

K05/980

AUG 19 2005

510 (k) Summary

Submitters Information

<u>Name:</u>	Imaging Sciences International Inc.
<u>Address:</u>	1910 North Penn Road Hatfield PA, 19440
<u>Phone Number:</u>	215-997-5666
<u>Fax Number:</u>	215-997-5665
<u>Person To Contact:</u>	David W. Cowan Vice President of Engineering, Quality Assurance and Government Compliance
<u>Date Of Summary:</u>	July 20, 2005
<u>Trade Name Of The Device:</u>	DVT Scanner
<u>Common Or Usual Name:</u>	Computed Tomography X-ray System
<u>Classification Name:</u>	Computed Tomography X-ray System

Substantial Equivalence Claim: The Imaging Sciences International Inc. DVT Scanner is substantially equivalent to the devices listed below:

Device: NewTom QR – DVT 900
Manufacturer: NIM s.r.l.
Via Silverstrini, 20
37135 Verona
Italy
510 (k) Number: K003787

Device: Advantage 3-D XR
Manufacturer: General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex
France
510 (k) Number: K945375

Device: 3D Accu-I-tomo XYZ Slice View Tomograph
Manufacturer: J. Morita Manufacturing Corporation
680 Higashihama Minami-cho, Fushimi-ku
Japan
510 (k) Number: K030450

Description Of The Device: The DVT Scanner is a dedicated X-Ray imaging device that acquires a 360 degree rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The DVT Scanner can measure distances and thickness on two dimensional images. Images produced by the DVT Scanner can be printed or exported on magnetic and optical media.

The DVT Scanner gantry is comprised of an X-ray source, image detector, and motorized gantry. The gantry facilitates the acquisition of a full X-ray sequence by the software. The software receives the two dimensional images acquired by the detector, transforms them into three dimensional images and displays them on the workstation monitor for viewing.

Intended Use Of The Device: The DVT Scanner is an X-ray imaging device that constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Comparison with Predicate Devices: The DVT Scanner reconstructs a three dimensional model from X-ray images similar to the model obtained using the predicate

devices. It displays either two-dimensional cross-sections or three dimensional views and allows the user to take measurements on reconstructed images.

Conclusions: The DVT Scanner Acquires an X-ray rotational sequence and provides three-dimensional information on the analyzed volume. The potential hazards (e.g. electrical, mechanical, thermal, radiation, incorrect measurements or misdiagnosis) are controlled by the design development, verification and validation process which includes a risk management system.

The DVT Scanner complies with the requirements of 21 CFR 807.87 and does not pose any new safety risks or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2005

Mr. Dave Cowan
Vice President of Engineering, Quality
Assurance and Government Compliance
Imaging Sciences International, Inc.
1910 North Penn Road
HATFIELD PA 19440

Re: K051980
Trade/Device Name: DVT Scanner
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 20, 2005
Received: July 27, 2005

Dear Mr. Cowan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051980

Indications for Use

510(k) Number (if known): -K051980

Device Name: DVT Scanner

Indications For Use: The Imaging Sciences International Inc. DVT Scanner constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051980

Page 1 of 1



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Imaging Sciences International, Inc.
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Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051980

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 28, 2005

IMAGING SCIENCES INTL., INC.
1910 NORTH PENN RD.
HATFIELD, PA 19440
ATTN: DAVID W. COWAN

510(k) Number: K051980
Received: 27-JUL-2005
Product: DVT SCANNER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 21, 2005

IMAGING SCIENCES INTL., INC.
1910 NORTH PENN RD.
HATFIELD, PA 19440
ATTN: DAVID W. COWAN

510(k) Number: K051980
Received: 21-JUL-2005
Product: DVT SCANNER
User Fee ID Number:

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

IMAGING SCIENCES INTERNATIONAL INC.

1910 North Penn Road
Hatfield, PA 19440, USA

Phone (215) 997-5666
Fax (215) 997-5665, 5667

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville Maryland 20850 USA

July 20, 2005

RE: 510(k) Notification

Attention: Document Mail Center

This is to notify you of the intention of Imaging Sciences International Inc.,
1910 North Penn Road, Hatfield, PA 19440 to manufacture and market the
following device.

Classification Name: Computed Tomography X-ray System

Common / Usual Name: Computed Tomography X-ray System

Proprietary Name: DVT Scanner

Establishment Registration Number: 2530069

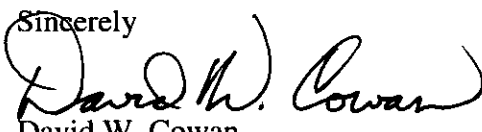
Classification Number: FDA has classified Computed Tomography X-ray
System Units in Class II, Product code JAK
(21 CFR 892.1740)

Performance Standard: Meets or exceeds the applicable sections of 21
CFR 1020.30 and 1020.33.

Promotional Material: Draft of Proposed Promotional Material.

Substantial Equivalence: This product is similar in design and function to
the NewTom QR-DVT 900 (K003787),
Advantage 3-D XR (K945375) and Accu-I-tomo
XYZ Slice View Tomograph (K030450)

David W. Cowan@imaging-science.com

Sincerely


David W. Cowan
Vice President of Engineering, Quality
Assurance and Government Compliance

*SKOS
RA
140
II*

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1910 North Penn Road
Hatfield, PA 19440, USA

Phone (215) 997-5666
Fax (215) 997-5665, 5667

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT FOR the DVT Scanner

[As Required by CFR 807.87 (j)]

I certify that, in my capacity as Vice President of Engineering, Quality Assurance and Government Compliance for Imaging Sciences International Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

A handwritten signature in black ink that reads "David W. Cowan". The signature is written in a cursive, flowing style.

David W. Cowan
Vice President of Engineering, Quality Assurance and Government Compliance

July 20, 2005

(Premarket Notification [510(k)] Number)

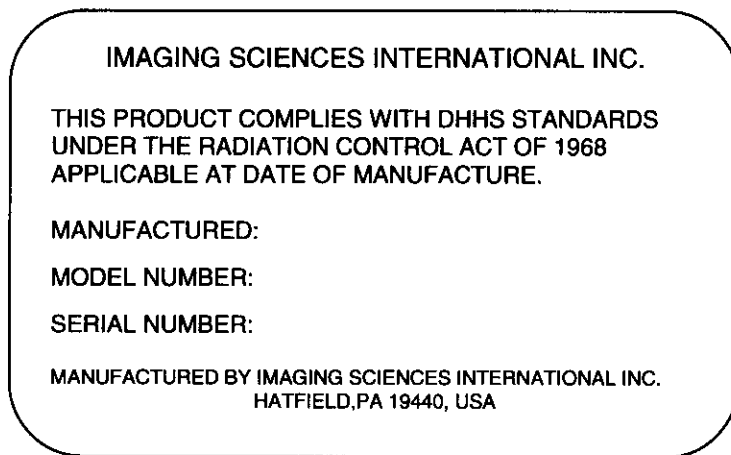
510 (k) Notification

Device Name:	Computed Tomography X-ray System
Proprietary Name:	DVT Scanner
Classification Name:	Computed Tomography X-ray System
Classification Type:	Class II, Product code JAK as per 21 CFR 892.1720
Establishment Registration Number:	2530069
Performance Standards:	Meets or Exceeds Applicable Sections of 21 CFR 1020.30 and 1020.33

DVT Scanner Labels

Imaging Sciences Identification Label:

This label will be applied to the machine, X-ray Tube Housing Assembly, X-ray Controller and Beam Limiter Device.



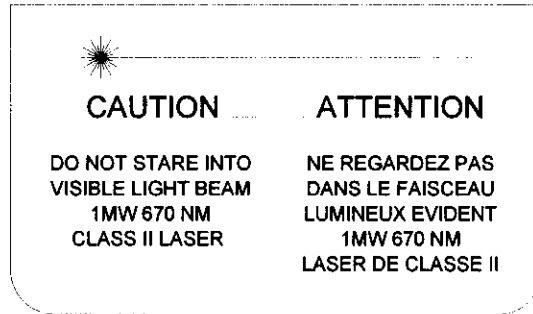
Warning Label:

This label will be affixed to the machine where removable covers are present.



Laser Light Caution Label:

This label will be affixed to the machine at a highly visible location.

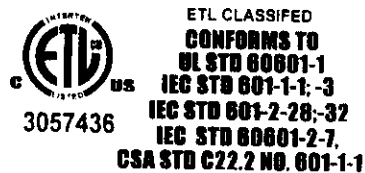


Certification Labels:

The equipment will be tested and/or evaluated to the following standards/requirements:

- UL 60601-1
- CSA C22.2 No. 601.1
- IEC/EN 60601-1
- IEC/EN 60601-1-1
- IEC/EN 60601-1-2
- IEC/EN 60601-1-3
- IEC/EN 60601-1-4
- IEC/EN 60601-2-7
- IEC/EN 60601-2-28
- IEC/EN 60601-2-32
- IEC/EN 60601-2-44
- IEC/EN 60825-1
- CE-MDD 93/42/EEC
- LVFS 2003:11 (Swedish regulation, transposing the MDD 93/42/EEC)
- CMDCAS (Canadian Medical Device Regulation)
- ISO 10993-1:2003
- ISO 14971:2000

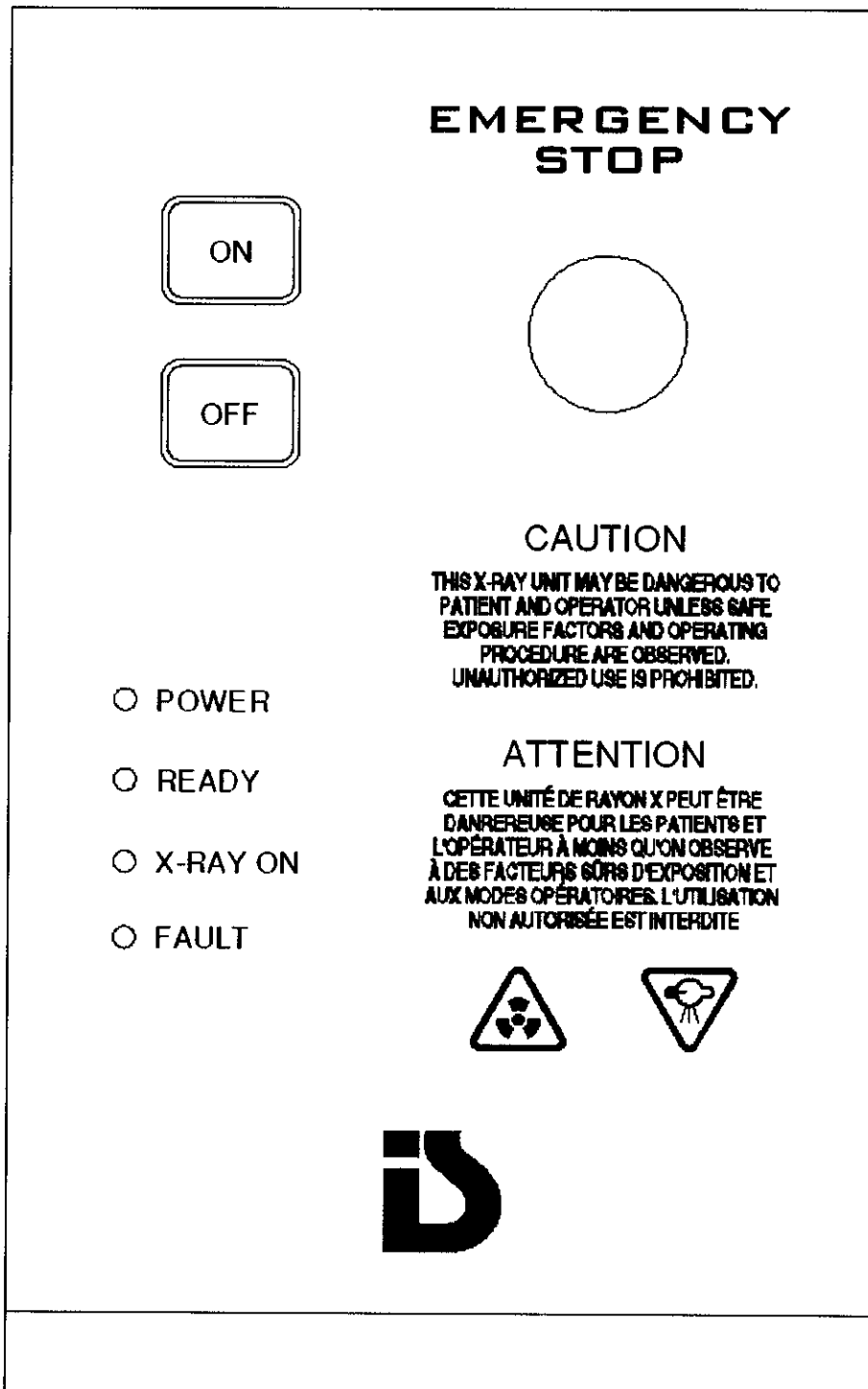
The following labels will be affixed to the rear of the machine.

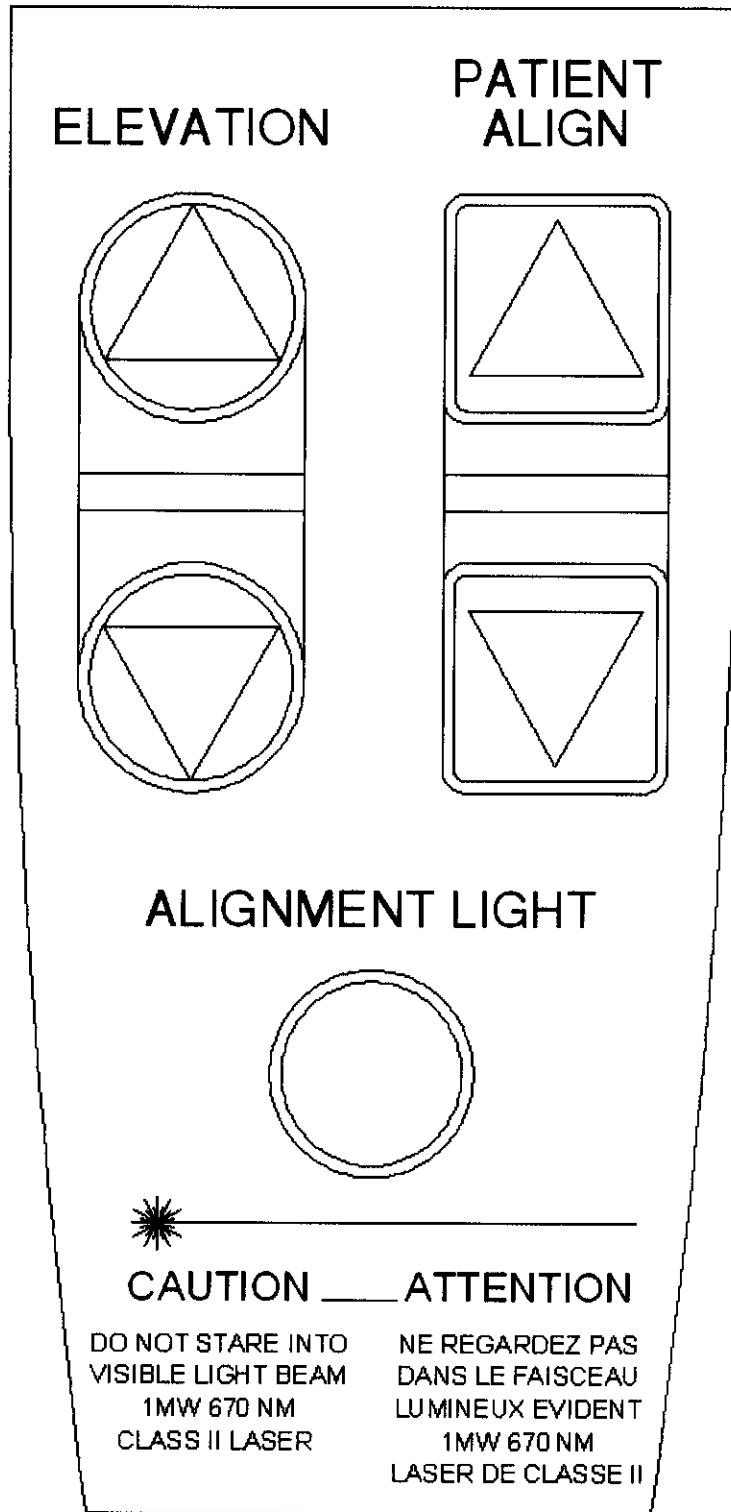


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Operator Control Labels:

The following labels will be located on the operator control boxes.





Software Analysis

(b)(4) Software



Computer Tomography X-Ray System Indications for Use

The Imaging Sciences International Inc. DVT Scanner constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Substantial Equivalence Comparison

The following discussion and charts will show that the Imaging Sciences International Inc. DVT Scanner and the NewTom QR-DVT 900 (K003787), Advantage 3-D XR (K945375) and Accu-I-tomo XYZ Slice View Tomograph (K030450) are substantially equivalent.

Intended Use:

The Imaging Sciences DVT Scanner has the same intended use as the predicate devices.

(b)(4)

A large black rectangular redaction box covering the content of the 'Intended Use' section.

Technical Comparison:

(b)(4)

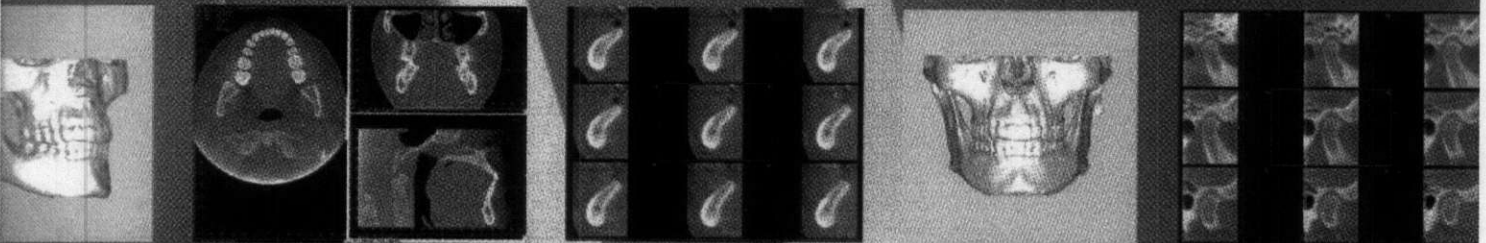
A very large black rectangular redaction box covering the entire 'Technical Comparison' section.



DVT

*Cone Beam 3-D Dental
Imaging System*

ENHANCING THE WAY YOU SEE PATIENTS.



Reduce costs while delivering better results

In-office, three-dimensional imaging is quick, easy, and cost effective

The DVT Cone Beam 3-D Dental Imaging System provides high-definition, in-office, three-dimensional, digital imaging at reduced cost and less radiation to the patient than traditional CT scans, as well as delivers quicker and easier image acquisition. Its small footprint and economic design allow practices to extend their service offerings and enhance the overall delivery of care, while offering the safest possible diagnostic techniques.



Scroll through anatomy in real-time. 1-minute reconstruction time for a standard scan provides an intuitive mapping tool for finding desired slice locations.

The DVT's technology and design place you at the center of patient care

Provides a full range of diagnostic services

The DVT's 3-D, volumetric imaging system provides dentists and specialists complete views of all oral and maxillofacial structures, giving the dental professional the most thorough diagnostic information possible for a variety of treatment areas, which allows for more accurate treatment planning and more predictable treatment outcomes.

Expands in-office continuum of care

The technology and design of the DVT puts advanced, in-office imaging within the realm of an expanding universe of practices- those that want to place themselves at the center of patient care by providing a full continuum of services, from diagnosis to treatment.

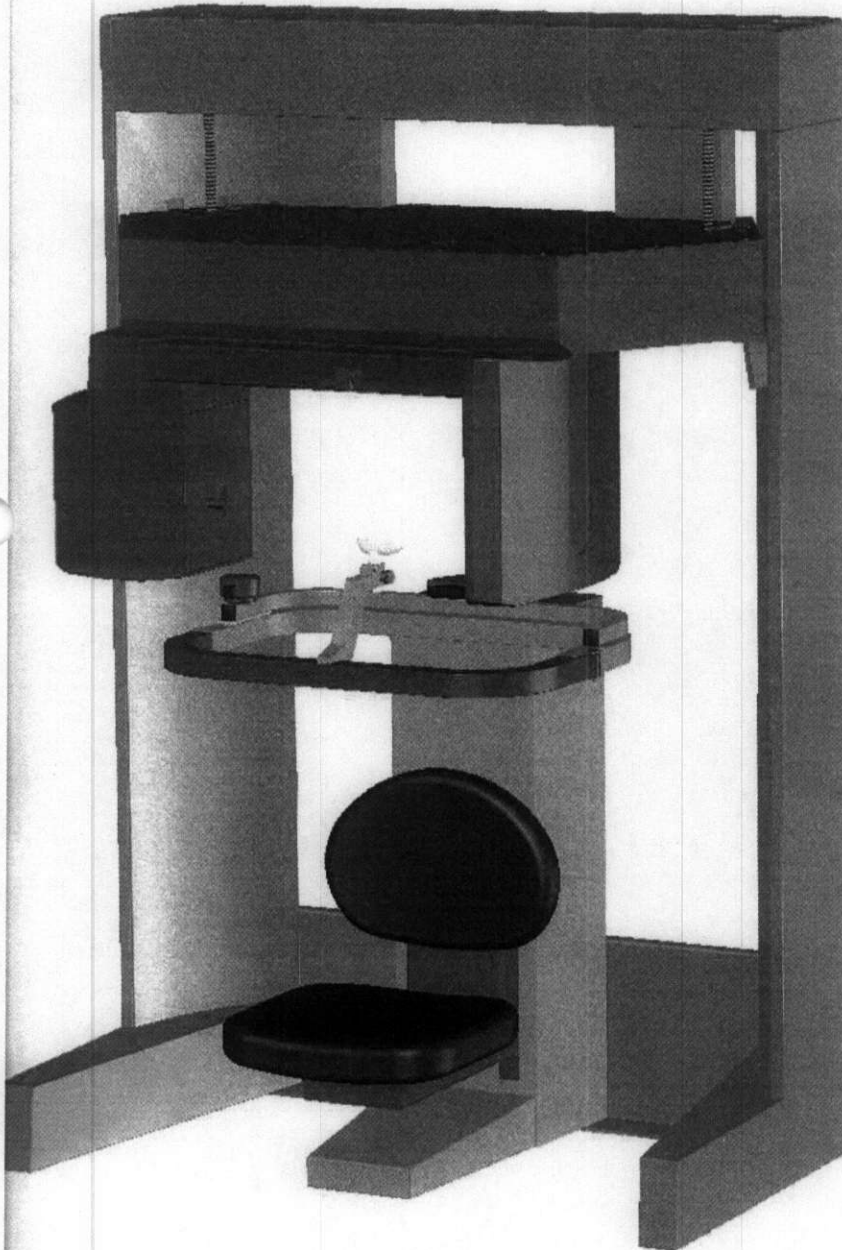
Saves chair-time with less radiation to patients

With a typical scan time of only 20 seconds or less, the patient is subject to significantly less radiation than traditional CT scans of the oral and maxillofacial region.



I used to order out at least five scans per week. With the DVT I do more scans than before right in my office and close more cases because there's no delay. The machine pays for itself, and I see a profit with five scans per month; but more importantly, the DVT gives my patients peace of mind about their procedures.

L. Scott Brooksby, D.D.S., M.A.C.P.
Las Vegas, Nevada



A small size unit delivering high quality imaging

DVT's design incorporates state-of-the-art digital imaging technology in a unit that makes economic sense, while delivering the quality of imaging demanded by today's practitioners.

The use of an advanced *amorphous silicon flat panel* image sensor reduces the overall size of the unit and delivers a higher image quality and resolution.

DVT Enhanced Features

Compact Design requires less than 60 square feet of floor space – can fit in place of most existing Pan machines

High Resolution Scan produces images at 2mm voxel size

Fast Scan Time (20 seconds) minimizes radiation and reduces chances of patient movement during scan – quicker and easier image acquisition

Adjustable Beam Collimation allows full height and targeted field of view scans, providing the ability to further minimize patient radiation

Comfort Design positions patient in an open environment seated position – allows patient comfort and captures natural orientation of anatomy

Fast Reconstruction Time provides the most complete views of all oral and maxillofacial structure in real-time – produces three-dimensional images in typically under one minute

Easy To Operate point-and-click remote makes **DVT** easy to use

DICOM 3 Compatible data makes it easy to share and integrate with 3rd party volume data software companies

12 bit Gray Scale quality allows more shades of gray to increase contrast for easier viewing

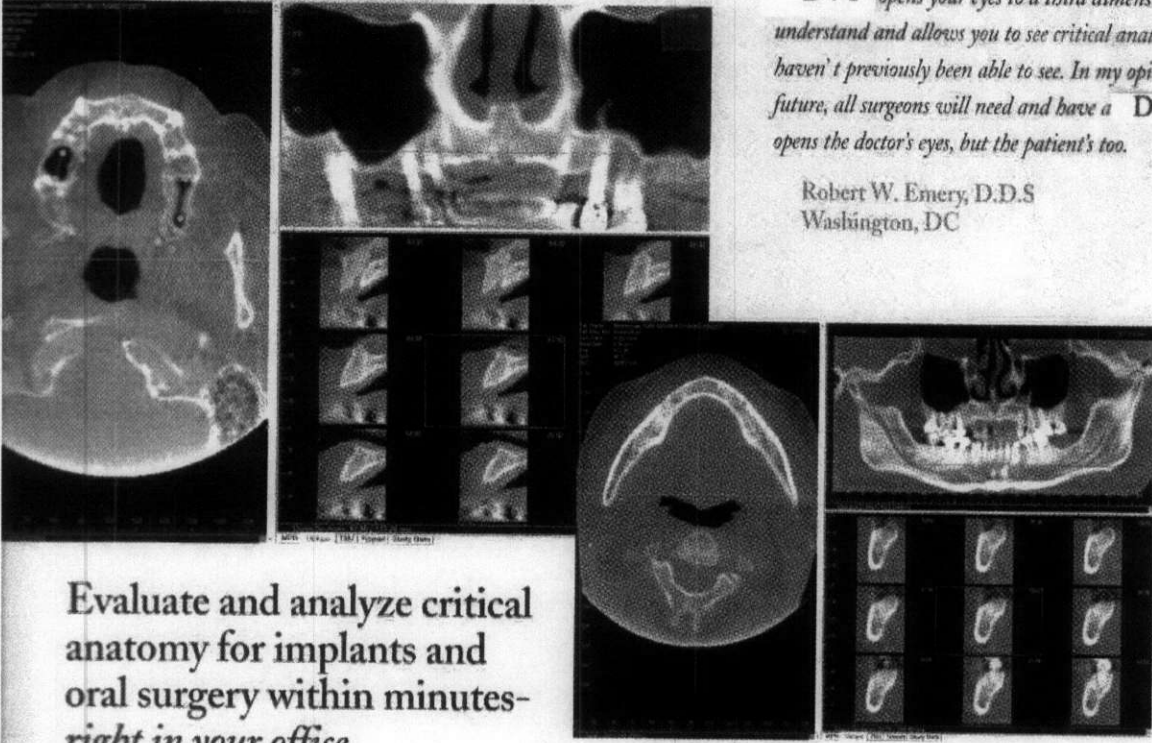
Report Printout function provides full-color reports with sophisticated clarity and precision

Priced Affordably (leasing options available)

3-D images assist in determining if bone grafting or sinus lift is warranted in areas of insufficient bone for the implant procedure.

DVT opens your eyes to a third dimension. It's easy to understand and allows you to see critical anatomy that you haven't previously been able to see. In my opinion, in the near future, all surgeons will need and have a DVT. It not only opens the doctor's eyes, but the patient's too.

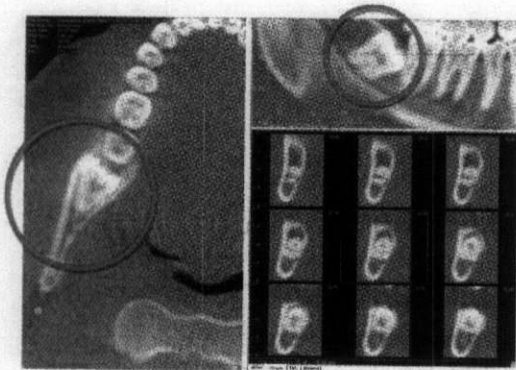
Robert W. Emery, D.D.S
Washington, DC



Precise, cross-sectional slices of any desired location in the maxilla or mandible provide exact anatomical information, including dimensions and locations.

Evaluate and analyze critical anatomy for implants and oral surgery within minutes—right in your office

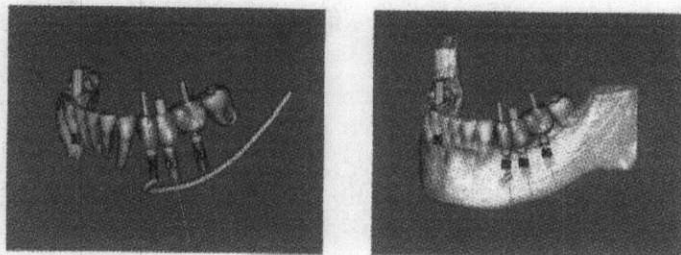
DVT's high resolution, volumetric images provide complete three-dimensional views of critical anatomy for more thorough analysis of bone structure and tooth orientation to optimize implant treatment and placement, and selection of the most suitable implant type, size, location, and angulations prior to surgery.



More accurate three-dimensional views of impacted molars
Determine more precise tooth position to visualize impaction within the alveolar bone, location relative to adjacent teeth, and proximity to vital structures, such as the nerve canal, sinus walls, and cortical borders.

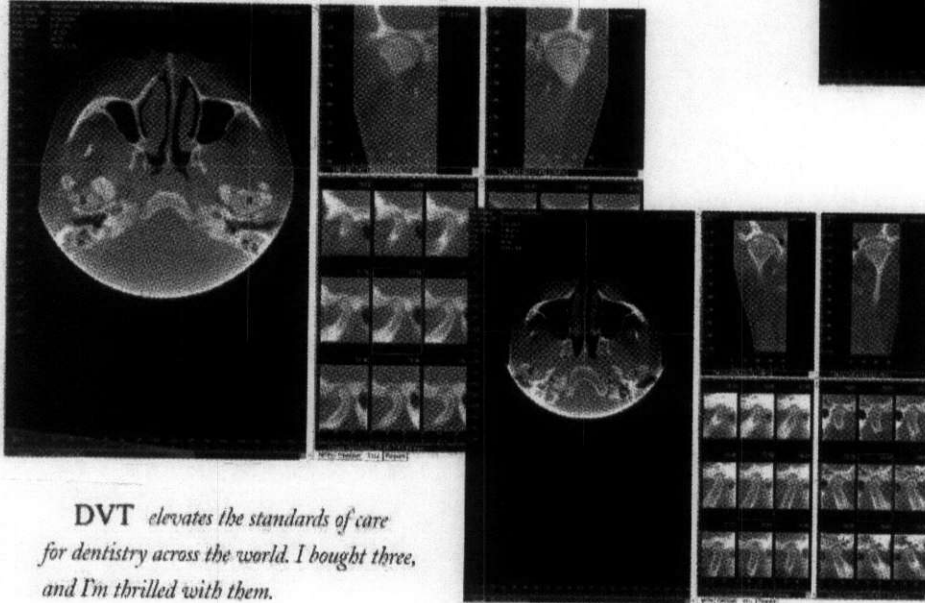
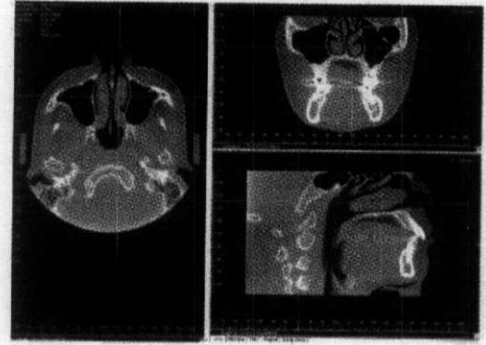
Detect and evaluate problems before they become serious
Accurately measure bone and jaw deformities, assess bone lesions and changes of the jaw, and detect other pathologies, such as cysts, tumors, and disease.

Send volume data to third-party software for 3-D model replacement



Three-dimensional views of critical structures for complete TMJ analysis

DVT's ability to provide three-dimensional images of the condyles and surrounding structures allows for complete analysis and diagnosis of bone morphology, joint space, and function – all critical to TMJ dysfunction treatment and care. Ten-second, high-speed scan captures TMJ open jaw views quickly and accurately.



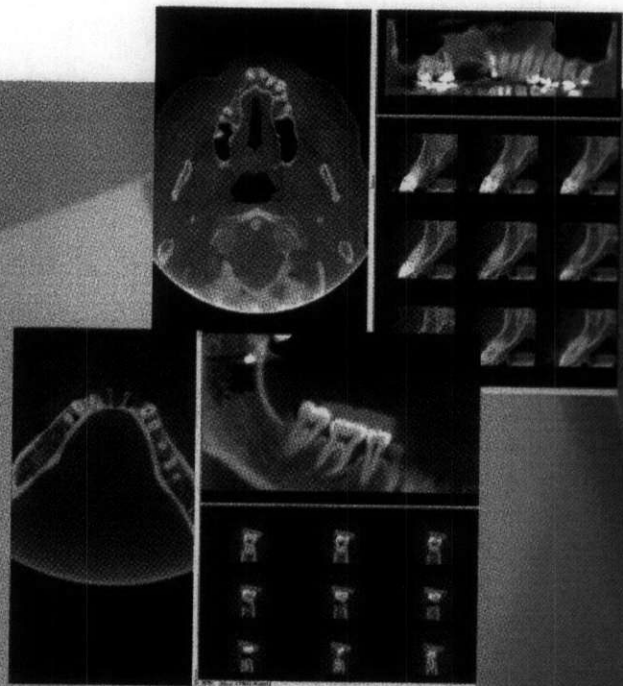
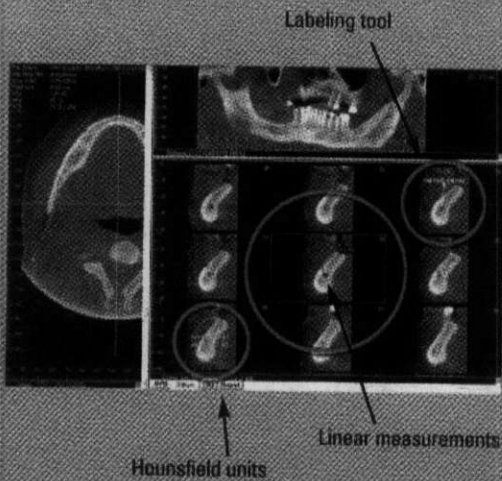
Detect restricted airways and determine appropriate treatments

Three-dimensional data enhances airway assessment and can result in reconsideration of the treatment plan if the patient has a typical airway, versus a restricted airway, which may be susceptible to collapse.

