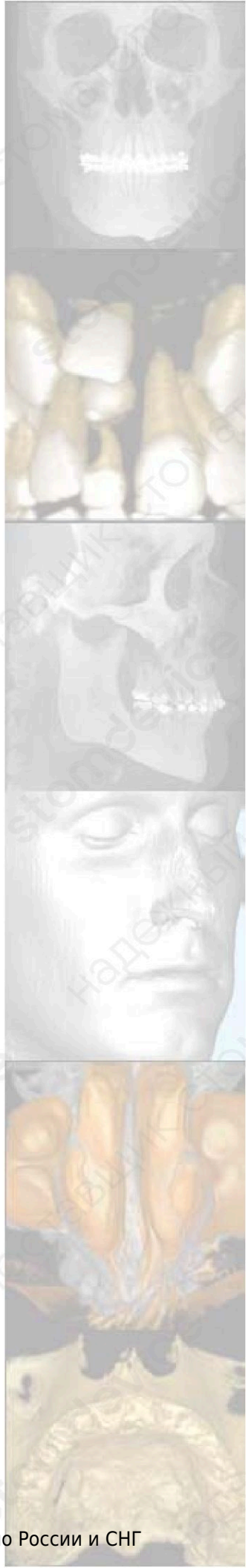
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KaVo 3D eXam®

Operators' Manual



Cone Beam Volumetric Tomography and Panoramic Dental Imaging System



k990400 September 19, 2007

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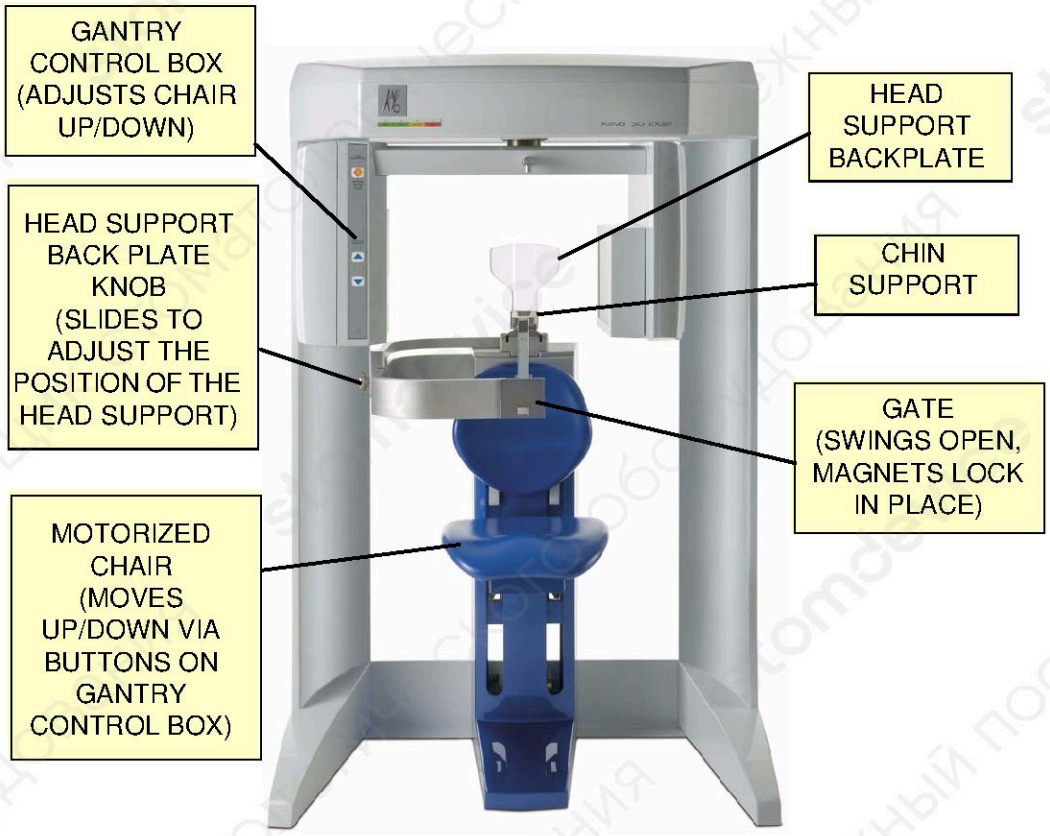
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Chapter 1 Introduction

System Description

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

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



KaVo 3D eXam® Imaging System

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The system consists of a Gantry and Computer Workstation. In order for the system to operate, both the Gantry 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.
- iPAN - Optional Conventional Digital Panoramic Feature

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

Major System Items

The system is comprised of the following major items:

- KaVo 3D eXam Scanner
- Computer Workstation
- Operator Control Box with 30 ft. (9.1m) Cable
- Patient Emergency Stop Box with 10 ft. (3m) Cable
- Interlock Jumper Cable, 8 inch (20cm)
- Chair Connection Cable, 10 ft. (3m)
- Power Cable, 15 ft.(4.6m)
- CAT 5 Ethernet Cable, 10 ft. (3m)

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.

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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

Imaging Sciences International (ISI) 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, ISI 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 ISI. The original purchaser must promptly notify ISI in writing if there is a defect in material or workmanship. Written notice in all events must be received by ISI before expiration of the warranty period. This warranty is not transferable.

This One-Year Limited Warranty covers normal use. **ISI 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;
- Defects 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;

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- Damage caused by any other abuse, misuse, mishandling, or misapplication.
- Damage to acquisition computer, software, or operating system caused by:
    - Additions or changes unauthorized by ISI
    - Viruses, spy ware, or gaming software
    - Damage caused by Network or Operating Engineers
    - Damage from the use of this machine or computer for any other
    - Applications other than its intended use
    - Damage caused by third party software
    - Damage caused by unauthorized changes to the ISI software
    - Damage caused by unauthorized upgrades, additions or deletions
    - Damage caused by internet use, or any other unauthorized application.

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Chapter 2 Safety Items

Important Safety Information

Imaging Sciences 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 that you 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.

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Safety Precautions

WARNING

The X-ray unit 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.

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.

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.

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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. 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.

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.

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Emergency Stop

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 should utilize the **Emergency Stop button** 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. There are two methods available to use this system:

Method 1: Externally provided power

An externally powered warning system can be connected to terminals 1 and 2 of the X-Ray Interlock printed circuit board inside the Lower Control Center. A relay contact capable of 250 volts, 50/60 hertz, and 3 amps is connected between these terminals. When X-ray power is energized this relay contact is closed and the warning system energized.

Method 2: Equipment provided power

A warning system may be powered from 12 volts DC within the System. The warning system cannot exceed 12 volts DC, 3 Amps. To use this provision connect the warning system as follows:

1. Connect the "common" of the warning system to terminal 6 of the X-Ray Interlock printed circuit board inside the Lower Control Center.
2. Connect terminal 1 to terminal 5 on the circuit board.
3. Connect the "positive" of the warning system to terminal 2 of the circuit board.

When X-ray power is energized 12 volts DC will be provided through the relay contact between terminal 1 and 2 of the X-ray Interlock printed circuit board and energize the warning system.

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NOTE: When using this method; ensure that the factory installed jumpers between terminals 3 & 5 and 4 & 6 are in place. These jumpers should only be removed when an interlock system is used.

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 jumper between terminals 3 & 5 of the X-Ray Interlock printed circuit board inside the Lower Control Center and connect door switches and/or emergency stop switches in series between terminals 3 & 5. 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.

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System Labels

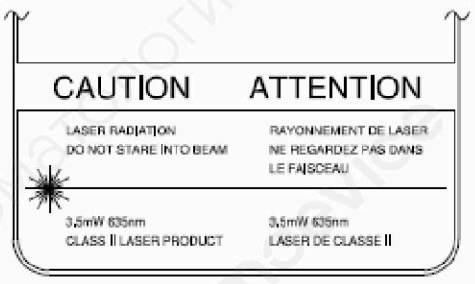
The following labels are attached to the system.







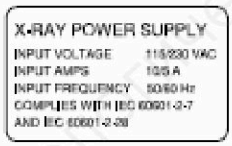






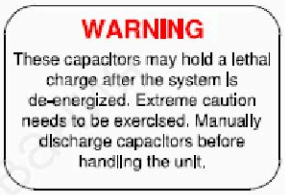


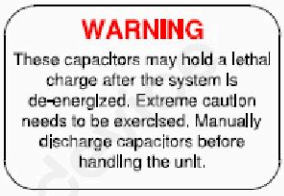














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Chapter 3 System Controls and Indicators

Controls and Indicators are found on the following system units:

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

Main Control Box

ON powers the Gantry and the POWER indicator lights to show that the Gantry is ON.

OFF removes power from the Gantry and the POWER indicators go OFF.

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

SCAN initiates Patient X-ray scanning via the Gantry. (This allows the Main 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).



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Emergency Stop Control



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 of the Gantry and the Main Control Panel.

POWER indicator is lit when the Gantry 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).



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Chapter 4 System Startup and Shutdown

System Startup

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



1. **Power up Computer Workstation:** press the power button on the front of the Workstation. The computer boots and loads the operating system.



2. **Launch iCATVision Software:** double-click the **iCATVision** icon on Workstation desktop. The iCATVision software application is launched.



3. **Power up Gantry:** press the **ON** button on the Main Control Box. The **POWER** indicator on the Main Control Box and Gantry light.

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

NOTE: The Gantry must be powered up **2 hours prior** to assessing a scan. The Gantry may be left ON overnight if the 2 hour period is a problem.

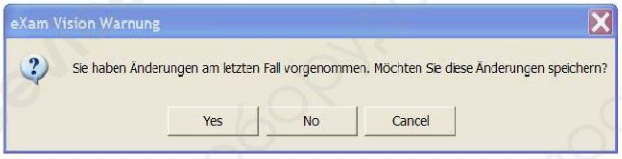
To shut down the system:

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

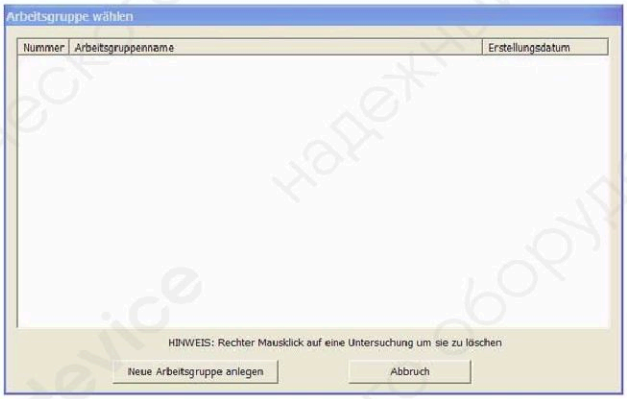
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If changes were made to a case study, the following dialog box appears.



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 Gantry:** press the **OFF** button on the Main Control Box. The Gantry shuts down and the POWER indicators on the Main Control Box and Gantry 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.



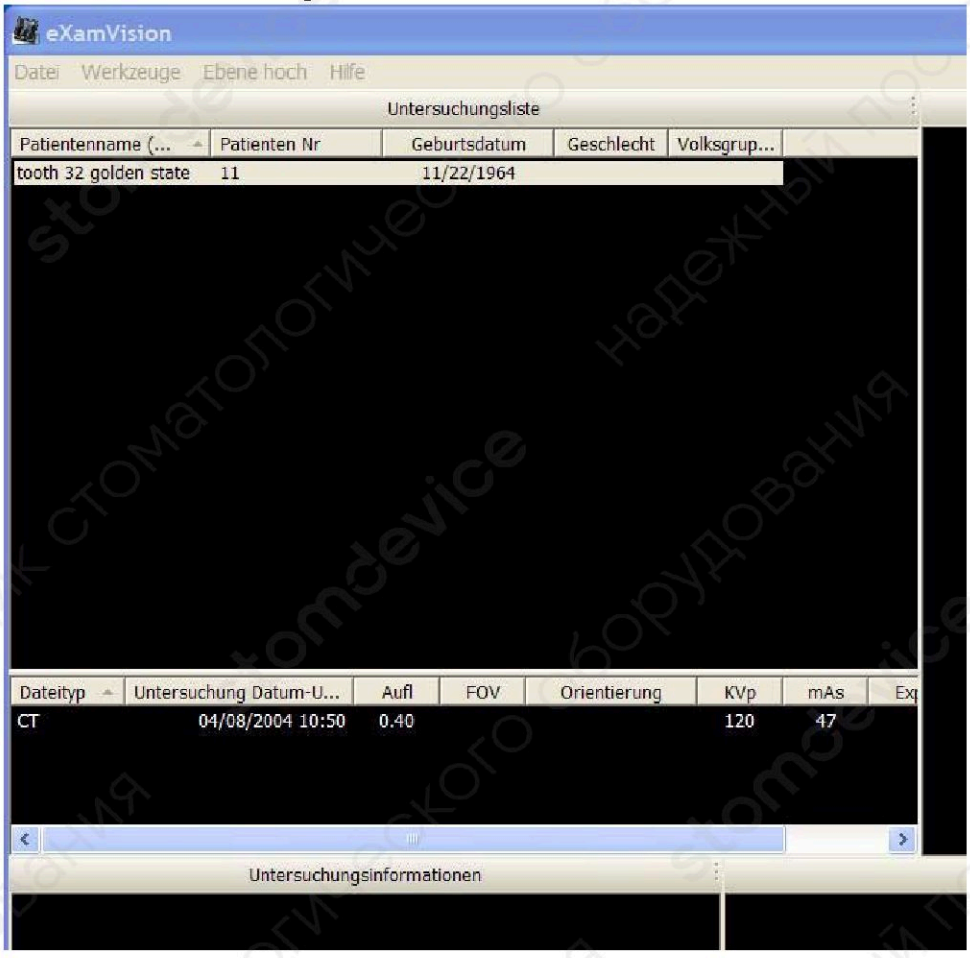
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Chapter 5 Managing Patient Data

Patient Information

When i-CATVision is launched, the Patient Information window is displayed. This window lists all the 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 Patient List.



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

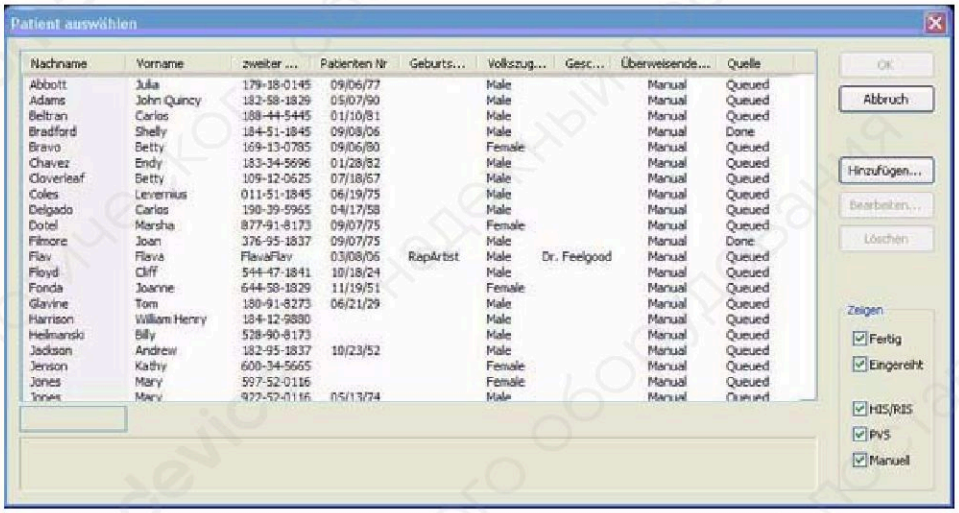
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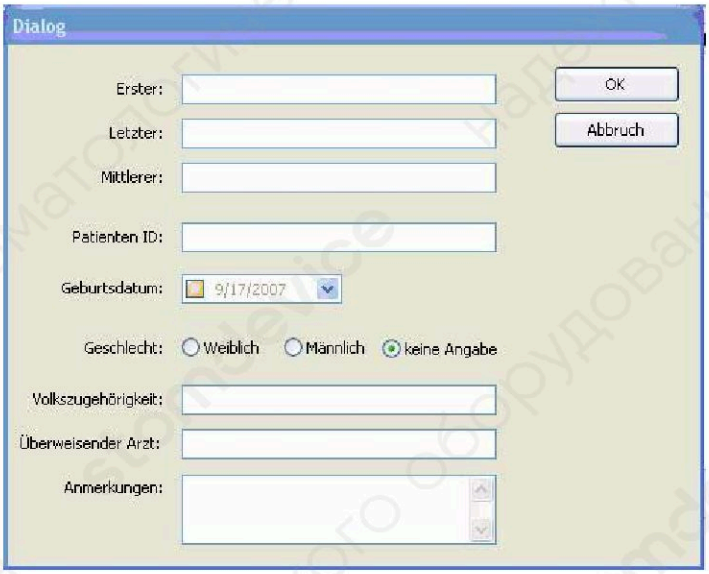
Add New Patient

To add a new Patient

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



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 check box in the **Birthdate** drop-down list box to enable the drop-down list box. Click the arrow to display the calendar tool.

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

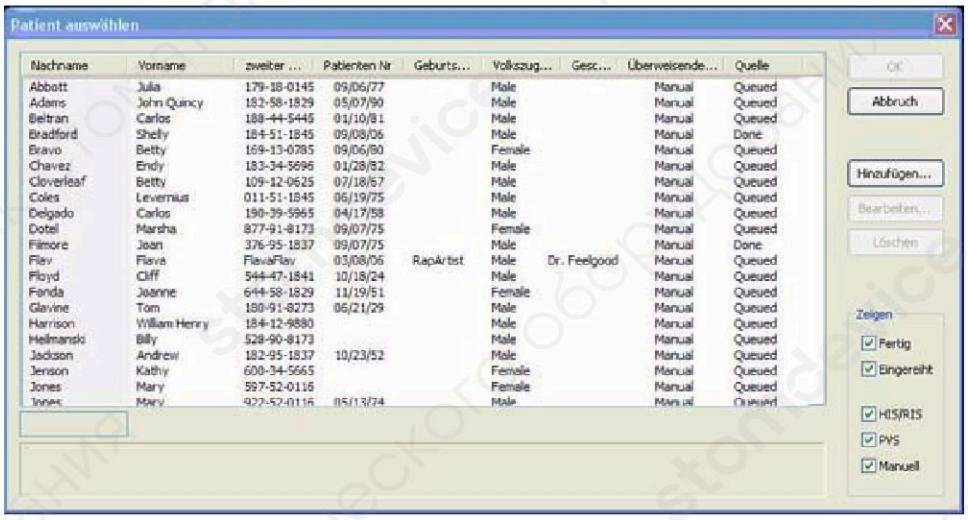
- The **Status** drop-down list box indicates whether data has been acquired for this Patient (by selecting the **Done** entry).

4. Click **OK** to add Patient data.
5. Click **OK** to close dialog box.

Edit Patient Details

To edit Patient details:

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



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.

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- **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 you wish to modify.
4. Click **Edit**.



5. Modify Patient data as desired.
6. Click **OK** to add Patient data.
7. Click **OK** to close dialog.

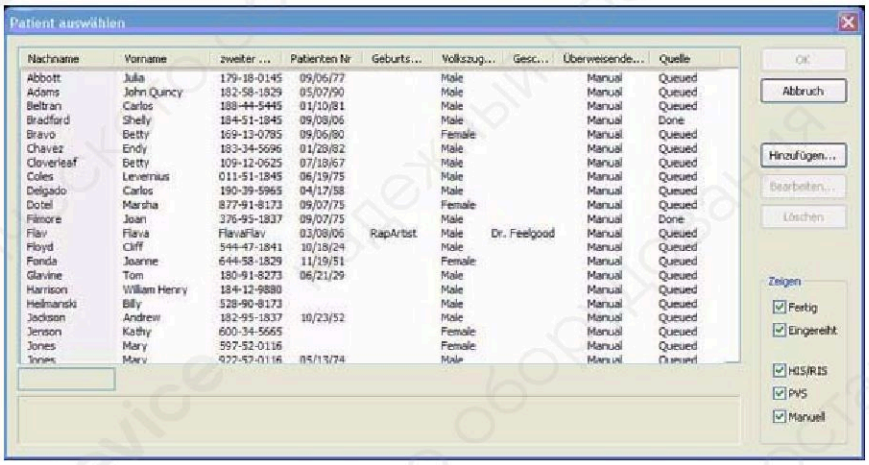
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Delete a Patient

To delete an existing Patient:

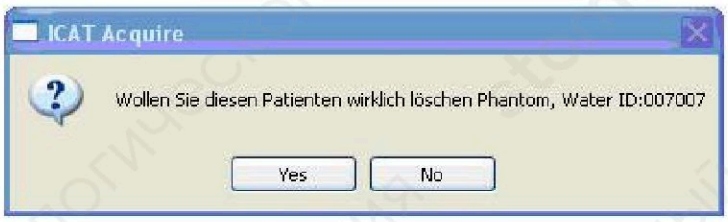
1. From the Main menu, select **File > New**



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 you wish to delete.
4. Click **Delete**.



5. Click **Yes** to delete Patient from database.
6. Click **OK** to close dialog box.

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Hide/Display Patient List

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

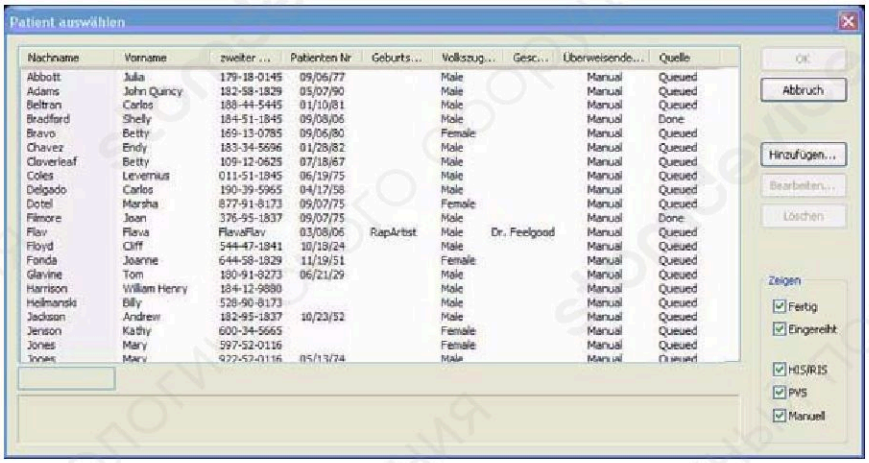


To display the Patient list, select **Tools > Show Patient** from the Main menu.

Load Patient Data

To load existing Patient details:

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



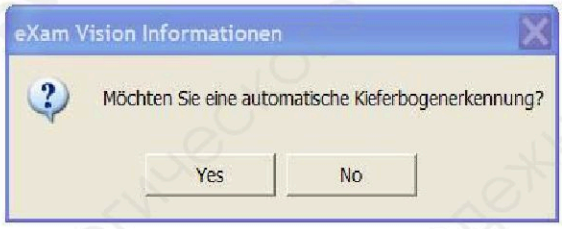
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2. If desired, limit the number of Patients listed by using the check boxes in the Show area at the lower right side of the dialog box. Only Patients whose data matches the selected criteria are displayed.
   - **Done -** Patient Data entered and scanned
   - **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 you wish to load.
4. Click **OK**.



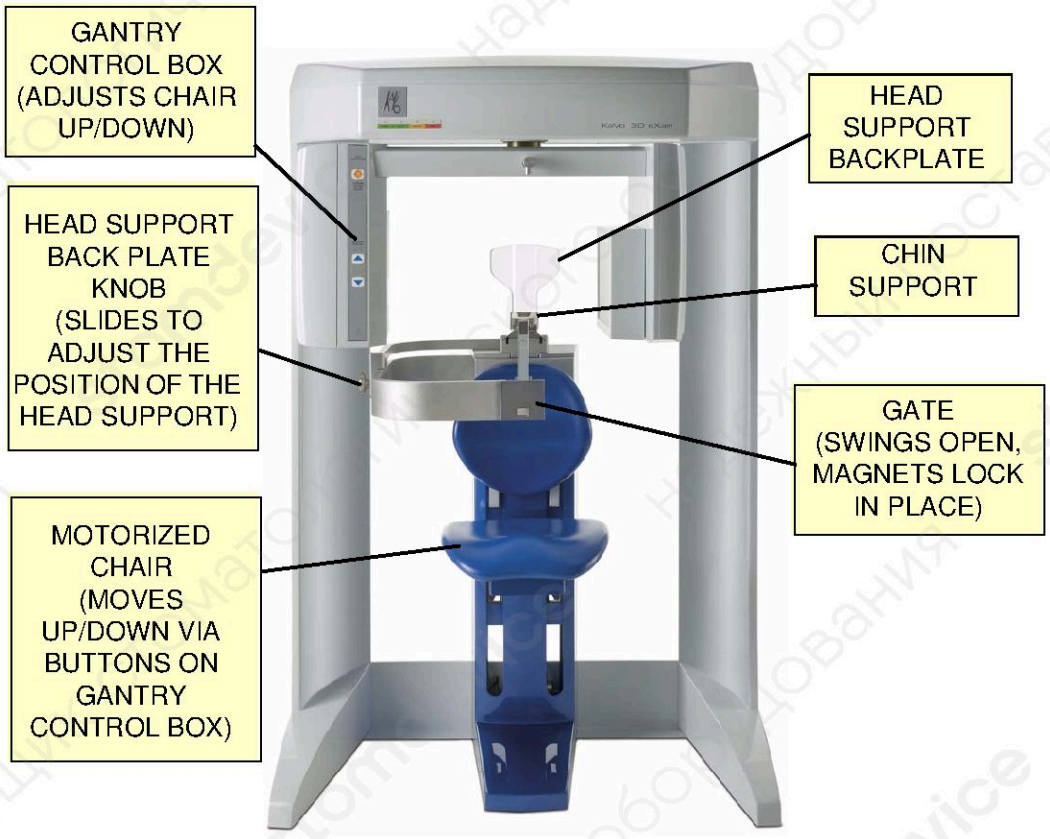
5. Click **Yes** to automatically detect the arches. (Clicking **No** skips the automatic detection of the arches.) The dialog box closes and the Patient data is loaded.

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Chapter 6 Acquisitioning (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 6’ 2”.
2. With the gate opened, have the Patient seated in the chair, facing forward. The Patient should be seated comfortably with hands in lap.

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3. Close Gate, making sure the magnet is secured in its locked position.
4. Use the **Patient ALIGN** buttons on the Alignment Control Panel to adjust the Patient Chair height. These controls allow movement of the Patient chair, up (Δ) and down (▽), 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 Frankfurt Horizontal is tilted up by about 5 degrees (see illustration below).



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.

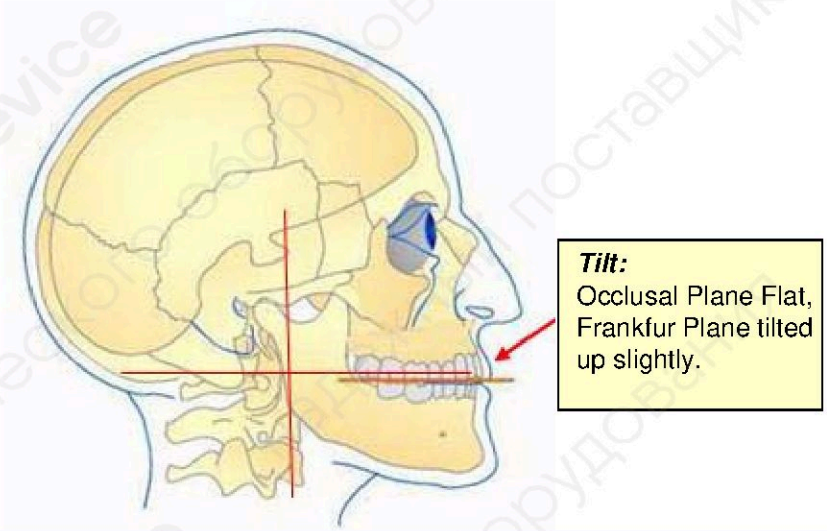
6. **Alignment Light:** In general, the Alignment Light shall be positioned at the horizontal Occlusal Plane.
   - **Full Head Scan:** The Horizontal light should be at the Occlusal Plane between the lips (smile line).
   - **Clearance:** Make sure that the sensor side of the turret has enough clearance 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.

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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 CT 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.

1. To acquire a new acquisition do one of the following:

   Once data is entered for the Patient in the Select Patient dialog box, with the Patient name selected (highlighted) click the **OK** button.

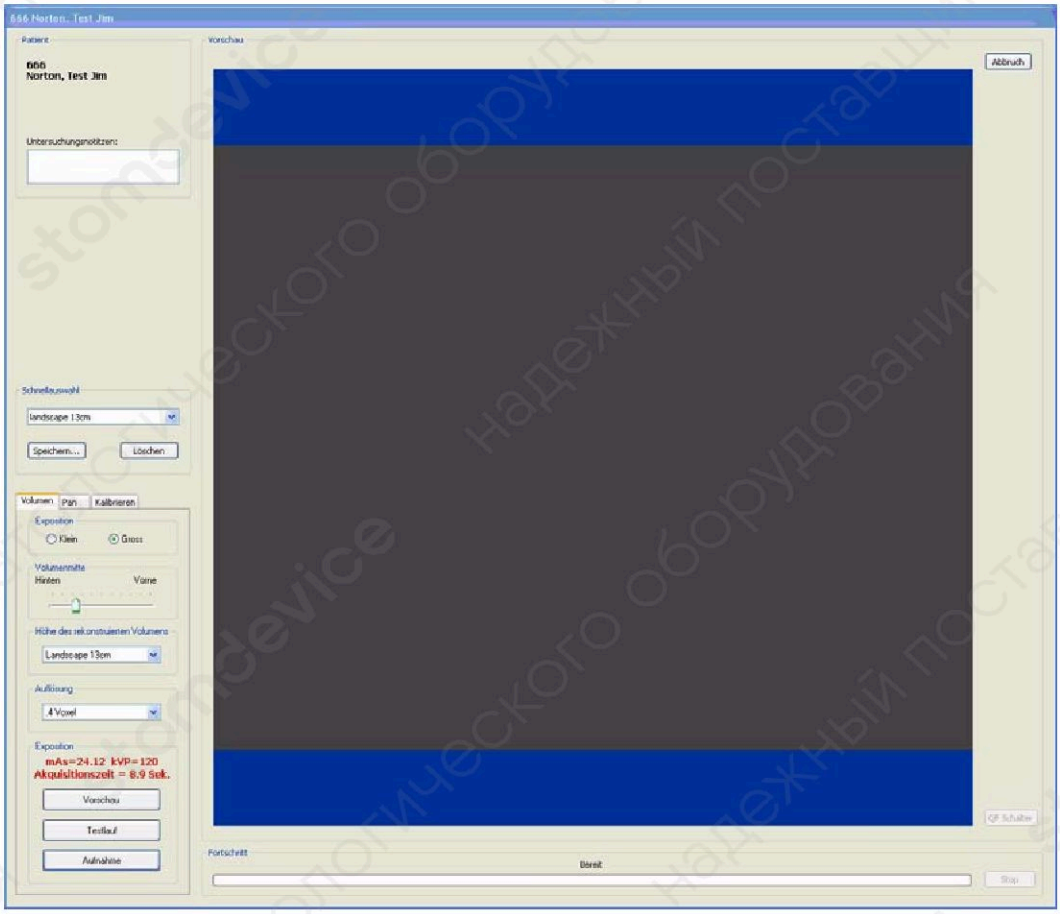
   - or -

   From the Patient Information Pane on the preview screen, double-click the Patient for whom new scans are to be acquired.

