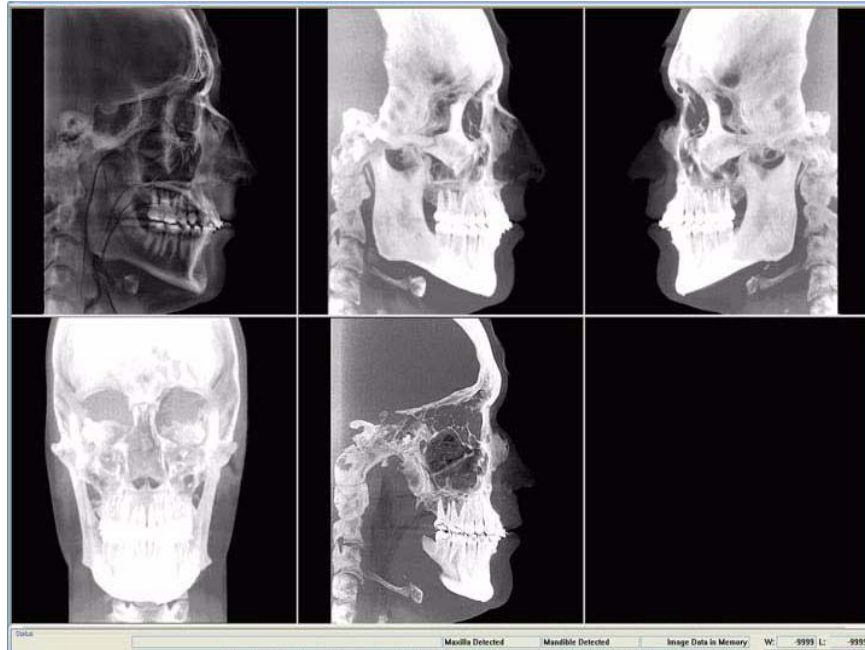
1. Right click, select **Remove Nerve Canal Estimation** and choose one of the three options on the drop-down, depending on the estimation to be removed.



2. Nerve canal estimation is removed.

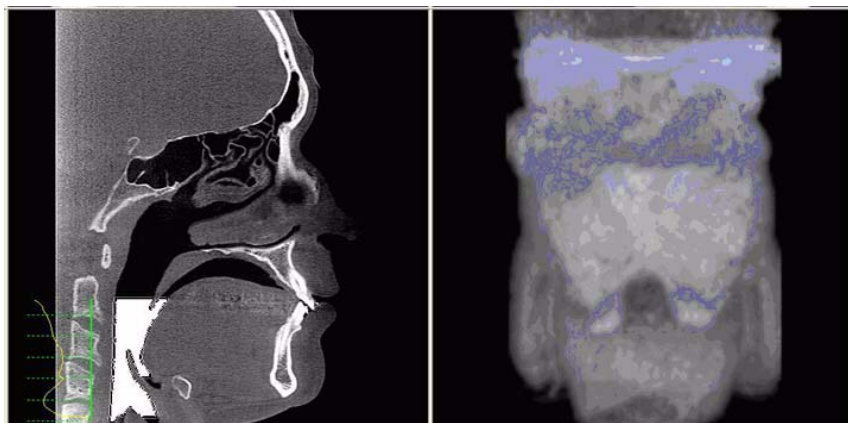
## Ceph Screen

Double-clicking the Sagittal View on the Preview Screen displays the Ceph Screen.



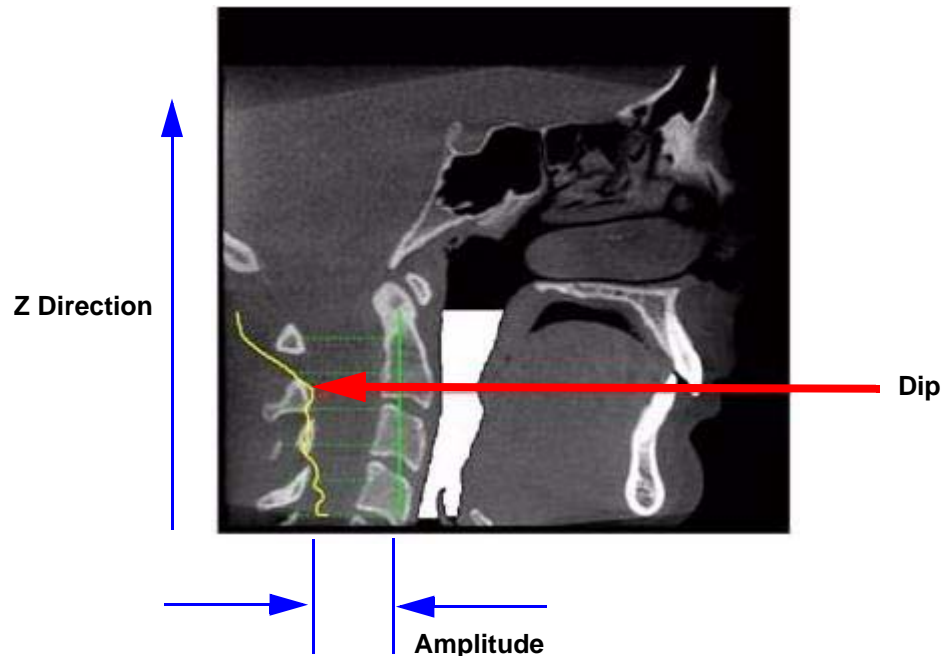
The Ceph screen displays the Lateral Ceph in Radiographic and MIP mode as well as a Coronal View in MIP mode, all at the thickness of the volume. The last image is a Mid Sagittal Slice at 20mm thick.

Right-clicking the blank view at the bottom right of the Ceph screen displays a single item popup menu. Clicking **Tag Airways** generates a 3D view of the airways for the patient in the blank view. In addition, the tagged airway data is graphed in the view at the bottom center of the Ceph screen.



In the example below, the plot shows the opening of the airway along the vertical axis of the graph. The green vertical line is the zero line in the graph. The yellow curve shows the 3D width of the airway along the Z direction of the volume and is proportional to the 3D airway voxel volume in each corresponding axial slice. The red line passes through an area in the airway which is narrower relative to the surrounding area. This is depicted by a dip in the yellow curve toward the green vertical zero line of the graph.

Since a constriction could be present in the depth of the image, a single image may not be sufficient to assess airway volume. However, the curve is accurate since it is created from the airway volume contained in each slice along the Z direction. The amplitude at every point in the yellow curve is a true 3D representation of the airway volume at the corresponding axial slice location.

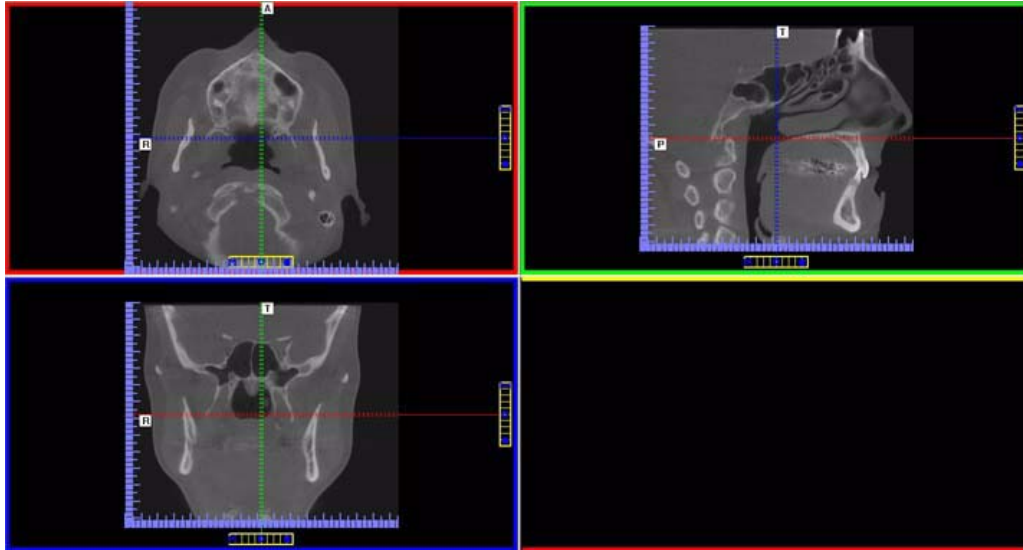


To remove the airway information from the View, right click the airway view and select **Untag Airways**.

If **Tag Airways** is reselected after certain image manipulations have occurred, a dialog is displayed. Click **OK** in the dialog, then in the Mid Sagittal image, click the airway below the flap. The airway tag is displayed.

## MPR Screen

Double-clicking the Coronal View on the Preview Screen displays the MPR Screen.



The MPR Screen allows scrolling through the Axial (upper left), Sagittal (upper right), and Coronal (lower left) slices. The resulting selections are displayed in the lower right view of the MPR Screen. The mouse scroll wheel is active to scroll through the slices.

### To use the MPR Screen:

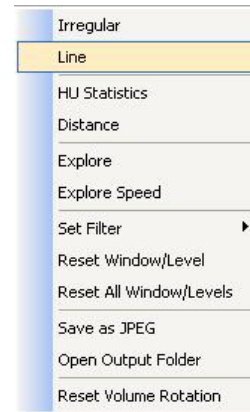
1. To move the slice location, drag the hollow circle (center of tool) in any of the views. The slice lines are color coded to correlate to the associated view that it is adjusting.
2. To adjust the slice thickness, click the solid circle (end of tool) and drag the mouse to spread or tighten slice thickness.



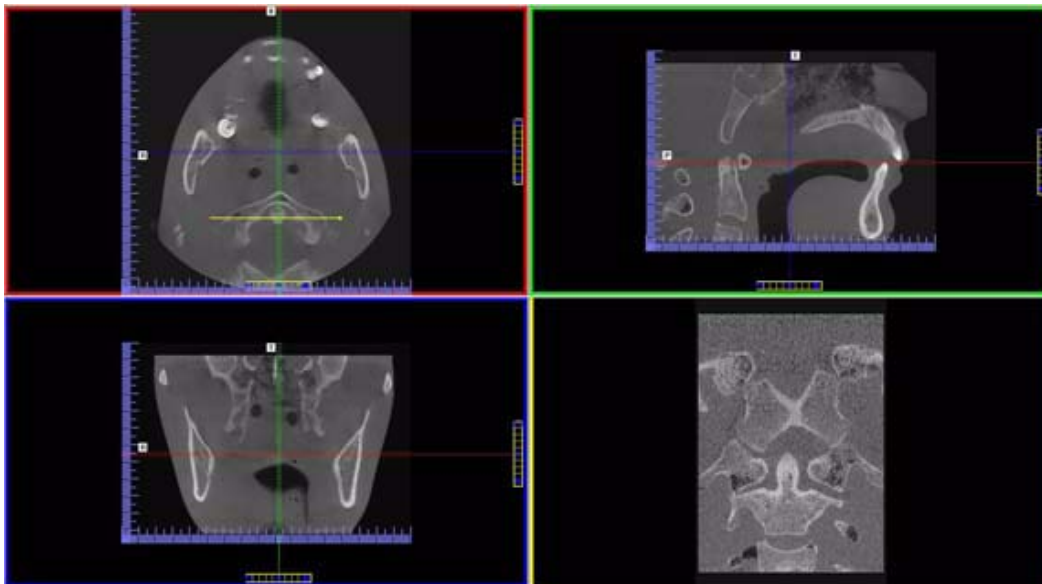
**To view the result of a linear slice:**

1. To view a linear slice, right click the view and select **Line**.

A pointer cursor is displayed.



2. Drag to position the linear slice.



The resulting slice is displayed (lower right of the MPR Screen.)

3. To reposition the line, drag either end point of the line.

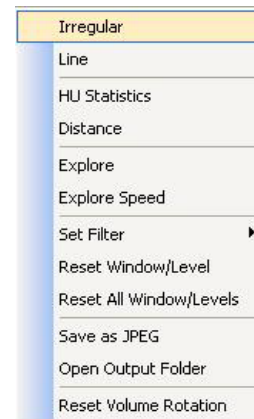
**To view the result of a non-linear (irregular) slice:**

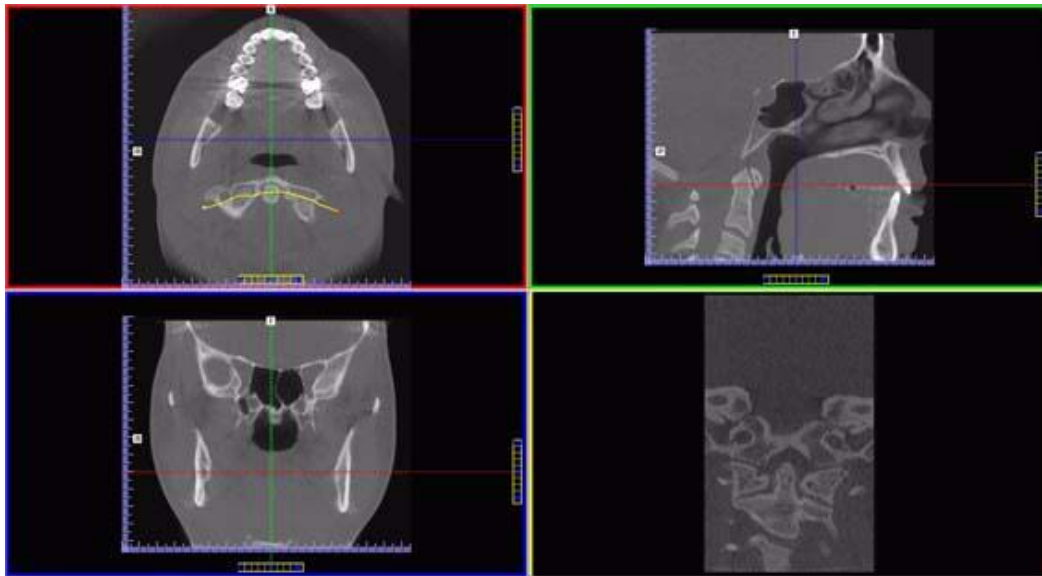
1. To view a non-linear slice, right click view and select **Irregular**.

A pointer cursor is displayed.

2. Drag cursor to create slice as desired.

The resulting slice is displayed in the view at the lower right of the MPR Screen.



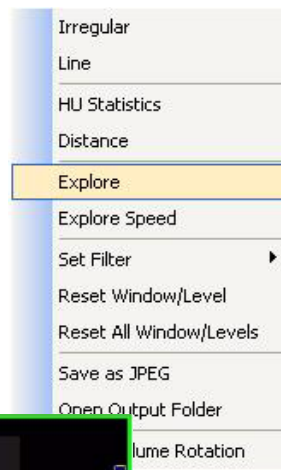


3. To reposition the line, drag either end point of the line.

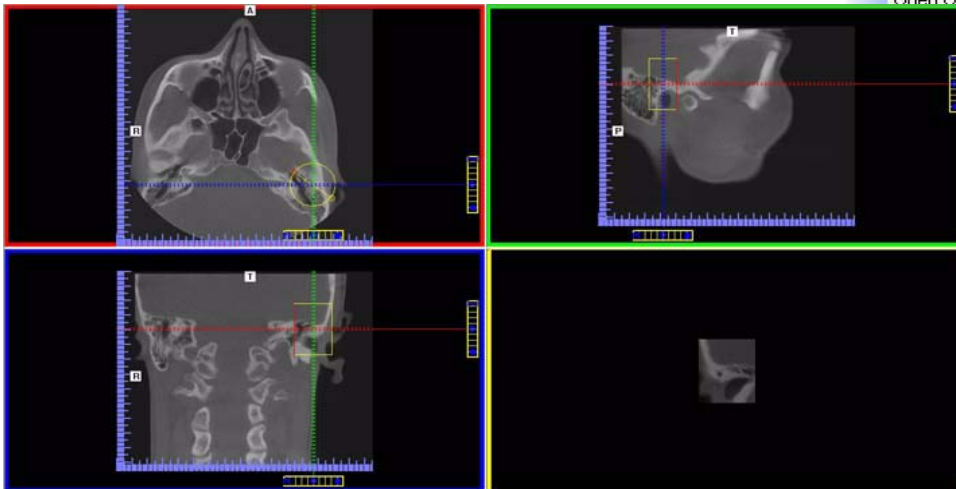
**To explore additional cut planes in an animated (consecutive) fashion:**

4. To view additional cut planes, right-click view and select **Explore**.

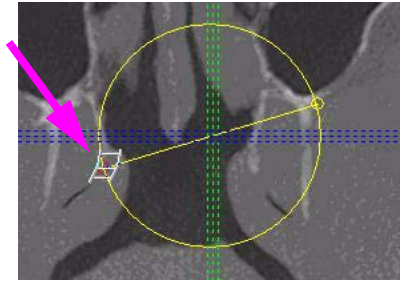
A pointer cursor is displayed.



5. Drag the center of the circle to position the cut planes slice.



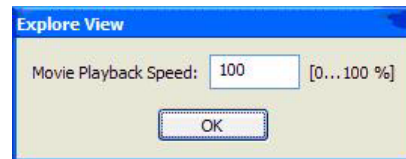
6. Move the cursor over the red end point and the cursor changes to a film icon.
7. Click cursor to start the animation which plays in the lower right view.



8. To adjust the playback speed, right-click any image and select **Explore Speed**



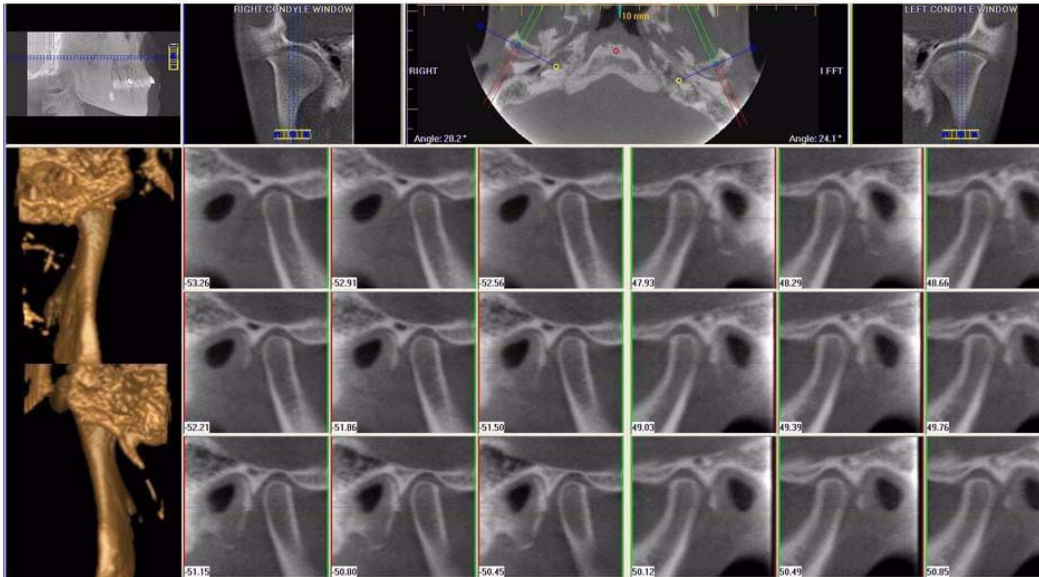
9. Enter desired animation speed in the *Movie Playback Speed* field.
10. Click **OK**.





## TMJ Screen

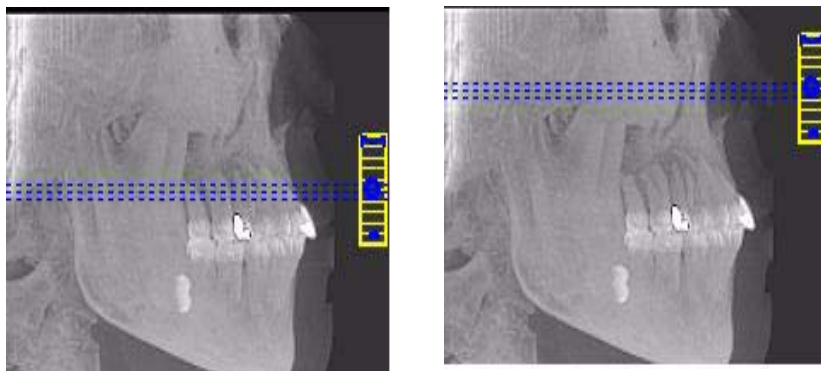
Double-clicking the Axial View on the Preview Screen displays the TMJ Screen.



TMJ Screen enables condyle mapping and creating corresponding coronal slice views.

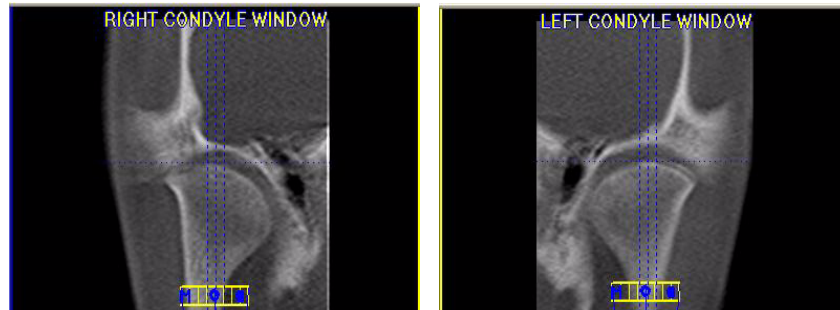
### To use the TMJ Screen:

1. If necessary, pan the Axial (SMV) View (upper left) down in the window to see the condyles. (See *Pan Feature*.)
2. Use the scroll bar center (O) tool to locate the condyles for proper mapping.





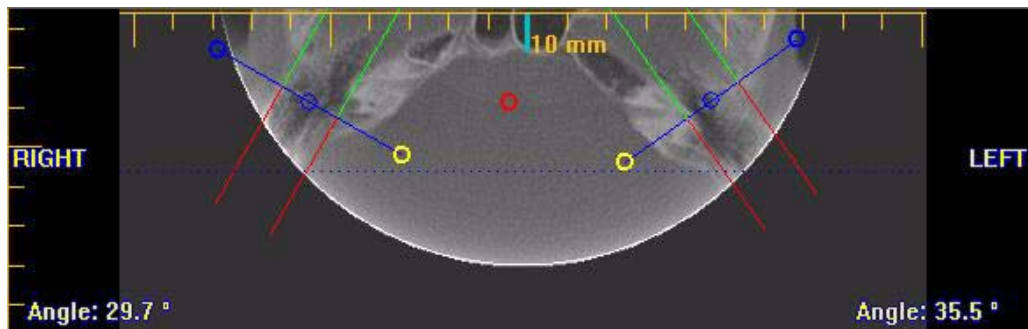
3. Drag center (O) tools from the RIGHT and/or LEFT CONDYLE WINDOWS to move the slice locations of the cross section views.



4. Drag the solid circle tool (right edge of toolbars) to adjust the slice thickness of the cross section views.

**To create lateral slices:**

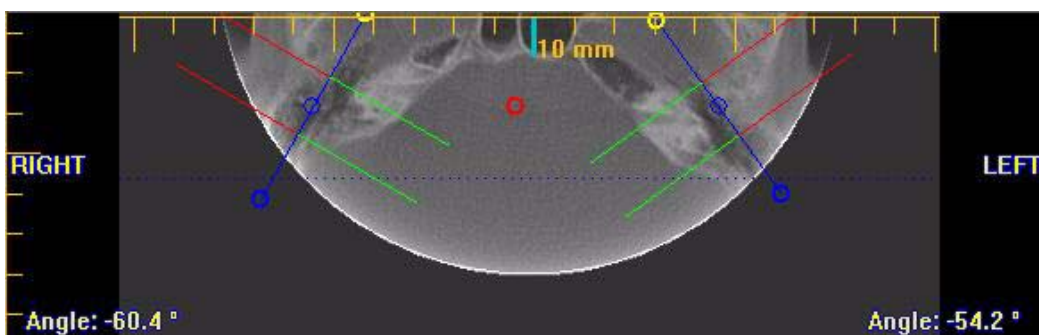
5. Drag the center blue circles on the Axial View to move the corresponding Condyle Map.



6. Drag the yellow and blue end circles to adjust the angle of each Condyle Map.

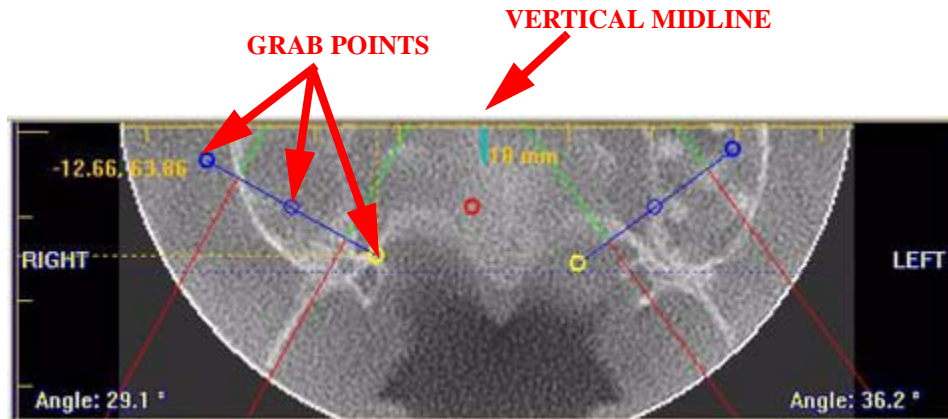
Green markings indicate the anterior of the Condyle.  
Red markings indicate the posterior of the Condyle.

7. To create Coronal Slices, click the red circle.



**To measure:**

- Click and drag any of the grab points on either side of the vertical midline. A set of measurements is displayed.



In the example above, the first number, -12.66, is the horizontal distance in millimeters of the grab point to the vertical midline. The second number, 63.86, is the distance in millimeters from the anterior start of the image. When the patient's left and right side grab points are touched, these numbers give an indication of symmetry.

The vertical midline represents the center of the slice and is determined by the point farthest anterior from the contour line when the contour line is created.

# Chapter 9 Tools

## *DICOM Database and DICOM Export Setup*

This procedure describes how Patient Data is converted into DICOM images and also determines where these DICOM image files are to reside.

1. From the top Main menu, select **Tools > Setup**.



- **DICOM Database Root Folder** - contains patient data that is required for creating DICOM images.
  - **DICOM Export Destination Folder** – this path selection determines where the DICOM images are to reside when executing the *Export DICOM* procedure.
2. Click **Browse** for both fields.
  3. Choose a path for the *DICOM Database Root Folder* and the *DICOM Export Destination Folder*.  
If required, click **Make New Folder**.
  4. Click **OK**.

## Check Read/Write Access to Image Database

This function tests the ability of Vision to read/write to the image root folder. Vision requires Write Access to this path to store or update Status information. Also displayed is the total disk space that is available in the Image Root directory.

Please consult with your Network Administrator if this test indicates a failure.

1. From Main menu, select **Tools > Check Read/Write Access to Image Database**

The *Read/Write Access Test Dialog* window is displayed.



2. Ensure that all tests have passed. Click **OK** to close.

## Export DICOM

DICOM (Digital Imaging and Communications) in Medicine, is an industry standard for digital images which is a means for medical imaging products to share images.

The following process demonstrates how to convert patient data files into DICOM images for export.

### To Export DICOM:

1. Click (highlight) a patient from the Study List. Allow time for the Patient Image to load.

- From the Main menu, select **Tools > Export DICOM**.



- Select desired Output Selections.
  - Single File DICOM** - one large image file (recommended)
  - Multi-File DICOM** - a separate file for each image slice, resulting in many small files. Some earlier model viewers require this format.
  - Compressed** - files are compressed to save space (smaller file size)
  - Uncompressed** - files are converted to DICOM and stored (original file size)
  - Use Lossy Compression** - files are compressed using lossy wavelet compression.
  - The *Destination* field was setup at the start of this section.
- Click **OK**. Done is displayed when the process is complete.

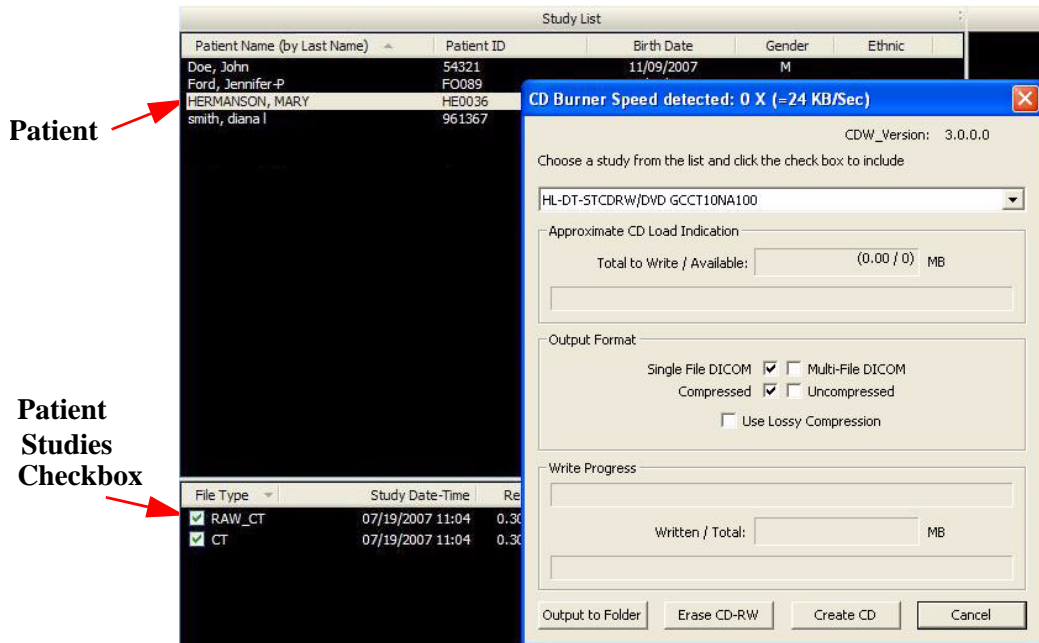
## Create CD

The internal DVDR drive provides an alternative means for archiving images or transferring patient images to referring Physicians.

**NOTE:** It is recommended to use a blank CD for recording. Upon completion of the writing process, verify that all required information was written to the CD.

### To create a DICOM CD:

1. From the top Main menu, select **Tools > Create Export CD**.



2. Select desired Output Selections.
  - **Single File DICOM** - one large image file (recommended)
  - **Multi-File DICOM** - a separate file for each image slice, resulting in many small files. Some earlier model viewers require this format.
  - **Compressed** - files are compressed to save space (smaller file size)
  - **Uncompressed** - files are converted to DICOM and stored (original file size)
  - **Use Lossy Compression** - files are compressed using lossy wavelet compression
3. Select (highlight) Patient from Study List.
4. Select Patient Studies by enabling check-boxes.
5. Click **Create CD**.
6. A confirmation window is displayed and CD ejects when CD is complete.
7. Click **OK**. Insert CD and check content on CD to ensure data was captured.