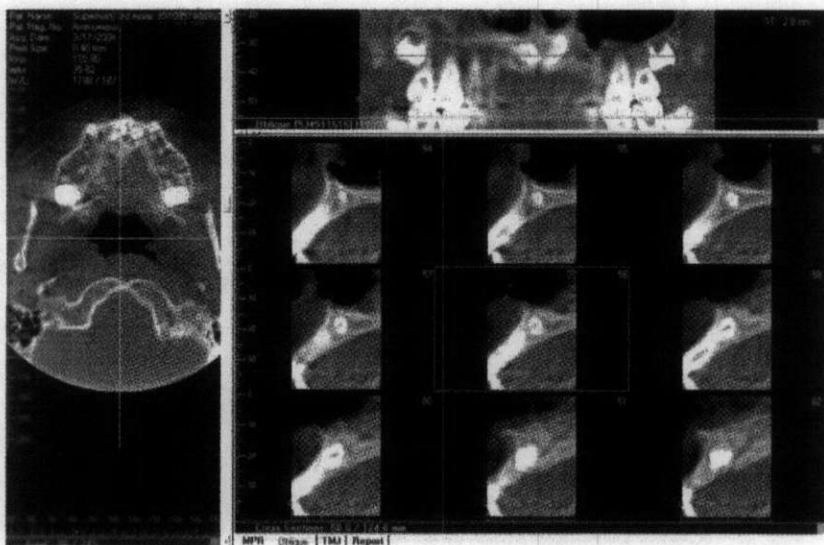
DVT elevates the standards of care for dentistry across the world. I bought three, and I'm thrilled with them.

Michael Gelbart, D.D.S.
New York, NY

DVT's Labeling and Measurement Tools



High resolution scans produce images at .2mm voxel size for 3rd molars, root canal relationships, small root fractures, periodontal conditions, and any other anatomy requiring detailed visualization.



*Patients with impacted cuspids, patients in need of implants, subtle and major asymmetries in orthodontic and orthognathic surgery cases, just to name a few, all can benefit greatly from **DVT's** ability to analyze the anatomic truth of the patient's actual anatomy.*

William Harrell Jr, D.D.S.
Alexander City, Alabama

Improving orthodontic diagnosis and treatment

The **DVT** gives today's orthodontists the tools to improve diagnosis and treatment planning by providing the multiple projection perspective necessary to accurately assess tooth relationships and further support the objective interpretation of anatomy.

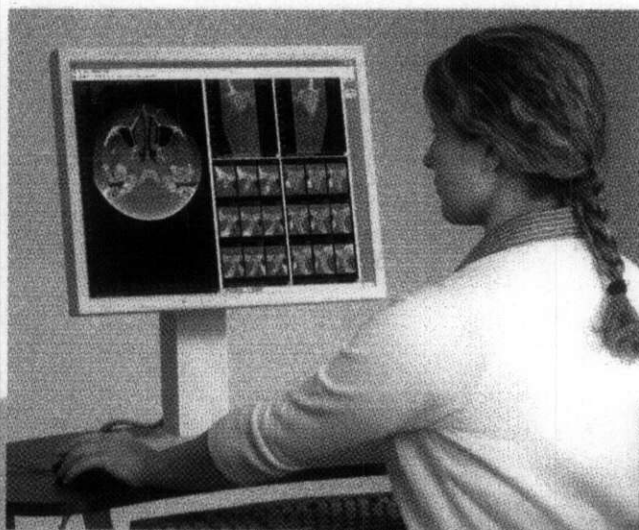
Understand exact tooth position and relationship of abnormal anatomy

Three-dimensional imaging technology provides more accurate viewing of impacted supernumerary or abnormal teeth in relationship to other anatomical structures, such as roots, nasal fossa, and sinuses to enhance accurate management of the treatment by understanding the tooth's position and its relationship to adjacent teeth and structures.

More accurate information can result in less invasive surgery if extracting the tooth and better designs to align the tooth if moving it.

**Picture
patient in DVT
with Gate open**

*Arm swings open
for easy access.*



*Follow the progress of patient treatment
with pre and post analysis scans.*

Machine Dimensions

DVT's Specs

X-ray Source: High Frequency, Constant Potential, fixed anode 120 kVp, 3-8 mA (Pulse mode).

X-ray Beam: Cone

Focal Spot: 0.5mm

Image Detector: Amorphous Silicon Flat Panel, 20 cm x 25 cm

Gray Scale: 12 bit

Voxel Size: 0.4 mm (typical), 0.2 mm (minimum)

Image Acquisition: Single 360 degree rotation

Scan Time: 20 seconds standard (options of 10, 20, 40)

Patient Position: Seated

Scan Dimensions: 17 cm (diameter) x 13 cm (height)

Primary Reconstruction: 1.5 minutes for standard 20 second scan

Secondary Reconstruction: Real Time



Enhancing the way you see patients.

Imaging Sciences International, Inc.
1910 North Penn Road
Hatfield, Pennsylvania 19440

phone 800.205.3570 215.997.5666
fax 215.997.5667

info@imagingosciences.com
www.imagingosciences.com

510 (k) Summary

Submitters Information

<u>Name:</u>	Imaging Sciences International Inc.
<u>Address:</u>	1910 North Penn Road Hatfield PA, 19440
<u>Phone Number:</u>	215-997-5666
<u>Fax Number:</u>	215-997-5665
<u>Person To Contact:</u>	David W. Cowan Vice President of Engineering, Quality Assurance and Government Compliance
<u>Date Of Summary:</u>	July 20, 2005
<u>Trade Name Of The Device:</u>	DVT Scanner
<u>Common Or Usual Name:</u>	Computed Tomography X-ray System
<u>Classification Name:</u>	Computed Tomography X-ray System

Substantial Equivalence Claim: The Imaging Sciences International Inc. DVT Scanner is substantially equivalent to the devices listed below:

Device: NewTom QR – DVT 900
Manufacturer: NIM s.r.l.
Via Silverstrini, 20
37135 Verona
Italy
510 (k) Number: K003787

Device: Advantage 3-D XR
Manufacturer: General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex
France
510 (k) Number: K945375

Device: 3D Accu-I-tomo XYZ Slice View Tomograph
Manufacturer: J. Morita Manufacturing Corporation
680 Higashihama Minami-cho, Fushimi-ku
Japan
510 (k) Number: K030450

Description Of The Device: The DVT Scanner is a dedicated X-Ray imaging device that acquires a 360 degree rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The DVT Scanner can measure distances and thickness on two dimensional images. Images produced by the DVT Scanner can be printed or exported on magnetic and optical media.

The DVT Scanner gantry is comprised of an X-ray source, image detector, and motorized gantry. The gantry facilitates the acquisition of a full X-ray sequence by the software. The software receives the two dimensional images acquired by the detector, transforms them into three dimensional images and displays them on the workstation monitor for viewing.

Intended Use Of The Device: The DVT Scanner is an X-ray imaging device that constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Comparison with Predicate Devices: The DVT Scanner reconstructs a three dimensional model from X-ray images similar to the model obtained using the predicate

devices. It displays either two-dimensional cross-sections or three dimensional views and allows the user to take measurements on reconstructed images.

Conclusions: The DVT Scanner Acquires an X-ray rotational sequence and provides three-dimensional information on the analyzed volume. The potential hazards (e.g. electrical, mechanical, thermal, radiation, incorrect measurements or misdiagnosis) are controlled by the design development, verification and validation process which includes a risk management system.

The DVT Scanner complies with the requirements of 21 CFR 807.87 and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) LOREN A. ZAREMBA

Subject: 510(k) Number K051980

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs)
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

90 - JAK, Class II

Review: R. A. Phillips RA03 8/11/05
(Branch Chief) (Branch Code) (Date)

Final Review: Nancy Brogdon 8-19-05
(Division Director) (Date)

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 051980

Reviewer: Zawanda

Division/Branch: DRARD/RDB

Device Name: DVT Scanner

Product To Which Compared (510(K) Number If Known): K003787

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Go To 10 If YES = Stop <u>SE</u>
8. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
9. Accepted Scientific Methods Exist?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Stop NE
10. Performance Data Available?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input type="checkbox"/>	<input type="checkbox"/>	Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: *Dental CT*
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(K) Review

K05-1980

GENERAL INFORMATION

Company Name: Imaging Sciences International, Inc.

Address: 1910 North Penn Road
Hatfield, PA 19440

Dated: July 20, 2005

Received: July 27, 2005

Contact: David W. Cowan
Vice President of Engineering, Quality Assurance
and Government Compliance
Phone: 215 997 5666, Email: cowand@imagingsciences.com

Tradename: DVT Scanner

Common Name: Dental CT Scanner

Intended Use: Dental CT

Device to Which Equivalence is Claimed:

Manufacturer: NIM s.r.l.
Tradename: NewTom QR – DVT 900
510(k) Number: K003787

Manufacturer: General Electric Medical Systems
Tradename: Advantage 3-D XR
510(k) Number: K945375

Manufacturer: J. Morita Manufacturing Corp.
Tradename: 3D Accu-I-Tomo XYZ Slice View Tomograph
510(k) Number: K030450

Applicable Guidance: None

Standard Questions:

1. Is the device subject to postmarket surveillance? No
2. Is a summary or certification of safety and effectiveness included? Summary
3. Is the device life supporting or life sustaining? No
4. Is the device implanted? (short term or long term) No
5. Does the device use software? Yes
6. Is the device sterile? No
7. Is the device for single, home or prescription use? Prescription
8. Does the device contain drug or biological products? No
9. Is the device subject to the Radiation Control Act or other Standards?
Radiation Control Act (21 CFR 1020.33)

DETAILED REVIEW

Device Description:

Indications –

The Imaging Sciences International, Inc. DVT Scanner constructs a three dimensional model from images taken during a rotational x-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM joint studies, mandible and maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Technical Characteristics –

(b)(4)



Laboratory and Clinical Data:

(b)(4)



Labeling:

(b)(4)



Software:

(b)(4)



Substantial Equivalence:

(b)(4)



Recommendation:


I believe that this device is substantially equivalent to:

90 – JAK – Computed Tomography X-ray System

Classification should be based on:

892.1750 – Computed Tomography X-ray System

Class: II



Loren A. Zaremba

8-16-05

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K051980

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	 ✓	
b) Sterilization and expiration dating information:	N/A	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method	/	
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: Joren H. Jansen
 Concurrence by Review Branch: _____

Date: _____

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?		
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Indications for Use

510(k) Number (if known): K051980

Device Name: DVT Scanner

Indications For Use: The Imaging Sciences International Inc. DVT Scanner constructs a three dimensional model from images taken during a rotational X-ray sequence. The DVT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The DVT Scanner is optimized for imaging of TM Joint studies, mandible & maxilla for implant planning, sinuses, the maxillofacial complex, temporal bone, etc.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



OPERATOR'S MANUAL

Cone Beam Volumetric Tomography and Panoramic Dental Imaging System



IMAGING SCIENCES INTERNATIONAL, INC.

1910 North Penn Road, Hatfield, PA 19440

United States of America

Phone 215-997-5666 Fax 215-997-5665, 5667



Part number 990310

August 01, 2005

IMAGING SCIENCES INTERNATIONAL, INC.

1910 North Penn Road, Hatfield, PA 19440
United States of America

Phone 215-997-5666 Fax 215-997-5665, 5667

For more information or an original version of documentation on the IS i-CAT Imaging System, please write, call or fax to Imaging Sciences International Inc. at the above address. This documentation has been drafted, approved & supplied in the English Language. Imaging Sciences International will make available under request any component parts, calibration instruments, circuit diagrams, etc.

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Printed in the United States of America



OPERATOR'S MANUAL

Cone Beam Volumetric Tomography and Panoramic Dental Imaging System



Part number 990310

August 01, 2005

I-CAT OPERATIONS MANUAL

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Part number 990310

August 01, 2005

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Standard Limited Warranty

Warranty

Imaging Sciences International, Inc. (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 during shipment;

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 lighting;

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;

Damage caused by any other abuse, misuse, mishandling, or misapplication.

Under no circumstances shall ISI be liable for any special, incidental, or consequential damages based upon breach of warranty, breach of contract, negligence, strict liability or any other legal theory. Such damages include, but are not limited to, loss of profits, loss of revenue, loss of use of hardware system or any associated equipment, cost of capital, cost of substitute or replacement equipment, facilities or services, down time, purchaser's time, the claims of third party, including customers, and injury to property.

Disclaimer of Warranties.

The warranty stated above is the only warranty applicable to this product, all other warranties, expressed or implied including all implied warranties of merchantability or fitness for a particular purpose, are hereby disclaimed. No oral or written information, or advice given by ISI, its agents or employees shall create a warranty or in any way increase the scope of this warranty.

Part number 990310

August 01, 2005

Technical Specifications

The i-CAT Imaging System is a Cone Beam Volumetric Tomography and Panoramic x-ray machine for Dental head and neck applications & is suitable for an in-office environment.

System Specifications:

X-ray Source

Tube Voltage: 120 kVp
 Tube Current: 3-8 mA
 Voltage Waveshape: Constant Potential
 Focal Spot: 0.0197 inches (0.5 mm)
 Duty Cycle: 3%
 Source to Sensor distance: 27 inches (68.58 cm)

Minimum Filtration (at 120 kVp)
 (mm of aluminum equivalent): greater than 3 mm

Maximum Specified Energy
 Input for 1 hour: 120 kVp at .5 mA
 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

Beam Size: Cone, 0.5" x 0.5" to 8" x 10"
 (1.27 cm x 1.27 cm to 20.32 cm x 25.4cm)

Image Detector:

Amorphous Silicon Flat Panel,
 7.87 inches x 9.84 inches
 (20 cm x 25 cm)

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

Gray Scale: 12 bit

Voxel Size: 0.0157 inches (typical), 0.0079 inches (minimum)
 (0.4mm (typical), 0.2mm (minimum))

Image Acquisition: Single 360 degree rotation (maximum)

Scan Time: 40 seconds or less

Scan Dimensions: 6.69 inches (diameter) x 4.33 inches (height)
 (17cm (diameter) x 11cm (height))

6.69 inches (diameter) x 6.69 inches (height)
 17cm (diameter) x 17cm (height)

Primary Reconstruction: About 2 minutes

Secondary Reconstruction: Real Time

*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.

Power Requirements:

Line Voltage: 115V or 230V
 (Factory set)
 Line Voltage Regulation requirement: ± 10%
 Line Current: 10 Amps (115V) or 5 Amps (230V)
 Line Frequency: 50 Hz / 60 Hz
 Phase: Single
 Main Circuit Breaker: 10 Amps (115V) or 5 Amps (230V)

Environmental Conditions:

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

Minimum Requirements for Acquisition Computer Provided with the System:

Pentium-4 Processor, 2.4 GHz minimum
 Windows 2000 Professional Operating System
 70 GB Hard drive
 2 GB RAM
 18" (46 cm) Flat Panel display
 Video Memory of 16MB minimum
 2 Network Interface Cards (Ethernet)
 1 serial port, 9-pin
 3 USB ports

Patient Support chair:

Overall dimensions: 30.5"d x 29"w x 50.5"h
 (77.5 cm x 73.7 cm x 128.3 cm)
 Weight: 115 lbs (52 kg)
 Seat height adjustment: 12.5" to 21.5"
 (31.8 cm to 54.6 cm)
 Maximum patient weight: 300 lbs (136 kg)
 Complies with IEC 60601-2-32:1994

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Machine Markings:



Non – ionizing radiation



Class B equipment



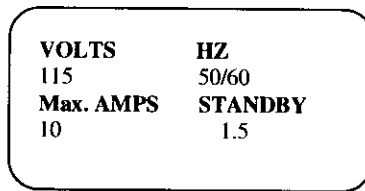
Attention, Warning



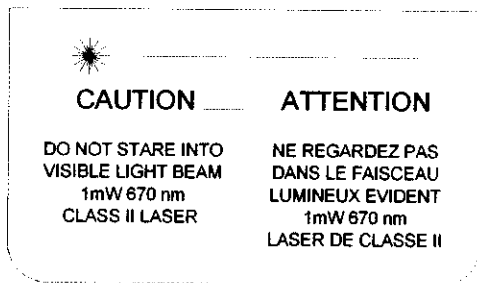
Danger, Electric Shock



Protective Earth, Ground



Typical Input Power Label



Laser Light Caution

CAUTION

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

ATTENTION

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



X-ray Caution



ATTENTION
Pinch point
Keep hands clear
during operation.

ATTENTION
Point d'invariance
Maintenez les mains claires
lors du fonctionnement.

Pinch Point Caution

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Safety Items:

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.

Radiation Protection Guidelines:

Dental X-ray equipment may cause injury if used improperly. All included operating instructions regarding the use of the i-CAT Imaging System must be followed. All government and local regulations pertaining to radiation safety must be observed. Maintain safe distance from the x-ray source. Refer to chapter 6 for details.

Warning System:

The i-CAT Imaging 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, 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 i-CAT Imaging 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.

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 being used.

Interlock System:

The i-CAT Imaging 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.

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 have not been provided with the i-CAT Imaging System.

External Item:

Do not connect any items or equipment to this i-CAT Imaging System which are not part of the system.

Cleaning:

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

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Electromagnetic or other Interference (Emissions and Immunity):

The i-CAT Imaging System has been 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 i-CAT Imaging 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. Proper precautions and equipment location should be observed, refer to the following table:

The i-CAT Imaging System is intended for use in an electromagnetic environment specified below. The customer or user of the i-CAT should ensure that it is used in such an environment.		
Immunity Test	Electrostatic Environment- Guidance	
Electrostatic Discharge (ESD) IEC 61000-4-2	Compliant to ± 4 kV. Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%	
EFT and Surge IEC 61000-4-4 and -4-5	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage Dips/Dropout IEC 61000-4-11	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 i-CAT be powered from an uninterruptible power supply.	
Conducted RF IEC 610000-4-6	Portable and mobile communication equipment should be separated from the i-CAT by no less than 19 feet (6 meters).	
Radiated RF IEC 61000-4-3	The i-CAT Imaging System is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user of the i-CAT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the i-CAT as recommended below, according to the maximum output power of the communications equipment.	
	Maximum Output Power (Watts)	Separation 150 kHz to 800 MHz
		Separation 800 MHz to 2.5 GHz
	0.01	15 in (38 cm)
	0.1	15 in (38 cm)
	1	46 in (117 cm)
	10	12 ft (3.7 m)
100	38 ft (11.7 m)	
Note: Field strengths from transmitters, as determined by an electromagnetic site survey, should be less than the compliance level of 3 V/m.		

If the i-CAT Imaging System does cause harmful interference to surrounding equipment which can be determined by turning the i-CAT off and on, the customer or user is encouraged to try to correct the interference by one or more of the following methods:

- Increase the separation between the i-CAT Imaging System and surrounding equipment.
- Connect the i-CAT Imaging System into an outlet on a circuit different from that to which the surrounding equipment is connected.
- Consult Imaging Sciences International, Inc., the dealer or an experienced technician for help.

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

Equipment Standards and Class:

The i-CAT Imaging System has been tested and/or evaluated against and found compliant to the following standards/requirements:

UL 60601-1
CSA C22.2 No. 601.1
IEC/EN 60601-1
IEC/EN 60601-1-1
IEC/EN 60601-1-2
IEC/EN 60601-1-3
IEC/EN 60601-1-4
IEC/EN 60601-2-7
IEC/EN 60601-2-28
IEC/EN 60601-2-32
IEC/EN 60601-2-44
IEC/EN 60825-1
CE-MDD 93/42/EEC
LVFS 2003:11 (Swedish regulation, transposing the MDD 93/42/EEC)
CMDCAS (Canadian Medical Device Regulation)
ISO 10993-1:2003
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
(Procedure for the Owner or User)**

Equipment Maintenance:

Daily:
Routine dusting - all surfaces

Monthly:
Clean all surfaces
Check for defective 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 Inc. 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)

<u>Tube Housing Assembly</u>	12 MONTHS	TEST	INSPECT
• Certification Label	x		
• Warning and Indicators	x		x
• Oil Leaks	x		x
• Physical Damage	x		x
• Mounting System Stability	x		x
<u>Beam Limiting Device</u>			
• Physical Damage	x		x
• Certification Label	x		x
<u>X-Ray Controller</u>			
• 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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Desktop Computer Maintenance:

The i-CAT system consists of both the Machine itself and the Desktop Computer which operates the machine. There are key files and subfolders which are automatically updated by the computer system during operation. These files and folders must be backed up daily or at the maximum weekly. The following files/folders should be copied:

XoranData.mdb
 Xoran.xml
 Profiles.xml
Data subfolder
Study subfolder

The files/folders are located in **Program Files\Imaging Sciences\iCAT** folder.

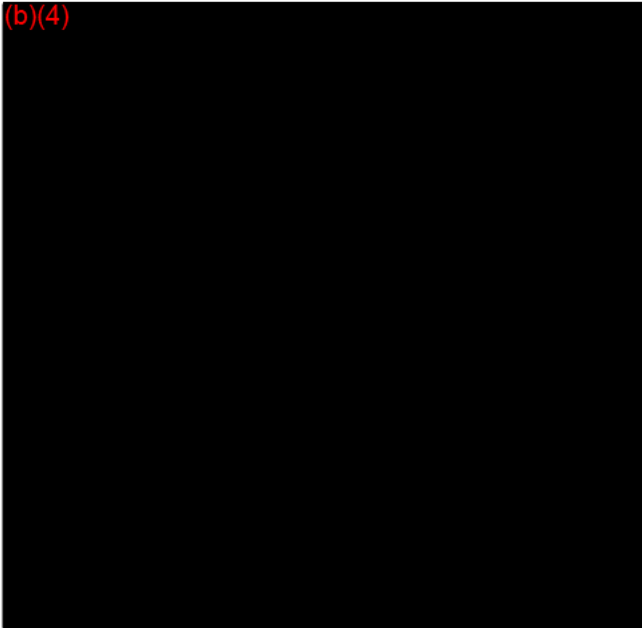
Recommended Spare Parts List

Sub Assembly No.	Description
700230	IO BOARD
800125	COMPUTER MONITOR & KEYBOARD
800180-1	VARIAN COMMAND PROCESSOR
800180-2	VARIAN RECEPTOR
800180-3	VARIAN POWER SUPPLY
800450	MOTHERBOARD
800451	COMPUTER BACK PLANE
800455	EPIX CARD
800505	COMPUTER POWER SUPPLY
9100-1101-0000	STEPPER MOTOR-34 ASSEMBLY
9100-1270-0000	STEPPER MOTOR POWER SUPPLY
9140-0035-0000	C.T. TUBE HEAD
9140-0037-0000	C.T. BEAM LIMITER
9140-1000-0000	X-RAY POWER SUPPLY ASSEMBLY
9140-1420-0000	ELEVATION REMOTE
9140-1421-0000	CT ON OFF BOX
9140-1422-0000	PATIENT E-STOP BOX
950159	EPIX DATA CABLE
9869-1539-0000	LASER, Straight Line
9140-1539-0000	LASER, Cross

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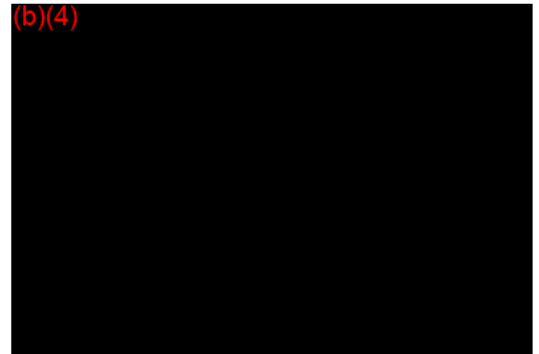
Equipment Diagram:



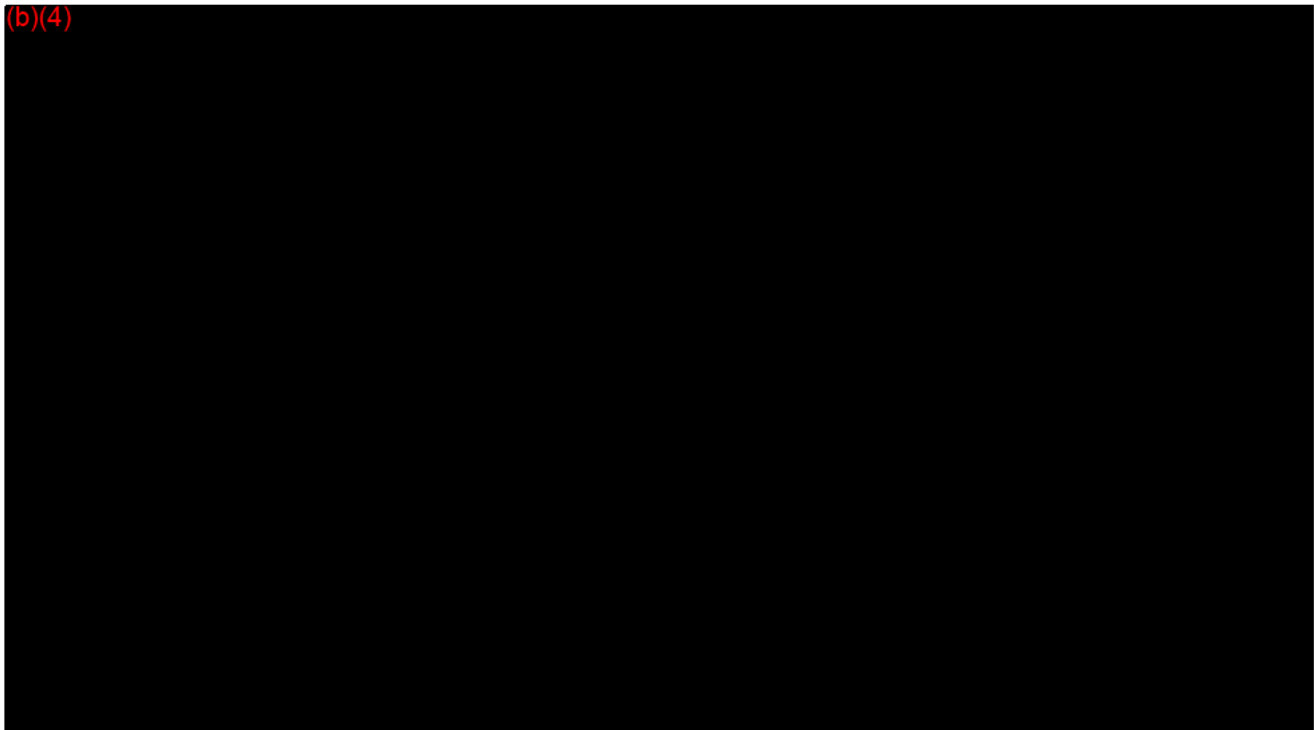
Internet Requirements

High Speed Internet
Connection Recommended
For Software Updates

Machine Weight 425 lbs.[193kg]



FRONT VIEW



Warning: The Computer, Main Control Box and Operator must be located a safe distance from the X-ray source, refer to Chapter 6 for details.

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i-CAT: Chapter 1

Machine Start Up

1.1 Start Up

The i-CAT system consists of both the Machine itself and the Desktop Computer which operates the machine. In order for the system to work, the machine and the desktop computer must be turned on and Ready to function.

The machine has an on-board computer that boots up similar to any desktop computer. Before launching the software on the desktop, the machine's on-board computer must be booted.

1. Turn On the computer via the computer ON button (on the face of the computer).
2. Turn On the machine via the Machine ON button (on the I-CAT Main Control Box, see picture below).



When the machine is ON, the *Power* light will shine green on the Main Control Box.

3. When both desktop computer and Machine are booted & Ready, then launch the I-CAT program by double clicking on the I-CAT icon. (NOTE: the machine should be ON at least 2 hours before an Acquisition for optimal results).

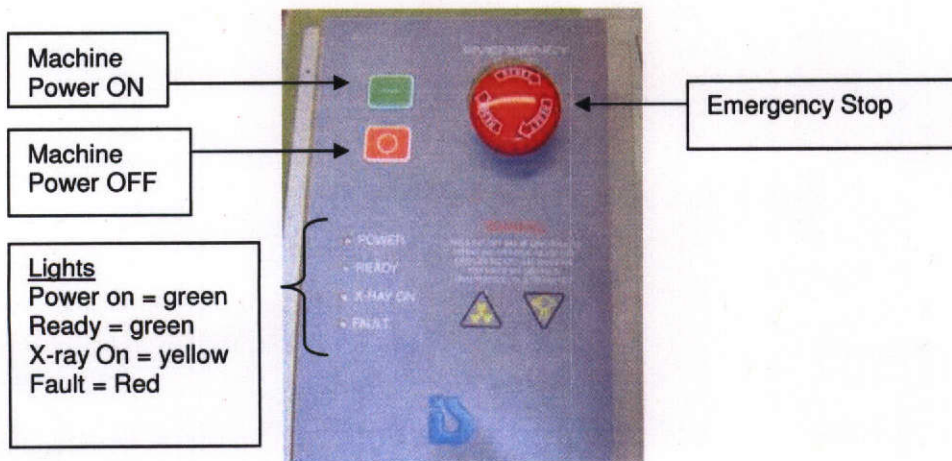
1.2 Controls

Main Control Box: below is a picture of the I-CAT Main Control Box.

This box contains:

1. Power ON / OFF buttons
2. Emergency Stop button
3. Lights for: Power On, Ready, X-ray On, Fault.

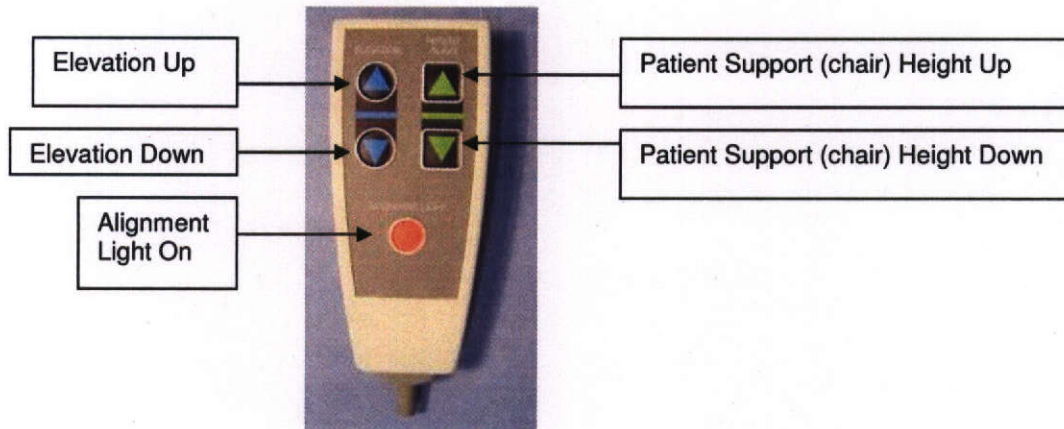
The same Light configuration is on the front overhead cover of the machine, except the fault light).



Hand Control Box: Below is a picture of the Hand Control Box.

This box contains:

1. Overhead Elevation Up and Down buttons (blue).
2. Patient Support (chair) height Up and Down buttons (green).
3. Alignment Light On button (red). This light will stay on for 10 seconds.



Patient Emergency Stop Control: Below is a picture of the patient Emergency Stop Hand control box. This can either hang on the head support mechanism within easy reach of the patient or be held in the patient's hand.

This box contains:

1. Emergency Stop button



1.3 Procedures

1. The i-CAT captures data for 3D Skull Reconstruction for the following procedures:
 - Implants
 - TM Joints
 - Panoramic
 - Airway / Sinus, etc.
 - 13.2 cm height Cephalometrics
 - Optional feature for 17 cm height Orthographic Cephalometrics (not yet available).
 - Optional feature for 17 cm height Conventional Cephalometrics (not yet available).
2. The i-CAT has an Optional Conventional Panoramic feature.

1.4 Shut Down

To Shut Down the i-CAT:

1. Close the i-CAT software by clicking *File / Close* from the Main Menu.
2. From the Main Control Box, press the OFF button.



The *Power* light will turn off.

i-CAT: Chapter 2**Acquisition of Scan****2.1 Software Setup****1. Entering a New Patient:**

From the I-CAT Main Menu, click PATIENTS / ENTER. This will display the window for entering patient information. Alternately, click on FIND / START OVER at the bottom of the Patient Database window.

The first item in the Patient data is a **Pat. Reg. No.** A Unique patient number must be added, such as a patient file number or social security number. The only fields requiring an entry are **Last and First names**. The other fields are optional and can also be entered at a later time.

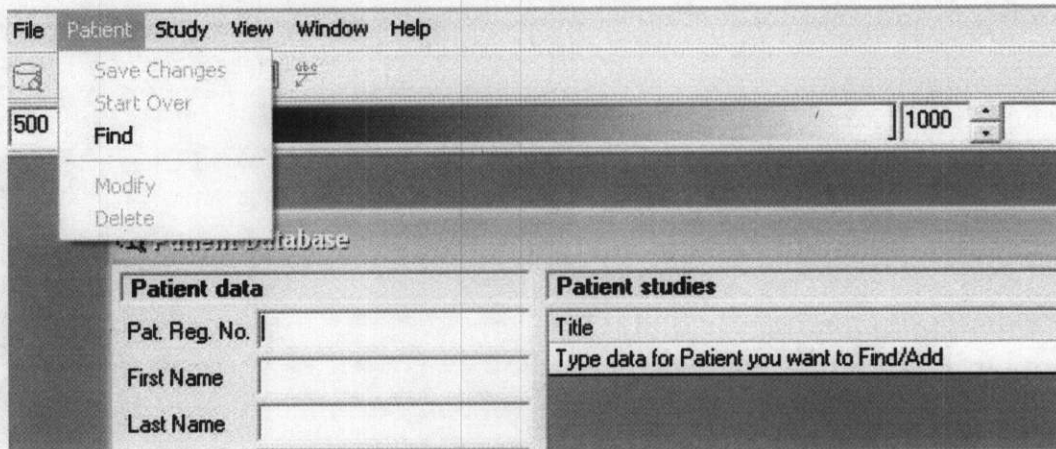
Once the Patient data is entered, click the **SAVE** button. Once you click SAVE, the patient name will display under the *Patient Studies* section, under Title (by Last Name). Highlight this Name.

Next, click on the **ACQUIRE NEW** button. Before proceeding, we must position the patient. See the next section **2.2 on Patient Positioning**.