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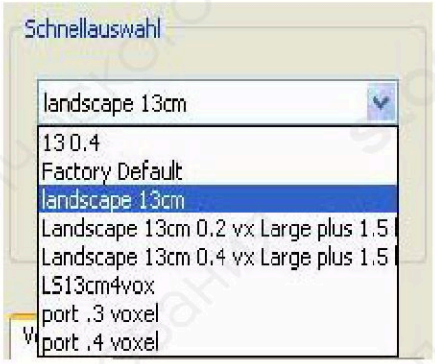
The Acquire window is displayed.



2. If desired, enter any remarks in the *Study Remarks* text field.
3. From the *Quick Picks* drop-down list box, select a standardized acquisition setup or create a new one (see details below).

Quick Picks

1. Select an acquisition from the *Quick Picks* drop-down list.



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- **2 arches/anchor, 8.5 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 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 the Height of Reconstructed Volume for adult Patients where cephalometric data is required.

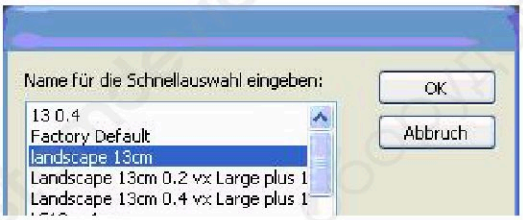
2. If the standardized setups do not meet your exact requirements, either select all of the desired criteria for the scan

   or

   Select a *Quick Pick* and make modifications to the available criteria.

To add new criteria to the Quick Picks list:

a. Click the **Save…** button, below the Quick Picks list box. The following dialog box appears.



b. Enter a name for the new Quick Pick in the text field on the dialog box.

c. Click **OK**. The dialog box closes. The newly created Quick Pick is now available from the Quick Picks drop-down list box.

To delete a Quick Pick from the list:

a. Select the Quick Pick to delete from the Quick Picks drop-down list box.

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b. Click the **Delete** button below the Quick Picks drop-down list box.

c. A confirmation box is displayed, click **Yes** to delete.

Volume Scan

After the acquisition is launched and the **Volume** tab is selected, do the following:



To acquire a Volume Acquisition:

1. From the Main menu select **File > New Patient**.
2. From the Patient Information Pane click **Add**.
3. From the *Acquire* window, click the **Volume** tab.
4. Select **Small** or **Large** *Exposure*

   The Operator is required to determine 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).
5. Select Resolution by using the corresponding 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 deliver a higher radiation dose.

   Standard scans should be taken at *Full 13cm, 8.5 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

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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.

6. Adjust the **Volume Center** slide control to select the position of the x-ray sensor (front to back).
7. Select the **Height of Reconstructed Volume** from the drop-down list to indicate the portrait or landscape position of the x-ray sensor.
8. 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 unit 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.

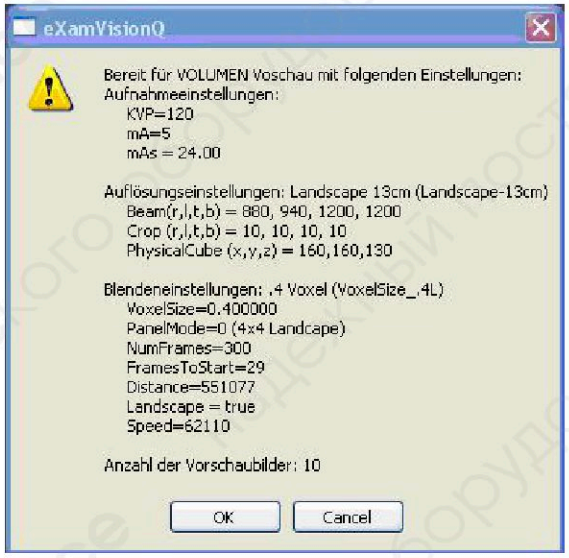
1. Click the **Preview** button under *Exposure*.



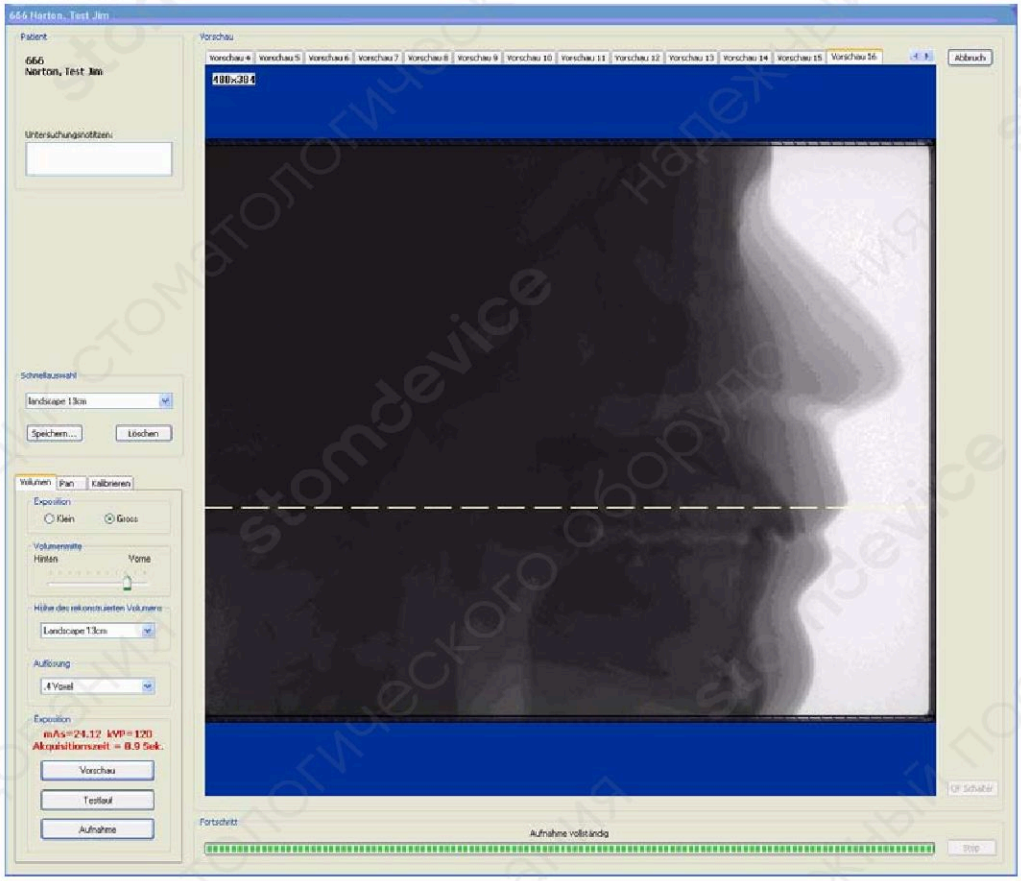
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The following dialog box is displayed.



2. Click **OK**. The system proceeds to take a Static Exposure "Quick Ceph." The resulting image is displayed on the screen.



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If the Horizontal & Vertical skull position looks correct, then proceed to the **Volume** scan. Otherwise, re-position the Patient or the volume center to achieve better positioning and restart this procedure. To ensure good quality, the required image should appear within a ¼ inch border of the Preview screen.

3. **Dry Run** is used to demonstrate the motion of the machine to the Patient, without exposing, as well as to check for shoulder clearance. The Dry Run scan performs half the revolution and resets immediately. 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

The X-ray unit 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.

4. Click **Capture** to start the acquisition.
5. Ensure that nobody is in the operator area or Patient area.
6. Click **OK** to start the 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.

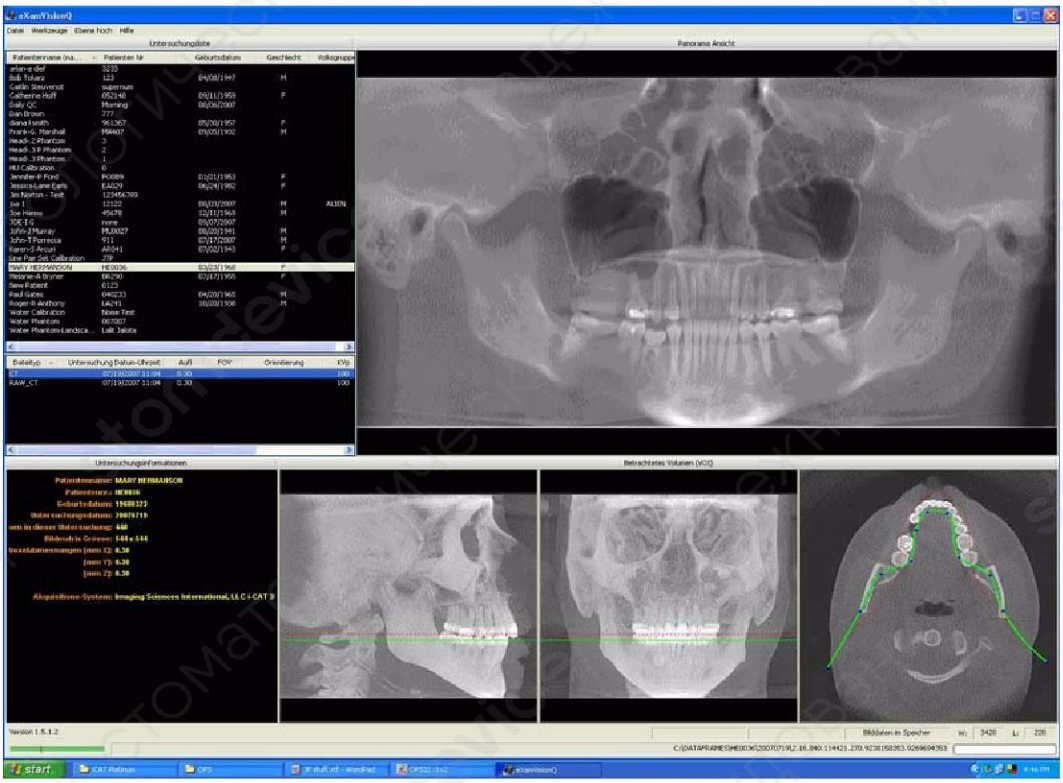
The progress of the scan is displayed on the *Progress* bar at the bottom of the Acquire window.

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Once the acquisition is complete, the machine rewinds. **Wait until the machine rewinds before releasing the Patient from the machine**. The software immediately begins the reconstruction of the image data. (The time required to reconstruct depends on the Scan Time and Voxel size selected.)

7. Click **Done** to close the Acquire window. The scans are ported to the iCATVision preview screen for anatomy reconstruction (shown below).



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PAN Scan (Optional)

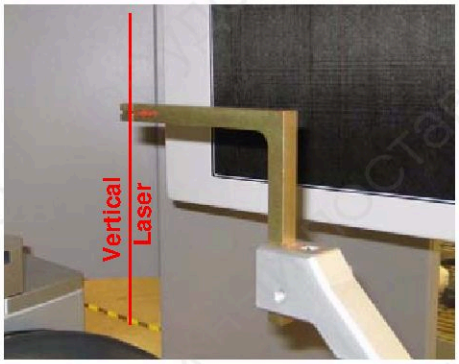
A PAN scan is a scan mode that creates a Panoramic exposure that is a two dimensional image.

Patient positioning is critical for PAN scans. The Gantry must also be properly aligned to ensure quality Patient images. Prior to performing a PAN scan, the Gantry alignment should be checked, to ensure optimal system performance. It is recommended to check the Gantry alignment monthly or if the image quality has degraded.

To check Gantry alignment:

1. Replace the Chin Cup with the Chair Center Locator.
2. Press the Alignment Light button on the Gantry Front Panel to display lasers.

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



3. Ensure that the Vertical Laser intersects the notch on the Chair Center Locator tool, as shown.
4. If the Vertical Laser is in the correct position, then the unit 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 Gantry.
   - **Turn nut driver counter-clockwise -** moves alignment tool towards front of Gantry.



To acquire a PAN scan:

1. Seat the Patient in the chair with an Erect posture.

   The neck must be straight as possible to avoid the spine getting in the view.

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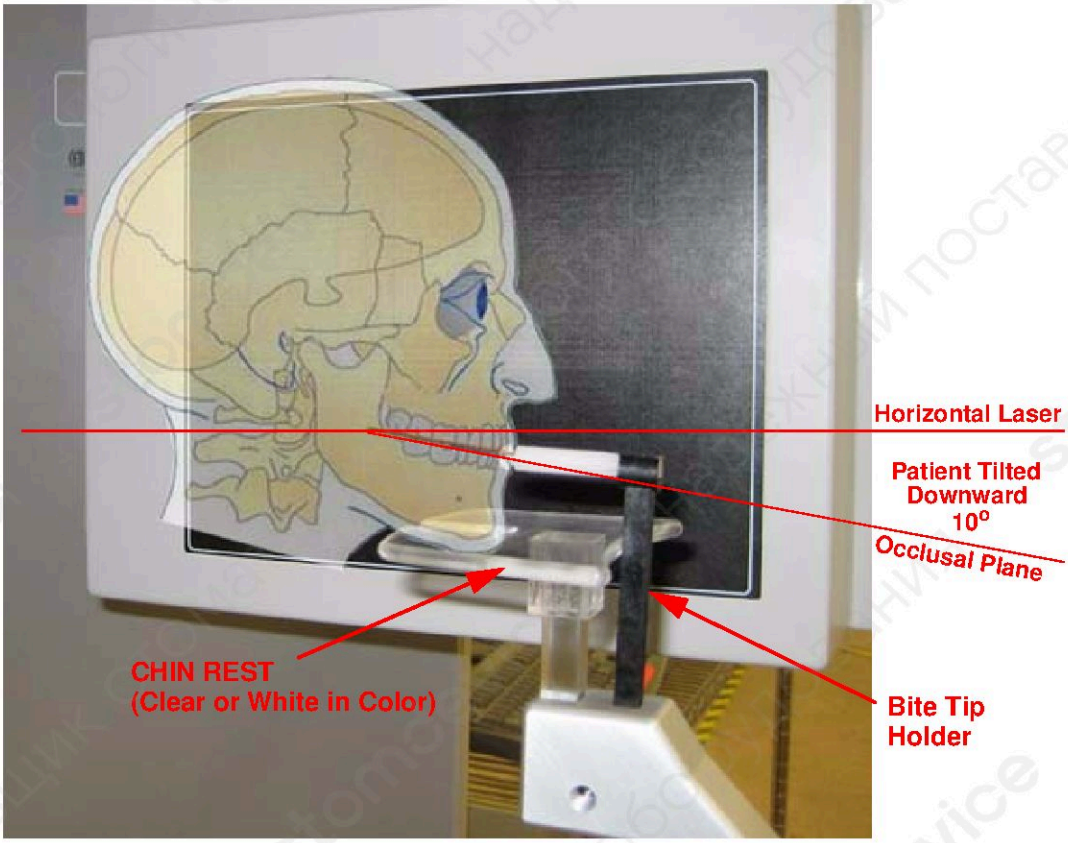
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2. Prepare the Bite Tip by inserting the narrow edges of white Bite Tip down into Bite Tip Holder uprights. Then turn the Bite Tip a 1/4 turn to lock into place.

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



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



4. Adjust Patient height to where the Patient's chin is on the Chin Rest, but keeping the Erect posture.

NOTE: The front-to-back Patient positioning is critical for a quality image. The PAN scan capture is a tall but narrow window.

5. Patient must bite in the grove of the white bite piece to ensure proper front-to-back positioning.

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6. From the Pan menu, make an *Exposure* selection: The Operator is required to determine 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).



7. *Patient Position*: click the **Open beam limiter** box to access the laser light for Patient tilt positioning.

   With this box checked, the collimator opens so the lasers are available for Patient tilt positioning.

8. Align the Patient Occlusal Plane so that it is level with the Horizontal Laser. Then have the Patient tilt their head downward approximately 10^{o}.

   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 foward.

9. After the Patient is properly positioned, uncheck the **Open beam limiter** box. This closes the collimator.

NOTE: Note: If Operator fails to uncheck the *Open beam limiter* box prior to clicking Capture, the system unchecks the box which closes the collimator prior to starting the scan.

10. The Patient's lips should be closed around the bite piece as if using a straw.

11. 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.

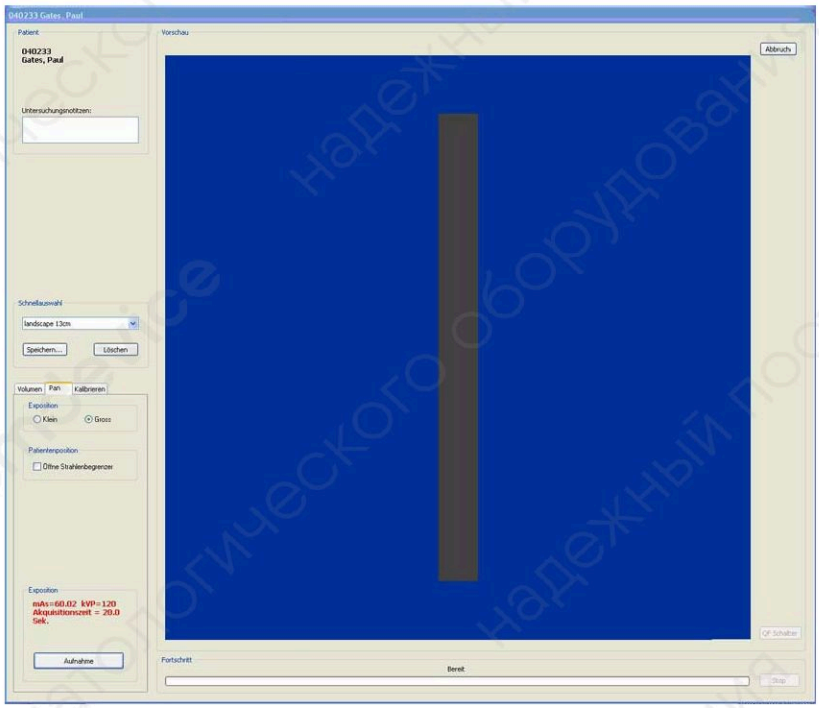
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WARNING

The X-ray unit 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.

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



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

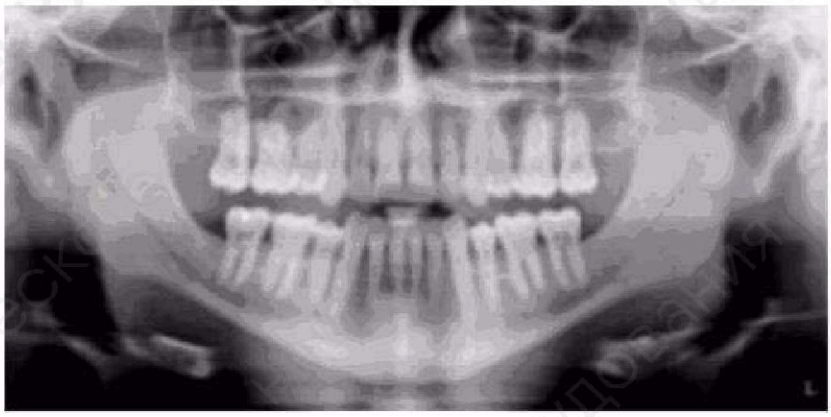


14. Click **OK** to start the scan process.

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15. The PAN scan runs a few minutes and then displays the reconstructed image.



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

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Chapter 7 Reconstruction of Anatomy

Preview Screen

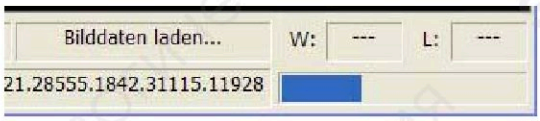
Once Patient data is acquired or data for a Patient is loaded, the iCATVision software immediately reconstructs the Patient anatomy images. (User modified Patient data, referred to as a *Workup*, can also be loaded to the preview screen. While data loading is occurring, a preview window appears in the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



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

CAUTION

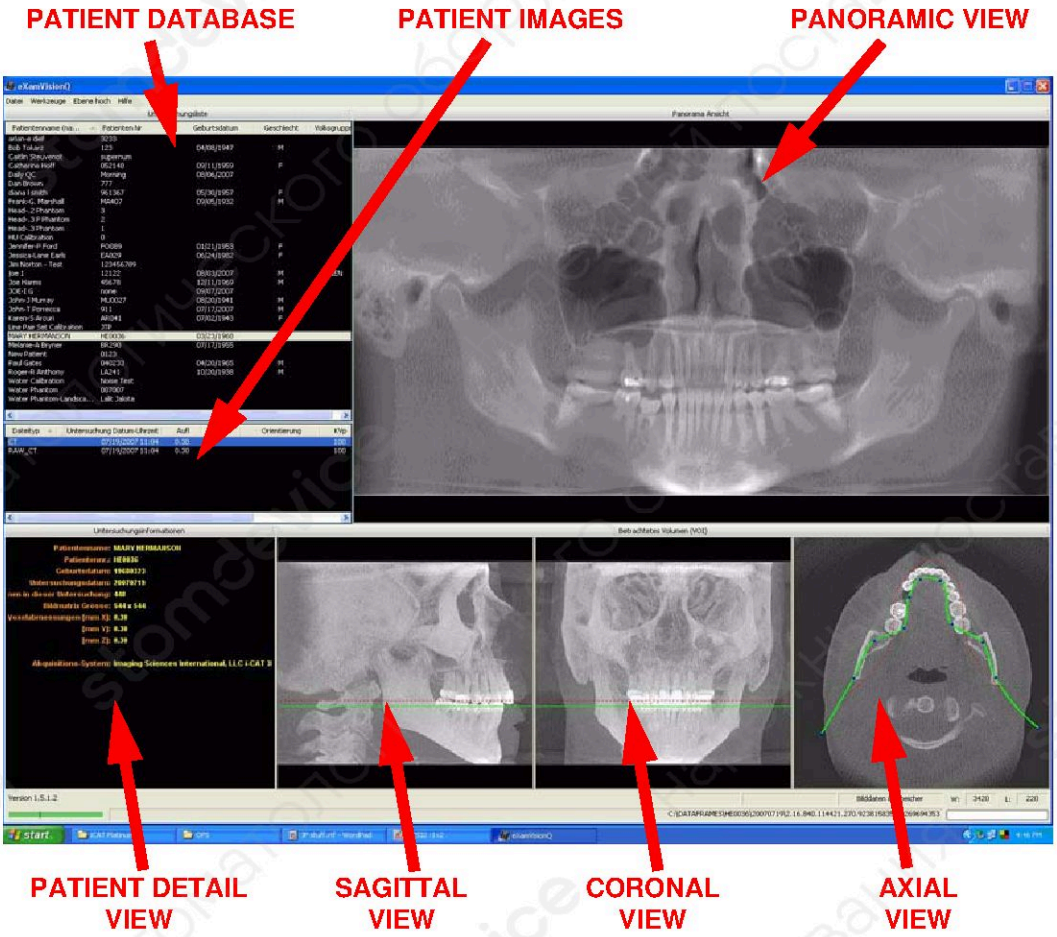
DO NOT do anything in a Patient study until the status bar located at the bottom right of the window indicates that the Patient data is fully loaded. Wait until the status bar reads "Image Data in Memory" prior to performing any tasks. Otherwise, data loss may occur.



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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 iCATVision database (even if they were not scanned).

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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 (highlighted in the Patients in Database list).

Panoramic View shows a wide detail view of the selected points on the Axial View. Distance and Housfield 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 Housfield Unit measurements can be taken on this view. Double-clicking on the Sagittal View brings up the Ortho (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.

Adjusting the Panoramic View

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

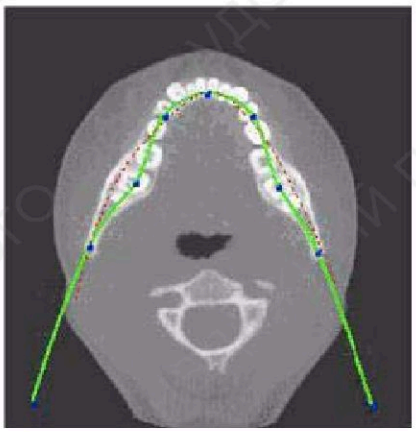
To adjust the Panoramic View:

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.

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4. Then move the next two points closer to the molars. See the example below.

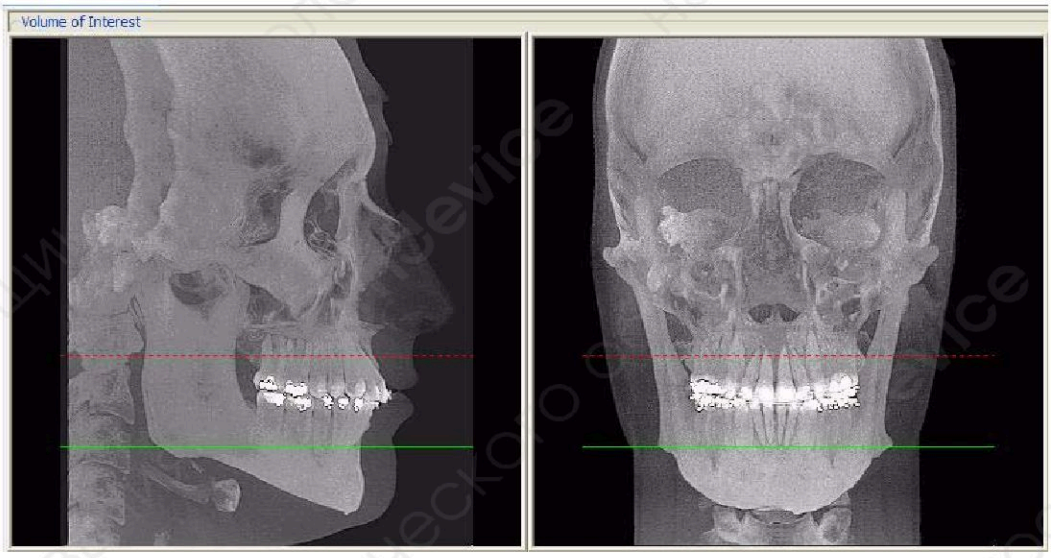


Any changes made are reflected in the Panoramic View.

Contour Line Setup

Contour Lines 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 Contour Lines can be repositioned with a click and drag to the desired location.



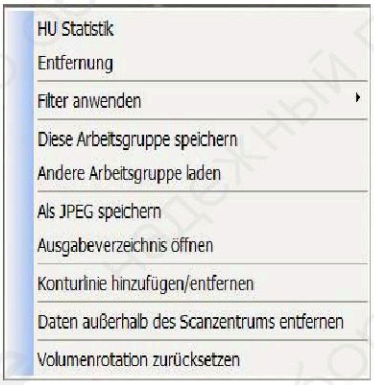
Clicking a Contour Line selects that line for use in adjusting the Panoramic View via the Axial View.

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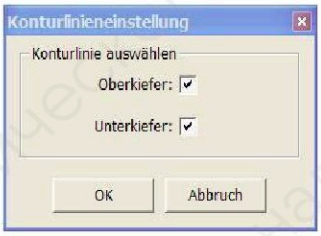
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One or both Contour Lines can be added/removed from the Sagittal and Coronal Views on the preview screen. To do this, do the following:

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



2. Click check box corresponding to the Contour Line you wish to add/remove.



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



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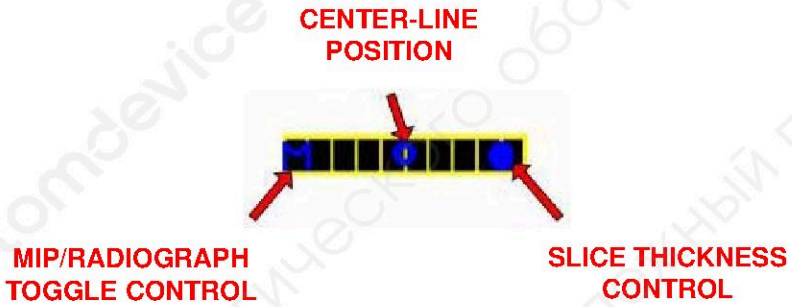
Removing Circumference Artifacts

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 Stray Voxels from Circumference**. 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 as applicable.
- **MIP/Radiograph Toggle Control -** clicking the *MIP/ Radiograph Toggle Control* toggles the images displayed between MIP and Radiograph (refer to page 7).
- **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

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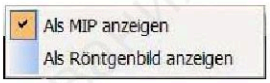
Selecting MIP or Radiograph Display

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 the cursor is an **M**. The following popup window appears.



3. Click the menu item corresponding to the desired image type. (The currently selected image type has a check mark to the right of the corresponding menu item.)

Adjusting Brightness and Contrast

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



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

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 in which you wish to use the pan function. The pan cursor tool appears.
2. Click and drag up, down, left or right to pan to the desired portion of the displayed image.

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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 in which you wish to use the zoom function. 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, you can use the X cursor 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 the left mouse button. You are returned to the preview screen.

   This can also be performed by clicking **Level Up** 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 (**Smooth**, **Normal**, **Hard**, **Sharp** or **Very Sharp**).

