Quality assurance: acceptance testing for digital dental intraoral sensors

Teresa E. Reeves, DDS,[a] Wen Lien, MS, DMD, MS,[a,b] and Peter Mah, DMD, MS[c]

Objective. The aim of this study was to demonstrate the need for acceptance testing with digital dental intraoral sensors (DIOS) as the first step of a comprehensive quality assurance (QA) program.
Study Design. Five commercially available DIOS were tested by using a QA test phantom, satisfying the requirements for intraoral QA testing as specified in American Dental Association Technical Report No. 1094 (TR 1094). All DIOS were evaluated for sensor discrepancies. QA parameters of contrast perceptibility, spatial resolution, dynamic range, and latitude were measured. Optimal radiation exposures for the adult molar bitewing were determined and compared with the diagnostic reference level (DRL), achievable dose (AD), and entrance skin exposure (ESE) for each DIOS.
Results. Thirty-five of the 147 DIOS (23.8%) evaluated were found to have discrepancies. The discrepancies included nonuniformity, latent images, delamination, a damaged USB (Universal Serial Bus) connector, and intermittent termination of image acquisition after radiographic exposure without generation of a radiographic image. Only 1 manufacturer's DIOS products were free from defects. The optimal exposure dose for every DIOS was within published limits.
Conclusions. Acceptance QA testing was effective in detecting discrepancies and establishing optimal exposure doses that were within the DRL and AD established by the National Council on Radiation Protection and Measurements and the ESE established by the state of Texas. (Oral Surg Oral Med Oral Pathol Oral Radiol 2020;129:388–400)

A quality assurance (QA) program involves the establishment of the strategic and systematic steps that are necessary to ensure that a product or service will meet performance requirements. With digital intraoral radiography, QA helps ensure the consistent production of high-quality radiographic images with maximal diagnostic information at the lowest radiation exposure to the patient. This precise balance between diagnostic information and radiation exposure to the patient is important. Reducing the radiation dose to the patient to a level that results in loss of diagnostic information is unacceptable. Conversely, increasing the radiation dose to produce a more aesthetic image with no improvement in diagnostic information is a failure to comply with optimal radiation safety practices: keeping radiation exposure to the patient "as low as reasonably achievable" (ALARA) and "as low as diagnostically acceptable" (ALADA).

Acceptance testing is a central part of QA undertaken by medical physicists[1] during the planned purchase of any radiographic imaging equipment—from delivery, installation, and acquisition of images to the assessment of image quality and safety issues associated with equipment in medical imaging. This includes digital radiography image receptors. The term "acceptance testing" is used in this article to describe a process that the dental team members perform by using the clinic's intraoral digital radiology system when the sensor is received from the manufacturer and before clinical use. Acceptance testing for the intraoral sensor used in clinical care must be considered equally important by the dental user.

Few are aware of the need for acceptance testing of the digital dental intraoral sensors (DIOS) to ensure proper operation of the DIOS when they are received. For example, Walker et al.[2] found that before the introduction of a QA program, the generation of diagnostic-quality radiographs in a number of private practice dental offices was highly inconsistent because of the variability of X-ray generator–intraoral sensor combinations and exposure techniques. After the introduction of a QA protocol, a much narrower and consistent range of radiographic exposures was achieved among the dental offices.

In 2017, the American Dental Association (ADA) published Technical Report No. 1094 (TR 1094), Quality Assurance for Digital Intra-Oral Radiographic Systems, to address the lack of QA for DIOS.[3] This report

Statement of Clinical Relevance

Digital dental intraoral sensors (DIOS) may be defective when manufactured or damaged in transit, and internal defects may not be readily apparent. An acceptance test as part of a quality assurance protocol can be used to discover deficiencies, establish baseline images, determine optimal radiation parameters, and ensure that radiographic image quality is adequate.

