Cone Beam Imaging
Agenda: Dental Cone Beam Imaging

*Definition and Functionality
*Usage and diagnostics benefits
*Comparative radiation information
*Federal regulatory responsibilities: manufacturing
*State regulatory responsibilities: usage
*Dental Supply Company responsibilities: installation
Definition of cone beam

**Technical Description of CBCT**

Cone Beam CT is a medical imaging modality, which has been applied in different fields of medicine (e.g. cardiac imaging, radiotherapy). Recently, this technique has been applied to dental imaging.

The principle behind this technique, as its name implies, is a cone-shaped X-ray bundle, with the X-ray source and detector (Image Intensifier or Flat Panel Detector) rotating around a point (or field) of interest of the patient (Figure 1). The conical shape of the beam distinguishes this technique from helical CT, which used a fan-shaped beam. As a result of the acquisition of two-dimensional projections throughout this rotation, only one rotation or less is needed to acquire a full (three-dimensional) dataset. The images received by the detector are then compiled by the computer into volumetric data (primary reconstruction). This can then be visualized as two-dimensional multi-planar reformatted slices or in three dimensions by using surface reconstruction or volume rendering.
Cone Beam compared to traditional Fan Beam
Dental Professional: uses for cone beam

• Implants: recommended by AAOMR June 2012 position for all implants.

• Endodontics: recommended in a joint statement by AAOMR and AAE for all PROBLEMATIC endodontics.

• Orthodontics: recommended for un erupted teeth, not as a general screening tool.

• Oral surgery: most extractions, tmj surgery and airway studies
Choosing a 3D unit: primary criteria

- Fields of View
- Voxel sizes
- Slices per rotation
- Radiation dosage
- modalities
- Ease of use
- Software capabilities
- Size/footprint
- Price
Comparative Radiation Dosages
Effective doses (μSv)

- Digital Panoramic: 4.7 – 14.5 μSv
- Panoramic: 10 – 15 μSv
- Highest Film Panoramic: 26 μSv
- Cone Beam CT: 25 – 150 μSv
- Full mouth series: 150 μSv
- Medical CT: 1200 – 3300 μSv

- Radiation from other sources
  - Daily background: 8 μSv
  - Commercial long haul flight: 6 μSv/hr
  - Lower limits occupational exposure: 20,000 μSv/yr

Dr. Sharon Brooks, Dept. of Radiology, University of Michigan
Dr. Stuart White, Dept. of Radiology, UCLA
Radiation Dosage

• ALARA Concept:
• As low as reasonably achievable
• Bi directional columnation
• 2 ways to reduce radiation
• A) sensitivity of the sensor
• B) reduction in slice per rotation
Slices per rotation

Data compilation

The CBCT scanner acquires hundreds of slices per rotation (see Figure 4). Once obtained, the computer processes these slices by assembling them into a full cylinder-shaped volume analogous to a stack of compact discs. The various proprietary software applications compress and compile the data into the DICOM format for use in the various applications.

Figure 4: Axial slices from a cone beam scan. Hundreds of reformatted axial slices comprise the volume of the scan.
Fields of View
Low dose solutions

• With the new PaX-i3D Green, one can conduct a single 3D CT scan of the most widely used 8x8 (cm) images, with effective dose of less than 30µSv. Its 75% revolutionary reduction of radiation compared to the previous system enables customers to enjoy the benefit of high-quality images with minimized radiation exposure. Microsievert (µSv) is a unit that measures the effect of radiation on our body; the effective dose of PaX-i3D Green is half of that of a one-way flight from Seoul to America, which is 60.6µSv on the average [1].
The United States (U.S.) Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) is responsible for regulating radiation-emitting electronic products. The CDRH goal is to protect the public from hazardous and unnecessary exposure to radiation from electronic products. For most electronic products, safety regulation is divided between CDRH and state regulatory agencies. CDRH regulates the manufacture of the products, and the states regulate the use of the products.
FDA and Cone beam manufacturing

• Dental CBCT systems are medical devices that are also radiation-emitting electronic products. The FDA regulates manufacturers of dental CBCT devices through the Electronic Product Radiation Control (EPRC)28 and medical device provisions29 of the Federal Food, Drug, and Cosmetic Act. Dental CBCT systems are classified under 21 CFR 892.1750.