Default filter values are selected for all screens as follows:

- Preview Screen: **Hard** (for all images)
- Implant Screen: **Hard** (for all images)
- TMJ Screen: **Normal** for (Condyle Ortho Images) and **Hard** for all other images)
- MPR Screen: **Normal** (for all images)
- Ceph (Ortho) Screen: **Very Sharp** (for Upper Left Right Lateral) and **Hard** (for all other images)

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

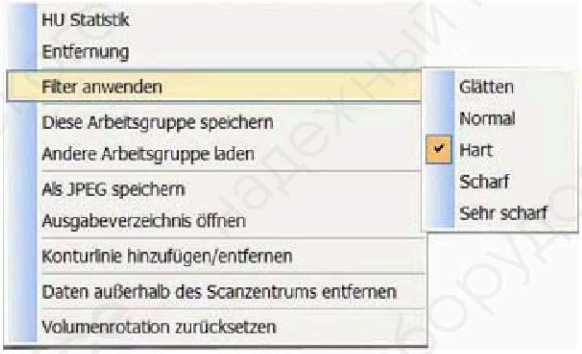
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Setting Filters for a Single Image

To change the filter setting for an individual image:

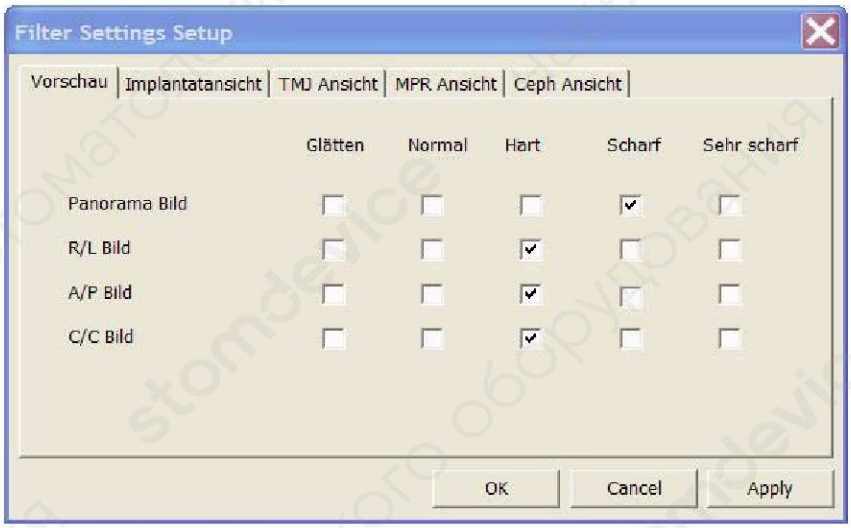
1. Right-click the image and select **Set Filter >** and select desired filter setting. The selected filter setting is applied to the corresponding image.



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**



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.

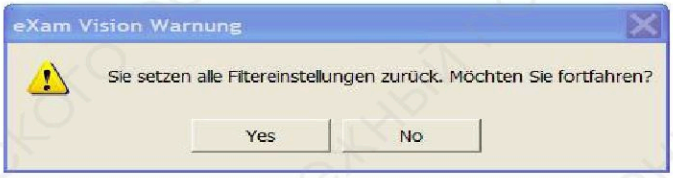
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Resetting all Filters to the Default Values

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 a measurement, right click the image and select **HU Statistics**.



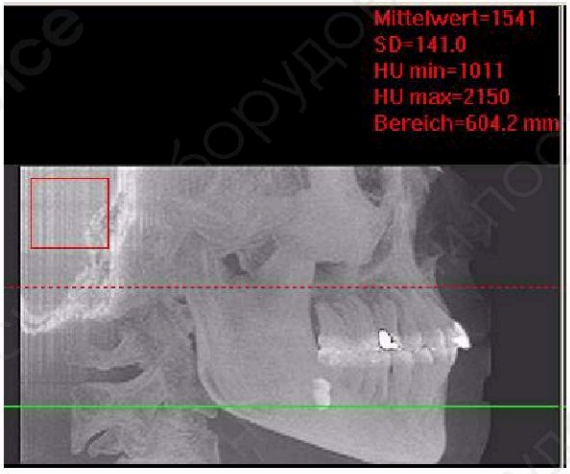
The menu closes and the cursor changes to the **hu** measurement symbol.



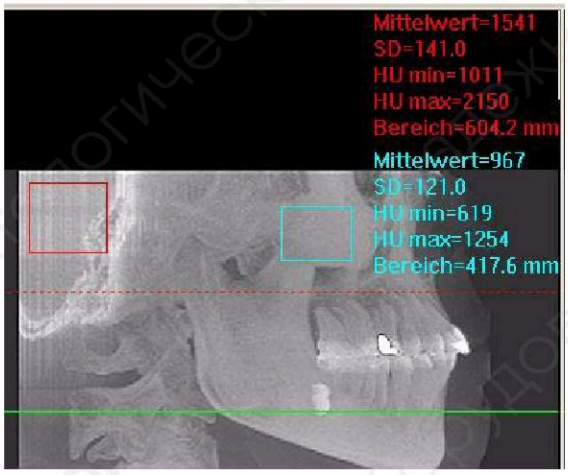
2. Click, drag, and click to define an area. Measurement statistics appear in the upper right corner of the image.

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3. 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:

1. Right click the image. A popup window appears.
2. 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.

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To remove a specific measurement:

1. Right-click the measurement that is to be removed.
2. 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.

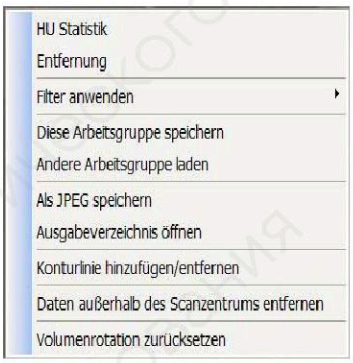
Reactivate All Measurements - restores all of the inactivated measurements to the selected view.

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**.



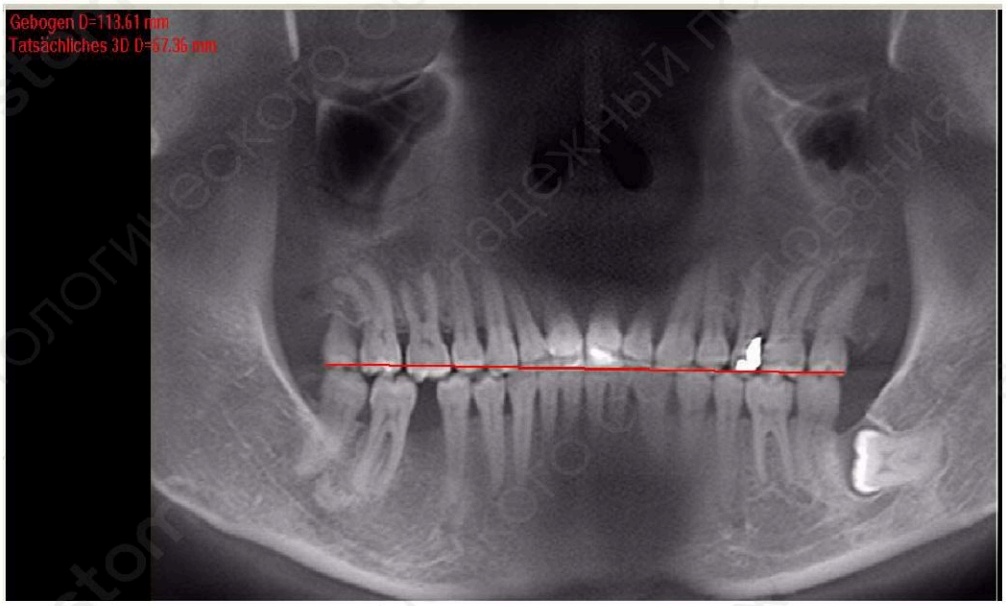
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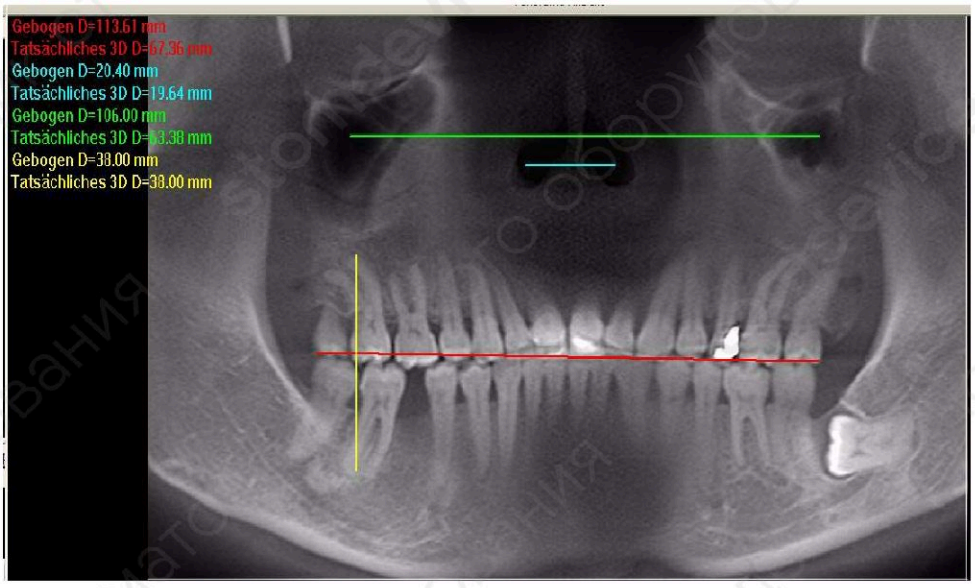
The menu closes and the cursor changes to the distance measurement symbol.



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.



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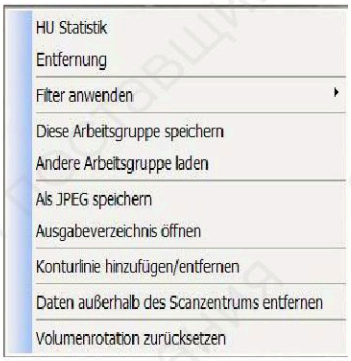
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To switch off the distance cursor:

1. Right click the image and select **Distance**.

   The cursor reverts to the default cursor.

2. 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:

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:

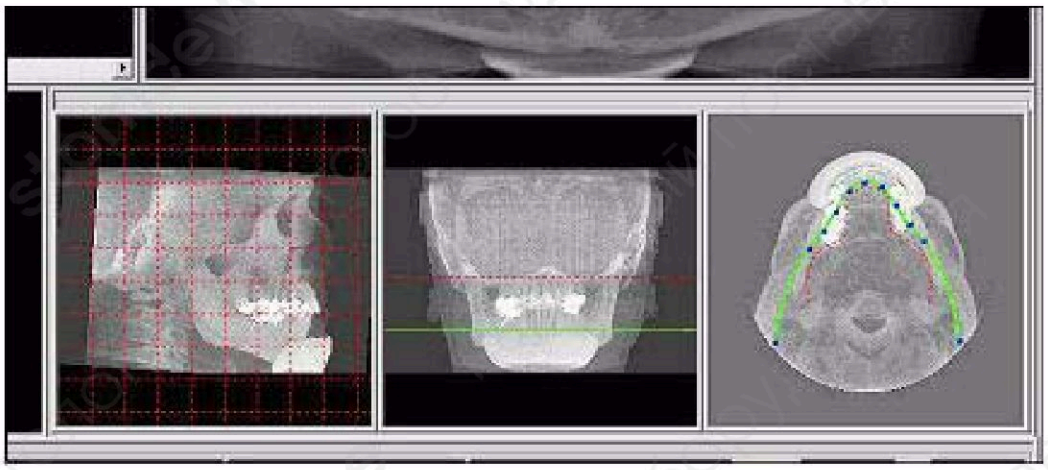
1. Hover the cursor over the lower right corner of the desired view. The cursor changes to the rotation tool.



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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.

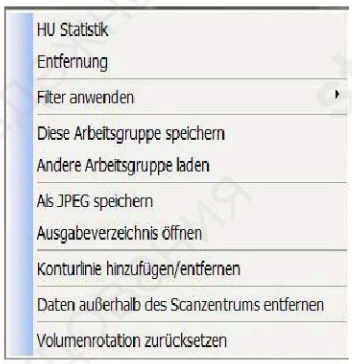


3. After the selected image is rotated, release the mouse. The grid is no longer present.

To complete the rotation of the entire data set:

4. Right click the image and select **Rotate Volume now**.

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



To return to the original rotation orientation:

5. Right click the image and select **Reset Volume Rotation**.

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

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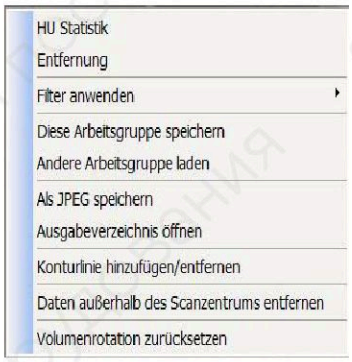
Saving Views as JPEG Image Files

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

To save view as a JPEG Image File:

1. Right click the 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 opening the directory in which the image was saved:

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

   Microsoft Internet Explorer opens to the selected directory.

Saving and Loading Workups

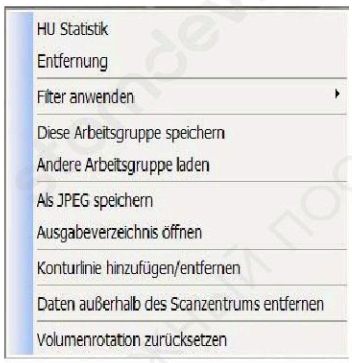
Once Patient data is acquired, it is reconstructed. Reconstruction allows you to make various modifications and markups (measurements, etc.) to the displayed information. Details can also be viewed and modified (see *Detail Screens*.

The modifications you make to reconstructed Patient data can be saved as a *Workup* (also referred to as a *Case Study*). This allows you to retrieve previously modified data as desired.

Save a Workup

To save the currently displayed data as a workup:

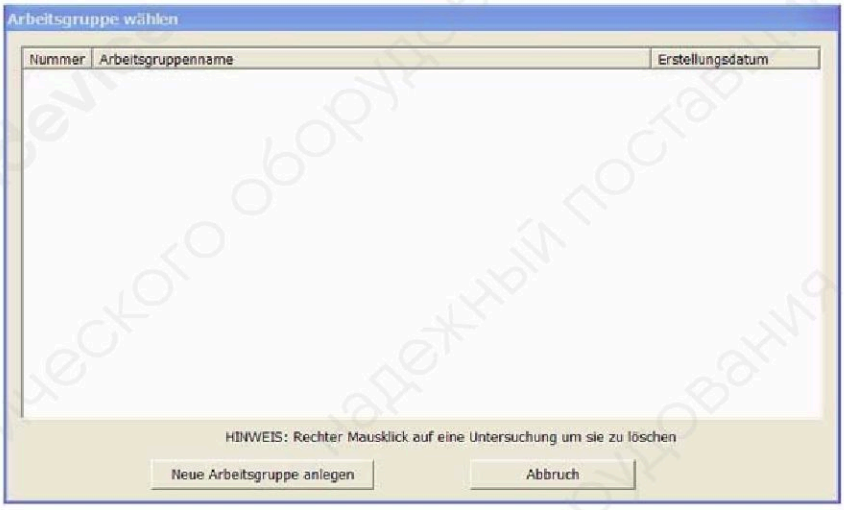
1. Right-click any image on the Preview screen and select **Save This Workup**.



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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.

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If you made or changed a workup and attempt to close the iCATVision software or switch to a different Patient, the following dialog box appears.



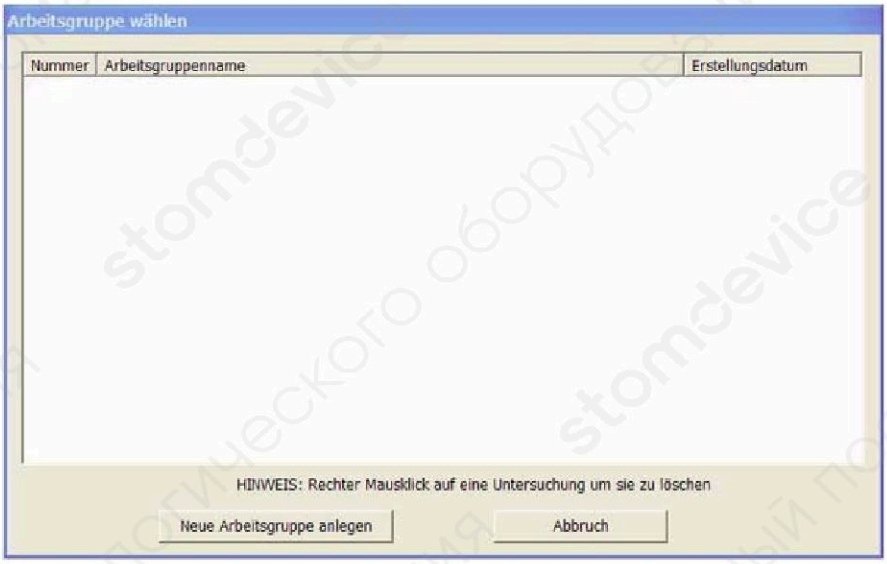
To save the changes made, click **Yes**. The Select a Workup dialog box appears. Continue the save procedure as described above.

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.

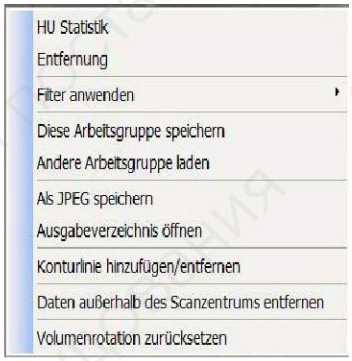
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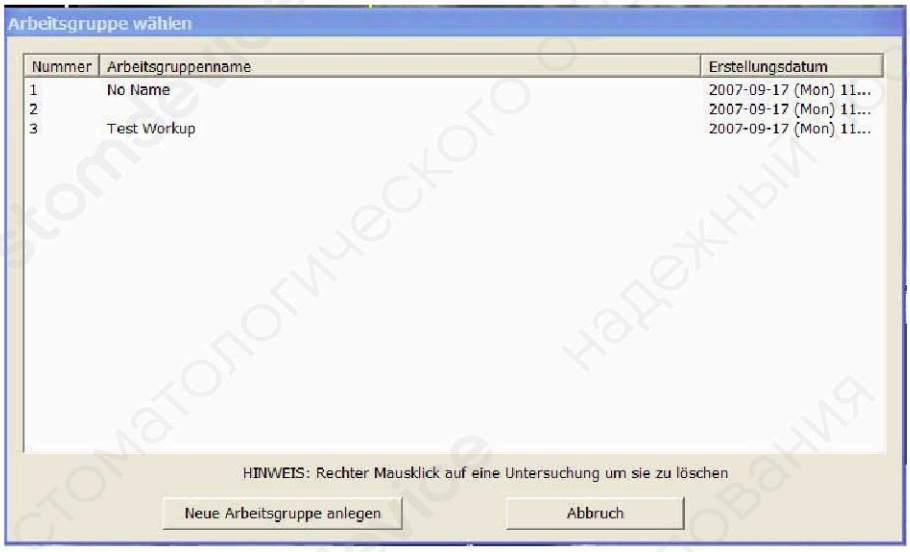
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Delete an Existing Workup

To delete an existing workup:

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





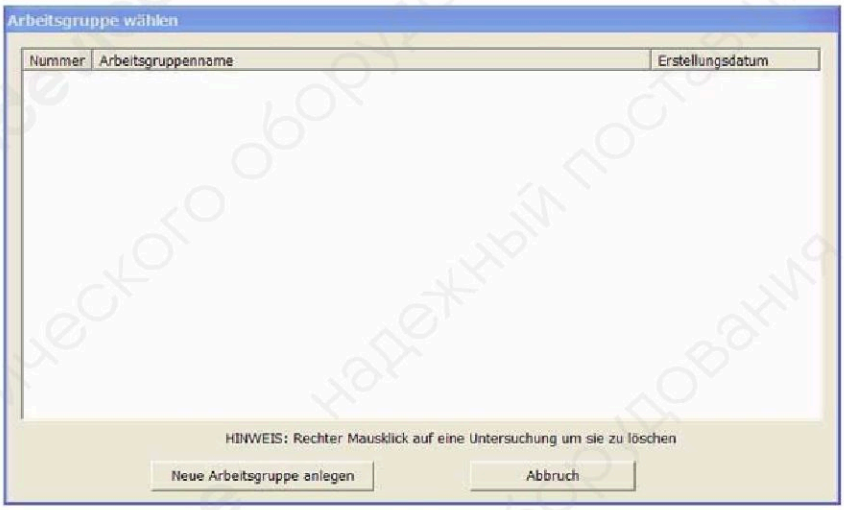
2. Right-click the Workup to delete.



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3. Click **Yes**. The dialog box closes and the selected Workup is deleted.



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

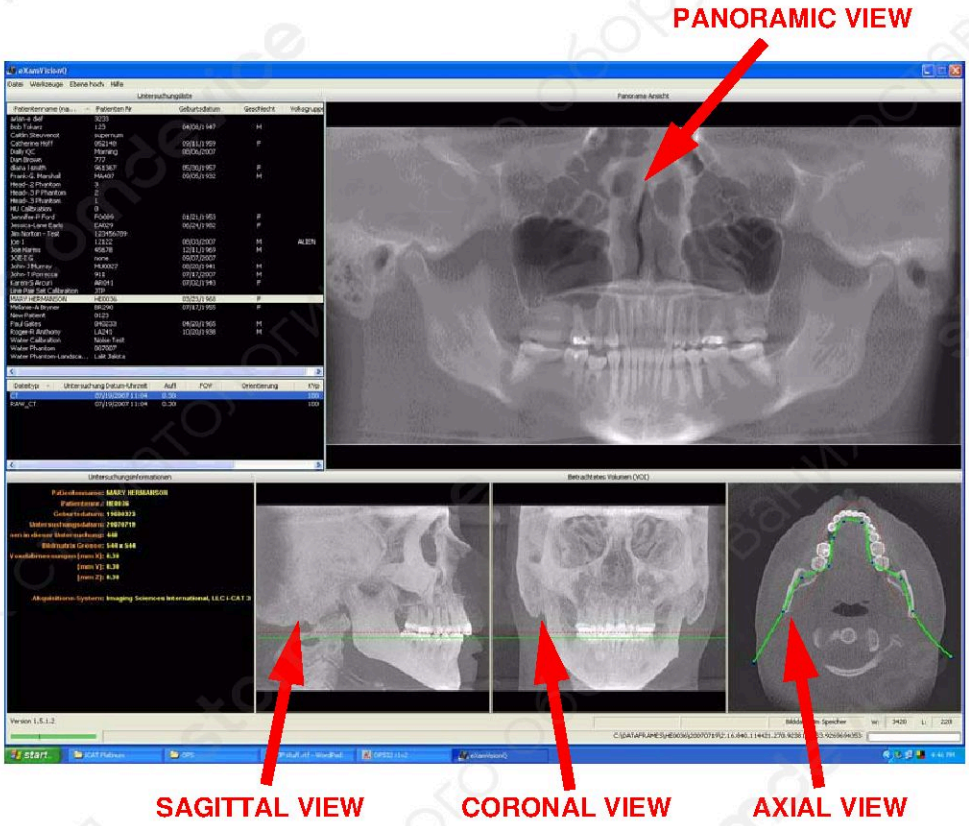
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Chapter 8 Detail Screens

Preview Screen

All Detail Screens are accessed via double-clicking a corresponding view on the Preview Screen.



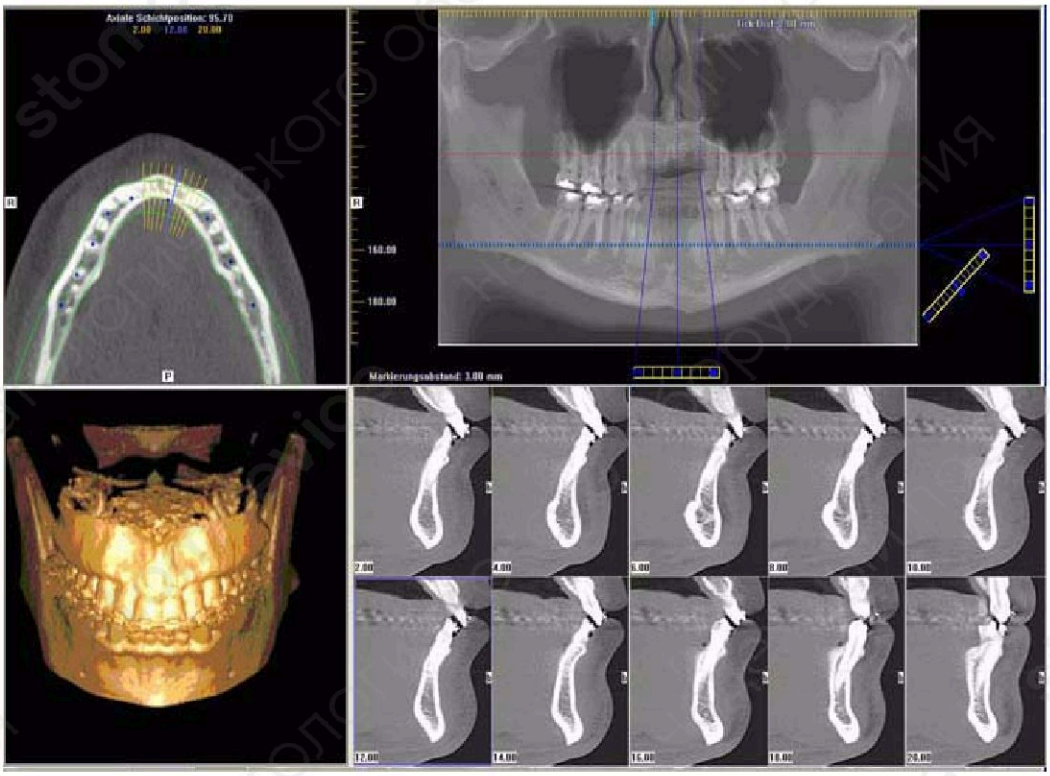
- **Panoramic View -** double-click displays the Implant Planning Screen.
- **Sagittal View -** double-click displays the Ortho (Ceph) Screen.
- **Coronal View -** double-click displays the MPR Screen.
- **Axial View -** double-click displays the TMJ Screen.

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Implant Planning Screen

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



The Implant Panning Screen is divided into four main viewing areas:

- **Axial Slice Position View (upper left)** used to adjust the panoramic map view (upper right).
- **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.
- **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.

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

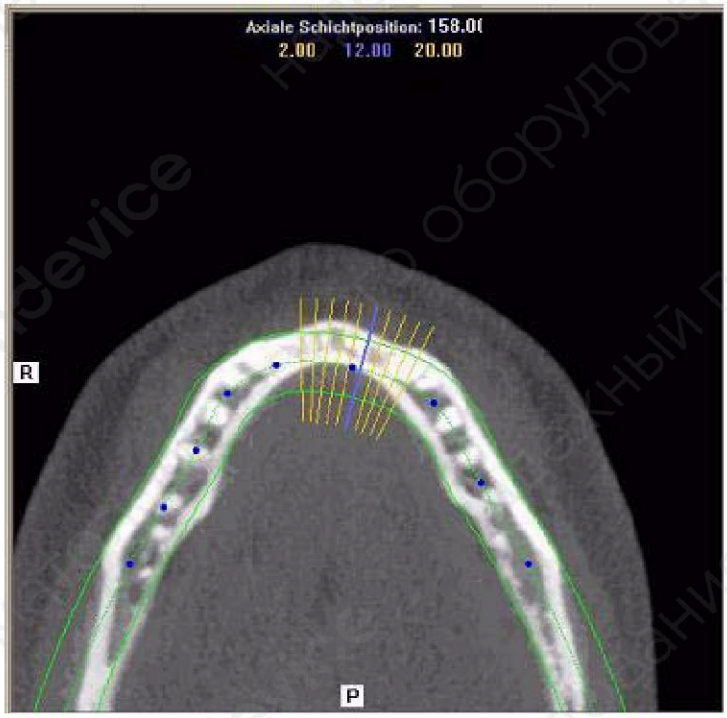
R = Right Side

P = Posterior

B = buccal

To use the Implant Panning Screen:

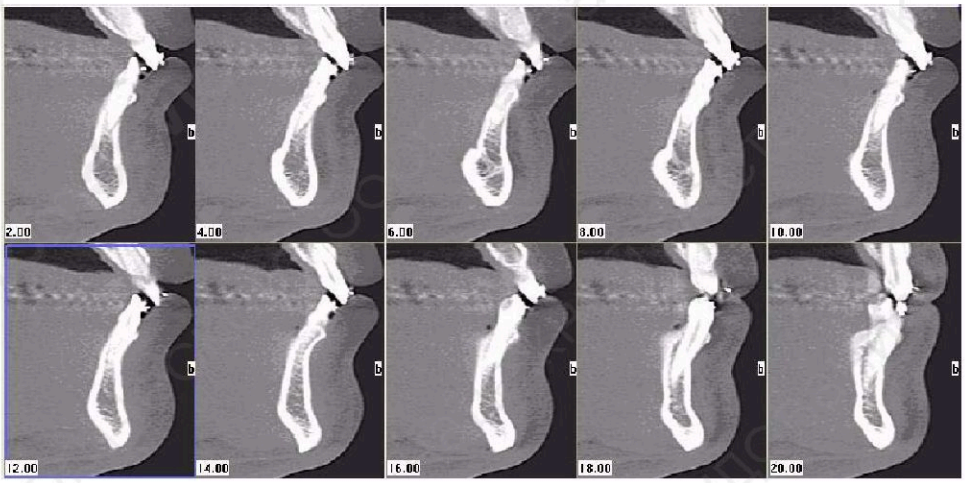
1. Click and drag the blue dots on the axial slice position view to adjust the image displayed on the panoramic map view.



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.

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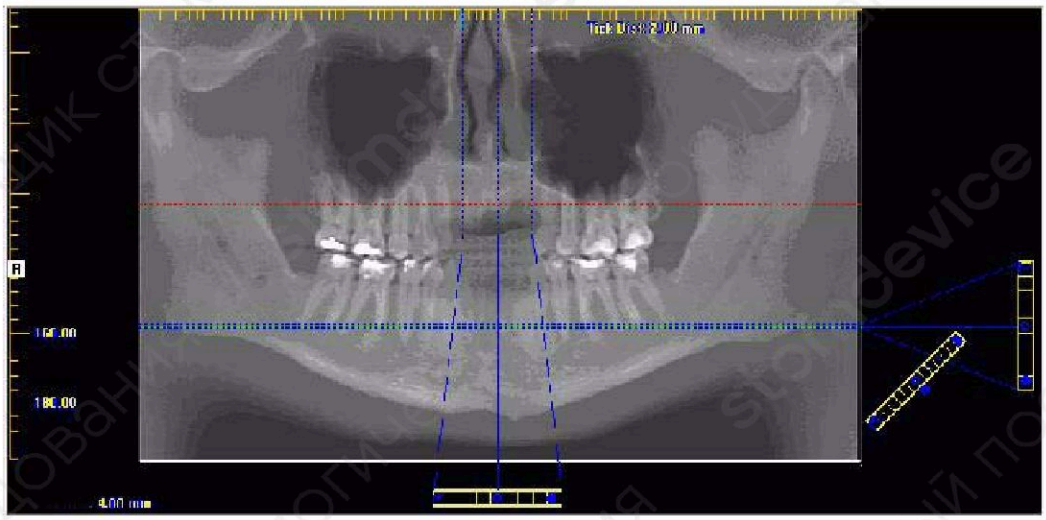
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The cross section views are located as indicated by the hash marks displayed in the axial slice position view. If the 0.00 position is displayed, it is outlined in red. All slices to the patient's right side are displayed as negative numbers. All slices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

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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.