[a]United States Air Force Postgraduate Dental School, San Antonio, TX, USA.
[b]United States Air Force Dental Evaluation & Consultation Service, San Antonio, TX, USA.
[c]Dental Imaging Consultants LLC, San Antonio, TX, and Consultant, Air Force Operations Agency, San Antonio, TX, USA.
Received for publication May 20, 2019; returned for revision Nov 1, 2019; accepted for publication Nov 8, 2019.

2212-4403/$-see front matter
https://doi.org/10.1016/j.oooo.2019.11.005

has been adopted by the American National Standards Institute (ANSI) (available as ADA TR 1094-2017 on the ANSI website: https://webstore.ansi.org/Standards/ADA/ADATR10942017) as the standard QA protocol for digital intraoral radiographic systems. It can also be accessed by visiting the ADA website (https://ebusiness.ada.org/productcatalog/33770/Informatics/ADA-Technical-Report-No-1094-Quality-Assurance-for-Digital-I/p).

ANSI/ADA TR 1094 specifies a universal QA protocol based on which objective assessments can be performed for any digital receptor modality, including photostimulable phosphor (PSP) plates, charge-coupled devices (CCD), and complementary metal oxide semiconductor (CMOS) digital sensors, regardless of manufacturer. The QA protocol includes the periodic assessment of 3 primary components of the radiographic system: (1) X-ray generator, (2) image receptor and computer, and (3) display monitor and imaging software. ANSI/ADA TR 1094 outlines and simplifies the processes such that these measurements can be performed by an appropriately trained dental team member and do not require the intervention of a medical physicist.[3] These assessments evaluate all the aforementioned components of the digital radiographic imaging chain. With regard to image quality, imaging parameters such as contrast perceptibility, spatial resolution, dynamic range, and latitude are assessed.

The exposure parameters for any DIOS are dependent on the combination of X-ray generator, the sensor itself, the computer workstation, the computer display monitor, and the software and software settings. Given the various combinations of the X-ray generator, DIOS, computer, workstation monitor, software, and software settings, it is difficult to develop a universal technique chart without considering each of the dental workstation combinations independently. Furthermore, the clinical user has minimal control over automatic preprocessing algorithms that may affect image quality. Hence, technique charts provided by the DIOS or X-ray generator vendors are only guidelines and cannot be absolute.

When an initial acceptance test is to be conducted, this basic procedure not only validates a baseline performance but also establishes a reference value for future comparison.[4] A popular misconception is that because DIOS are solid state image receptors, they only fail catastrophically, but this is not supported by evidence. Without acceptance testing, it is difficult to appreciate loss of image quality over the lifespan of a digital sensor.

The purpose of this study was to demonstrate the need for DIOS acceptance testing as part of a comprehensive QA program for dental radiography by performing acceptance testing on a large sample of DIOS from 5 manufacturers and evaluating the results.

MATERIALS AND METHODS

X-ray generator

A direct current (DC) X-ray generator (Planmeca ProX, Planmeca, Roselle, IL) with a 0.4 mm focal spot and 30 cm position indicating device (PID), operated at 63 kV and 6 mA, was used with Firmware 4.03 software.

Radiation meter

A calibrated Raysafe Unfors ThinX Intra meter (Fluke Biomedical Cleveland, OH) was used to measure and validate the radiation output from the X-ray generator. It is capable of measuring radiation doses in the 45 to 100 kVp range, with 3% uncertainty.[5]

The Raysafe Unfors ThinX Intra meter was placed at the end of the PID. Measurements were made for each exposure time, from 10 ms to 800 ms. The values were recorded for later comparison with the diagnostic reference levels (DRL), achievable doses (AD), and entrance skin exposures (ESE).

Computer and image display

A laptop computer model 8570 w (Hewlett-Packard, Palo Alto, CA), with a Windows 7 Enterprise 64 bit operating system (Microsoft, Redmond, WA) and MiPACS software version 3.1.1404, (Medicor Imaging, Charlotte, NC), was used for all radiographic image acquisitions. The manufacturer's proprietary drivers were installed into the MiPACS software, along with the calibration file for each size 1 and size 2 sensor.