• Manufacturers are required to maintain records and submit reports to CDRH regarding their radiation emitting products.
c. Facility Design Requirements.

i. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

ii. Viewing Systems.

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, Calibrations, Spot Checks, and Operating Procedures.

i. Surveys.

1. All CT x-ray systems installed after [insert the effective date of the regulations] and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant (licensee) shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the Agency upon request.
• ii. Radiation Calibrations.
• (1) The calibration of the radiation output of the CT x-ray system shall be performed
  • by, or under the direction of, a qualified medical physicist who is physically
  • present at the facility during such calibration.
• (2) The calibration of a CT x-ray system shall be performed after initial installation
  • and before use on human patients, annually or at intervals specified by a
  • qualified medical physicist, and after any change or replacement of components
  • which, in the opinion of the qualified medical physicist, could cause a change in
  • the radiation output.
• (3) The calibration of the radiation output of a CT x-ray system shall be performed
  • with a calibrated dosimetry system. The calibration of such system shall be
  • traceable to a national standard. The dosimetry system shall have been calibrated
  • within the preceding 2 years.
• (4) CT dosimetry phantom(s) shall be used in determining the radiation output of a
  • CT x-ray system. Such phantom(s) shall meet the following specifications and
  • conditions of use:
iii. Spot Checks.

(1) The spot-check procedures shall be in writing and shall have been developed by a qualified medical physicist.

(2) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(3) All spot checks shall be included in the calibration required by F.11d.ii. and at time intervals and under system conditions specified by a qualified medical physicist.

(4) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by F.11d.ii. The images shall be retained, until a new calibration is performed, in two forms as follows:

(a) Photographic copies of the images obtained from the image display device; and

(5) Written records of the spot checks performed shall be maintained for inspection by the Agency.
iv. Operating Procedures.
(1) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.
(2) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:
(a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;
(b) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;
(c) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
(d) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.
CRCPD protocol continued

• (3) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.
December 31, 2013

Dear Dental Cone Beam Computed Tomography (CBCT) Registrant:

The Bureau of X-ray Compliance (Bureau) received two requests from the New Jersey Dental Association (NJDA). The first request sought Department approval of an alternative quality assurance program for Dental CBCT units (N.J.A.C. 7:28-22.3(g)). The second sought an exemption to permit licensed dental radiologic technologists to perform radiographic procedures involving CBCT units (N.J.A.C. 7:28-19.4(e)). These requests were forwarded to the Commission on Radiation Protection (Commission) for consideration.
New Jersey State regulation: cone beam usage:

State of New Jersey

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

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Division of Environmental Safety and Health
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Ph: (609) 984-5370 Fax: (609) 984-5811
www.xray.nj.gov

BOB MARTIN
Commissioner

December 31, 2013

Dear Dental Cone Beam Computed Tomography (CBCT) Registrant:

This letter is in regards to the following two important decisions made by the Commission on Radiation Protection (Commission) at its November 20, 2013 meeting that affects all registered users of dental CBCT units.
A. The Commission approved a request made by the New Jersey Dental Association (NJDA) for the approval of an alternative quality assurance (QA) program for dental (CBCT) units and to permit dentists, dental hygienists and dental radiologic technologist to perform quality control tests items 1 through 5 in the attached Table 3A. Additionally, the Commission granted registrants of dental CBCT units six months to implement NJDA’s alternative QA program. This approval includes all dental CBCT units classified by FDA as computed tomography units.

All dental CBCT facilities must implement the NJDA’s alternative QA program by June 30, 2014 and adhere to the following conditions:
1. Ensure that the dental CBCT unit complies with all radiation protection regulations (registration, surveys and quality assurance).

2. Ensure that all tests listed in Table 3A are properly performed at the required frequencies.

3. Ensure that a New Jersey certified medical physicist is hired to perform the initial and annual Medical Physicist Computed Tomography QC survey.

4. Ensure that only appropriately credentialed and properly trained staff perform quality control test items 1 through 5 in Table 3A. All remaining items must be performed by the certified medical physicist during the initial and annual Medical Physicist Computed Tomography QC survey.