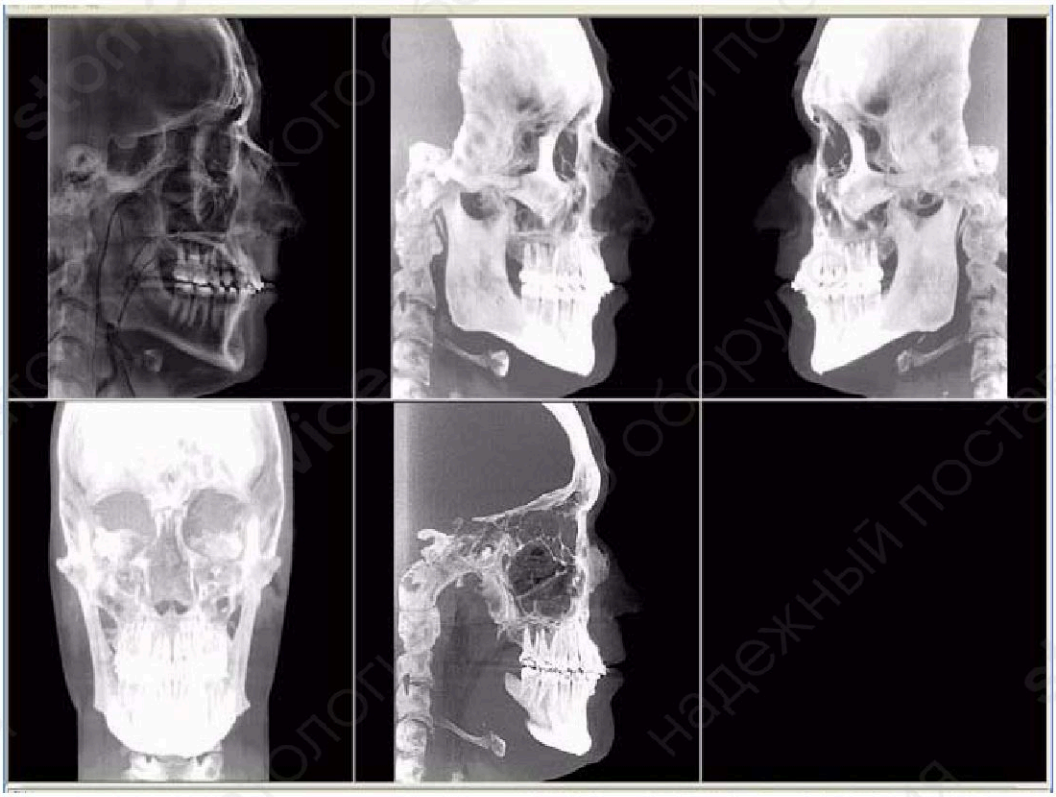


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Ortho Screen

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



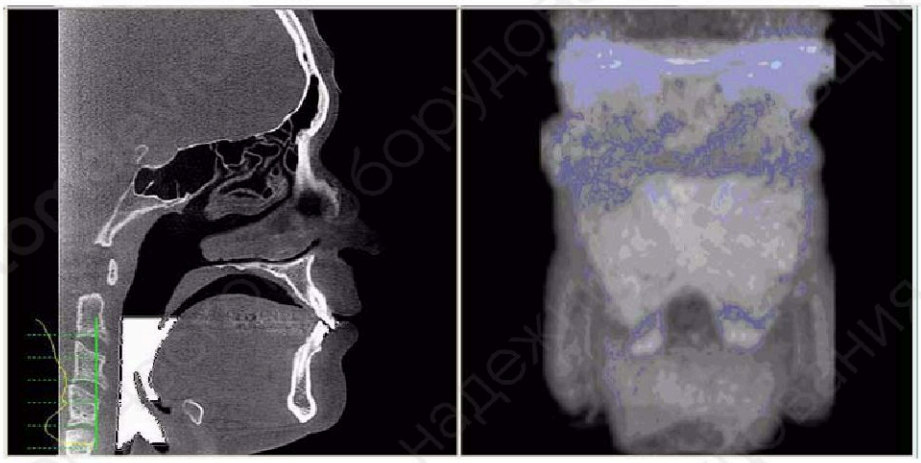
The Ortho screen displays the Lateral Cephs in Radiographic and MIP mode as well as a Coronal View in MIP mode, all at the thickness of the volume. The last image is a Mid Sagittal Slice at 20mm thick.

Right-clicking the blank view at the bottom right of the Ortho 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 displayed in the view at the bottom center of the Ortho screen.

The graph is a vertical x/y plot. The vertical axis is the slice position, and the curve itself shows the open airway volume at the slice locations of the vertical extent axis. The further the curve extends to the left the larger the air slice volume. If the curve has a kink to the right or extends close to the vertical base line, that would indicate an airway restriction.

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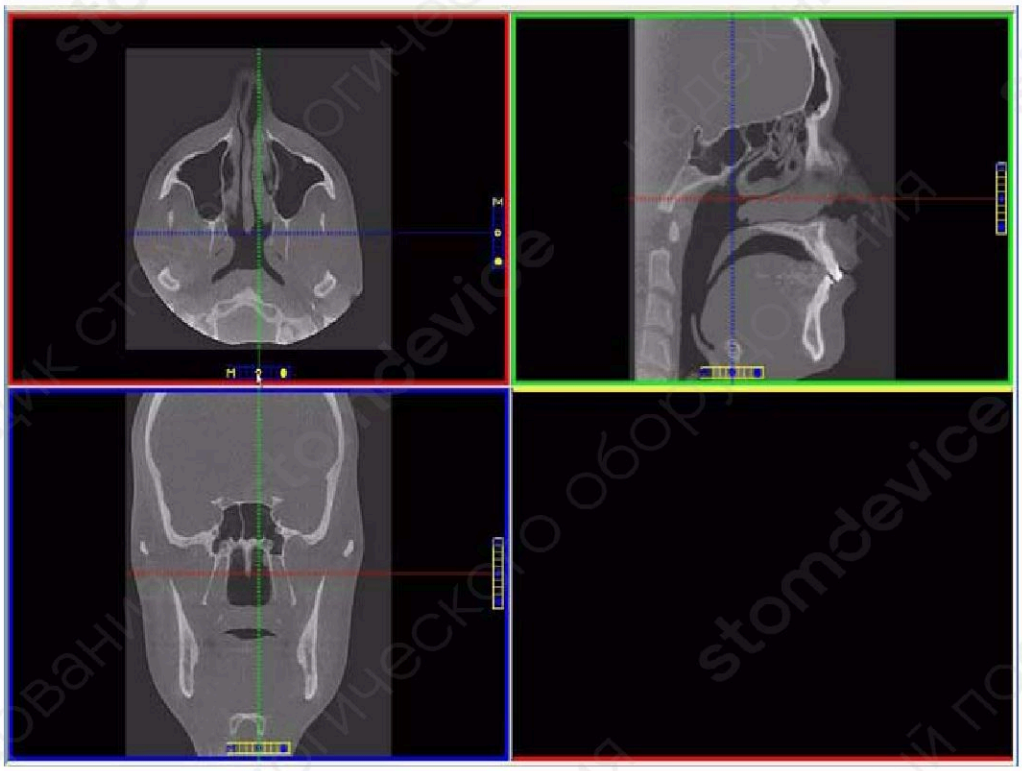
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To remove the airway information from the View, right click the airway view and select **Untag Airways**.

MPR Screen

Double-click Coronal View on Preview Screen displays MPR Screen.



The MPR Screen allows you to scroll 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.

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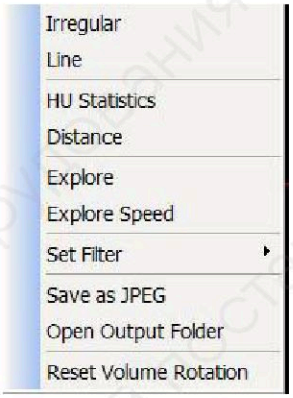
To use the MPR Screen:

1. Drag center (**O**) tools from any view to move the slice location. The views are colored coded to correlate to which view is adjusted by which tools.
2. Drag the solid circle tool (to the right for horizontal toolbars; on the bottom for vertical toolbars) to adjust the slice thickness of the corresponding color coded view.

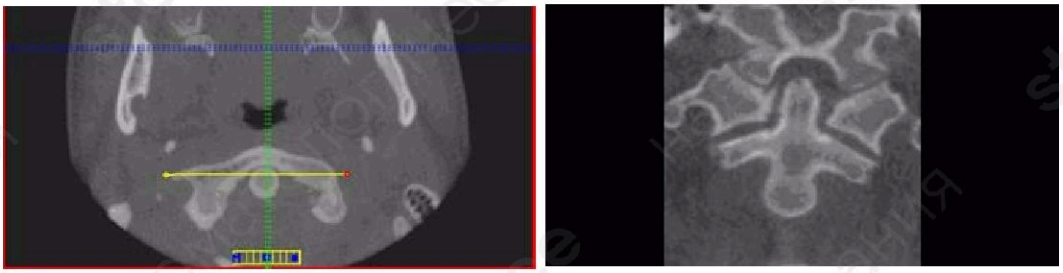
To view the result of a linear slice:

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.



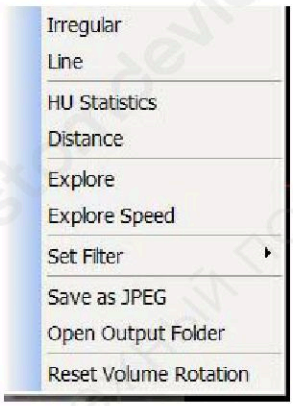
The resulting slice is displayed (lower right of the MPR Screen.)

3. To reposition the line, drag the end points 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**.

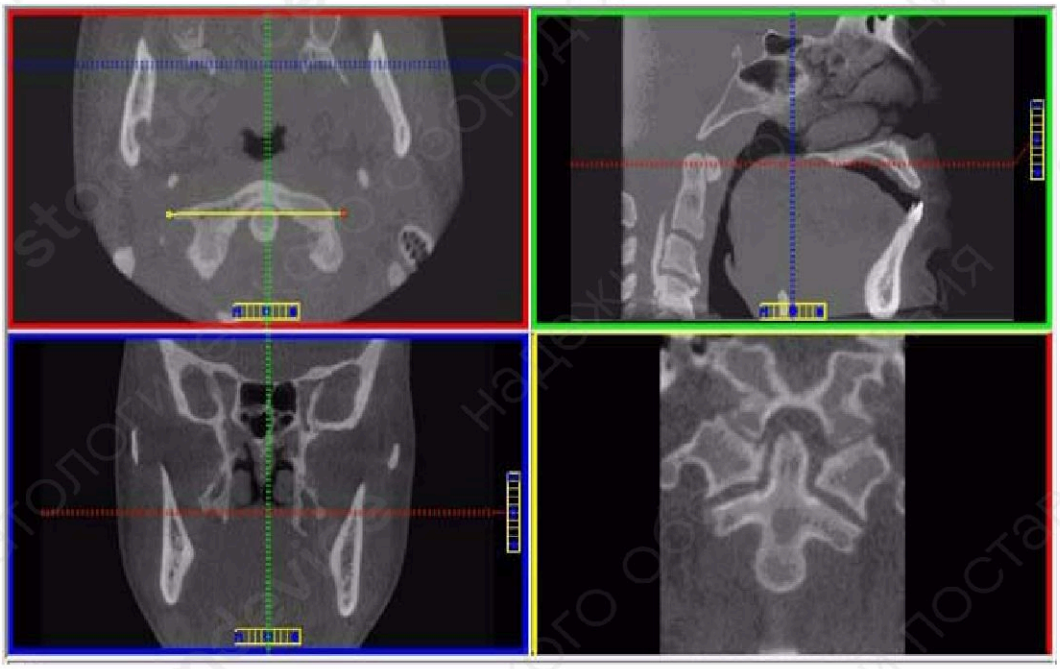
   A pointer cursor is displayed.



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2. Drag to position the linear slice as desired.



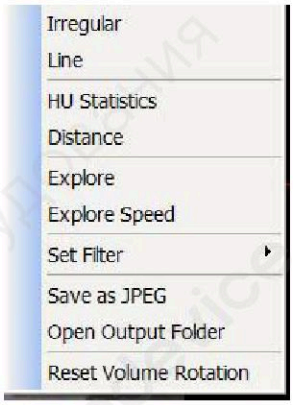
The resulting slice is displayed in the view at the lower right of the MPR Screen.

3. To reposition the line, drag the end points 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**.

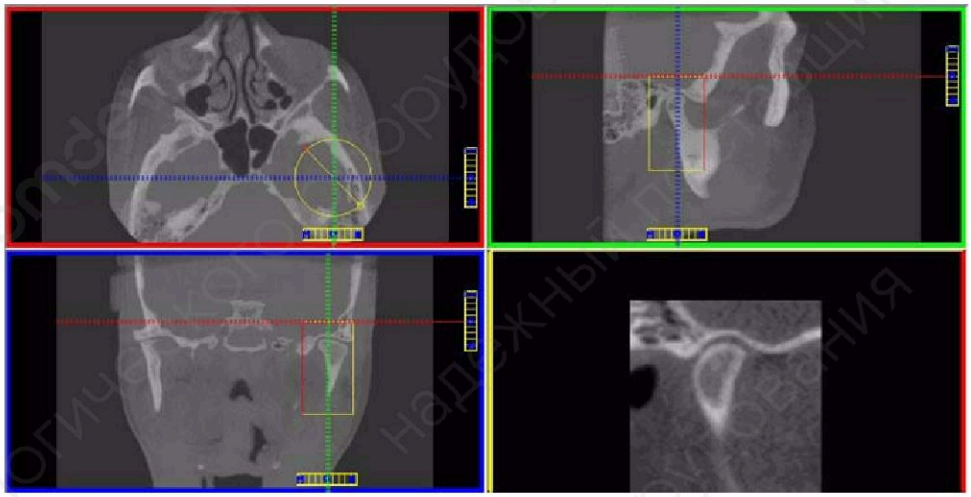
   A pointer cursor is displayed.



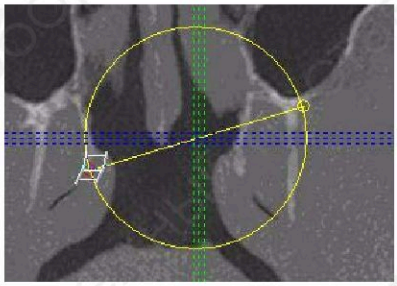
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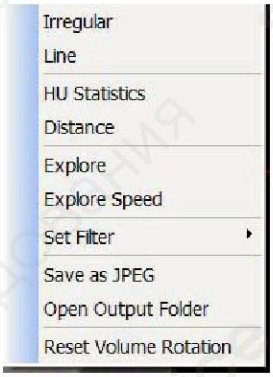
5. Drag to position the cut planes slice as desired.



Cursor changes to a film icon.



6. Right-click image. and select **Explore Speed**



7. Enter desired animation speed in *Movie Playback Speed* field.



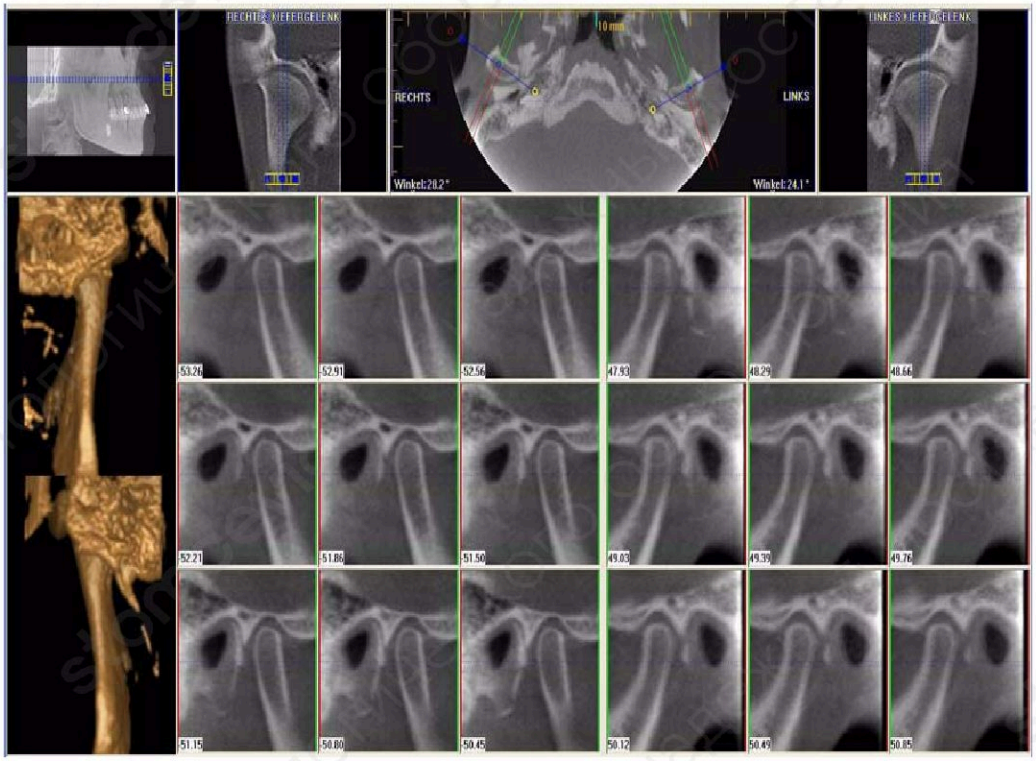
8. Click **OK**.
9. Click film icon. The animation plays in the lower right view on MPR Screen.

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TMJ Screen

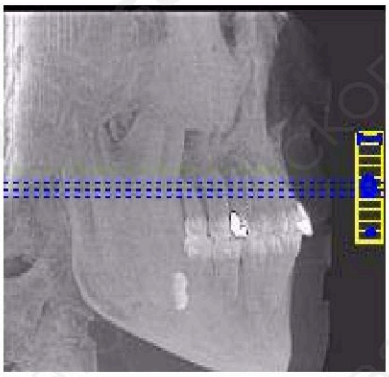
Double-click Axial View on Preview Screen displays TMJ Screen.

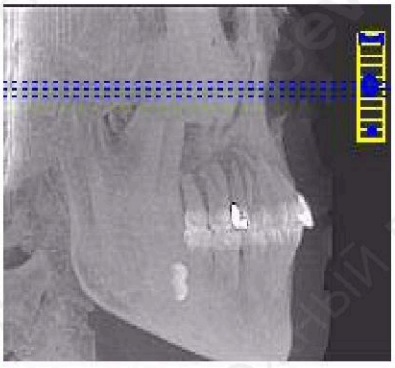


TMJ Screen enables condyle mapping and creating corresponding coronal slice views.

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 so they can be properly mapped.

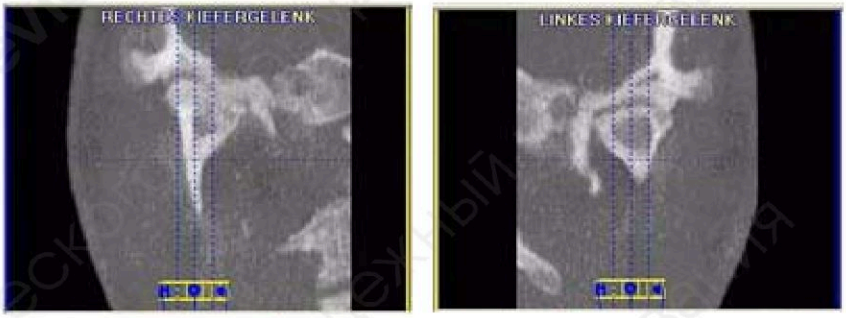




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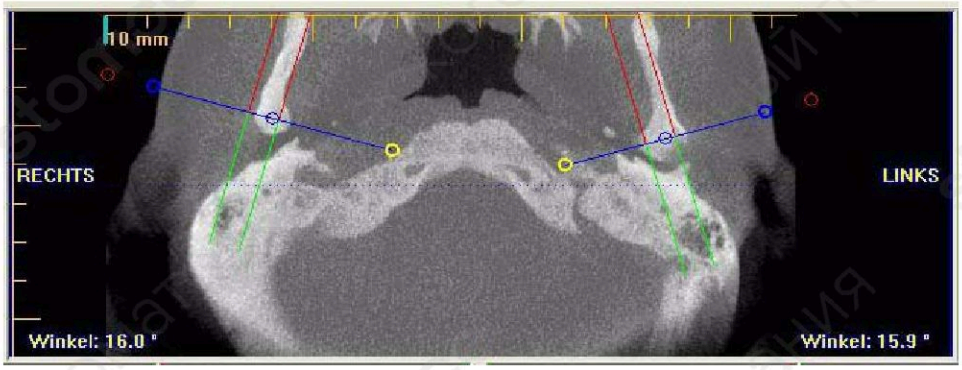
3. Drag center (**O**) tools from the RIGHT and/or LEFT CONDYLE WINDOWS to move the slice locations of the cross section views.



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

To create lateral slices:

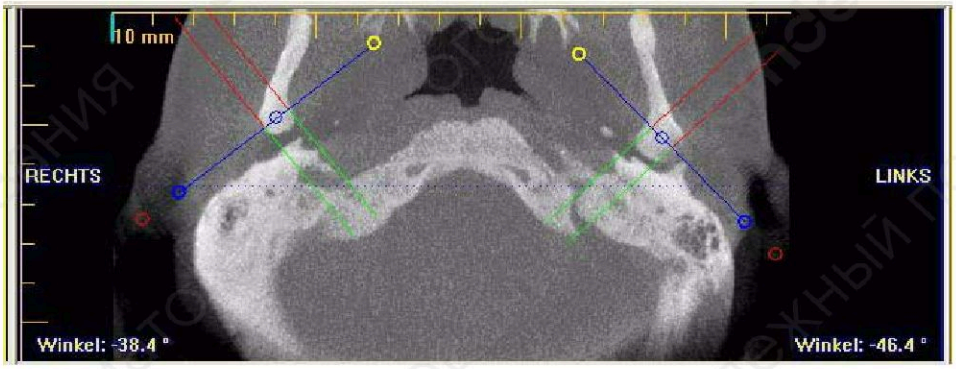
5. Drag the center blue circles on the Axial View to move the corresponding Condyle Map.



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 on either end map.



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Chapter 9 Tools

DICOM Database and DICOM Export Setup

The next procedure describes how Patient Data is converted into DICOM images. This procedure is used to determine 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.
- **Export DICOM Destination Folder –** this path selection determines where the DICOM images are to reside when executing the ***Export DICOM*** procedure.

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2. Click **Browse** for both fields.



3. Choose a path for the *DICOM Database Root Folder* and the *Export DICOM Destination Folder*.

   If required, click **Make New Folder**.

4. Click **OK**.

DICOM Import Controls

This feature is not presently used.

Check Read/Write Access to Image Database

This function tests the ability of iCATVision to read/write to the image root folder. iCATVision 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.

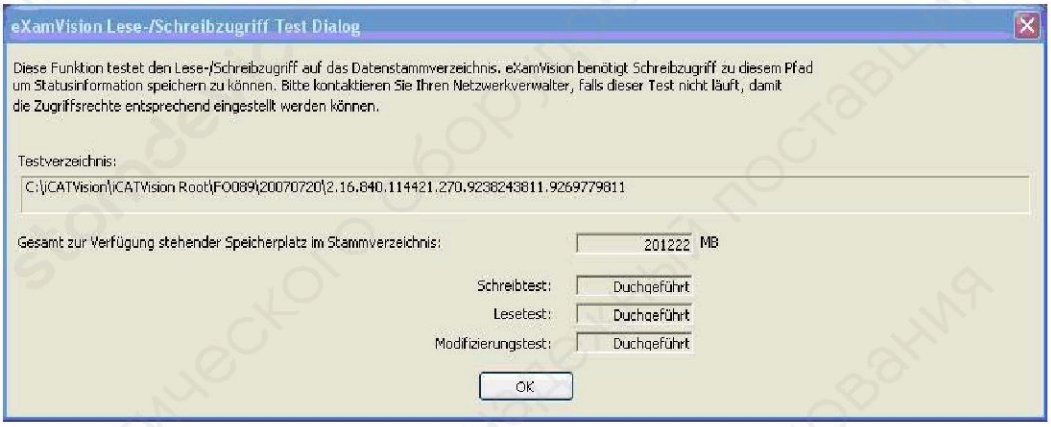
Please consult with your Network Administrator if this test indicates a failure.

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

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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 Patient List. Allow time for the Patient Image to load.
2. From the Main menu, select **Tools > Export DICOM**.



3. Select desired Output Selections.
   - **Single File DICOM -** one large image file (recommended)

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- **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)
- **Delete previous folder content -** the new files are stored to the folder, replacing old files.
- The *Destination* field was setup at the start of this section.

4. 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**.



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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)

2. Click **Create CD**.
3. A confirmation window is displayed when CD is complete.

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**.

   An option menu is displayed.



- **Full Erase –** Not used
- **Quick Erase –** all files are erased

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.

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3. Choose a path for the *Export DICOM 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 > Reporting** to display the following three report options:

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

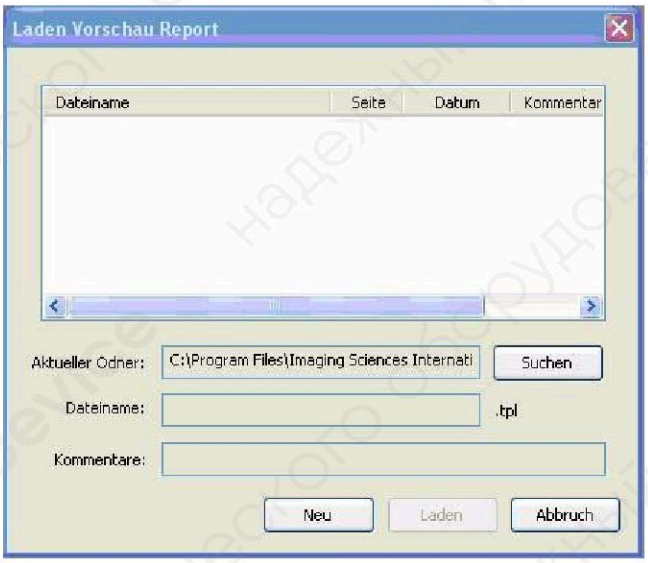
Run Report

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

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1. Click (highlight) a patient from the Patient List. Allow time for the Patient Image to load.
2. From the Main menu, select **Tools > Reporting**.
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 Patient List. Allow time for the Patient Image to load.
2. From the Main menu, select **Tools > Reporting**.
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.

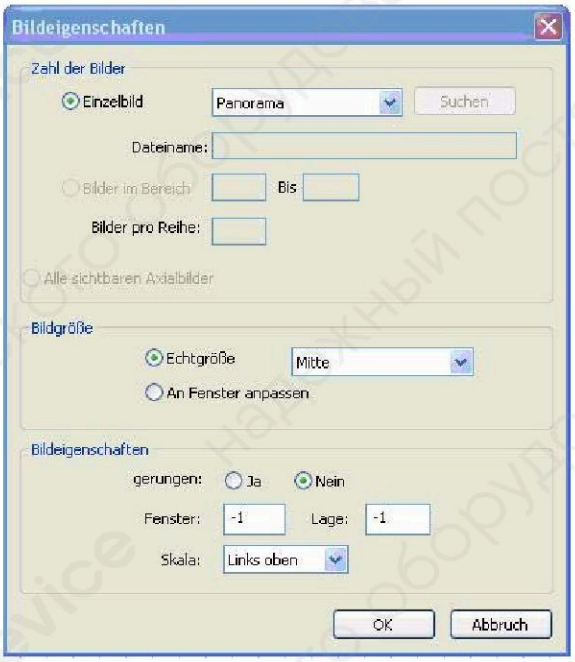
Insert Image into Patient Report:

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

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

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

Number of Images

- **Single Images** – used to select images within iCATVision or from a file (select FILE)
- **Images in Range** – used to select specific cross sections within iCATVision
- **All Screen Images** – 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 you to specify 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 iCATVision are displayed
- **Window** and **Level** – adjusts the brightness and contrast
- **Ruler** – designates where the ruler appears on the image

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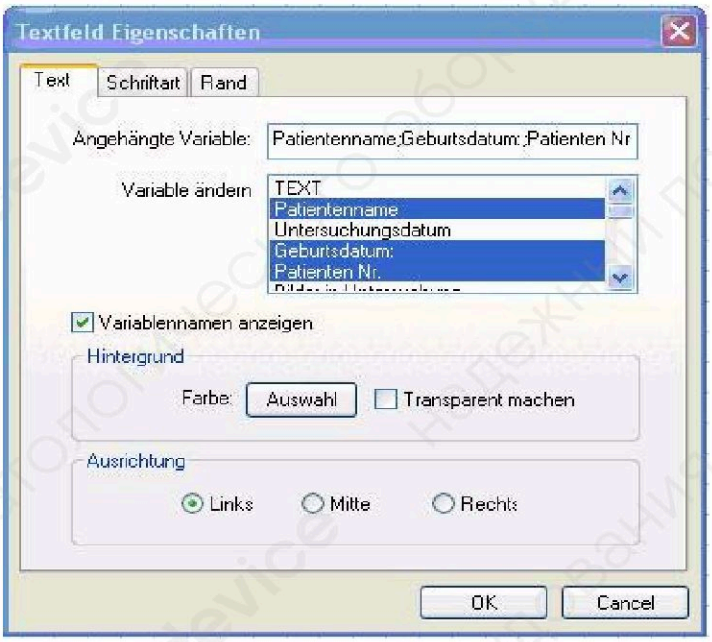
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The Image Properties box can be displayed at any time by right-clicking inside the image box and selecting **Properties**.

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.

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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**.



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16. 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 > Reporting**.
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.