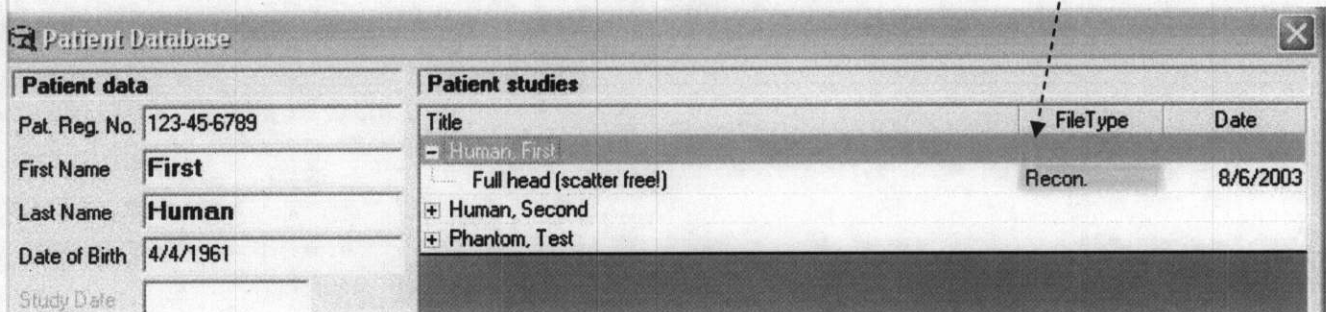
Note: You will be prompted to enter a "**Study Title**" upon Acquiring a New scan. This is optional, but recommended for clearly identifying each scan if doing multiple scans. If you do multiple scans, each scan will be saved under the Patient Name as the Study Title.

2. If you want to *Retrieve an Existing Patient* that has already been scanned, follow these instructions:

At the Main Menu, Click *Patient / Find*



The list of Patients will now display under **Patient Studies**. Click on the + next to the Patient you wish to retrieve. This will show a list of all the scans that have been completed for that patient. If a patient has multiple scans (eg: TMJ closed, TMJ open), then both will be listed. Next to the scan of choice (Study Title), click on **Recon** (Reconstructed) button.

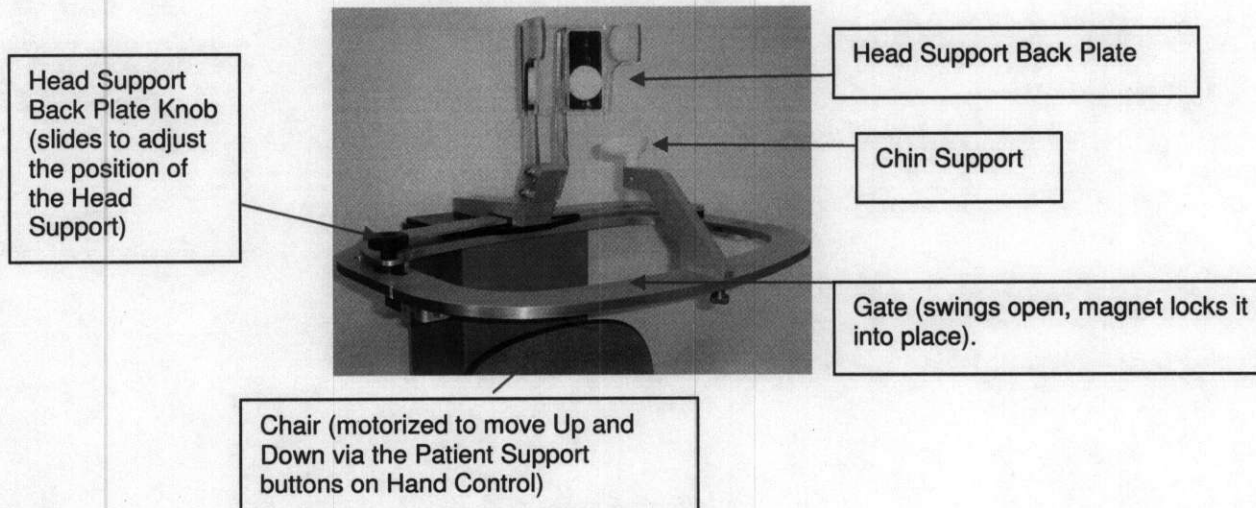


This will load the Patient data to the Main display for this patient. The Main Display is the viewing area of the axial, coronal and sagittal views of the skull through midline.

If you want to Acquire a New scan, then click on the ACQUIRE NEW button. Again, before proceeding, see the next section **2.2 on Patient Positioning**.

2.2 Patient Positioning

Patient Chair and Support Gate



1. With the gate open, have the patient seated in the chair facing forward. The patient should be seated comfortably with hands in lap.
2. Close and Lock the Gate, making sure the magnet is secured in its locked position.
3. Adjust the Patient Chair height:

To do this, Use the Hand Control Box, **Patient Support Alignment Arrow buttons (green), Up or Down** to the correct height for the Patient, so that the patient's chin is able to sit on the chin cup at the appropriate tilt (below).

Tilt:

Make sure that 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 on next page).

NOTE: If the User opts to utilize the Velcro strap instead of the chin support, first remove the chin support from the gate, then make sure that the chair height is high enough so that the patient's head can rest against the back plate and the Velcro strap can be used.

4. Now adjust the **Back Head Support Plate** against the back of the patients head to secure. Gently adjust the knob on the side of the gate to bring the Back Plate forward to a point at which the patient feels secure.
5. Alignment Lights:

Next, Adjust the Overhead position with the Hand Control Box, **Elevation Arrow buttons (blue) Up and Down** so that the Horizontal Alignment Light (*press*

Alignment Light, red button on Hand Control box is at the center of the area of interest on the patient's skull for a **Full Head Scan** (see illustration below).

Full Head Scan:

The Horizontal light should be at the Occlusal Plane between the lips (smile line).

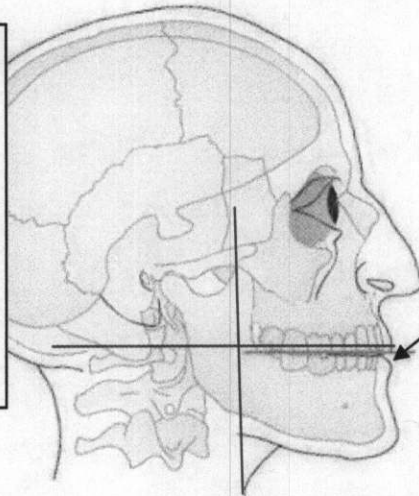
Clearance: Make sure that the sensor side of the turret has enough clearance as to NOT brush the patient's shoulders as it rotates. This may cause movement.

(If using the Velcro strap, make sure the Vertical light is approximately 1.5 inches in front of the condyle. Adjust the Head Support Back Plate if necessary to achieve this).

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).



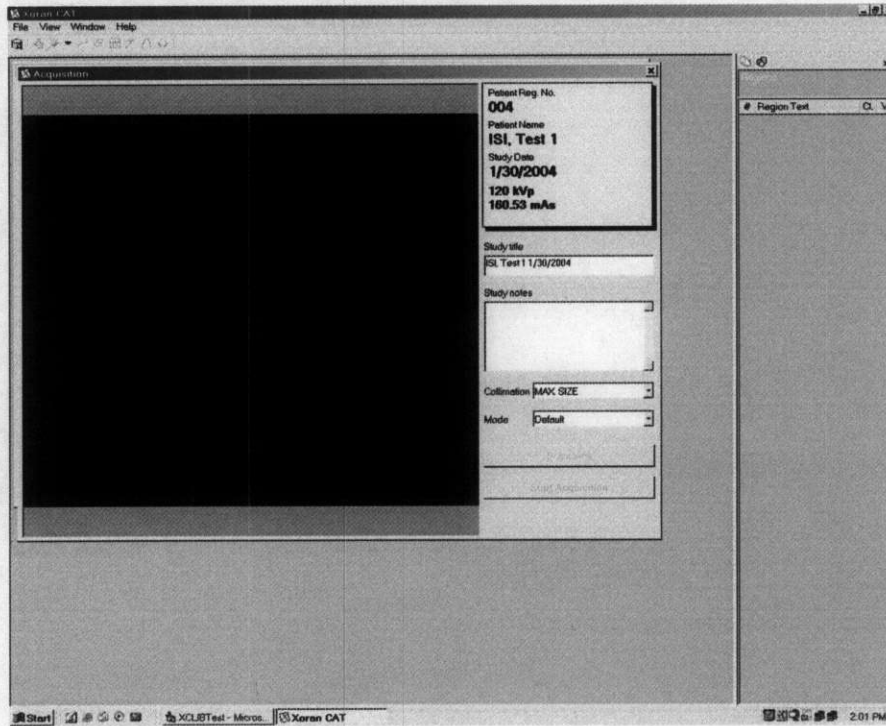
Tilt:

Occlusal Plane Flat, Frankfurt Plane tilted up slightly.

Note: The horizontal light will vary in position according to the selected height of scan desired (see **Protocols** on page 2-6). Presently, there are 3 options: Full height (13.2cm), Medium height (7cm), and Small height (3cm). If choosing Medium, Ultra High Resolution (also 7 cm) or Small, the horizontal light should shine in the center of the area of interest.

2.3 Acquire New

1. From the Patient Database Window, click on the **Acquire New** button. First, enter the "Study Title". Once entered, the screen will open to the *Acquisition Window*.

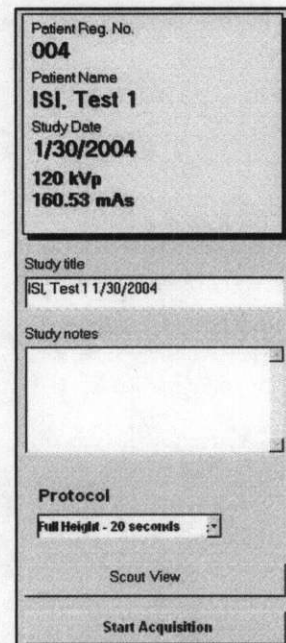


2. This Acquisition Window displays the Patient data, as well as Exposure Factors. There is a section called **Protocol**, to select the **Collimation and Resolution**.

Protocols: There are 9 available protocol options:

- Full Height, 40 seconds
- Full Height, 20 seconds
- Full Height, 10 seconds
- 1 Arch – Mandible, 20 seconds
- 1 Arch – Maxilla, 20 seconds
- Both Arches, 20 seconds
- Ultra High Res (Mandible), 40 seconds
- Ultra High Res (Maxilla), 40 seconds
- High Res (Full Height 0.25 voxel), 40 seconds

- Most standard scans will be taken at **"Full Height, 20 seconds"**. This is a .4mm voxel scan at 13 cm height.



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- We recommend using the “**Full Height, 10 seconds**” for children, some elderly (if movement is a big issue), or if you require only a quick pan or tmj scan. Since it is only a 10 second scan, the radiation is less and the opportunity for patient movement is less. This is a .4mm voxel scan at 13 cm height.
- We recommend using the “**Both Arches, 20 seconds**” for TMJ secondary scans (Open Jaw views). Remember, when using this Medium height for TMJ, make sure to position the laser light at the height of the condyle to center the anatomy in the window. This is a .4 mm voxel scan at 8 cm height).
- We recommend using the “**Ultra High Res (Mandible or Maxilla), 40 seconds**” for specialized cases such as 3rd molars, root canal relationships, small root fractures, Supernumerary or Impacted teeth, periodontal condition & other anatomy requiring detailed visualization. This is a .2mm voxel scan at 7 cm height. This means that there is 4 times as much detail in an Ultra High Res scan.

With Ultra High Res Scans the data is larger so the reconstruction time will take 3 to 4 minutes instead of 1.5 minutes. Lastly, the Ultra High Res Scans are more sensitive to movement. It is really critical to restrict all movement in Ultra High Res scans.

3. Optional Scout View: once the Collimation & Mode is selected, the user has the option of taking a Scout View to verify the position of the patient. Click the **Scout View** button to obtain the scout.

The Scout View will take a Static Exposure “Quick Ceph” that will display on screen. If the Horizontal & Vertical skull position looks correct, then you can proceed to Start Acquisition. If not, re-position the patient and re-take the Scout View.

4. Start Acquisition: click the Start Acquisition button. When the prompt to START EXPOSURE appears, first give the patient his/her last instructions (swallow and hold still).

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 eyes so he won't be tempted to follow the turret during the scan.

Ensure that nobody is in the operator area or patient area. Then click OK to start the exposure.

Note: The turret will rotate around the patient's head. The exposure buzzer will sound for the duration of that rotation, although the true exposure time is much less because the exposure pulses on and off.

Emergency Stop: to stop the machine motion in the middle of an exposure, the Operator or the Patient can press one of the Emergency Stop buttons. There are 2 Emergency Stop buttons, 1 on the Main Control Box and 1 Hand held button for the

patient to hold during the imaging process. Pressing the Emergency Stop button will halt the Exposure and the Motors. To re-set, twist the E-stop button to pop it up.

5. Once the Acquisition is complete, the machine will automatically Rewind. Wait until the machine rewinds before releasing the patient from the machine.

6. The software will automatically begin the Reconstruction of the image data. This will take approximately 1.5 minutes.

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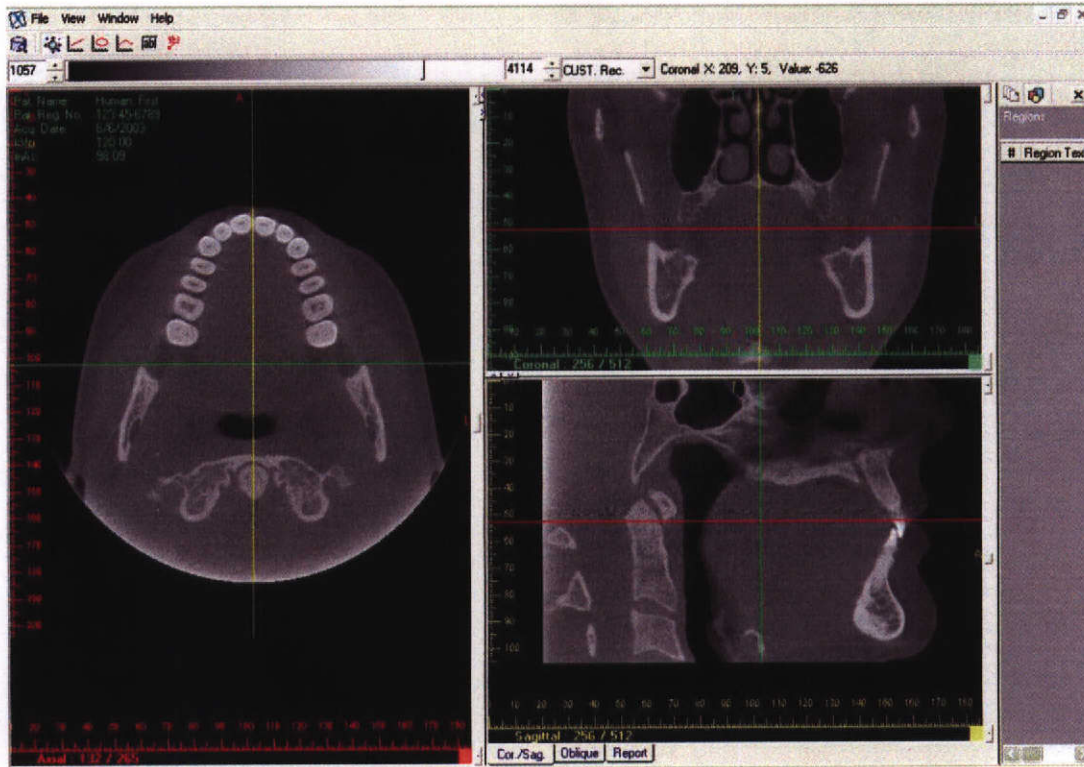
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i-CAT: Chapter 3

Reconstruction of Anatomy

3.1 Main Display Viewing screen

Once the software has performed its Reconstruction for this patient, the Main Display will appear on the screen, showing the axial, coronal and sagittal views of the skull through midline. (see sample below).

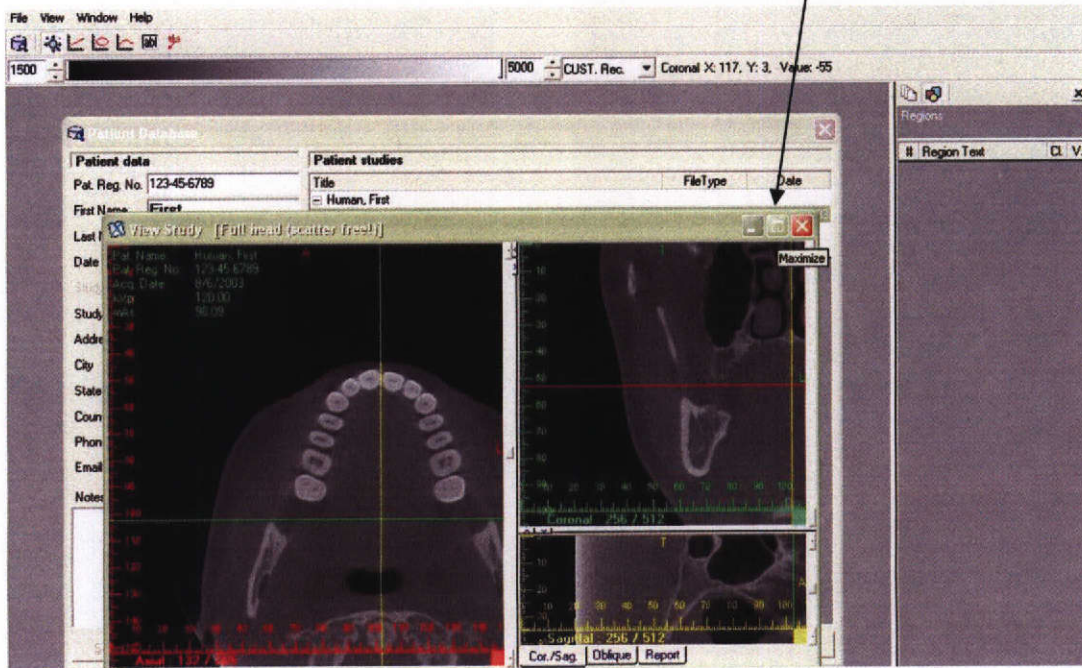


In the Axial and Coronal views, the Patient's Left is on the Right side of the screen.

3.2 Optimizing the Viewing Area:

There are a few items that should be adjusted in order to optimize the view area.

1. To maximize the viewing screen, first click on the Maximize button at the top right corner of the "View Study" window.



2. Next, point, click & drag the right edge of the "View Study" window to your right in order to resize the window. Leave about 1/2 inch clearance for the area that reads "Regions".

3.3 Adjusting Grayscale:

There is a Contrast / Brightness (Windows / Level) Button on the Main Menu bar (see below) that is used for adjusting grayscale.

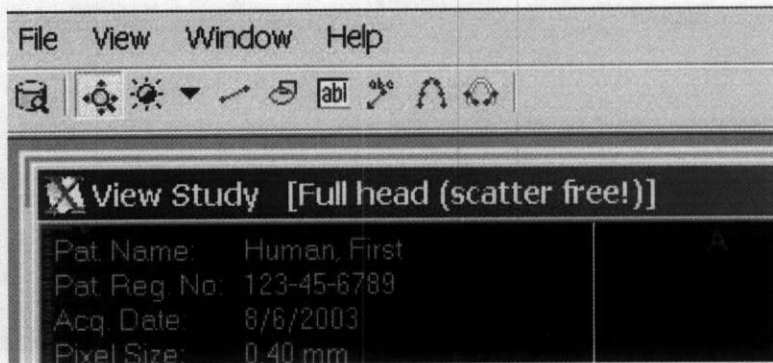


Click on the Contrast / Brightness button to enable. Then move the cursor to any of the 3 Main Display windows (Axial, Coronal or Sagittal).

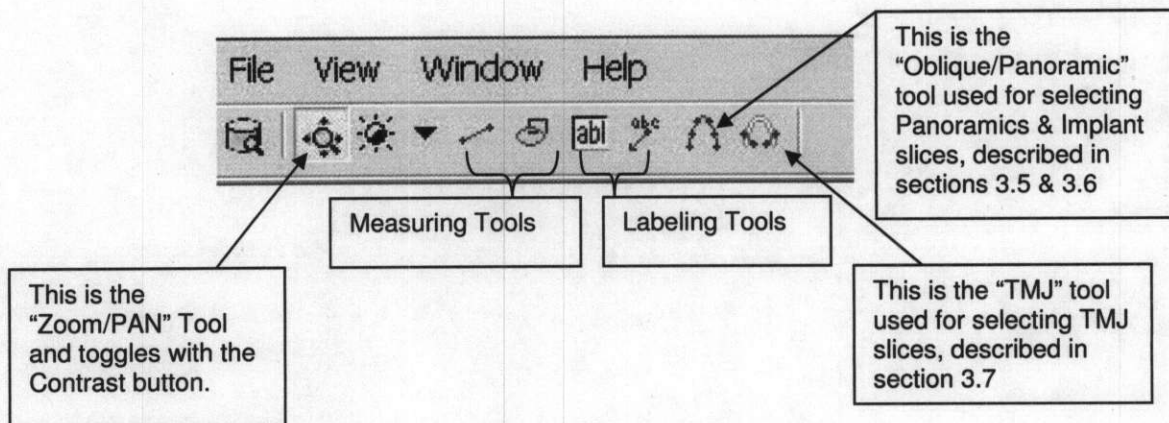
- To adjust *Level* (brightness/darkness), drag the mouse left to right.
- To adjust *Contrast*, drag the mouse up and down.

The level and contrast numbers will display in the upper left hand corner of the window.

There are also Contrast / Brightness *Preset Ranges*. Click on the arrow down button next to the Contrast / Brightness button to access the preset options. Presently, there are options named Default and Bone.



3.4 Other Tools:



Zoom/Pan:

The Zoom/Pan tool is always enabled. This means that the operator can Left click on any of the 3 views (Axial, Coronal, Sagittal) and the image will Zoom in. Continue clicking to zoom more. To Un-Zoom, click over the image with the Right mouse button.

The Pan function of this tool means that the mouse can be used to move the image within the window. Point, click and drag with the Left mouse button on an image and the image will change location in the window.

Interpolate:

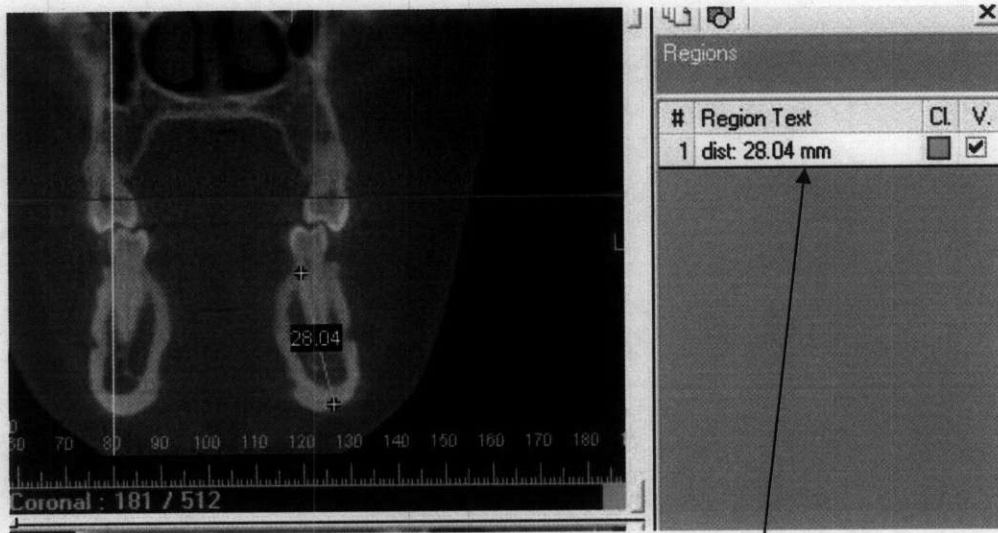
Currently when the images are zoomed in any of the views, they appear to be pixilated. The pixilation increases when zoom size increases. There is a tool that will smooth out the edges of this pixilation in all views. To use this tool, click on **View / Interpolate** from the Main Menu. You will visually see less pixilation when Interpolate is clicked.

Line Measurement Tool (named "Distance"):



The first Measurement tool is the *Line* button.

Click on this button then move the cursor over the anatomy of interest to be measured. Point, click, drag and click again. This will create a line and will display the length of that line in mm. (see sample below).



The Line Measurement will also display in the Regions section where you can choose to hide the line by un-checking the box.

This measurement tool can be used in any views; Axial, Coronal, Sagittal and cross-sections.

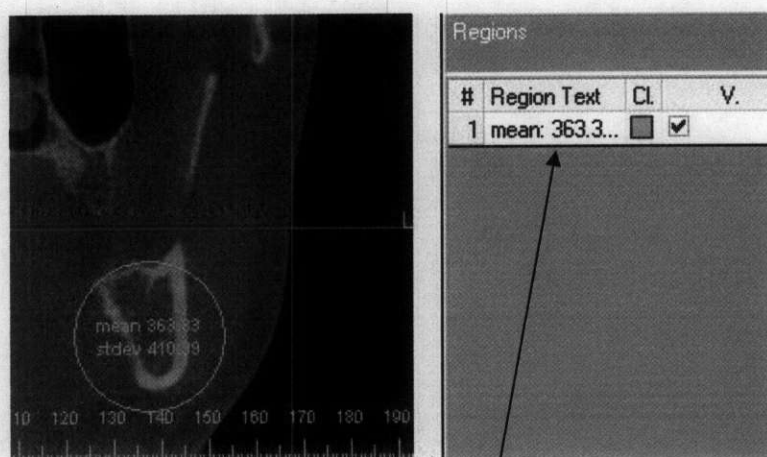
The line position and/or size can be moved by pointing the mouse over the line to highlight it, clicking and dragging the entire line to move it or clicking on one end & dragging to re-size it.

Hounsfield Measurement Tool:

The second Measurement Tool is the Hounsfield Units (Ellipse button).



Click on this button then move the cursor over the anatomy of interest to be measured. Point, Click, drag & release the mouse to create the elliptical / circular shape around the anatomy. This will calculate & display the average (**Mean**) grayscale level of the area enclosed from -1000 to 3000, where 0 equals the density of water. The **Standard Deviation** will also be calculated, where the smaller the number, the closer each shade of gray is in density to the others in the enclosed area.



The Hounsfield Unit (Ellipse) information will also display in the Regions section where you can choose to hide the ellipse by un-checking the box.

This measurement tool can be used in any of the 3 views; Axial, Coronal, and Sagittal.

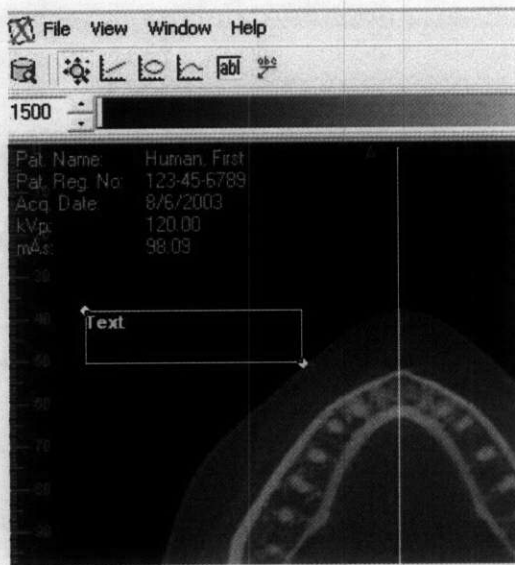
The ellipse position and/or size can be moved by pointing the mouse over the ellipse to highlight it, clicking and dragging the entire ellipse to move it or clicking on one end & dragging to re-size it.

Text Labeling Tool:

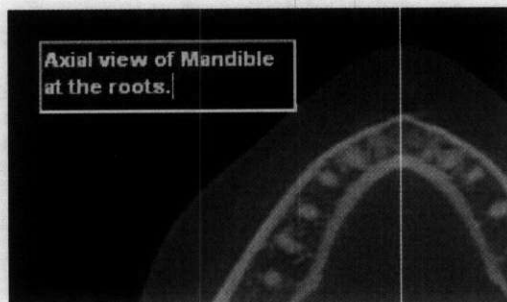
The first labeling tool is the Text button.



Click this button then move the cursor to the location where you want to enter text. Point, click drag & release the mouse to create a text box. The original text box will read "text" inside it.



Next, double click inside the text box to access the cursor where you can now delete the word "text" and type in your own text.



The text information will also display in the Regions section where you can choose to hide the text by un-checking the box.

This labeling tool can be used in any of the 3 views; Axial, Coronal, and Sagittal.

The text inside this label can be changed by moving the cursor over the text to highlight the text box and then double clicking inside the box to access the cursor.

The size of the text box can be changed by moving the cursor over the text to highlight the text box and then clicking on one corner of the text box, dragging to resize and releasing the mouse.

The location of the text box can not be moved.

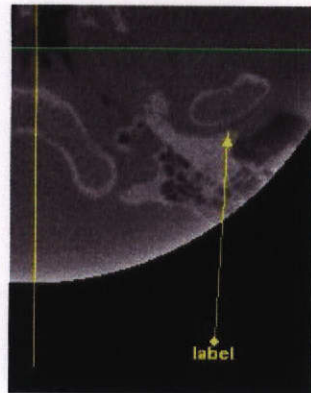
Text with an Arrow Labeling Tool:

The second labeling tool is the Label (with arrow) button.



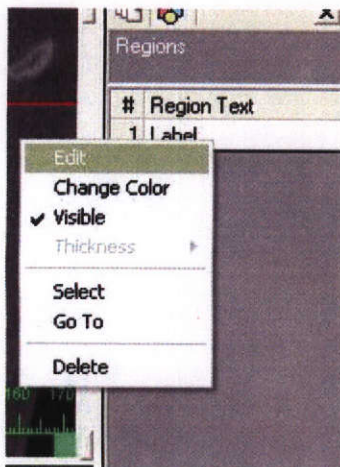
Click this button and move the cursor to the location where you want an arrow pointing to with text. Be sure to click first at the location you want the arrow to point and then drag away to where you want the text to be.

This will create the arrow with the word "label" displayed.

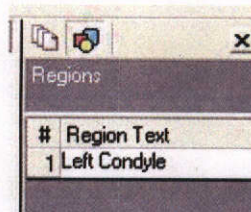


In order to now change the word "label" to the desired text, you must edit the text from the Regions section. From Regions, Right click on the designated label and click *Edit*. This will allow access to type in new text. Type in desired text and hit enter. Now the arrow label will display with your text.

1.

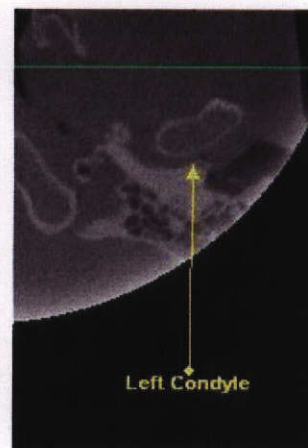


2.



1. At Regions, right click on label & select Edit.
2. Type in desired text and hit Enter
3. The new text will display with the arrow.

3.



This text can be edited again via the same method.

The text with arrow can be moved by moving the cursor over it to highlight and then click and drag to a new location. To resize or rotate the arrow, click either end of the arrow and drag the mouse.

Traveling through consecutive layers Tool:

This can be done in any of the 3 views; Axial, Coronal, Sagittal.

Simply Scroll the mouse wheel while the cursor is positioned within any view in the Main Display viewing window. Reversing the direction of the wheel will reverse the direction of travel.

Tilt:

The software has the ability to adjust the tilt in all 3 views; axial, coronal and sagittal. To tilt, first **hold down the Shift key, then point click and drag the mouse in the desired window. Drag the mouse left to right or up and down.** Place the mouse at the outermost parameter of the view to have more rotation control. When one view is tilted, the other views will adjust the anatomy accordingly.

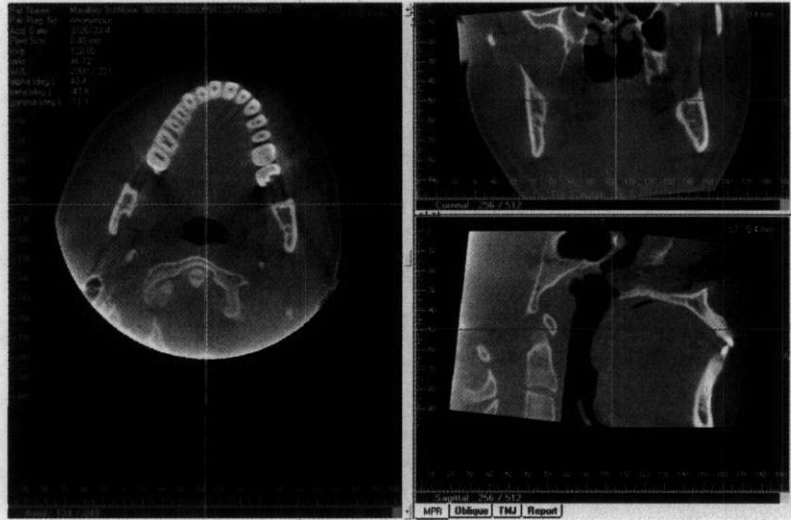
Hint: This tool can be helpful for tilting the chin down in the sagittal view so that the mapped arch will display the oblique pan view in a more traditional style with a slight smile (see section 3.5, Panoramic Reconstruction).

Sample of Original Tilt:

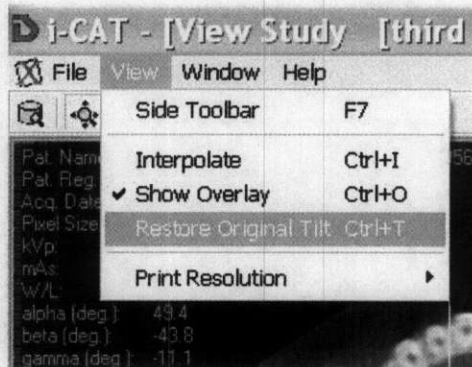


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Sample of all views tilted: you can tilt one or all views:




If you want to restore the original tilts, at the main menu click on **View / Restore Original Tilt.**

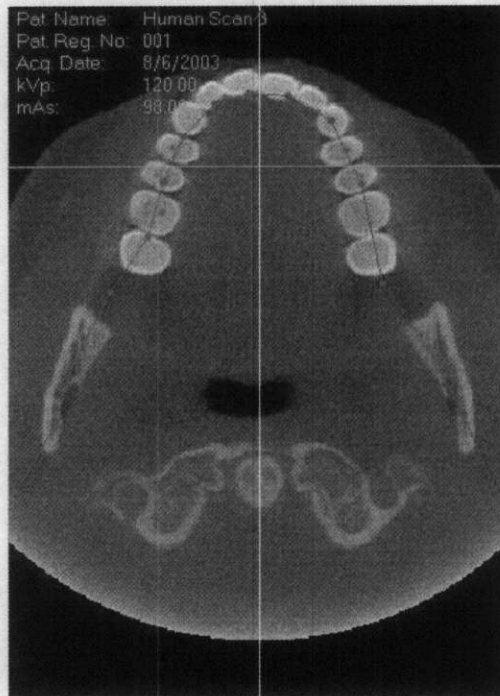


3.5 Panoramic Reconstruction

The occlusal arch must first be mapped in the Axial view in order to view a reconstructed Panoramic image.