The viewing conditions were a quiet and dimly lit room and adjustable lighting. The digital images were reviewed on a SyncMaster SA850 and S27 D850 monitor (Samsung, Seoul, South Korea) connected to a laptop. Exposure of a Society of Motion Picture and Television Engineers (SMPTE) Medical Diagnostic Imaging Test Pattern was performed to ensure proper image display.[2-4,6]

Software

MiPACS software was used, as opposed to proprietary sensor manufacturer software, because the United States Air Force (USAF) dental clinics require interoperability of equipment and employ a number of different pieces of dental imaging equipment from various vendors throughout its dental clinics. Other institutional users, such as universities, governmental agencies, hospitals, and large dental service organizations, also use MiPACS. However, smaller institutions and independent dental practices may opt to use the sensor manufacturer's supplied software for radiographic image acquisition, viewing, and storage instead of a picture archiving and communication system (PACS).

The acceptance test images were captured with minimal preprocessing. The default for histogram stretch was as follows: upper cut = 0.5%; lower cut = 2.0% in

MiPACS. These settings would have no impact on the resultant radiographic image in the presence of the step wedge contained in the Digital Dental Quality Assurance (DDQA) phantom because it spanned the entire digital width of the histogram (0−4095) for all 12-bit sensors. Gamma adjustment was set at 1.0. Application of brightness and contrast were minimized. Filtering algorithms that could be controlled were turned off to obtain the minimally processed radiographic image for each DIOS brand.

Intraoral radiographic phantom

A DDQA Phantom (Dental Imaging Consultants LLC, San Antonio, TX) was used to evaluate contrast perceptibility, spatial resolution, dynamic range, and latitude, which met the requirements set out in TR 1094 (Figure 1).[7] The phantom consisted of various components. Four upward projecting tabs, made of polymethylmethacrylate, ensured parallel placement of X-ray PID and offered consistency and repeatability in geometry and location. Inserted between the guiding tabs and the internal test objects, a piece of 7-mm thickness 1100 aluminum alloy was embedded to simulate supporting hard and soft tissues of the oral cavity. The internal test objects included 3 components: (1) contrast perceptibility wells in 2 rows to detect low contrast: The contrast wells in top row were constant in diameter, but varied in depth from 0.125 to 0.75 mm; the contrast wells in the second row were constant in depth but varied in diameter from 2.5 to 0.2 mm; (2) a high-contrast spatial resolution pattern ranging from 5 to 20 line pairs/mm; and (3) a step wedge consisting of 7 steps with 1 lead step, 5 aluminum steps of varying thicknesses, and 1 air step; visualization of all 7 steps represented the full dynamic range of the image (Figure 2).

Image exposure and evaluation

This study did not involve animals or clinical patients and therefore did not require institutional review board (IRB) approval. Each radiographic image set consisted of 20 radiographic images. The first image was captured at the lowest exposure possible, followed by incrementally increased exposure times, until the sensor was saturated or the highest exposure at 800 ms was reached. The images were oriented with the contrast wells at the top and the step wedge along the bottom to allow for ease of analysis. Each radiograph was labeled with the appropriate kilovoltage peak, milliamperage, and exposure time.

We performed a visual inspection for artifacts, nonuniformity, or physical defects and excluded sensors (n = 26) that produced images with gross artifacts,