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Chapter 10 Calibration and Quality Assurance

The Panel 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 runs in both Portrait and Landscape positions. The entire calibration takes about 8 to 10 minutes to complete. The process runs 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

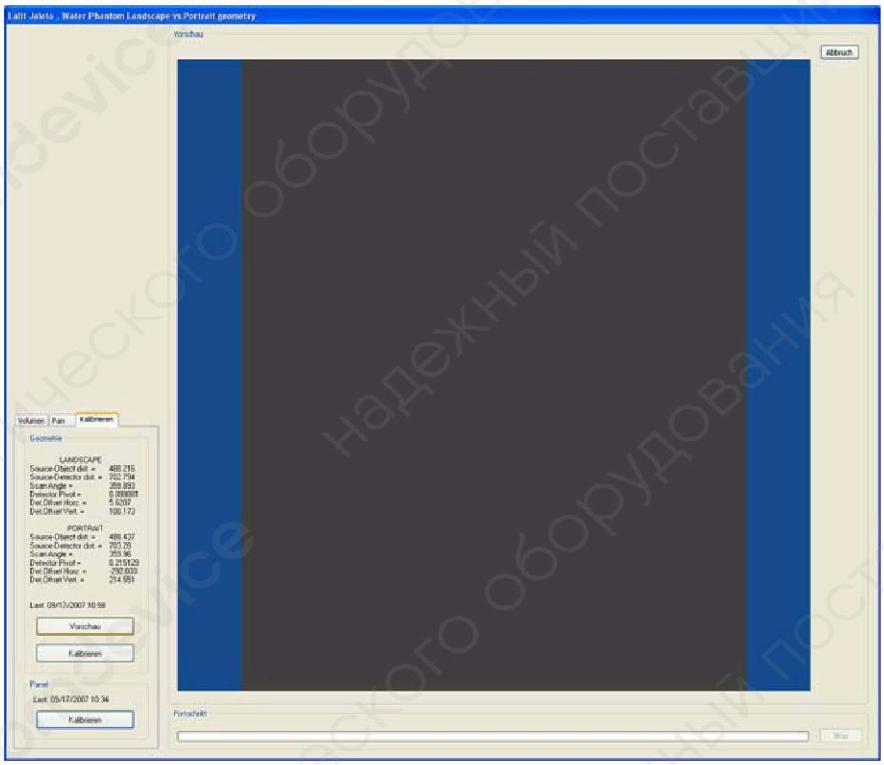
To run the Panel Calibration:

1. Ensure room temperature is in the range of 50 to 95°F (10 to 35°C).
2. From the Main menu select **File > New Patient**.
3. From the Patient Information Panel, click **Add** or open (double click) an existing *Panel Calibration* scan.

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4. Click **OK** to close Patient Information box.



5. Click the **Calibration** tab.
6. Click the *Panel* **Calibration** button (bottom button).

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



7. Click **OK**.
8. The Panel Calibration runs for about 10 minutes. The progress of the scan is displayed on the *Progress* bar at the bottom of the Acquire window.

   "Panel Calibration is complete" is displayed when the process is finished.

9. Click **OK**.
10. If you are running the Geometry Calibration next, then do not close the Calibration screen when the Panel Calibration is completed.

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Geometry Calibration

The Panel Calibration must be performed prior to running the Geometry Calibration. It is recommended to run the Geometry Calibration once a year or if image quality becomes degraded. The Geometry Calibration also runs in both Portrait and Landscape positions and takes about 12 to 15 minutes to complete.

11. Perform the Panel Calibration (procedure listed above).
12. Mount the Phantom Platform (shown below).
13. Ensure that the BB Phantom is level.
14. Center the BB Phantom on the platform using the alignment holes on the platform and bottom of phantom.



15. Align the BB Phantom crosshair slits with the laser cross beams. For an accurate alignment, the laser beams should penetrate though the phantom crosshairs and appear on the receptor panel.
16. From the Calibration menu (already displayed from the Panel Calibration) click the **Preview** button.
17. The settings screen is displayed, click **OK**.

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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.

    To move the phantom to the right or left on the Preview screen, use the **Back / Front** feature on the Volume tab and then return to the Calibration tab.



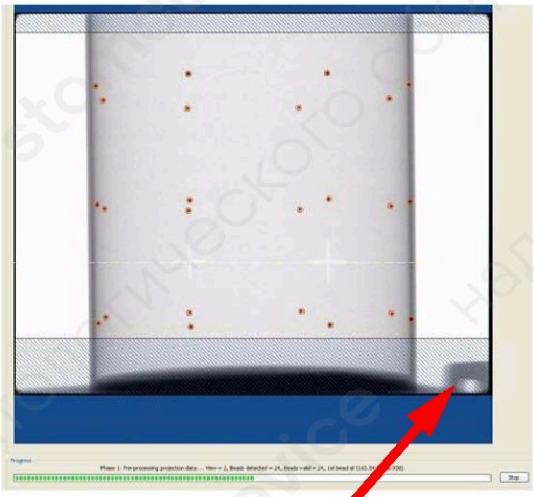
20. When BB Phantom is centered and level, click **Calibrate** from the Geometry Calibration window.
21. Click **OK** to start the X-ray exposure.

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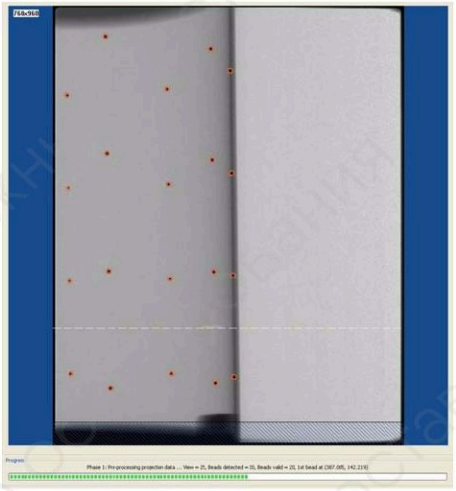
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22. The Geometry Calibration scans both Landscape and Portrait Modes.

LANDSCAPE SCAN



PORTRAIT SCAN



Metal Platform Support (below FOV)

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

23. Calibration progress is displayed on the bottom of screen. Ensure that all beads are detected and valid in both scans. Data is displayed above the green progress bar, ensure the following:
    - **Landscape Scan -** 24 Beads detected, 24 Beads valid
    - **Portrait Scan -** 20 Beads detected, at least 16 Beads valid
24. Click **OK** when the calibration completes.

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

25. Restart iCATVision software. This completes the Geometry Calibration.

CAUTION

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

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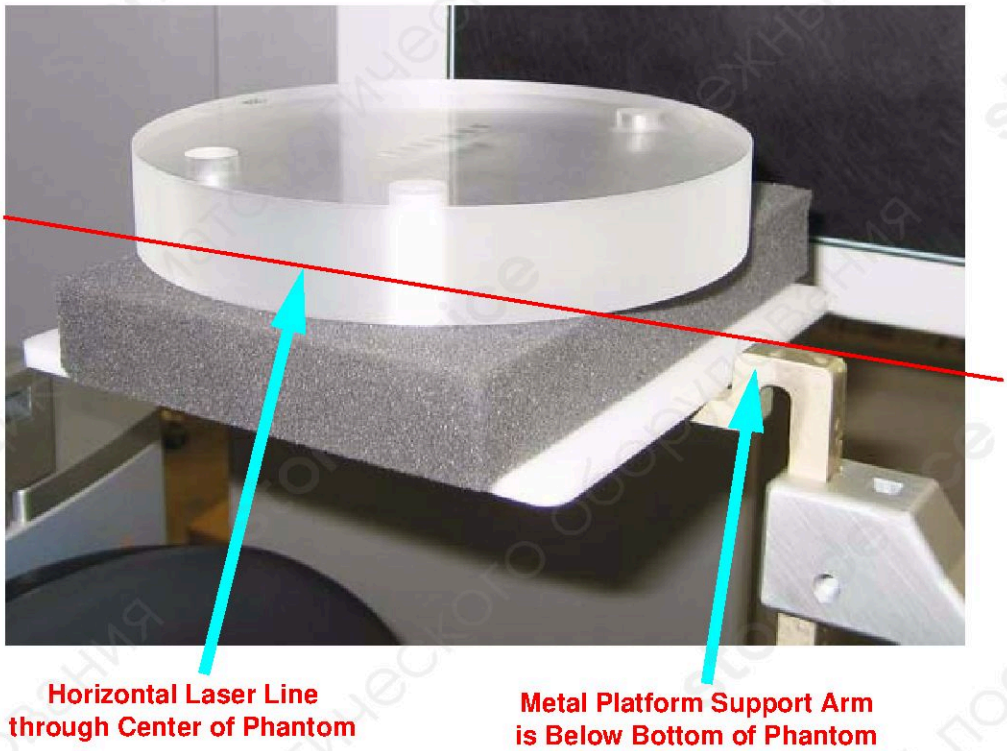
QA Phantom Test

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 elevated it above the Metal Platform Support Arm, as shown below.
3. Use the alignment lasers to adjust the Phantom Platform height.

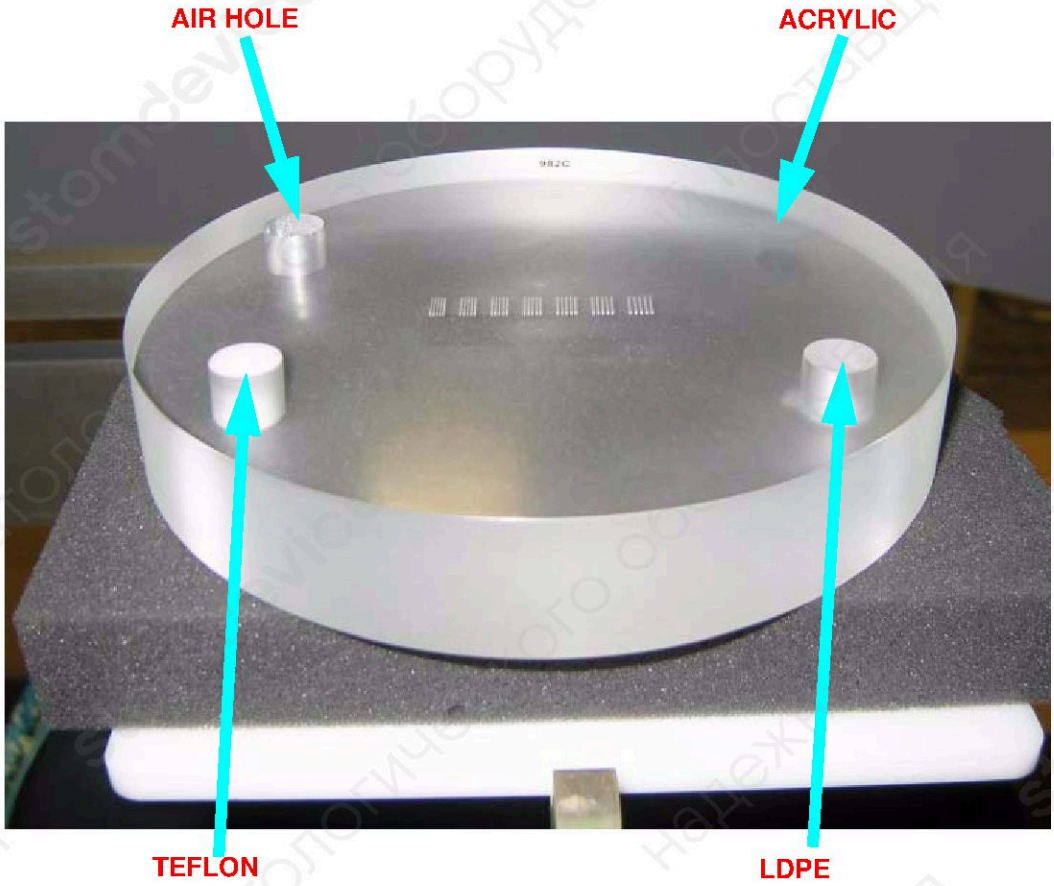
   Adjust the height so that the Axial Laser is positioned at the center of the QA Phantom.



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



5. Start the test by selecting **File > New Patient** from the Main menu.
6. From the Patient Information Panel, click **Add** or right click an existing image from database and select **Acquire Now**.

   If adding a new patient, enter **QA Test** in the *First Name* field and **Line Pair** in the *Patient ID* field.
7. Click **OK** to close the Patient Information box.
8. From the Volume tab in the Acquisition window, select the following:

   Exposure: **Large**

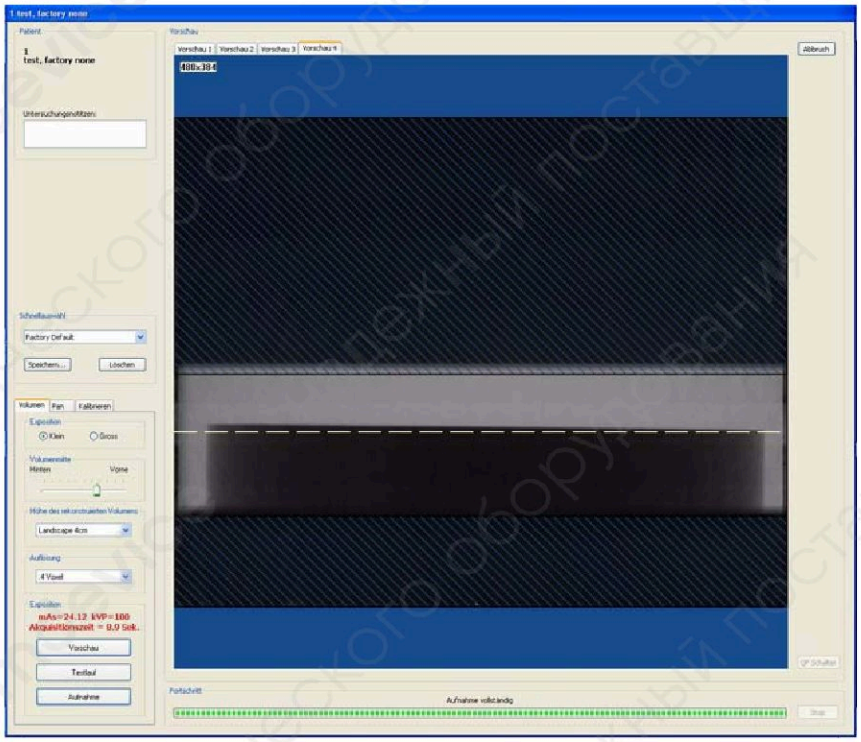
   Height of Reconstruction Volume: **Landscape 6cm**

   Resolution: **.2 voxel**
9. Click **Preview** to check the phantom position.
10. Click **OK** on the settings screen.

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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.



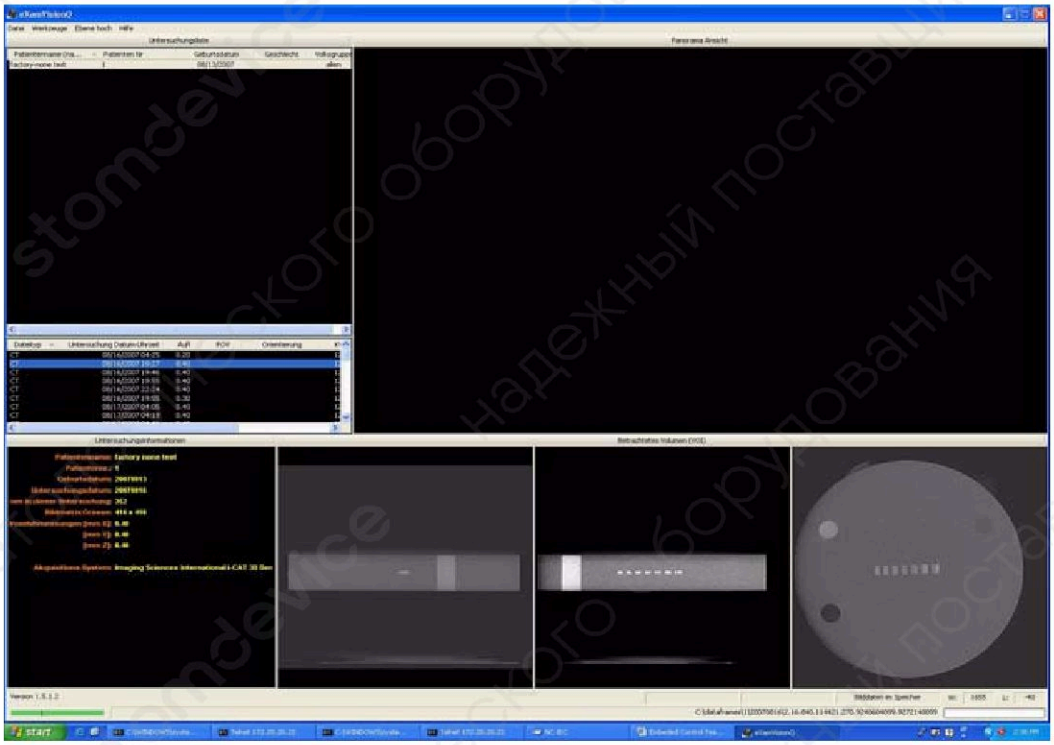
If required, make adjustments and click **Preview** again. Repeat as required.

14. Click **Capture** to start the scan process.
15. When the scan is completed, select **NO** when prompted to automatically detect arches.
16. Select **Cancel** at the *Contourline Setup* prompt.

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17. The following preview screen is displayed.

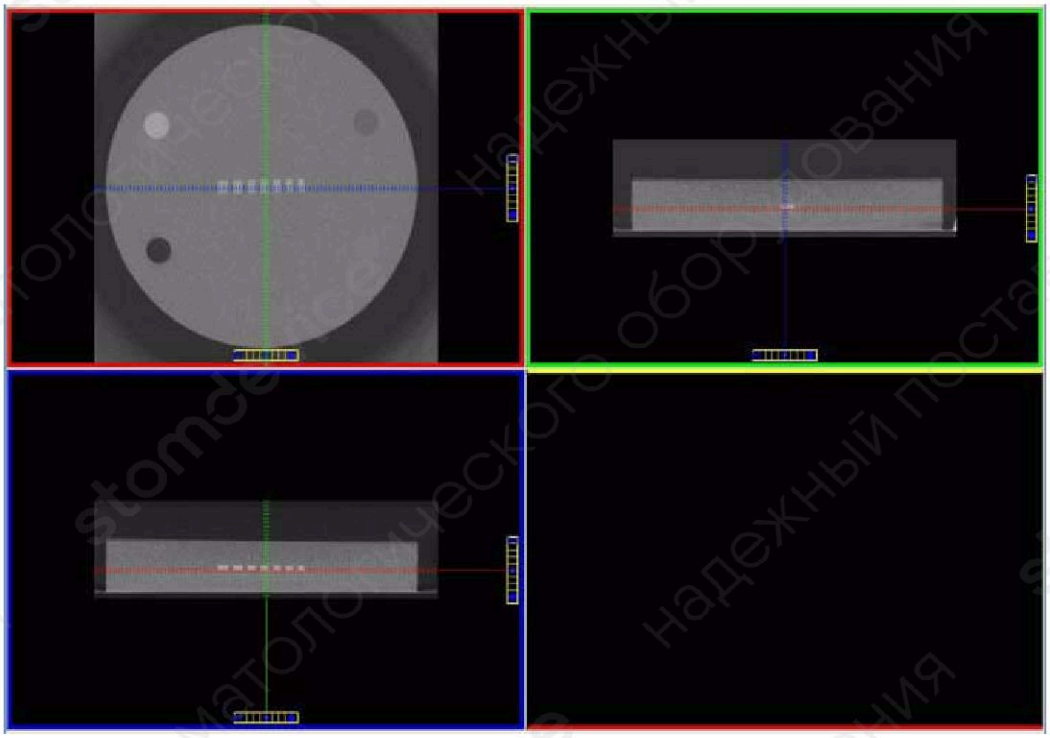


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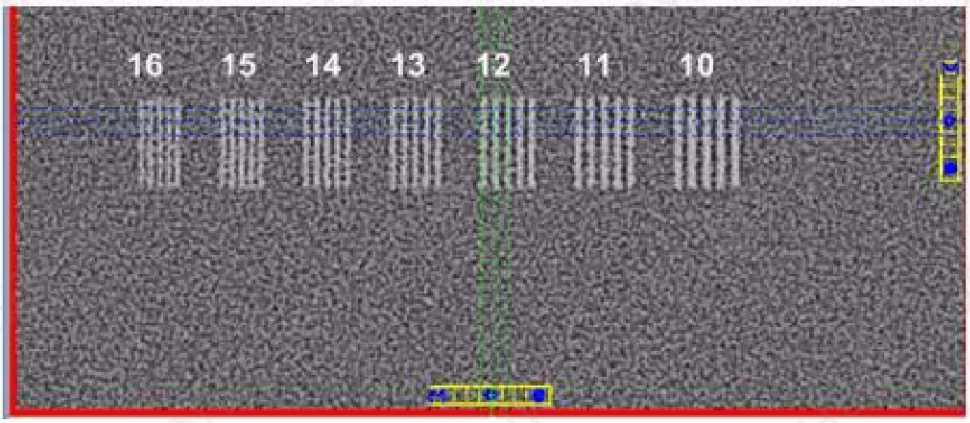
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Line Pair Evaluation

18. Access the QA Test images for evaluation by double clicking **Coronal View**. (bottom image, 3rd from the left).
19. 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.



20. Zoom Line Pair image (upper left). To zoom, start at the upper right corner of the image and drag the cursor across the image.



21. Right click the image and select **Set Filter > Hard**.

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22. Adjust Brightness and Contrast level for the best image quality. Evaluate the image.

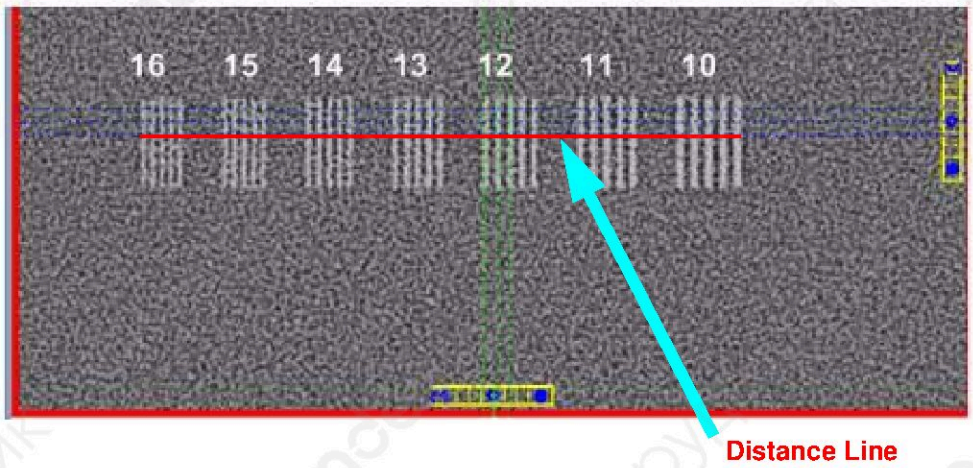
    Line Pair - Line Pairs consists of a resolution of 10 lines per cm (5 dark wish 5 light). Line Pairs 10 through 16 are displayed in image (shown above).

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

23. Verify that definition is present within line pairs 10, 11, and 12. Compare your 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.



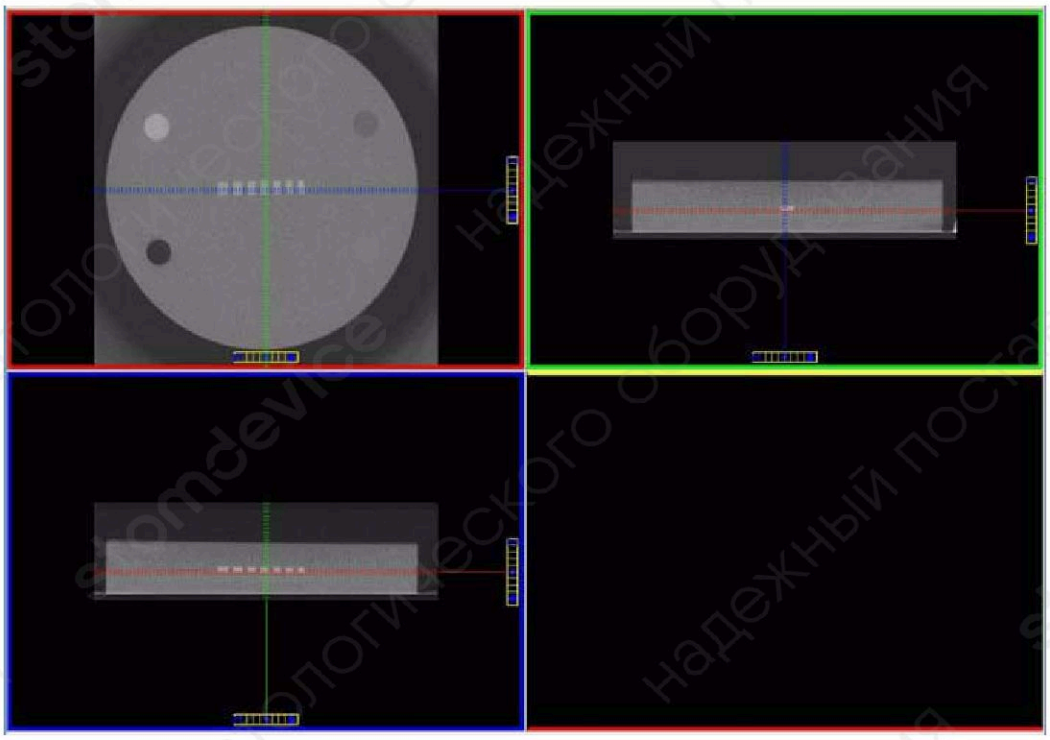
24. Right click view and select **Distance**.
25. Drag the Distance cursor to draw a line from the outside line of set 16 to the outside line of set 10, as shown above.
26. The measurement (displayed in upper corner of image) should be between 41 and 42 mm.
27. Call Service, if the measured value is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

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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.



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

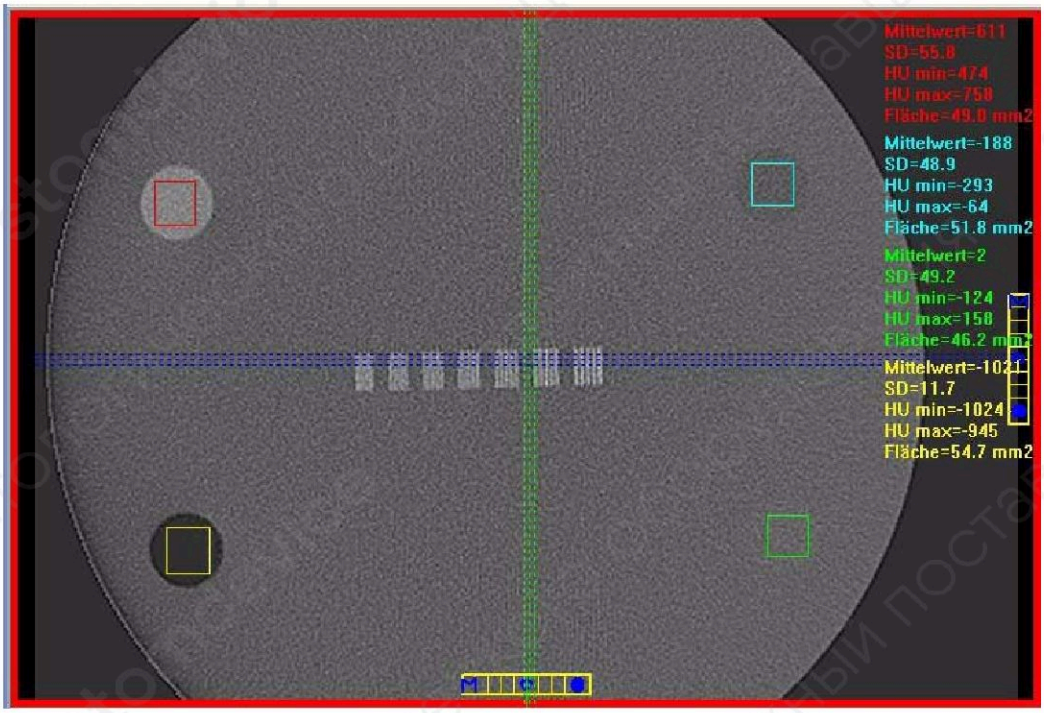
    c. At the bottom of the scale, click and hold the cursor on the ● symbol. The slice thickness is displayed.

    Sliding the cursor up and down changes the value. The minimum value is 0.2 mm in this case, which is selected on this slice.

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



29. Right click the image and select **HU Statistics** from the menu.
30. Area of ROIs should be at least 40mm^2 but less than 46mm^2.

    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.**
31. Note and record the Hounsfield value of each material. See table below.

Material	Scanned Value (Hounsfield Units)	Lower Limit	Upper Limit
Air (Black) (lower left)		-1000	-800
Acrylic (Light Gray) (lower right)		10	85
LDPE (Dark Gray) (upper right)		-135	-50
Teflon (White) (upper left)		600	900

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

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

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QA Water Phantom Test

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

1. Remove Chin Cup and insert Phantom Platform.
2. Fill Phantom with water, approximately one inch from the top.
3. Carefully place Phantom on platform.
4. Using the Alignment Lasers such that the water bath is in the center of rotation and the horizontal laser line is located across the center of water depth.
5. Start test by selecting **File > New Patient** from the Main menu.
6. From the Patient Information Panel, click **Add** or right click an existing image from database and select **Acquire Now**.

   If adding a new patient, enter **Water Calibration** in the *First Name* field and **Noise Test** in the *Patient ID* field.
7. Click **OK** to close the Patient Information box.
8. From the Volume tab in the Acquisition window, select the following:

   Exposure: **Large**

   Height of Reconstruction Volume: **Landscape 13cm**

   Resolution: **.4 voxel**
9. Click **Preview** to check the phantom position.



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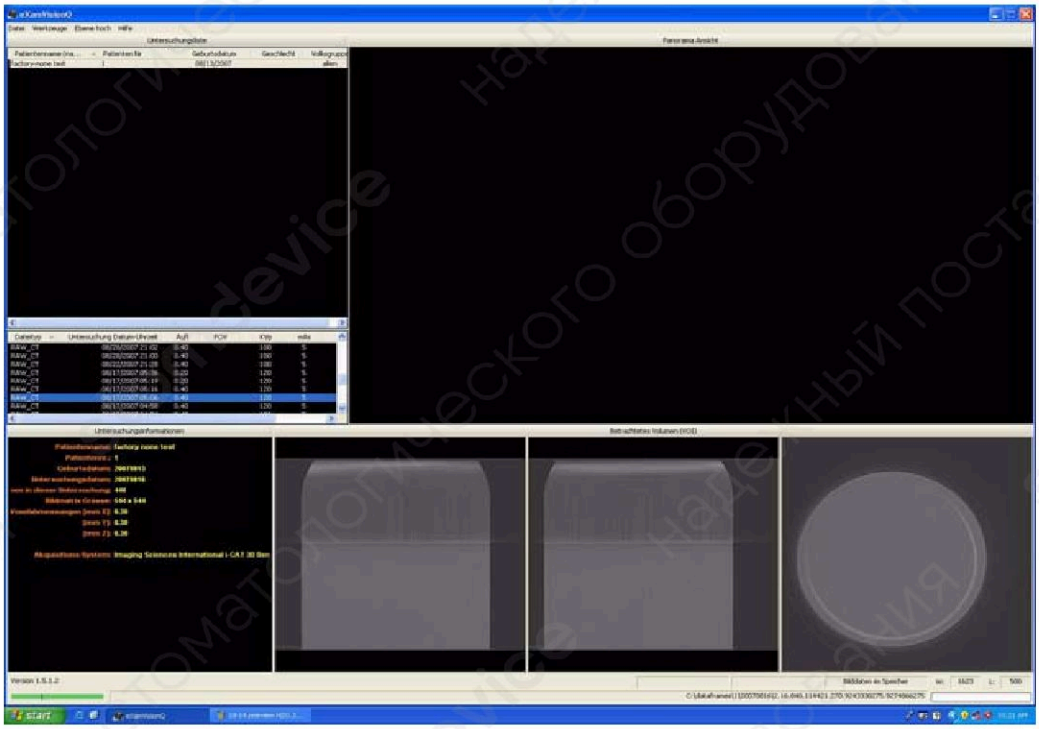
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10. The white dotted line, in the preview screen, is use to set the water height. The line should appear near the middle of the water height.