5. Ensure that all CBCT procedures performed on patients follow the established scan protocol (i.e., patient age, mA, kVp, field of view, etc.) as evaluated by a New Jersey certified medical physicist as part of the initial and on-going annual Medical Physicist Computed Tomography QC Survey.
NJ State usage regulations cont:

Each Registrant that permits a licensed dental radiologic technologist to operate CBCT equipment and the licensed dental radiologic technologist shall:

1. Ensure that, prior to the first use of the CBCT unit by a licensed dental radiologic technologist, the technologist has been initially trained by the CBCT manufacturer in scan protocol and in the operation of the CBCT unit or trained by a licensed dentist, registered dental hygienist or licensed dental radiologic technologist who has been trained by the manufacturer in CBCT scan protocol and its operation. Training must be documented on the attached form, maintained in the facility file and made available upon the request of the Department.

2. Ensure that after initial training is completed, the licensed dental radiologic technologist competently performs a minimum of five (5) CBCT procedures under the direct supervision of a licensed dentist, registered dental hygienist or license dental radiologic technologist who has been trained in CBCT scan protocol and its operation. Direct Supervision requires the supervisor to be in the room with the operator to observe and supervise the procedure and post-procedure processing. Attestation of competency must be documented on the attached form, maintained in the facility file and made available upon the request of the Department.
3. Ensure that a licensed dentist who has been trained by the CBCT manufacturer in CBCT scan protocol and its operation is present in the office or department to provide supervision and assistance to the trained licensed dental radiologic technologist, if needed.

4. Ensure that if a trained licensed dental radiologic technologist should take a leave of absence for more than six months, prior to performing CBCT procedures, the technologist must repeat the competency training described in 2. above. Retraining should be documented using similar forms as above.

5. The exemption is not transferrable to another facility or to other CBCT dental units. If a licensed dental radiologic technologist should seek employment with a new employer, they must receive training and competency testing at the new facility. If the facility purchases a new CBCT unit of a different model, the dental radiologic technologist must receive training in the new device.
Alternative QA Program below

<table>
<thead>
<tr>
<th>Item</th>
<th>Required Test or Procedure</th>
<th>Frequency</th>
<th>Standard</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Equipment Function Test, Mechanical, &amp; other Safety Checks</td>
<td>Daily</td>
<td>Must work properly</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Film Processing QC Testing</td>
<td>Daily</td>
<td>As specified in Table 1 Radiographic Quality Control Requirements</td>
<td>If Present</td>
</tr>
<tr>
<td>3</td>
<td>CT Number for Water</td>
<td>Daily</td>
<td>CBCT Equipment or Phantom manufacturer's specification*</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Field Uniformity</td>
<td>Daily</td>
<td>CBCT Equipment or Phantom manufacturer's specification*</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Laser Film Printer QC</td>
<td>Weekly</td>
<td>As specified in Table 3 Computed Tomography Quality Control Requirements</td>
<td>If Present</td>
</tr>
<tr>
<td>6</td>
<td>Low Contrast Repro.</td>
<td>Initial &amp; Annually</td>
<td>CBCT Equipment or Phantom manufacturer's specification*</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>High Contrast Resolution</td>
<td>Initial &amp; Annually</td>
<td>CBCT Equipment or Phantom manufacturer's specification*</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Noise</td>
<td>Initial &amp; Annually</td>
<td>CBCT Equipment or Phantom manufacturer's specification*</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Scan Localization Light Accuracy</td>
<td>Initial &amp; Annually</td>
<td>± 5% MAV</td>
<td></td>
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<tr>
<td>10</td>
<td>Medical Physician's QC Survey</td>
<td>Initial &amp; Annually</td>
<td>As required in NMAC 7:2022-22.10</td>
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</tr>
<tr>
<td>11</td>
<td>Quality Assurance Program Review</td>
<td>Initial &amp; Annually</td>
<td>As required in NMAC 7:2022-22.41-17</td>
<td></td>
</tr>
</tbody>
</table>
Dental Supply Co: protocol

• ProPhysics Innovations, Inc. is a medical and health physics consultant group based in the Research Triangle area of North Carolina. Our central location makes us easily accessible to client facilities for On-Site services throughout the Southeast while Consulting and Educational Services are provided nationwide. ProPhysics provides high quality, professional Medical Physics and Health Physics services to an expanding base of medical, dental, research, academic and industrial client facilities.
Dental Supply Co: protocol