## Erase CD-RW

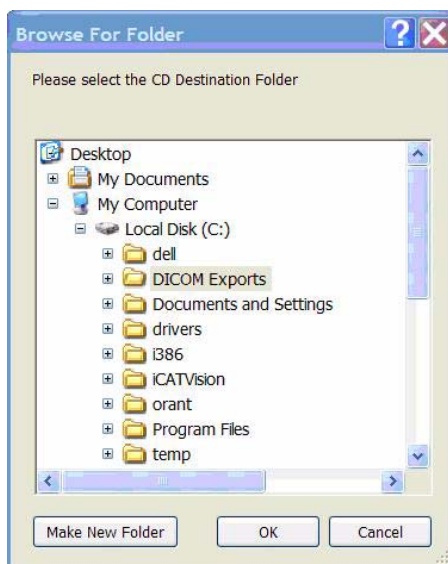
This Erase CD option can only be used if using re-writable CDs.

1. From the top Main menu, select **Tools > Create Export CD**.  
The CD Burner window is displayed (shown above).
2. Click **Erase CD-RW**.
3. Click **Yes** when prompted to erase data on CD.

## Output to Folder

The *DICOM Export Destination Folder* can be changed using this procedure. For reference, the alternate path to change this folder is **Tools > Setup** which is described at the start of this section.

1. From the top Main menu, select **Tools > Create Export CD**.  
The CD Burner window is displayed (shown above “To create a DICOM CD”.)
2. Select **Output to Folder**. A *Browse For Folder* is displayed.



3. Choose a path for the *DICOM Export Destination Folder*.  
If required, click **Make New Folder**.
4. Click **OK**.

## Reporting

Patient reports are generated by inserting patient images into a single or multiple page document. Patient information and text notes can also be inserted as required. Once these reports are created and saved, they are readily available for printing and distribution. Patient reports can also be accessed for editing.

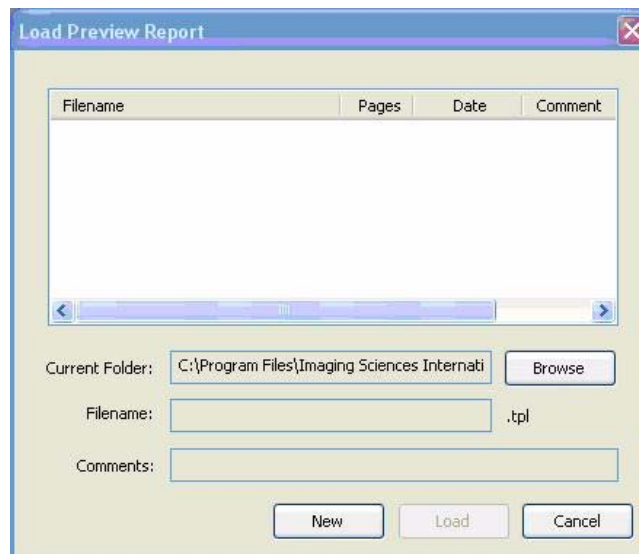
From the top menu bar, select **Tools > Create Report** to display the following three report options:

- Run Report
- Create New Report
- Modify Existing Report
- Exit

### Run Report

This feature enables the user to access a sample report to modify and and save as a new patient report.

1. Click (highlight) a patient from the Study List. Allow time for the Patient Image to load.
2. From the Main menu, select **Tools > Create Report**.
3. Click **Run Report** from the Options box.
4. Use the Browse button to locate a report to Run.

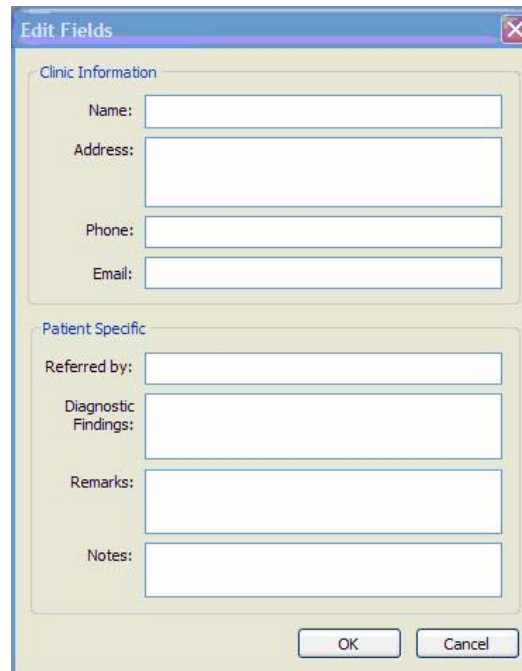




## Create New Report

### To create a new Patient Report:

1. Click (highlight) a patient from the Study List. Allow time for the Patient Image to load.
2. From the Main menu, select **Tools > Create Report**.
3. Click **Create New Report** from the Options box.



4. The Edit Fields box is displayed. Enter all required Clinic and Patient Specific information and click **OK**.

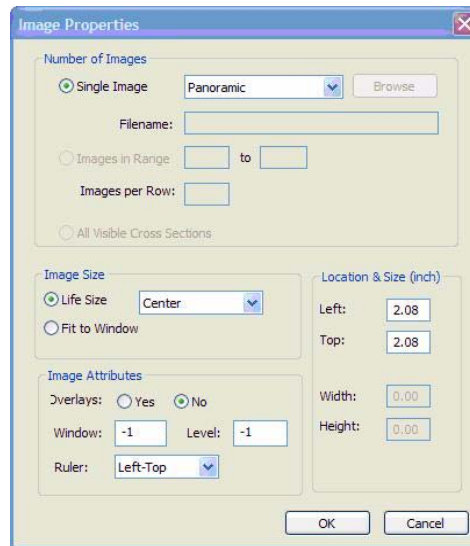
This information is imported into the report template and is displayed when the text fields are inserted into the report.

### Insert Image into Patient Report:

5. Select **Insert > Image** from the Main menu **or** right-click the report page and select **Add Image**.

Images can be both Vision images and external images (jpg or bmp).

6. Select required parameters and click **OK**.



#### Number of Images

- **Single Images** – used to select images within Vision or from a file (select FILE)
- **Images in Range** – used to select specific cross sections within Vision
- **All Visible Cross Section** – used to select all currently displayed cross sections

#### Image Size

- **Life Size** – used to depict the image in life size (able to measure directly on the paper). The drop-down list box allows specifying where the image originated. For example, if Left Top Corner is selected, the image fills in the image box starting in the top left corner.
- **Fit to Window** – used to autofit the image to the available page area.

#### Image Attributes

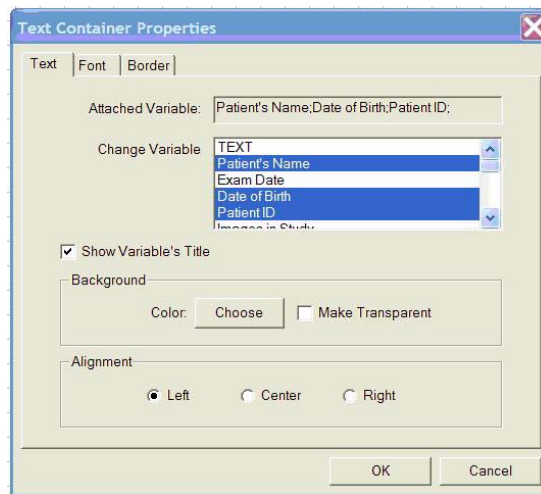
- **Overlays** – when selected, markings that were generated on the image within Vision are displayed
- **Window** and **Level** – adjusts the brightness and contrast
- **Ruler** – designates where the ruler appears on the image

The Image Properties box can be displayed at any time by right-clicking inside the image box and selecting **Properties**.

7. Images can be repositioned or sized by clicking the image and then holding down left mouse button and dragging the cursor.
  - **Cross Arrows** – used to move image
  - **Double Headed Arrow** – used to size image

***Insert Text Box:***

8. Select **Insert > Text** from the Main menu **or** right-click the report page and select **Add Text**.



9. Select desired variable from the Change Variable list. Holding down the **CTRL** key and selecting multiple variables allows all selected variables to be displayed in one Text box.

The TEXT selection does not allow multiple variables to be selected.

10. Select **Show Variable's Title** check box to display each title next to the variable information.
11. Backgrounds, Colors, Alignments, Fonts, and Borders are also modified from this menu.

Double click an existing Text box to display the Text Container Properties box.

12. Images can be repositioned or sized by clicking the image and then holding down left mouse button and dragging the cursor.
  - **Cross Arrows** – used to move Text box
  - **Double Headed Arrow** – used to size Text box

## Add Page

13. Select **Insert > Page** from the Main menu **or** right-click a report page and select **Add Page**.

The new page appends to the end of the report.

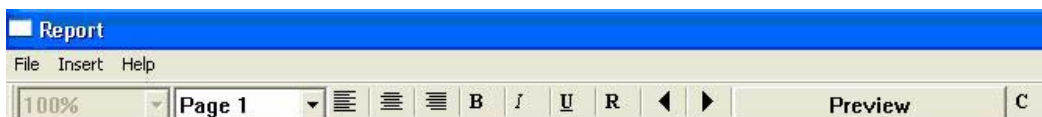
14. To change the page properties, select **File > Page Setup** from the Main menu **or** right-click the page and select **Page Properties**.

15. Select required parameters and click **OK**.



## Toolbars

The toolbar at the top of the screen can be used to manipulate the text, scroll through pages and preview the report.





## ***Modify Existing Report***

This function is used to edit reports that were previously created.

### **To create a new Patient Report:.**

1. From the Main menu, select **Tools > Create Report**.
2. Click **Modify Existing Report** from the Options box.
3. The Load Preview box is displayed. Select the Patient Report to modify and click **Load**.

The Patient Report is displayed.

4. Edit the report and select **File > Save Report**.
5. Click the **X** (upper right corner) to close Patient Report.



# *Chapter* **10** *Calibration*

The Panel, Collimators, and Geometry Calibrations can be conducted by the Owner / Operator of the device. It is recommended that the Panel Calibration be performed once a week.

## *Panel Calibration*

The Panel Calibration performs in both Portrait and Landscape positions. The entire calibration takes approximately 8 to 10 minutes to complete. The process performs a five mode calibration as listed below:

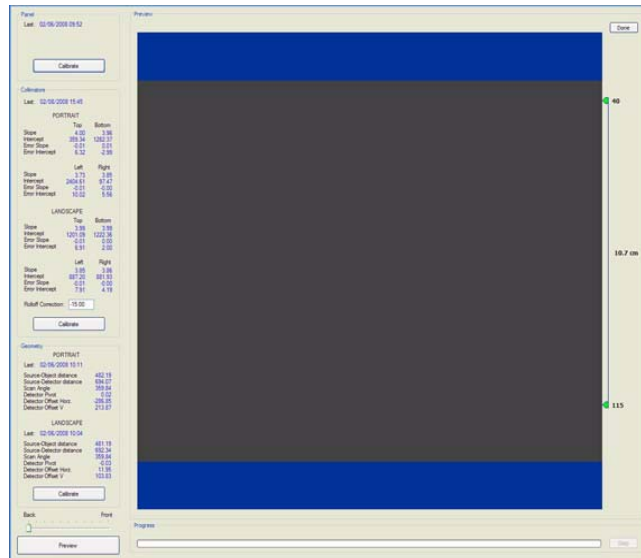
- Mode 0 (4 x 4) Landscape
- Mode 1 (2 x 2) Landscape
- Mode 2 (2 x 2) PAN (Landscape)
- Mode 3 (4 x 4) Portrait
- Mode 4 (2 x 2) Portrait

### **To run the Panel Calibration:**

1. Ensure room temperature is in the range of 50 to 95°F (10 to 35°C).
2. From the desktop, double click the **Calibration** icon.



The Calibration screen is displayed.



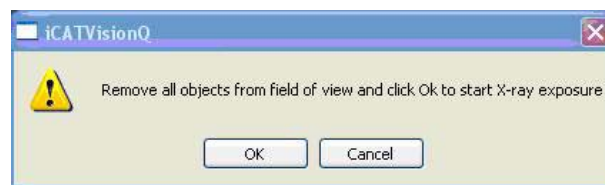
- Click the **Calibration** button (top) in the *Panel* field.



### **WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

A window is displayed “Remove all objects from the field of view and click OK to start X-ray exposure.”



- Click **OK**.
- When prompted, press the **Scan** button on the Control Box. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.
- The progress of the scan is displayed on the *Progress* bar at the bottom of the Acquire window. You will be prompted to press the **Scan** button several times as the calibration progresses.

“Panel Calibration Complete” is displayed when the process is finished. Click **OK**.



## Collimators Calibration

It is recommended to perform the Collimators Calibration annually to ensure optimal image quality. This calibration is also necessary if a mechanical adjustment is made to the Beam Limiter or if image quality has degraded. The Panel Calibration must be performed prior. The Collimator Calibration runs in both Portrait and Landscape positions and takes less than 3 minutes to complete.

Perform Collimators Calibration:

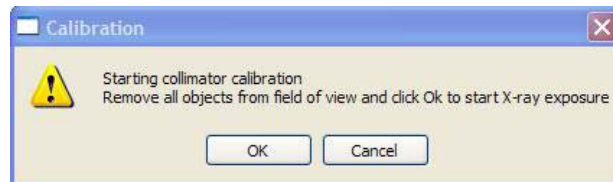
- After performing the Panel Calibration click the **Calibration** (middle) button in the *Collimators* field.



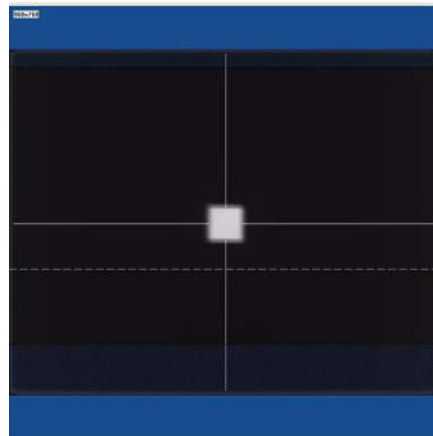
### WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

A window is displayed “*Starting Collimator Calibration Remove all objects from the field of view and click OK to start X-ray exposure.*”



- Click **OK** to start the X-ray exposure.
- On the Control Box, press **Scan** when prompted. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.
- The scan starts in the Landscape and continues into the Portrait mode, displaying three screen shots in both modes.



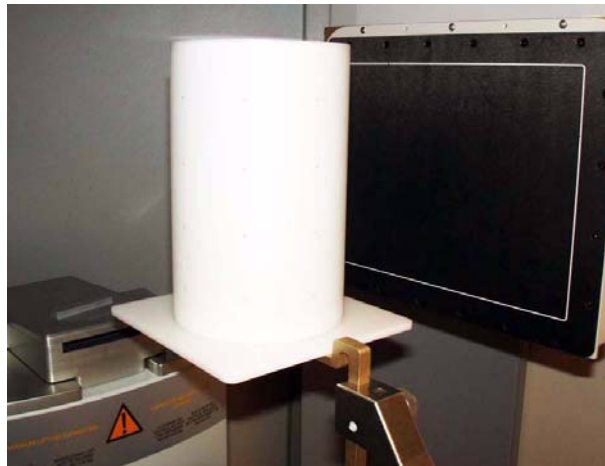
11. Click **OK** when calibration completes (less than 3 minutes)

## ***Geometry Calibration***

It is recommended to perform the Geometry Calibration annually to ensure optimal image quality or if the image quality is degraded. The Panel Calibration must be performed prior. The Geometry Calibration runs in both Portrait and Landscape positions and takes about 12 to 15 minutes to complete.

Perform Geometry Calibration:

12. Mount the Phantom Platform and center the BB Phantom on the platform using the alignment holes on the bottom of phantom. (shown below).



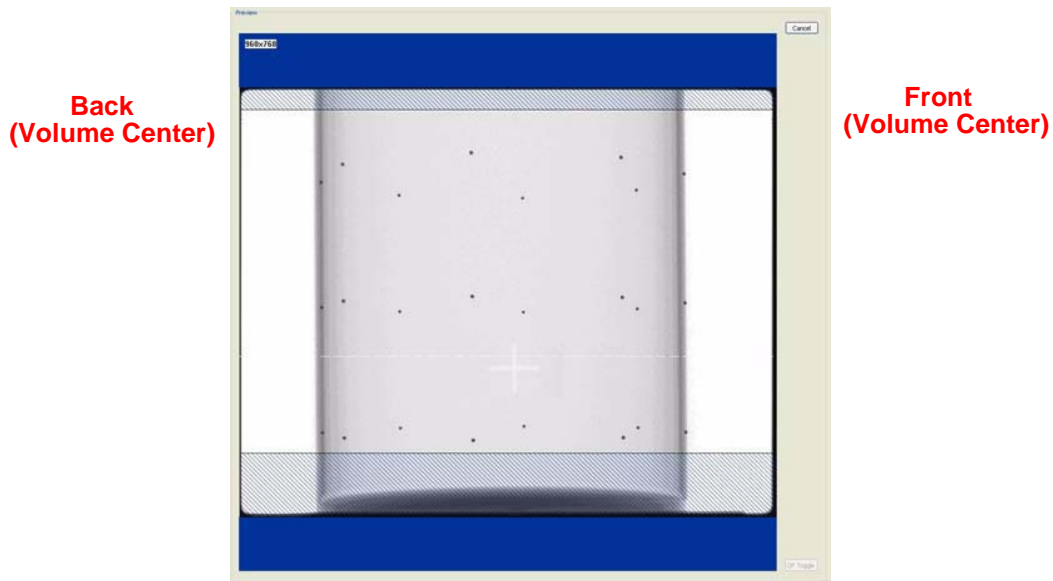
13. Ensure that the BB Phantom is level. Achieving levelness may require placing pieces of paper beneath the phantom.
14. Align the BB Phantom crosshair slits with the laser cross beams. For an accurate alignment, the laser beams should penetrate through the phantom crosshairs and appear on the receptor panel.
15. Click the **Preview** button which is located at the bottom of the Calibration screen.



### **WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

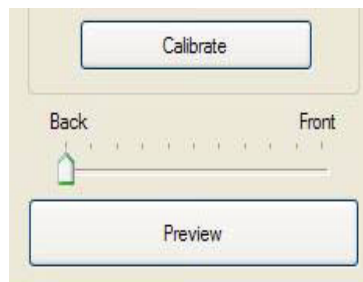
16. The ready window is displayed, click **OK**.
17. On the Control Box, press **Scan** when prompted. An audible is sounded and the X-ray light illuminates during radiation exposure.
18. The BB Phantom image is displayed (shown below).



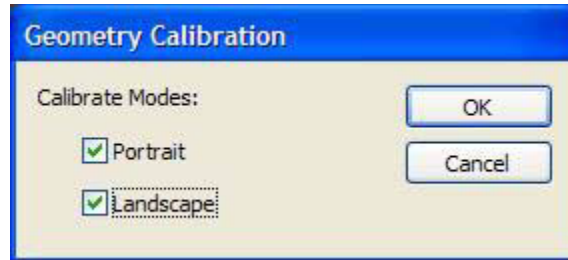
19. Ensure that the phantom is centered, level, and **all** BBs (dots) appear in the FOV. If required, make adjustments and click **Preview** again. Repeat as required.

Height adjustments are made by raising or lowering the phantom platform. BBs should not touch the top or bottom lines.

To reposition the phantom right or left on the Preview screen, use the **Back / Front** feature.



20. When the BB Phantom is centered and level, click the **Calibrate** button on the Geometry panel (bottom).
21. Select both the Landscape and Portrait calibration modes.

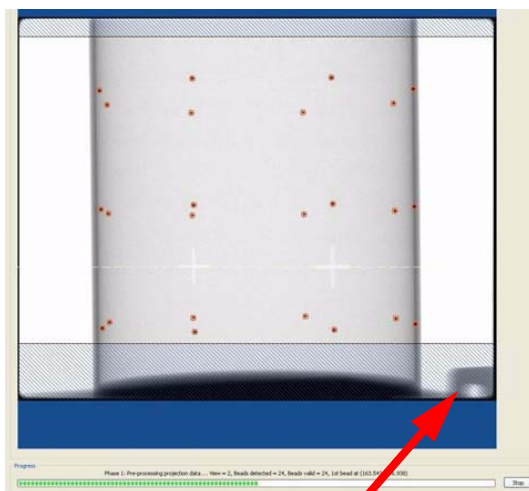


### WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

22. Click **OK** to start the X-ray exposure.
23. On the Control Box, press **Scan** when prompted. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.
24. The calibration starts with the Landscape Scan.

### LANDSCAPE SCAN



**Metal Platform Support  
(below FOV)**

### PORTRAIT SCAN



**NOTE:** Ensure that the metal platform support is below the Field of View (as shown above.)

25. At the start of the scan, red circles are displayed around each BB. At this point, check data (above green progress bar), to ensure the following is displayed:

Beads detected = 24, Beads valid = 24

26. At the prompt, press **Scan** on the Control Box, to start the Portrait Scan.

27. During the Portrait Scan, ensure the following is displayed:

Beads detected = 20, Beads valid = 20

**NOTE:** Check to ensure that all beads are in tact on the BB Phantom, if the calibration did not detect a bead at a certain location.

28. Click **OK** when the completion window is displayed and restart Vision software.



**CAUTION** \_\_\_\_\_

Failure to restart Vision software at this point may result in a system failure.

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# Chapter **11** *Quality Assurance*

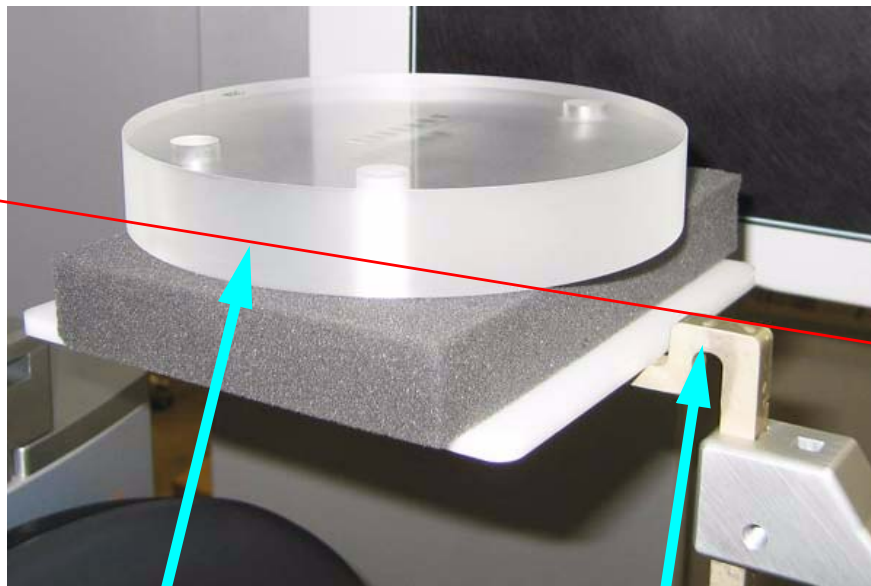
## ***QA Phantom Test***

The following Quality Assurance Tests can be conducted by the Owner / Operator of the device. It is recommended that the System Quality Assurance be performed annually or if image quality becomes degraded. For this purpose, the following procedures are provided with a QA Phantom Test and QA Water Test.

This procedure is performed to check the High Contrast Spatial Resolution.

1. Remove Chin Cup and insert Phantom Platform.
2. Place QA Phantom on Platform. Use a piece of foam beneath the phantom to elevate it above the metal Platform Support Arm, as shown below.
3. Use the alignment lasers to adjust the Phantom Platform height.

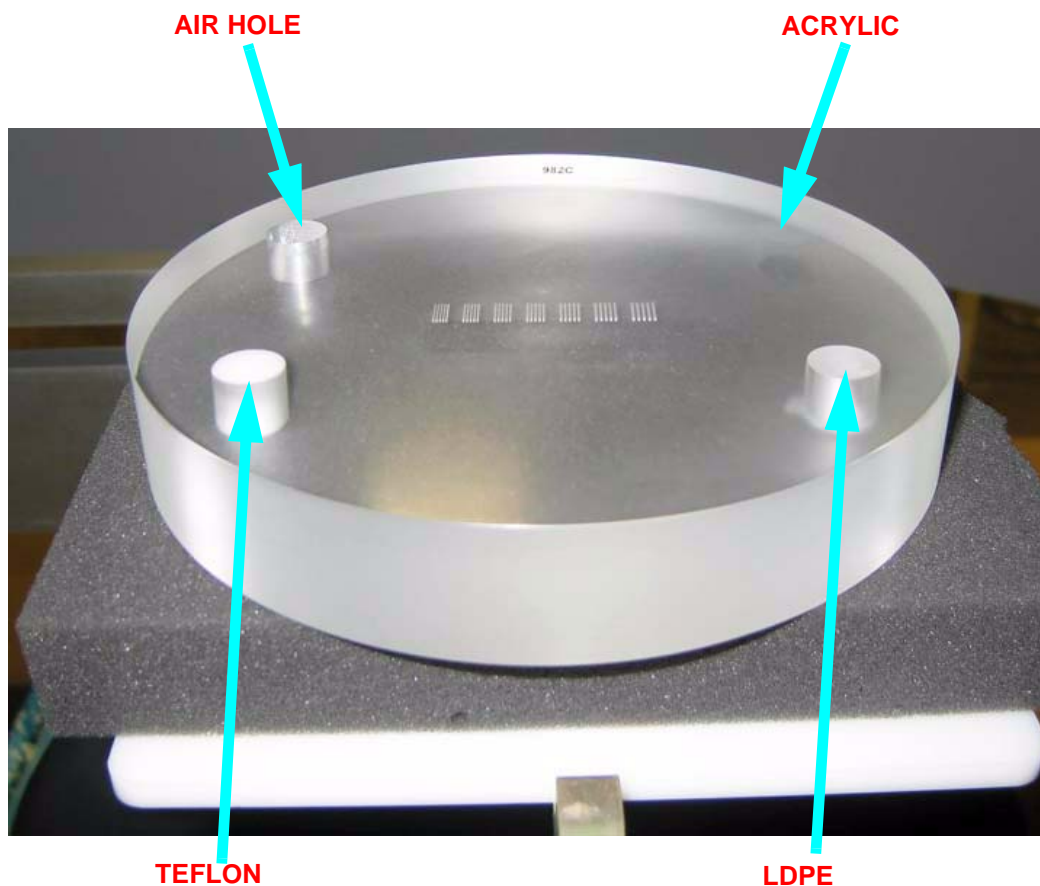
Adjust the height so that the Axial Laser is positioned at the center of the QA Phantom.



**Horizontal Laser Line  
through Center of Phantom**

**Metal Platform Support Arm  
is Below Bottom of Phantom**

- Center the QA Phantom on the platform with the Air Hole positioned at the left rear of the Gantry (shown below).



- Start the test by selecting **File** > **New Patient** from the Main menu.
- From the Patient Information Panel, click **Add**.  
Enter **QA Test** in the *First Name* field and **Line Pair** in the *Patient ID* field.
- Click **OK** to close the Patient Information box.
- From the **Volume** tab in the Acquisition window, select the following:  
*Size of Reconstruction Volume:* **Landscape 6cm maxilla**  
*Resolution:* **.2 voxel**
- Click **Preview** to check the phantom position.

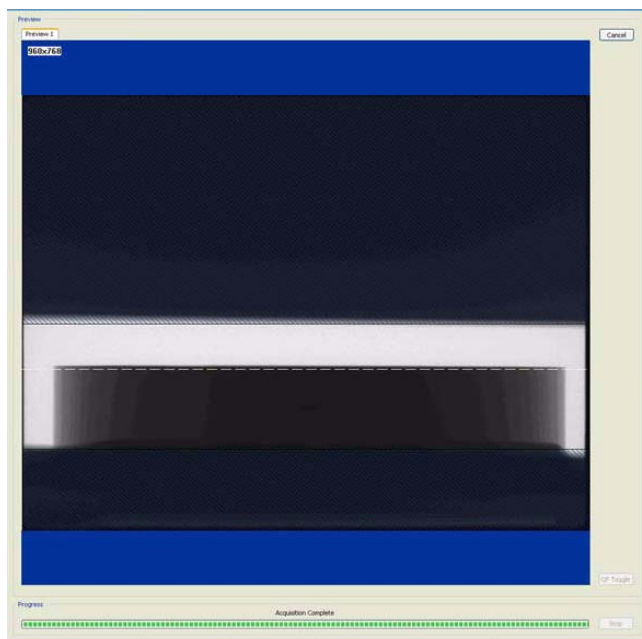




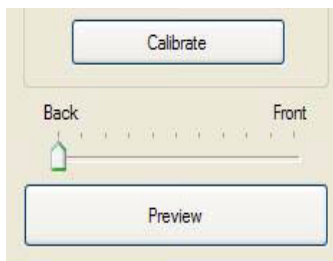
**WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

10. Click **OK** and press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
11. As shown below, the Phantom Platform must appear below the Field of View and the Phantom must be centered.



12. Adjust the Phantom Platform to achieve the proper height.
13. To move the phantom to the right or left, use the **Back / Front** feature on the Volume tab and then return to the Calibration tab.



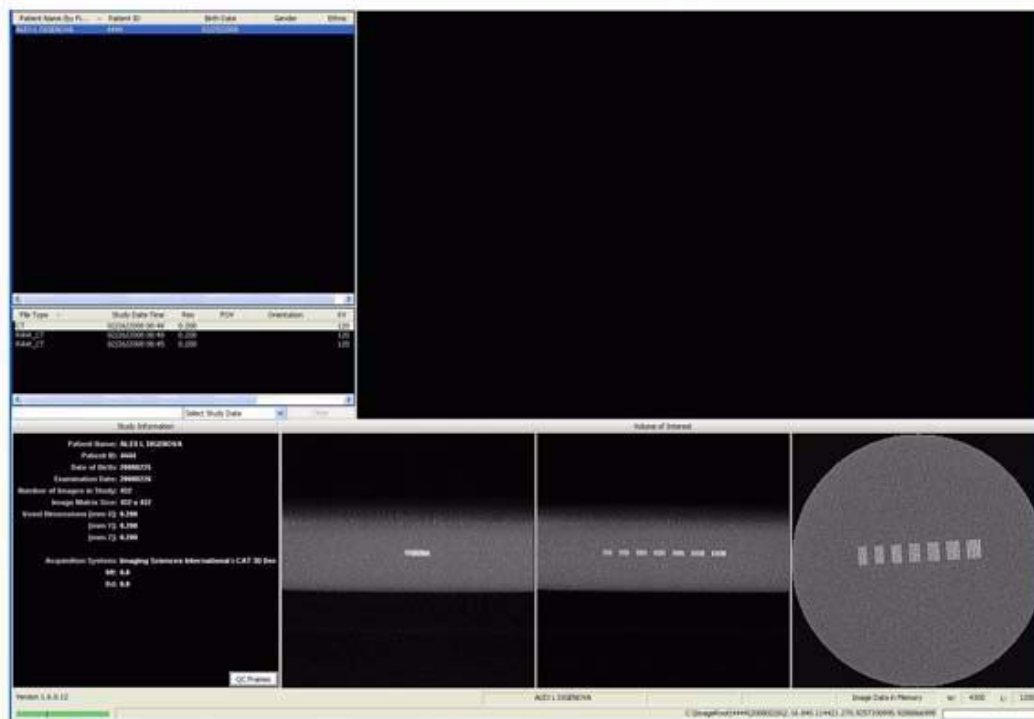
If required, make adjustments and click **Preview** again. Repeat as required.