    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.

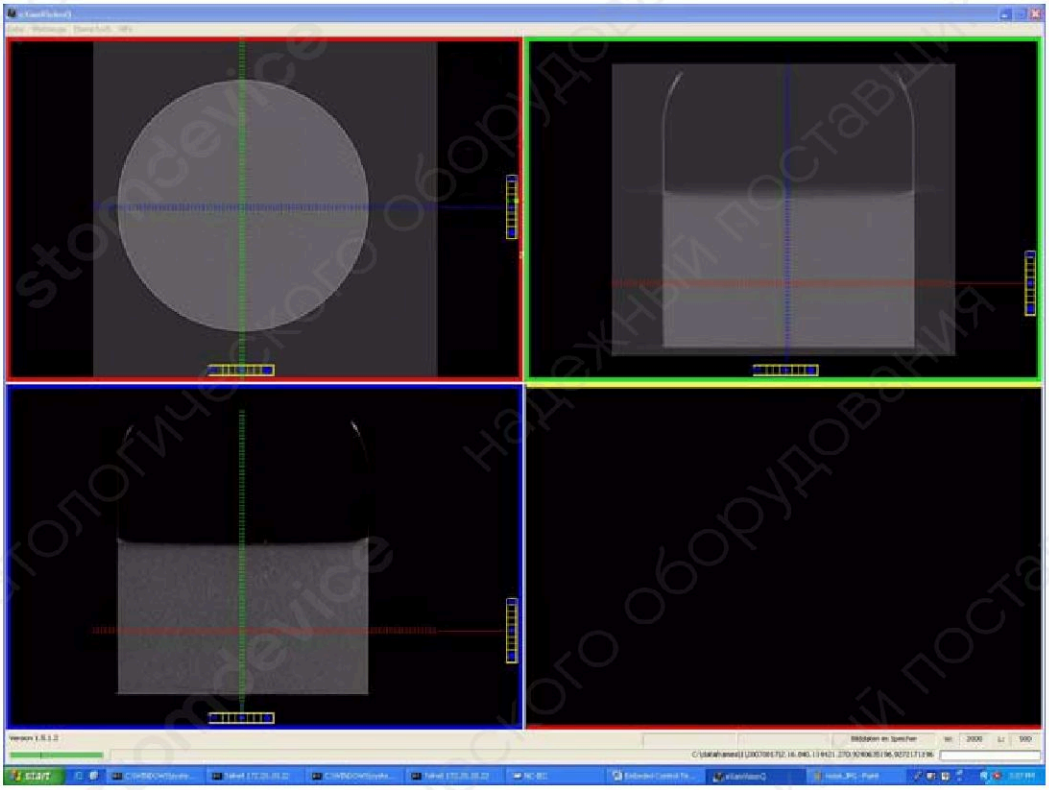
11. Click **Capture** to start the scan process.



12. Access the HU measurement image for evaluation by double clicking **Coronal View** (bottom image, 3rd from the left).

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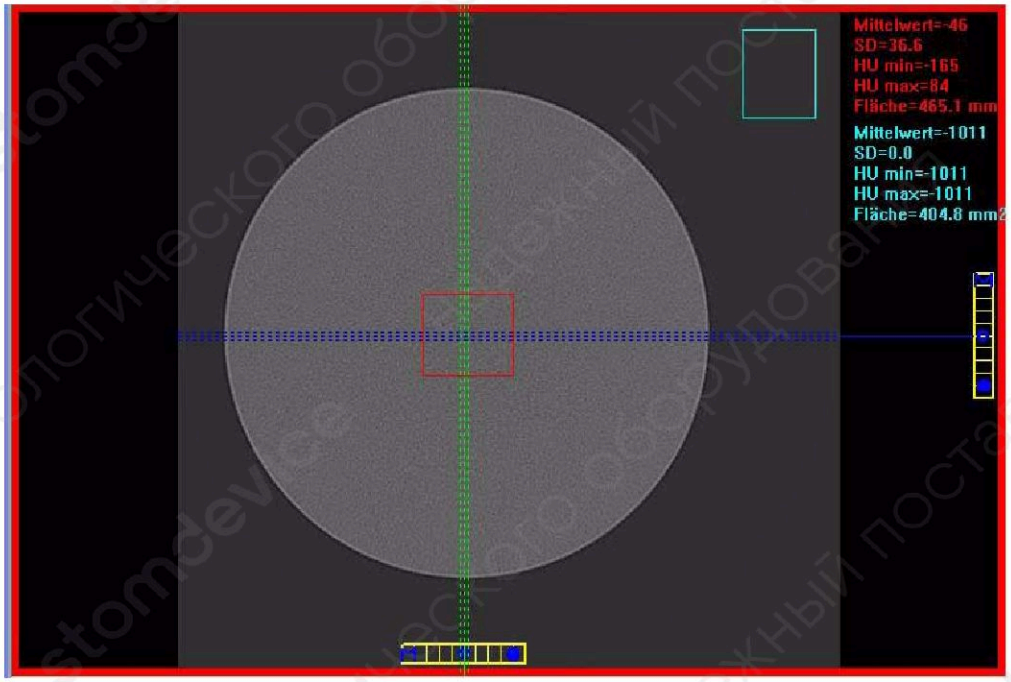
13. The red dotted line, in the upper right screen, should appear in the middle of the water height. Use the Center Line Positioning tool to make the height adjustment.

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Noise Level Test

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



15. Right click the image and select **HU Statistics** from the menu.

    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:
    1000.0 mm^2 inside the Water Phantom area
    400.0 mm^2 outside the Water Phantom area (AIR)

16. Note and record the 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).

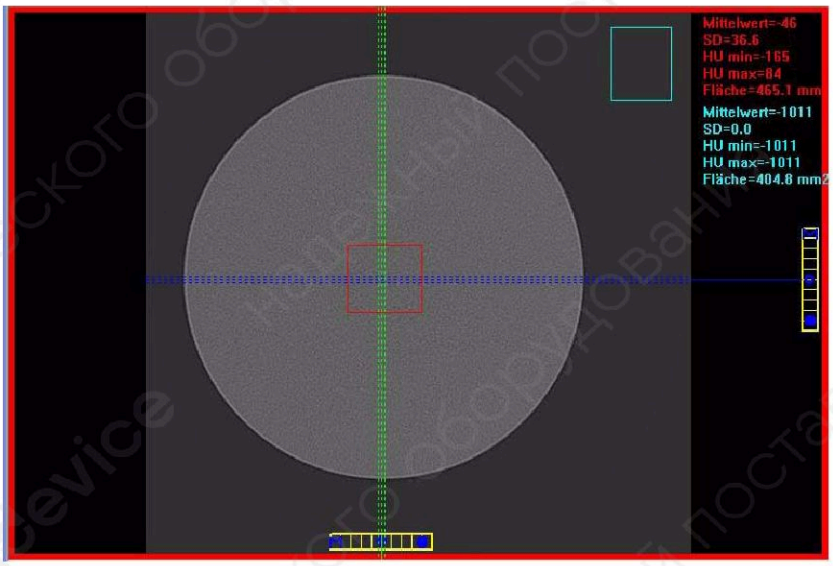
17. If the Standard Deviation (**SD**) Measured Value **exceeds 100**, call Service.

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Uniformity Test

18. 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**.

19. Right click the image and select **HU Statistics** from the menu.

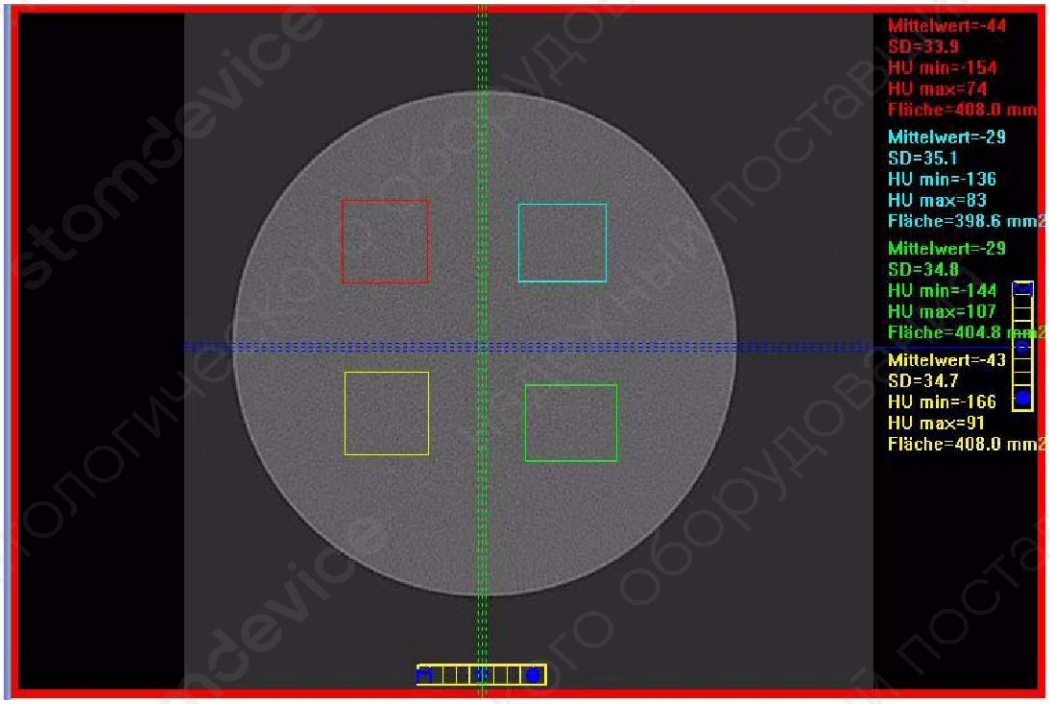
Use the Region Tool to define a ROI (Region of Interest) in four areas of Water, as shown above.

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

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The HU Area (box size) should be approximately 400.0 mm^2.



20. Note and record the Mean and SD values of the four regions. See chart below.
21. 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 is the limit.
22. 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					

23. Subtract the lowest **Mean Value** from the highest **Mean Value**. If the remainder is **greater than 100**, call Service.

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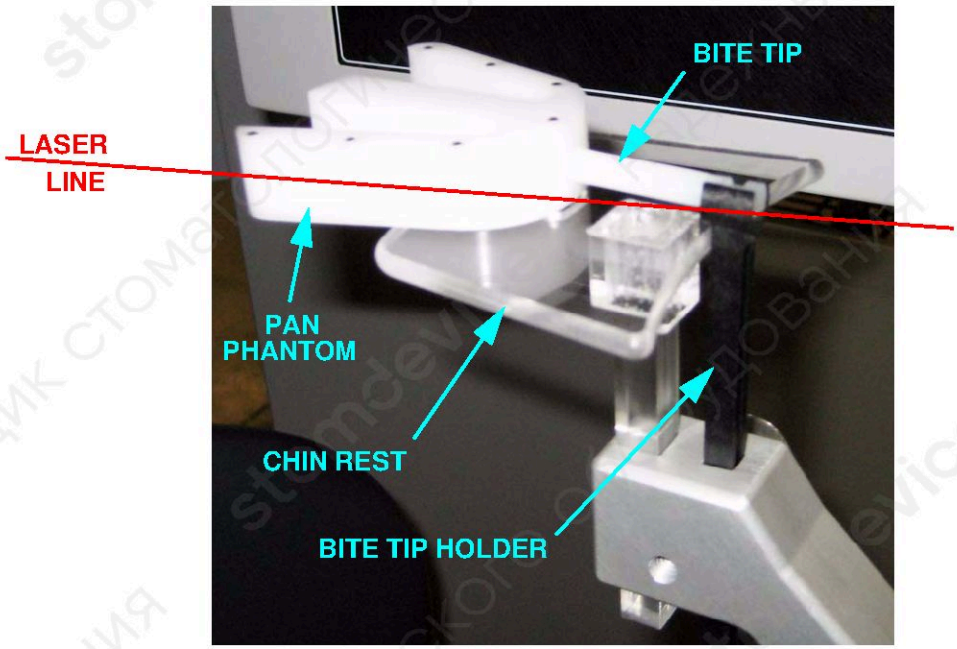
PAN Phantom Test

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 Gantry Front 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).



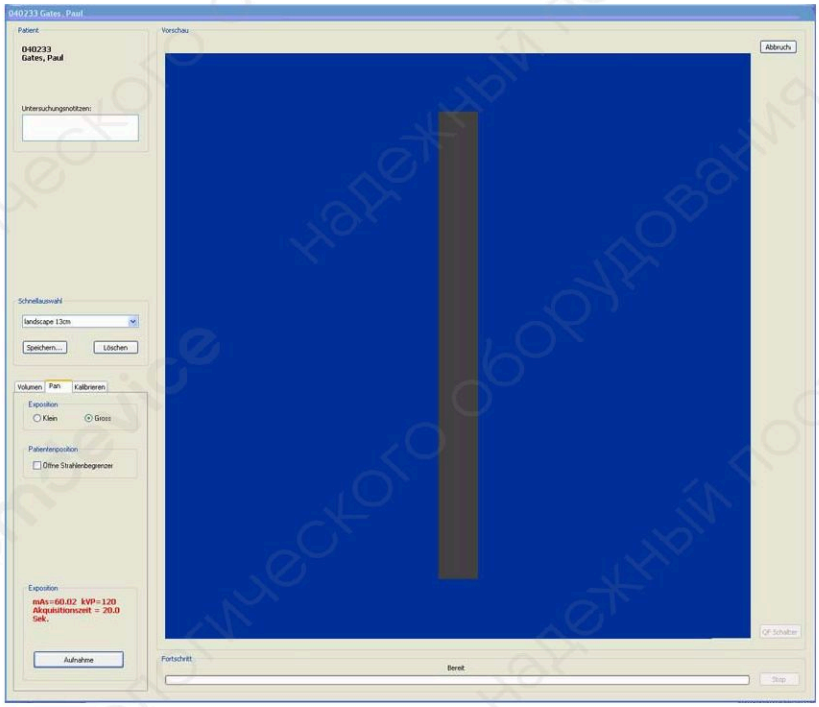
6. Start test by selecting **File > New Patient** from the Main menu.
7. From the Patient Information Panel, click **Add** or right click an existing image from database and select **Acquire Now**.

   If adding a new patient, enter **PAN Test** in the *First Name* field and **QA** in the *Patient ID* field.

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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.



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.

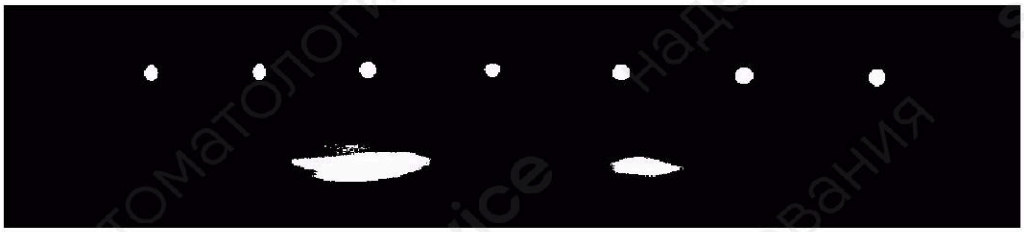
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13. The PAN scan runs a few minutes and then displays the reconstructed image.



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



15. Call Service if all seven balls do not appear in the image.

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Radiation Output Test

It is recommended that a check of the kVp 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 9 second, 13 cm, 0.4 voxel scan and record time and dose from meter.
3. Repeat step 2 for 27 seconds and record.

Measured Dose

The table below shows measurements performed on the detector.

Tube Potential (kV)	**120**
Selected Scan Time (seconds)	**27**
Mechanical Rotation Time (seconds)	**21.06**
Approximate Exposure Time (seconds)	**3.6**
Displayed mAs	**37.07**
Measured Exposure at Detector (mR)	**225**
Measured Exposure at Detector / mAs (mR/mAs)	**6.25**
Measured Exposure at 1m (mR/mAs)	**2.98**
Measured Dose at 1m (μGy/mAs)	**25.89**
Dose at Detector per Frame (μGy/fr)	**5.39**
Tube Output (μGy/mAs @ 1m)	**25.89**
Distance Source to Detector (cm)	**68**
Conversion Factor for Absorbed Dose (R to Gy)	**0.87**

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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 9 second scan
   = 619 for 27 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:

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

Where Source to detector distance = 0.68m for the KaVo 3D eXam®

Declaration of Conformity

Manufacturer and Technical File Holder:

Imaging Sciences International LLC
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 LLC
Western Europe Service Centre,
Corinium Industrial Estate,
Raans Road,
Amersham
Buckinghamshire HP6 6JL

guy.long@imagingsciences.com
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 LFS 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

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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

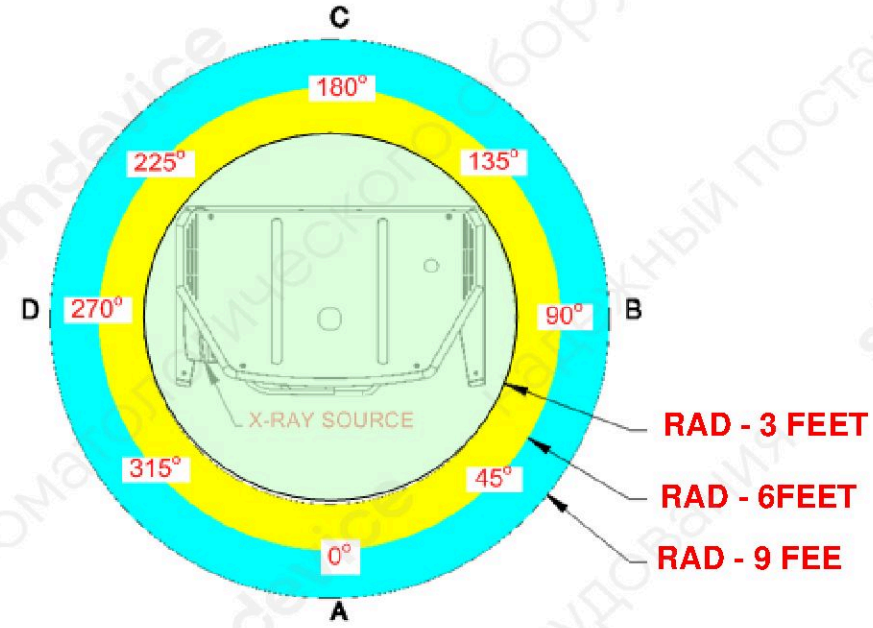
The next section describes how Patient data is converted into DICOM images. This procedure is used to determine where these DICOM image files are to reside.

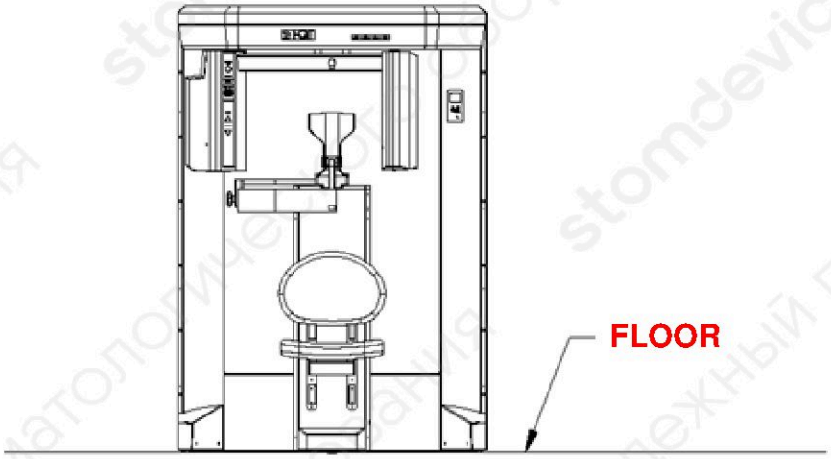
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Chapter 11 Radiation Environment Survey

The useful 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.





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Conditions of Operation – 9 and 27 Second Scans

All data was acquired using Victoreen Model 450P Survey Meter (S/N 3159) in integrate mode. 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, 5 mA with an assumed use and occupancy factor of 1 and the following parameters:

Estimated usage: 10 scans per week yielding a workload of 16.7 mA-min/week
25 scans per week yielding a workload of 41.7 mA-min/week
50 scans per week yielding a workload of 83.3 mA-min/week

Total scan time: **9 seconds**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure (μR)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	0.120	119.81	1.20	3.00	5.99
	6 [1.82m]	0.035	34.94	0.35	0.87	1.75
	9 [2.74m]	0.018	18.47	0.18	0.46	0.92
45°	3 [0.91m]	0.140	139.77	1.40	3.49	6.99
	6 [1.82m]	0.041	41.43	0.41	1.04	2.07
	9 [2.74m]	0.023	23.46	0.23	0.59	1.17
90° (B)	3 [0.91m]	0.140	139.77	1.40	3.49	6.99
	6 [1.82m]	0.055	54.91	0.55	1.37	2.75
	9 [2.74m]	0.018	17.97	0.18	0.45	0.90
135°	3 [0.91m]	0.015	15.47	0.15	0.39	0.77
	6 [1.82m]	0.010	10.48	0.10	0.26	0.52
	9 [2.74m]	0.006	5.99	0.06	0.15	0.30
180° (C)	3 [0.91m]	0.062	61.90	0.62	1.55	3.09
	6 [1.82m]	0.017	17.47	0.17	0.44	0.87
	9 [2.74m]	0.008	8.49	0.08	0.21	0.42
225°	3 [0.91m]	0.014	13.98	0.14	0.35	0.70
	6 [1.82m]	0.006	6.49	0.06	0.16	0.32
	9 [2.74m]	0.003	3.49	0.03	0.09	0.17
270° (D)	3 [0.91m]	0.140	139.77	1.40	3.49	6.99
	6 [1.82m]	0.038	37.94	0.38	0.95	1.90
	9 [2.74m]	0.014	14.48	0.14	0.36	0.72
315°	3 [0.91m]	0.110	109.82	1.10	2.75	5.49
	6 [1.82m]	0.030	30.45	0.30	0.75	1.52
	9 [2.74m]	0.013	13.48	0.13	0.34	0.67
1 meter above		0.004	4.49	0.04	0.11	0.22
1 meter above and 1		0.011	10.98	0.11	0.27	0.55

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Total scan time: **27 seconds**

Location	Distance in Feet [meter]	Exposure mR	Exposure (μR)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	3 [0.91m]	0.24	240	2.40	6.00	12.00
	6 [1.82m]	0.07	70	0.70	1.75	3.50
	9 [2.74m]	0.037	37	0.37	0.93	1.85
45°	3 [0.91m]	0.28	280	2.80	7.00	14.00
	6 [1.82m]	0.083	83	0.83	2.08	4.15
	9 [2.74m]	0.047	47	0.47	1.18	2.35
90° (B)	3 [0.91m]	0.28	280	2.80	7.00	14.00
	6 [1.82m]	0.11	110	1.10	2.75	5.50
	9 [2.74m]	0.036	36	0.36	0.90	1.80
135°	3 [0.91m]	0.031	31	0.31	0.78	1.55
	6 [1.82m]	0.021	21	0.21	0.53	1.05
	9 [2.74m]	0.012	12	0.12	0.30	0.60
180° (C)	3 [0.91m]	0.124	124	1.24	3.10	6.20
	6 [1.82m]	0.035	35	0.35	0.88	1.75
	9 [2.74m]	0.017	17	0.17	0.43	0.85
225°	3 [0.91m]	0.028	28	0.28	0.70	1.40
	6 [1.82m]	0.013	13	0.13	0.33	0.65
	9 [2.74m]	0.007	7	0.07	0.18	0.35
270° (D)	3 [0.91m]	0.28	280	2.80	7.00	14.00
	6 [1.82m]	0.076	76	0.76	1.90	3.80
	9 [2.74m]	0.029	29	0.29	0.73	1.45
315°	3 [0.91m]	0.22	220	2.20	5.50	11.00
	6 [1.82m]	0.061	61	0.61	1.53	3.05
	9 [2.74m]	0.027	27	0.27	0.68	1.35
1 meter above		0.009	9	0.09	0.23	0.45
1 meter above and 1		0.022	22	0.22	0.55	1.10

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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.

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- 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. Leveled 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 CT chamber X, in coulombs (C).
8. Calculated CTDI using the equation:

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

Where:

- Xr = 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

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(f) appropriate to the task at hand to convert exposure (R) to absorbed dose (rad):

- 0.78 rad/R for comparison to FDA-required, manufacturer-reported data (Lucite), and this is also appropriate for acrylic
- 0.93 or 0.98 rad/R for patient dose estimates (tissue or water)
- 0.87 rad/R for calculation of, or comparison to, CTDIw (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 27s scan, 120 kVp, 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

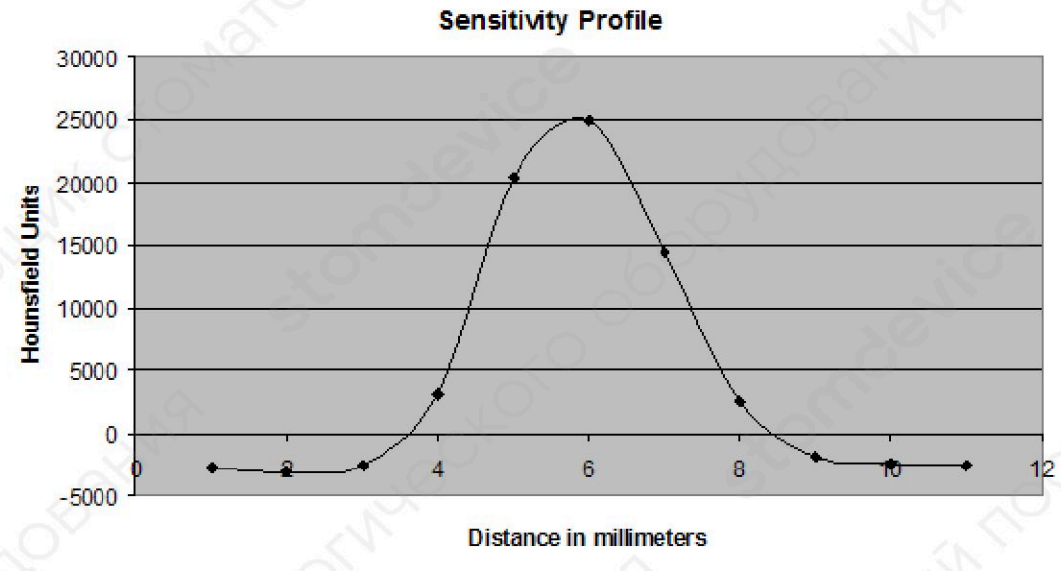
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Sensitivity Profile

For the ultra high resolution mode when the bead SIZE in the phantom is scanned the following sensitivity profile is obtained.

mm	Hounsfield value
1	-2752
2	-3104
3	-2560
4	3104
5	20352
6	24928
7	14496
8	2528
9	-1888
10	-2368
11	-2560



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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 sizes (mm): **0.5**

Available target angles: **15°**

Anode construction:

Vacuum cast copper with tungsten target

Cathode construction:

Vacuum tube nickel with tungsten filament

Max. Tube operating voltage:

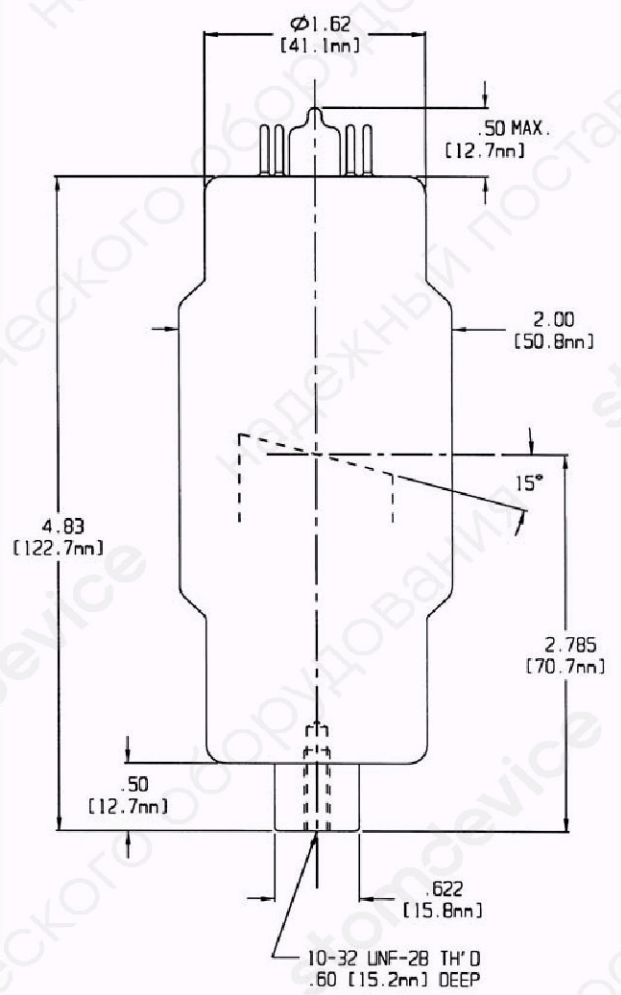
130 kVp Full wave rectified

Inherent filtration/Window material:

2.0 mm/Glass

Cooling Method:

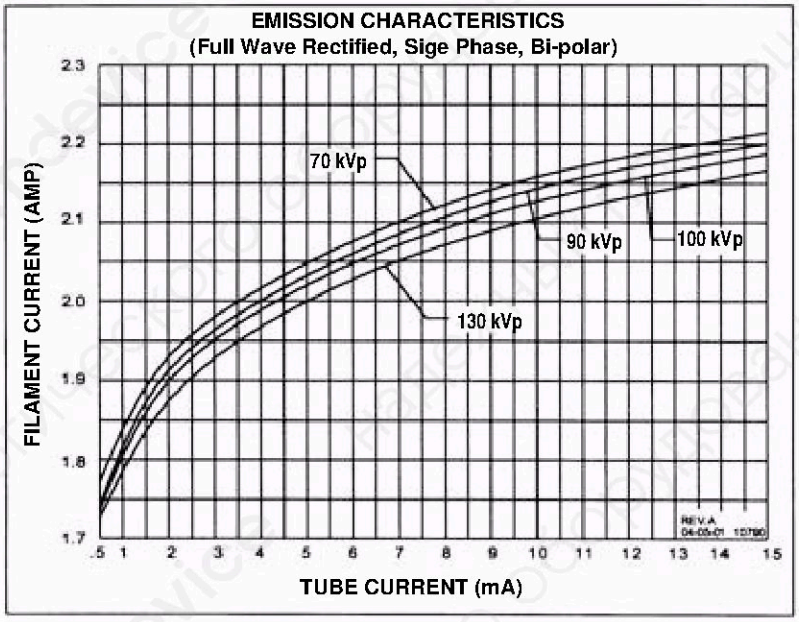
High dielectric transformer oil



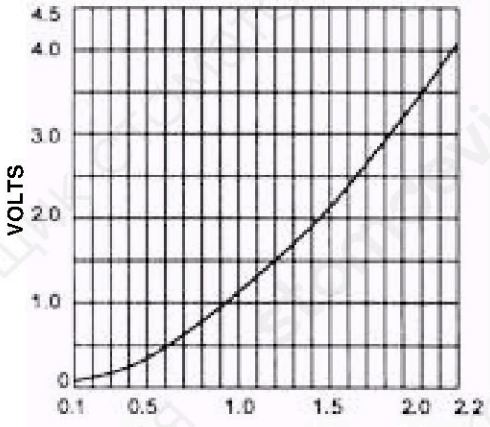
SXR-130-15-0.5
FOCAL SPOT

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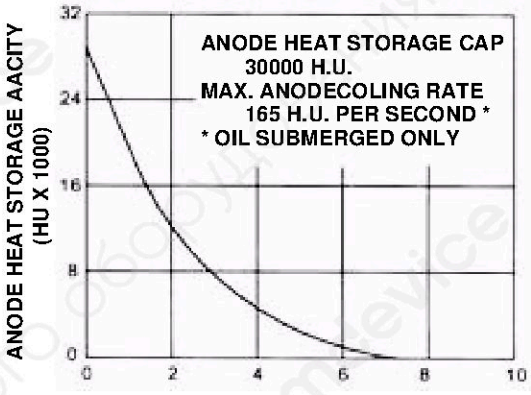


FILAMENT VOLT/AMP HARACTERISTICS:
60 Hz AC & DC



AMPS

ANOD OOLING CURVE



TIME IN MINTS

H.U. (Heat Unit)= kVp (Kilovolts Peak)
xmA (rms) x Time (sec.)
Joules = .707 x H.U.