Mapping the Occlusal view:

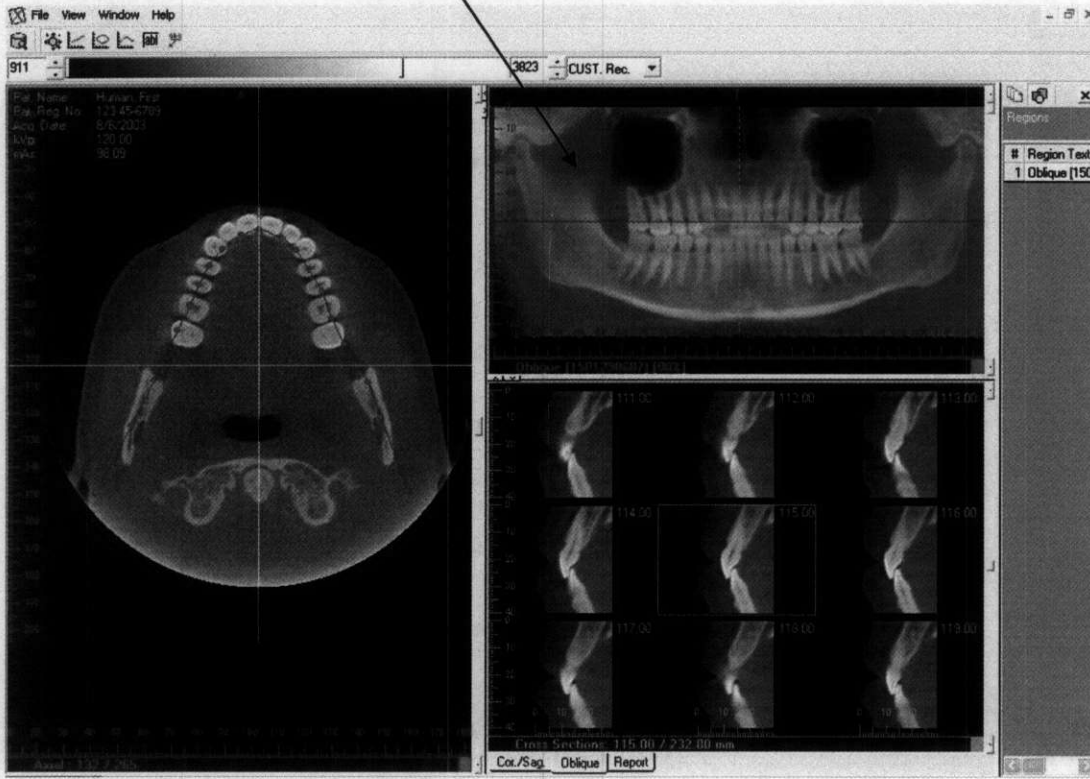
1. Start by clicking on the "Oblique/Panoramic" button on the menu bar. This will allow us to start **mapping the arch**. 
2. Next, **Map the occlusal arch** by pointing, clicking and dragging the mouse around the arch in the Axial view. Start the first click posterior to the condyle and move the mouse over the estimated roots of the arch in 1 tooth increments. Finish the last click posterior to the other condyle.



When the map is complete, double click at the last point. This will create a Panoramic view in the "Oblique" window (as well as Implant slices)

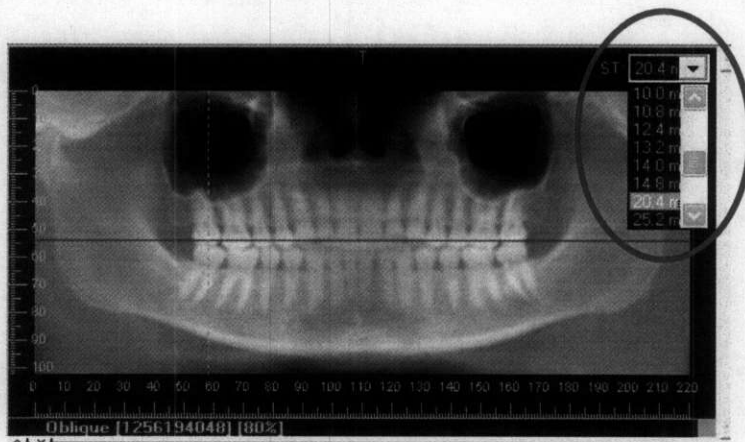
- **NOTE:** if the mapped arch does not depict all the teeth in perfect focus, you can reposition the map by clicking anywhere on the Red curve, other than the dots, and dragging it to move the entire arch towards the anterior or posterior. Or you can click on & drag any of the Red dots to change the position of that section bucco-lingually.

Mapped arch creating the Panoramic view



3. Panoramic Slice Thickness: It may be desirable to change the slice thickness on the Panoramic view. This can be done from the "Oblique" view.

In the Oblique view, click at the top Right **ST** (for slice thickness) arrow down button and select the desired slice thickness value. The slice thickness ranges from .4mm to 150mm. We recommend anywhere from 10 mm to 20 mm for optimal results.



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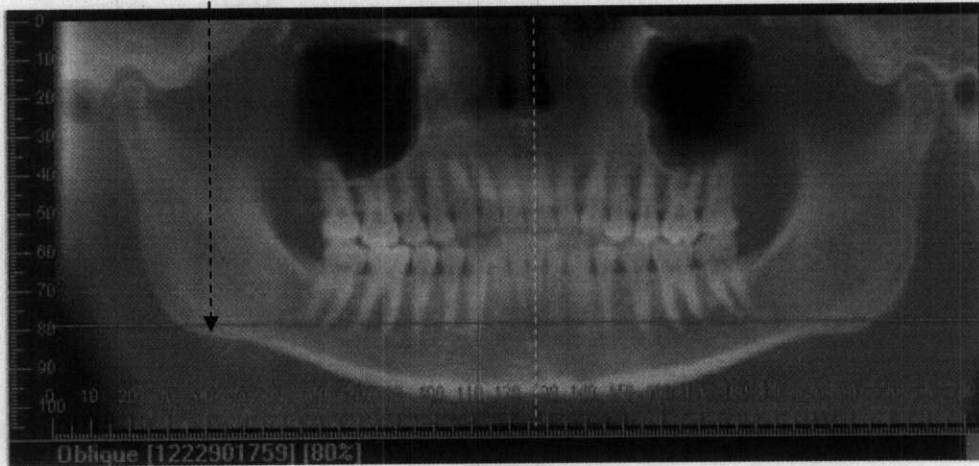
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3.6 Implant Slice Reconstruction

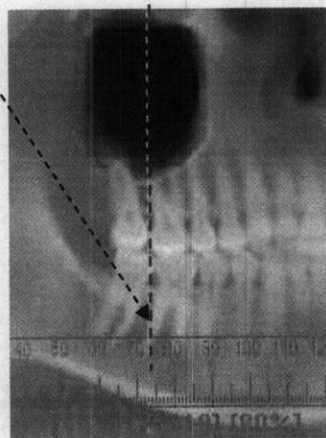
Selecting Desired areas for an Implant Series:

Once the Occlusal Map and Panoramic view are satisfactory, the image location can be adjusted to display implant slices in the desired arch (Mandible or Maxilla). These adjustments are done in the Panoramic view

1. *Height Location:* In the Panoramic view, point click and drag the red horizontal line to the desired height (up or down), either the center of the bone in the Mandible or Maxilla.

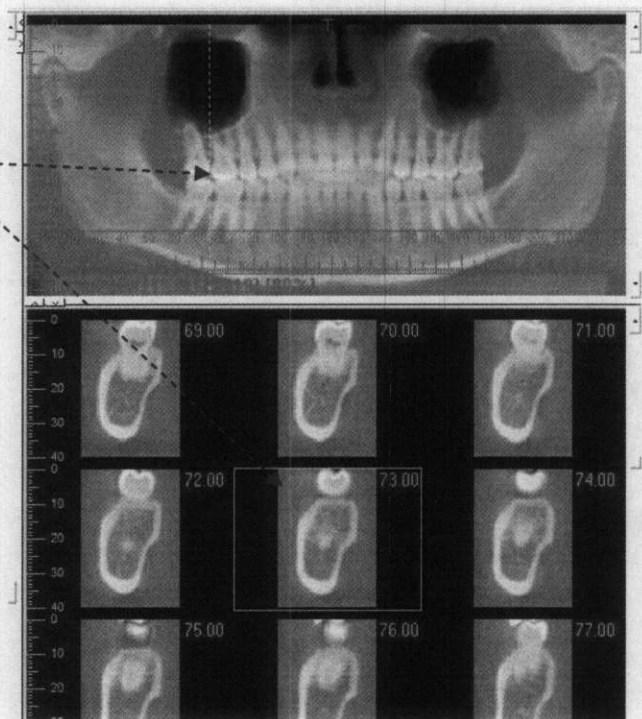


2. *Slice Location:* Next, point click and drag the vertical purple dotted line to the area of interest (left or right). In this sample it is in the Right Posterior Mandible.



When these two lines are adjusted, the reconstructed implant slices will display under the Panoramic view. The slices are 1 mm apart. Note that the purple line in the Pan view will correlate to the cross-section that is highlighted in purple.

The Purple dotted line in the Pan correlates to the highlighted slice



Note: To zoom the implant slices in the display, first zoom out the panoramic view by clicking in that window with the Right mouse button. Then expand the bottom window by pointing, clicking & dragging the top edge to resize the window to a larger size. This will enlarge all the cross-sections.

To view the rest of the slices throughout the jaw, scroll down via the scroll bar to the right of the slices.

Cross section Window Sizes: There are options to change the display of the cross-section window sizes. The options are "Wide", "Tall" and "Wide & Tall".

To access the tool for changing the cross section window size, you must first have the Regions Side Toolbar displayed on the Right hand side of the screen. (If not already displayed, press the F7 key or at the main menu click View / Side Toolbar).

When in Oblique, right click on the Side Toolbar Region named Oblique. This will display a Pop Up menu. On this menu, select Panoramic Settings. This will display another Pop Up menu with different choices.

- If you select **Wide**, the cross section widows will now display wider. This will bring a larger width of anatomy into the window. If you select Wide, the cross sections will only display a slice every 3 mm instead of every mm.

- If you select **Tall**, the cross section windows will now display taller, bring more height of anatomy into the window. This can be useful if you want to visualize both the mandible and maxilla cross sections together.
- If you select **Wide & Tall**, the cross section windows will now display wider and taller. This can be useful for full edentulous upper and lower arch cases. If you select Wide & Tall, the cross sections will only display a slice every 3 mm instead of every mm.

(When in **TMJ**, you have the same options, just right click in Regions Toolbar at the region named **TMJ** and right click on Panoramic Settings. In **TMJ**, Wide may be a useful tool in order to show from the ear canal to the eminence in the view).

3.7 TMJ Reconstruction

Selecting Condyles for the TMJ series:

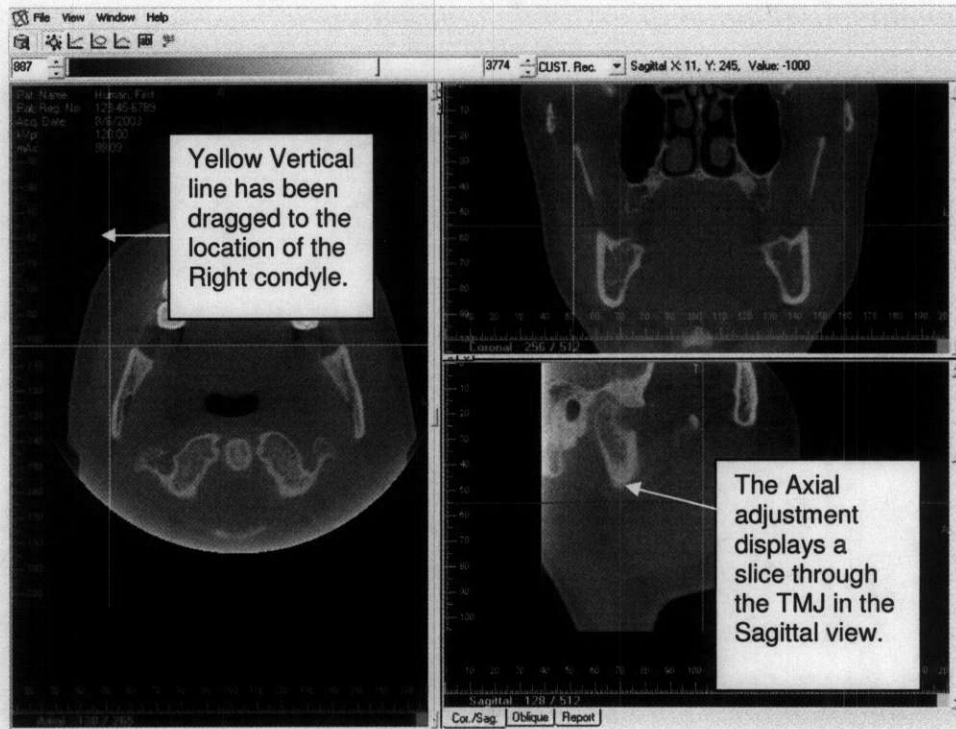
1. Start from the Main Display Viewing screen (Axial, Coronal, Sagittal Views). If not viewing that screen, click on the **MPR (Multi Planer Reconstruction) Tab** at the Bottom right side of the screen.
2. Drag the yellow Vertical line in the Axial view either left or right to the location of one of the condyles.



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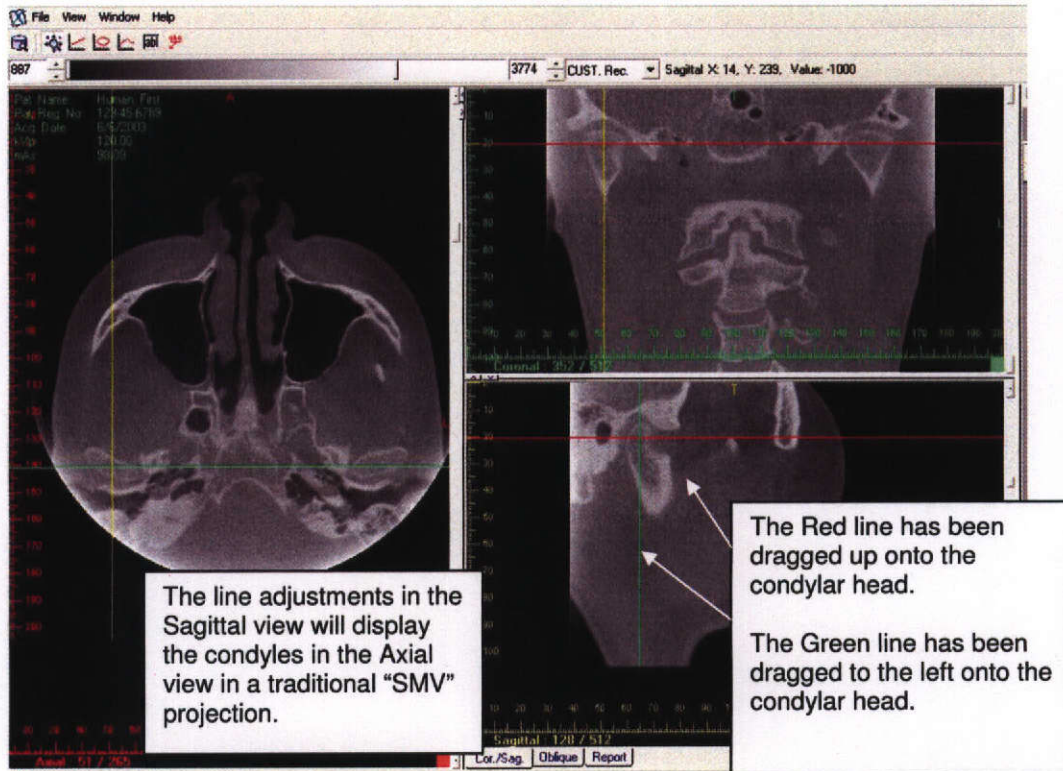
This will display a Lateral view of the condyle in the Sagittal window (see below).



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3. Next, in the **Sagittal view** drag the **Red Horizontal line** & the **Green Vertical line** to the **condylar head**. This will reconstruct the Axial view to display the condyles in a traditional "SMV" projection.

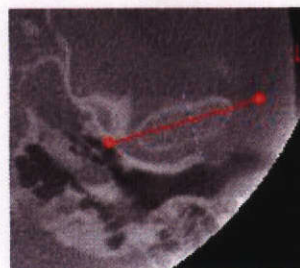


Now the condyles can be mapped.

4. Mapping the condyles: **To map the condyles**, first click on the "TMJ" button on the Main Menu bar.

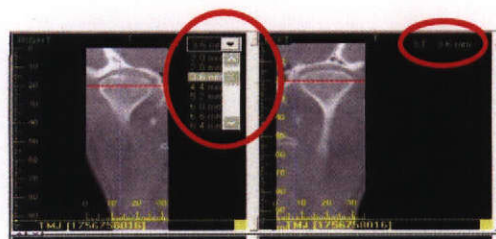


Next, in the Axial view, point, click and drag the mouse through the poles of one condyle. When finished, click the mouse once to complete the map. This identical map will then reflect on the other condyle.



If the map on the other condyle needs adjusting, then point, click & drag one or both ends of the mapped line. To move the position of both mapped condyle lines, point, click & drag either of the 2 mapped lines.

This map will then display both Right & Left Frontal views in the TMJ Tab in "Oblique Window" and both Right & Left Lateral slices in the "Cross-sections Window". The slices are 1 mm apart.



To change Slice Thickness in Frontal TMJ: The **ST** tool is in the same location in the **TMJ** window as in Panoramic, but in both the Right and Left sides. The slice thickness will change for both sides, no matter which side the selection is made.

5. In the Frontal view (Oblique window), the vertical dotted purple line can be dragged left to right to change the Lateral slice location. The location of the dotted purple line correlates to the Lateral slice that is highlighted in purple in the cross-sections view.
6. The rest of the slices can be viewed via the scroll bar on the right side of the Cross-section Window.

iCAT Warning for Reading Anatomy on Screen: Oblique - Cross sections for Implants, Coronal – Lateral for TMJ:

Implants:

The starting point of your "oblique" map in the Axial view will always appear on the Left hand side of the oblique (panoramic) window .

It is critical to correlate the cross-section slice numbers with the "tick-marks" in the Oblique (panoramic) view to ascertain the exact slice locations in the jaw.

The buccal-lingual orientation of the cross-section slices is based on viewing them from behind the direction of the mapped arch.

When viewing the Oblique & Cross section slices, please be aware that the direction in which you map the anatomy dictates how the oblique view and cross section slices are displayed on the screen.

Examples: Mapping an Arch for Panoramic with the Oblique Tool (creating an Oblique & Cross section Slices):

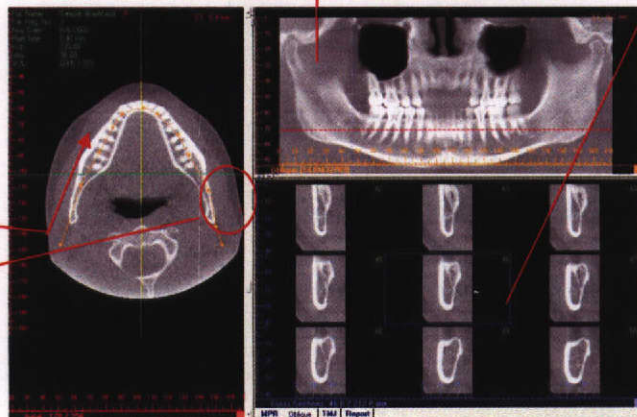
1. **If you are mapping an entire arch from condyle to condyle and you start the map in the Axial view on the patient's Right side** (your left side of Axial window) and proceed around the arch to the patient's Left side (this sequence is strongly recommended), then the Oblique and Cross-section slices will display as follows:

- **Oblique (panoramic) view:** the oblique view will display with the Patient's Right on the Left side of the window. The numbering (tick-mark) scale will always start at 0 and proceed to as high as the map dictates (210 for example). The numbering system will always display left to right.
- **Cross section Slices:** The cross-section views will be numbered from 0 to 210 in this example, starting from Left side of the Oblique Window which is the Patient's Right side in this case. **It is critical to correlate the cross-section slice numbers with the tick-marks in the Oblique view to ascertain where the slices lie in the jaw.**

Map was started on patient's Right side at the condyle, proceeding around the occlusion to Left side.

Since the Axial map started on the patient's Right at the condyle, the patient's Right in pan view is on the display window Left side.

"L" for Patient's Left Side



The slice numbers in Cross-Sections correlate to the horizontal scale (tick-marks) on the Oblique window.

When mapping the arch from patient's right to left side, the cross-sections will always display with the buccal side on your left and the lingual on your right.

The buccal-lingual orientation of cross-section slices, as seen from behind the arrow in the picture above, will be buccal on your left, lingual on your right. This orientation will apply around the entire arch.

If you start the map on the patient's left side and proceed to the right, the above orientations would reverse. However, we strongly recommend that you always map from patient's right to left, even when mapping a partial arch, to keep everything consistent and to avoid confusion.

TMJ

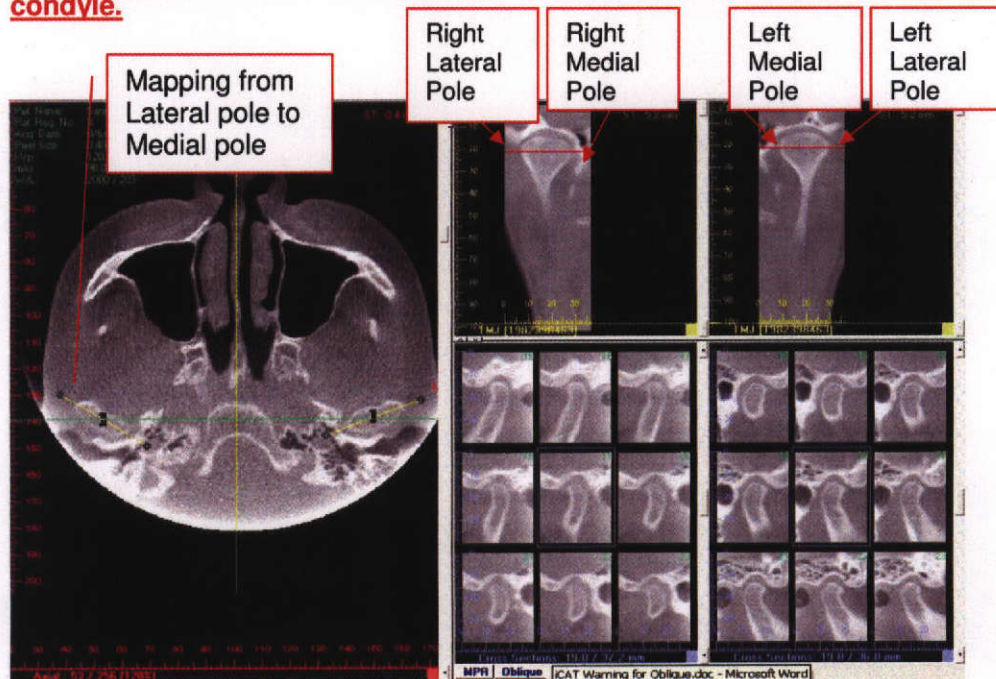
In TMJ mapping, whether you start mapping from Lateral pole of condyle or Medial pole of condyle, the display of the coronal and cross section (Lateral) slices will always be the same (refer to sample below).

Example: TMJ mapping with the TMJ tool (creating Coronal (frontal) and Cross section (Lateral) slices).

1. If you map the condyles from Lateral Pole towards Medial Pole or Medial Pole towards Lateral Pole, the Coronal and Cross section (Lateral) slices will always display as follows:

- The Patient's Right condyle will always display on the Left side of the TMJ window and the Patient's Left condyle will always display on the Right side of the TMJ window.
- The cross-section (Lateral) slices for the patient's Right side will display from 0 being most Lateral to the higher number being the most Medial. The cross-section (Lateral) slices for the patient's Left side will display from the higher number being the most Lateral slice to 0 being the most Medial slice. **It is critical to correlate the Cross section (Lateral) view slice numbers with the "tick-marks" in the Coronal view to ascertain where the slices lie on each condyle.**

The orientation of the condyles will be as if looking from the center of the head in the lateral views, looking from front of the face in the frontal views.



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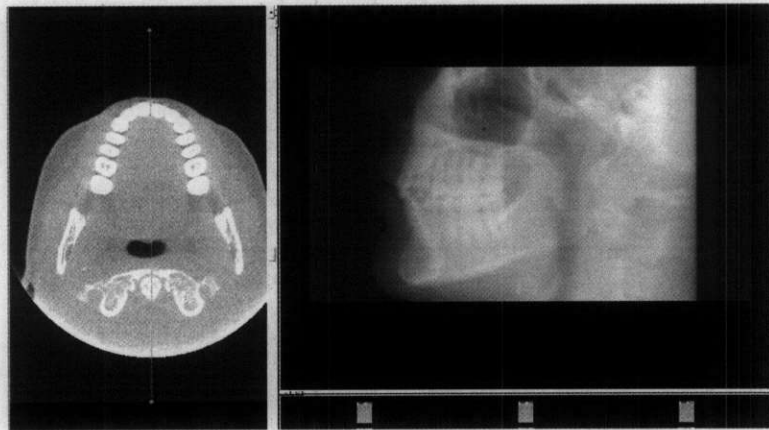
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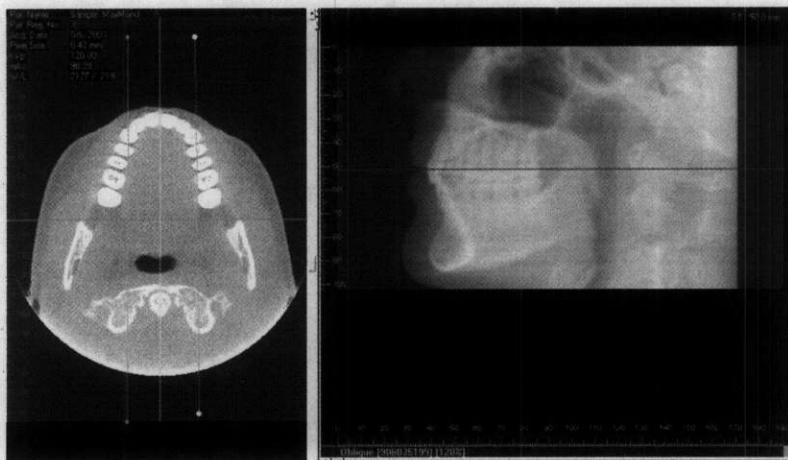
3.8 Traditional Cephalometric Reconstruction (with Limited Height, 13.2 cm):

The Slice Thickness option also allows us to Map out a more traditional type Cephalometric image at a thick slice (although the height of the scan will not cover the entire height of the skull). To do this, use the Oblique tool and map in one of the following methods:

1. One Thick Slice through Midline. Create a map at Midline from Anterior to Posterior. Then, in the Oblique window change the Slice Thickness to a larger value such as 100 mm. Adjust Contrast / Brightness to desired level.



2. Two slices; one on either side of the jaw at a thinner slice thickness of 50 mm. Create 2 maps on either side of jaw from Anterior to Posterior, then change the slice thickness in the Oblique window. Adjust Contrast / Brightness. Remember, the map that is highlighted is the one that will be viewed in the Oblique window.

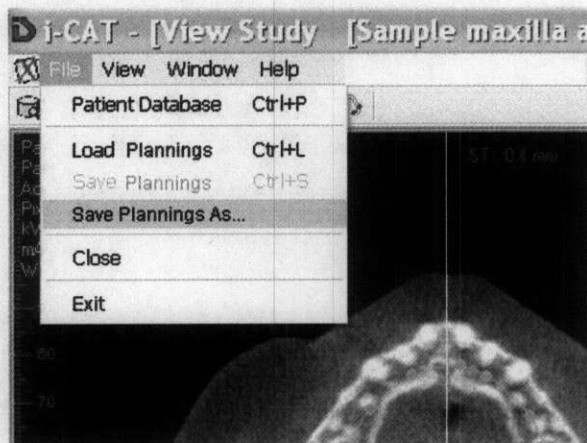


Use the same concept to create a Frontal Ceph view by mapping from Left to Right side of skull.

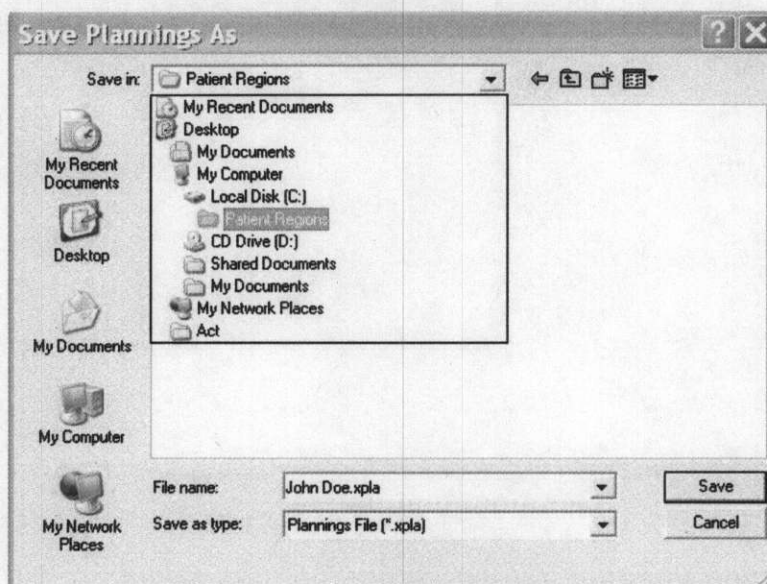
3.9 Save Plannings (mapped regions, etc):

An entire plan can be saved, which includes not only the regions (maps, measurements, labels) but the Brightness / Contrast, Zoom sizes of the windows and exactly what is being viewed on the screen at that time. This will basically save a screen capture in the study that can be re-loaded to display exactly what was saved.

Once the Planning for that particular study is completed on screen as you desire, click **File / Save Plannings As....**

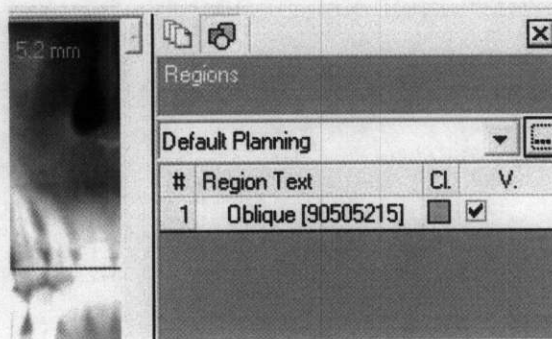


This will open the window where you can name and save the file (if not already present, create a Folder to contain the plannings in, ex: Patient Regions).

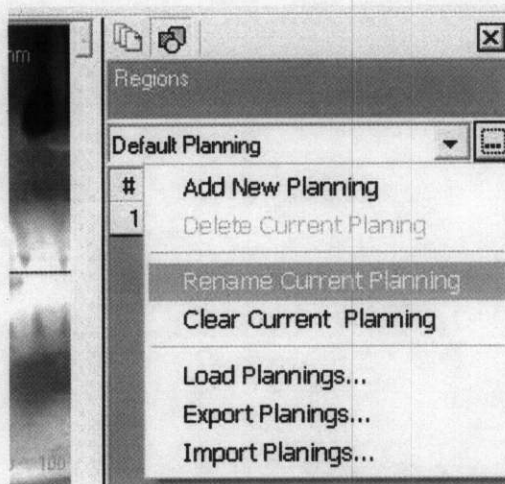


The plan can be retrieved when you re-open that case by clicking **File / Load Plannings**. Select the appropriate file and open to display the plan.

These plans, once saved or reloaded, will also now display in the **Regions Side Toolbar**. When the plan is saved, it defaults to the name of "Default Planning".

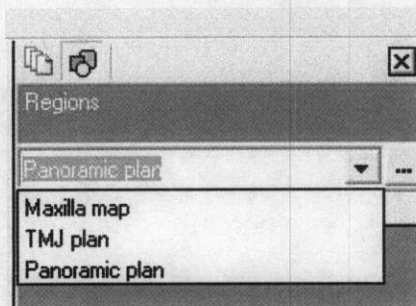


You can re-name the Default Planning by clicking on the triple dot icon next to the text and selecting the option of "Rename Current Planning". For example, you might rename a map of a maxilla as "Maxilla Plan", or a TMJ series as "TMJ plan".



To Rename the plan:
Click on this icon and select
Rename Current Planning,

If you want to make a new plan, click on the "Add New Planning" item, create a new map/plan and then Rename the plan from "New Planning" to the desired name.



If there are multiple saved plans, they will be in the list, accessed by clicking on the arrow down button.

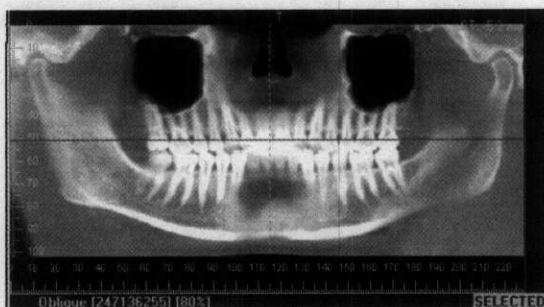
3.10 Orthographic Cephalometric Reconstruction (17 cm height) (Optional feature) –*Not yet available***3.11 Conventional Cephalometric (17 cm height) (Optional feature) – *Not yet available*****3.12 Image Output / Reports**

In order to fully understand the way in which the i-CAT software displays images, a few terms should first be described along with the hierarchy of the reports. The highest level is called an Action. Once an Action is set up, it is the easiest to use and requires the least amount of user input. All that is needed is for the user to select the items to print or export and then select the appropriate Action. It is important that the Action names be extremely meaningful so that the user is able to immediately determine which Action is the one that they should be selecting. Setting up the various Actions is described in detail, later in this section.