## WARNING

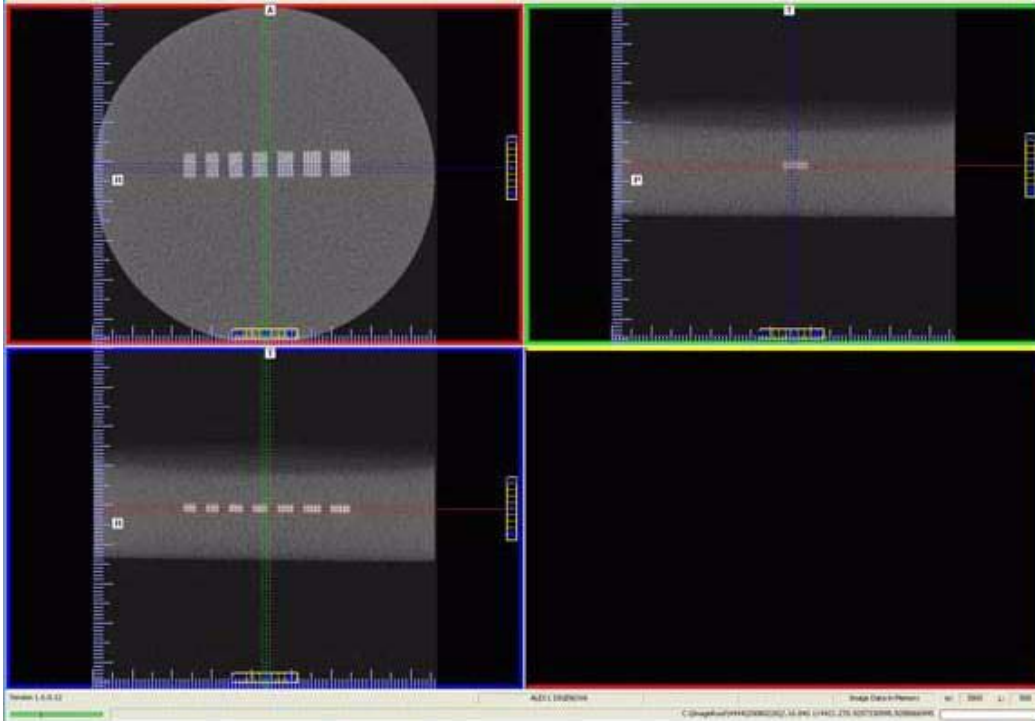
The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

14. Click **Capture** to start the scan process.
15. Click **OK** and press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
16. When the scan is completed, select **NO** when prompted to automatically detect arches.
17. Select **Cancel** at the *Contourline Setup* prompt.
18. The following preview screen is displayed.

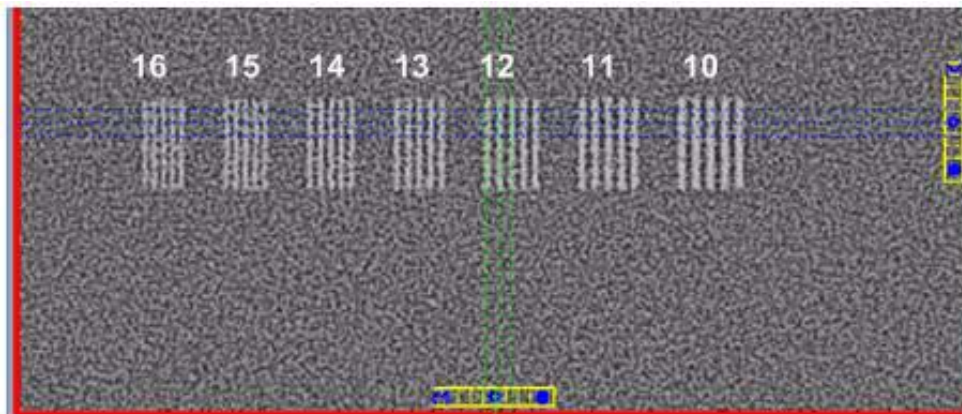


## Line Pair Evaluation

19. Access the QA Test images for evaluation by double clicking **Coronal View**. (bottom image, 2<sup>nd</sup> from the right).
20. The image below is displayed. In the upper right corner view, slide the Vertical and Horizontal lines to the Line Pairs centers as shown below.



21. Zoom Line Pair image (upper left). To zoom, start at the upper right corner of image and hold down left mouse button and drag cursor across the image.



22. Right click the image and select **Set Filter > Hard**.
23. Adjust Brightness and Contrast level for the best image quality. Evaluate the image.

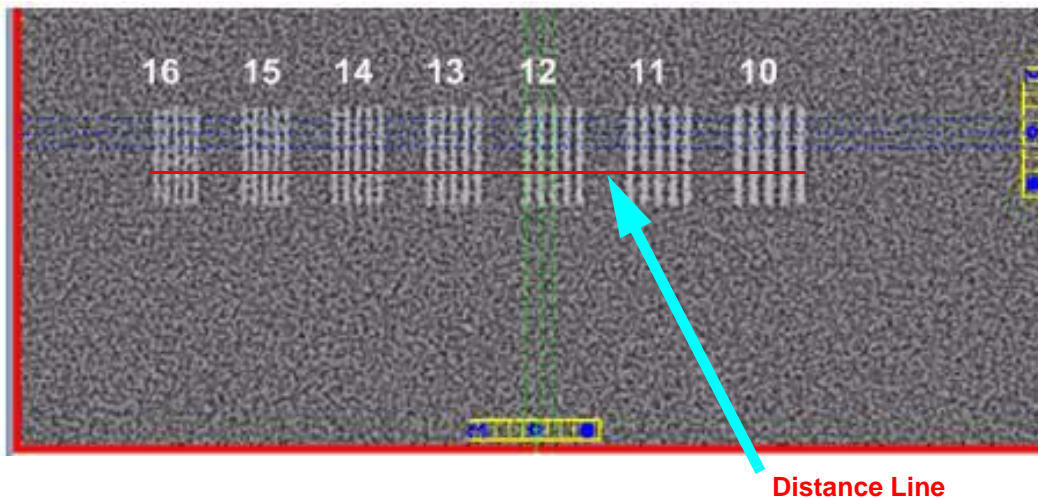
**Line Pair** - Line Pairs consists of a resolution of 10 lines per cm (5 dark with 5 light). Line Pairs 10 through 16 are displayed in the image (shown above).

The picture depicts expected appearance of the **Line Pairs per cm** present within the QA Phantom.

24. Verify that definition is present within line pairs 10, 11, and 12. Compare image quality to the image shown above. Your Line Pair #12 should have the same image quality (definition) as the #13 Line Pair displayed above or better.

### ***Distance Measurement Test***

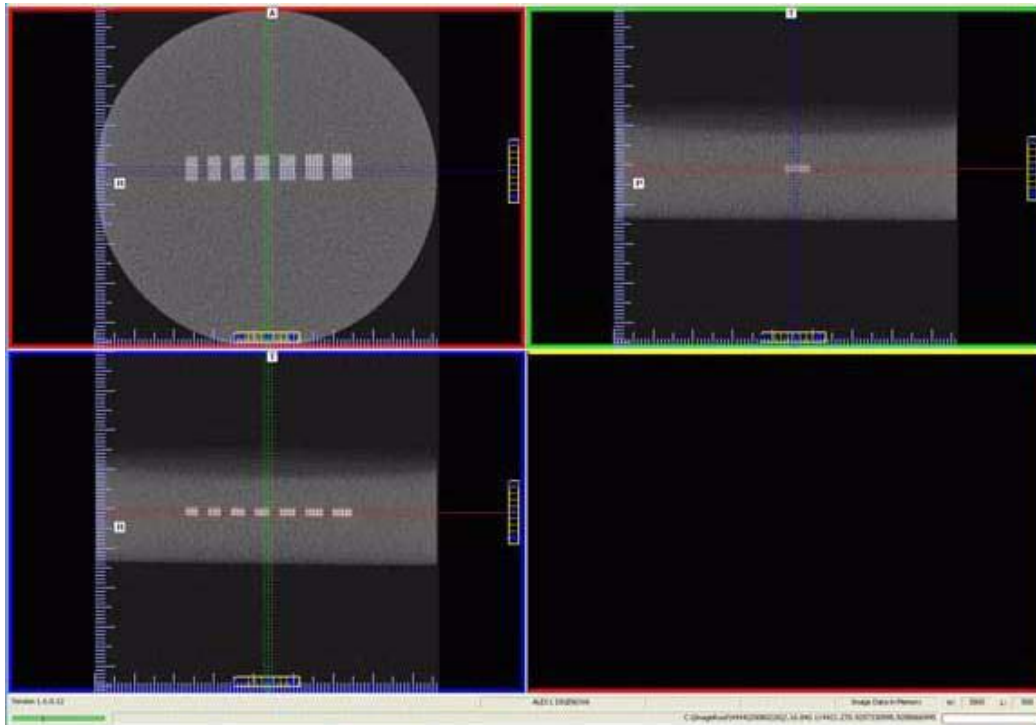
To ensure measurement accuracy, this procedure checks Distance measurements.



25. Right click view and select **Distance**.
26. Drag the Distance cursor to draw a line from the outside line of set 16 to the outside line of set 10, as shown above.
27. The measurement (displayed in upper corner of image) should be between 41 and 42 mm.
28. Call Technical Support, if the measured value is not within this range.

## Hounsfield Unit (HU) Measurements

This procedure checks consistency in various measurements. The positioning and dimension of each Region of Interest (ROI) is very important. Be consistent between each assessment to achieve the minimum deviation.



29. Zoom the Axial image (upper left). To zoom, start at the lower right corner of the image and hold down left mouse button and drag cursor across the image.

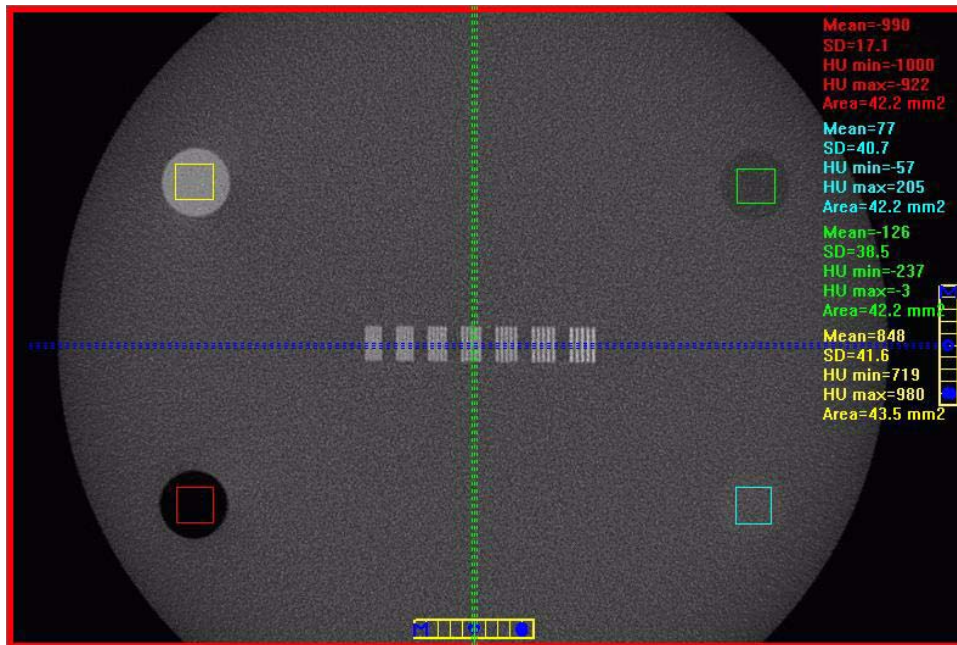
For consistency, ensure that the slice selection to be measured is setup as follows.

- a. Right click top-left image and select **Set Filter > Normal**
- b. Click the top of the right-hand scale, and select **Show as MIP**.
- c. At the bottom of the scale, click and hold the cursor on the ● symbol. The slice thickness is displayed.

Sliding the cursor up and down changes the value. The minimum value is 0.4 mm in this case, which is selected on this slice.



- d. Move the position of the slice to the middle of the phantom as shown in the figure.



30. Right click the image and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).
31. Area of ROIs should be at least 40mm<sup>2</sup> but less than 46mm<sup>2</sup>.

Use the Region Tool to define a ROI in the center of each circle of material implanted within the QA phantom. Note: to achieve an accurate measurement, **boxes should be as large as possible without touching the circle diameter.**

32. Record the Hounsfield value of each material. See table below.

Material	Mean Scan Value (Hounsfield Units)	Lower Limit	Upper Limit
<b>Air</b> (Black) (lower left)		-1000	-980
<b>Acrylic</b> (Light Gray) (lower right)		-50	186
<b>LDPE</b> (Dark Gray) (upper right)		-245	-46
<b>Teflon</b> (White) (upper left)		580	1160

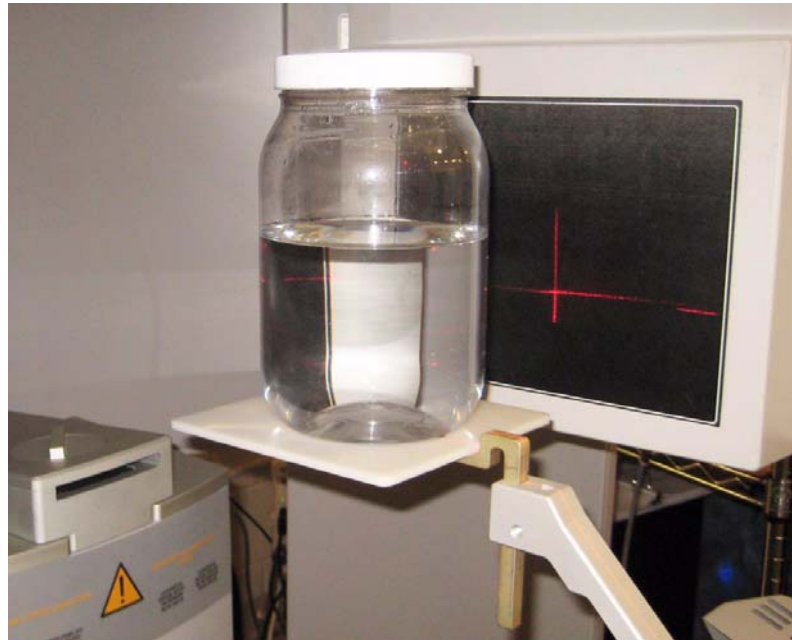
The Upper and Lower Limits are based on the baseline value of air (-1000)

33. Call Service, if any of the four measured values exceed the Low or High limit.

## QA Water Phantom Test

The Water Phantom Test is a noise level test. The HU measurements are taken at five different regions within the Water volume.

1. Remove Chin Cup and insert Phantom Platform.
2. Half-fill Phantom with water and carefully place on platform.



3. Using the Alignment Lasers, water bath is to be centered and the horizontal laser to appear across the center of the water depth.
4. Start test by selecting **File > New Patient** from the Main menu.
5. From the Patient Information Panel, click **Add**.

Enter **Water Calibration** in the *First Name* field and **Noise Test** in the *Patient ID* field.

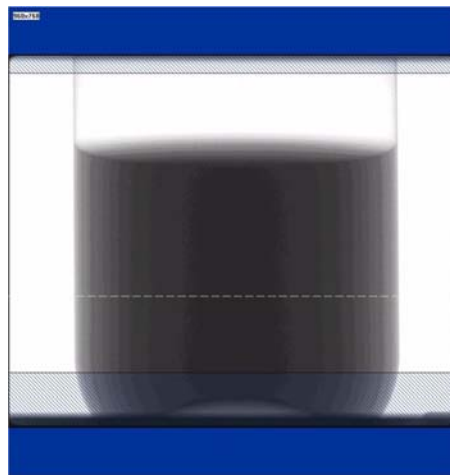
6. Click **OK** to close the Patient Information box.
7. From the **Volume** tab in the Acquisition window, select the following:

*Size of Reconstruction Volume:* **Landscape 13cm**  
*Resolution:* **.4 voxel**

**WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

8. Click **Preview** to check the phantom position.
9. Click **OK** and press the **Scan** button on the Control Box when prompted. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.



10. White dotted line in preview screen, is used to align water height. Line should appear near the middle of the water height. Adjust the Phantom Platform to achieve the proper height. Use the menu **Back/Front** arrow-slide to adjust the phantom side-to-side position.  
If required, make adjustments and click **Preview** again. Repeat as required.

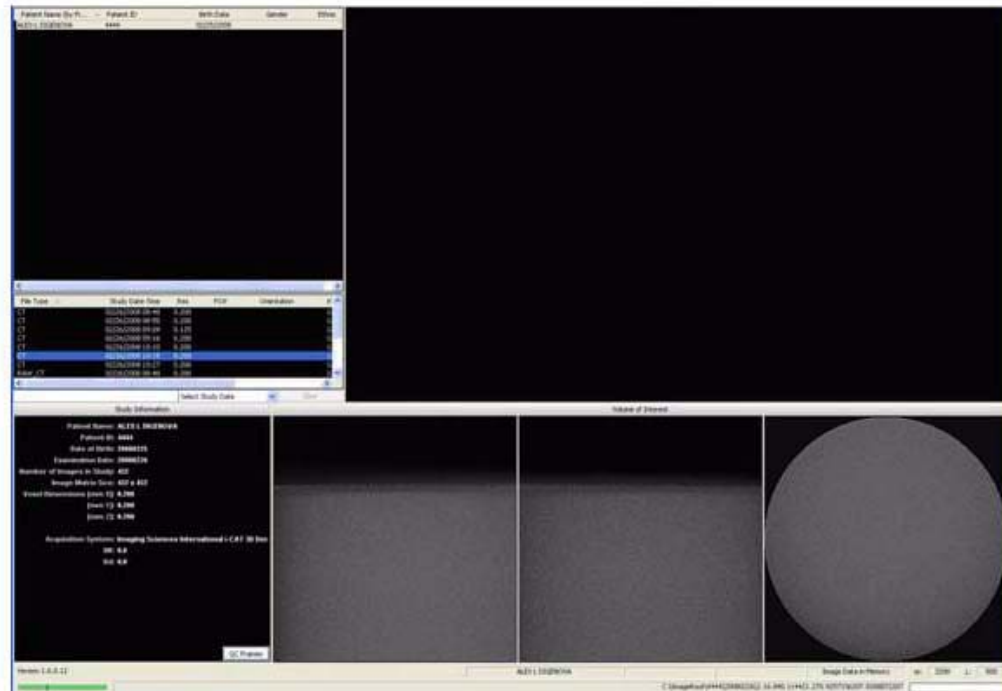
**WARNING**

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.

11. Click **Capture** to start the scan process.
12. Click **OK** to start the scan process.

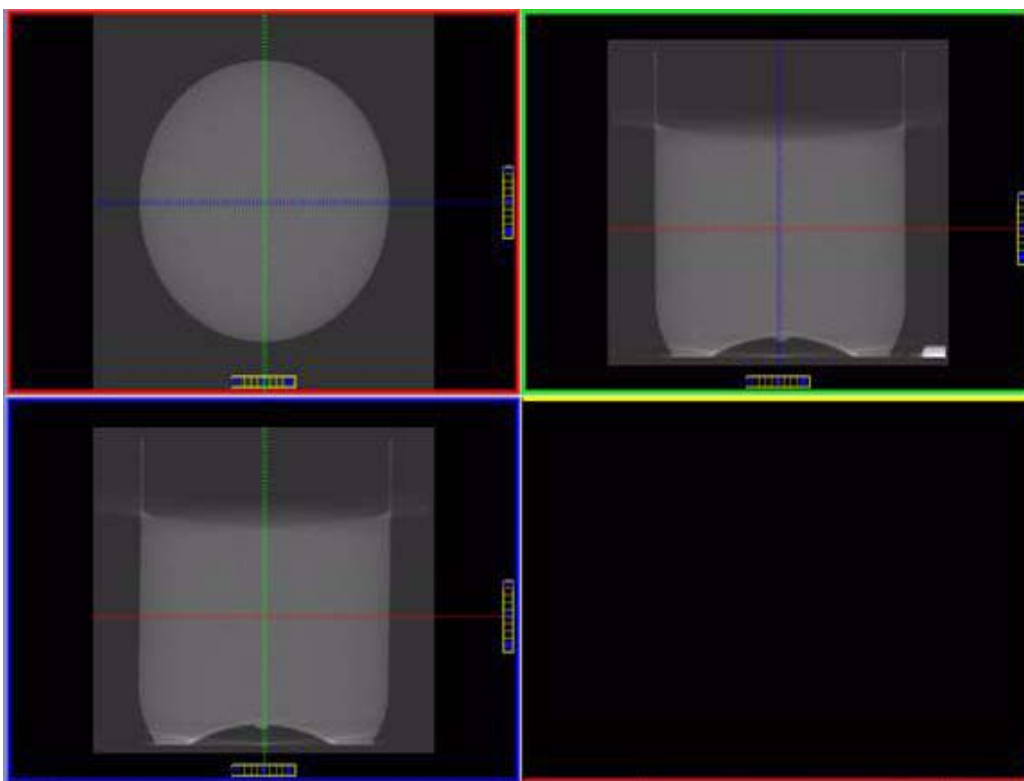


- Press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.



- At the Contourline prompt, select **No** and **Cancel**.

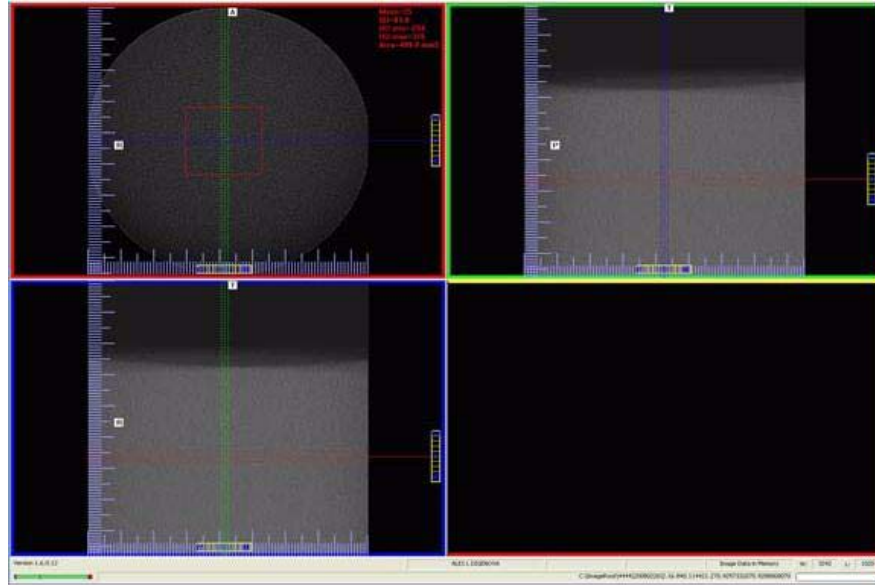
15. Access the HU measurement image for evaluation by double clicking **Coronal View** (bottom image, 2<sup>nd</sup> from the right).



16. The red dotted line, in the upper right screen, should appear in the middle of the water height. Use the Center Line Positioning tool to make the height adjustment.

## Noise Level Test

17. Zoom the Axial image (upper left). To zoom, start at the lower right corner of the image and drag the cursor across the image.



18. Right click the image and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

Use the Region Tool to define a ROI (Region of Interest) in the center of Water and also the Air (outside area of the water bowl), as shown above.

HU Area (box size) should be approximately:

400.0 mm<sup>2</sup> inside the Water Phantom area

400.0 mm<sup>2</sup> outside the Water Phantom area (AIR)

19. Note and record the Mean and Standard Deviation values of both the Water and Air areas. See chart below.

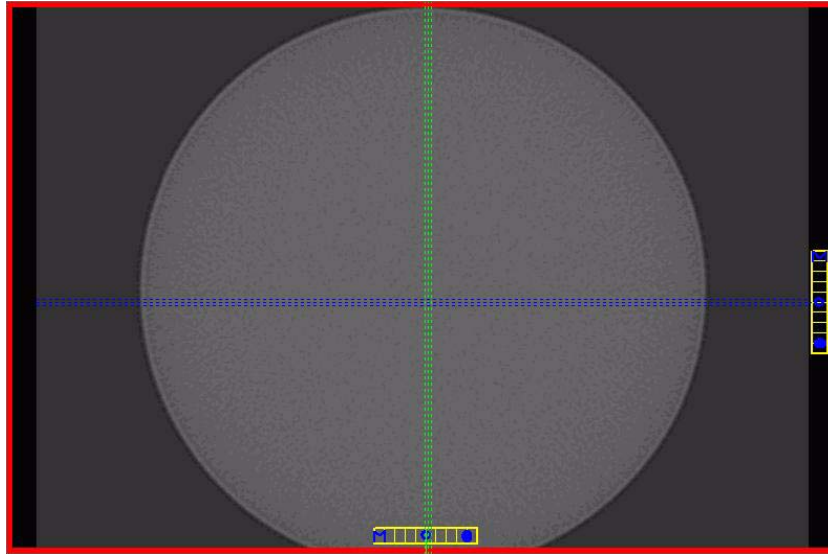
Measured Values	Water	Air
Mean		
Expected Values	0 ±50	-1000 ±50
SD		

**NOTE:** Do not close image. This image is also used for the Uniformity Test (next procedure).

20. If the Standard Deviation (SD) Measured Value **exceeds 70**, call Service.

## Uniformity Test

21. Use the Noise Level Test dataset (previous procedure), if not available, perform steps 1 to 13.



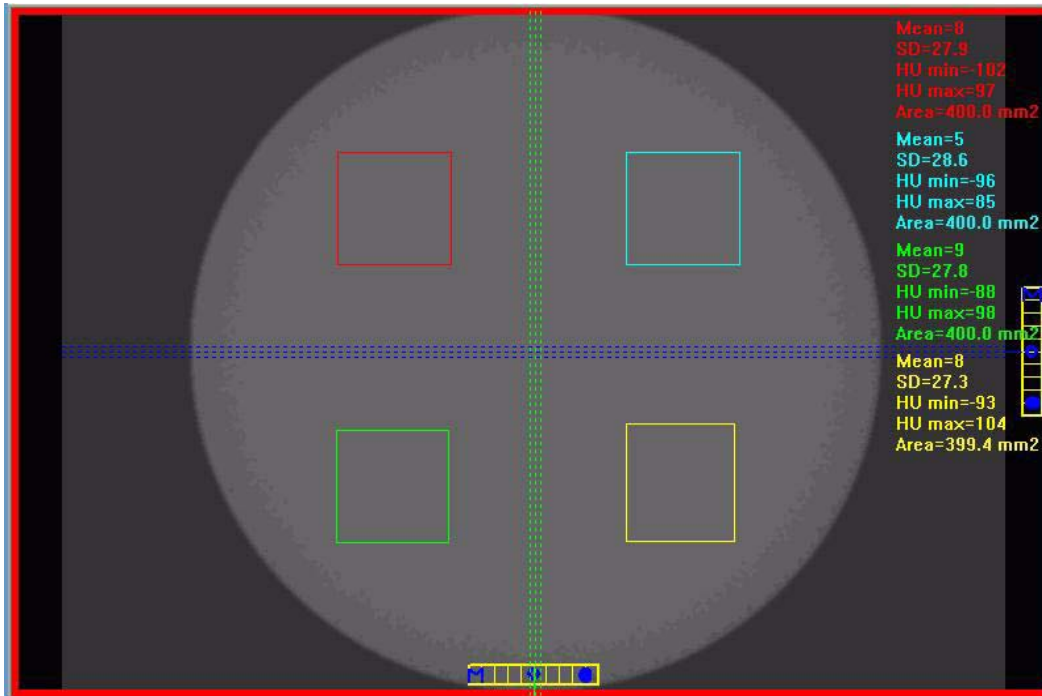
If using the Noise Level Test, right click the HU data (upper right corner of image) and select **Remove all measurements**.

22. Right click the image and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

Use the Region Tool to define a ROI (Region of Interest) in four areas of Water, as shown above.

**NOTE:** Four regions is the number of regions that can be displayed at one time. Creating another region (fifth) will overwrite the first.

The HU Area (box size) should be approximately 400.0 mm<sup>2</sup>.



23. Note and record the Mean and SD values of the four regions. See chart below.
24. After recording values, **a fifth ROI is required from the center of the water area**. The fifth measurement replaces the first measurement, since four measurements are the limit.
25. Note and record the Mean and SD values of the center ROI.

Measured Values	Upper Left	Upper Right	Lower Left	Lower Right	Center
Mean					
SD					

26. Subtract the lowest **Mean Value** from the highest **Mean Value**. If the remainder is **greater than 90**, call ISI Technical Support.

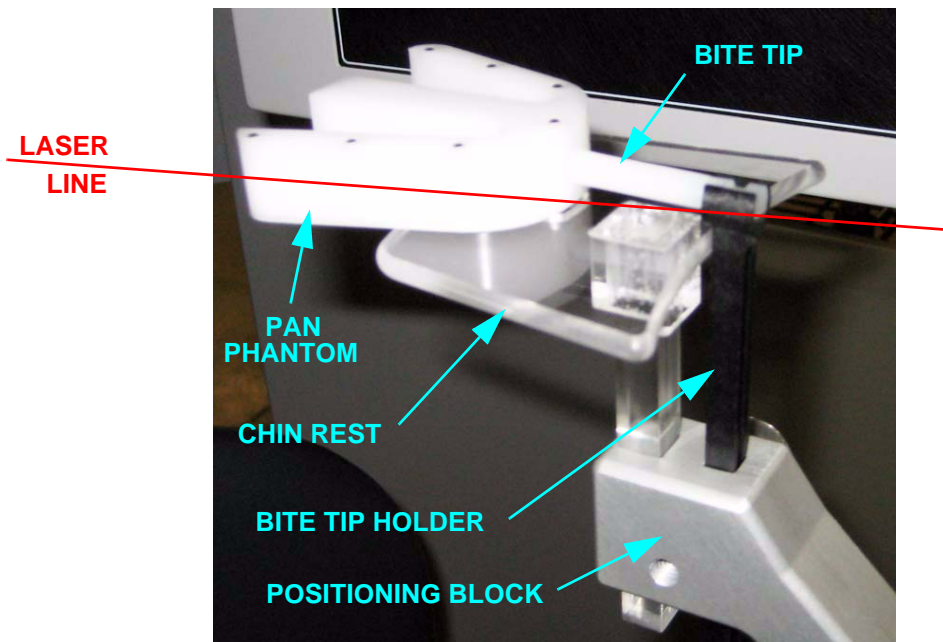
## PAN Phantom Test

PAN Phantom Test is used to validate the PAN scan data capture.