SXR-130-15-0.5

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Chapter 12 General Product Information

Technical Specifications

X-ray Source:

Tube Voltage:	120 kVp
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) (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: kVp: +/- 5 kVp

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)

i-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)

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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: 27/9 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 27 sec scan @ 0.4 voxel

Secondary Reconstruction: Real Time

Power Requirements

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 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.

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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

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” (46 cm) 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 unit 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.

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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)	±6 kV Contact ±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	±2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±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 frquency 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).

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<table>
<tr><td colspan="4">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.</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td></td><td colspan="2">The 17-19 Imaging System is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user of this 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.
<table><tr><th>Maximum Output Power (Watts)</th><th>Separation 150 kHz to 800 MHz</th><th>Separation 800 MHz to 2.5 GHz</th></tr><tr><td>0.01</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr><tr><td>0.1</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr><tr><td>1</td><td>46 in (117 cm)</td><td>8 ft (2.4 m)</td></tr><tr><td>10</td><td>12 ft (3.7 m)</td><td>24 ft (7.3 m)</td></tr><tr><td>100</td><td>38 ft (11.7 m)</td><td>77 ft (23.4 m)</td></tr></table>Note: Field strengths from transmitters, as determined by an electromagnetic site survey, should be less than the compliance level of 3 V/m.</td></tr>
<tr><th>Emission Test</th><th>Compliance</th><th colspan="2">Electrostatic Environment - Guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td colspan="2">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.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td colspan="2">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.</td></tr>
<tr><td>Harmonics
IEC 61000-3-2</td><td>Class A</td><td colspan="2"></td></tr>
<tr><td>Flicker
IEC 61000-3-3</td><td>Complies</td><td colspan="2"></td></tr>
</table>

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.

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- 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 60601-2-44
JIS Z4703	IEC/EN 60825-1JIS T0601
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

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

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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 film density

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 Imaging Sciences International dealer or by any other competent serviceman of the user's choice who has had 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)

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Preventive Maintenance Schedule Table

Assembly / Component	12 MONTHS	TEST	INSPECT
Tube Housing Assembly			
Certification Label	X		X
Warning and Indicators	X		X
Oil Leaks	X		X
Physical Damage	X		X
Mounting System Stability	X		X
Beam Limiting Device			
Physical Damage	X		X
Certification Label	X		X
X-Ray Controller			
Timer	X	X	X
Line Voltage	X	X	
Calibration	X	X	
Exposure Switch and Cord	X	X	
Line Switch	X	X	
Visual Warning Indicator	X	X	X
Audible Exposure Signal	X	X	
Certification Label	X		X

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Replaceable Parts - Reference List

Sub Assembly Number	Description
11-0	Rotation Stepper Motor
27-0	Head Rest, Carbon Fiber
35-0	Tube Head Assembly
102-16	Platform Motor
109-2	Receptor Motor
137-0	Beam Limiter Assembly
1000-0	X-ray Power Supply 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
K1304-0	Patient E-stop Box
K1305	Patient Alignment Panel
K1306-0	Operator Control Box
1539	Laser, Cross
1540	Laser, Straight Line
1543	Motor, Beam Limiter, 7.5 Stepper
K1701-0	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	Varian 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	Varian Power Supply (15 VDC)
9140-0026-0006	Chin Cup

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Accessories

Item	Description	Part Number	Quantity
1	Door Interlock Cable	1524	1
2	Warning Cable	1527	1
3	Patient E-stop	1304-0	1
4	E-net Cable 50	1000116	1
5	Tool Kit	5-0	1
7	Foot Stool	1000197	1
8	Booster Seat	1000196	1
10	Glide	1000179	4
11	Control Box	1306-0	1
12	Chair Patch Cable	1520	1
13	Cable Clips	101-6	6
14	Head Rest	27-0	1
15	Head Band	27-1	100
16	Pan Phantom	12-0	1
17	Phantom Assembly	14-1-0	1
18	Line Pair Phantom	13-00	1
19	Water Bucket	10000224	1
20	Bite Tip Holder	980220	2
21	Bite Tip	980180	25
22	Chin Rest	9105-0026-0006	1
23	Chin Cup	9140-0026-0006	1
24	Platform Assembly	14-4-0	1
25	Chair Center Locator	26-8	1

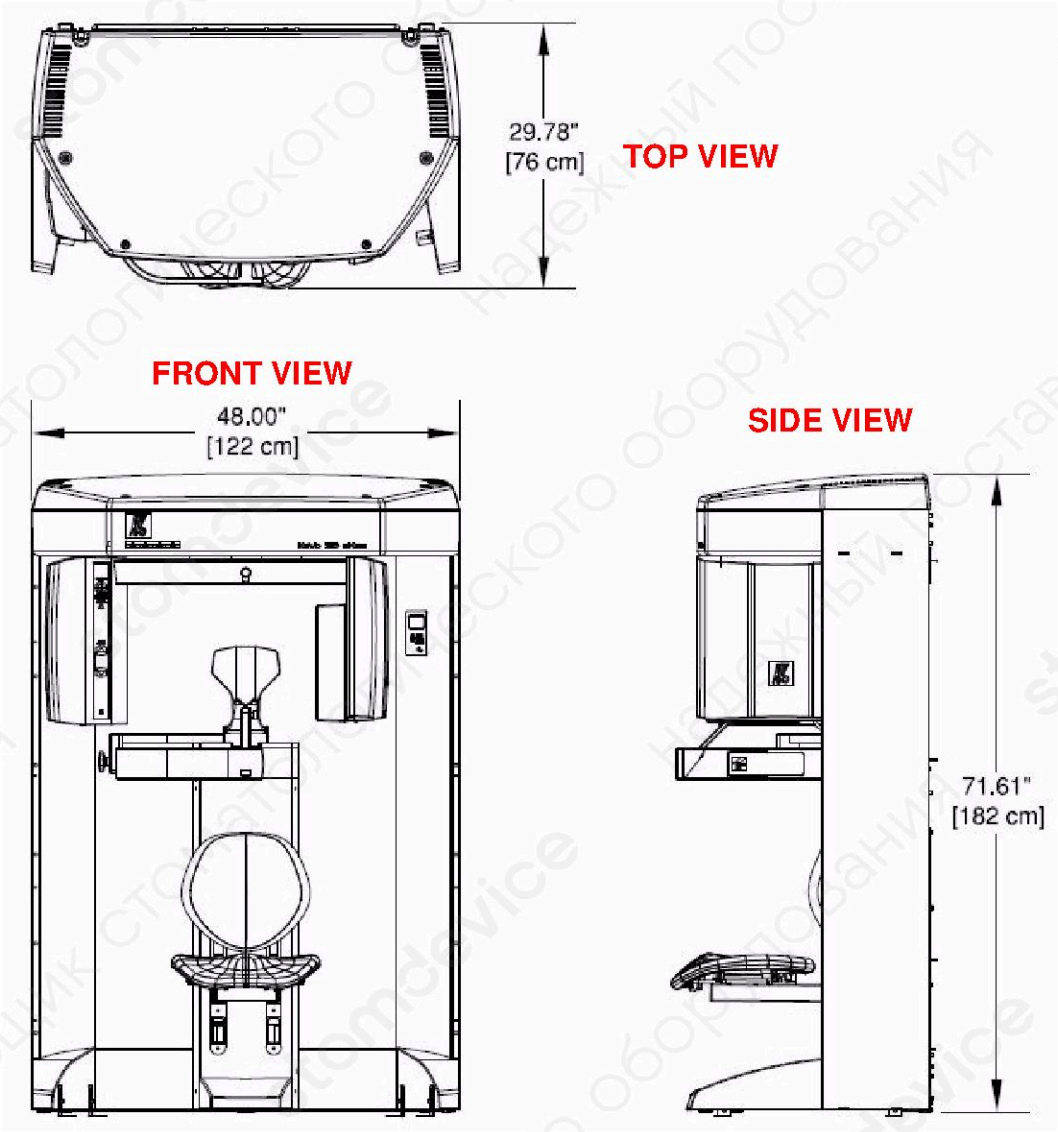




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System Gantry Dimensions



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Chapter A Three Dimensional Volume Rendering (3DVR)

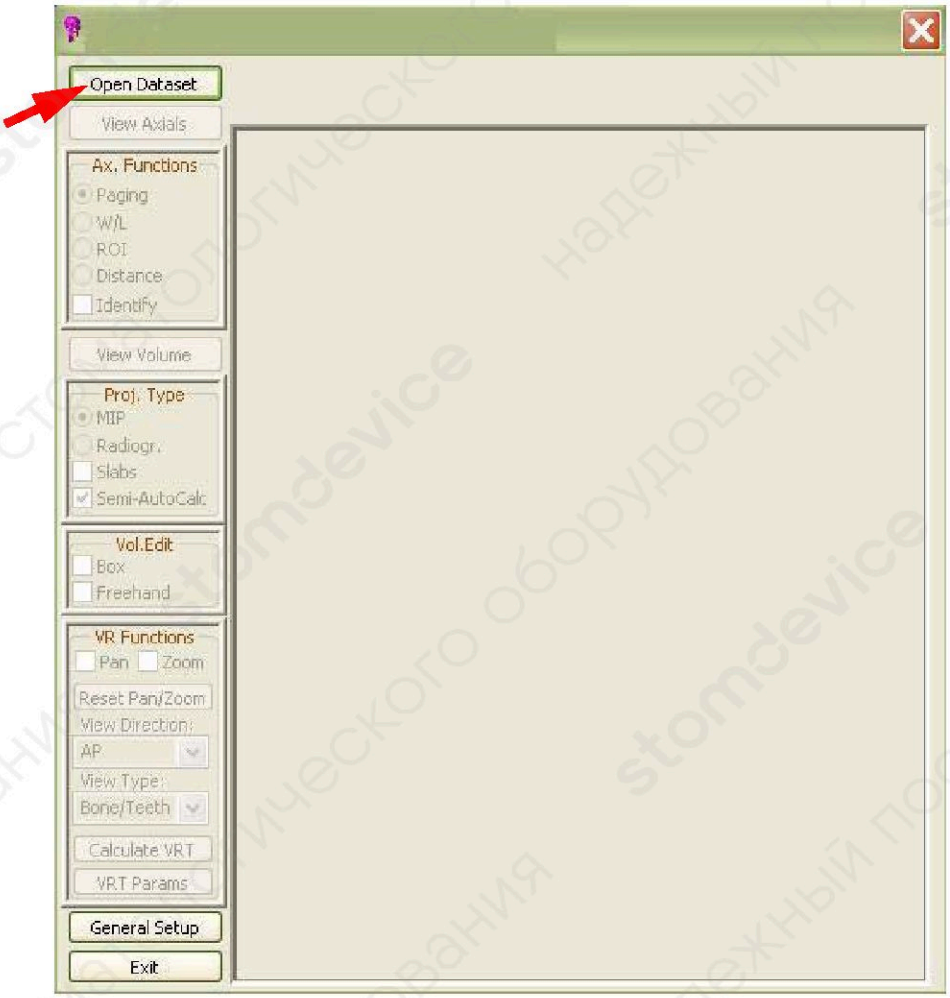
Open Database

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

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



The Program Main menu is displyed.



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



If importing a case from iCATVision, 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.



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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 ragging 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.

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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



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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.)



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Identify

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

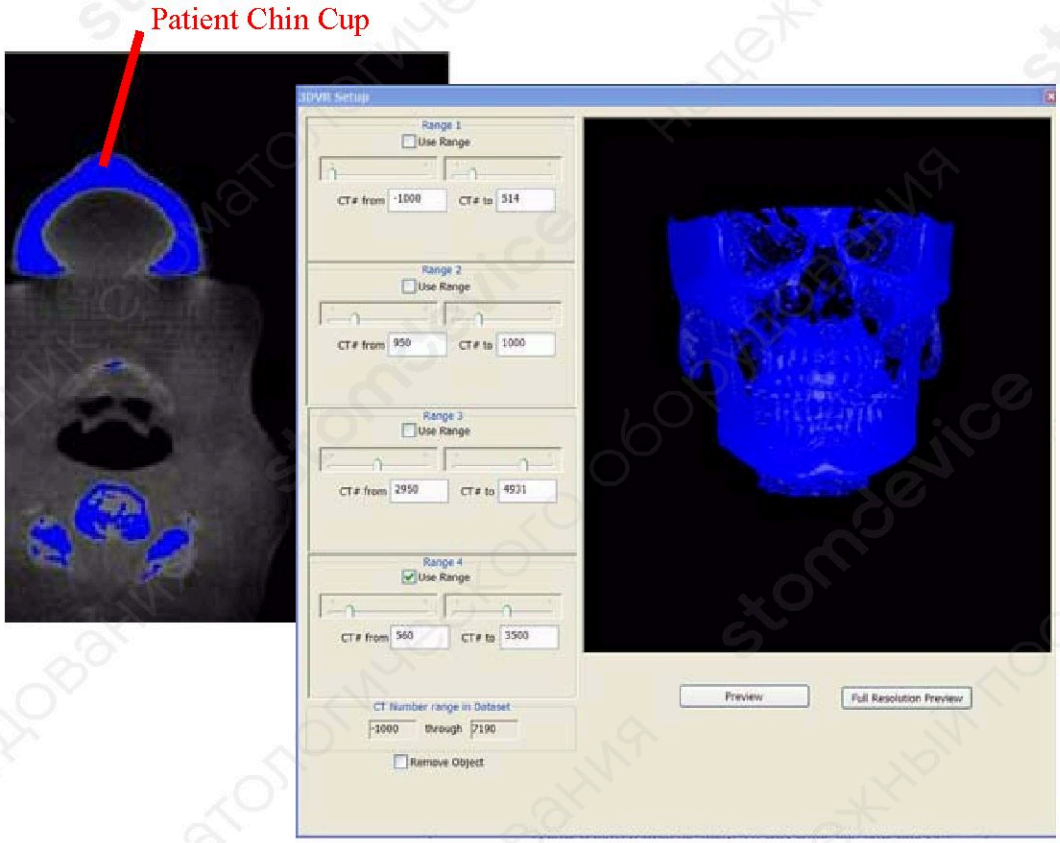
This tool is often used to remove a piece of anatomy from the image. One major use is to remove the Patient Chin Cup that may appear in the scan. See the sample below (Patient Chin Cup highlighted in blue.)

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. Click **Preview** or **Full Resolution Preview** to display a 3D image in the 3DVR Setup window.
   - **Preview -** reduced resolution, but faster VR rendering
   - **Full Resolution Preview -** full resolution, but slower
3. Drag cursor on 3D image to rotate.



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Display the slice range of interest:

4. 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 ragging downward scrolls towards the bottom of the skull.

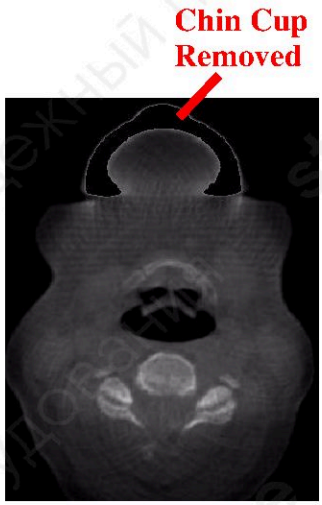
   or

   On the 3DVR Setup screen, select a CT 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.

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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.

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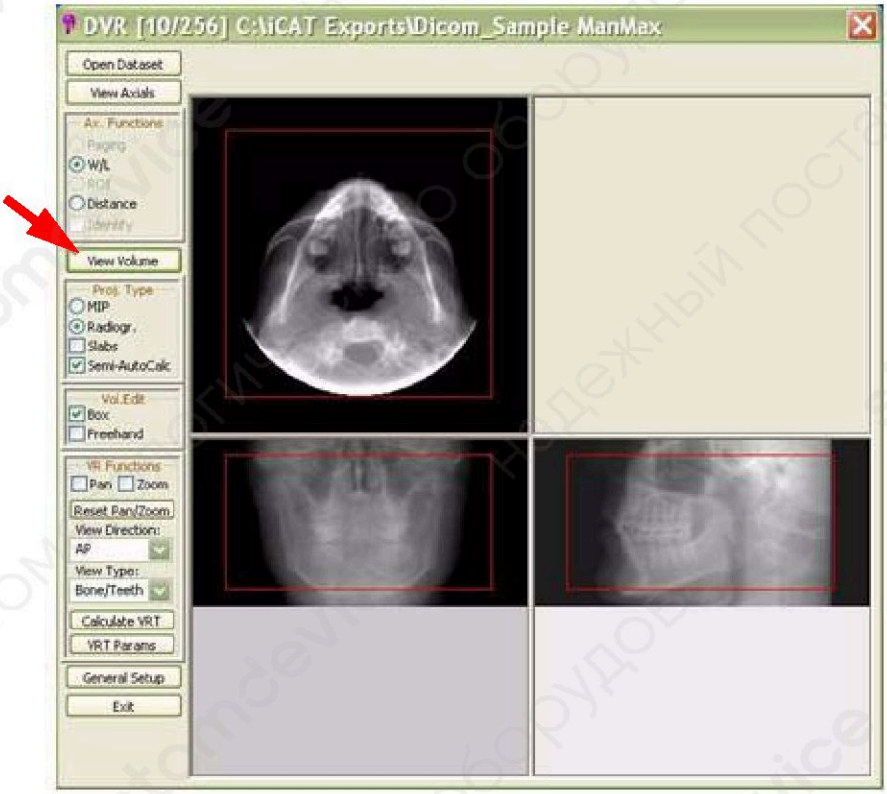
6. Enter Calculation Offset which currently has a value of 0.
7. Click **OK**.



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.



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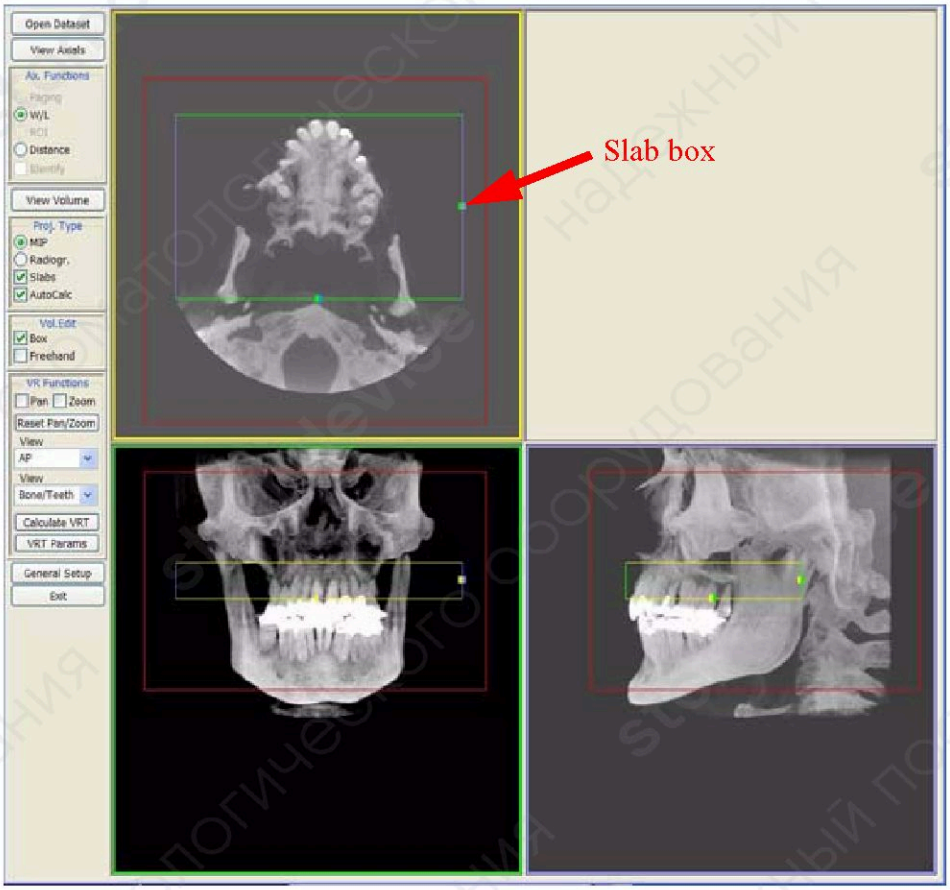
Projection Type

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 boxe 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.



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Volume Edit

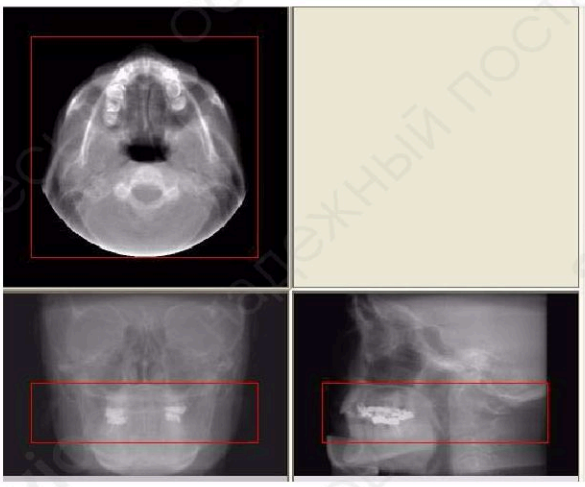
Volume Editing is used to select an area of interest to create a 3D rendering. The two methods used are **Box** and **Freehand**.

- **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.

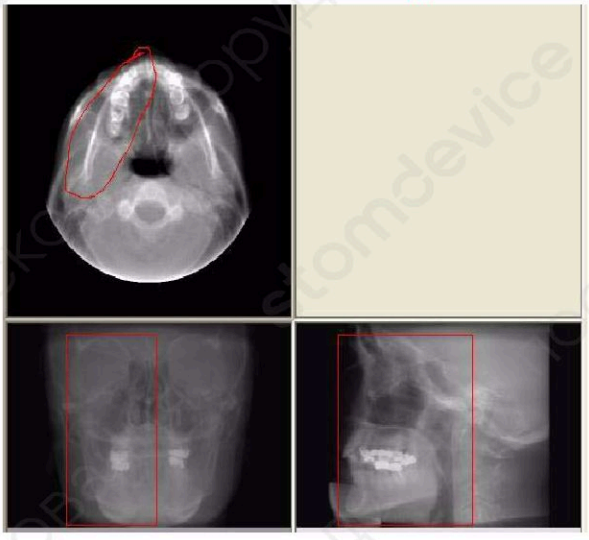
Box Editing

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.



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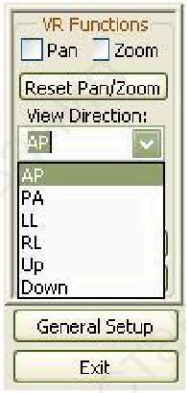
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VR Functions

VR Functions (Volume Rendering) is a tool used for selecting the type of 3D image to create.

To Create a 3D Image:

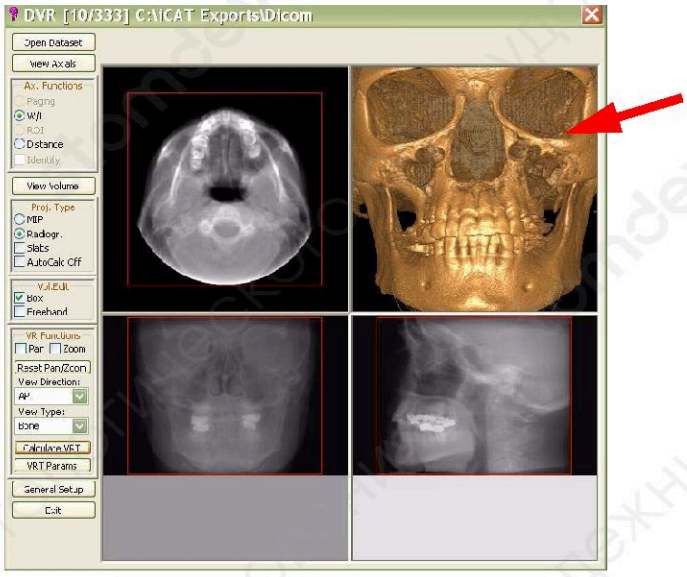
1. From the first **View** drop-down menu select a direction to display. The choices are:
   - AP (Anterior Posterior)
   - PA (Posterior Anterior)
   - LL (Left Lateral)
   - RL (Right Lateral)
   - Up
   - Down



2. From the second **View** drop-down menu select the type of display. The choices are:
   - Bone/Teeth
   - Bone
   - Skin
   - Sinus/Bone
3. Click the **Calculate VRT** button.

   This displays the 3D image (upper right box.)



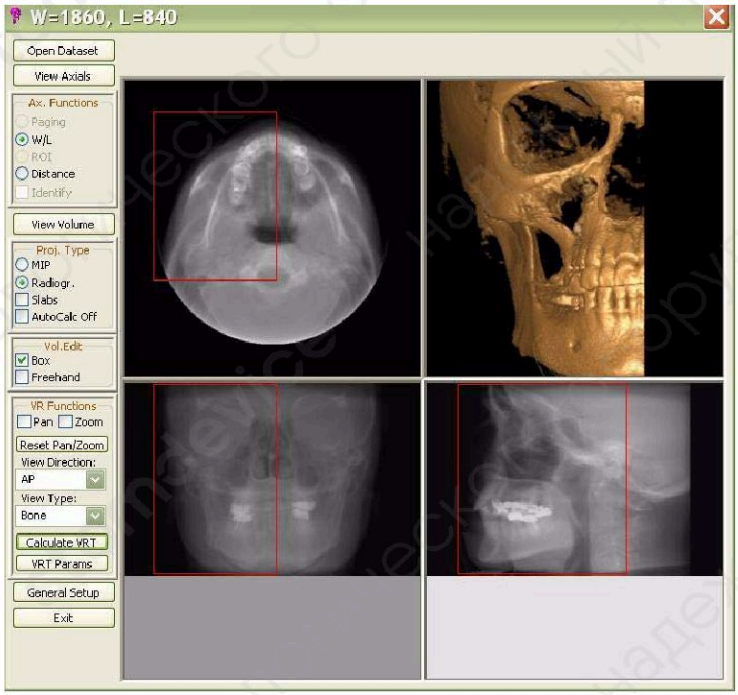


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NOTE: Remember that the 3D data is calculated using the boxed or freehand selected areas of interest in the Axial, Coronal & Sagittal views. In this sample, the entire volume data is selected in all 3 views.

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



Each View Type has its own Parameters, which can be viewed by clicking the **VRT Params** button.

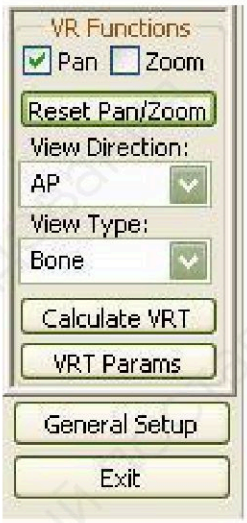
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The 3Dimage can be rotated, enlarged or changed to another direction or type. These functions can be performed from the top right corner viewing area or you can choose to enlarge the 3D image to Full Screen (Right click on the 3D image and select **View 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.