Once the Action is created, that is the end of the hierarchy for the Export and Print Images Actions. But for the Print Template there are a few other items that compose an Action. The second level for an Action is a Profile, which can be Implant, TMJ or Custom. The next level under Profiles will have you select a Report. If you choose to modify a Report, you are doing so by modifying a Template. If you select to add a Template, the name of the new Template will appear as the Report name. So, a modifiable Report is considered a Template. Technically you do not modify a Report, you modify a Template.

3.12.1 Selecting Images for Actions and Reports

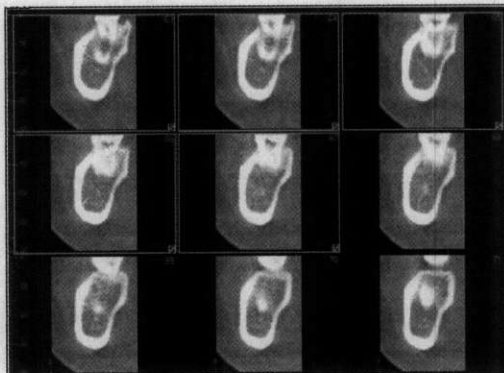
To select a view for an Action to print or export, the view must be selected by holding down the CTRL key and clicking on the view with the mouse (CTRL-Click). When selected, the view will display the word "Selected" in the lower right hand corner. The image selected will also appear in the toolbar on the right side of the screen, under "Selected Images". If you wish to select multiple slices in any view, you can scroll through the view (for example the Axial View) and select a slice with the CTRL-Click, scroll through and select another slice again. The slices selected will appear on the toolbar on the right.



This Pan view is now **Selected** for an Implant Report.

To de-select any highlighted views, just CTRL-Click again on that view and the word "Selected" should no longer appear in the lower right hand corner. Optionally you can de-select an image from the right toolbar, by clicking on the image with the Right mouse button and selecting "Unselect".

When selecting a cross-section view, a slice is selected by using a CTRL-Click. Each selected slice will be highlighted in Green.



Each Green highlighted cross-section has been selected.

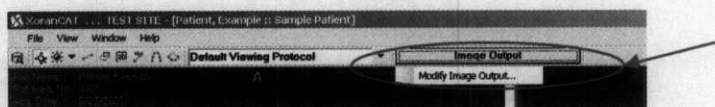
To De-select any highlighted views, just CTRL-Click again on that view.

To select all images, right mouse over the cross sections and select "Select All". To deselect all images, right mouse over the cross sections and select "Unselect All".

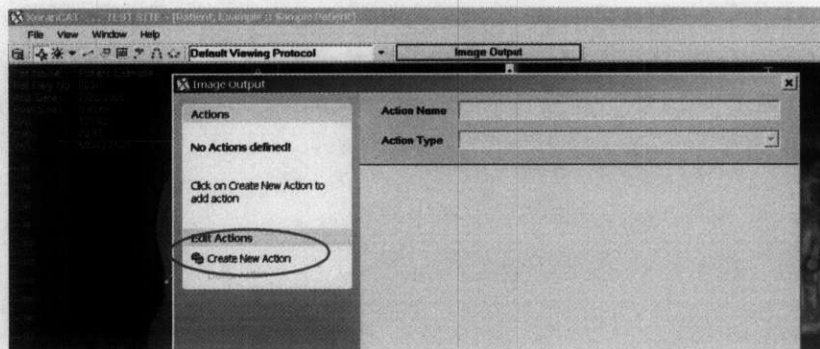
To select a range of slices, Ctrl-Click on the first cross section in the range you would like selected. Then Shift-Click on the last cross section of your range. All cross sections in between the first and last selections will now be selected.

3.12.2 Creating an Action

On your first use of the i-CAT software, you must create a new action in order to create a report. This is done by selecting "Image Output" then "Modify Image Output"



From there, you then select "Create New Action".

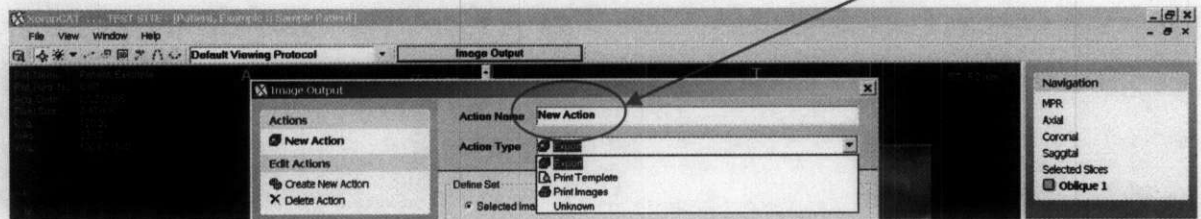


3.12.3 Action Types

There are four "Action Types" to select from, they are as follows:

- Export
- Print Template
- Print Images
- Unknown (this selection is currently not used and is for future enhancements)

For any new action, you will need to name your action – be as specific as you can, so that the name is easily understood by everyone that uses the program.



Action Type – Export: This is used when you would like to export selected images, slices or studies. This is also used for Exporting to an older version of software.

Action Type – Print Template: This is used to create a new template that can be used then to print to paper or to a PDF file. This will probably be your most common selection when creating new actions and is described in more detail later.

When you select "Print Template", you will then be able to select which "Profile", "Report" and "Printer" you'd like to use.

Currently, there are 3 report **Profiles** (Implants, TMJ & Custom) with multiple **Reports** for Implants and TMJ, and Custom.

Action Type – Print Images: This is used when you would like to print only selected images, but not in a report format.

Action Type – Unknown: This is an unused type, reserved for future expansion.

3.12.4 Existing Reports

The following lists the reports and uses for the existing report templates:

Implant Report Templates:

Implants Report: this is the standard template for scans taken at Full Height (13.2 cm). It will display the selected Panoramic view and selected cross-sections. It is in Portrait format.

Panoramic Landscape: this is the standard template for just printing a panoramic with the paper layout in Landscape format. This is recommended for wide skull patients where the whole Pan from left to right will not display on the Portrait format.

Implants Report 5 pages: this is the same as the Implants Report, except that it allows for 4 additional pages of cross section selections.

Implants Report 5 pages – Wide slices: this is the same as the Implants Report 5 pages, except that it is for when Wide cross sections are selected from the Oblique Panoramic Settings.

Implants Report 5 pages – Tall slices: this is the same as the Implants Report 5 pages, except that it is for when Tall cross sections are selected from the Oblique Panoramic Settings.

Implants Report, Limited Height: this is the standard template for scans taken at a Medium Height or Ultra High Res Scans (height of 7 cm). Since the height of the anatomy in these scans is less than a Full height, the template is adjusted for that difference.

TMJ Report Templates:

TMJ Basic: this is the standard Lateral TMJ template for scans taken at Full Height (13.2 cm). It will display the selected Axial (mapped SMV) view, with a Frontal slice on each side and 9 Lateral slices on each side.

TMJ Basic, Limited Height: this is the standard Lateral TMJ template for scans taken at Medium Height or Ultra High Res (7 cm). It will display the selected Axial (mapped SMV) view, with a Frontal slice on each side and 9 Lateral slices on each side.

TMJ Frontal: this is the standard Frontal TMJ template for scans taken at Full Height (13.2 cm). It will display the selected Axial (mapped SMV) view, with a Lateral slice on each side and 9 Frontal slices on each side.

TMJ Frontal, Limited Height: this is the standard Frontal TMJ template for scans taken at Medium Height or Ultra High Res (7 cm). It will display the selected Axial (mapped SMV) view, with a Lateral slice on each side and 9 Frontal slices on each side.

TMJ Open: this is the standard Open view Lateral TMJ template for scans taken at Full Height (13.2 cm). It will display the selected Axial (mapped SMV) view, with a Frontal slice on each side and 9 Lateral slices on each side.

TMJ Open, Limited Height: this is the standard Open view Lateral TMJ template for scans taken at Medium Height or Ultra High Res (7 cm). It will display the selected Axial (mapped SMV) view, with a Frontal slice on each side and 9 Lateral slices on each side.

Custom Report Templates:

Right Angle Views: this report is for Axial, Coronal and Sagittal views. The first page has 3 axial views (Mandible, Occlusion, Maxilla), 1 Coronal view at Midline and 1 Sagittal view at Midline. Page 2 displays one large Axial view.

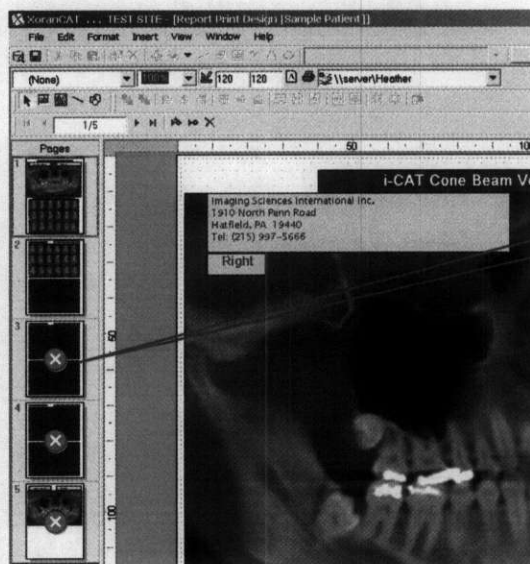
Multiple Selected Images Report: this report will display multiple pages of the selected images. They will be displayed in the order in which they appear in the Selected Images

window (right side tool bar). Cross sections, even if selected, will not appear in this report.

3.12.5 Printing Reports

From within the Image Output window, you can select your Profile and Report and Printer, then print your template after viewing it. To do this, select either "Modify Template" or "Preview Template". The difference is that with Modify, you will be able to move things around on the template prior to printing. From the template, you can then select which printer to send the report, and then select the Print icon or select "File" then "Print". If you have a PDF writer, you can change the printer to display the PDF software and when you select "Print", it will print to a PDF file after asking you to name the file.

If you have selected a multi page report, you can deselect pages of the report so that they don't print. To do this, double click on the small page(s) to the Left of the report that you do not want to print. A red circle with a white "X" will appear on the page and this page will then NOT print.



The three pages with X's will not print with this report.

3.12.6 Print Template – Setting Up Image Output Screen (Fields, Printer, Checkboxes)

Select a Profile from which to select your report. If you wish to create a New Profile, select the "Create New Profile" from the Template Edit section. Then type in the name for the new Profile. Conversely, a Profile can be removed by selecting "Remove Profile".

Then select the desired Report. If the report does not exist in the given Profile, it can be added to the Profile by selecting "Add Template" – this will add the Template (or Report) to the current Profile.

When Print Template is selected, you can select the printer to use, or select PDF file (if a PDF writer is installed on your PC). When PDF is selected, the report will go to a .pdf file. This file can then be emailed.

Below the printer selection is the Fields section. To change information in this section, double click in the white and type. If a second line is needed, you must space over to the end of the first line (using the Enter key will not move you to the next line). Information entered here will be the default for all Reports created for this Profile. If additional fields are needed, select the "Add Field" from the Template Edit section. Then name the new Field. Conversely, if you wish to remove a field, select "Remove Field".

When you select the box at the bottom, "Open template for preview", the Fields section will appear when you run an Action. At this point, you are able to modify the fields on a per use basis. Meaning that each time you run the Action you can modify any entry for that single report – this is helpful when there are multiple "Referred by" or "Interpreted by" entries that may be used.

Before you continue, it is advisable that you select the two check boxes at the bottom of the screen. Check the box for "Open template for preview" to be able to view the template before it gets sent to the printer – this way you ensure that you did get the correct images and report before you send it to the printer. Also check the box for "Edit fields before printing" to be able to modify all entries in the "Fields" section of the report that might change with every patient, prior to viewing the template and printing.

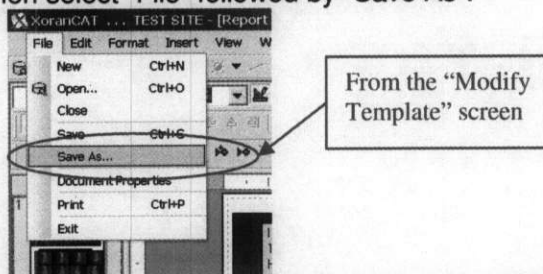
Select "OK" at the bottom of the screen to Save your new Action. If you close the window without selecting "OK", the action will not be saved. To then go back and modify the action further, just select "Modify Image Output" from the main i-CAT screen.

3.12.7 New Template – Add Template vs Create New Template

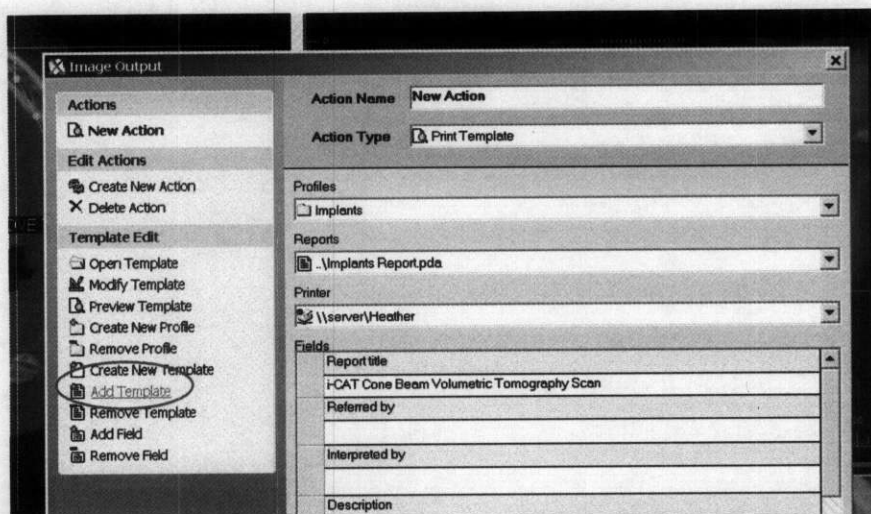
There are two ways to create a new template. Method #1 is much easier although it appears to have more steps at first. After the template is created, Method #1 is easier because the template at least has the headers that you can maintain, as opposed to creating everything from a blank page if you use Method #2.

New Template Method #1 – Copy an existing template, rename it, then modify it

To do this, you first need to select a template to "copy". If your new template will be nothing like any existing templates, it still helps to use an existing template as a starter so that at the very least, the header information is present. To "copy" a template, open it with Modify Template. Then select "File" followed by "Save As".



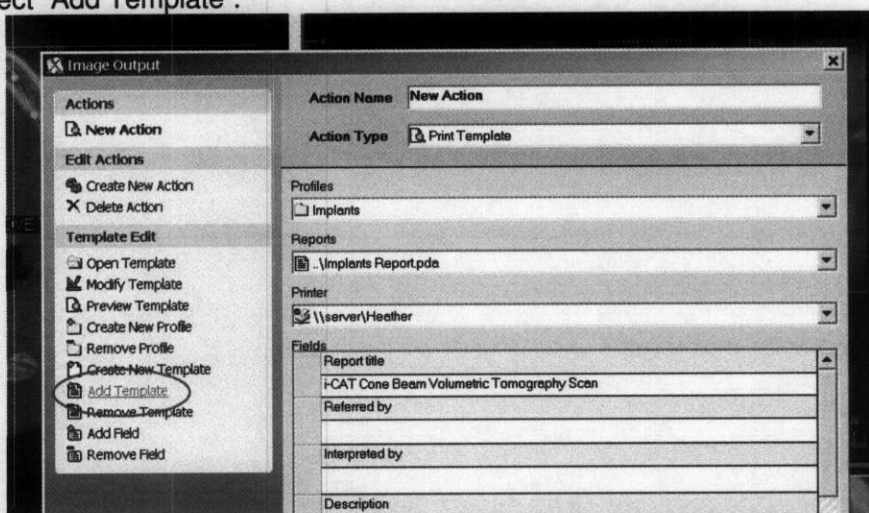
Navigate to the Reports directory and name the new report. Then CLOSE the report. This is important because you don't know which template you are modifying (old or new). Once you are back on the "Image Output" screen, you will need to ADD your template to the appropriate Profile. To do this, select "Add Template".



Then navigate to the Reports directory and select your new report to add. Ensure that you are adding it to the correct Profile – in this example above, the new report would go into the Implants Profile. Now select “Modify Template” and make any changes to the new template.

New Template Method #2 – Create a NEW template, then modify it

To do this, select “Create New Template” from the “Image Output” screen. You will be asked to enter a name, but first navigate to the Reports directory, then enter a name for the new report. You will then see a blank template that you can modify. Once you are done modifying, Save your changes and close the template. Once you are back on the “Image Output” screen, you will need to ADD your template to the appropriate Profile. To do this, select “Add Template”.



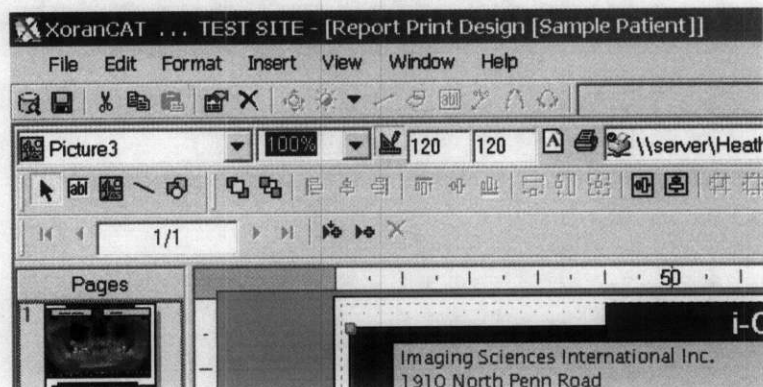
Then navigate to the Reports directory and select your new report to add. Ensure that you are adding it to the correct Profile – in this example above, the new report would go into the Implants Profile.

3.12.8 Modify Template

Probably the most often used feature in the Template Edit section of Image Output. This allows you to personalize the reports (or templates). You can move images and text to

different locations, insert your company logo on the reports or create new reports entirely.

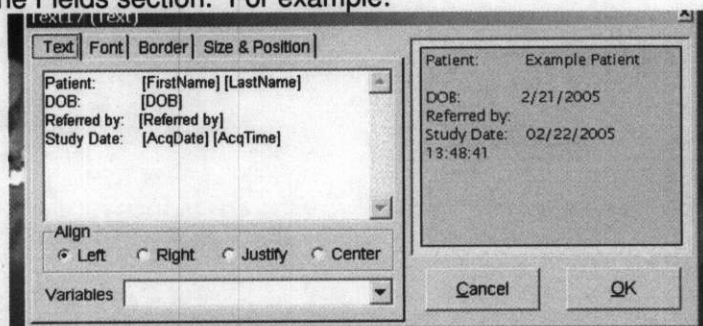
Overview of the keys available:



To create a Text Box, click on:



Then click once in the main screen and drag the box to the desired size and release the mouse button, the size can be readjusted later as well. To populate the box, double click in the new text box to open the Properties pop-up. Other changes to text including font and color can also be made in this Properties pop-up. Reserved words will have [] brackets around the word. These values are then taken from the entry in either the Patient Database or the Fields section. For example:

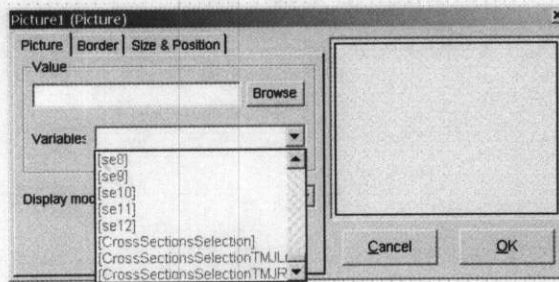


The reserved words [FirstName] and [LastName] are taken from the Patient Database and [Referred by] is taken from the Fields entry – which in this example was left blank.

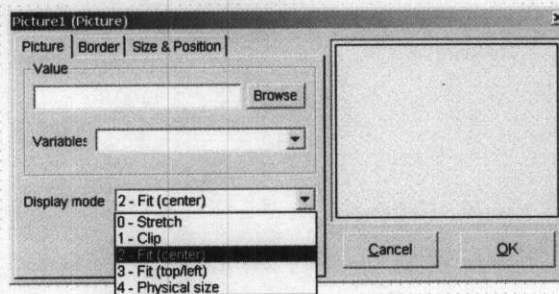


To create a Picture Box, click on:

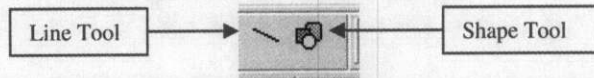
Then click once in the main screen and drag the box to the desired size and release the mouse button, the size can be readjusted later as well. To populate the box, double click in the new text box to open the Properties pop-up. From here, you can insert a selected image or a named image – click on the “Variables” pull-down and scroll to the bottom of the list as shown below:



The [se8] would be the Selected Image #8, which can be found in your Selected Images window on the right side of your screen. The other items named items can also be entered for display inside the picture box. Additionally, you can select the Display Mode on this screen, your options are shown below:

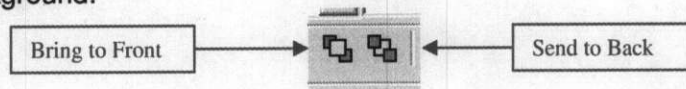


To draw a line or a shape, use the following icons:

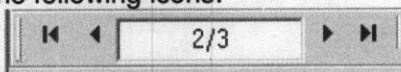


If you select the Shape tool, the default shape is a rectangle, but you can then double click in the shape to change the shape to a circle, oval, etc.


The following icons are used to bring an image to the front or to send an image to the background:




To advance through the pages, you can click on the small page previews on the left of the screen, or click on the following icons:



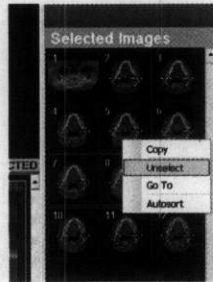
The center block represents which page you are on and the number of pages, the above image shows that we are on page 2 of 3. The blue arrows allow you to advance page by page or to the first or last page.

To Add a page, the following icons are used:  The icon on the Left will insert a page BEFORE the current page. The icon on the Right will insert a page AFTER the current page.

To Delete a page, the following icon is used:  The page deleted will be the current page.

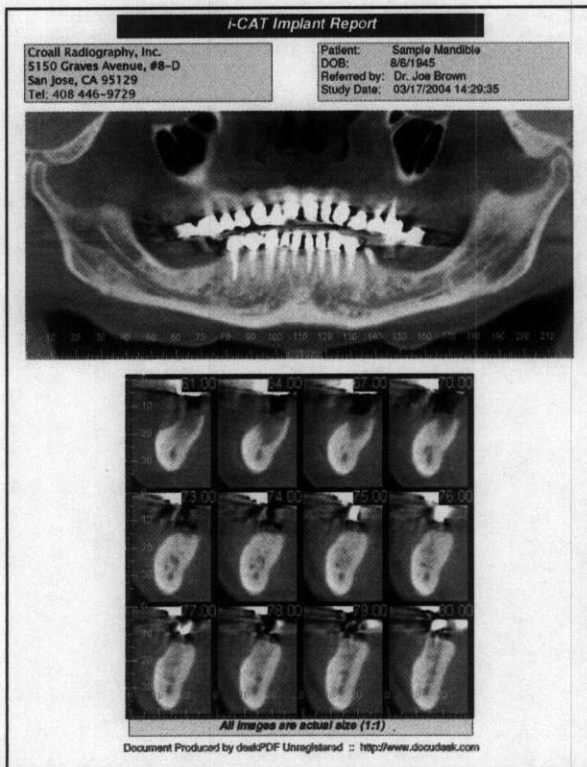
REPORT HINTS:

- When selecting images for each Report Profile, you must select in the sequence that you want the images to display.
- Any additional images selected but not necessary for that Report template may interfere in the correct image being imported into the template. For example, if you are selecting for an Implant report, do not Select an Axial view. The implant reports do not use an axial view so it may display in the Pan window instead of the Pan.
- To Remove an image from Selected views, right click on the Thumbnail and select "Remove".



- Markings made to the images WILL appear in the reports if those images are selected for printing.

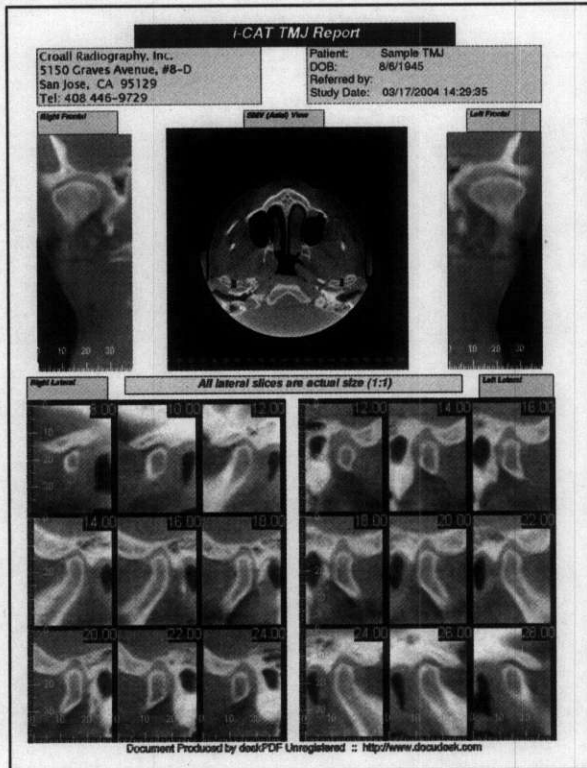
Below are samples of an Implant Report and a TMJ Report:



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3.13 Exporting Studies

The iCAT studies can be exported in 2 different formats.

1. **XoranCAT Study File (.xstd)** which is the proprietary format. The case would be exported in this format if using to import into another iCAT workstation.
2. **Dicom 3 - Multi File (.dcm)**, which is the universal format for 3D volume data. The case would be exported in this format if using to import into a 3rd party 3D volume software (ex: SimPlant)

We MUST first export the case to the computer hard drive and then can burn it to a CD if desired. If accessible, we can export to a designated directory on shared network drive.

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To Export:

1. In Patient Database, **highlight the desired study to be exported. The Reconstructed File Type (Recon) must always be used.** Next, click on the EXPORT button at the bottom of the screen.

The screenshot shows the i-CAT software interface. The main window is titled "Patient Database" and contains two panes: "Patient data" and "Patient studies".

Patient data:

- Pat. Reg. No. 3
- First Name MaxMand
- Last Name Sample
- Date of Birth 1/1/2001
- Study Date
- Study Title Sample maxilla and mandible
- Address
- City
- State Zip
- Country
- Phone
- Email
- Notes

Patient studies:

Title	FileType	Date
+ 3rd Molars, 975057106977110812277841075177		
+ Child Pan II, 975070489912210312178681071199		
+ Child Panoramic, 891097010689875311277847350798		
+ Edentulous, no bone, 895070121907186117898877120778		
+ Maxillary 3rd Molar, 985182108991095612077106691227		
+ Phantom, Test		
- Sample, MaxMand	Recon.	8/6/2003

The "Export Study" dialog box is open, showing a file selection process. The "Export in" field is set to "SYSTEM32". The file list includes folders like 3COM_DMI, 1025, 1028, 1031, 1033, 1037, 1041, 1042, 1054, 2052, 3076, bits, CatRoot, CatRoot2, Com, CONFIG, DHCP, DirectX, DRI, EXF, IAS, ICS, IME, and INE. The "File Name" field is "Sample maxilla and mandible study.xstd" and the "Export Type" is "XoranCAT Study File (*.xstd)". The "Export" button is highlighted by a callout bubble.

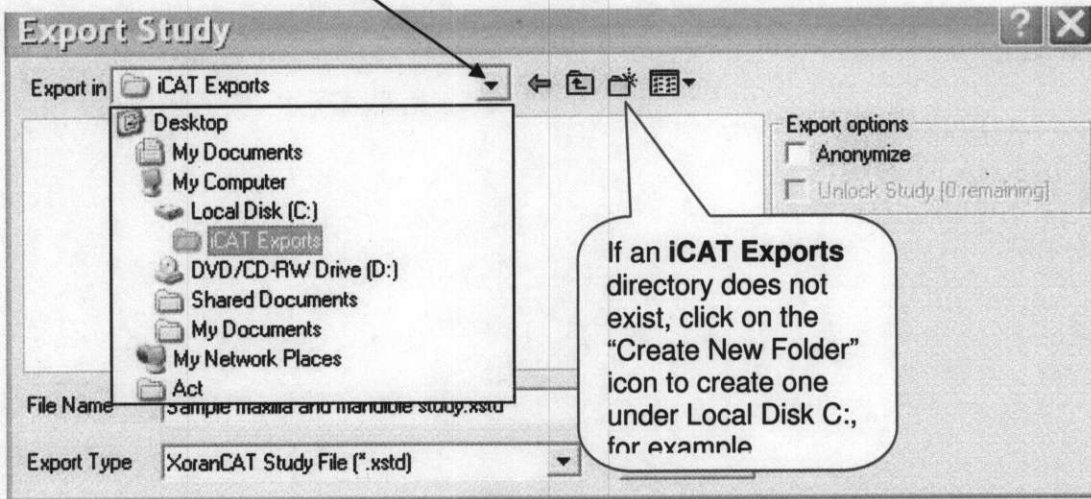
Export options:
 Anonymize
 Unlock Study (0 remaining)

Callout bubble: Clicking the Export button will display the Export Study Window

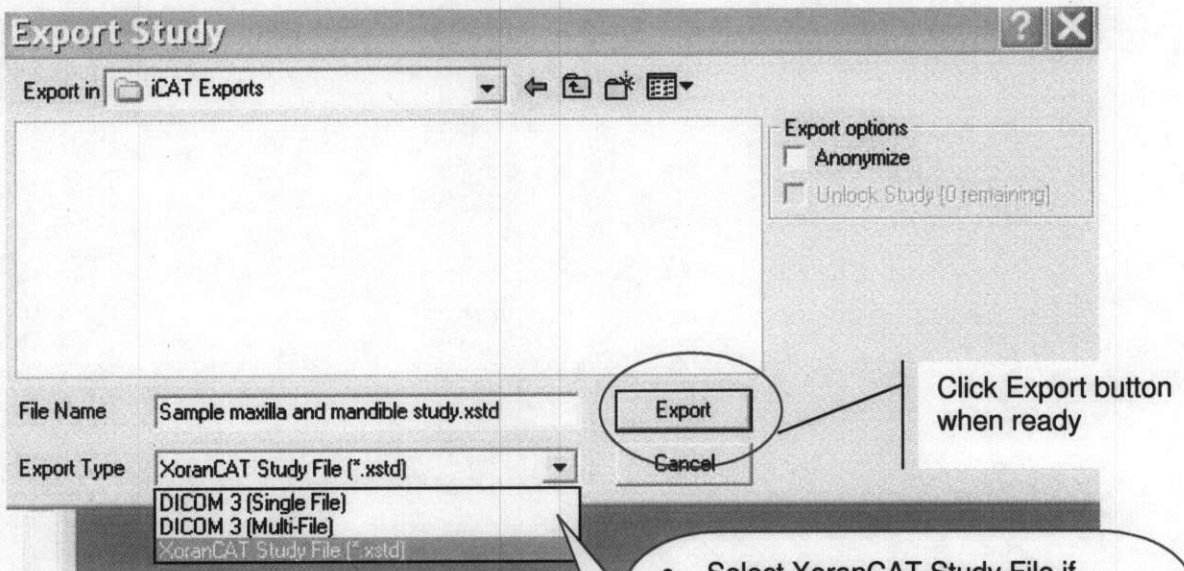
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2. When the **Export Study** Window appears, you must first select the appropriate directory in which you would like to save the exported case. At **Export In:** click on the **drop down arrow** to select the desired directory path.
(ex: Local Disk C: / iCAT Exports)



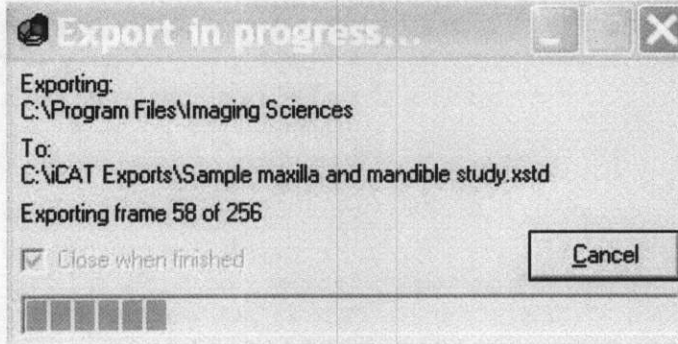
3. Now, you must select the desired **Export Type:** click on the drop down arrow to view the available options. The type will default to "XoranCAT Study File".



- Select **XoranCAT Study File** if planning to import into an iCAT workstation.
- Select **Dicom 3 (Multi-File)** if planning to import into a 3rd party volume data software (SimPlant, etc.).
(Dicom 3 Single File is no longer standard & is not used)

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4. The File Name will default to the Patient Study Name. You can change this if desired. You also have an option of enabling the "Anonymize" button before exporting. This means that when the case is imported, there will be no name assigned to it, just the word "Anonymous" with an ID number.
5. Once the *Export In*, *Export Type* and *File Name* are established, click on the **Export** button in the Export Study Window to begin the export process. A progress box will appear.



256 frames will be exported.

- For the XoranCAT Study File, the export will be one file with an extension of .xstd
- For the Dicom 3 – Multi File, the export will consist of 256 files, all but one with extensions of .dcm. **NOTE:** If burning to a CD, make sure all files are copied to the CD.