### To perform a PAN Phantom Test:

1. Prepare the Bite Tip by inserting the narrow edges of the Bite Tip down into the Bite Tip Holder uprights. Then turn the Bite Tip a 1/4 turn to lock into place.
2. Insert the Chin Rest and Bite Tip Holder into the Positioning Block.
3. Slide PAN Phantom into Chin Rest slot (balls facing up).
4. Insert Bite Tip into the phantom front mounting hole to lock phantom into place.
5. Press the Alignment Light button on the Patient Alignment Panel to display lasers. Use the Horizontal Laser to adjust the height of the phantom as shown below.

Lasers are available while the Volume tab is selected (not PAN).



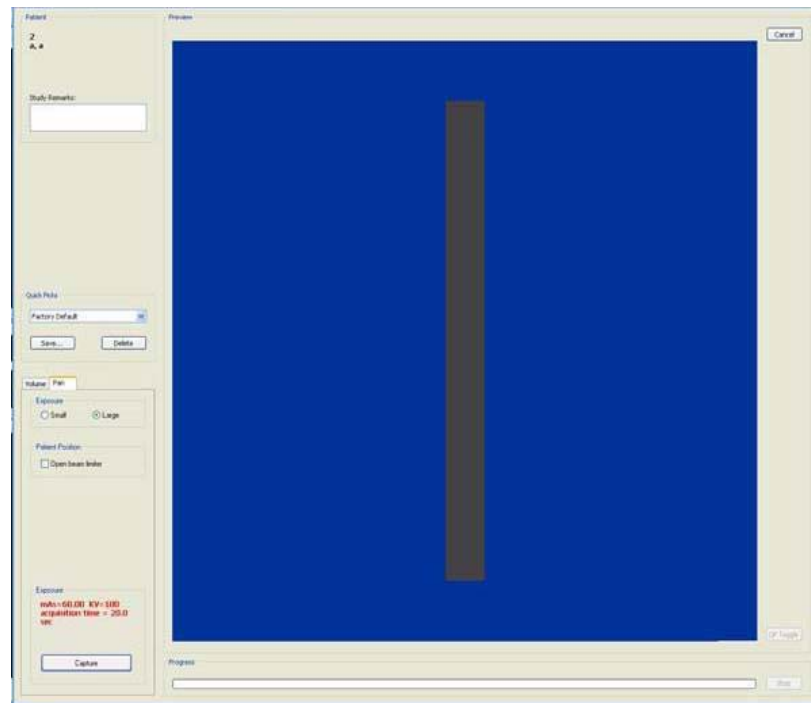
6. Start test by selecting **File > New Patient** from the Main menu or right click an existing image from database and select **Acquire New Scan**.
7. From the Patient Information Panel, click **Add**.  
Enter **PAN Test** in the *First Name* field and **QA** in the *Patient ID* field.

8. Click **OK** to close the Patient Information box.
9. Click the **Pan** tab in the Acquisition window and select, *Exposure: Large*
10. Click the **Capture** button to start the test.



**WARNING**

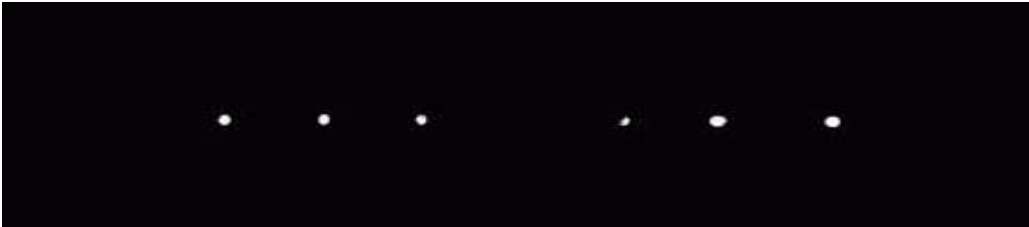
The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the safe exposure factors and operating instructions. Do not operate this system unless you have received training to perform a procedure.



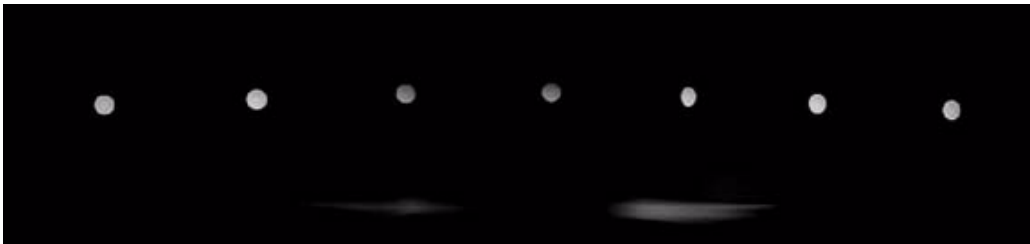
11. The system moves approximately 1/4 rotation to the Home Position and then displays the scan parameters.



12. Click **OK** to start the scan process.
13. Press **Scan** button on Control Box. An audible is sounded and the X-ray ON light is illuminated during radiation exposure.
14. The PAN scan runs a few minutes and then displays the reconstructed image.



15. Adjust the Brightness/Contrast by dragging the cursor across the image (vertical/horizontal). All seven metal balls should become visible as shown below.



**Good Image Quality**

16. The image above is an example of a system properly aligned for PAN scanning. All but two of the metal balls are circular in shape.



**Poor Image Quality**

17. The image above is an example of a system that is not properly aligned for PAN scanning. This is easily seen by the fact that only two metal balls are circular. Elongation of the Metal Balls indicate that the phantom is not in the middle of the focal trough due to poor chair alignment.
18. Check chair alignment if all seven balls do not appear circular.



## *Radiation Output Test*

It is recommended that a check of the kVp(eff) and Radiation Output of the X-ray source be performed annually by a **qualified Physicist**.

The incident Absorbed Dose at the detector may be measured using a dosimeter. Tests are performed to assess output value and to check for tube output consistency and timer accuracy.

1. Attach a dosimeter to the detector such that the sensor is positioned where the vertical (coronal) and horizontal (axial) lasers intersect. This is in the lower center of the detector.
2. Perform a Landscape scan 8.9 second, 13 cm, 0.4 voxel and record time and dose from meter.
3. Repeat step 2 for 26.9 seconds and record.

## *Measured Dose*

The table below shows measurements performed on the detector.

<b>Tube Potential (kV)</b>	<b>120</b>
<b>Selected Scan Time (seconds)</b>	<b>26.9</b>
<b>Mechanical Rotation Time (seconds)</b>	<b>21.06</b>
<b>Approximate Exposure Time (seconds)</b>	<b>3.6</b>
<b>Displayed mAs</b>	<b>37.07</b>
<b>Measured Exposure at Detector (mR)</b>	<b>225</b>
<b>Measured Exposure at Detector / mAs (mR/mAs)</b>	<b>6.25</b>
<b>Measured Exposure at 1m (mR/mAs)</b>	<b>2.98</b>
<b>Measured Dose at 1m (<math>\mu</math>Gy/mAs)</b>	<b>25.89</b>
<b>Dose at Detector per Frame (<math>\mu</math>Gy/fr)</b>	<b>5.39</b>
<b>Tube Output (<math>\mu</math>Gy/mAs @ 1m)</b>	<b>25.89</b>
<b>Distance Source to Detector (cm)</b>	<b>68</b>
<b>Conversion Factor for Absorbed Dose (R to Gy)</b>	<b>0.87</b>

## ***Interpretation***

1. The dose per frame at the detector may be calculated by:

Dose per frame at Detector = Dose at Detector / Number of Frames

Where Number of Frames = 309 for 8.9 second scan

= 619 for 26.9 second scan

The tube output per mAs may be normalized to 1m using the inverse square law for the purposes of assessing consistency of tube output:

$$\text{Tube Output } (\mu\text{Gy/mAs}) = \frac{\text{Dose at Detector} \times (\text{Source to detector distance})^2}{\text{Displayed mAs}}$$

Where Source to detector distance = 0.68m for the system.



## ***Declaration of Conformity***

**Manufacturer and Technical File Holder:**

Imaging Sciences International<sup>LLC</sup>  
1910 North Penn Road  
Hatfield, PA 19440  
United States of America

Phone: (215) 997-5666

Fax: (215) 997-5665

**European Representative:**

Guy Long  
Imaging Sciences International<sup>LLC</sup>  
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Phone: +44 (0) 149 473 3000  
Mobile: +44 (0) 7917 500 202  
Fax: +44 (0) 149 443 1168

**Equipment:** KaVo, Model 3D eXam

In accordance with Annex II, we hereby declare that the equipment identified above is in conformity with the applicable requirements of the European Union Council Directive concerning Medical Devices 93/42/EEC and LVFS 2003:11. The Technical Document supporting our Declaration of Conformity is held at the disposal of National Authorities at the address identified above. The equipment listed above meets or exceeds all Imaging Sciences International published specifications. The test equipment used to test and calibrate the equipment listed above is regularly calibrated against company standards that are directly traceable to National Institute of Standards Technology. The equipment has also been tested and/or evaluated against and found compliant to the following standards/requirements:

UL 60601-1	IEC/EN 60601-1-4
CSA C22.2 No. 601.1	IEC/EN 60601-2-32
JIS Z4701	IEC/EN 60601-2-44
JIS Z4703	IEC/EN 60825-1
JIS T0601	CE-MDD 93/42/EEC
IEC/EN 60601-1	LVFS 2003:11 (Swedish regulation, transposing the MDD 93/42/EEC)
IEC/EN 60601-1-1	CMDCAS (Canadian Medical Device Regulation)
IEC/EN 60601-1-2	ISO 10993-1:2003
IEC/EN 60601-1-3	ISO 14971:2000

The Quality System of Imaging Sciences International has been assessed and registered to ISO 13485:2003 and ISO 9001:2000. The Quality System of Imaging Sciences International also complies with applicable requirements of the European Union Council Directive concerning Medical Devices 93/42/EEC, LVFS 2003:11, Food and Drug Administration (FDA), applicable sections of 21CFR parts 800 to 1050 and Canadian Medical Devices Regulations (CMDR), relevant sections 2 to 65 for medical devices.

Mario P. Infanti  
Director of Regulatory Affairs and Quality Assurance



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## ***Equipment Class Determination***

The equipment class was determined by reviewing the Essential Requirements of the European Union Council Directive concerning Medical Devices 93/42/EEC, Annex 9, rule 10, Food and Drug Administration (FDA) 21CFR part 860, Canadian Medical Devices Regulations (CMDR), schedule 1 and Health Canada “Medical Device Keyword Index” for “X-ray” equipment and IEC standards 60601-2-7 and 60601-2-28. The following class of equipment was determined:

Protection against electric shock: Class I

Applied part has a degree of protection against electric shock: Class B

Class of equipment against ingress of liquids: Ordinary Equipment, IPX0

Radiated emissions: Class B

CE-MDD 93/42/EEC: Class IIb

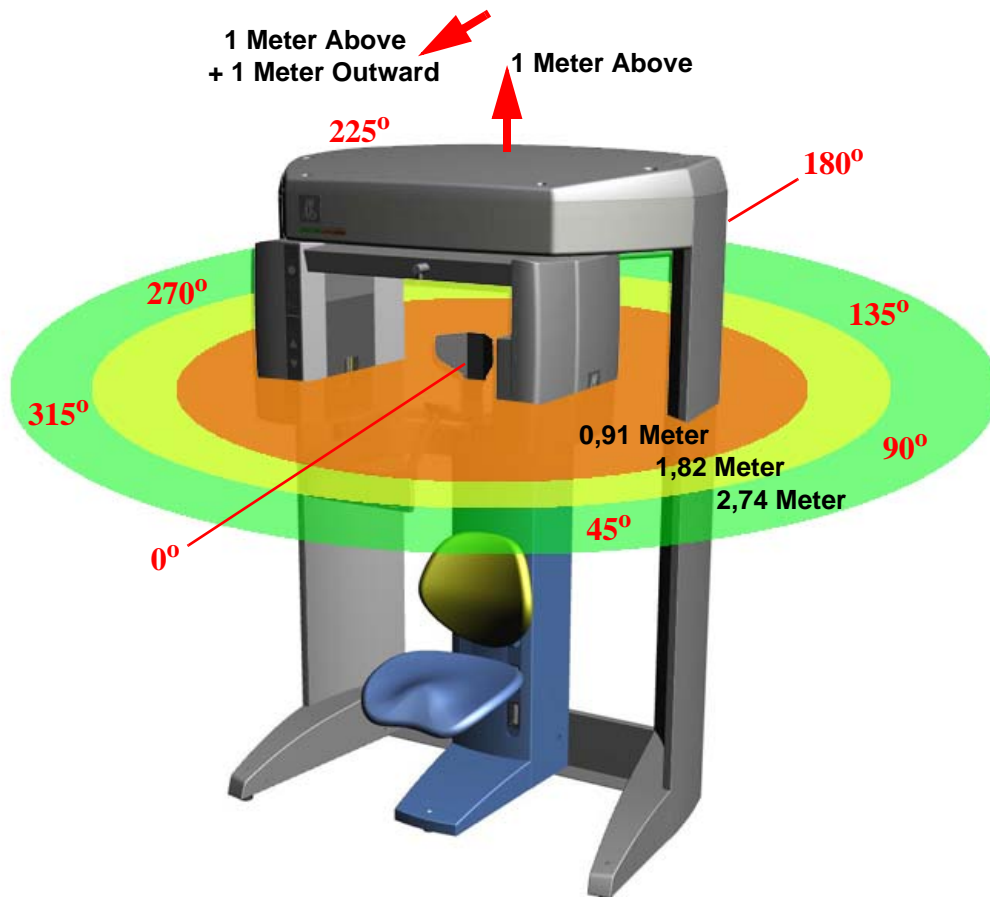
CMDR (Canada): Class 2

FDA: Class 2

The next section describes how Patient data is converted into DICOM images. This procedure is used to determine where these DICOM image files are to reside.

# Chapter 12 Radiation Environment Survey

The direct and scattered beams can produce serious bodily injuries to Patients and persons in the surrounding area. Adequate precautions must always be taken to avoid or reduce exposure to the useful beam, as well as scattered radiation. Refer to the following figure and related table to determine scattered beam measurements.



## ***Conditions of Operation – 8.9 and 26.9 Second Scans***

All data was acquired using Radcal Model 9010 Radiation monitor, with 10 x 5-180 chamber. The data was acquired in concentric circles of radii listed in table below. A lab head phantom was placed within the beam to act as the scattering agent. The Survey Meter was placed at a height of 112 cm [44 in] while the mid-point of the beam exit window was located 118 cm [46.5 in] above the floor. The detector was in the portrait position and X-ray field was at its maximum opening.

Locations listed in the table are for 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. Looking out from the system 0° was located directly in front (A location).

This table consists of data gathered with the system operating at 120 kVp(eff), 5 mA with an assumed use and occupancy factor of 1 and the following parameters:

### ***Scatter Measurements for 8.9 Second Scans***

**8.9 second scan** using pulsed X-ray: 309 frames, 12 ms pulse width at 5 mA. Based on this, the Estimated workload is:

- 10 scans per week yielding a workload of 3.1 mA-min/week
- 25 scans per week yielding a workload of 7.8 mA-min/week
- 50 scans per week yielding a workload of 15.5 mA-min/week

**Landscape 8.9 Second Scan**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	0.30	304.5	3.0	7.6	15.2
	6 [1.82m]	0.08	77.2	0.8	1.9	3.9
	9 [2.74m]	0.04	35.5	0.4	0.9	1.8
45°	3 [0.91m]	0.31	314.6	3.1	7.9	15.7
	6 [1.82m]	0.08	81.4	0.8	2.0	4.1
	9 [2.74m]	0.04	36.3	0.4	0.9	1.8
90° (B)	3 [0.91m]	0.29	289.1	2.9	7.2	14.5
	6 [1.82m]	0.07	73.3	0.7	1.8	3.7
	9 [2.74m]	0.03	32.9	0.3	0.8	1.6
135°	3 [0.91m]	0.24	243.1	2.4	6.1	12.2
	6 [1.82m]	0.06	63.7	0.6	1.6	3.2
	9 [2.74m]	0.03	28.7	0.3	0.7	1.4
180° (C)	3 [0.91m]	0.27	272.5	2.7	6.8	13.6
	6 [1.82m]	0.06	64.3	0.6	1.6	3.2
	9 [2.74m]	0.03	29.4	0.3	0.7	1.5
225°	3 [0.91m]	0.26	256.6	2.6	6.4	12.8
	6 [1.82m]	0.06	63.6	0.6	1.6	3.2
	9 [2.74m]	0.03	29.4	0.3	0.7	1.5
270° (D)	3 [0.91m]	0.30	301.1	3.0	7.5	15.1
	6 [1.82m]	0.07	73.2	0.7	1.8	3.7
	9 [2.74m]	0.03	31.5	0.3	0.8	1.6
315°	3 [0.91m]	0.32	320.3	3.2	8.0	16.0
	6 [1.82m]	0.08	80.1	0.8	2.0	4.0
	9 [2.74m]	0.04	36.9	0.4	0.9	1.8
<b>1 meter above</b>		0.03	34.8	0.3	0.9	1.7
<b>1 meter above + 1 Outward</b>		0.08	84.6	0.8	2.1	4.2

## Portrait 8.9 Second Scan

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	0.63	628.9	6.3	15.7	31.4
	6 [1.82m]	0.17	168.8	1.7	4.2	8.4
	9 [2.74m]	0.08	79.2	0.8	2.0	4.0
45°	3 [0.91m]	0.59	594.2	5.9	14.9	29.7
	6 [1.82m]	0.16	160.9	1.6	4.0	8.0
	9 [2.74m]	0.08	77.4	0.8	1.9	3.9
90° (B)	3 [0.91m]	0.54	541.3	5.4	13.5	27.1
	6 [1.82m]	0.14	143.8	1.4	3.6	7.2
	9 [2.74m]	0.07	65.1	0.7	1.6	3.3
135°	3 [0.91m]	0.48	482.4	4.8	12.1	24.1
	6 [1.82m]	0.13	126.6	1.3	3.2	6.5
	9 [2.74m]	0.06	58.2	0.6	1.5	2.9
180° (C)	3 [0.91m]	0.56	556.6	5.6	13.9	27.8
	6 [1.82m]	0.13	130	1.3	3.3	6.5
	9 [2.74m]	0.05	54.7	0.5	1.4	2.7
225°	3 [0.91m]	0.57	566.6	5.7	14.2	28.3
	6 [1.82m]	0.13	128.6	1.3	3.2	6.4
	9 [2.74m]	0.06	56.8	0.6	1.4	2.8
270° (D)	3 [0.91m]	0.59	588.7	5.9	14.7	29.4
	6 [1.82m]	0.15	145.8	1.5	3.6	7.3
	9 [2.74m]	0.06	63.6	0.6	1.6	3.2
315°	3 [0.91m]	0.64	639.1	6.4	16.0	32.0
	6 [1.82m]	0.16	164.8	1.6	4.1	8.2
	9 [2.74m]	0.08	78.6	0.8	2.0	3.9
1 meter above		0.05	49.2	0.5	1.2	2.5
1 meter above + 1 Outward		0.12	118.8	1.2	3.0	5.9





## Scatter Measurements for 26.9 Second Scan

26.9 second scan using pulsed X-ray: 619 frames, 12 ms pulse width at 5 mA. Base on this, the Estimated workload is:

- 10 scans per week yielding a workload of 6.2 mA-min/week
- 25 scans per week yielding a workload of 15.5 mA-min/week
- 50 scans per week yielding a workload of 31.0 mA-min/week

### Landscape 26.9 Second Scan

Location	Distance in Feet [meter]	Exposure mR	Exposure ( $\mu$ R)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	0.61	609	6.1	15.2	30.5
	6 [1.82m]	0.15	154.4	1.5	3.9	7.7
	9 [2.74m]	0.07	71	0.7	1.8	3.6
45°	3 [0.91m]	0.63	629.2	6.3	15.7	31.5
	6 [1.82m]	0.16	162.8	1.6	4.1	8.1
	9 [2.74m]	0.07	72.6	0.7	1.8	3.6
90° (B)	3 [0.91m]	0.58	578.2	5.8	14.5	28.9
	6 [1.82m]	0.15	146.6	1.5	3.7	7.3
	9 [2.74m]	0.07	65.8	0.7	1.6	3.3
135°	3 [0.91m]	0.49	486.2	4.9	12.2	24.3
	6 [1.82m]	0.13	127.4	1.3	3.2	6.4
	9 [2.74m]	0.06	57.4	0.6	1.4	2.9
180° (C)	3 [0.91m]	0.55	545	5.5	13.6	27.3
	6 [1.82m]	0.13	128.6	1.3	3.2	6.4
	9 [2.74m]	0.06	58.8	0.6	1.5	2.9
225°	3 [0.91m]	0.51	513.2	5.1	12.8	25.7
	6 [1.82m]	0.13	127.2	1.3	3.2	6.4
	9 [2.74m]	0.06	58.8	0.6	1.5	2.9
270° (D)	3 [0.91m]	0.6	602.2	6.0	15.1	30.1
	6 [1.82m]	0.15	146.4	1.5	3.7	7.3
	9 [2.74m]	0.06	63	0.6	1.6	3.2
315°	3 [0.91m]	0.64	640.6	6.4	16.0	32.0
	6 [1.82m]	0.16	160.2	1.6	4.0	8.0
	9 [2.74m]	0.07	73.8	0.7	1.8	3.7
1 meter above		0.07	69.6	0.7	1.7	3.5
1 meter above +1 Outward		0.17	169.2	1.7	4.2	8.5

## Portrait 26.9 Second Scan

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	1.26	1257.8	12.6	31.4	62.9
	6 [1.82m]	0.34	337.6	3.4	8.4	16.9
	9 [2.74m]	0.16	158.4	1.6	4.0	7.9
45°	3 [0.91m]	1.19	1188.4	11.9	29.7	59.4
	6 [1.82m]	0.32	321.8	3.2	8.0	16.1
	9 [2.74m]	0.15	154.8	1.5	3.9	7.7
90° (B)	3 [0.91m]	1.08	1082.6	10.8	27.1	54.1
	6 [1.82m]	0.29	287.6	2.9	7.2	14.4
	9 [2.74m]	0.13	130.2	1.3	3.3	6.5
135°	3 [0.91m]	0.96	964.8	9.6	24.1	48.2
	6 [1.82m]	0.25	253.2	2.5	6.3	12.7
	9 [2.74m]	.012	116.4	1.2	2.9	5.8
180° (C)	3 [0.91m]	1.11	1113	11.1	27.8	55.7
	6 [1.82m]	0.26	260	2.6	6.5	13.0
	9 [2.74m]	0.11	109.4	1.1	2.7	5.5
225°	3 [0.91m]	1.13	1133.2	11.3	28.3	56.7
	6 [1.82m]	0.26	257.2	2.6	6.4	12.9
	9 [2.74m]	0.11	113.6	1.1	2.8	5.7
270° (D)	3 [0.91m]	1.18	1177.4	11.8	29.4	58.9
	6 [1.82m]	0.29	291.6	2.9	7.3	14.6
	9 [2.74m]	0.13	127.2	1.3	3.2	6.4
315°	3 [0.91m]	1.28	1278.2	12.8	32.0	63.9
	6 [1.82m]	0.33	329.6	3.3	8.2	16.5
	9 [2.74m]	0.16	157.2	1.6	3.9	7.9
<b>1 meter above</b>		0.10	98.4	1.0	2.5	4.9
<b>1 meter above + 1 Outward</b>		0.24	237.6	2.4	5.9	11.9



## Scatter Measurements for PAN Scan

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	0.11	112.7	1.1	2.8	5.6
	6 [1.82m]	0.04	35.5	0.4	0.9	1.8
	9 [2.74m]	0.02	16.4	0.2	0.4	0.8
45°	3 [0.91m]	0.14	135.1	1.4	3.4	6.8
	6 [1.82m]	0.04	35.6	0.4	0.9	1.8
	9 [2.74m]	0.02	17.1	0.2	0.4	0.9
90° (B)	3 [0.91m]	0.10	98.6	1.0	2.5	4.9
	6 [1.82m]	0.03	26	0.3	0.7	1.3
	9 [2.74m]	0.01	12.3	0.1	0.3	0.6
135°	3 [0.91m]	0.10	95.2	1.0	2.4	4.8
	6 [1.82m]	0.02	24.6	0.2	0.6	1.2
	9 [2.74m]	0.01	10.3	0.1	0.3	0.5
180° (C)	3 [0.91m]	0.11	113.6	1.1	2.8	5.7
	6 [1.82m]	0.02	24.6	0.2	0.6	1.2
	9 [2.74m]	0.01	11.6	0.1	0.3	0.6
225°	3 [0.91m]	0.09	93.1	0.9	2.3	4.7
	6 [1.82m]	0.02	19.8	0.2	0.5	1.0
	9 [2.74m]	0.01	10.2	0.1	0.3	0.5
270° (D)	3 [0.91m]	0.09	93.1	0.9	2.3	4.7
	6 [1.82m]	0.02	21.9	0.2	0.5	1.1
	9 [2.74m]	0.01	10.9	0.1	0.3	0.5
315°	3 [0.91m]	0.12	124.5	1.2	3.1	6.2
	6 [1.82m]	0.03	32.8	0.3	0.8	1.6
	9 [2.74m]	0.02	15.1	0.2	0.4	0.8
1 meter above		0.03	30.7	0.3	0.8	1.5
1 meter above + 1 Outward		0.01	7	0.1	0.2	0.4



## ***Drywall Attenuation***

The attenuation properties of drywall were studied. A drywall consisting of two 4 feet x 8 feet x 5/8 inch [1.2m x 2.4m x 1.6 cm] sheets were attached to either side of a 2 feet x 4 feet [.6m x 1.2m] board. The wall was placed 51 inches [1.3m] from the center of the scatter phantom. Using a calibrated Radcal Model 9010 Radiation monitor, with 10 x 5-180 chamber, the exposure was measured as 28 uR. The ion chamber was placed 12 inches [.3m] from the wall and 67.5 inches [1.7m] from the midline of the scatter phantom. Without the drywall the exposure was 56 uR. The drywall affords a 50% transmission factor or one half-value layer.

## ***Recommended Operating Requirements***

Local agencies or government bodies or international standards may dictate different and/or additional requirements for installation of the system in order to protect personnel and the public from exposure from the radiological output of the device. Consult your local agencies, government bodies, or international standards for actual requirements which apply.

It is recommended that a **qualified Physicist or Radiologist** determine where appropriate, the applicable lead shielding to be installed in the area around the system equipment. The minimum lead thickness required is 0.8 mm [1/32 in] lead. Thicker lead can be used if desired. Below are highlights of some other common requirements that may apply to your location:

- The Computer Workstation and X-ray Operator should be located at a minimum of two meters or behind a properly shielded permanent barrier. A viewing window (or alternative method such as a mounted mirror) should be present to enable the X-ray Operator to view the Patient and operate the computer while the exposure is present.
- The Operator Control Box and Acquisition Computer shall be located within 1 meter [3.28 ft] from door. If not, an interlocked door may be required.
- A room door may be required.
- Radiation warning signs may be required next to the entrance to the room.
- A Warning light may be required by the entrance to the room.
- A shielding plan should be performed where the system is being installed. Some local agencies or government bodies

require that a shielding plan be conducted by a **qualified Physicist or Radiologist** and a copy of the shielding plan be submitted and approved prior to installation of the system.

- An area radiation survey by a **qualified physicist or Radiologist** may then be required within 30 days of initial clinical use of the system. This survey may be required to be submitted to the local agency or government body.
- An annual radiation survey may be typically required. This survey is typically required to be submitted to the local agency or government body.
- A phantom or patients may be used for system training. Employees of the facility may not be used for this training.
- The system shall be registered with the local agency or government body.

## ***Dose and Imaging Performance Information***

### ***Conditions of Operation***

The dose measurements were made using a PMMA Head Phantom with a diameter of 16 centimeters and a 10cc ion chamber with an active length of 10 centimeters.

#### **Procedure Performed:**

1. Levelled the Head Phantom and used a light localizer to position phantom in center of scan, so slice cuts through the center of the phantom.
2. Performed a Capture view to assess the alignment.
3. Performed a scan.
4. Used image viewer to verify that the center hole is within 5 mm from the center of the scan in all directions. The central position is a position where the CTDI values are the maximum.
5. Placed the ionization chamber in the center hole. Inserted acrylic rods in all other holes.
6. Used typical technique factors.
7. Performed a single scan and read out of the ionization detected with the chamber X, in coulombs (C).
8. Calculated CTDI using the equation:

$$\text{CTDI (rad)} = X_r \times f \text{ rad/R} \times 10(\text{cm}) / \text{NST (cm)}$$



Where:

- $X_r$  = the measured exposure in Roentgens
  - $f$  = a factor to convert exposure in air to absorbed dose in tissue or other attenuating matter. One must use the  $f$ -factor ( $f$ ) appropriate to the task at hand to convert exposure ( $R$ ) to absorbed dose (rad):
    - i 0.78 rad/R for comparison to FDA-required, manufacturer-reported data (Lucite), and this is also appropriate for acrylic
    - i 0.93 or 0.98 rad/R for patient dose estimates (tissue or water)
    - i 0.87 rad/R for calculation of, or comparison to, CTDI<sub>w</sub> (air)
  - 10 (cm) = the active length of the pencil-beam ion chamber
  - NST = vertical dimension of the beam (6 cm)
9. Repeating these steps for different slice thicknesses is not required as this is not applicable to the 17-19 Cone Beam Volumetric Tomography technology.
10. Repeat for chamber in peripheral locations (1 cm interior to the surface of the phantom) with all other holes filled with acrylic rods.

