November 23, 2010

Dear Valued i-CAT Customer,

The *New York Times* today published an article about CBCT technology that included a number of references to the i-CAT and Imaging Sciences. The article presents what we think is an incomplete view of CBCT technology and mischaracterizes the professional relationships that Imaging Sciences has with dentists. Imaging Sciences takes seriously issues concerning the technology's application and safety. We support the AAOMR's initiative to develop guidelines for the use of CBCT based on fact and within a professional, scientific framework. In addition, the FDA/CDRH has announced its intention to develop guidance regarding these matters for 2011.

While there are clinical benefits to CBCT, we recognize that there is an ongoing discussion in the dental community concerning the technology's application and safety. We believe that this discussion should be based on fact and be held in a professional and rigorous scientific manner. We also recognize and acknowledge that there are legitimate concerns regarding radiation safety. We understand that clinicians are keenly aware of ALARA[1] with respect to any radiographic modality. The i-CAT features are designed to assist dental professionals in meeting their ALARA goals while weighing the risk of exposure with the scan's clinical benefit for the application that the clinician selects.

Imaging Sciences has a reputation within the dental community for the manufacture of quality radiographic equipment. Members of the company's design and development team have substantial expertise in dental imaging, and they actively collaborate with clinical professionals to further expand their knowledge of the science of radiology. The goal of Imaging Sciences is to deliver quality CBCT systems and to advance education on the technology and its use.

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We want to assure you that we take seriously the issues that have been raised by the article and any resulting concerns that you and your patients may have. To help you address these concerns, we have created a dedicated phone line and email address. Please feel free to contact us at 800-205-3570 or questions@imagingsciences.com.

In the meantime, please find below information and resources that address important issues relating to CBCT technology and Imaging Sciences.

Thank you for your continued support of CBCT and Imaging Sciences.

Kind regards,

Henrik Roos, President, Imaging Sciences International

Why do doctors and dentists use CBCT as part of their radiographic armamentarium?

- X-rays are an established and essential part of every dental practice.
- A CBCT scan provides dentists with views that were previously unavailable other than through medical CT.
- CBCT offers views of patient anatomy in three dimensions, without the magnification, distortion, and superimposition.[2,3]
- The precision of CBCT scans assists in precise diagnosis and treatment plans with the goal of better clinical outcomes.[4]
- The effective dose from a standard i-CAT scan[†] is at least 10 times less radiation than that from a medical CT of the skull used for dental purposes.[5]

It is important to note that clinicians make the decision on when a case warrants a CBCT scan and on what settings to use for the specific patient's needs, based on their clinical expertise and ALARA principles.

How do natural, dental, and medical radiation levels compare?

CBCT technology exposes patients to a lower radiation dose than a number of other imaging modalities and far less than medical CT. The following tables provide dose comparisons for natural and medical radiation exposures.

Table 1

Natural Radiation Exposure ~ 3 milliSeiverts (mSv) per year[6]	Estimated mSv	Comparable to natural radiation exposure for:
Daily exposure to natural radiation	0.008	~ 1 day
Flight: London to Los Angeles	0.080[7]	~ 10 days

Table 2

Dental Imaging	Estimated mSv (2007 ICRP tissue weights)	Comparable to natural radiation exposure for:
Single intraoral x-ray, film	<0.0083 mSv*[8]	~1 days
Intraoral full mouth series (film x-rays; F-speed, round cone)	0.170 mSv[9]	~22 days
2-D Panoramic (digital)	0.014 - 0.024 mSv[10]	~ 2 – 3 days
3-D Dental Cone Beam (includes multiple Fields of View)	0.003 – 1.073 mSv[11,12]	~ 8 – 134 days
3-D Cone Beam (i-CAT 0.3 voxel, 13x16 cm)†	0.087 mSv[13]	~ 11 days
Medical CT of skull (Somaton 64MDCT)	0.860 mSv[14]	~ 108 days

*no data available calculated subsequent to ICRP2007

Table 3

Medical Imaging [15] (table)	Estimated mSv	Comparable to natural radiation exposure for:
CT abdomen	10 mSv	3 years
CT body	10 mSv	3 years
CT colonography	10 mSv	3 years
CT lower GI	2 – 4 mSv	1 year
CT upper GI	6 – 8 mSv	2.5 years
Chest x-ray (not CT)	0.080 mSv	10 days

What are the i-CAT features that reduce radiation & allow for the management of emitted radiation?

- Settings enable the user to take a lowered-dose scan that emits less radiation than the above-mentioned standard i-CAT scan.
- Pulsed-beam technology employed by i-CAT produces lower radiation than continuous beam technology by only activating the x-ray source when the panel is ready to capture an image.[16]
- Collimation is standard on all i-CAT systems, providing the ability to limit the radiation exposure to the specific area of interest.[17]
- Voxel selection to adjust resolution and radiation exposure is based on clinical need.
- Selectable traditional 2-D panoramic mode; digital panoramic effective doses commonly range from 0.014 – 0.024 mSv (see table 2).

Who is allowed to operate the i-CAT?

State law and/or the state dental board regulate who can take or supervise all dental radiographs, including CBCT.

What are general i-CAT safety features?

- For all new i-CAT installations, a contracted independent radiation physicist firm configures i-CAT installation areas for proper shielding.

- There are both software and hardware safeguards built into every i-CAT to avoid unintended over-exposures.

What are Imaging Sciences' Educational Objectives?

Imaging Sciences sponsors educational programs, designed and delivered by dental professionals, to educate dentists on the implementation, application, use, and benefits of Cone Beam 3-D imaging technology. The company provides customers with system training.

System Training:

- Every delivery of an i-CAT machine is accompanied by 1.5 days of training.

- Imaging Sciences utilizes dedicated instructors that are qualified for this purpose through training.

The 3D Imaging Institute:

- Speaker education programs, sponsored by Imaging Sciences, deliver clinical information through the first-hand experiences of doctors using CBCT imaging to treat their patients.

- Other trained professionals also instruct dentists on non-clinical aspects of the CBCT.

- Scan interpretation and radiation biology review are taught by Certified Oral & Maxillofacial Radiologists; courses now expanding.

- Clinical lectures are also offered at the Annual International Congress on 3D Dental Imaging.

- Imaging Sciences also sponsors additional online courses covering many aspects of CBCT for differing levels of knowledge.

- Beyond clinical training, the company provides assistance to CBCT users by supplying a list of oral and maxillofacial radiologists who provide scan-reading services.

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