Sample of Dicom files

Address		C:\VCAT Exports	
Folders	Name	Size	Type
Desktop	Dicomdir	81 KB	File
My Documents	Sample maxilla and mandible study0001.dcm	514 KB	DCM File
My Computer	Sample maxilla and mandible study0002.dcm	514 KB	DCM File
Local Disk (C:)	Sample maxilla and mandible study0003.dcm	514 KB	DCM File
Bitmaps	Sample maxilla and mandible study0004.dcm	514 KB	DCM File
CE Credits	Sample maxilla and mandible study0005.dcm	514 KB	DCM File
Chris pictures	Sample maxilla and mandible study0006.dcm	514 KB	DCM File
CMT_PLUS	Sample maxilla and mandible study0007.dcm	514 KB	DCM File
CommCAT	Sample maxilla and mandible study0008.dcm	514 KB	DCM File
DELL	Sample maxilla and mandible study0009.dcm	514 KB	DCM File
Dmi	Sample maxilla and mandible study0010.dcm	514 KB	DCM File
Documents and Settings	Sample maxilla and mandible study0011.dcm	514 KB	DCM File
DRIVERS	Sample maxilla and mandible study0012.dcm	514 KB	DCM File
Ep173	Sample maxilla and mandible study0013.dcm	514 KB	DCM File
epson	Sample maxilla and mandible study0014.dcm	514 KB	DCM File
Epson2.10	Sample maxilla and mandible study0015.dcm	514 KB	DCM File
Epson1600XP	Sample maxilla and mandible study0016.dcm	514 KB	DCM File
Epson1680 XP	Sample maxilla and mandible study0017.dcm	514 KB	DCM File
Epson10265 for 1600_98	Sample maxilla and mandible study0018.dcm	514 KB	DCM File
Epson Latest	Sample maxilla and mandible study0019.dcm	514 KB	DCM File
EpsonReg	Sample maxilla and mandible study0020.dcm	514 KB	DCM File
hdd32	Sample maxilla and mandible study0021.dcm	514 KB	DCM File
Home	Sample maxilla and mandible study0022.dcm	514 KB	DCM File
I386	Sample maxilla and mandible study0023.dcm	514 KB	DCM File
ICAT	Sample maxilla and mandible study0024.dcm	514 KB	DCM File
ICAT Exports	Sample maxilla and mandible study0025.dcm	514 KB	DCM File
ICAT Regions	Sample maxilla and mandible study0026.dcm	514 KB	DCM File
	Sample maxilla and mandible study0027.dcm	514 KB	DCM File
	Sample maxilla and mandible study0028.dcm	514 KB	DCM File
	Sample maxilla and mandible study0029.dcm	514 KB	DCM File
	Sample maxilla and mandible study0030.dcm	514 KB	DCM File

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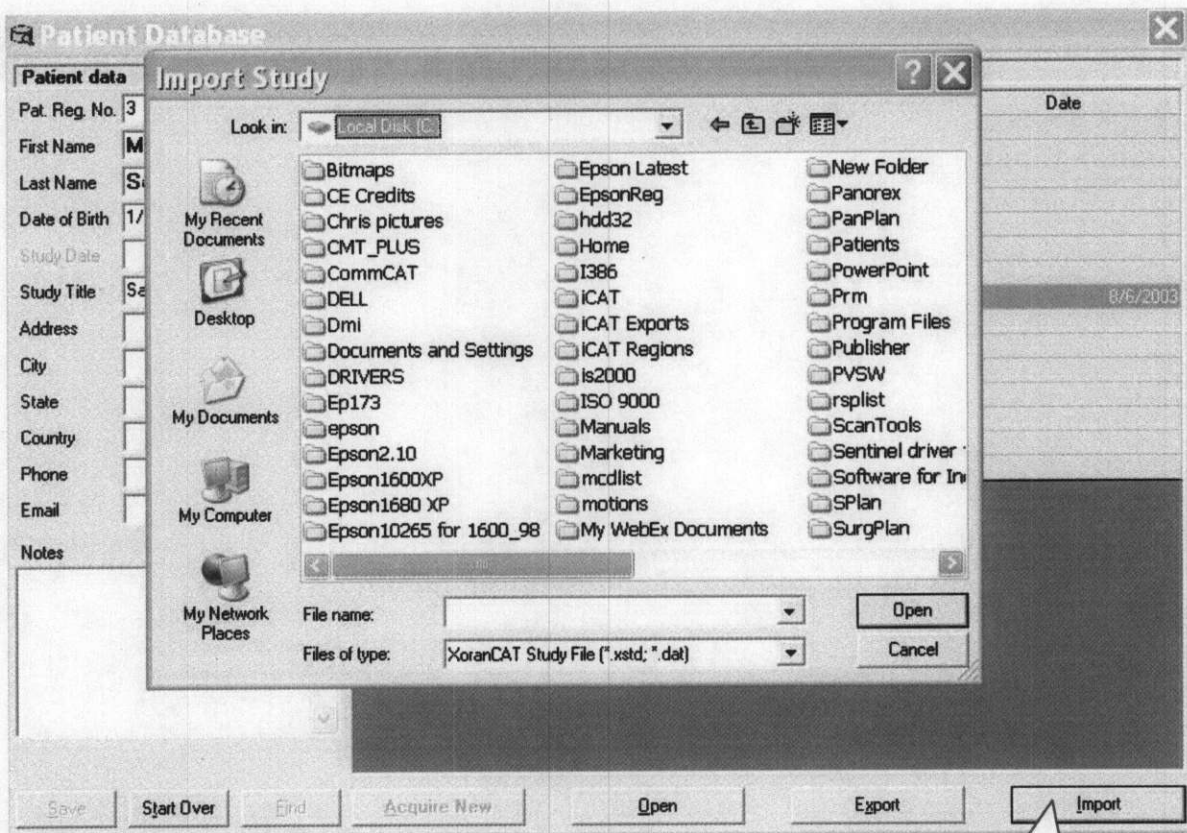
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3.14 Importing Studies

The iCAT program can only import cases that have been exported as XoranCAT Study Files (.xstd format).

To Import:

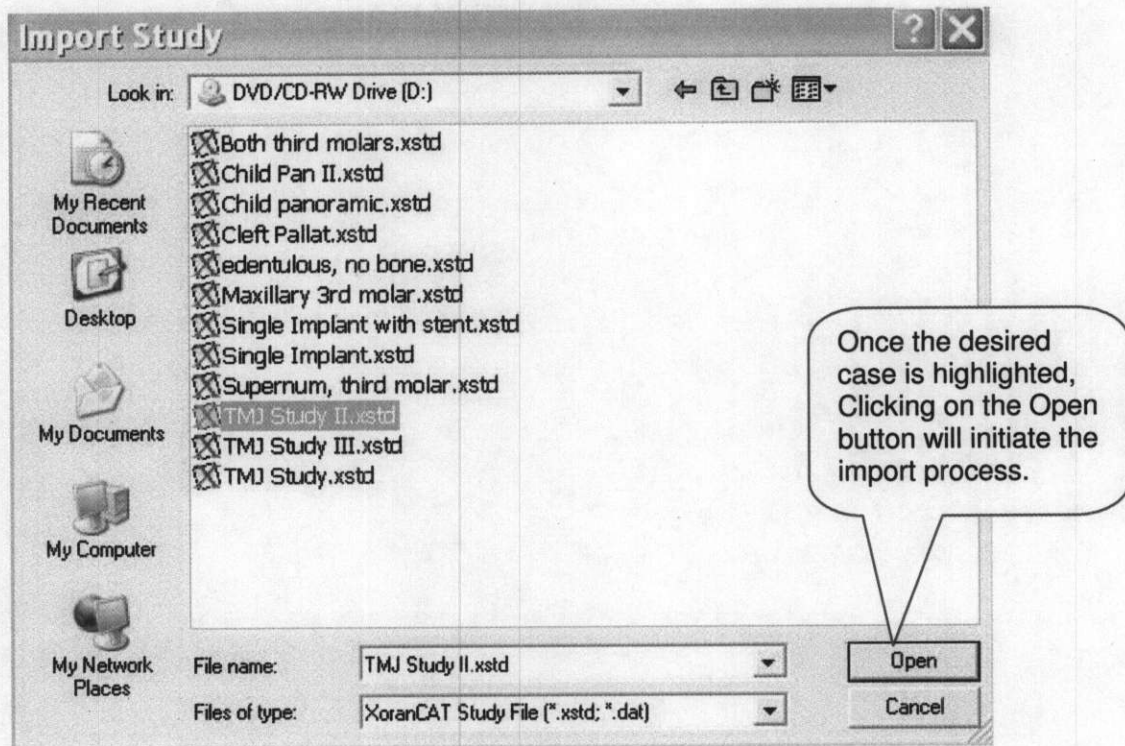
1. At the Patient Database window, click on the IMPORT button.



Clicking on the Import button will open the Import Study window.

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2. In the Import Study Window, at **Look In:**, click on the drop down arrow and select the appropriate directory path where the exported study is contained. Then **highlight the desired file and click on the OPEN button** and the case will import. (**NOTE:** multiple cases can be highlighted and imported at one time).



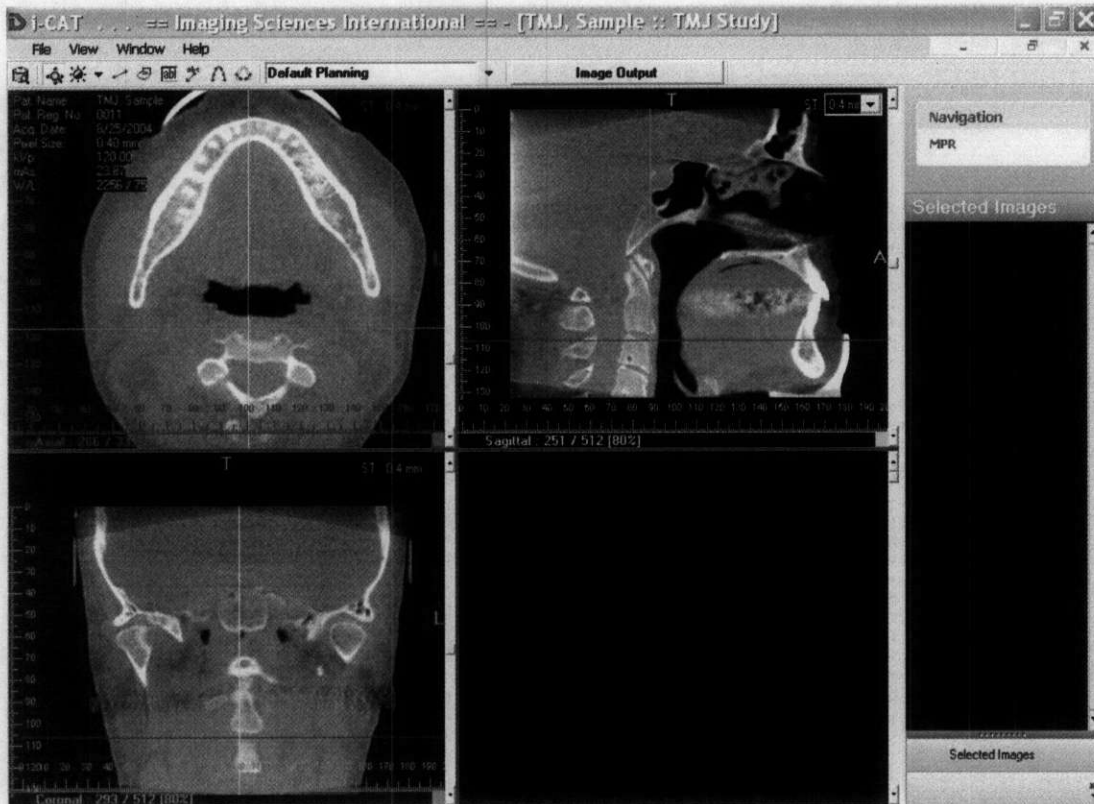
Once the case is imported, it will display in the iCAT Patient Database for access.

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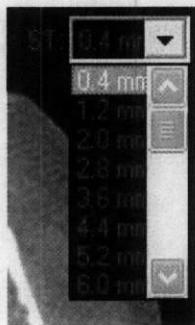
iCAT v2.0.8 Upgrade: Changes to Operations Software:

1. The Main Display (MPR) window now looks as follows, with the Axial view in the Upper Left hand corner, the Coronal below the Axial in the Lower Left hand corner and the Sagittal in the Upper Right hand corner. The Lower Right hand corner is empty.

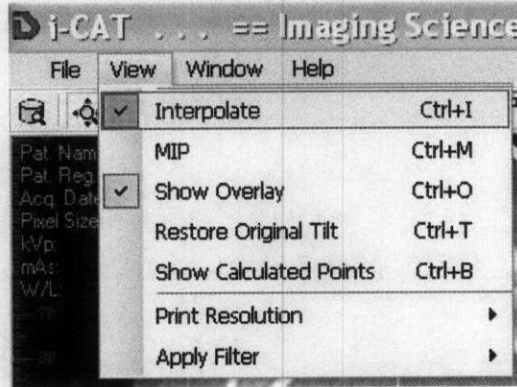
The Side Tool Bar is now called **Navigation** and is always open. It can not be closed or minimized. The Maps will continue to be listed under Navigation.



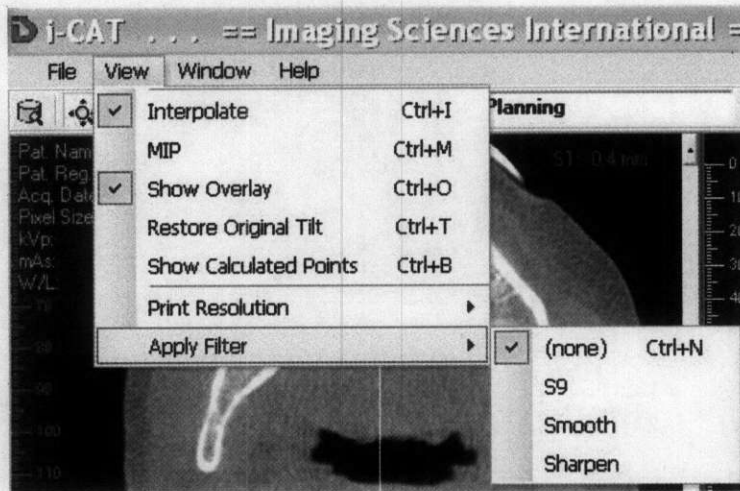
2. It is now possible to change **Slice Thickness** in all 3 MPR views from .4 mm to 150 mm. To do this, move the mouse over the ST item in the upper right hand corner of any of the 3 views to access the drop down menu of slice thickness selections.



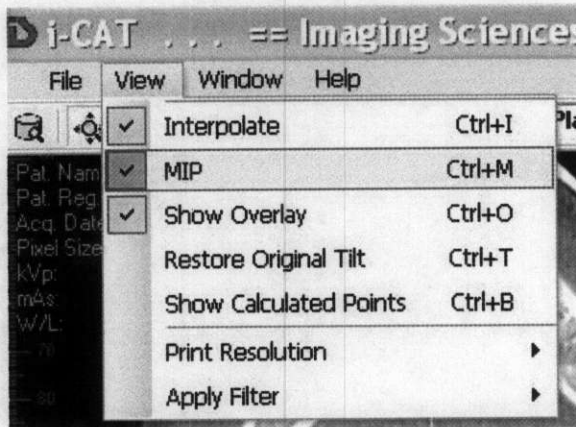
3. The **Interpolate** function is now always enabled under View. Interpolate smooths out edges when images are zoomed in.



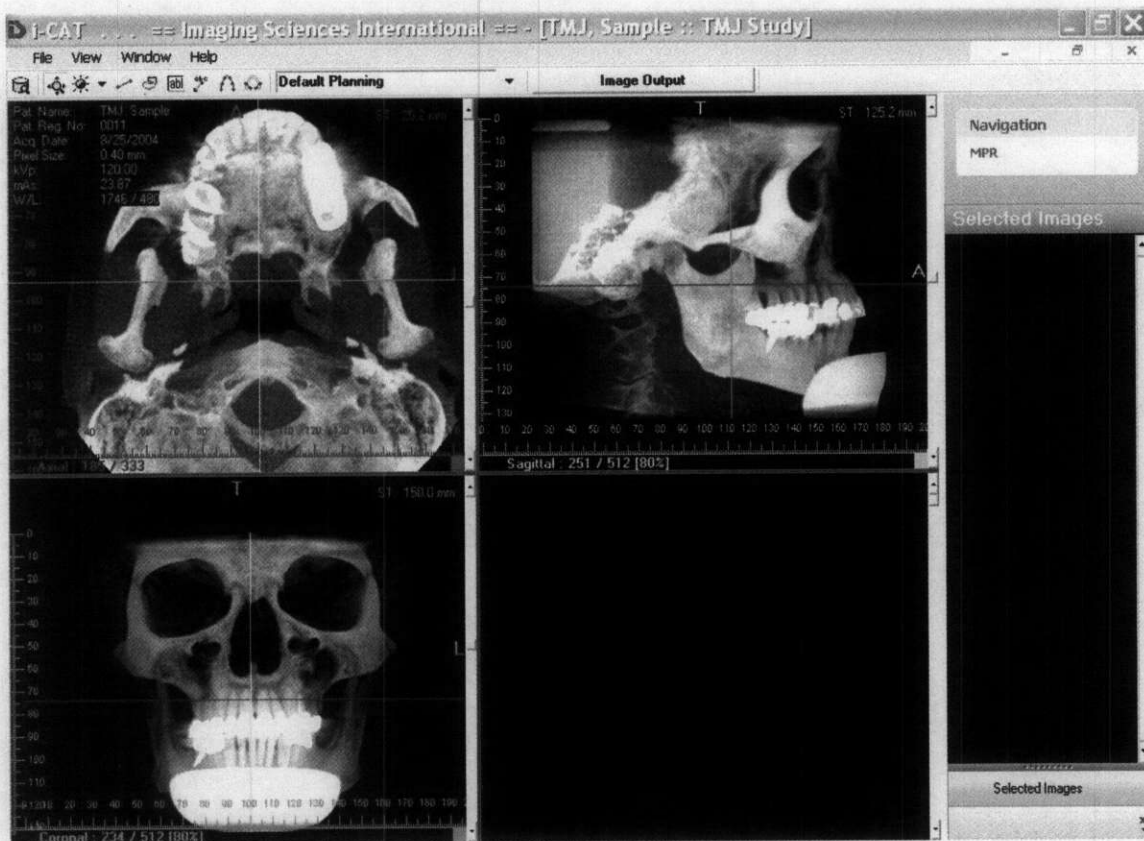
4. There is now an **Apply Filter** option under View. Click on **View / Apply Filter** and select the desired filter option. (For now, the **Sharpen** selection is the only recommended item to select). If you decide you don't want that filter applied, go back to View / Apply Filter and select (**none**).



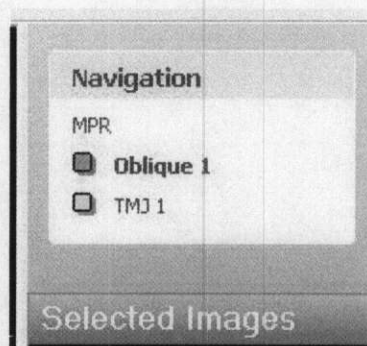
5. There is now an MIP option under *View*. Click *View / MIP* and the Radiographic views will display as an MIP projection. It is optimal to make the slice thickness of the views thicker in order to see the effect of this projection (see sample below, all slice thicknesses were made thicker). (This projection is often used for Orthodontic purposes).



MIP sample: Notice that the Slice Thickness in the Axial view was changed to 25.2 mm, the Coronal view to 150 mm and the Sagittal view to 125.2 mm.



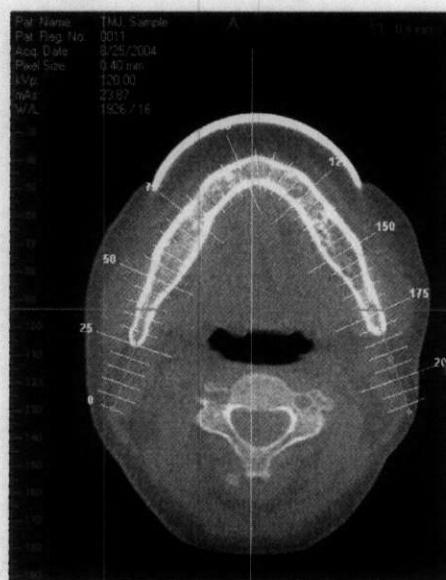
6. You will no longer have to Save Plannings. The Plannings will automatically save when the case is closed. This means you will no longer have to Load Plannings. If there is a case that already has a Plan saved, it can be imported by clicking **File / Import Viewing Protocol**. Navigate to the location of the saved plan and select. It will load into the case as in the past, and now when the case is closed, the plan will automatically be saved without having to retrieve again.
7. Now, when Exporting a case via the Patient Database window, the **Export To** window will automatically default to the last folder selected (not System32).
8. There are no longer Tabs for MPR, Oblique, TMJ and Reports. The MPR, Oblique and TMJ are listed in the Navigation section. Click on the item to view the desired screen.



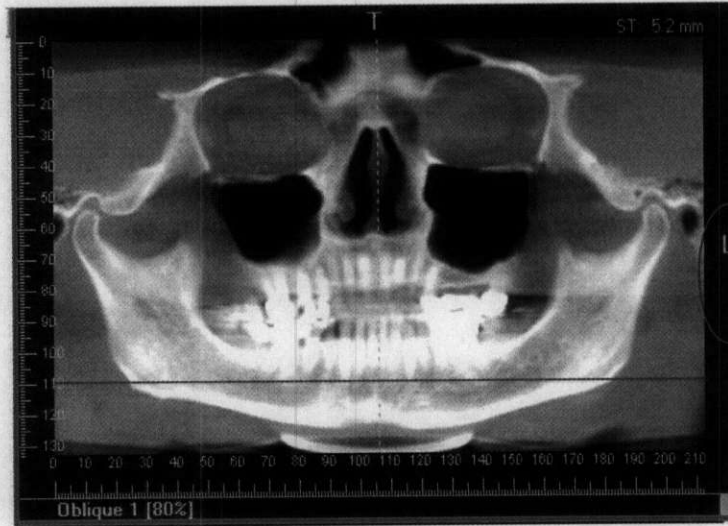
Reports are now located under a new button called **Image Output** (more details on Image Output at the end of this list).

9. Mapping an arch for Implants:

- When an arch is now mapped, hash marks will display over the map showing slice location numbers.



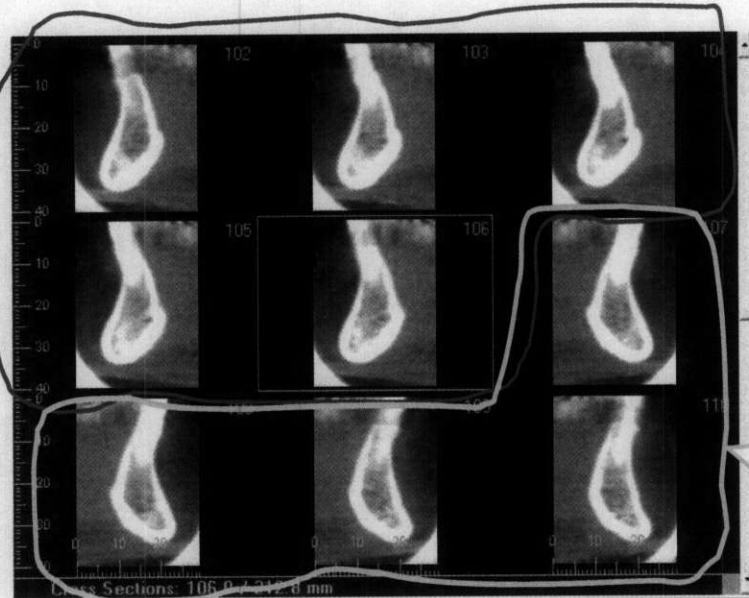
- Now, no matter what direction you map the arch, the oblique (Pan) view will **Always** display the **Patient's Right side on your Left and Patient's Left side on your Right.**



The Patient's Left side is always on your Right.

- Now, once the arch is mapped, the cross-sections will display differently for right side vs. left side. **For the patient's Right side, the buccal side will be on your left. For the patient's Left side, the buccal side will be on your right.** All of it corresponds to looking at the patient from the front.

These slices are on the Patient's Right side; the buccal side is on your left.



These slices are on the Patient's Left side; the buccal side is on your right.

10. TMJ Mapping:

- Now you need to point, click then move the mouse to the next desired location and click again. (it is no longer a point, click, drag and release, but **click-move-click**).
- Now, TMJ lateral and frontal views are displayed with orientations corresponding to looking at the patient from the front.



11. Distance (Measurement), Labels and Ellipse tools: Now you need to point, click then move the mouse to the next desired location and click again. (it is no longer a point, click, drag and release, but **click-move-click**).

12. The **Ellipse tool Shape** can be changed to Rectangle after created. (right click on ellipse, select Shape / Rectangle).

13. WorkStation keys can now be moved around from computer to computer without any need for the .xml codeword.

14. In **Acquire New**, there is now an option for taking a **“Dry Run”**. Click the box to check it off and the **Start Acquisition** button will toggle to a **Dummy Acquisition** button. This should be used to demonstrate to the patient the motion of the machine without exposing, as well as to check for shoulder clearance. The dummy scan performs half the revolution and resets immediately.

The image shows two side-by-side screenshots of a software interface for patient data and acquisition settings. Both screenshots show the following information:

- Patient data:** Patient Reg. No. 0000, Patient Name Test, Factory, Study Date 3/9/2005, 120 kVp, 36.52 mAs.
- Study:** Study title Test, Factory 3/9/2005, Protocol Sinus.
- Acquire:** Scout View button, Start Acquisition button (left) / Dummy Acquisition button (right), and a checkbox for Dry Run.

In the left screenshot, the 'Start Acquisition' button and the 'Dry Run' checkbox are circled in red. In the right screenshot, the 'Dummy Acquisition' button and the checked 'Dry Run' checkbox are circled in red.

15. Selecting Cross-section views for Reports:

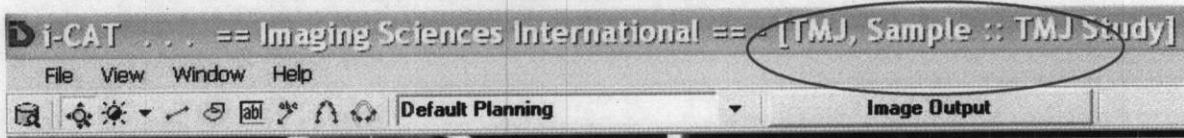
- You can now select multiple slices by **CTRL click on the first slice of the range and SHIFT click on the last slice of the range.**
- You can now **select every slice** by right clicking and selecting **Select All** from the Pop up menu.
- You can now **de-select every slice** by right clicking and selecting **Unselect All** from the Pop up menu.

Other Report Changes:

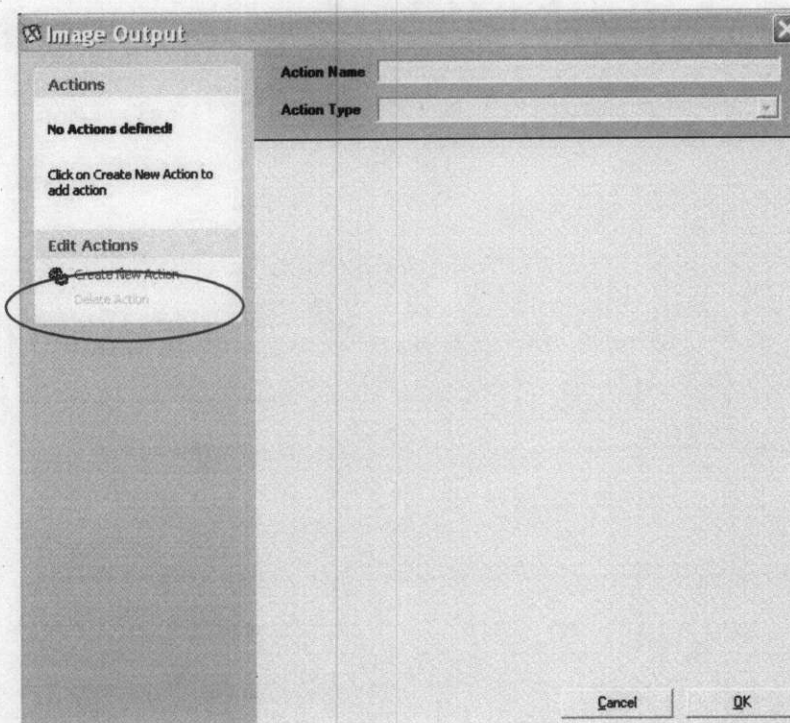
- The Report Design Functions are now permanently enabled.
- Ultra high Res scan reports now print with the slice location numbers larger.
- Reports can now be created for Multiple pages so that cross-sections can now overflow from one page to the next without having to go back and de-select the current slices and re-select new slices.
- The matrix size of the cross-sections window can now also be changed.

16. **Image Output:** This new button contains the Report Templates and Report Design functions as well as others. It is located on the Main Menu Tool Bar:

When you click on Image Output, a Modify Image Output item is in the drop down list:

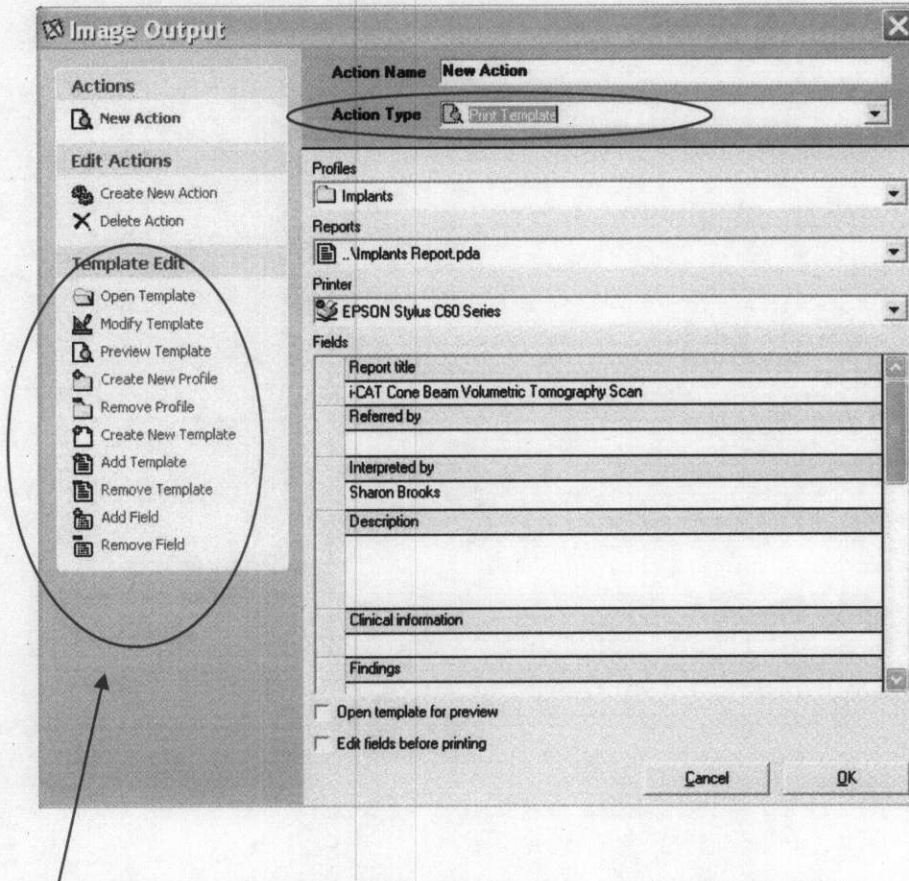


When you click on **Modify Image Output**, an Image Output window appears that allows for several functions including Report Templates, Exporting and Printing images:



Click on **“Create New Action”** to add a new action. This will now display the text **“New Action”** in the Action Name field and a drop down list of items in the Action Type field.

If we select **Print Template** from the Action Type list, then the Profiles and fields that were present in v1.3.7 Report Tab will appear. The existing 3 Profiles (Implants, TMJ, Custom) and Reports will be in their respective lists. All fields should have your existing data entered as well. We can generate reports directly from here as in the past, or save (create) each report as an **Action** that will be added to a list of common Output functions (as a short cut).



You will also notice that once in the Print Template window, on the Left hand side of this window will be a list of items under **Template Edit**. These are all the **Report Design Functions** that are now permanently enabled. (Editing templates is discussed in detail on page...)

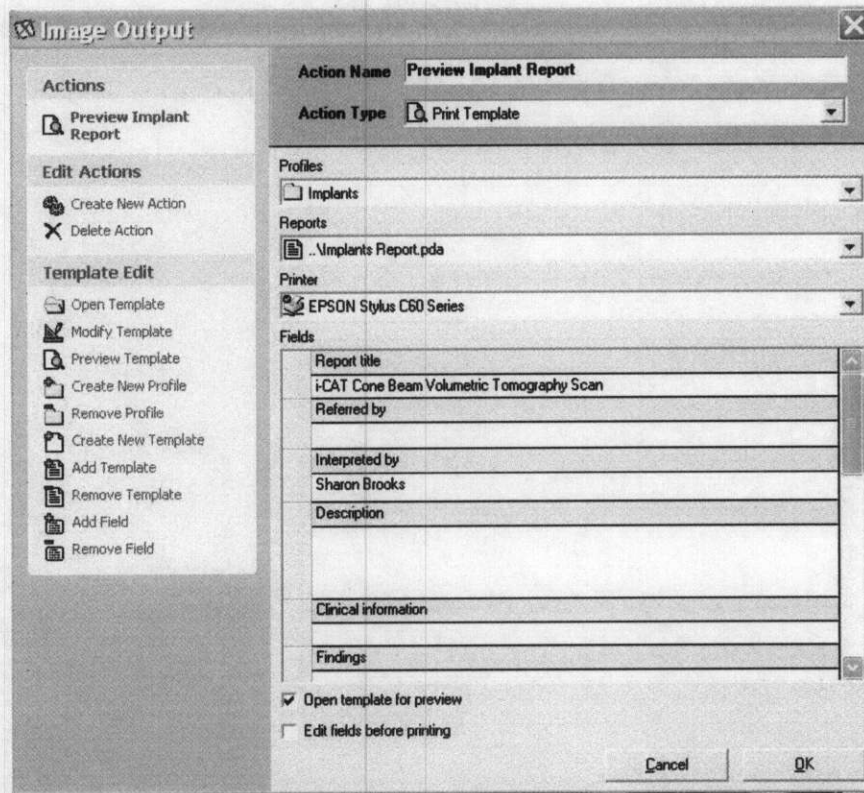
If you wish to just Preview the report as in the past, select the desired Profile and Report and then from the Template Edit list select "Preview Template". The report will Preview as in the past and then you can print or save as a PDF as in the past.

Create New Action:

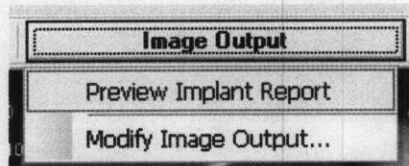
If you would like to Save (create) this Action to add to the Image Output list, you can enter a desired name in the Action Name field, select the Action Type and then select the desired functions.

1. Print Template:

For example, if I wanted to create an Action for a standard Implant Report, I would make sure I have the Implant Profile selected, then the Implants Report.pda selected (see below). I could also check off the item at the bottom of the page called "Open Template for Preview". Then in Action Name, I will change "New Action" to "Preview Implant Report". Now click OK.