## Measurements

The following table consists of data gathered with the system 26.9s scan, 120 kVp(eff), and 5mA. For completeness, the CTDI values are calculated for all the three  $f$  factors given above.

radR Factor =	0.78		0.87		0.93	
	mrad	mGy	mrad	mGy	mrad	mGy
Center	238.2	2.38	265.7	2.66	284.0	2.84
Back Periphery	254.4	2.54	283.8	2.84	303.3	3.03
Left Periphery	220.2	2.20	245.6	2.46	262.5	2.63
Right Periphery	215.4	2.15	240.3	2.40	256.8	2.57
Front Periphery	172.2	1.72	192.1	1.92	205.3	2.05

## X-ray Tube Assembly

Imaging Sciences International utilizes the SXR 130-15-0.5 X-ray Tube to manufacture our X-ray head assemblies.

### Operator Data

Available focal spot size (mm): **0.5**

Available target angle: **15°**

Anode construction:

Vacuum cast copper with tungsten target

Cathode construction:

Vacuum tube nickel with tungsten filament

Max. Tube operating voltage:

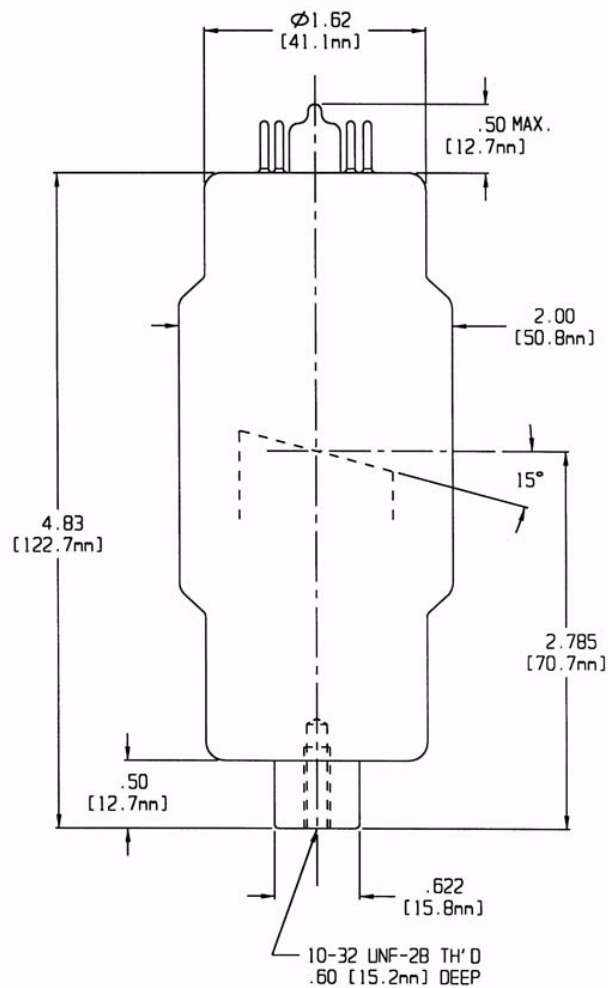
130 kVp Full wave rectified

Inherent filtration/Window material:

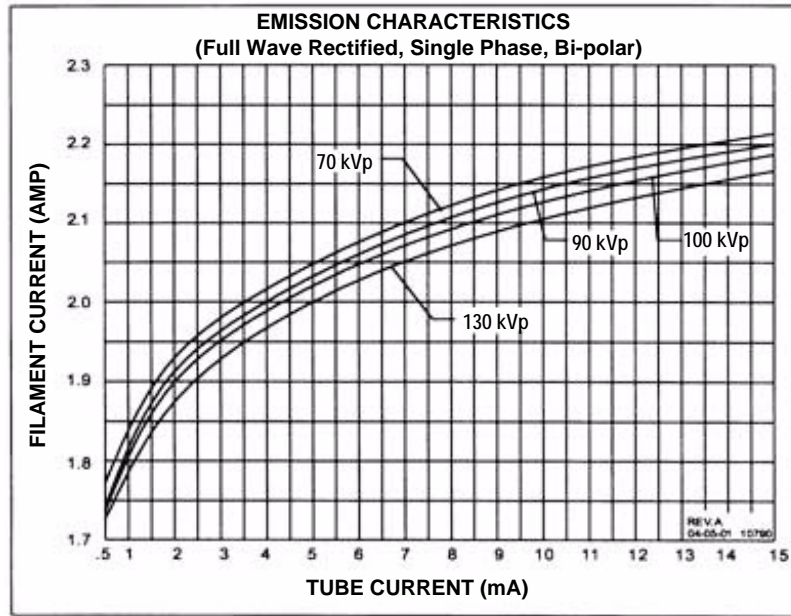
2.0 mm/Glass

Cooling Method:

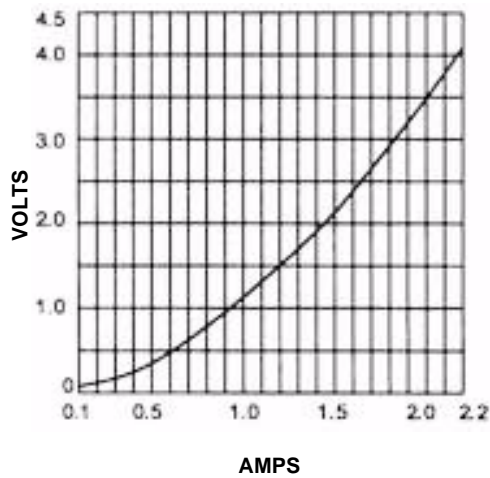
High dielectric transformer oil



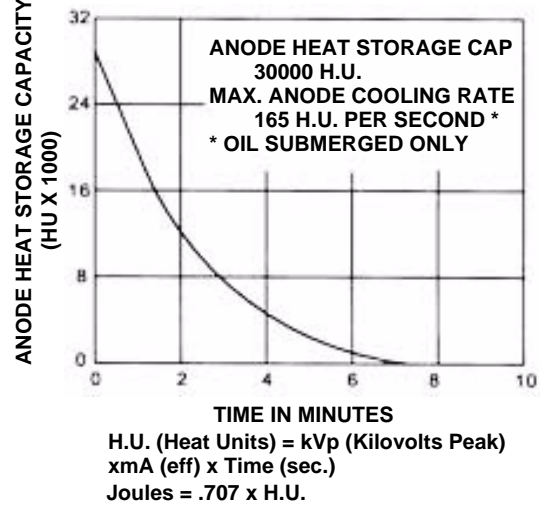
**SXR-130-15-0.5  
FOCAL SPOT**



**FILAMENT VOLT/AMPS CHARACTERISTICS:**  
60 Hz AC & DC



**ANODE COOLING CURVE**



**SXR-130-15-0.5**



# Chapter **13** *Product Information*

## **Technical Specifications**

### **X-ray Source**

Tube Voltage:	120 kVp(eff)
Tube Current:	3-7 mA
Voltage Wave Shape:	Constant Potential
Focal Spot:	0.0197 inches (0.5 mm)
Duty Cycle:	3%

**Source to Sensor distance:** 28.1 inches (71.4 cm)

**Source to Patient distance\*:** 19.5 inches (49.53 cm) (center of rotation)

- \* The patient must be properly positioned in the Head Support Positioner Mechanism for each patient for all applications in order to have the focal spot to skin distance as large as possible.

**Minimum Filtration (at 120 kVp(eff)) (mm of aluminum equivalent):**  
10 mm or greater

**Maximum Rated Continuous Tube Operation:** 130 kVp @ 0.5 mA

**Maximum Rated Pulsed Tube Operation:** 130 kVp @ 1mA

**NOTE:** Leakage technique factors are measured at the maximum specified energy.

**Maximum Deviation:** kV: +/- 5 kV

**mA:** + 10%

**Timer:** ± .01 seconds or 5%, whichever is greater

**X-ray Beam Size:** Rectangular cone 9.37" wide x 1.97" to 7.56" high  
(23.8 cm width x 5 cm to 19.2 cm height)

**PAN option:** Rectangular cone 0.39" width x 6.30" height  
(1cm width x 16 cm height)

(Automatically collimated not to exceed image detector readable area)

**Image Detector:** Amorphous Silicon Flat Panel (readable area), 9.37" width x 7.56" height (23.8 cm width x 19.2 cm height)



**Sensor Front Panel Attenuation Value:** Less than 1mm of aluminum equivalent

**Gray Scale:** 14 bit

**Voxel Size:** 0.4/0.3/0.25/0.2 mm

**Image Acquisition:** Single 360 degree rotation (maximum)

**Scan Time:** 26.9/8.9 seconds

**Field of View:** (standard) 6.50 inches diameter x 5.33 inches height (maximum) (16.5 cm diameter x 13.5 cm height (maximum))

**Extended Field of View:** (optional) 9.15 inches diameter x 6.67 inches height maximum) (23.2 cm diameter x 17 cm height (maximum))

**Note:** Maximum values can be collimated down.

**Primary Reconstruction:** Less than 2 minutes for 26.9 second scan @ 0.4 voxel

**Secondary Reconstruction:** Real Time

## ***Power Requirements***

The Scanner requires a Dedicated Line. A Surge Protector is recommended.

**Line Voltage:** 115VAC, 200VAC or 230VAC (Factory Set)

**Line Voltage Regulation requirement:** + 10%

**Line Current:** 10 Amps (115V), 7.5 Amps (200V) or 5 Amps (230V)

**Line Frequency:** 50 Hz / 60 Hz

**Phase:** Single

**Main Circuit Breaker:** 10 Amps (115V), 7.5 Amps (200V), or 5 Amps (230V)

## ***Power Cords***

Power Cords are not supplied with the system. Three Power Cords are required, one each for the Gantry, Computer, and Monitor.

**Power Cord Specifications:**

10 Amp, 220-240VAC, 50 Hz / 60 Hz, 16/3 Gauge (minimum) Length 6 to 12 ft. (2m to 4m), IEC-320-C13 Connector End.

## ***Environmental Specifications***

### ***Operating***

50 to 95 degrees Fahrenheit  
(10 to 35 degrees Celsius)  
45% to 75% humidity

### ***Transportation and Storage***

32 to 104 degrees Fahrenheit  
(0 to 40 degrees Celsius)  
30% to 80% humidity

## ***Acquisition Computer***

Acquisition Computer requires a Dedicated Line and a Surge Protector is recommended.

### **Tower Computer Dimensions:**

17" h x 18" d x 8.5" w (43cm x 47cm x 22cm)

### **Monitor with Stand Dimensions:**

20" (51cm) LCD Monitor 17.5" h x 13.5" w (45cm x 34cm)

### **Keyboard Dimensions:**

17" w x 7" d (43cm x 18cm)

Minimum Specifications for Acquisition Computer Provided with the System:

- Pentium-4 Processor, 3.8 GHz minimum
- Windows XP Professional w/SP2
- 120 GB Hard drive
- 2 GB RAM
- 20" (51cm) Flat Panel Display
- Video Memory of 128MB minimum
- 2 Network Interface Cards (Ethernet)
- 1 serial port, 9-pin
- 3 USB ports



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## ***Patient Support Chair***

**Overall dimensions:**

28.5"d x 24"w x 43"h (72.4 cm x 61 cm x 109.2 cm)

**Weight:** 125 lbs (56.7 kg)

**Seat height adjustment:** 14" to 29" (35.65 cm to 73.7 cm)

**Maximum patient weight:** 400 lbs (181 kg)

Complies with IEC 60601-2-32:1994

## ***Disposal***

Follow local regulations on disposal of waste parts. The *X-ray source assembly, image sensor* and *all electronic circuits* should be regarded as non environmental friendly waste product.

## ***Extension Cords***

Do not use any extension cords which are not provided with the system.

## ***External Item***

Do not connect any items or equipment to this system which are not part of the system.

## ***Cleaning***

Routinely clean and disinfect all items which come in contact with the patient. Use Biocide ® from Biotrol International or equivalent cleaner and disinfectant. Biocide® is an Iodophor formulation that kills HIV, Tuberculosis and Polio in 10 minutes.



## ***Electromagnetic or other Interference (Emissions and Immunity)***

The System was tested and found to comply with the limits for Class B equipment, pursuant to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. The system generates, uses, and can radiate electromagnetic energy and if not installed and used in accordance with these instructions, may cause harmful interference to surrounding equipment. Also portable and mobile RF communications equipment can effect the operation of the system. Proper precautions and equipment location should be observed, refer to the following table:

The System is intended for use in an electromagnetic environment specified below. The Customer or User should ensure that the system is used in such an environment.		
Immunity Test	Compliance Level	Electrostatic Environment - Guidance
IEC 61000-4-2 Electrostatic Discharge (ESD)	$\pm 6$ kV Contact $\pm 8$ kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
EFT IEC 61000-4-4	$\pm 2$ kV Mains $\pm 1$ kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1$ kV Differential $\pm 2$ kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 cycle 60% Dip for 5 cycles 30% Dip for 25 cycles >95% Dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 610000-4-6	3 Vms 150 kHz to 80 MHz	Portable and mobile communication equipment should be separated from the system by no less than 19 feet (6 meters).



The System is intended for use in an electromagnetic environment specified below. The Customer or User should ensure that the system is used in such an environment.				
Emission Test	Compliance	Electrostatic Environment - Guidance		
Radiated RF IEC 61000-4-3		This Scanning System is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the system as recommended below, according to the maximum output power of the communications equipment.		
		Maximum Output Power (Watts)	Separation 150 kHz to 800 MHz	Separation 800 MHz to 2.5 GHz
		0.01	15 in (38 cm)	30 in (76 cm)
		0.1	15 in (38 cm)	30 in (76 cm)
		1	46 in (117 cm)	8 ft (2.4 m)
		10	12 ft (3.7 m)	24 ft (7.3 m)
		100	38 ft (11.7 m)	77 ft (23.4 m)
		<b>Note:</b> Field strengths from transmitters, as determined by an electromagnetic site survey, should be less than the compliance level of 3 V/m.		
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF Emissions CISPR 11	Class B	The system is suitable for use in all establishments, including domestic, and those directly connected to the public low - voltage power supply network that supplies buildings for domestic purposes.		
Harmonics IEC 61000-3-2	Class A			
Flicker IEC 61000-3-3	Complies			

If the System does cause harmful interference to surrounding equipment which can be determined by turning the system OFF and ON, the customer or user is encouraged to try to correct the interference by one or more of the following methods:

- Increase separation between the system and surrounding equipment.
- Connect the System into an outlet on a circuit different from that to which the surrounding equipment is connected.

- Consult Imaging Sciences International, the dealer or an experienced technician for help.

Use only the interface cables provided with the System. Using other interface cables may exceed the limits of Class B equipment, pursuant to IEC 60601-1-2.

## ***Equipment Standards***

The System was tested and/or evaluated against and found compliant to the following standards/requirements:

UL 60601-1	IEC/EN 60601-1-4
CSA C22.2 No. 601.1	IEC/EN 60601-2-32
JIS Z4701	IEC/EN 60825-1/JIS T0601
JIS Z4703	CE-MDD 93/42/EEC
JIS T0601	LVFS 2003:11 (Swedish regulation, transposing the MDD 93/42/EEC)
IEC/EN 60601-1	CMDCAS (Canadian Medical Device Regulation)
IEC/EN 60601-1-1	ISO 10993-1:2003
IEC/EN 60601-1-2	ISO 14971:2000
IEC/EN 60601-1-3	

## ***Equipment Class***

Protection against electric shock: Class I

Applied part has degree of protection against electric shock: Class B

Class of equipment against ingress of liquids: Ordinary Equipment, IPX0

Radiated emissions: Class B

CMDR (Canada): Class 2

CE-MDD 93/42/EEC: Class IIb (Annex 9, Rule 10)

FDA: Class 2



## ***Preventive Maintenance Schedule - for Owner / User***

**Daily:** Routine Dusting - all surfaces

**Monthly:** Clean all surfaces and check for failed/faulty indicator lights.

**Yearly:** Check for satisfactory image quality.

IT IS THE RESPONSIBILITY OF THE USER TO INSURE THAT THE EQUIPMENT IS MAINTAINED IN COMPLIANCE WITH THE MANUFACTURER'S RECOMMENDED MAINTENANCE SCHEDULE. THE MANUFACTURER AND THE ASSEMBLER / INSTALLER ARE RELIEVED FROM RESPONSIBILITY IN THOSE CASES WHERE NON-COMPLIANCE WITH THE STANDARD RESULTS FROM THE USER'S FAILURE TO HAVE THE MANUFACTURER'S RECOMMENDED MAINTENANCE PERFORMED.

The actual maintenance inspection and consequent service must be accomplished either by an authorized dealer or by a competent serviceman of the user's choice who has adequate training in those aspects of the Performance Standards of the Radiation Control for Health and Safety Act of 1968 that are applicable to this equipment.

Neither the inspection nor service is part of the equipment warranty. (To be arranged for by the Owner or User with the Dealer's Service Department).

## ***Planned Maintenance - 12 Month Schedule***

The Planned Maintenance philosophy for this system is based upon the assumption that a periodic inspection of the equipment, along with periodic cleaning and calibration, will maintain image quality.

The system requires normal periodic inspection and maintenance. Scheduled periodic inspections are necessary to detect problems which can result from excessive wear, loose items, chafing wires, and mis-adjusted parts from continual system use.

In addition to mechanical inspection and calibration, a series of image performance tests are to be conducted. These tests verify that the system meets or exceeds operational specifications and that it will provide continued excellent image quality.

Planned maintenance is to be performed annually by a factory trained Service Representative.



## Cleaning

Cleaning the equipment frequently, especially if corroding chemicals are present is a function of the Operator. Unless otherwise instructed, use a cloth moistened with warm water and mild soap. Do not use strong cleaners and solvents as these may damage the finish. Be careful when cleaning to avoid liquid leaking inside the Gantry.



### **WARNING**

USE EXTREME CARE WHEN WORKING INSIDE THE SYSTEM. VOLTAGES ARE PRESENT WHEN THE SYSTEM COVERS ARE OFF. ACCIDENTAL CONTACT WITH THESE VOLTAGES MAY CAUSE SERIOUS INJURY OR DEATH.

## Planned Maintenance Checklist

<b>Perform Calibrations</b>	
	Panel Calibration
	Collimator Calibration
	Geometry Calibration
<b>Check Detector Pivot</b> (displayed under Geometry, both Portrait and Landscape)	
	Ensure Detector Pivot is between <b>-0.10 &amp; 0.10</b> . If measurements are not within tolerance, call Service to have Receptor Panel leveled.
<b>Perform QA Water Phantom Tests</b>	
	Noise Level Test (Landscape Mode)
	Uniformity Test (Landscape Mode)
	Noise Level Test (Portrait Mode)
	Uniformity Test (Portrait Mode)
	PAN Phantom Test
	Radiation Output Test (performed by qualified Personnel, per local requirements)
<b>Check Chair Alignments</b>	
	Check Chair Center Alignment (using Chair Center Locator)
	Check Chair Level (using Chair Center Locator)

















<b>Check Laser Alignments</b>	
	Check Centerline Alignment (using Chair Center Locator)
	Check Crosshair Laser (align with notches on Receptor Panel Cover)
<b>Inspect Tube Housing Components</b>	
	Certification Label
	Warning and Indicators
	Oil Leaks
	Physical Damage
	Mounting System Stability
<b>Inspect Beam Limiting Device</b>	
	Physical Damage
	Certification Label
<b>Check/Inspect X-Ray Controller</b>	
	Visual Warning Indicator
	Audible Exposure Signal
	Certification Label


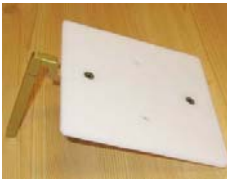












## Replaceable Parts - Reference List

Sub Assembly Number	Description
11-0	Rotation Stepper Motor
27-0	Head Rest, Carbon Fiber
35-0	Tube Head Assembly and
1000-0	X-ray Power Supply Assembly (sold together)
102-16	Platform Motor
109-2	Receptor Motor
137-0	Beam Limiter Assembly
1203	System PCB
1207	Beam Limiter Drive
1210	Motherboard
1255	Circuit Breaker, 10A for 115 Volt Systems
1256	Circuit Breaker, 5A for 230 Volt Systems
1257	Circuit Breaker, 7A for 200 Volt Systems
1304-0	Patient E-stop Box
1305	Patient Alignment Panel
1306-0	Operator Control Box
1539	Laser, Cross
1540	Laser, Straight Line
1543	Motor, Beam Limiter, 7.5 Stepper
1701-0	Isolation Transformer
420315	Plug for Patient E-stop Box
440170	Pins for Plugs, Male
440171	Pins for Plugs, Female
800130	Computer & Keyboard
800145	Monitor, LCD
800184	Receptor Panel
800550	Acquisition Key, Cobra
1000005	Fuse, 2.5A, 3AG, Sow Blow
1000010	Fuse, 10A, 250 VAC
1000011	Fuse, 0.25A, 250 VAC, Slow Blow
1000028	Chair, Linear Actuator
1000032	24VDC Power Supply (Silver Box)
1000036	Plug for Chair
1000068	Plug for Operator Control Box
1000111	Power Supply (15 VDC)
9140-0026-0006	Chin Cup

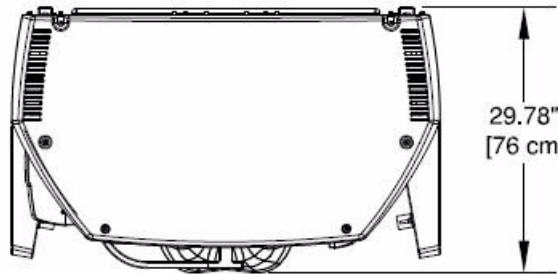
## Accessories

	<p><b>Patient E-stop</b> Part # 1304-0 Quantity 1</p>		<p><b>Carbon Fiber Head Rest</b> Part # 27-0 Quantity 1</p>
	<p><b>Glide</b> Part # 1000179 Quantity 4</p>		<p><b>Head Restraint Band</b> Part # 27-1 Quantity 100</p>
	<p><b>Tool Kit</b> Part # 5-0 Quantity 1</p>		<p><b>Velcro Head Restraint Kit</b> Part # 903-0 Quantity 1</p>
	<p><b>Booster Seat</b> Part # 1000196 Quantity 1</p>		<p><b>Phantom Assembly</b> Part # 14-1-0 Quantity 1</p>
	<p><b>Foot Stool</b> Part # 1000197 Quantity 1</p>		<p><b>Line Pair Phantom</b> Part # 13-00 Quantity 1</p>
	<p><b>Chair Patch Cable</b> Part # 1520 Quantity 1</p>		<p><b>Water Phantom Jar</b> Part # 1000224 Quantity 1</p>
	<p><b>Cable Clips</b> Part # 101-6 Quantity 6</p>		<p><b>Pan Phantom</b> Part # 12-0 Quantity 1</p>

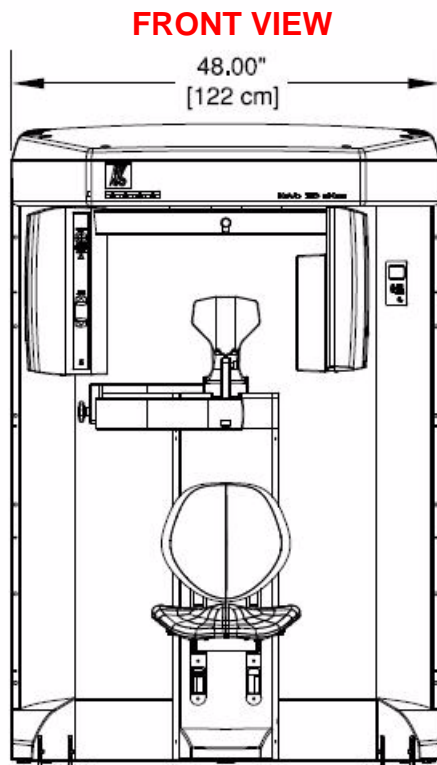
	<p><b>Chair Center Locator</b> Part # 26-8 Quantity 1</p>		<p><b>Platform Assembly</b> Part # 14-4-0 Quantity 1</p>
	<p><b>Bite Tip Holder</b> Part # 980220 Quantity 2</p>		<p><b>Chin Rest</b> Part # 9105-0026-0006 Quantity 1</p>
	<p><b>Bite Tip</b> Part # 980180 Quantity 25</p>		<p><b>Chin Cup</b> Part # 9140-0026-0006 Quantity 1</p>
	<p><b>Surge Suppressor</b> Part # 98028 Quantity 1</p>		<p><b>Power Cord</b> Part # 1000117 Quantity 1</p>

<p><b>Part # 90-0</b></p>			
	<p><b>Door Interlock Cable</b> Part # 1524 Quantity 1</p>		<p><b>E-net Cable 50</b> Part # 1000116 Quantity 1</p>
	<p><b>Warning Cable</b> Part # 1527 Quantity 1</p>		<p><b>Control Box</b> Part # K1306-0 Quantity 1</p>

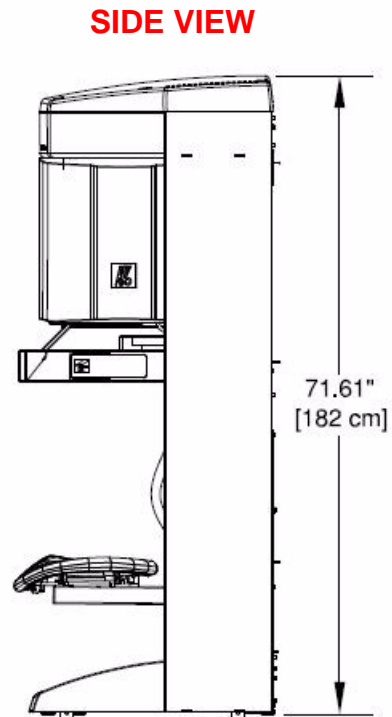
## System Gantry Dimensions



**TOP VIEW**



**FRONT VIEW**



**SIDE VIEW**

# Chapter **14** *Networking Support Setup*

## *Networking Support Overview*

Networking support within VisionQ and standalone Vision creates a convenient mechanism for sharing image data within an office or clinic. Using network storage provided and maintained by the customer, system software monitors the connection and allows scanning to proceed even if the network is temporarily broken. Then, the software will automatically update the server with new patient scans when the connection is restored.

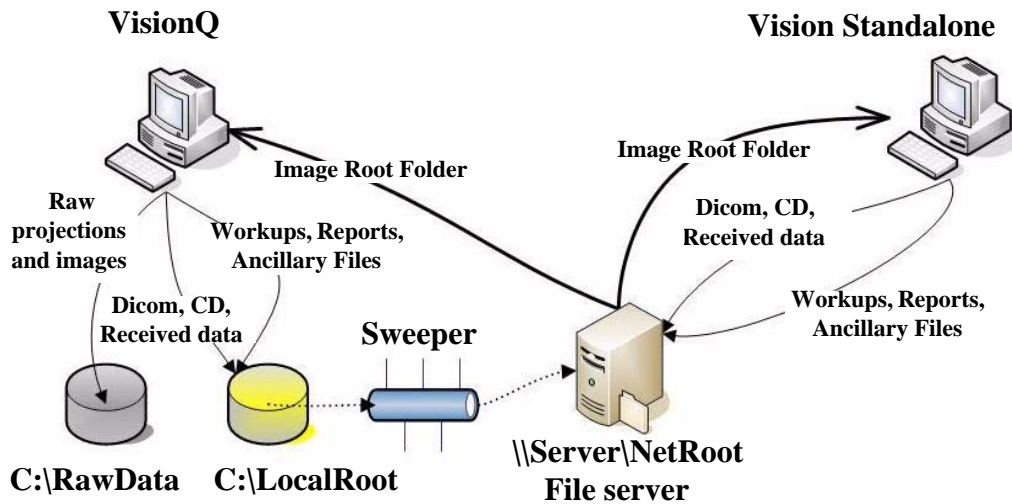
**NOTE:** The customer is responsible for providing the network accessible storage at their location, including security, backup, and archive functions.

## *Networking Data Flow*

When the Image Root Folder is set to a location on the local disk, networking software is automatically disabled, and all data acquisition goes to the local disk. But if the Image Root Folder is setup on a remote network shared folder, acquired data flow is altered somewhat and networking software takes part in the flow. In this case, VisionQ stores newly-acquired, DICOM-format projection data (RAW\_CT) and reconstructed images (CT) on its local disk (in C:\LocalRoot), *regardless* of the Image Root Folder setting. If a study is immediately viewed or manipulated, that work is also saved locally. At the same time, the networking software's background Sweeper service automatically tries to copy this new data to the designated Image Root Folder.

For VisionQ and standalone Vision, the Study List displayed on the left side is derived from the Image Root Folder on the network server. Previously-acquired studies are also manipulated from that location. Because of this, there is a delay from the time an acquisition or reconstruction completes to the time when the study is displayed on the Study List.

Note that changes made to studies on the network by a standalone Vision are not transferred back to the VisionQ local disk.



**If network breaks, VisionQ cannot access Study List, but can continue to scan patients.**

**If network breaks, Vision cannot access Study List. Network must be restored.**

## *Network Support Installation/Setup*

### *Provide Network Storage*

The customer is required to provide network storage that is accessible to the user. To verify proper operation, log in as the system operator and use Windows Explorer to navigate to the intended networked shared folder, using \\server\folder syntax. Create a new text document, enter text into it, save it, and then delete it. Do not proceed unless this succeeds.

### *Install Sweeper Service*

1. Double-click the SweeperSetup icon in the Program Files\Kavo\eXamVision folder to execute the program. A setup wizard is displayed.
2. Click **Next** on all wizard screens to install the Sweeper service.
3. When complete, click **Close** on the Installation Complete screen.



## Configure Sweeper Service

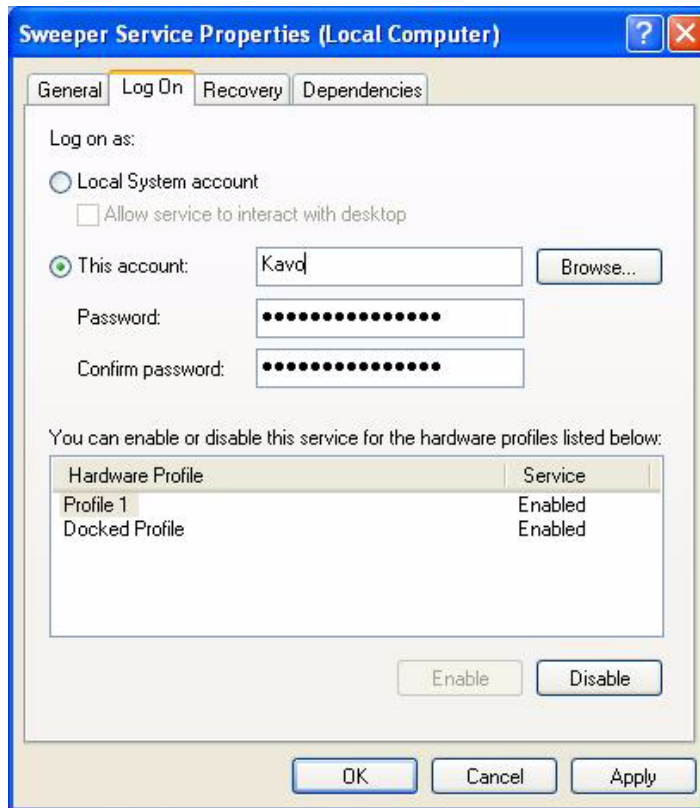
1. Access **Control Panel > Administrative Tools > Services** and double-click Sweeper Service.
2. On General tab, confirm Startup type is set to Automatic.