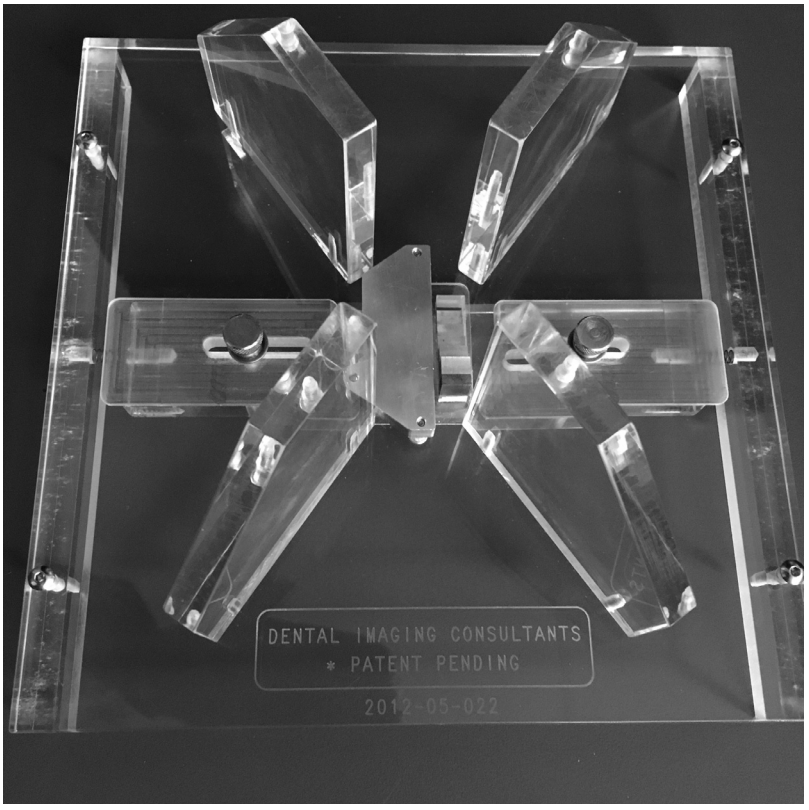

Fig. 1. Digital dental quality assurance (DDQA) phantom. (Dental Imaging Consultants LLC, San Antonio, TX, USA).

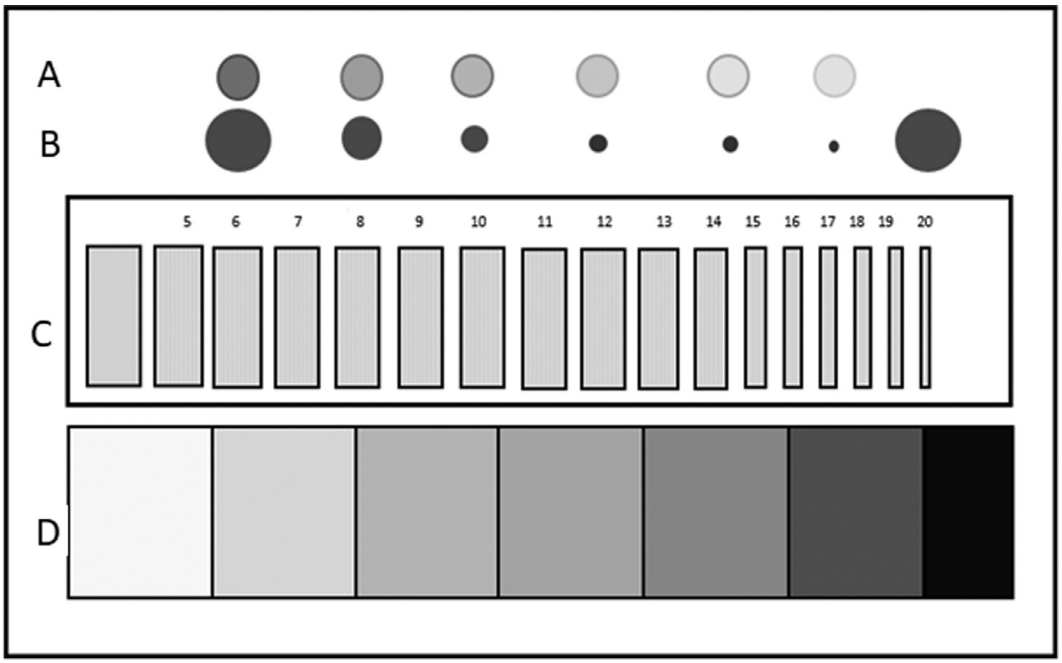

Fig. 2. Schematic drawing of test objects in digital dental quality assurance (DDQA) phantom. *Row A* consisted of contrast wells that were constant in diameter but varied in depth from 0.125 to 0.75 mm. *Row B* consisted of contrast wells that were constant in depth but varied in diameter from 2.5 to 0.2 mm. *Row C* contained a high contrast spatial resolution pattern ranging from 5 to 20 line pairs/mm. *Row D* included a step wedge consisting of 7 steps that covered the full dynamic range with 1 lead step, 5 aluminum steps of varying thicknesses, and 1 air step.