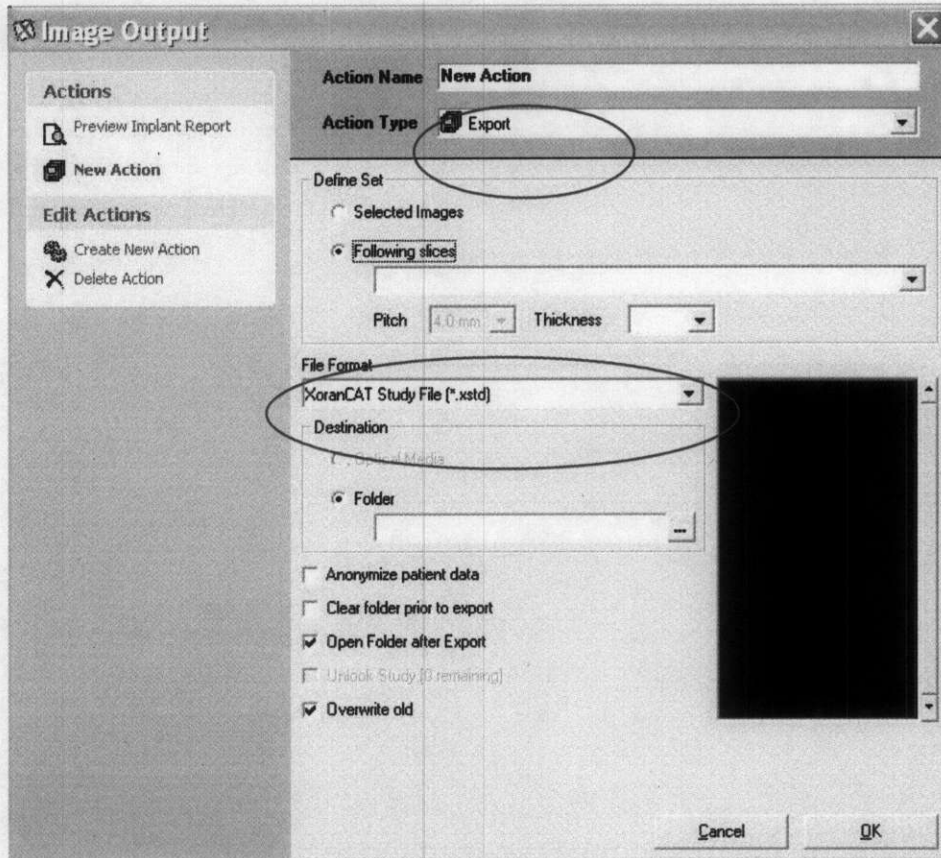


Now, when I go to the **Image Output** button, there is a New Action in the list named "Preview Implant Report. When I click on this, my Implant Report Preview will automatically open.

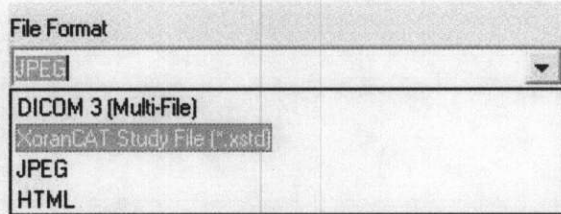


2. Export:

A New Action can be created for Exporting a case. For example, if you wanted to create a new action to export a case in the XoranCAT.xstd format or Dicom 3-Multi File, etc., click on **Image Output /Modify Image Output**. Select the **Action Type** as Export.



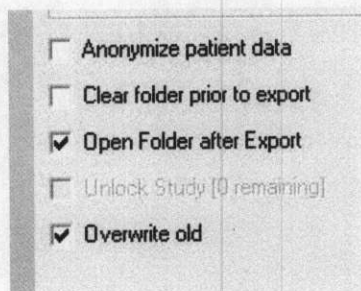
Now, you can select the **File Format** as desired. (Dicom 3-Multi File, XoranCAT Study File, JPEG, HTML).



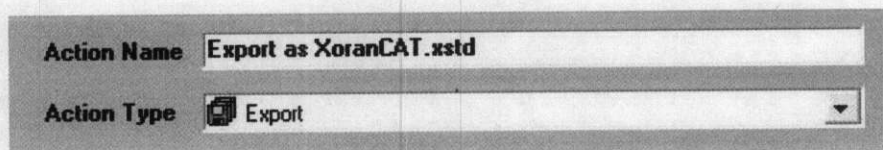
You can also map to a **Destination folder**:



Select or Make a New Folder (ex: iCAT Exports) and click OK. Then there are 5 more options that you can choose from (see below).

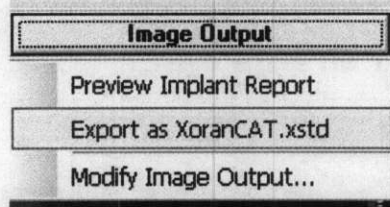


Once the desired options are enabled, then make sure to enter the Action Name into the top field (such as "Export as XoranCAT.xstd"). Then click OK at the bottom of the Image Output window.



Now when you go to **Image Output**, the New Action "Export as XoranCAT.xstd" will be in the drop down list:

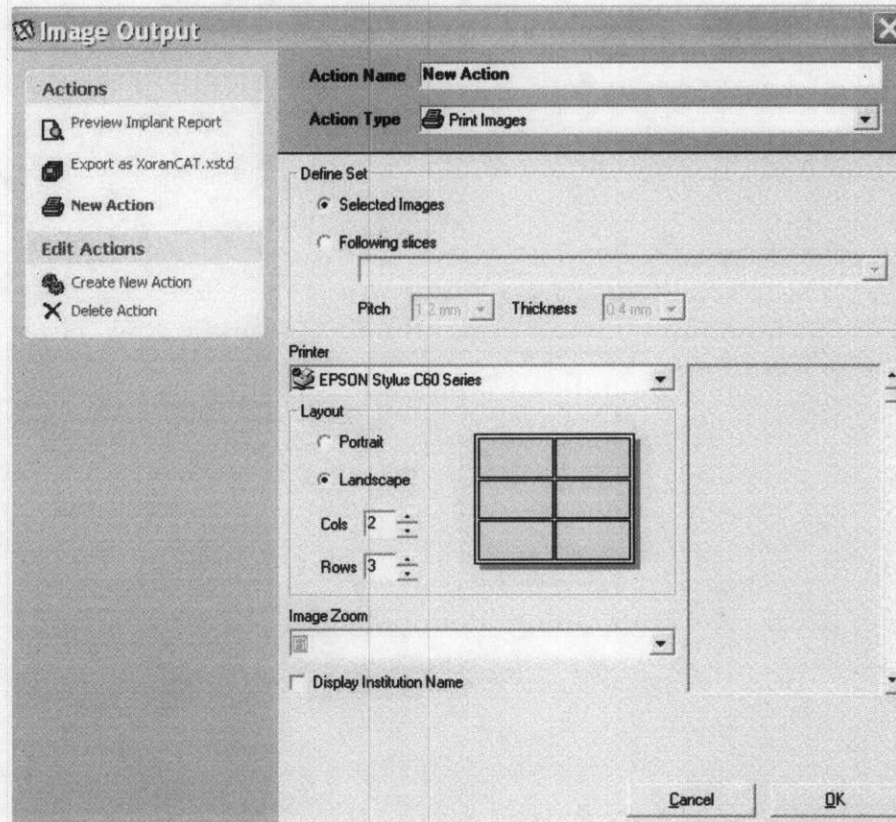
When you click on this, the case will automatically Export as a XoranCAT.xstd file as you programmed.



3. Print Images:

The last Action Type is called Print Images. This allows you to Create a New Action to print any images that have been Selected (other than cross-section images). They can be printed in different formats (not as the Report Templates).

For example, when you click on Image Output / Modify Image Output / Create New Action, select the Action Type as Print Images. The following Image Output window will appear:



In this window, you can select “Define Set”, “Layout” and “Image Zoom”.

Define Set means that you can select any Select Images or define a certain slice. If you have Selected Images, they will be displayed in the small preview window to the right.

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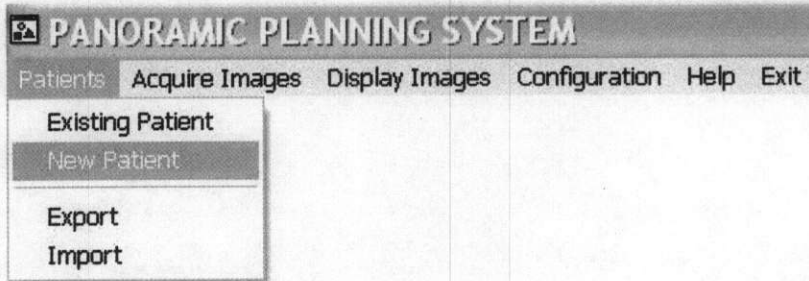
Optional Digital Panoramic (iPAN)

4.1 Acquisition

To acquire a digital panoramic image on the iCAT, the iCAT software must first be closed and the iPAN software must be launched.

Once the iPAN software is open, a Patient must first be entered into the Patient database.

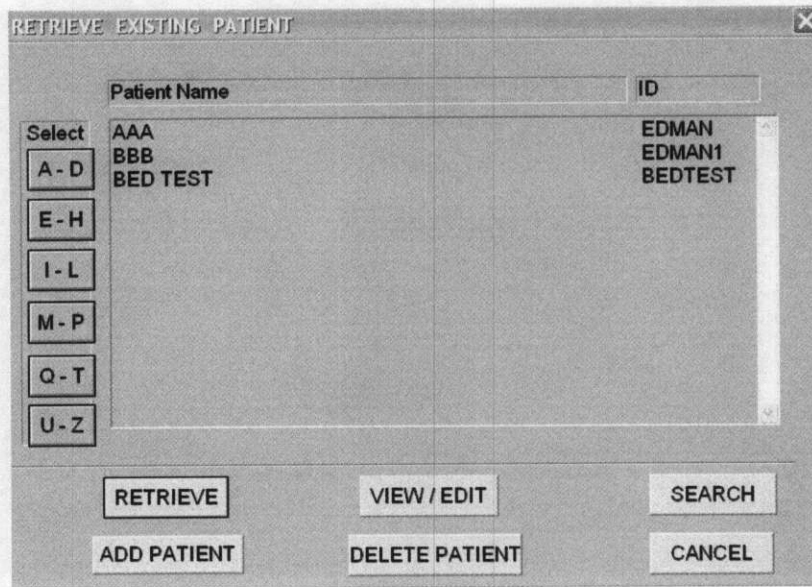
From the MAIN MENU BAR (below), click on **Patients / New Patient**.



OR, if the Existing Patient Window is open, click on **ADD PATIENT**.

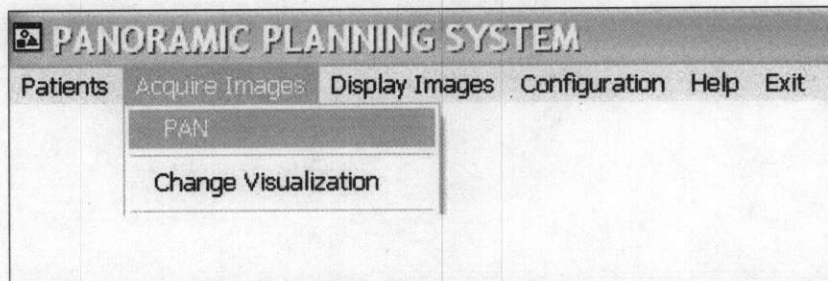
When you select New Patient or Add Patient, the window below will appear. Enter the patient data into the patient data screen. The **Name and ID # must** be entered. The ID # must be a unique number such as a chart number or SS#. The remaining information is optional.

If any Existing Patient needs to be accessed, click on **Patients / Existing Patient** and the Existing Patient Retrieval list (below) will appear.

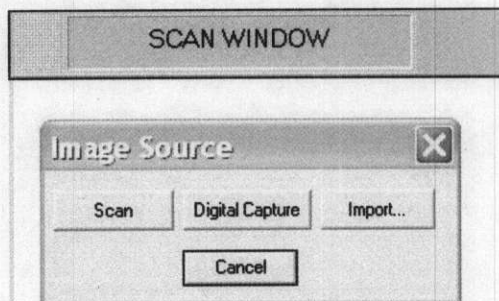


Just double click the desired patient name or highlight and click OK and the patient display will appear. If you wish to add new scans, click on Cancel and proceed as follows.

From the MAIN MENU BAR (below), click on **Acquire Images / PAN**



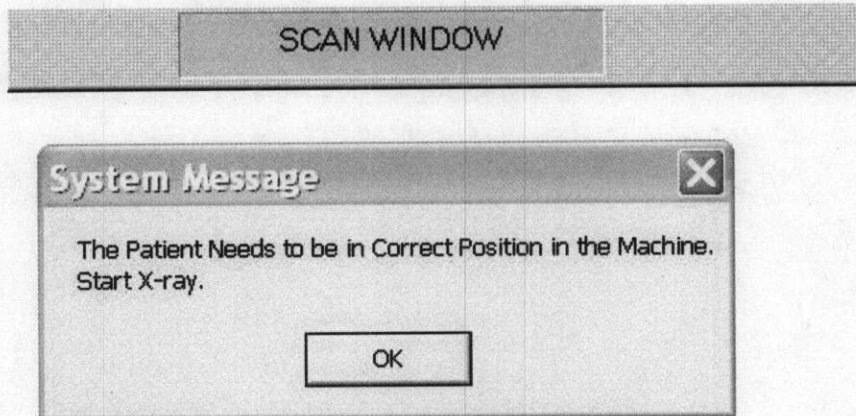
The following message box will appear.



111

Click on the **Digital Capture** button. This will initiate the imaging process. (If you wish to scan in an x-ray, click Scan or to import an x-ray, click on Import).

Then the following message will appear: Before clicking on OK, make sure the patient is correctly positioned in the machine.



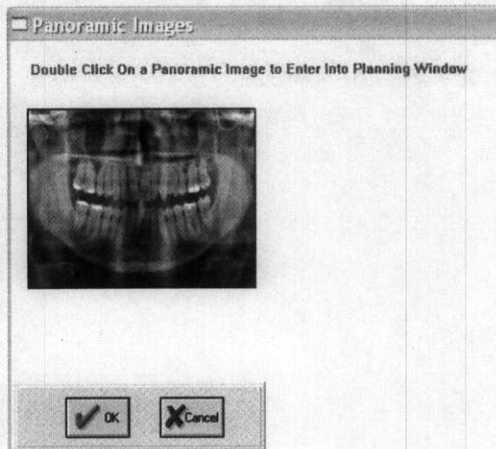
4.2 Patient Positioning for Digital Panoramic

The Patient must be positioned in the machine as follows:

1. The Chin cup must be removed and must be replaced with the bite stick.
2. The bite stick position must be adjusted to the designated position for panoramic imaging, marked at 80.
3. The patient is sitting in the chair with an Erect posture. The neck must be as straight as possible.
4. Patient must bite in the groove of the bite stick
5. Patient Tilt: Frankfurt Plane Horizontal (line from the center of tragus to bottom of orbital parallel to floor).
6. Laser light: adjust the Overhead so that the horizontal laser light is through the maxilla, centered between the nostril and the upper lip.
7. Lips closed around the bite stick like a straw.
8. Before exposing, instruct the patient to swallow and put the tongue to the roof of the mouth and hold for the duration of the exposure.

Once the Patient is positioned correctly, click OK and the machine will begin its exposure. The panoramic exposure is 20 seconds long.

When the exposure is complete, the Panoramic image will display in the patient file as a thumbnail.

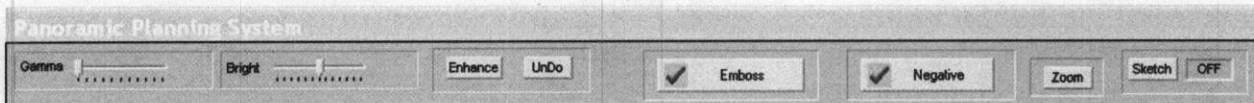


Double click on the thumbnail image to view in full screen and to utilize the Planning features explained in the next section.

If you wish to acquire an additional Pan, click on Cancel, then at the Main Menu, click on **Acquire Image / Additional Pan** and select Digital Capture. Additional Images will display as additional thumbnails.

4.3 Image Enhancements

A toolbar is displayed on the top of the iPAN display screen with **Gamma, Brightness, Contrast, Enhance, Emboss, Zoom** and **Sketch** buttons.



Gamma, Bright:

The features **Gamma, Bright** and **Enhance** allow you to enhance the displayed panoramic view. They are accessed through buttons displayed across the top of the screen. These buttons are accessible in all sections of the program.

When using **Gamma or Bright**, make adjustments by clicking and dragging the sliding scale for the respective functions. Please be aware that an adjustment can be reversed or re-adjusted as many times as desired.

Enhance:

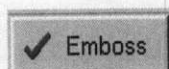
The **Enhance** feature will enhance a desired **section** of the image. First click on the **Enhance** button. (The cursor will change to an "*" once the arrow is moved inside the desired window). Then with the mouse, enclose an area that you would like to enhance

(point, drag and click). The enhancement will take place in that boxed region. To Undo an enhancement, just click on the **Undo** button which is located next to the **Enhance** button.

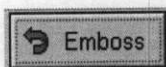
Important Tip: Enclosing different sized areas produces different results. If one particular choice did not yield the desired result, try a smaller or larger area.

Once enhancements have been performed, you have the option of saving those changes permanently. The system would prompt you to save the changes once you attempt to leave that screen. Just respond with clicking on **Yes** or **No**.

Emboss:



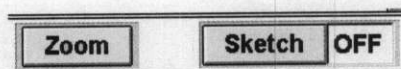
The Emboss feature displays the entire image in emboss form. It converts the gray levels into contours with varying depth perceptions (topographical). This allows for visualization of different bone detail as three-dimensional. To activate Emboss, click on the **Emboss** button (above) and the image will transform. The Emboss button will change (below) while in Emboss. To de-activate Emboss, click the button again.



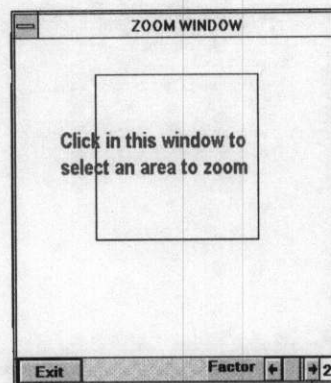
Negative:

The Negative feature displays the entire image as a negative. Click on the Negative button to activate. To de-activate Negative, click the button again.

Zoom:



Zoom will allow you to magnify an area within any view on the screen. To activate the Zoom Feature, click on the **Zoom** button. A Zoom box will be created in the lower right hand corner of the screen (See below). With the mouse, click inside this Zoom box and a box will appear. Now move this box over with the mouse to the desired area of the image. Click again and that section of the image would appear in the zoom window. A zoom factor of 2 or 3 should be sufficient for most cases.



4.4 Sketch

Sketch allows you to trace freehand on the Panoramic image. To activate the Sketch feature, click on the **Sketch** button. A sketch control window will appear on the bottom right hand corner of the screen (See below).



You can now draw on the image. It is possible to sketch a curve in either continuous or discreet fashion. Just select **discreet** or **continuous** in the sketch control.

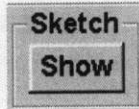
Discreet: In the discreet method, a series of points can be clicked, and the software would automatically join those points forming segments of the curve. Please remember to **right click** to **signal the end** of a discreet curve. All other buttons would be **non-functional** until the right click is done. The "Delete" key on the keyboard can be used to delete the last segment of a discreet sketch.

Continuous: In Continuous mode, just drag the mouse to draw the desired curve. To draw a dot, just click and release at any spot. A series of dots or dashes can be used to outline a structure. Any combination of line thicknesses and colors can be used for color coding various structures. Click on **size** to change the thickness of the line or diameter of the dots. Size (line thickness) can be selected either numerically (enter a number between 1 and 8) or visually from a set of choices. For numeric selection, click on the **Numerical** radiobutton, and for visual selection, click on **Dialog**. Click on **Color** to select a different color.

The last item drawn can be deleted by clicking on **Last** under **Delete**. All items drawn can be erased by clicking on **All**. The "Delete" key on the keyboard can also be used to delete the last drawn item.

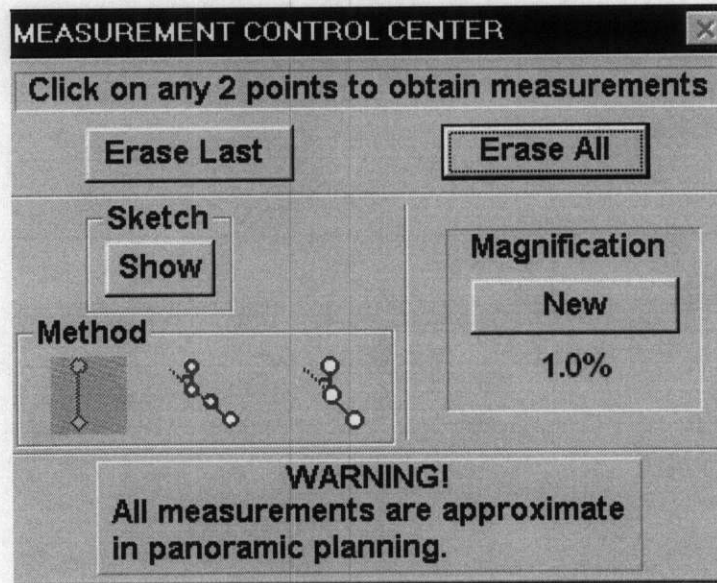
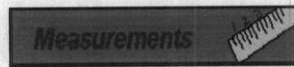
When finished, click on **End** in the sketch control box. A prompt would appear for saving the newly drawn sketch. You may choose to save or discard the changes.

The drawn sketch is saved as an overlay to the original image. This overlay can then be shown at any time. To show the sketch, just click on **Show** under **Sketch** in the applicable control box. Subsequently, click on **Hide** to remove the sketch from the image. This can be repeated at any desired time.



4.5 Measurements

Click on the **Measurements** button to access the Measurement Control Center (below).



The actual magnification of panoramic images produced in various equipment varies. This magnification factor should be set for the applicable equipment before proceeding with measurements. There is a display of currently set magnification, in %, in the measurement control center, which 1.0% for the iPAN. If you scanned or imported an image from another machine, you would want to change the magnification specific to that equipment. To change this magnification, just click on the **New** button next to this display and type in the new magnification.

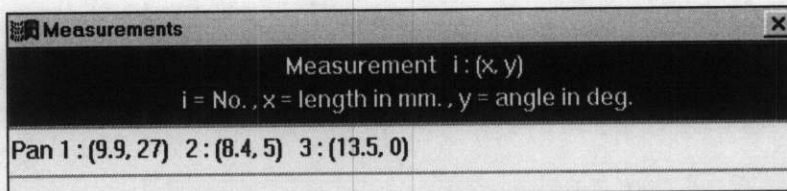


Click on the method of measurement that you desire. **(Please be aware that all measurements are approximate in any panoramic view, even with the magnification % adjusted).**

1. The first **Measurements** button



allows you to obtain measurements, in millimeters, when you click on any two points within the panoramic view. A line would be drawn between the selected pair of points, which would be tagged by a sequence number (starting with 1). The actual distance and angle from vertical would appear in a **Measurement Display** window (below). Multiple pairs of points can be selected to measure various anatomical dimensions.



The **Measurement Display** window is moveable. It can be moved out of the way if desired by clicking and dragging on the caption bar.

2. The second **Measurements** button



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allows for measurement of the angle between 2 disjoint lines, which requires clicking on a total of 4 points. The button signifies this by depicting 4 small circles representing the clicked points. Once the 4 points are clicked, the corresponding pair of lines is drawn and the angle between them is calculated and displayed. Please note that only the acute angle is displayed, regardless of the layout of the 4 points. The measurement is numbered just like previously, except that the distance entry is replaced by an "A", which stands for **Angle**. Since this method is designed for angular measurement only, no distance is displayed.

3. The third **Measurements** button



allows for measurement of an angle between a joined pair of lines, which requires clicking on a total of 3 points. This button depicts 3 points corresponding to the clicked points. Otherwise, this method works identical to the above.

Once measurements are made they are preserved in a file. At any time when one returns to the **Measurements Display** window, all the previous measurements will be displayed.

Within the **Measurements Control**, one or more measurements can be erased if so desired.

Erase Last

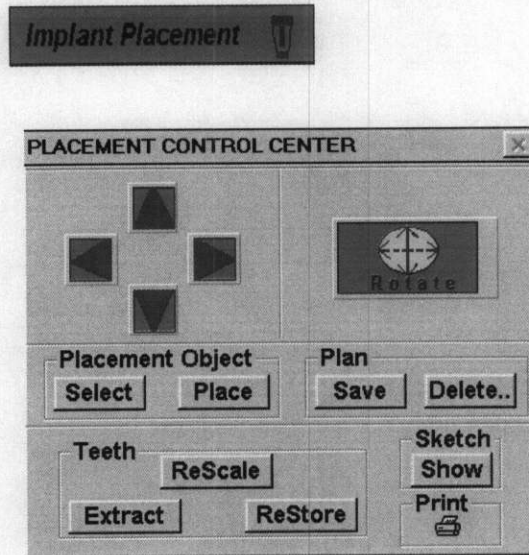
Erase All

Note: It may be desirable to record the measurements in order to refer to the numbers when selecting an implant template size. The measurement view can be re-visited at any time where all the measured distances are intact.

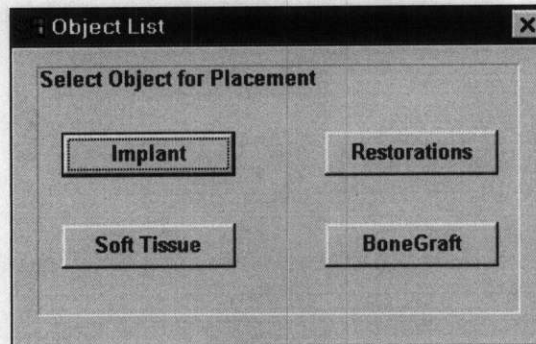
4.6 Implant Placement

Implant Placement procedure allows for implant placement simulation at the desired sites in the panoramic image. It also provides numerous other features including **Bonegraft depiction**, **Soft tissue depiction**, **Restorations**, and **Tooth extraction**.

Click on **Implant Placement** button to open up the Placement control center (below).



To select an implant as well as one of the other types of objects, click on **Select** in **Placement Object**. Four choices will appear: **Implants**, **Bonegrafts**, **Soft tissue** and **Restorations**.



Implants:

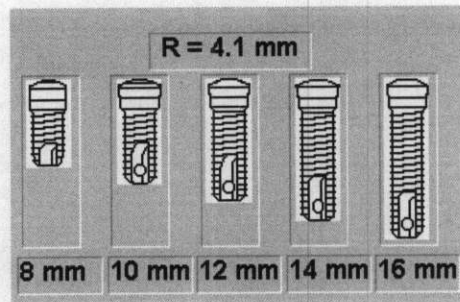
Click on **Implants** to display the choices of implant manufacturers.

Sampling of Implant Manufacturers



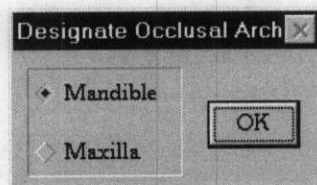
Click on the desired Manufacturers logo to display its templates.

Sample of Implant Templates



Double click on an implant (or single click and then click on the OK button) to select an implant for placement simulation.

Once an implant is selected, just click at the desired site of the panoramic image to place the implant. The center of the implant will appear at the clicked point. If this is the first implant to be placed in this image, a prompt would appear asking if the placement site is in the mandible or maxilla.



Once selected, all subsequent implants would be automatically determined to be either in mandible or maxilla. Just click on the placement site to place the implant. To place another copy of the previously selected implant, just click on the **Place** button and click on the desired site. If another implant is desired, make a new selection by clicking on **Select** followed by **Implant**, and repeat the procedure.

Placed implants can be maneuvered and rotated.

1. To **Move** the implant: with the Left mouse button, Point, Click and drag the template up and down, left and right.

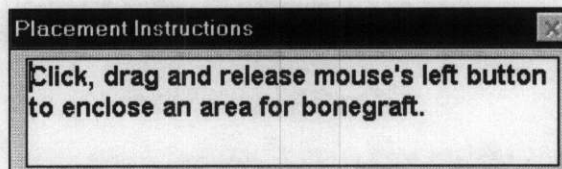
(**Hint:** When moving an implant, click at the center of the implant before dragging).

2. To **Rotate** the implant: with the Right mouse button, Point, Click and roll left to right.

(**Hint:** When rotating, click at the **tip** of the implant template before making the rotation movement with the mouse; this will result in better control and ease of rotation).

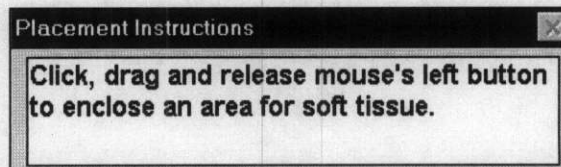
Bonegrafts:

Click on **Select** followed by **Bonegraft**. A prompt will appear asking to draw a closed-curve representing the bonegraft simulation. The depicted bonegraft will display in a gray color.



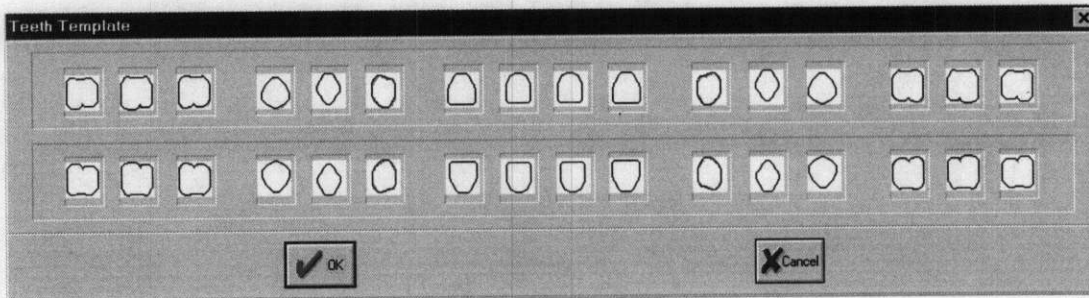
Soft tissue:

Click on **Placement objects** followed by **Soft tissue**. It works identical to bonegraft, except that the filled in mass is colored in pink. This could be utilized to depict the level of soft tissue in conjunction with other proposed fixtures.



Restorations:

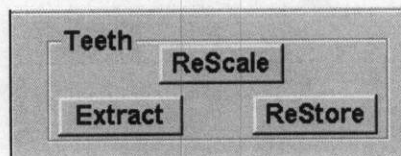
Click on **Placement objects** followed by **Restorations**. A template of 32 teeth will appear in a natural layout. Any particular tooth can be selected for placement by double-clicking on it.



Once selected, click on **the desired site** to place the tooth. If this is the first tooth to be placed in this image, a prompt would appear asking for the top and bottom points of this tooth. These points are utilized for scaling the size of the tooth to the actual panoramic image, whose magnification can vary. Please select the 2 points according to the proportional size of the restoration with respect to the rest of the image. Once the scaling points are entered, the system will prompt for the placement site. Just click at the desired site to place the tooth. All subsequent teeth will be scaled automatically.

If an error message "**Tooth height too small: please re-enter top and bottom points of the tooth**" appears when scaling points are entered, it means the height is too short. This could have been caused by inadvertently repeated clicks. Re-enter the points in this case.

If the scaling factor is not correct and it is desired to be re-adjusted, just click on the **Rescale** button in the **Teeth** section of the control center (see below). The prompts would re-appear asking for the top and bottom points. All placed teeth will be rescaled once the points are entered.

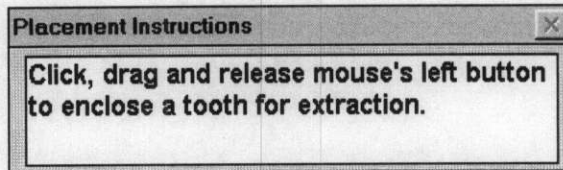
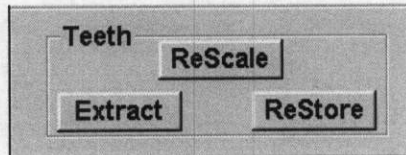


To place another copy of the same tooth, just click on the **Place** button followed by the desired site. To select another tooth, click on **Select / Restorations** and repeat the procedure.

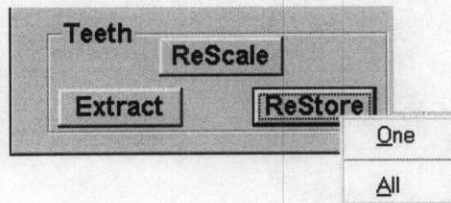
The restorations can be maneuvered by dragging them with the left mouse button, and tilted by dragging them with the right mouse button, just as with implants.

Extractions:

A tooth can be effectively extracted from the panoramic image by using this tool. Just click on the **Extract** button in the **Teeth** group in the control center. A prompt will appear requesting the desired tooth to be outlined (see below). Drag the left mouse button to enclose the applicable tooth with a closed curve. Once the button is released, the tooth will be effectively extracted.



If it is desired to "restore" one or more extracted teeth, just click on the **Restore** button in the **Teeth** group. Select **One** or **All** in the subsequent window (see below). If **One** is selected, double click on the general area of the desired extracted tooth. That particular tooth will re-emerge after a confirmation prompt. If **All** is selected, all extracted teeth will re-appear after a confirmation prompt.

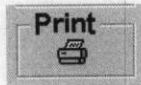


Please note that a maximum of 10 teeth can be extracted in any given Panoramic

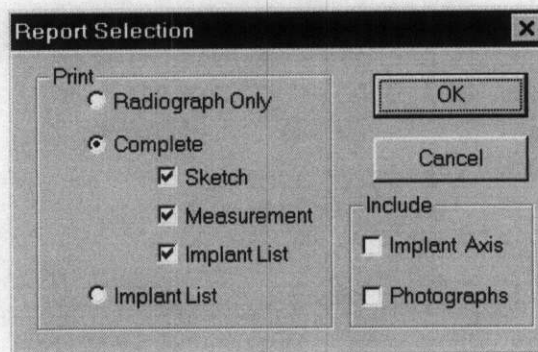
4.7 Reports

iPan Reports:

A report can be printed using the printer icon in **the Placement control center**.



A menu appears with choices of **Radiograph Only** and **Complete** with sketch, placed objects, measurements, and/or **Implant List**. You also have the option to include the **Implant Axis** and **Photographs**. The choice defaults to **Complete**. (See below).



In the first 2 choices, the user is prompted for custom remarks, and if entered, the remarks are printed below the image, the measurements and the implant list, if any.

When **Implant list** is selected in PanPlan as the main choice the heading of the page appears as **"Implant list as placed in Panoramic View"**.