3. Click Log On tab:
  - a. Click **This account** radio button.
  - b. Enter and confirm an account and a password.

**NOTE:** Be sure to use the same account that was used to log on to the computer.

- c. Click **OK**.



## *Migrate from Standalone to Server*

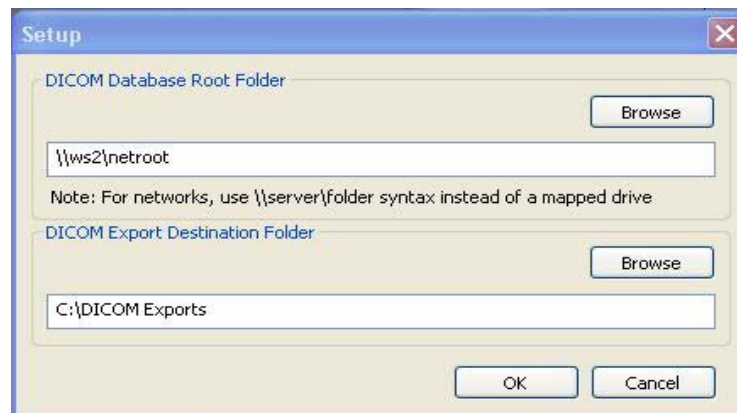
### **NOTE:**

- Perform this procedure only if upgrading or migrating from an existing standalone setup.
  - If the existing network setup shares a portion of the local disk of the VisionQ computer, it is still considered standalone and this procedure should be followed.
1. Using the Sweeper controller, stop the Sweeper service if it is running or paused.
  2. Start VisionQ and reconstruct any scans that have not yet been reconstructed.
    - a. Make a note of the standalone Image Root Folder name using **Tools > Setup**. (It is probably C:\DATAFRAMES.) Do not change the name at this time.
    - b. Exit VisionQ.

3. Using Windows Explorer, navigate to the Image Root Folder and delete any files named proj0000.raw, proj0001.raw, ..., proj2000.raw.
4. If a folder named **bak** is present in the Image Root Folder, the proj0000.raw files in it, as well as the bak folder itself, can be deleted.
5. Check that the folder C:\LocalRoot does not exist. If it does exist, check if it is empty. If it is empty, remove it. If it is not empty, call Technical Support for help. Continue only when C:\LocalRoot does not exist.
6. Using Windows Explorer, change the name of the Image Root Folder to C:\LocalRoot.

### *Change Image Root Folder*

1. From VisionQ, select **Tools > Setup**.



2. Under DICOM Database Root Folder, enter or browse for the Image Root Folder on the network server and click **OK**. Use Universal Naming Convention syntax, such as \\server\NetRoot, to identify the network location and not a mapped drive syntax.

### *Start the Sweeper*

Start the Sweeper service. After 30 seconds, it will start transferring any prior scan data to the server. Watch it for a few minutes in case there are any network or configuration problems.

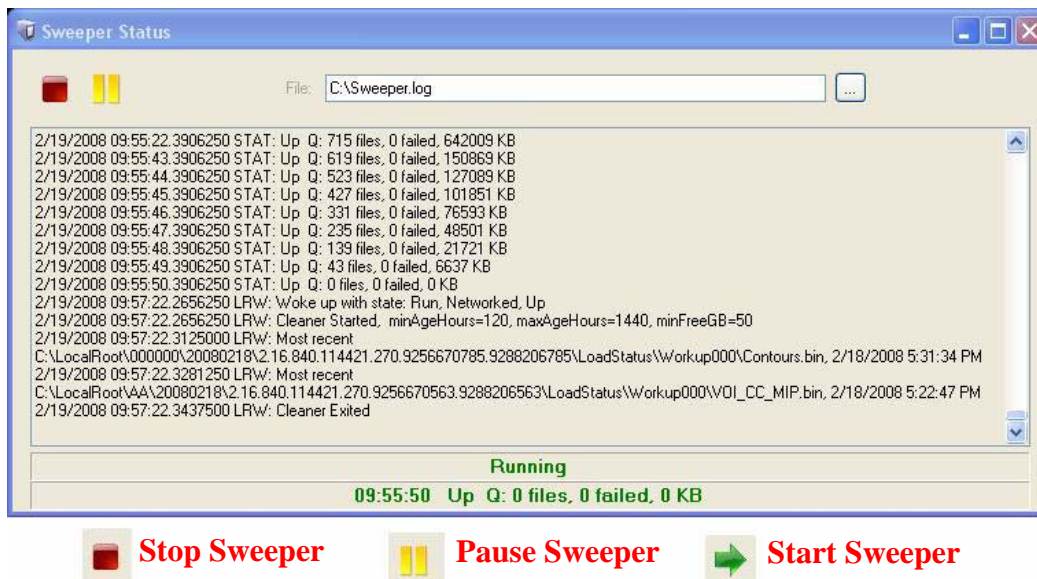
## Sweeper Service

The Sweeper service starts automatically on system power-up and stops on system shutdown. It copies any changed files from the local disk (C:\LocalRoot) to the network Image Root (but only if the local file is bigger than its network counterpart.) It retries failed transfers when the network is up. The Sweeper service will suspend data copying and declare itself "Down" if the network disk has less than 1 GB of free space. It will automatically resume when more space is made available by the user.




The Sweeper service periodically cleans the local disk by deleting all studies older than 60 days. If there is less than 50 GB of free space available on the local drive, the oldest study that is at least 5 days old is deleted. Studies that are less than 5 days old are never automatically deleted.

## Sweeper Controller

The Sweeper controller provides the user interface to the Sweeper service and is accessed by clicking the Sweeper icon in the system tray. If the controller screen is accidentally closed, click **Start > All Programs > Kavo > SweeperController.exe** to restore it.



The Status screen allows the user to start/stop and pause/resume the Sweeper service. It displays the Sweeper log file C:\Sweeper.log, extracts status from the log, and displays it at the bottom of the screen. It reduces to a system tray icon showing the Sweeper state and a tooltip with the current status.

	09:55:50 Up Q: 0 files, 0 failed, 0 KB
 <b>Working</b>	<b>Tooltip shows:</b>
 <b>Idle</b>	<b>Time</b>
 <b>Down</b>	<b>Network Status</b>
	<b># of files in Transfer Queue</b>
	<b># of files that Failed at Least Once</b>
	<b># of bytes in Transfer Queue</b>

## Network Failures

In the event of a network failure, the best action is to try to quickly restore the network. If that is not possible, fallback operations are available.

### No Network Access at Startup

When VisionQ or standalone Vision is first launched, it tests whether the Image Root Folder is accessible on the network. If it is not, the No Network Access dialog is displayed. Use fallback operations if desired. Fallback operations differ for VisionQ and standalone Vision.



## *Fallback Operations For VisionQ*

If there is no network access for VisionQ, the best approach is to fix the network. When the network is restored, click **Retry** on the No Network Access screen and continue work as usual.

If network access cannot be quickly restored and scanning must continue:

1. Click **Cancel** to fallback and use C:\LocalRoot.
2. Scan patients.
3. Exit VisionQ and restore the network as soon as possible. Any changes made to studies such as workups, reports, or jpegs will be swept to the server when the network connection is restored.

**NOTE:** Fallback is temporary until VisionQ exits unless the user manually changes the setup, which is not recommended.

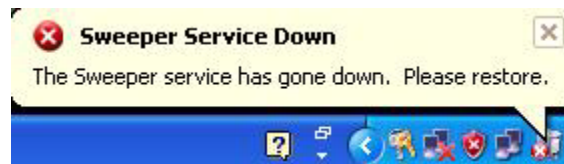
## *Fallback Operations For Vision*

If there is no network access for standalone Vision, it is essential to fix the network because C:\LocalRoot is most likely empty. When the network is restored, click **Retry** on the No Network Access screen and continue work as usual.

## *Network Fails During Operations*

If a network failure occurs during use of VisionQ or standaloneVision, the following occurs:

- The Study List goes blank (since it comes from the server which is no longer accessible.)
- Error messages are displayed in the Sweeper log file.
- The Sweeper icon in the system tray of VisionQ changes to the down state and a balloon is displayed for the state change.



**NOTE:** Be aware that unsaved workups, reports, or jpegs may be lost as a result of a network failure.

Try to restore the network. If the network can be restored, operations can continue. If the network cannot be quickly restored and scanning must continue, new scans will be safely stored locally, but will not be transferred to the server until the connection is restored.

Therefore, new scans will not appear on the Study list, which will remain blank. To see these new scans in the list, exit and follow the fallback operations for VisionQ.

## *Limitations of Networking Support*

Known limitations of networking support are:

- There is a network transfer delay between acquisition or reconstruction, and the appearance of the study on the Study List. Although they may not appear on the list immediately, the images are available for review and workup on the scanner immediately.
- There is no study locking mechanism to prevent two users from simultaneously editing or updating the same study. Clinic workflow must ensure this does not happen. However, if it does occur, only workups, and not patient scan data, are at risk of being lost.
- Unsaved workups, reports, or jpegs may be lost as a result of a network failure that happens during the save operation.





## *Chapter*

# *15 Remote System Import and Export*

## *Remote System Import and Export Overview*

The VisionQ Remote Service application enables the import of patient data from a remote system to Vision Q and enables the export of DICOM images to a remote system from VisionQ. This service functions to reduce data entry redundancy and to synchronize the output generated by VisionQ to a remote system once the study acquisition is completed. The Remote Service application is available to all VisionQ customers.

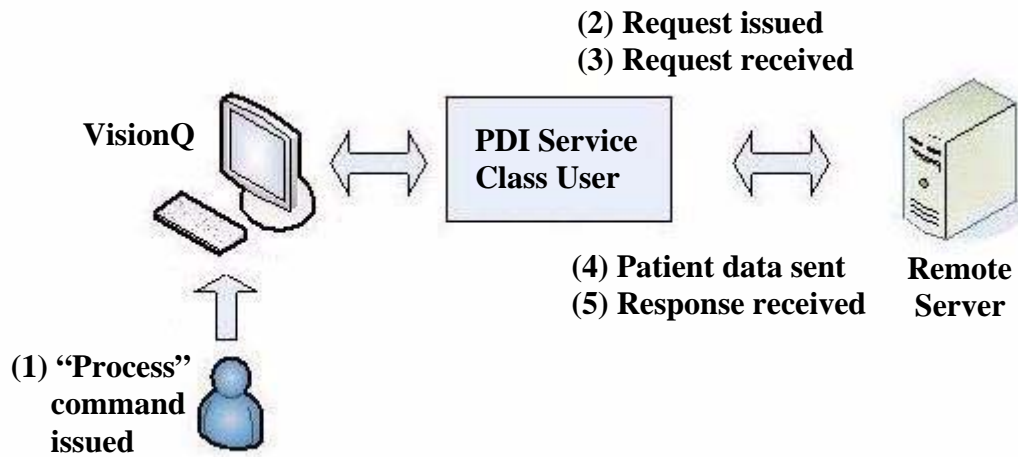
## *Remote System Import*

VisionQ provides two ways to import “scheduled” patient data into the system:

- DICOM Worklist - this interface requests and displays patient records that match the user-specified criteria from the remote DICOM Worklist server.
- Practice Management (PM) - this interface loads and displays patient records from an XML file, generated by the PM server.

Users can choose which of the two interfaces is suitable for their workflow and set up the interface accordingly.

When the VisionQ user selects to import data, the PDI service class user (PDI.dll) issues a DICOM C-FIND request to pull patient records from the remote system. All VisionQ “scheduled” patient records are sent from the Worklist or PM system to VisionQ.



## *Import Installation and Setup*

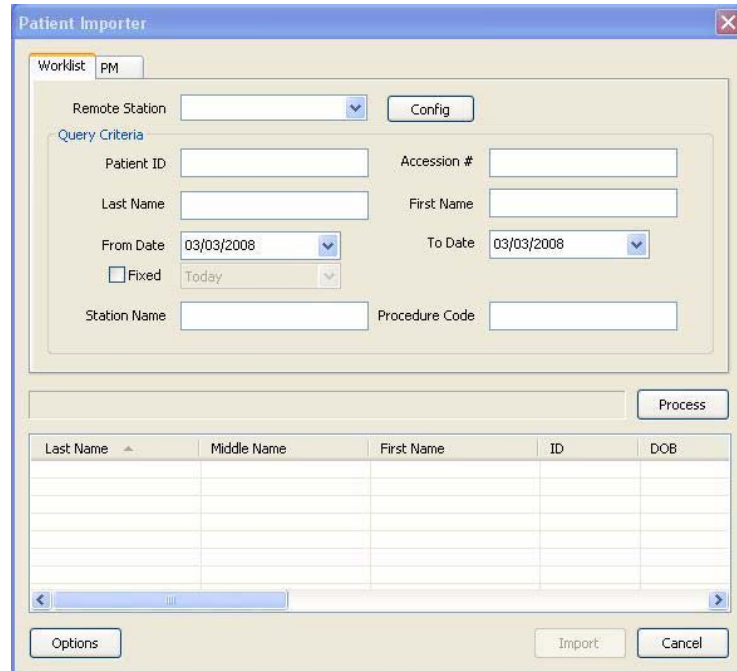
If the PDI.dll has not been installed, unzip the PDI folder and place the PDI.dll in the same folder where the VisionQ.exe resides. The PDI.dll must be in place before setup can continue.

Determine which interface type, DICOM Worklist or PM, is to be used for import, and follow the appropriate setup procedure below.

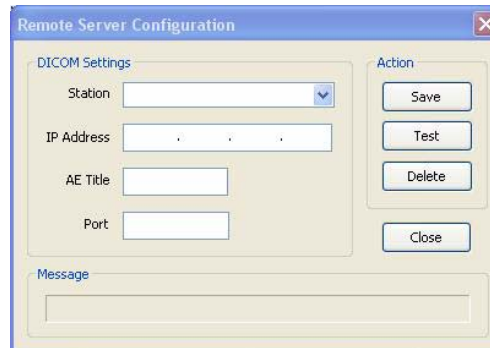
### *Set Up DICOM Worklist Interface*

1. Start VisionQ.
2. From the VisionQ Main menu, select **File > New Patient**.

3. Click **Import**. The Patient Importer screen is displayed.

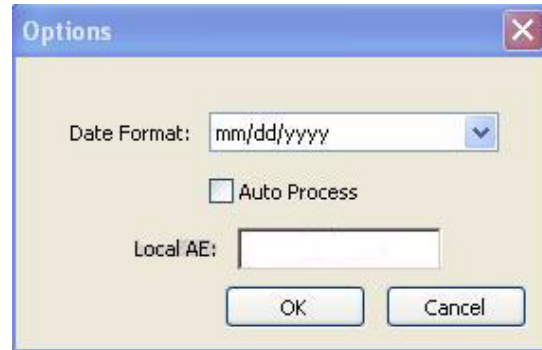


4. Click **Config**.



5. Enter Station name, IP Address, AE Title, and Port number for the remote server from where files are to be imported.
6. Click **Save**, and then **Close**.
7. Click **Cancel** on Patient Importer to close window.

**NOTE:** The **Options** button on the Patient Importer window enables setting of the date format and the AE title for the local Acquisition computer, and enabling auto process. These settings are optional and do not have to be changed..



## *Set Up Practice Management Interface*

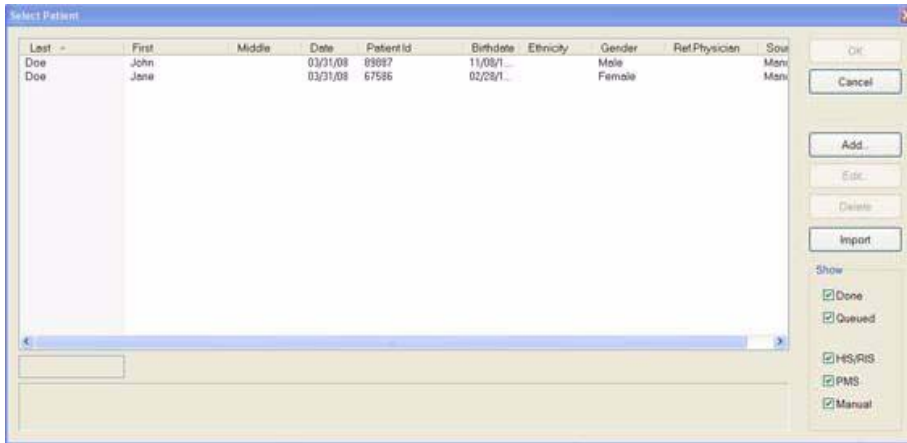
1. Start VisionQ.
2. From the VisionQ Main menu, select **File > New Patient**.
3. Click **Import**. The Patient Importer screen is displayed.
4. Click the **PM** tab.



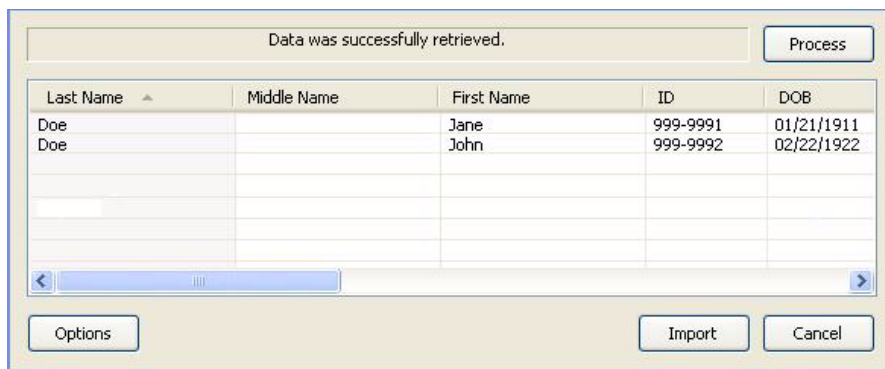
5. Click **Browse** and browse to the PM Interchange location. This is the location where an XML file, generated by the PM server, is saved.
6. Click **Cancel** on Patient Importer to close window.

## Import Patient Data

1. From the VisionQ Main menu, select **File > New Patient**.
2. Click **Import**.



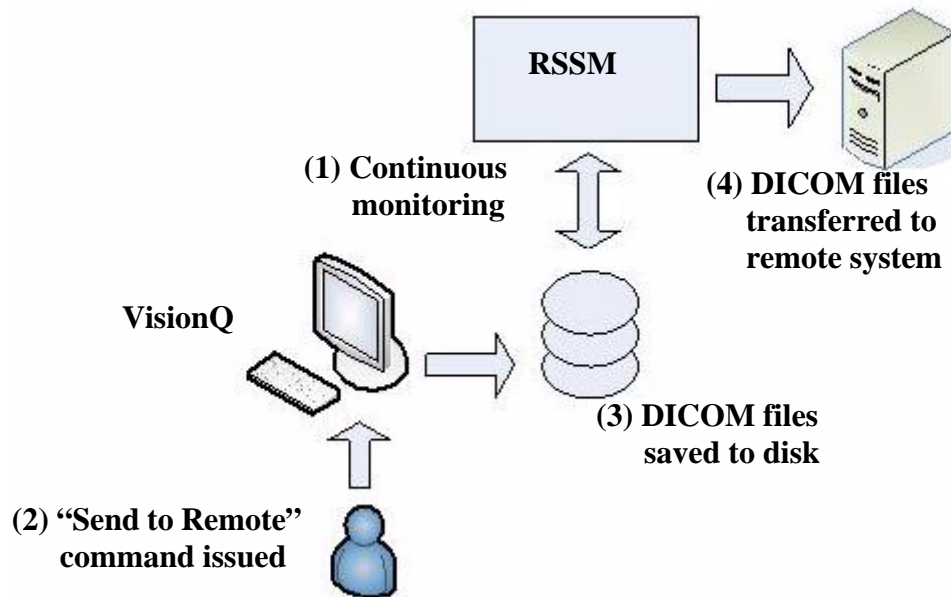
3. On the Patient Importer screen, click **Process**. Patient data is retrieved from the remote system and listed at the bottom of the screen.



4. Select (highlight) a patient on the list and click **Import**.
5. The Acquisition screen is displayed for the selected patient.

## Remote System Export

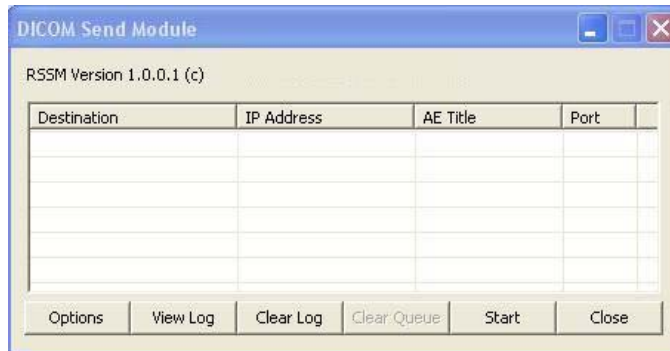
VisionQ enables DICOM images to be transferred from the VisionQ to a remote system, such as a Picture Archive and Communications System (PACS). The Remote Service Send Module (RSSM) enables the transfer using DICOM storage protocol (C-STORE). RSSM continuously monitors the local folder that is setup to receive the images to be exported. When DICOM images are exported to the folder, RSSM transfers them to the user-defined remote destination.



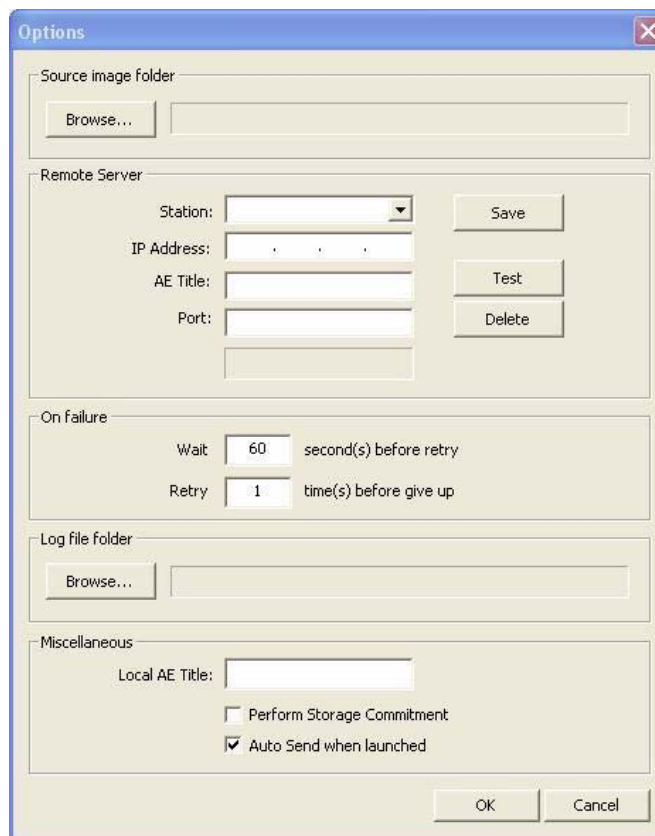
## Export Installation and Setup

1. Place the RSSM.exe in the same folder where the VisionQ.exe resides.

2. Double-click RSSM.exe. The DICOM Send Module is displayed.



3. Click **Options**.



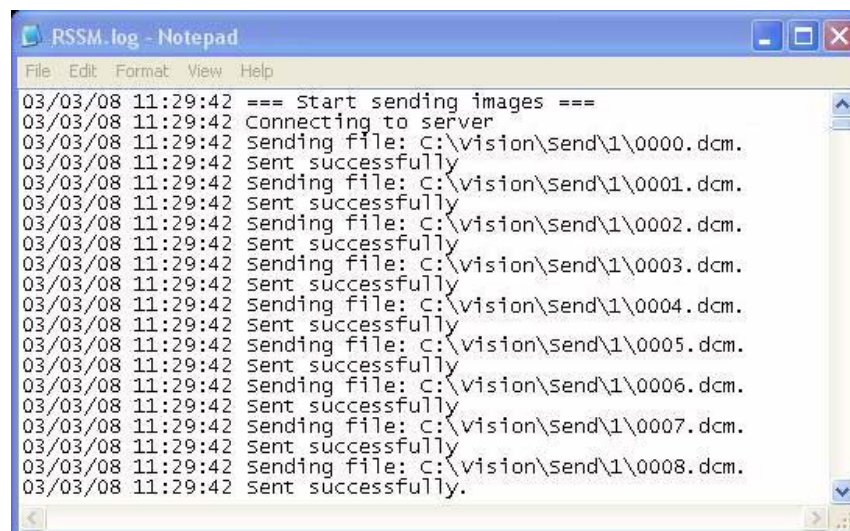
4. Click **Browse** in **Source image folder** section and browse to the folder where the DICOM files are to be placed for export. Create a new folder if desired.
5. In **Remote Server** section:
  - a. Enter Station name, IP Address, AE Title, and Port number for remote DICOM server (C-STORE SCP).

- b. Click **Save**.
  - c. Click **Test** to perform DICOM validation (C-ECHO) to check whether the remote server is accessible.
6. Click **Browse** in the **Log file folder** section and browse to the folder where the RSSM log file is to reside.
7. In the **Miscellaneous** section:
  - a. Enter Local AE Title for the VisionQ system.
  - b. If DICOM server supports **Perform Storage Commitment** feature, this option can be selected, if desired. Otherwise, leave unchecked.
  - c. If transmission should begin automatically whenever RSSM is started, select **Auto Send when launched**. Otherwise, leave unchecked.
8. Click **OK**.
9. Click **Close** on the DICOM Send Module.

## RSSM Log

While RSSM is transferring data to the remote system, an icon is displayed in the system tray. Right-click the icon and select **View Log** to display the log.

The log shows the status of each transferred file.



 A screenshot of a Notepad window titled "RSSM.log - Notepad". The window contains a log of file transfer operations. The text in the log is as follows:
 

```

03/03/08 11:29:42 === Start sending images ===
03/03/08 11:29:42 Connecting to server
03/03/08 11:29:42 Sending file: C:\vision\send\1\0000.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0001.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0002.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0003.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0004.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0005.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0006.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0007.dcm.
03/03/08 11:29:42 Sent successfully
03/03/08 11:29:42 Sending file: C:\vision\send\1\0008.dcm.
03/03/08 11:29:42 Sent successfully.
  
```

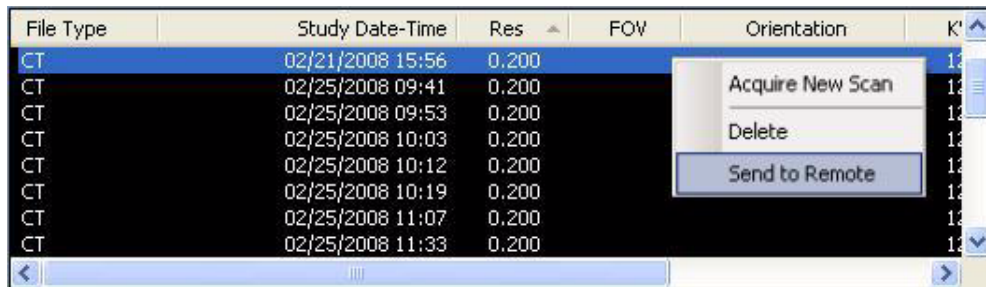


The log can also be accessed by selecting **Show**. This displays the DICOM Send Module with the following options:

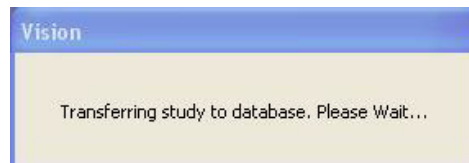
- **Options** - Used to set date format.
- **View Log** - Displays RSSM log.
- **Clear Log** - Clears RSSM log of all previous activity.
- **Clear Queue** - Clears the queue of all studies. A study is queued when RSSM has exhausted all attempts to transmit the study.
- **Start/Stop** - Toggles to either start or stop RSSM.
- **Close** - Closes the DICOM Send Module window.

## Send Patient Data to a Remote System

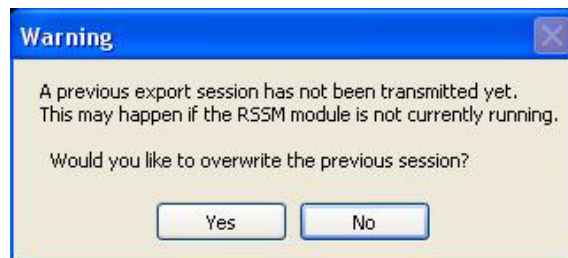
1. With a Patient selected in the Study List, right-click on the scan to be sent and select **Send to Remote**.



2. A dialog is displayed and the dataset is transferred.



3. If a previous export session has not been successfully transferred, a warning is displayed.





4. Check the RSSM log to determine status of the last transmitted file. If file did not transfer successfully, investigate the cause, such as a network failure to the remote system and correct the problem.

If the file no longer needs to be transferred, click **Yes** to overwrite the previous session.

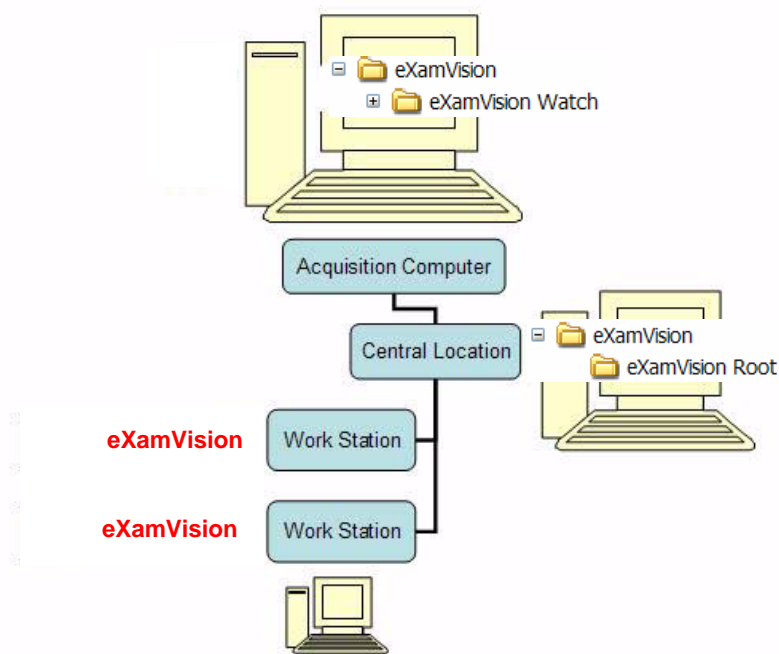
If the file needs to be sent, click **No** to cancel and wait for previous file to transfer.