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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

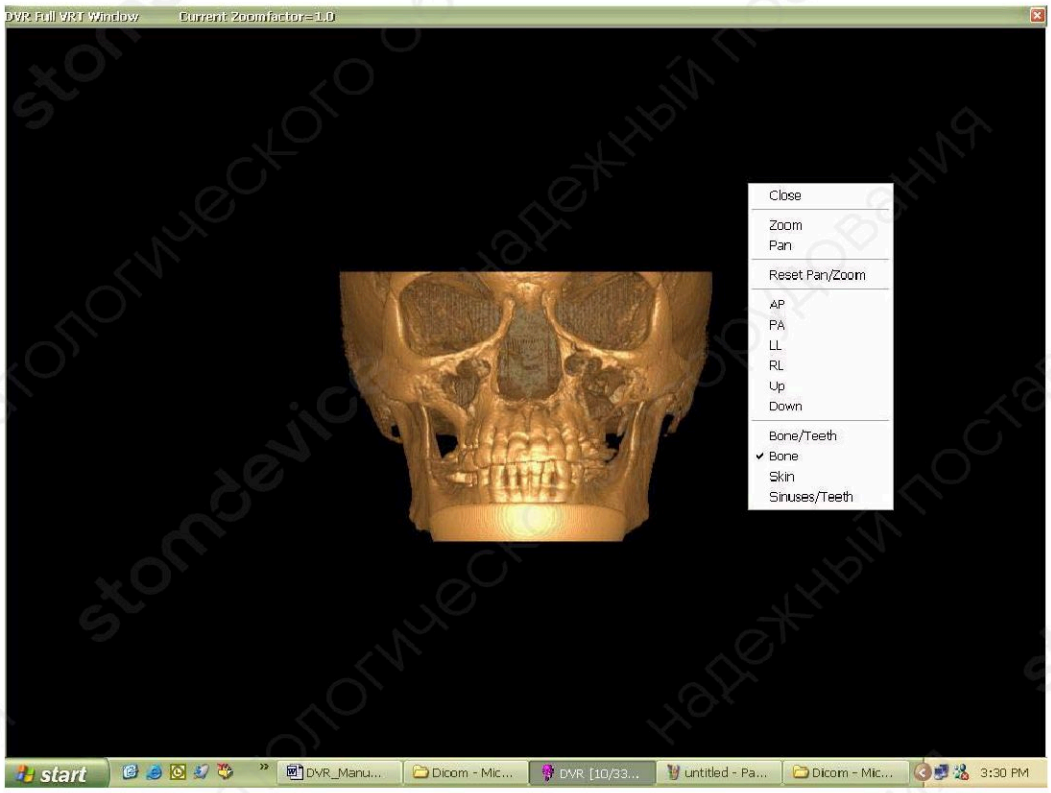
Opens the file structure where the JPG and TIFF picture files are saved. The current working folder can be changed.

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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

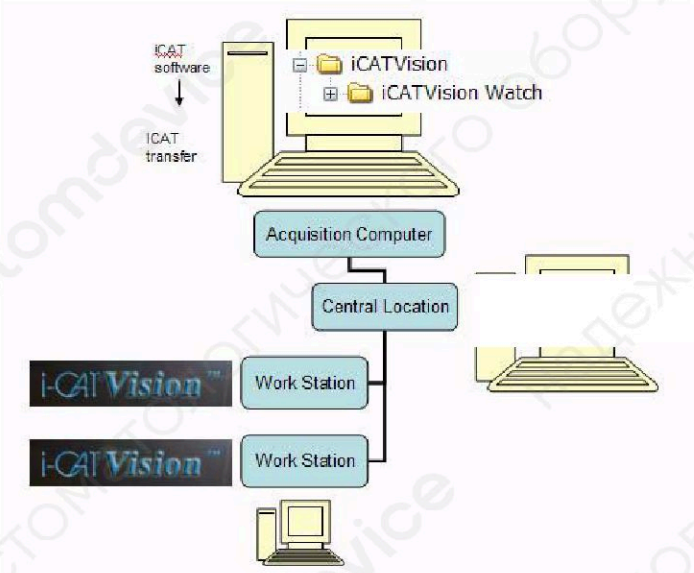
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Chapter B iCATVision & iCATTransfer Installation

iCATVision

iCATVision can be installed on any computer where iCAT® images are viewed. We are pleased to provide iCATVision free of charge to anyone with access to iCAT® scans with no limit on usage and the number of copies.

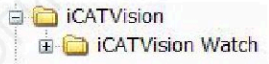


File Structure Setup

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

   This is where the DICOM 3 data is exported. NOTE: OnlyDICOM files are placed here, NO FOLDERS.

   File structure on iCAT® Acquisition Computer:

   C:\ 

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

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

   File structure on server/central storage location:

   C:\ 

   If a server/central storage location is not available, then create the iCATVision Root directory on the iCAT® Acquisition Computer's C: drive under the iCAT Vision 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 iCATVision

1. Unzip the iCATVision.zip file to the iCAT Vision folder, it unzips to iCATVision.exe.
2. Double click the .exe file to execute the program.

   A shortcut can be created for this program on your desktop.

To unzip a file:

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

To create a shortcut:

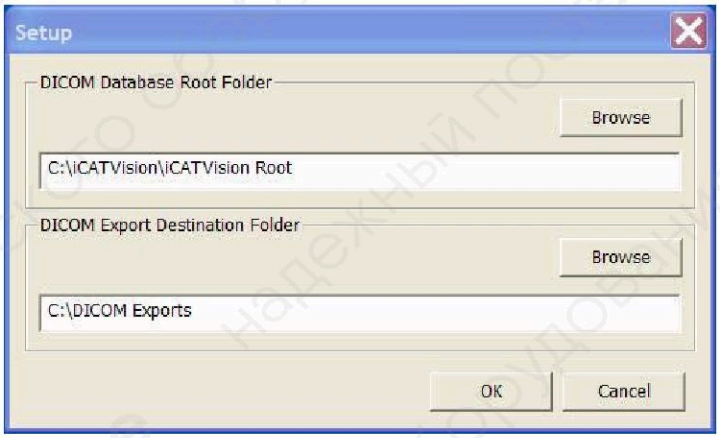
Right click file and select **Send to > Desktop (create shortcut)**.

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iCATVision Setup

1. From iCAT Vision select **Tools > Setup**.

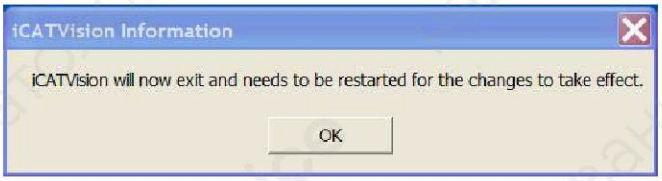


2. Under *DICOM Database Root Folder,* browse to the iCAT Vision\ iCAT Vision Root and click **OK**.

   (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 iCATVision software is displayed, click OK.



NOTE: It is currently recommend that when using iCAT Data for 3rd party software, perform a separate DICOM export from iCAT®. The data will be interchangeable when third party systems start accepting compressed DICOM.

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iCATTransfer

NOTE: iCATTransfer is not required for iCAT® 17-19 Systems.

iCATVision is restricted to iCAT® DICOM scans and necessitates an "authentication" of DICOM data (Digital Imaging Communications). Authentication is performed by a program called "iCATTransfer" which is installed and executed on the iCAT® Acquisition Computer (computer capturing the scan) or another computer on the same network, in special cases. iCATTransfer authenticates and stores all newly exported DICOM data (from iCAT® software, to the Watch folder, and then to the Image Root folder.) The Image Root folder typically resides on a server or another central storage location.

If the computers are on the same network as the iCATTransfer, then there is direct access to the patient images. If running outside this network (e.g. a referring doctor's office), then patient data may be transferred via a CD to the remote computer's Image Root folder.

To reiterate, iCATVision only accepts iCAT® DICOM data that is authenticated by iCATTransfer. **Images from iCAT® 17-19 Systems do not require iCATTransfer.**

Install iCATTransfer

1. Unzip the iCATTransfer.zip file to the iCAT Vision folder, it unzips to iCATTransfer.exe.
2. Double click the .exe file to execute the program.

   A shortcut can be created for this program on your desktop.

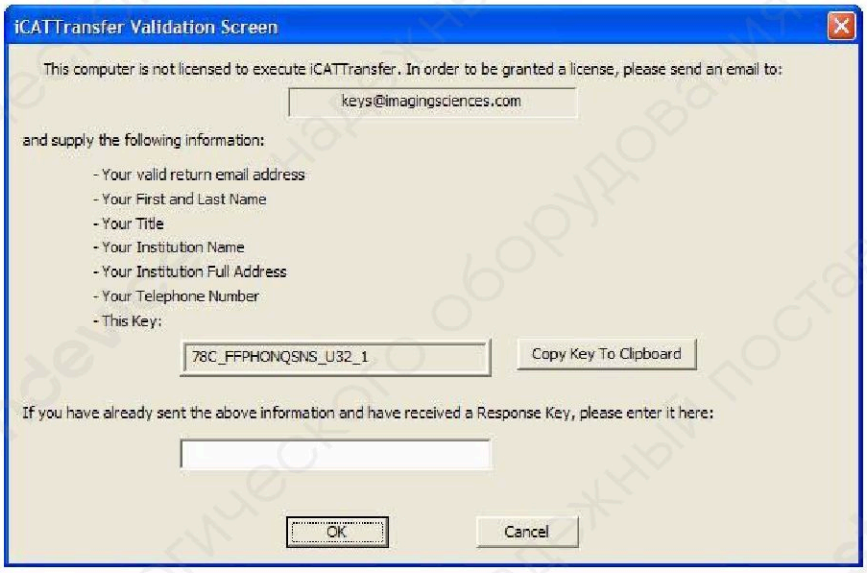
   To unzip a file: Right-click the file and click **Extract** on the shortcut menu.

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iCATTransfer Passcode

When iCATTransfer is first launched, it opens to the iCATTransfer Validation Screen (below). Instructions are displayed to send an email to Imaging Sciences at keys@imagingsciences.com with your customer information and the authentication code shown on screen. We will return an email with the Passcode to be entered into the iCATTransfer Validation Screen.



The program then opens, click **accept** to accept the License Agreement and then follow the instructions below.

iCATTransfer Setup

The program must be configured to "watch" for exported DICOM data from iCAT® in order to authenticate and transfer it to the image root directory. The program needs to be running in the background in order to detect the exportation of the DICOM Data. You may want to place the iCATTransfer program into the StartUp Menu of the iCAT® Acquisition Computer (or server).

Putting iCATTransfer into the StartUp Menu

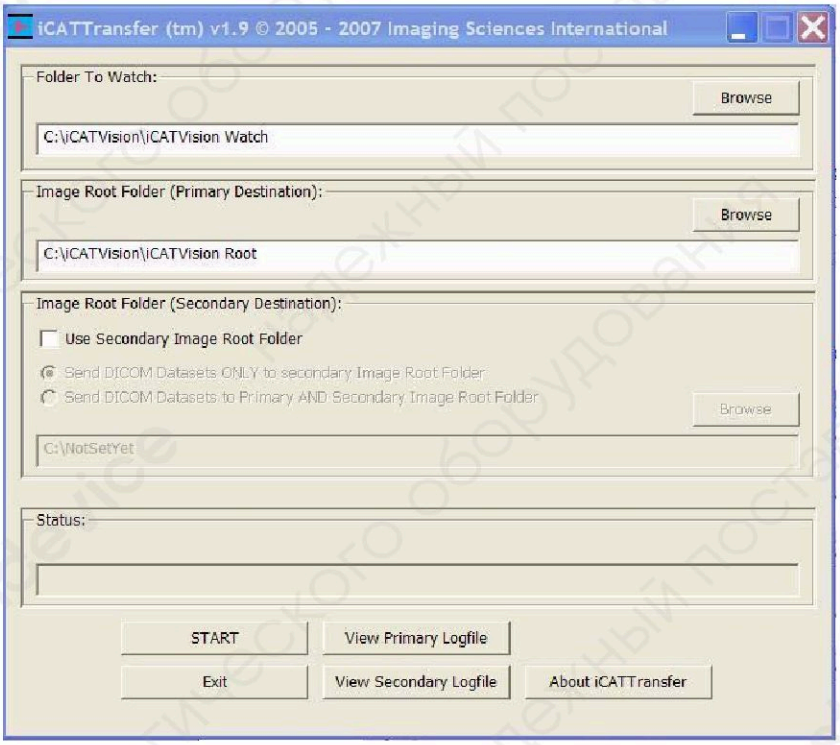
1. Right click the **START** button and select **OPEN**.
2. Double click **Programs** folder to open and then double click the **StartUp** folder to open.
3. Copy the iCATTransfer.exe file into this StartUp folder.

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Configure iCATTransfer

1. Launch iCATTransfer, the following window is displayed.



2. Under *Folder to Watch*, Browse to **iCATVision\ iCATVision Watch** folder and select. (This is most likely on the C: drive of the iCAT® Acquisition Computer).
3. Under *Image Root Folder (Primary Destination),* Browse to **iCATVision Root** folder and select. (This is most likely on a server/central storage location).
4. Click **Start**. This saves the preset Watch and Root destinations.

NOTE: If START is not clicked the transfer program will not work.

Remember, iCATTransfer must be running in order for the data to transfer (iCATTranfer can be minimized).

Accessing i-CAT® DICOM Data

iCATTransfer requires data to be exported from the iCAT® software in DICOM3 format.

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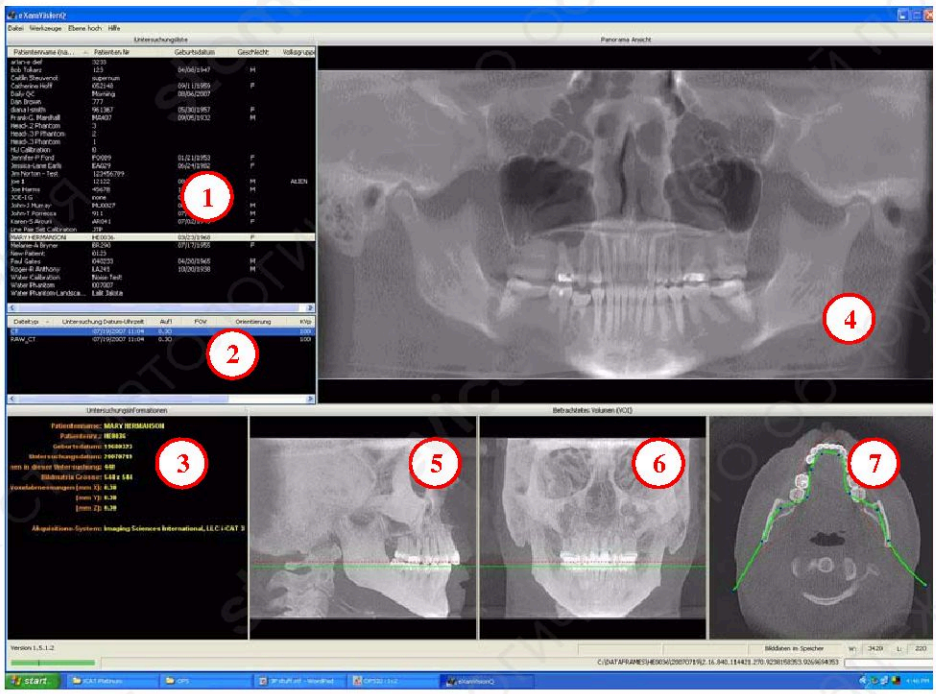
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iCATVision Quick Reference

Navigating the i-CATVision Intrerface

This guide shows how to:

- View reconstructed images
- Use main features and tools to optimize an image



Tools for Viewing this Image

HIDING THE PATIENT LIST

Patient List can be hidden by selecting **Tools > Hide Patient List**. To show, select **Tools > Show Patient 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.



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.



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 **ORTHO** 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.

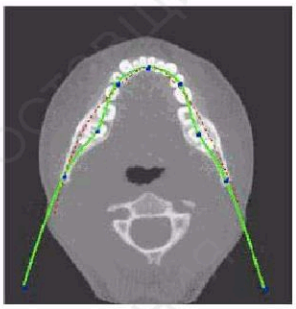
Right click and select "HU Stats" or "Distance" again to turn the tool off

Right click the actual measurement statistic to remove, inactivate, or activate them.

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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** all images.
2. Implant Screen: **Hard** all images.
3. TMJ Screen: **Hard** for first 3 and **Normal** for Condyle Ortho Images.
4. MPR Screen: Normal all images.
5. Ceph (Ortho) Screen: **Very 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, iCATVision 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 your workup or choose an existing workup name (if one) from the list to overwrite. Once the workup is named, click **OK** to save.

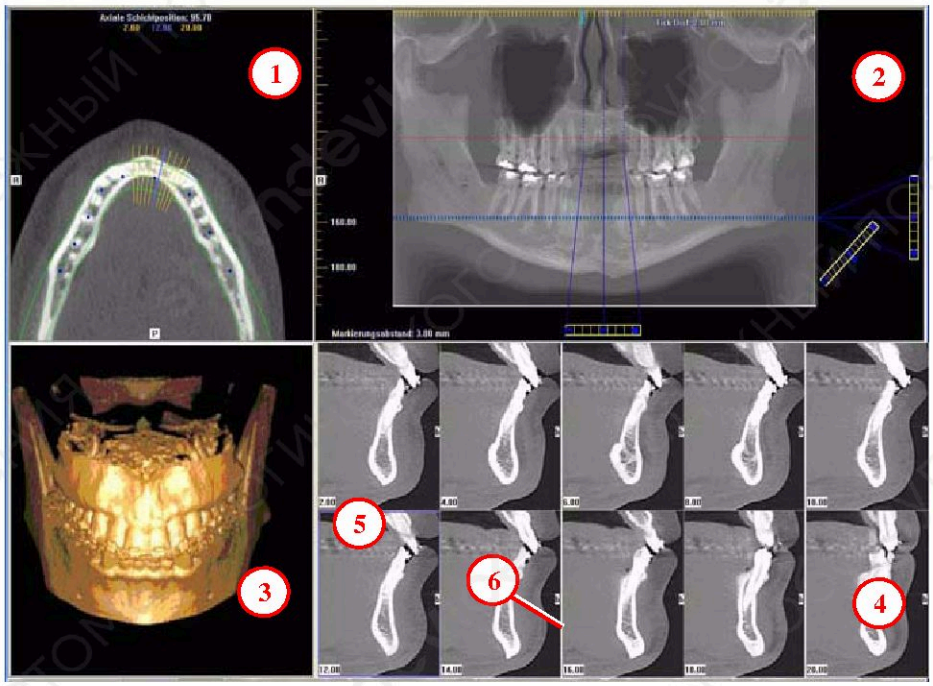
Or, before exiting or switching patients, from the Preview Screen, right click to access the pop up menu and select **Save this Workup**. Then proceed as instructed above.

To load a workup, click a Patient Name, and Patient Image, and then a workup. If you want to select another workup (if you have multiple workups), right click the screen to access the pop up menu and select **Load Different Workup**. Then select the workup from the list.

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Implant Planning Screen



- 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 MENUS

Right click cross section views to display the Pop Up menu to select:

- HU Statistics
- Distance
- Display Formats : The default is 5 x 2. The other options are 7 x 3 and 3 x 1. Nerve Canal detection is not yet functioning.
- Set Filters
- Save as JPEG
- Open Output Folder

CURSOR TOOLS

- All views, except the 3D Model, have Brightness/Contrast, Rotate, Drag, Zoom and Pan. 3D Model only has Rotate.
- **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 **Level Up** button on the Main Menu bar.

REMINDER

Implant Screen is acquired by double clicking Panoramic View from Preview window.

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.

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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.

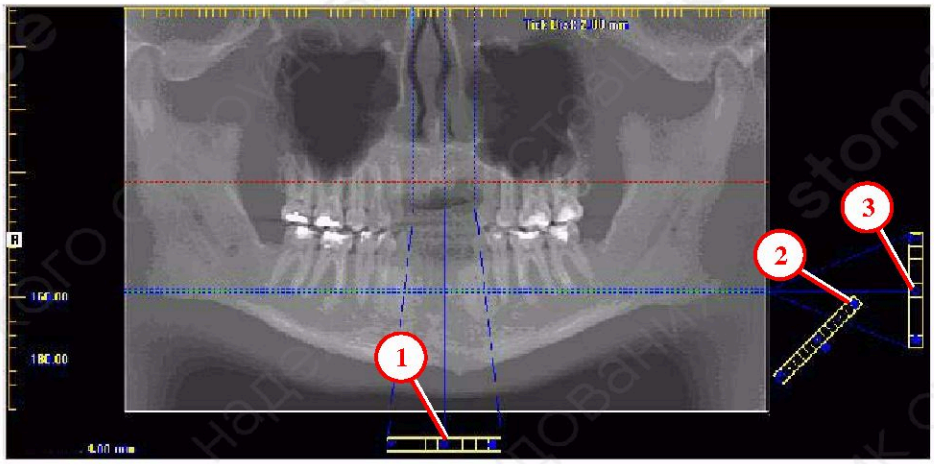
   Drag the center tool to adjust Pan Focal Trough.

   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.

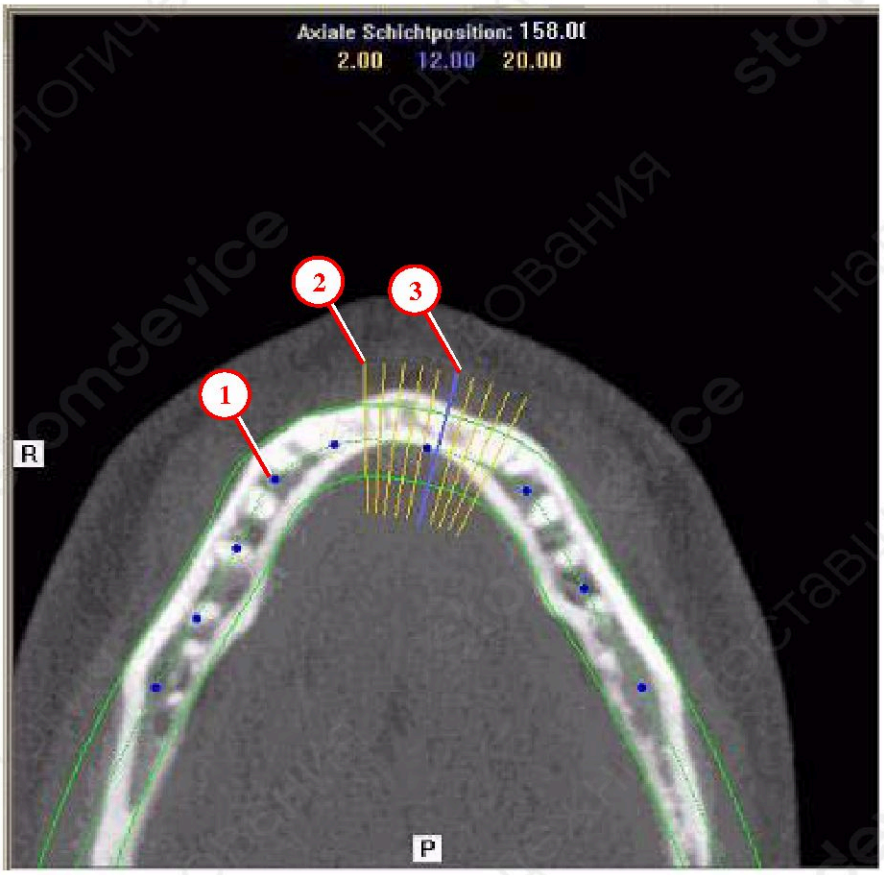
AXIAL TOOLS

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



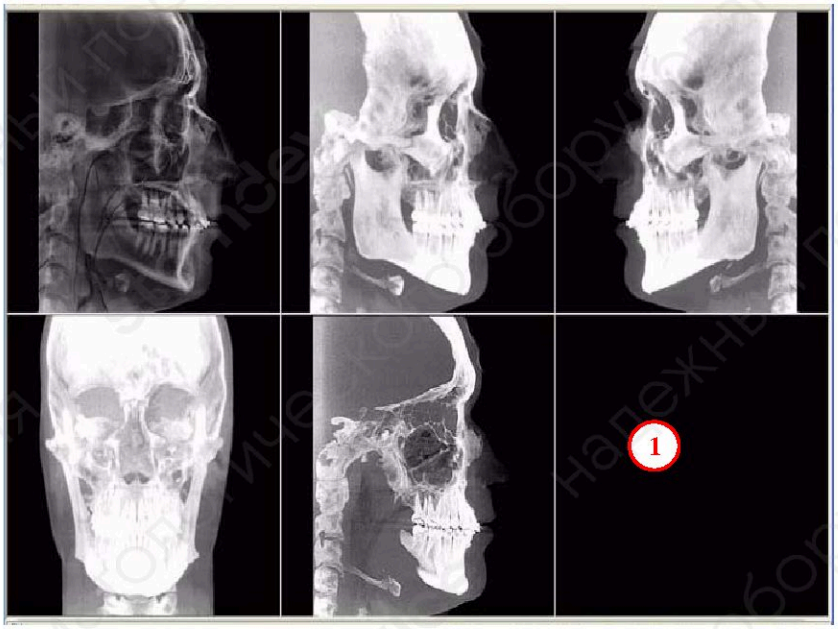
Axial Slice Position



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Ortho 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 Ortho screen.

REMINDER

Ortho Screen is acquired by double clicking Sagittal View from Preview window.

DISPLAYED VIEWS

The Ortho Screen displays the Lateral Cephs in Radiographic and MIP mode as well as a Coronal View and a Mid Sagittal Slice (15mm thick).

CURSOR TOOLS

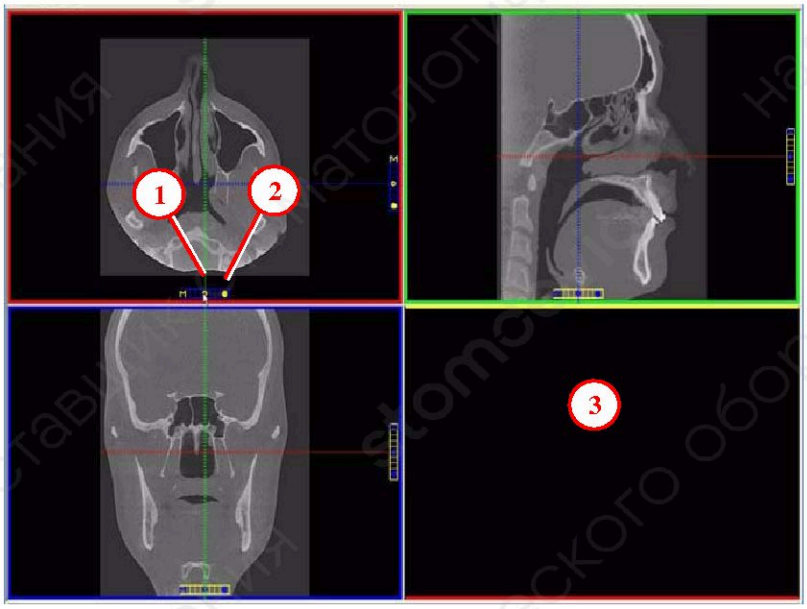
All views have Brightness/ Contrast, Zoom and Pan.

POP UP MENUS

Right click to display the Pop Up menu to select:

- Set Filters
- Save as JPEG
- Open Output Folder

MPR Screen



1. Drag center tools from any view to move slice location. The views are colored 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

MPR Screen is acquired by double clicking Coronal View from Preview window.

DISPLAYED VIEWS

The MPR Screen allows you to scroll through the Axial, Sagittal, and Coronal Slices.

CURSOR TOOLS

All views have Brightness/ Contrast, Zoom and Pan.

POP UP MENUS

Right click to display the Pop Up menu to select:

- Irregualar
- Line
- HU Statistics
- Distance
- Explore
- Explore Speed
- Set Filters
- Save as JPEG
- Open Output Folder
- Reset Volume Rotation

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REMINDER
TMJ Planning Screen is acquired by double clicking Axial View from Preview window.

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

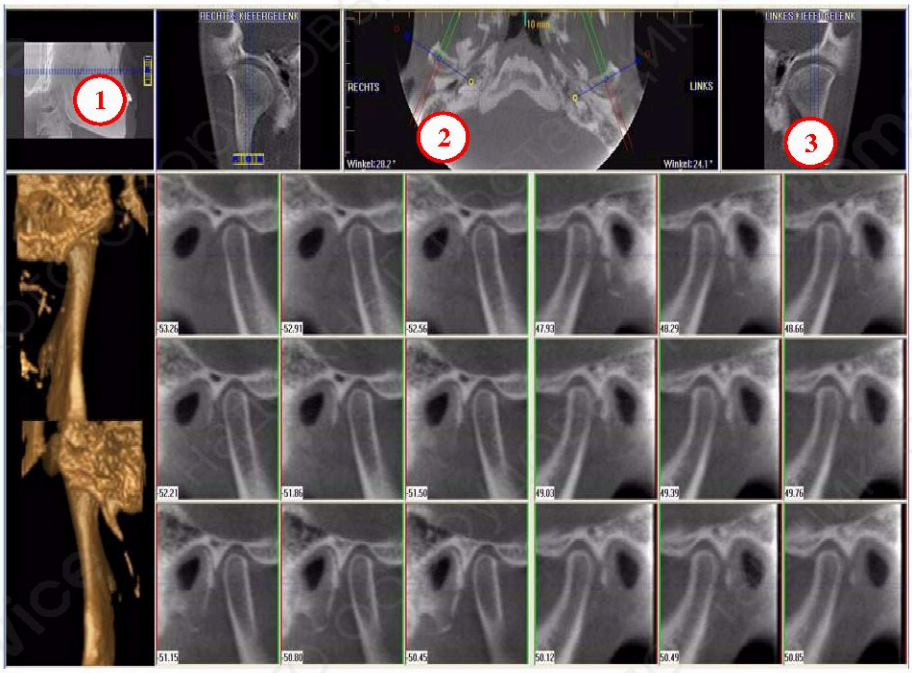
HINT
You may have to first drag the Axial (SMV) view down in the window to see the condyles. Move the cursor to the lower left of the SMV (axial) view until you see the "P" for pan tool to drag the image downward.

NOTE:
Make sure to Save Workups before attempting to burn to a CD,

Install Case Studies from CDs

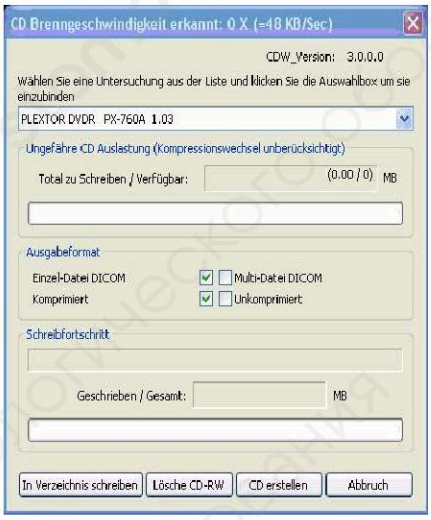
The iCATVision program will auto-run when the CD is inserted into the computer drive. The User can choose to install iCATVision and the case(s) Permanently or Temporarily. Once installed, the iCATVision program opens and the new case is highlighted in the patient list and ready to be loaded. Just click the patient name.

TMJ Planning Screen



1. Drag center tool to scroll up and down Sagittal view to locate condyles in the Axial view so you can see 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.

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