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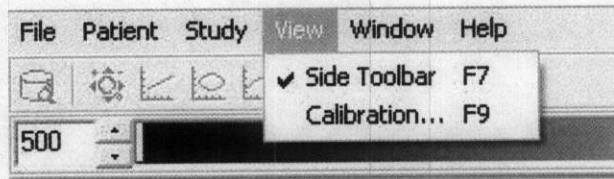
Calibration and Quality Assurance

5.1 Calibration

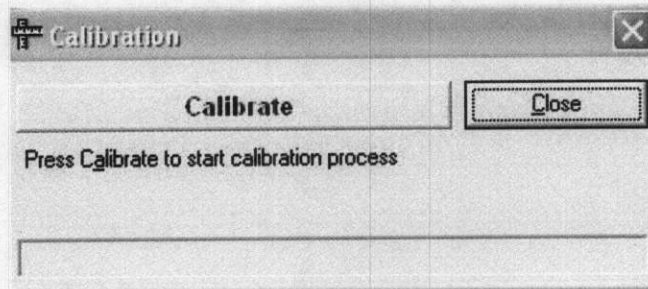
The i-CAT will require Calibration daily.

To ensure the proper functioning of the detector, make sure that the room temperature is in the range of 50 to 95°F (10 to 35°C).

From the Main Menu bar, click on **View / Calibration**



This will display the following window:



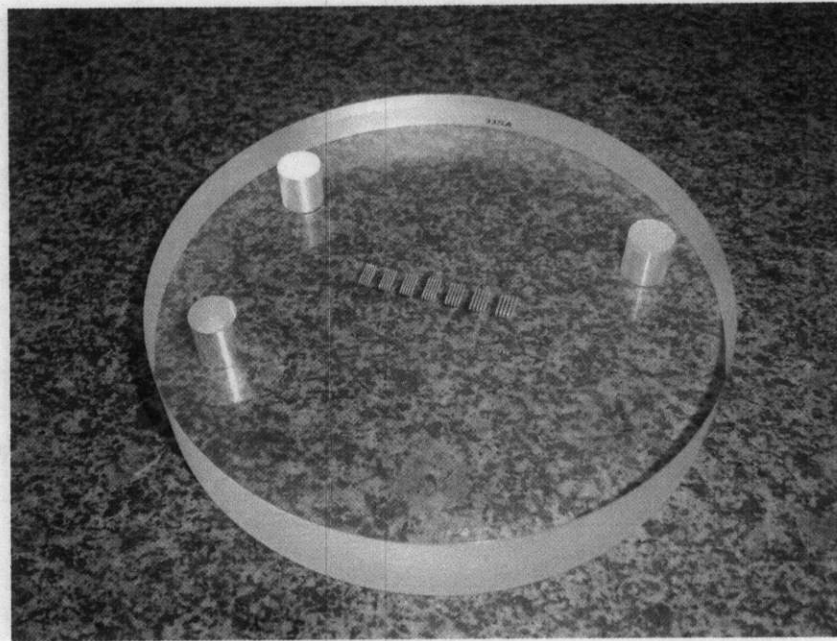
Click on "Calibrate". This will initiate the first of 2 items. When this phase is complete, another message will appear on the screen prompting to "Turn on X-ray". Before clicking OK, make sure that the machine gate is Open and there are no objects obstructing the path of the exposure. When ready, click OK and the machine will take an x-ray for approximately 20 seconds. This will complete the calibration sequence.

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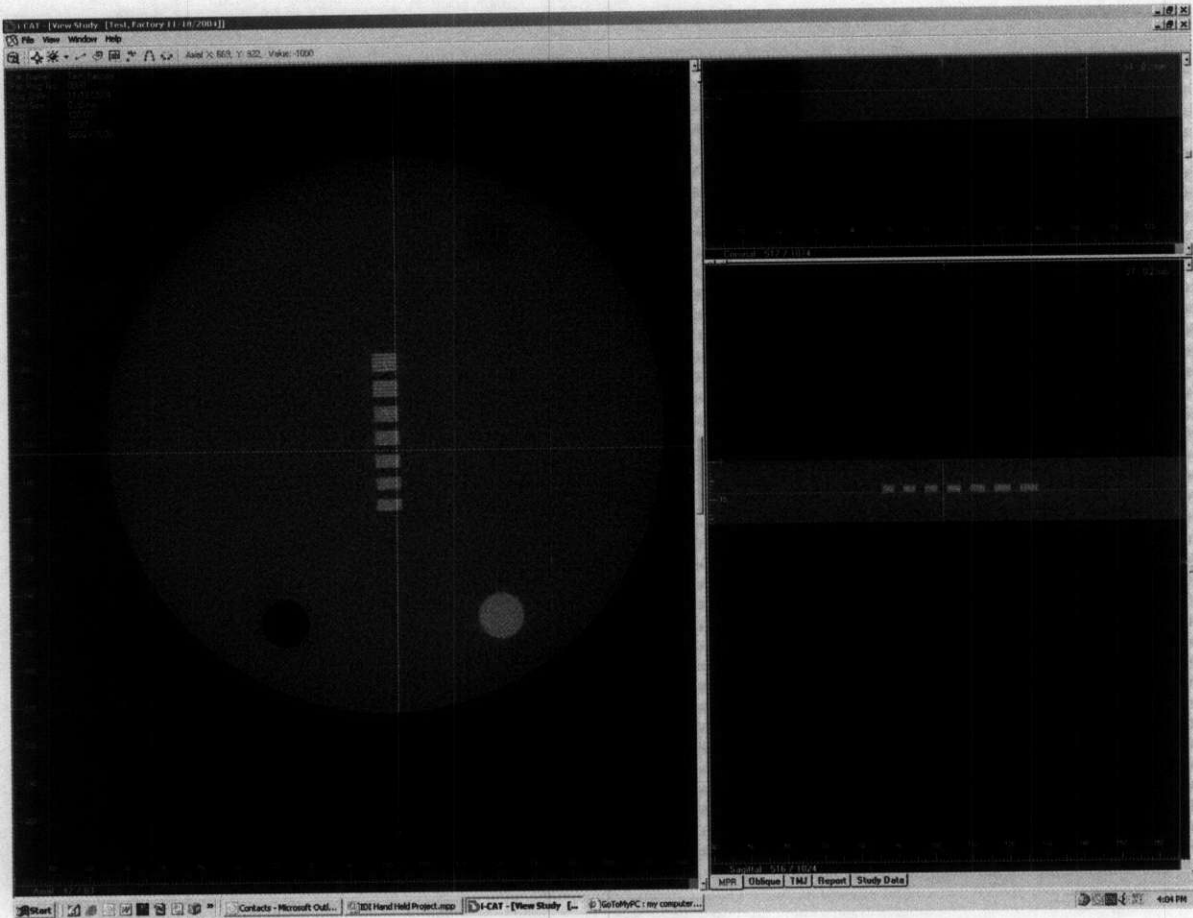
5.2 Quality Assurance

It is recommended that an annual check of the mA and KVP of the x-ray source is performed by a trained service person.

It is recommended that the system quality assurance procedure is performed at least once annually. For that purpose a Quality Assurance phantom and container is provided. The procedure consists of measuring the visibility of the bar pattern phantom and the mean and standard deviation of the four inserts and water with different CT numbers (Hounsfield units).



QA Phantom



The expected appearance of the bar pattern insert on a normal scan performed in "Ultra-High Res" imaging protocol. You should be able to distinguish 10, 11, and 12 lp/cm.

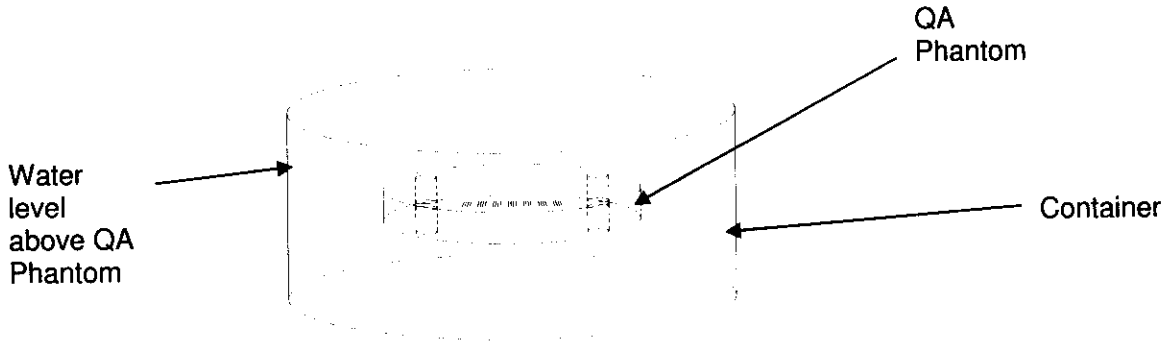
Material	CT Number(Hounsfield unit)
Air	-1000
LDPE	-100
Acrylic	120
Teflon	990
Water	0

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August 01, 2005

Setup:

Insert the QA phantom into the container. Fill the container with enough water to cover the QA phantom. See below:



Affix the QA phantom/container in the head holder and make sure it is centered in the field of view. Start image acquisition; protocols; "Ultra-High Res (Maxilla) 20 sec" mode. Once the reconstructed image is displayed on the screen, use the provided tool in the toolbar to measure the mean and standard deviation of the four inserts and water. You should be able to distinguish 10, 11, and 12 LP/CM at a minimum.

Material	CT Number (Hounsfield Unit)	
	Measured	Should be
Air	()	-1000 (40)
DPE	()	-100 (40)
Acrylic	()	120 (40)
Teflon	()	990 (40)

Bar pattern: _____ lp/cm

i-CAT: Chapter 6

Radiation Information

6.1 Radiation Environment Survey

(b)(4)



Part number 990310

August 01, 2005

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All data was acquired using Victoreen Model 450P survey meter (S/N 3159) in integrate mode. Data was acquired in concentric circles of radii 1 m (3.28 ft), 2 m (6.56 ft) and 3 m (9.84 ft). Skull 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.

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

This table consists of data gathered with the i-CAT operating at 120 kVp, 5 mA and the following parameters:

Total scan time: 20 seconds

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

Assumed use and occupancy factors: 1

Location	Distance m (ft)	Exposure (μ R)	mR/h	mR/mAmin	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	1 (3.28)	178	32.04	0.1068	1.78	4.45	8.9
	2 (6.56)	31	5.58	0.0186	0.31	0.775	1.55
	3 (9.84)	20	3.6	0.012	0.2	0.5	1
45°	1 (3.28)	184	33.12	0.1104	1.84	4.6	9.2
	2 (6.56)	37	6.66	0.0222	0.37	0.925	1.85
	3 (9.84)	21	3.78	0.0126	0.21	0.525	1.05
90° (B)	1 (3.28)	186	33.48	0.1116	1.86	5	9.3
	2 (6.56)	43	7.74	0.0258	0.43	1.075	2.15
	3 (9.84)	21	3.78	0.0126	0.21	0.525	1.05
135°	1 (3.28)	143	25.74	0.0858	1.43	3.575	7.15
	2 (6.56)	33	5.94	0.0198	0.33	0.825	1.65
	3 (9.84)	17	3.06	0.0102	0.17	0.425	0.85
180° (C)	1 (3.28)	139	25.02	0.0834	1.39	3.475	6.95
	2 (6.56)	33	5.94	0.0198	0.33	0.825	1.65
	3 (9.84)	14	2.52	0.0084	0.14	0.35	0.7
225°	1 (3.28)	168	30.24	0.1008	1.68	4.2	8.4
	2 (6.56)	42	7.56	0.0252	0.42	1.05	2.1
	3 (9.84)	18	3.24	0.0108	0.18	0.45	0.9
270° (D)	1 (3.28)	170	30.6	0.102	1.7	4.25	8.5
	2 (6.56)	47	8.46	0.0282	0.47	1.175	2.35
	3 (9.84)	22	3.96	0.0132	0.22	0.55	1.1
315°	1 (3.28)	165	29.7	0.099	1.65	4.125	8.25
	2 (6.56)	37	6.66	0.0222	0.37	0.925	1.85
	3 (9.84)	21	3.78	0.0126	0.21	0.525	1.05

This table consists of data gathered with the i-CAT operating at 120 kVp, 5 mA and the following parameters:

Total scan time: 40 seconds

Estimated usage:

10 scans per week yielding a workload of 33.3 mA-min/week

25 scans per week yielding a workload of 83.3 mA-min/week

50 scans per week yielding a workload of 166.7 mA-min/week

Assumed use and occupancy factors: 1

Location	Distance m (ft)	Exposure (μ R)	mR/h	mR/mAmin	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	1 (3.28)	330	29.7	0.099	3.3	8.25	16.5
	2 (6.56)	76	6.84	0.0228	0.76	1.9	3.8
	3 (9.84)	37	3.33	0.0111	0.37	0.925	1.85
45°	1 (3.28)	350	31.5	0.105	3.5	8.75	17.5
	2 (6.56)	85	7.65	0.0255	0.85	2.125	4.25
	3 (9.84)	39	3.51	0.0117	0.39	0.975	1.95
90° (B)	1 (3.28)	320	28.8	0.096	3.2	8	16
	2 (6.56)	86	7.74	0.0258	0.86	2.15	4.3
	3 (9.84)	38	3.42	0.0114	0.38	0.95	1.9
135°	1 (3.28)	290	26.1	0.087	2.9	7.25	14.5
	2 (6.56)	65	5.85	0.0195	0.65	1.625	3.25
	3 (9.84)	31	2.79	0.0093	0.31	0.775	1.55
180° (C)	1 (3.28)	275	24.75	0.0825	2.75	6.875	13.75
	2 (6.56)	63	5.67	0.0189	0.63	1.575	3.15
	3 (9.84)	28	2.52	0.0084	0.28	0.7	1.4
225°	1 (3.28)	310	27.9	0.093	3.1	7.75	15.5
	2 (6.56)	71	6.39	0.0213	0.71	1.775	3.55
	3 (9.84)	34	3.06	0.0102	0.34	0.85	1.7
270° (D)	1 (3.28)	290	26.1	0.087	2.9	7.25	14.5
	2 (6.56)	67	6.03	0.0201	0.67	1.675	3.35
	3 (9.84)	39	3.51	0.0117	0.39	0.975	1.95
315°	1 (3.28)	320	28.8	0.096	3.2	8	16
	2 (6.56)	83	7.47	0.0249	0.83	2.075	4.15
	3 (9.84)	40	3.6	0.012	0.4	1	2

This table consists of data gathered with the i-CAT operating in **panoramic mode (adult patient)**. In this mode the i-CAT operates at 110 kVp, 5 mA and the following parameters:

Total scan time: 20 seconds

Estimated usage:

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

Assumed use and occupancy factors: 1

Location	Distance m (ft)	Exposure (μ R)	mR/h	mR/mAmin	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	1 (3.28)	183	32.94	0.1098	4.58	9.15
	2 (6.56)	22	3.96	0.0132	0.55	1.10
	3 (9.84)	13	2.34	0.0078	0.33	0.65
45°	1 (3.28)	47	8.46	0.0282	1.18	2.35
	2 (6.56)	23	4.14	0.0138	0.58	1.15
	3 (9.84)	10	1.8	0.006	0.25	0.50
90° (B)	1 (3.28)	94	16.92	0.0564	2.35	4.70
	2 (6.56)	14	2.52	0.0084	0.35	0.70
	3 (9.84)	7	1.26	0.0042	0.18	0.35
135°	1 (3.28)	32	5.76	0.0192	0.80	1.60
	2 (6.56)	9	1.62	0.0054	0.23	0.45
	3 (9.84)	5	0.9	0.003	0.13	0.25
180° (C)	1 (3.28)	27	4.86	0.0162	0.68	1.35
	2 (6.56)	11	1.98	0.0066	0.28	0.55
	3 (9.84)	3	0.54	0.0018	0.08	0.15
225°	1 (3.28)	17	3.06	0.0102	0.43	0.85
	2 (6.56)	9	1.62	0.0054	0.23	0.45
	3 (9.84)	5	0.9	0.003	0.13	0.25
270° (D)	1 (3.28)	35	6.3	0.021	0.88	1.75
	2 (6.56)	12	2.16	0.0072	0.30	0.60
	3 (9.84)	1	0.18	0.0006	0.03	0.05
315°	1 (3.28)	97	17.46	0.0582	2.43	4.85
	2 (6.56)	21	3.78	0.0126	0.53	1.05
	3 (9.84)	9	1.62	0.0054	0.23	0.45

This table consists of data gathered with the i-CAT operating in **panoramic mode (child patient)**. In this mode the i-CAT operates at 100 kVp, 5 mA and the following parameters:

Total scan time: 18.4 seconds (rounded to 19 seconds for calculations in the table)

Estimated usage:

25 scans per week yielding a workload of 39.6 mA-min/week

50 scans per week yielding a workload of 79.2 mA-min/week

Assumed use and occupancy factors: 1

Location	Distance m (ft)	Exposure (μ R)	mR/h	mR/mAmin	25 scans/wk mR/wk	50 scans/wk mR/wk
0° (A)	1 (3.28)	68	12.88	0.0429	1.70	3.40
	2 (6.56)	11	2.08	0.0069	0.28	0.55
	3 (9.84)	4	0.76	0.0025	0.10	0.20
90° (B)	1 (3.28)	24	4.55	0.0152	0.60	1.20
	2 (6.56)	5	0.95	0.0032	0.13	0.25
	3 (9.84)	3	0.57	0.0019	0.08	0.15
180° (C)	1 (3.28)	8	1.52	0.0051	0.20	0.40
	2 (6.56)	3	0.57	0.0019	0.08	0.15
	3 (9.84)	1	0.19	0.000	0.03	0.05
270° (D)	1 (3.28)	22	4.17	0.0139	0.55	1.10
	2 (6.56)	4	0.76	0.0025	0.10	0.20
	3 (9.84)	2	0.38	0.0013	0.05	0.10

Measurements with drywall as a shield:

Measurements were also made comparing exposure difference with 2.54 cm (1") of drywall as a shield. Two distances were measured at the 270° position. The survey meter was located a total of 142 cm (56") away from the center of the X-ray beam for the first distance. The survey meter was located 30.5 cm (12") behind the drywall for all readings when the drywall was in place. The second distance was a total of 235 cm (92.5").

With the i-CAT operating at 120 kVp, 5 mA, 20 second scan, the exposure was 58 μ R behind the drywall and 83 μ R without the drywall at the first distance. With the i-CAT operating at 120 kVp, 5 mA, 40 second scan, the exposure was 114 μ R behind the drywall and 159 μ R without the drywall at the first distance.

At the second distance, 20 second scan, the reading was 21 μ R behind the drywall and 31 μ R without the drywall. At the second distance, 40 second scan, the reading was 41 μ R behind the drywall and 61 μ R without the drywall. All readings corresponded to an average reduction of 31% \pm 2% with the drywall in place.

Note: In the United States typical limits for radiation workers is 100 mR/wk or 5 Rem/yr. Typical limits for the general public at 2 meters (6.56 feet) or more from the equipment is 2 mR/wk.

The International Commission on Radiation Protection (ICRP) recommends limits for radiation workers of 5 Rem/yr and a cumulative of 10 Rem over 5 years. Limits for the general public per ICRP are 100 mR /yr.

Local agencies or government bodies or international standards may dictate higher or lower limits than these limits. Consult your local agencies or government bodies or international standards for actual limits which apply.

Patient Dose Measurements:

Effective patient dose is summarized in the table below. All doses are expressed as *effective dose* in μSv and mR. They are reported as “without/with salivary glands”, which refers to how the dose to the salivary gland is treated in the calculation of the effective dose. The dose “with salivary glands” is probably a better representation of the real risk.

Examination	Effective dose (Without sal gl)		Effective dose (With sal gl)		Reference
	mR	μSv	mR	μSv	
20 second scan	6.87	68.7	10.15	101.5	1
Background radiation	300 mR/yr, ~800 μR /day (3 mSv/yr, ~8 μSv /day)				2

References:

1. Ludlow JB, Brooks SL, Davies-Ludlow LE, Howerton B. Dosimetry of 3 CBCT units for oral and maxillofacial radiology. To be presented at the IADMFR meeting in Cape Town, South Africa, May 2005.
2. Frederiksen NL. Health physics. In: White SC, Pharoah MJ. *Oral radiology: Principles and interpretation*, 5th ed. Philadelphia: Mosby, 2004.

Recommended Shielding Requirements:

The following tables list suggested lead shielding for certain combinations of scan time, number of scans per week, and distance.

40sec scan	Scans/wk	Distance, in meters (feet), with 2mR/wk
	10 scans/wk	1 (3.28)
	25 scans/wk	2 (6.56)
	50 scans/wk	3 (9.84)

20sec scan	Scans/wk	Distance, in meters (feet), with 2mR/wk
	10 scans/wk	No shielding
	25 scans/wk	1 (3.28)
	50 scans/wk	2 (6.56)

To use the table, first determine the workload by combining scan time and number of scans per week. The distance listed is the minimum distance from the center of the X-ray beam to the occupied space where lead shielding is needed. Any distance less than that listed in the table will require lead shielding. The lead thickness in all cases is 0.8 mm (1/32in) lead. As an example, with a scan time of 40seconds and 25 scans per week, 0.8 mm (1/32in) of lead is needed if the distance from the center of the X-ray beam to the next room is 2 meters (6.56 feet) or **LESS**. While these recommendations are based on measured scatter radiation, it is recommended that the services of a qualified expert be used to ensure adequate shielding so that the weekly exposure to spaces surrounding the iCAT is less than 2mR.

6.2 Dose and Imaging Performance Information

Conditions of Operation

120 kVp, 46.72 mAs, collimation of 5 cm, voxel size of 0.4 mm, axial coverage of 5cm.

Dose Information

Procedure

A head CTDI phantom was used as shown below:



The following steps were performed:

1. Level the head phantom.
2. Use light localizer to position phantom in center of scan and so slice cuts through the center of the phantom
3. Perform a scout view to assess the alignment
4. Perform a scan
5. Use 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 will be maximum.
6. Place the ionization chamber in the center hole. Insert acrylic rods in all other holes.
7. Use typical technique factors.
8. Perform a single scan and read out ionization detected with CT chamber X_r in coulombs (C).
9. Calculated CTDI using the equation: $CTDI = X_r \times \frac{1.05R}{10^{-9} C} \times 0.78 \frac{rad}{R} \times \frac{10.2 cm}{NST (cm)^2}$

where NST stands for nominal slice thickness, 0.78 is f-factor for acrylic at 70 keV, the calibration factor C ~ 1.05R/10⁻⁹C at 120 and 140 kVp; and the chamber length is 10.2 cm. Please note that this formula accommodates cone beam CT scanning geometry by using the axial coverage as a value for NST.

10. Repeat for different slice thicknesses (skipped as this is not applicable to our scanner)
11. 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 measurements were obtained:

Position	Axial coverage (cm)	X _r (pico Coulombs)	CTDI (Rad)
Center	5	134	0.22
back periphery	5	109.5	0.18
left periphery	5	114	0.19
right periphery	5	131	0.22
front periphery	5	125	0.21

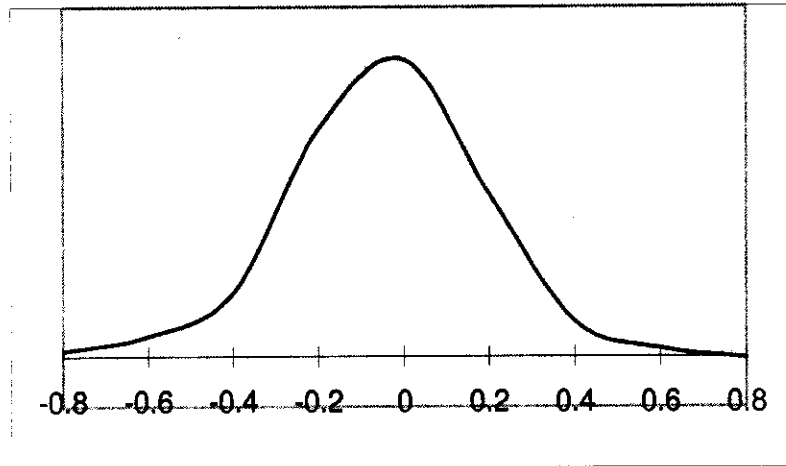
Given the potential variations in the equipment and positioning the measured values for other units or for the same unit in the future should not vary more than 15%.

Because of the cone beam CT scanning principle, the **dose profile** in the center only has one point: the one measured value in the central position.

Sensitivity Profile

For the ultrahigh resolution mode when the bead in the phantom is scanned the following sensitivity profile is obtained.

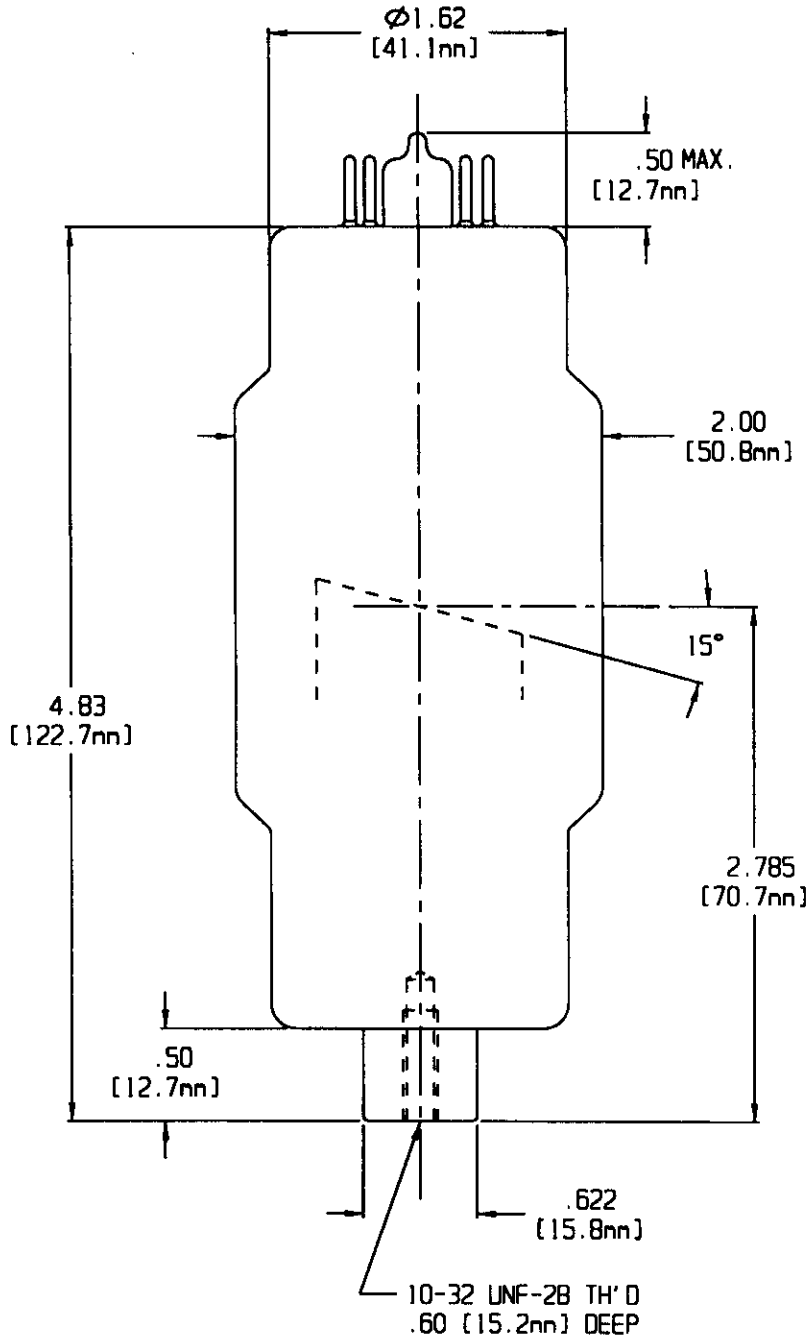
-0.8	236
-0.6	848
-0.4	2590
-0.2	9154
0	11906
0.2	6496
0.4	1408
0.6	380
0.8	-34



Given the potential variations in the equipment and positioning the measured values for other units or for the same unit in the future should not vary more than 15%.

6.3 X-ray Tube assembly

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



Operating 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

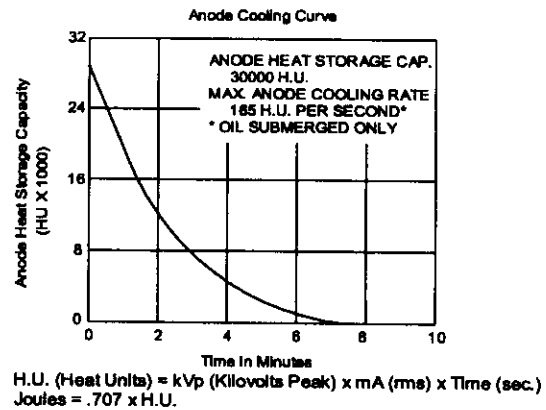
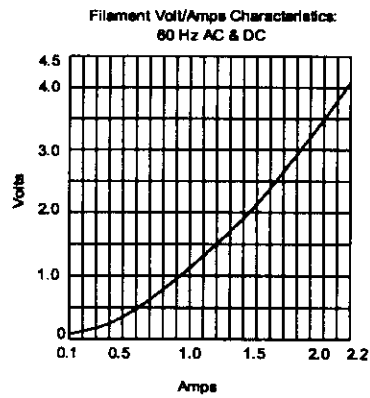
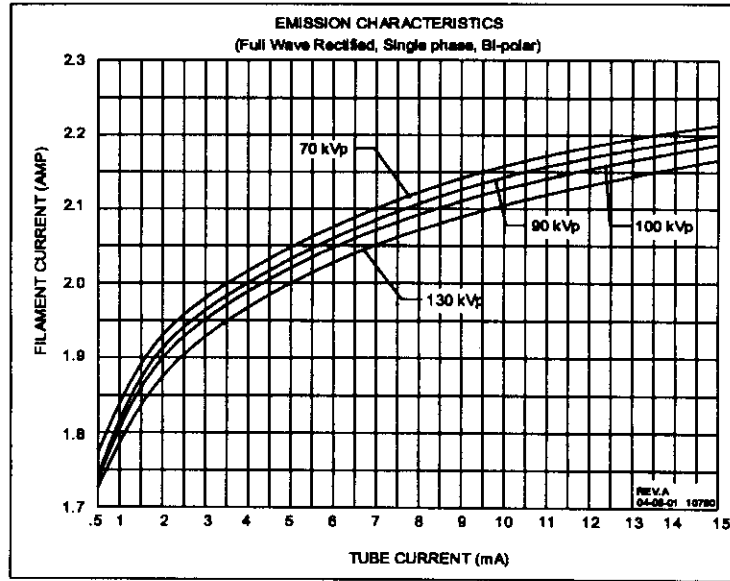
Inherent filtration/Window material:
2.0 mm/Glass

Cooling Method:
High dielectric transformer oil

SXR-130-15-0.5 FOCAL SPOT

Part number 990310

August 01, 2005



Ser-130-15-0.5
Rev. A 08-29-04

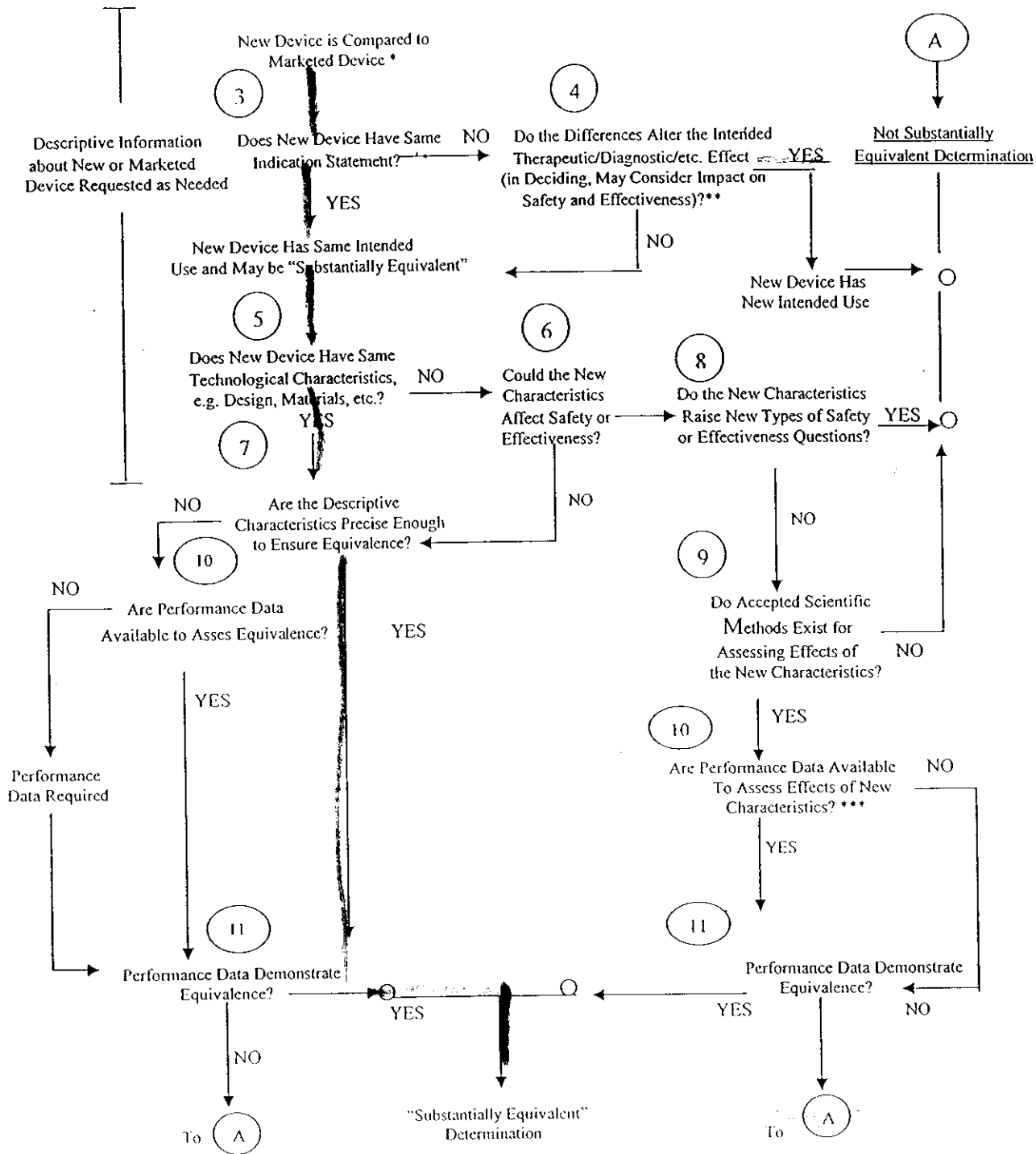
SXR-130-15-0.5

Part number 990310

August 01, 2005

1309

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- * 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

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