## Appendix

# A *eXamVision Installation*

## *eXamVision*

eXamVision standalone is used to view images that have been acquired by the Acquisition Computer. We are pleased to provide eXamVision free of charge to anyone with access to KaVo scans with no limit on usage and the number of copies.



## ***Laptop Minimum Requirements***

- Intel Processor M 1.5Ghz
- 1GB of RAM (2GB for peak performance)
- Windows XP Professional
- 40GB Hard Drive
- CD/DVD Drive
- Integrated Gigabit Ethernet 10/100/100 Network Connection

## ***Workstation Minimum Requirements***

- Processor 2Ghz
- 1GB of RAM (2GB for peak performance)
- Windows XP Professional
- Video Display capabilities of 1600 x 1200 resolution
- 18 or 19 inch Monitor (recommended)
- 40GB Hard Drive
- CD/DVD Drive
- Integrated Gigabit Ethernet 10/100/100 Network Connection

## ***File Structure Setup***

1. On the KaVo Acquisition Computer, create an eXamVision folder under the C: drive.
2. Create a subfolder under eXamVision called **eXamVision Watch**

This is where the DICOM 3 data is exported.

NOTE: Only DICOM files are placed here, NO FOLDERS.

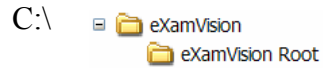
File structure on KaVo Acquisition Computer:

```
C:\ > eXamVision
      > eXamVision Watch
```

**NOTE:** It is not recommended to have the Watch folder located on a server because it would slow down the Network speed.

3. On the server or central storage location, create another folder named eXamVision.
4. Under this eXamVision folder create a sub folder named **eXamVision Root**

File structure on server/central storage location:



If a server/central storage location is not available, then create the eXamVision Root directory on the KaVo Acquisition Computer's C: drive under the eXamVision Folder.

### ***Create a new Folder***

1. Open the folder where the new folder is to reside.
2. Right click and select **New > Folder**.
3. Type the name for the new folder.

### ***Install eXamVision***

1. Unzip the eXamVision.zip file to the eXamVision folder, it unzips to eXamVision.exe
2. Double click the **.exe** file to execute the program.

A shortcut can be created for this program onto the desktop.

### ***To unzip a file:***

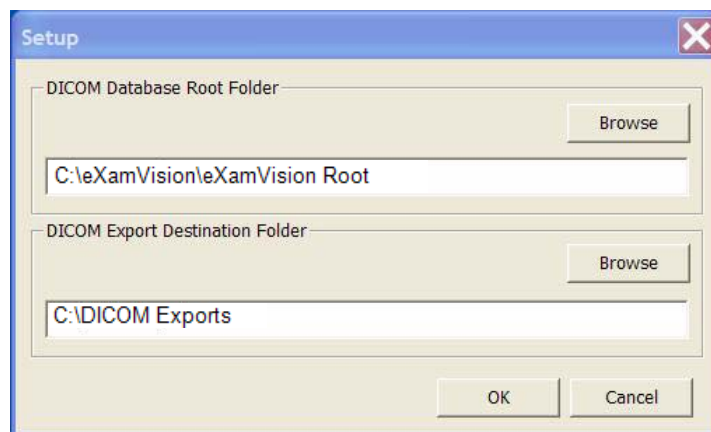
Right-click file and click **Extract** on the shortcut menu.

### ***To create a shortcut:***

Right click file and select **Send to > Desktop (create shortcut)**.

### ***eXamVision Setup***

1. From eXamVision select **Tools > Setup**.





2. Under *DICOM Database Root Folder*, browse to the eXamVision\eXamVision Root and click **OK**.  
(This may be on the C: drive or on a networked drive).  
Setup is the same on all networked and non-networked computers or workstations.
  3. A prompt to restart eXamVision software is displayed, click OK.
- NOTE:** It is currently recommend that when using KaVo Data for 3<sup>rd</sup> party software, perform a separate DICOM export from KaVo. The data will be interchangeable when third party systems start accepting compressed DICOM.

## Appendix

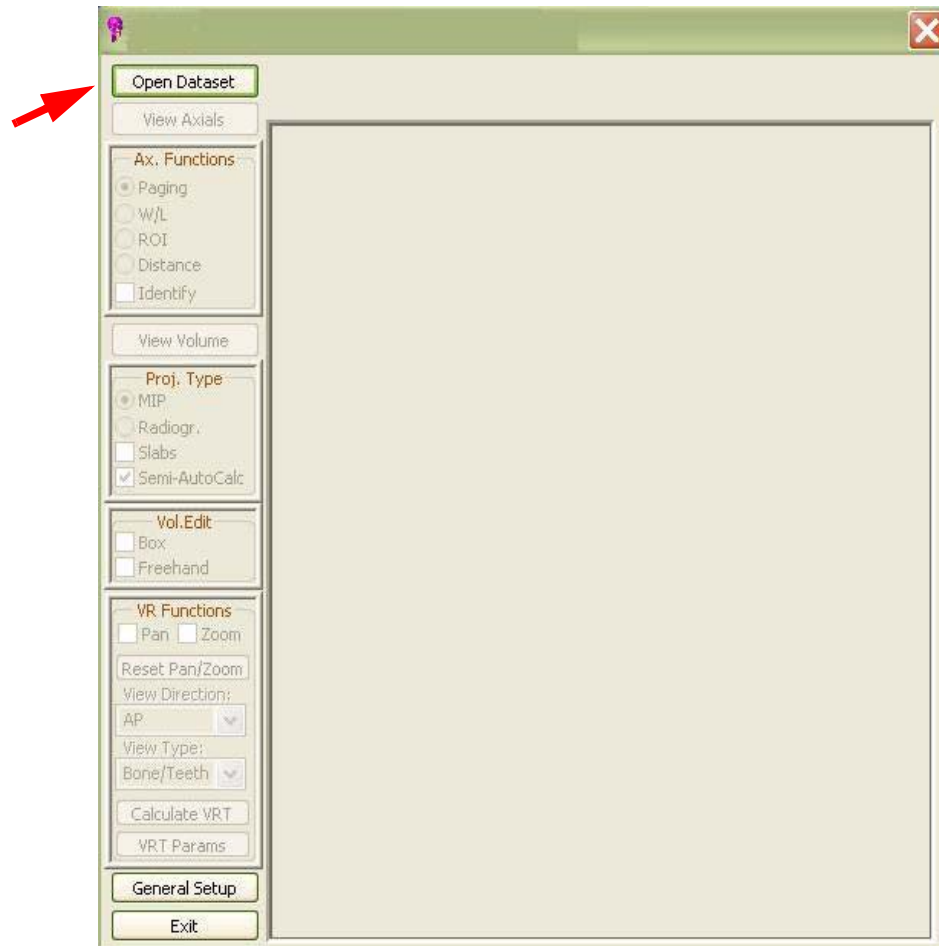
# B Three Dimensional Volume Rendering (3DVR)

### Open Database

3 DVR is a standalone program which runs independently and is not part of Vision.

1. To open DVR (Diagnostic Volume Rendering,) double click the DVR icon.

The Program Main menu is displayed.



To get started, an image dataset must be loaded. The case **MUST** be in DICOM format.

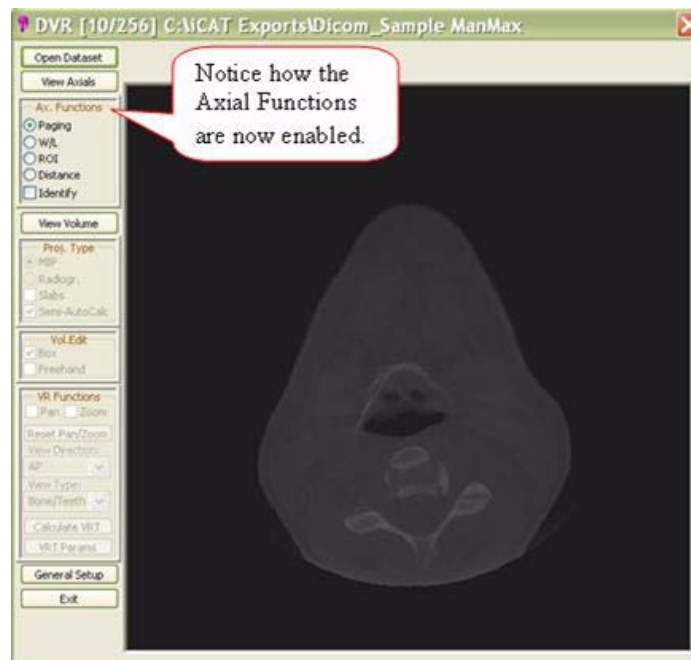
If importing a case from Vision, make sure to export the case in *DICOM3-Multi File* format.

2. Click **Open Dataset**, a browse window is displayed.
3. Select the drive/folder for the DICOM dataset and click **OK**.



The first view displayed is an *Axial* slice.

The **Axial Functions** menu, under the *View Axial* button, is enabled.







---

## ***Axial Functions***

There are 5 tools under Axial Functions.

- Paging
- W/L (Window Level)
- ROI (Region of Interest)
- Distance
- Identify

### ***Paging***

Paging is the tool that allows for scrolling through all the axial slices of the dataset. Notice at the top of the DVR window, the axial slice number currently displayed is next to the word DVR. In this sample it is slice 10 of 256.

#### **To scroll through each slice:**

1. Click **Paging** Radio button.
2. Drag the cursor either UP or DOWN to scroll through the axial slices.

Dragging the cursor upward scrolls towards the top of the skull and dragging downward scrolls towards the bottom of the skull.

### ***W/L (Window/Level)***

W/L is a tool to adjust Grayscales (Brightness / Contrast).

#### **To adjust Brightness/Contrast:**

1. Click **W/L** Radio button.
2. Drag cursor Left/Right to adjust Contrast and Up/Down for Brightness.

The W/L values are displayed at the top of screen.

## ***ROI (Region of Interest)***

ROI is a tool used for determining Hounsfield Units.

### **To activate the ROI tool:**

1. Click **ROI** Radio button.
2. Drag cursor to create a box around region of interest. Release the mouse button to move box, then click again to complete the box.

Calculated items are displayed (upper left corner.) The displayed values are:

- Mean
- SD (Standard Deviation)
- HU min (minimum Hounsfield Units)
- HU max (maximum Hounsfield Units)
- Area





## *Distance*

The distance tool measures linear distance.

### **To activate Distance tool:**

1. Click **Distance** radio button.
2. Drag cursor from point to point to create a measurement line (see below in green).

Linear measurement is displayed in millimeters (upper left corner.)



## Identify

The Identify tool identifies areas of interest at different densities. It is defaulted to detect the most dense anatomy or material.

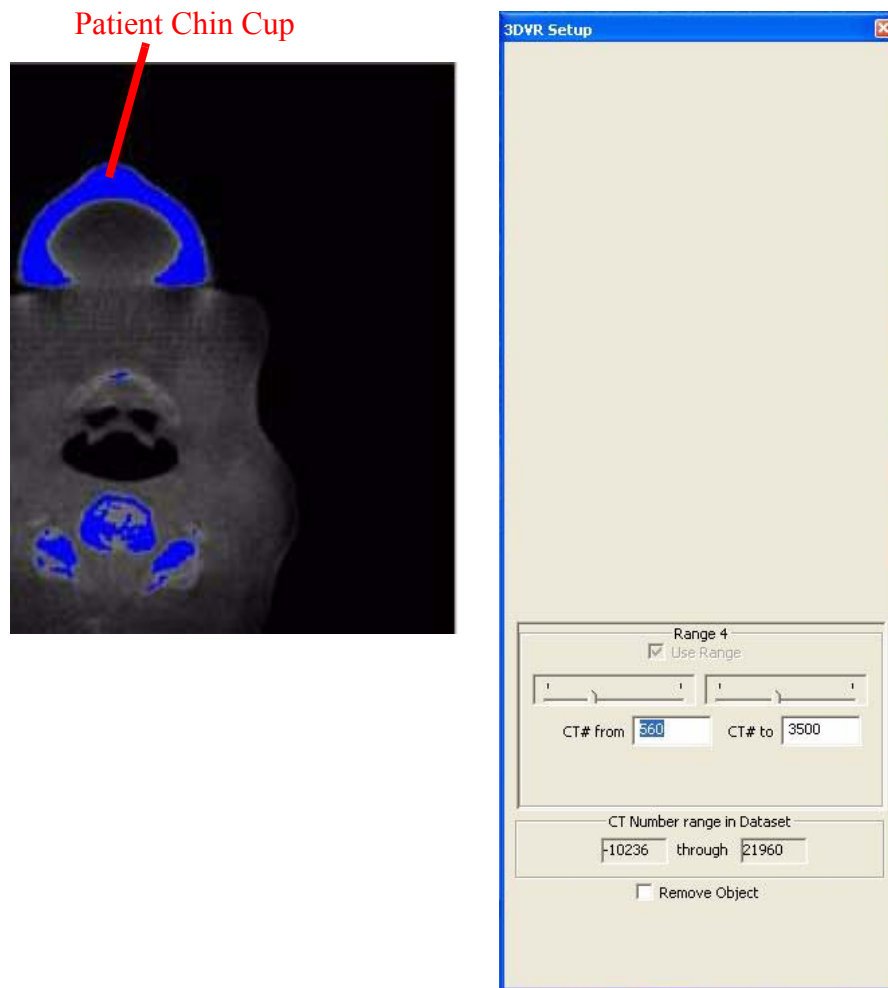
This tool is often used to remove a piece of anatomy from the image. One major use is to remove the Patient Chin Cup that may appear in the scan. See the sample below (Patient Chin Cup highlighted in blue.)

### To activate Identify tool:

1. Click **Identify** Box.

The 3DVR Setup window is displayed and the dense material in the Axial window is highlighted in blue.

2. Drag cursor on 3D image to rotate.





**Display the slice range of interest:**

3. On the Axial screen, drag the cursor either UP or DOWN to scroll through the axial slices.

Dragging the cursor upward scrolls towards the top of the skull and dragging downward scrolls towards the bottom of the skull.

or

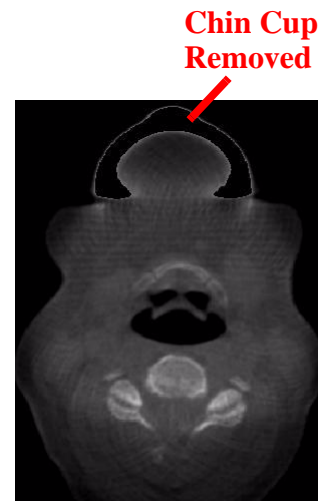
On the 3DVR Setup screen, select a Range (1 to 4). Ranges are adjusted by using the slide bars or type a new range number in the box.

## ***Remove Object***

**To remove a piece of anatomy from image:**

1. Click the **Remove Object** box to enable (checkmark).
2. Then click the object of interest highlighted in blue.
3. Close 3DVR Setup window by clicking **X** (upper right corner of window).
4. Scroll through the Axial views to verify that the object is removed from the image (was white, now black).

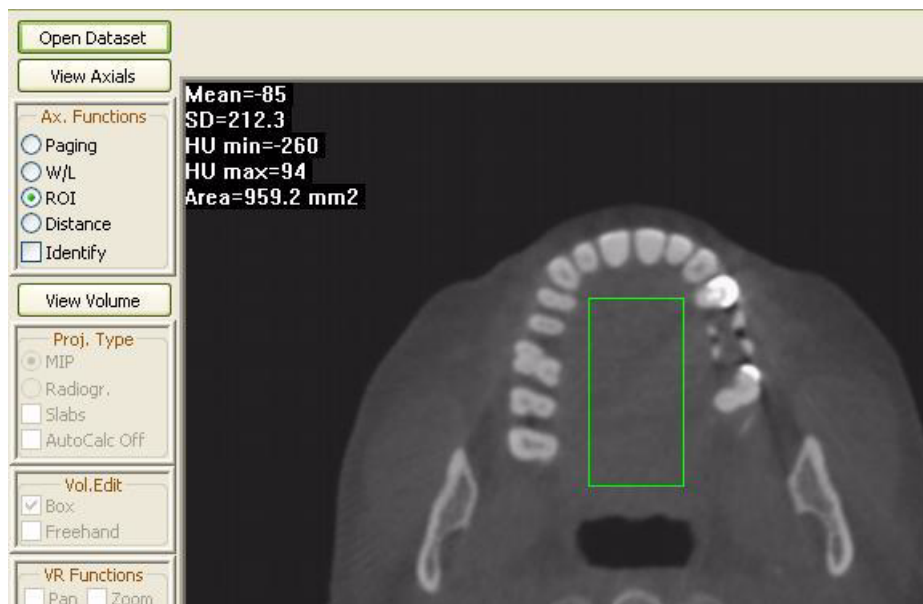
**NOTE:** Please be aware that any adjoining anatomy or material will also be removed, if there is continuity, or “leakage”. This includes any adjoining tissue in the rest of the volume that is not necessarily visible in this particular axial view.



## Hounsfield Unit Calibration Offset

Before proceeding to the View Volume functions, first enter a calculated offset into the General Setup for Hounsfield Units. The value that is required is based on the RIO function.

1. Enable the **Paging** button.
2. Scroll to the tongue area in the axial view which is just above the maxillary crowns. (look for a region that has relatively even grayscales).
3. At this location, enable the **ROI** function.
4. Drag the cursor in the area between the dental arch, making sure not to include any teeth or bone. This displays the Hounsfield data.



The **MEAN** value is the data of interest in this calculation. It reads a value (most likely a negative value). Whatever this number is, we want to add a value that will result in the Mean being around positive 50. In this example, the Mean reads -85 and we want the Mean to be +50, therefore the offset calculation will be +135.

5. Click the **General Setup** button on the menu bar.

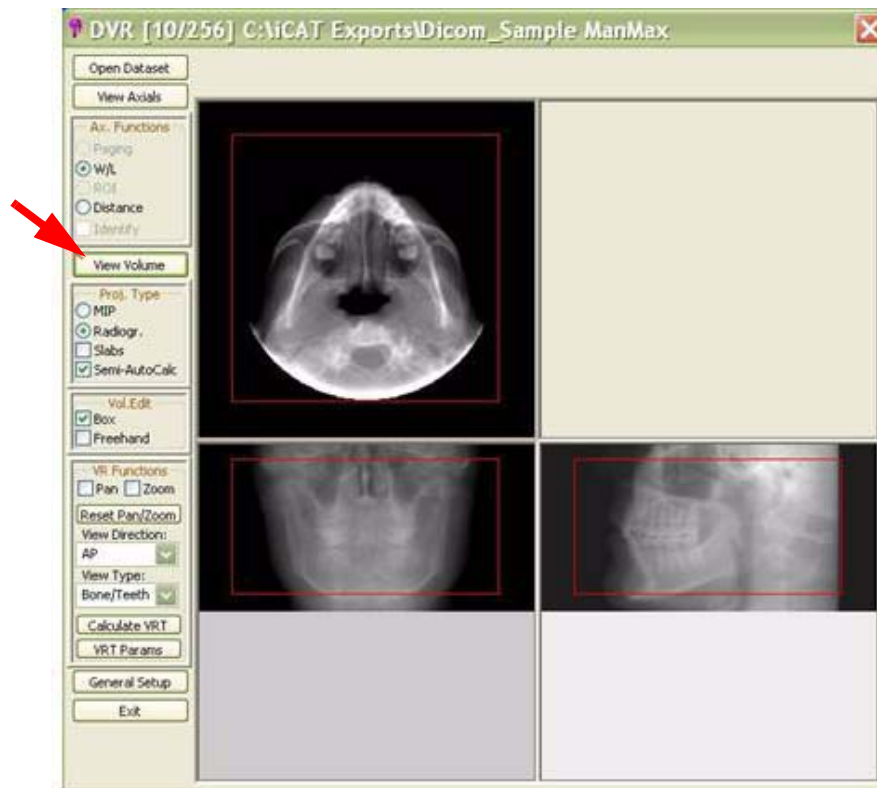
6. Enter Calculation Offset which currently has a value of 0.
7. Click **OK**.



## View Volume

View Volume allows viewing all 3 projections of the 3D data: Axial, Coronal and Sagittal. Also enables the creation of 3D Renderings.

Enable View Volume Tools, click the **View Volume** button.



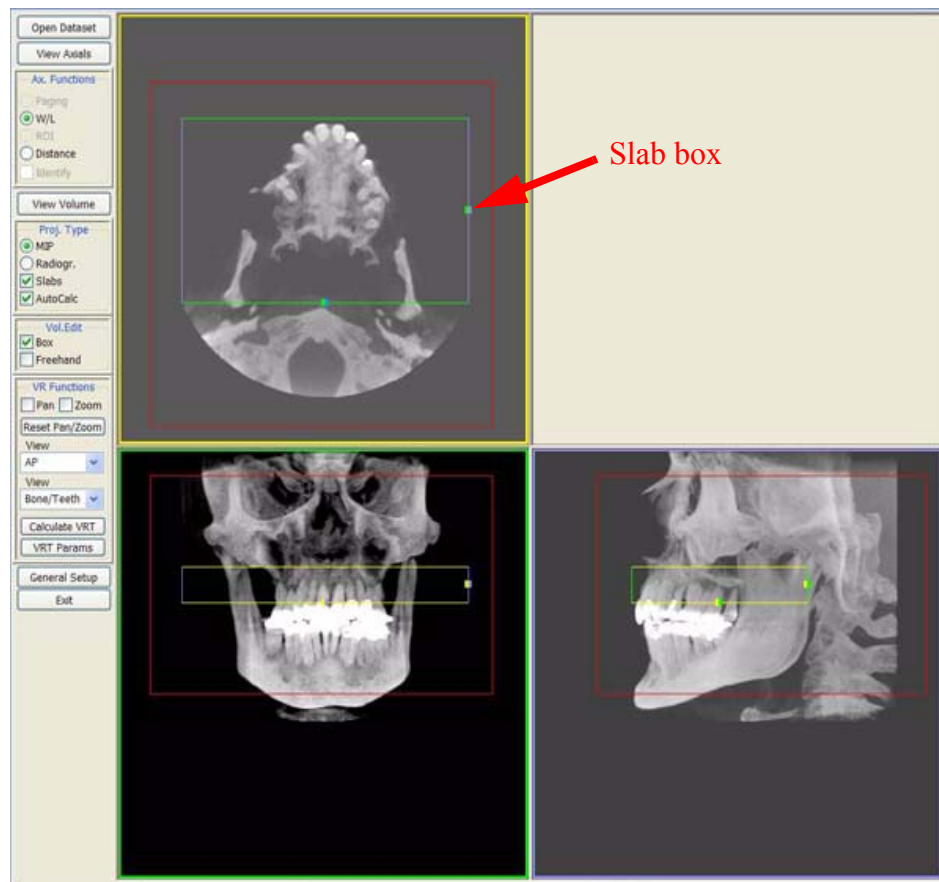
## Projection Type

Projection Type enables viewing 3D data in 2 different projections or modes: **Radiographic** and **MIP**.

- **Radiographic** mode - The above example has Radiographic mode enabled. The Axial, Coronal, and Sagittal views are all in Radiographic mode.

**NOTE:** Window/Level can be adjusted in each of the 3 views by dragging the cursor in each window.

- **MIP** mode - Maximum Intensity Projection (views displayed below.)
- **Slabs** - Displays an additional box in each window which can be sized and moved to change the areas of interest in the other windows.
- **Auto/Semi Auto Calc** - calculates the image displays as the Slab boxes are adjusted.







## Volume Edit

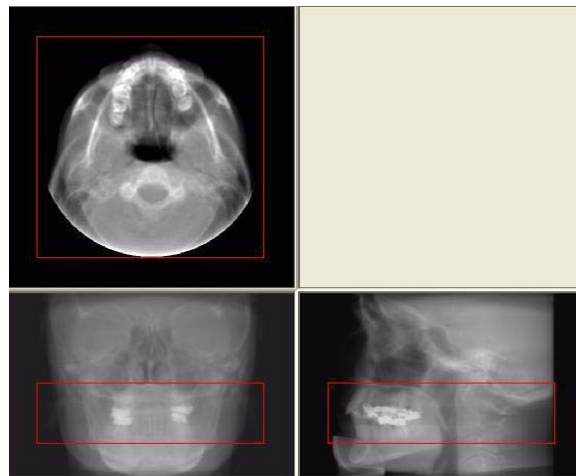
Volume Editing is used to select an area of interest to create a 3D rendering. The two methods used are **Box** and **Freehand**.

- **Box** - with this option, each of the 3 views are displayed with a red box around the data. Boxes can be resized to select different areas of interest.
- **Freehand** - drag the cursor around an area of interest in the Axial view (see below). This selects a new area of interest in the Coronal and Sagittal views.

Again, the selected data is used to calculate the 3D image. Once the area of interest is determined, the 3D image can be displayed by utilizing the VR Function tools.

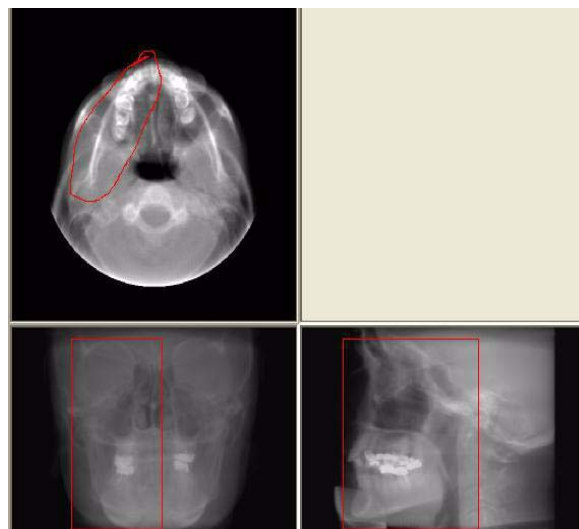
### Box Editing

In this sample, we resized the box from the Coronal view to include only a portion of the upper and lower jaw. Note how this resized the matching area in the Sagittal view.



### Freehand Editing

In this sample, we used the Freehand tool to draw an area of interest in the Axial view of only the right side of the jaw. Notice how the boxes resized the matching areas in the Coronal and Sagittal views.

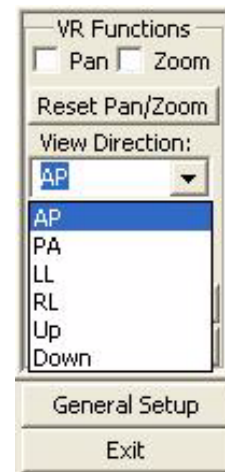


## VR Functions

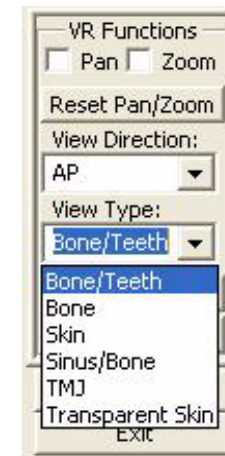
VR Functions (Volume Rendering) is a tool used for selecting the type of 3D image to create.

### To Create a 3D Image:

- From the first **View** drop-down menu select a direction to display. The choices are:
  - AP (Anterior Posterior)
  - PA (Posterior Anterior)
  - LL (Left Lateral)
  - RL (Right Lateral)
  - Up
  - Down

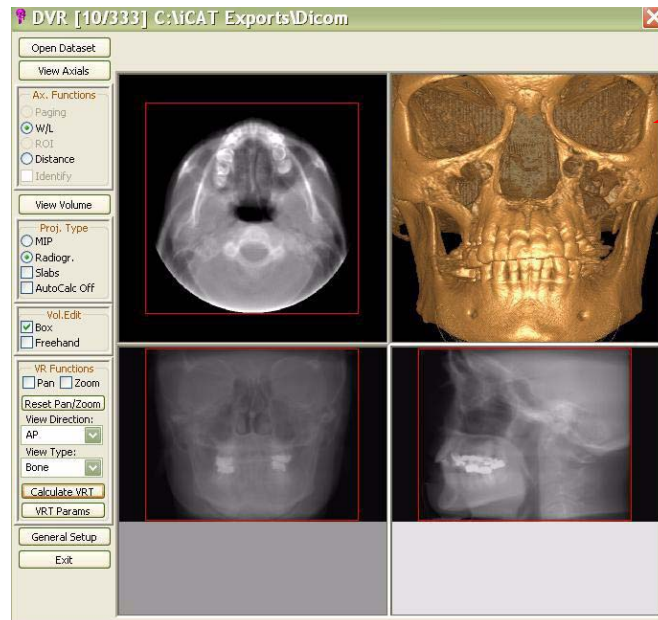


- From the second **View** drop-down menu select the type of display. The choices are:
  - Bone/Teeth
  - Bone
  - Skin
  - Sinus/Bone
  - TMJ
  - Transparent Skin



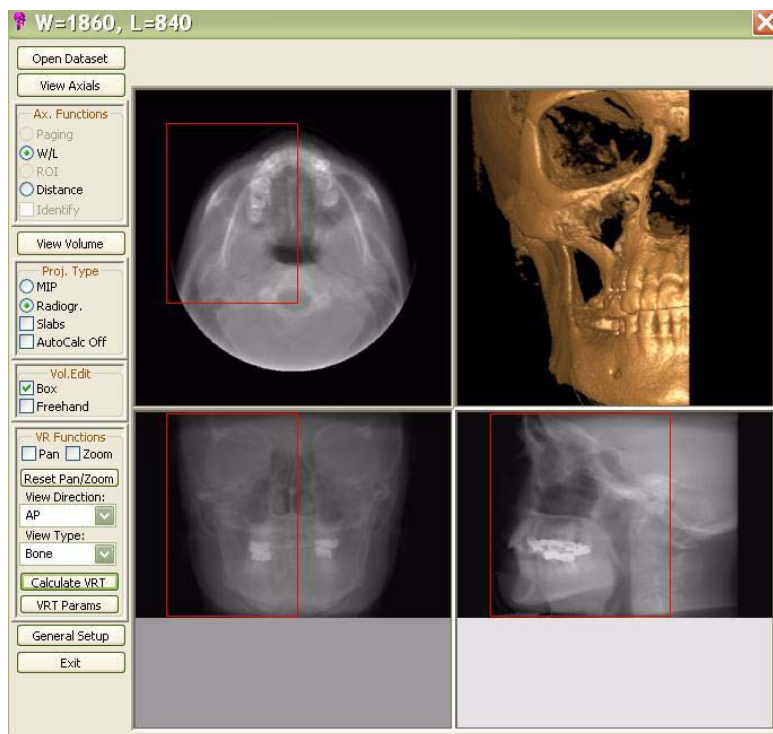
- Click the **Calculate VRT** button.

This displays the 3D image (upper right box.)