• ProPhysics is an industry leader in providing radiation safety consulting and expertise to our valued clients. When you work with ProPhysics, you gain access to the knowledge that our experienced consultants continually develop via assessment, research and training. Through collaborative efforts with state regulators nationwide, we are apprised of the latest regulations and requirements regarding radiation protection.
Cone Beam Shielding Plan Review Data Sheet

Facility Name:

Facility Address (include city, state & zip code):

Facility Contact and Title:

Contact Phone Number:  
Fax Number or email:

Mailing Address (include city, state & zip code):

Cone Beam Data

- Cone Beam Model:
  - 1-Cat Classic
  - 1-Cat Platinum (17-19)
  - 1-Cat Precise
  - Gendex CB-500
  - Sirona Galileo
  - Gendex GXDP 700
ProPhysics: review data sheet cont.

**Workload:**
- **iCat Classic:** 
  - scans per week @ 10 sec: ___
  - scans per week @ 20 sec: ___
- **Platinum/Precise/CB-500:** 
  - scans per week: ___
- **Sirena Galileo:** 
  - scans per week: ___
- **CXDP 700/OP300D:** 
  - Cone Beam Small FOV per week: ___
  - Cone Beam Large FOV per week: ___
  - Fans per week: ___
  - Cycles per week: ___
- **Soredex Scanora:** 
  - XL FOV: ___
  - Large FOV: ___
  - Medium FOV: ___
  - Small FOV: ___
  - Fans: ___
- **Other:** ___

**Interior Wall Coverings (not the frame) are made of:**
1. [ ] wood (paneling) [ ] gypsum [ ] concrete [ ] other (specify) ___
2. The thickness of the wall material is ___ inches.

**Exterior Wall Coverings (not the frame) are made of:**
1. [ ] wood (paneling) [ ] gypsum [ ] concrete [ ] other (specify) ___
2. The thickness of the wall material is ___ inches.
Pro physics: Review data sheet cont.

Floor & Ceiling Information
- Single story structure – ground below and sky above the imaging room

Above Room
- The space above is used as a [ ]
- The distance from the floor of the imaging room to the floor above is [ ]
- The floor above is composed of [ ] with a minimum thickness of [ ] inches

Below Room
- The space below is used as a [ ]
- The distance from the floor of the imaging room to the floor below is [ ]
- The floor below is composed of [ ] with a minimum thickness of [ ] inches

Room Drawing – must contain all of these elements:
- Length and width of the x-ray room (show the beginning and end of the measurement)
- Proposed location of the control switch
- The method the operator will use to view the patient during exposures (window, mirror, video camera, etc.)
- Identify all areas beyond the walls of the x-ray room
- Proposed location and orientation of the x-ray unit
- Width of any adjacent corridors and the identity of areas beyond the corridors.
Terms of Service
1. A plan review report cannot be issued unless we have all information required to complete the report.
2. All information submitted must be legible.
3. ProPhysics Innovations is not responsible for obtaining or providing information being requested on the application.
4. Any additional information, not requested on the application, but incidental to the performance of the service is subject to items 3-5 of these terms.
5. The report is a recommendation only, based on industry standards and state regulation.

6. Please contact our plan review department for pricing.

Payment

☐ Credit Card (Visa, MasterCard, American Express and Discover)
In order to accept payment via credit or debit card, we will need the following information:

Cardholder’s Name: 

Cardholder’s Billing Address:  

City: State: Zip:  

Credit Card Number:  

ProPhysics Report Distribution

• Copies of the report are distributed to the facility, the sales representative (if applicable), and to the state where mandatory, and for states that allow for third party report submissions. Some states require that additional information accompany the plan review report and desire that the registrants of the equipment submit all associated forms. We will provide such forms as identified and needed in these cases for the facility to submit. Please notify us of any other individuals requiring a copy of the report and we will gladly include them in our distribution.
Accreditation for dental-specific CBCT available

By Kelly Soderlund, ADA News staff

Dentists who use cone beam computed tomography in their office may find a new accreditation program helpful.

The Intersocietal Accreditation Commission is offering a dental CT accreditation program to help dentists comply with federal and state laws and show their patients they provide safe quality care. Dentists will also learn about the amount of radiation they are exposing their patients to.
Conclusions

• The use of CBCT imaging in the dental industry has definite clinical value and its related use will continue to grow.

• Radiation levels continue to drop as fields of view become focused and sensors evolve to become more sensitive.

• State and Federal regulatory agencies will continue to evolve their policies.