**NOTE:** Remember that the 3D data is calculated using the boxed or freehand selected areas of interest in the Axial, Coronal & Sagittal views. In this sample, the entire volume data is selected in all 3 views.

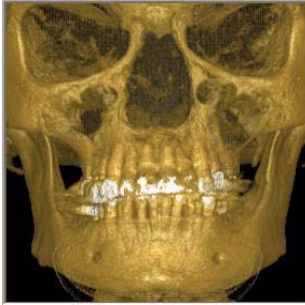
Below is a sample of a 3D image calculated from the selected volume area seen below.



In this sample, only a portion of the volume data is boxed, which is reflected in the 3D image

## Sample of View Types

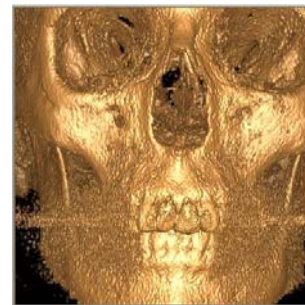
**Bone/Teeth**



**Skin**



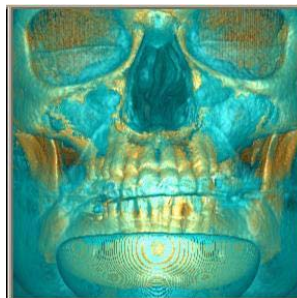
**TMJ**



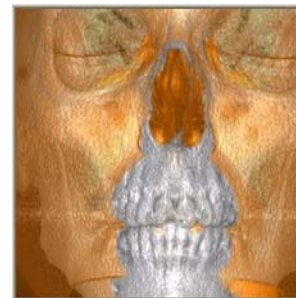
**Bone**



**Sinus/Bone**



**Transparent Skin**



Each View Type has its own Parameters, which can be viewed by clicking the **VRT Params** button.

The 3D image can be rotated, enlarged or changed to another direction or type. These functions can be performed from the top right corner viewing area or the 3D image can be enlarged to a Full Screen (Right click on the 3D image and select **View Full Screen**).

### **PAN**

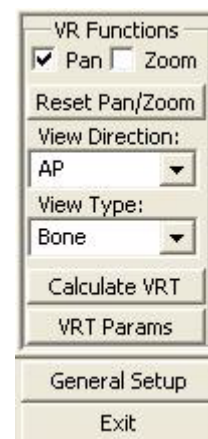
Move the 3D image within the window by dragging cursor on image.

### **Zoom**

Zoom 3D image. Drag cursor on image.  
UP to Zoom OUT / Down to Zoom IN.

### **Reset Pan/Zoom**

Resets 3D image to original position and size.





## ***Rotate 3D Image***

To **Rotate** the 3D image, both the Pan and Zoom functions must be disabled (unchecked). Drag the cursor on the 3D image in the desired rotation direction.

## ***Pop Up Menu***

Pop Up Menu contains the same VR Functions and also some additional functions. To access the Pop Up Menu, right click the 3D image.

### ***Save to JPG***

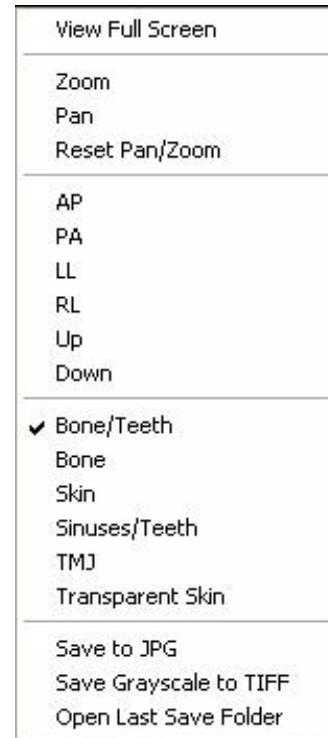
Saves full color 3D image in current working folder (adds .jpg extension). The current working folder is the folder opened from the *Open Dataset*.

### ***Save Grayscale to TIFF***

Saves 3D image in current working folder (adds .tiff extension). The current working folder is the folder opened from the *Open Dataset*.

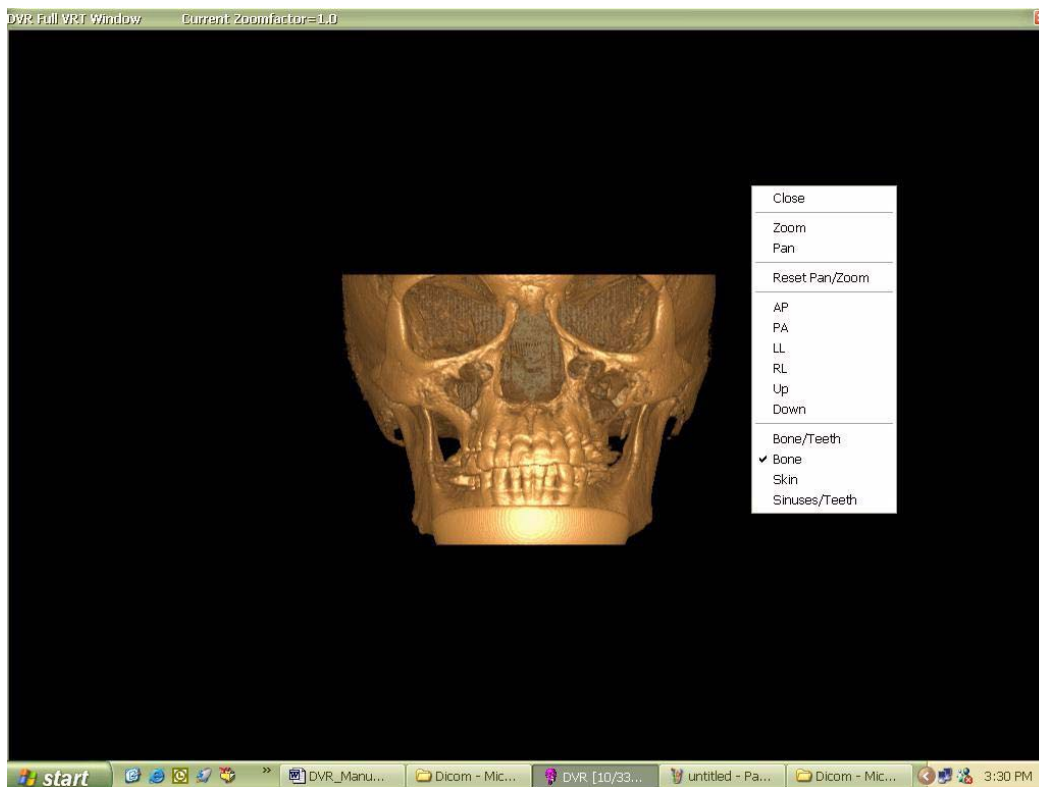
### ***Open Working Folder***

Opens the file structure where the JPG and TIFF picture files are saved. The current working folder can be changed.



## View Full Screen

Full Screen displays the 3D image on the entire computer screen. All the same manipulation functions and 3D options are used in this display. Right click to display Pop Up menu to utilize functions.



To return to the original viewing format, press <Esc> or select Close from the popup menu.

To close the DVR software, click the **EXIT** button at the bottom of the Menu Bar



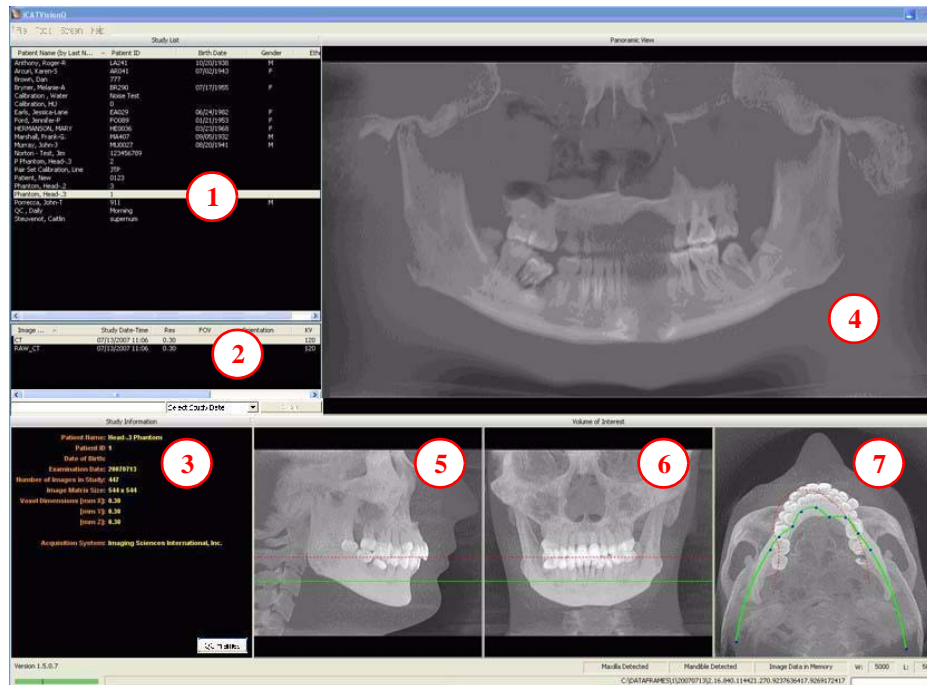
# eXamVision Quick Reference



## Navigating the eXamVision Interface

This guide shows how to:

- View reconstructed images
- Use main features and tools to optimize an image



### REMINDER

Images are displayed as if you are looking at the patient from the front.

### TO DISPLAY PATIENT IMAGE

1. Click Patient Name.
2. Click Patient Scans

### DISPLAYED VIEWS

3. Patient Study Info
4. PANORAMIC View  
Opens to **IMPLANT** Screen
5. SAGITTAL View  
Opens to **CEPH** Screen
6. CORONAL View  
Opens to **MPR** Screen
7. AXIAL View  
Opens to **TMJ** Screen

### MEASUREMENTS

#### HU Statistics

(Bone Density) Right click a view and select **HU Statistics**. Drag and click to define an area. Statistics appear in upper right corner. A maximum of 4 HU stats can be taken at a time in a normal view and 2 in a cross section view.

#### Distance

(Linear Measurement) right click a view and select **Distance**. Point, click, drag, and release to draw a line. A measurement in mm appears in upper left corner. A maximum of 9 distance measurements can be taken at a time in a normal view and 4 in a cross section view.

Right click and select "HU Stats" or "Distance" again to turn the tool off

Right click the actual measurement statistic to remove, inactivate, or activate them.

## Tools for Viewing this Image

### HIDING THE STUDY LIST

Study List can be hidden by selecting **Tools > Hide Study List**. To show, select **Tools > Show Study List**.

### CURSOR TOOLS

**ROTATION TOOL** - Hover cursor over the lower right corner of the desired view. Cursor changes to the rotation tool.

**BRIGHTNESS / CONTRAST TOOL** - Drag cursor up, down, left, and right to adjust brightness and contrast. Use Reset Window/Level options on Pop Up menu to reset brightness and contrast settings.

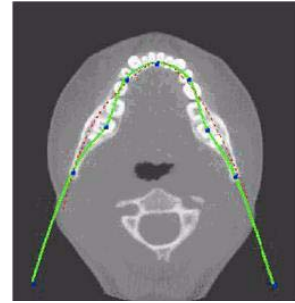
**MIP/RADIOGRAPH** - The system software enables displaying images as MIP or Radiograph. Move cursor to the top right of any image. The cursor becomes an **M**, toggle a selection.

**MAXILLA and MANDIBLE CONTOUR LINES** - can be repositioned with a click and drag to the desired location.



## Suggestions for Adjusting Panoramic Map

Start adjusting the Panoramic map from the Preview Screen. It is recommended to center the anterior point at midline and then move the next two points up closer to the anterior point on each side. Place them a few teeth away from anterior center. Then move the next two points closer to the molars.



## Filtering Defaults

There are already filters applied to all images. The filters are defaulted as seen below.

1. Preview Screen: **Hard**on Panoramic and **Sharpen Mild** for all others.
2. Implant Screen: **Sharpen Mild** on Axial Slice and Cross Sections - **Hard** on Panoramic Map.
3. TMJ Screen: **Hard** for top row images and **Sharpen Mild** for Condyle Ceph Images.
4. MPR Screen: **Sharpen Mild** all images.
5. Ceph Screen: **Sharp** for Upper Left Right Lateral and **Hard** for all others.

These defaults can always be changed by clicking **Tools > Filter Settings > Set Filters**. They can also be changed “on the fly” by right clicking an individual image, selecting **Filter Setting > Set Filter** and clicking the desired option (Smooth, Normal, Hard, Sharp, Very Sharp). They can be changed back to the default by clicking **Tools > Filter Settings > Reset to Default**.

## Removing Circumference Artifact

Circumference Artifact are seen visually in the Preview Screens as horizontal lines in the Coronal and Sagittal images and a white partial circle around the axial image. This can be removed from the dataset by right clicking the screen and selecting **Remove Data Outside of Center Scanfield**. The data re-calculates and the image is displayed without that artifact.

## Saving and Loading Workups

Created plans can be saved for retrieval. When a plan is changed and an attempt to exit or switch patients is made, eXamVision prompts to save the workup. To save the workup, click **Yes**. A window is displayed to **Create New Workup**. Click this button and enter a new title for the workup or choose an existing workup name (if one) from the list to overwrite. Once the workup is named, click **OK** to save.

Or, before exiting or switching patients, from the Preview Screen, right click to access the pop up menu and select **Save this Workup**. Then proceed as instructed above.

To load a workup, click a Patient Name, and Patient Image, and then a workup. To select another workup (if there are multiple workups), right click the screen to access the pop up menu and select **Load Different Workup**. Then select the workup from the list.

## Keyboard Shortcuts

**Alt + S** - Opens Setup dialog

**Alt + F** - Opens File menu

**Alt + T** - Opens Tools menu

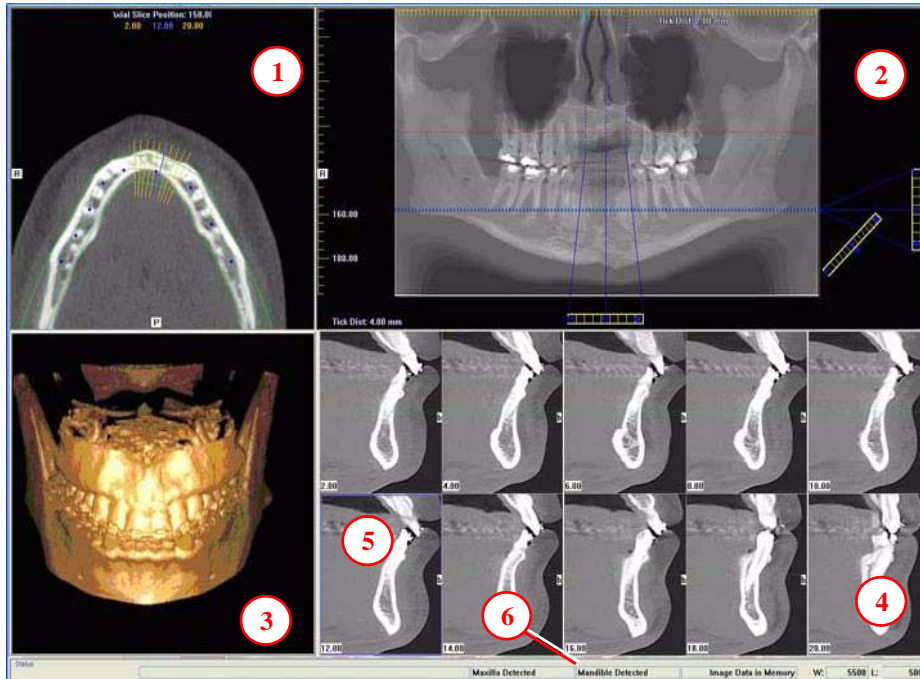
**Alt + R** - Opens Screen menu

**Alt + H** - Opens Help menu





## Implant Planning Screen



### REMINDER

Implant Screen is acquired by double clicking Panoramic View from Preview window or selecting it from the Screen menu.

### DISPLAYED VIEWS

1. AXIAL SLICE POSITION
2. PANORAMIC MAP
3. 3D MODEL
4. CROSS SECTIONS
5. Center Slice is outlined in Blue.
6. Slice Location Number

Slice Location numbers start at "0" for center of anatomy or midline. (The "0" slice is outlined in Red). All slices to the patient's right are negative #'s. All slices to the patient's left are positive #'s.

Midline is determined by axial map.

- Double click an individual Cross Section to zoom in. Double click again to reduce to original size.

### LABELS:

The following labels on the images help clarify the orientation of the anatomy:

- R: Right Side (Axial, Pan)
- P: Posterior (Axial)
- B: Buccal (Cross Sections)

### POP UP MENU

Right click views to display a Pop Up menu containing a subset of these options:

- HU Statistics
- Distance
- Display Formats: The default is 5 x 2. The other options are 7 x 3 and 3 x 1.
- Set Filters
- Save as JPEG
- Open Output Folder
- Estimate Nerve Canal

### CURSOR TOOLS

- All views, except the 3D Model, have Brightness/Contrast, Rotate, Drag, Zoom and Pan. 3D Model only has Rotate.
- The mouse scroll wheel is active on the Axial Slice Position, 3D Model and Cross Sections to scroll through slices.
- **Back Tool:** to exit out of a planning screen back to the Main Display, move cursor to the very top left corner of screen until **X** is displayed and click. Or click the **Screen** option on the Main Menu bar.



PAN TOOLS

1. **Horizontal Tool Bar**

Drag this center tool left to right to move the slice location of the Cross Sections. The center slice is outlined in Blue on the Cross Sections.

Drag the tool to the right to adjust the slice thickness of the Cross Sections.

2. **Diagonal Tool Bar**

Drag this tool to adjust slice thickness of Panoramic View.

Drag the center tool to adjust Pan Focal Trough.

Click the bottom tool to change the Pan view from Radiographic to MIP.

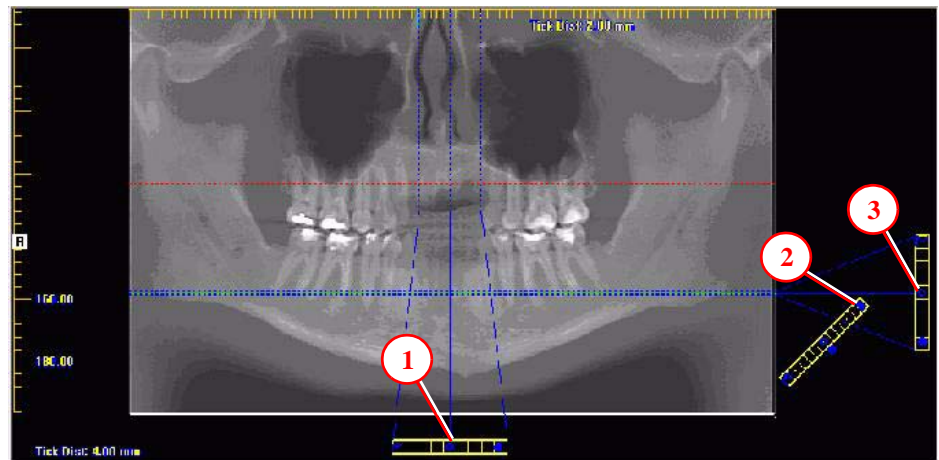
3. **Vertical Tool Bar**

Drag this center tool up or down to adjust height of anatomy viewed in the Cross Sections and Axial.

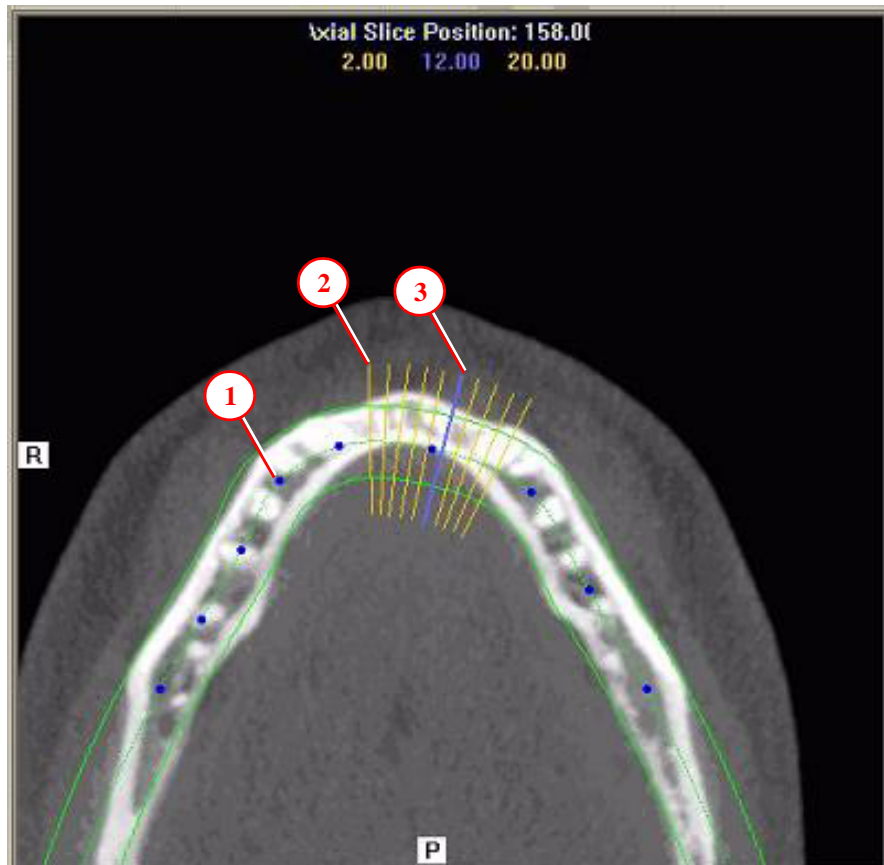
AXIAL TOOLS

1. Drag blue dots to adjust Pan Map.
2. Orange hash marks are Slice Location Indicators.
3. Blue hash mark represents the centerline of the axial slices displayed on the Cross Section views.

**Panoramic Map**

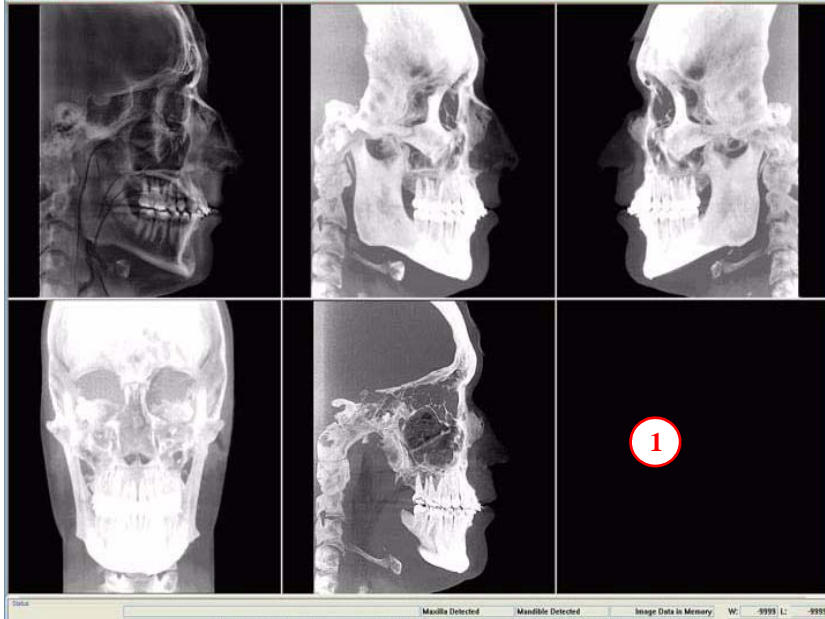


**Axial Slice Position**



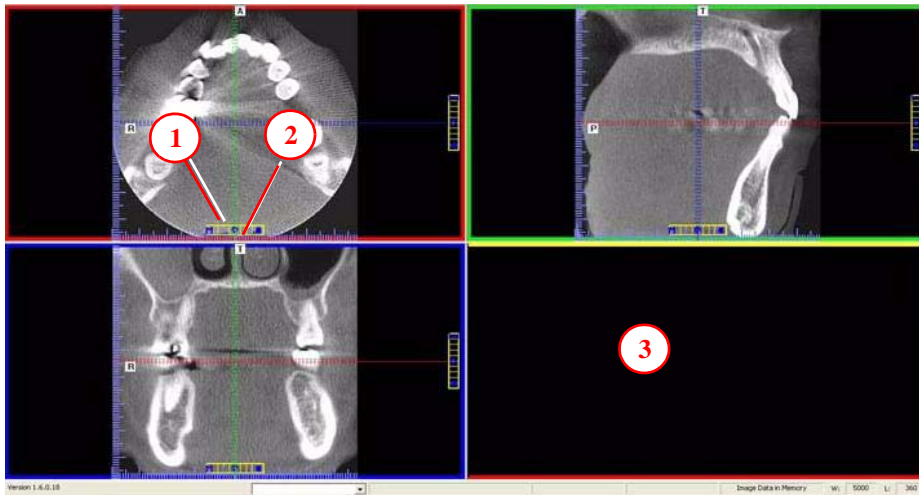


## Ceph Screen



1. Right click blank screen and select **Tag Airways**. This generates a 3D view of the airways for the patient in the blank view. In addition, the tagged airway data is displayed in the view at the bottom center of the Ceph screen.

## MPR Screen



1. Drag center tools from any view to move slice location. The views are color coded to correlate which view will adjust.
2. Drag tool to the right for horizontal and bottom for vertical bars to adjust slice thickness of the corresponding color coded view.
3. Right click any of the 3 views and select Irregular, Line, or Explore for additional cut planes to be displayed in the blank area.

### REMINDER

Ceph Screen is acquired by double clicking Sagittal View from Preview window or selecting it from the Screen menu.

### DISPLAYED VIEWS

The Ceph Screen displays the Lateral Ceph in Radiographic and MIP mode as well as a Coronal View and a Mid Sagittal Slice (15mm thick).

### CURSOR TOOLS

All views have Brightness/Contrast, Zoom and Pan.

### POP UP MENU

Right click to display the Pop Up menu to select:

- Set Filters
- Save as JPEG
- Open Output Folder

### REMINDER

MPR Screen is acquired by double clicking Coronal View from Preview window or selecting it from the Screen menu.

### DISPLAYED VIEWS

The MPR Screen allows scrolling through the Axial, Sagittal, and Coronal Slices.

### CURSOR TOOLS

All views have Brightness/Contrast, Zoom and Pan.

### POP UP MENU

Right click to display the Pop Up menu to select:

- Irregular
- Line
- HU Statistics
- Distance
- Explore
- Explore Speed
- Set Filters
- Save as JPEG
- Open Output Folder
- Reset Volume Rotation



**REMINDER**

TMJ Planning Screen is acquired by double clicking Axial View from Preview window or selecting it from the Screen menu.

**DISPLAYED VIEWS**

TMJ Screen enables condyle mapping and creating corresponding coronal slice views.

**CURSOR TOOLS**

All views have Brightness/Contrast, Zoom and Pan.

**POP UP MENUS**

Right click to display the Pop Up menu to select:

- Set Filters
- Save as JPEG
- Open Output Folder

**HINT**

It may be necessary to first drag the Axial (SMV) view down in the window to see the condyles. Move the cursor to the lower left of the SMV (axial) view until displayed is the “P” for pan tool to drag the image downward.

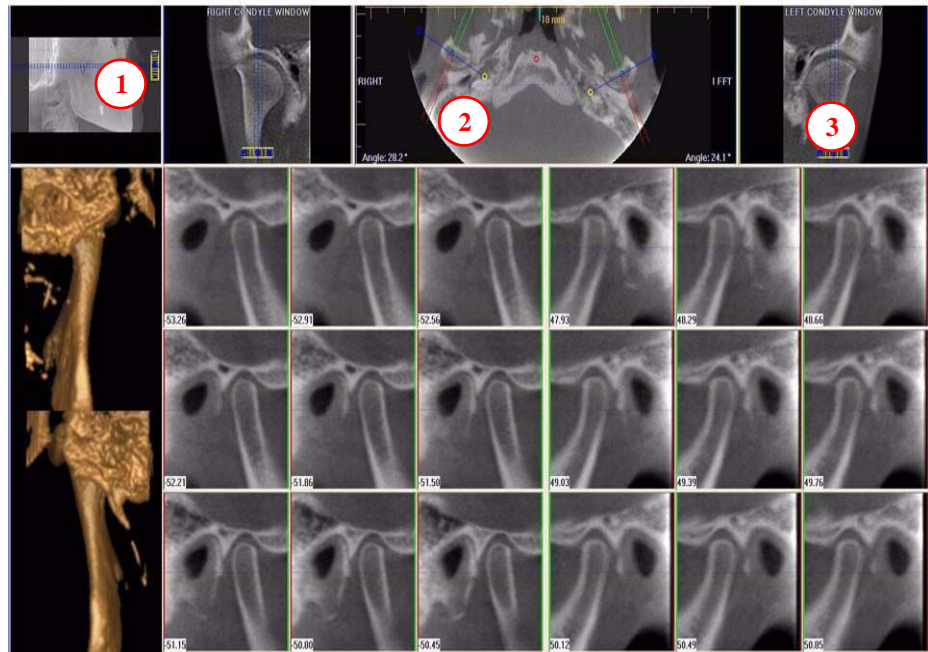
**NOTE:**

Make sure to Save Workups before attempting to burn to a CD,

**Install Case Studies from CDs**

The eXamVision program will auto-run when the CD is inserted into the computer drive. The User can choose to install eXamVision and the case(s) Permanently or Temporarily. Once installed, the eXamVision program opens and the new case is highlighted in the study list and ready to be loaded. Just click the patient name.

**TMJ Planning Screen**



1. Drag center tool to scroll up and down Sagittal view to locate condyles in the Axial view to display condyles properly for mapping.
2. **Create Lateral Slices:**  
 Drag center blue circles to move condyle map (do this for each condyle)  
 Drag yellow and blue end circles to adjust the angle of each condylar map.  
 Green markings indicate anterior to condyle.  
 Red marking indicate posterior of condyle.  
**Create Coronal Slices:** Click red circle on either end map to create Coronal views.
3. **Horizontal Tool Bar:** Drag center tool left to right to move slice location of Cross Section views. Drag tool right to change slice thickness of Cross Section views

**Create Export CDs**

1. From the top Main menu, select **Tools > Create Export CD**.
2. If you have multiple CD drives, select the hardware from the drop down list. If using a CD-RW and need to erase data, choose Erase CD-RW.
3. Click the patient for burning to CD. If selecting multiple patients, hold down the CTRL key and click on additional patients. All highlighted patients are copied to the CD.
4. Click **Create CD** in CD burner window. A message is displayed when the burn is complete and the CD ejects.