severe nonuniformity, and intermittent failures. One sensor was replaced as a result of physical damage to the universal serial bus (USB) connector. Artifacts included dark and light nonuniform regions, delamination, and vertical striation patterns. We included radiographic images captured with a tooth phantom to illustrate the difficulty of visualizing some artifacts and defects in a typical image of teeth. Radiographic images of teeth were acquired at the same exposure parameters as the images by using the DDQA phantom to highlight the need for a phantom designed for QA.

The radiographic image sets were randomly assigned to be reviewed by 10 examiners. The examiners were not blinded to the DIOS brand or the exposure parameters. The examiners were assigned random sets of 3 size 1 and 3 size 2 radiographic images from each DIOS brand, and each image set was reviewed twice by 2 different examiners to reduce bias. All examiners were licensed dentists. Six of the examiners had 5 to 10 years of clinical practice. The remaining 4 examiners, including 1 oral and maxillofacial radiologist (T.R.), had more than 15 years of clinical practice.

For calibration purposes, the examiners were advised on the test objects in the radiographs to be evaluated. The examiners were asked to count and record the number of visualized contrast wells, spatial resolution pattern observed with distinct bars separated by a space, and the number of steps seen on the step wedge pattern.

The evaluations of the 10 examiners were tabulated and analyzed by using Microsoft Excel software (Microsoft, Redmond, WA) to establish the median optimal exposure for each sensor. The optimal exposure is discussed further in Image Analysis.

Digital dental intraoral sensors

Five DIOS brands were evaluated by using 24 sensors per brand (12 size 1 and 12 size 2 sensors), for a total of 120 DIOS. However, of the 120 DIOS, 27 sensors were found to have severe problems and had to be replaced: Carestream RVG 6200: n = 24 plus 1 replacement (Carestream Dental LLC, Atlanta, GA)[8]; Gendex GXS-700: n = 24 plus 1 replacement (Gendex Dental Systems, Hatfield, PA)[9]; Planmeca ProSensor HD: n = 24 plus 1 replacement (Planmeca USA, Inc., Roselle, IL)[10]; Sirona Schick 33: n = 24 plus 24 replacements (Dentsply Sirona, York. PA)[11]; and XDR Radiology: n = 24 with no replacements (XDR Radiology, Los Angeles, CA).[12] As a result, the investigation consisted of examination of a total of 147 DIOS. All products were new and sent directly from the manufacturer. All 5 DIOS brands were 12-bit CMOS sensors having similar technology and were equipped with common components such as (1) a cesium iodide scintillator; (2) a fiberoptic plate; (3)

CMOS pixel matrix; (4) an analog-to-digital convertor; and (5) a USB 2.0 connector.

The DIOS was placed underneath the DDQA phantom. The anteroposterior placement was made to ensure the sensor was able to capture all of the test objects in the phantom from one end of the step wedge pattern with the lead step to the air step at the other end. This ensured that the contrast wells, spatial resolution, and full dynamic range were being accurately imaged each time. The latitude of the DIOS was determined by using a very low radiographic exposure and incrementally increasing the exposure time from 10 to 800 ms, while kilovoltage peak and milliamperage were kept constant at values of 63 and 6, respectively. This process was repeated for all sensors in the study until the sensor was saturated or the exposure time of 800 ms was reached to ensure the complete coverage of the useful clinical range of all DIOS. In total, 2900 radiographic images were captured.

Image analysis

The results of this study were aggregated together to derive a median optimal exposure value for each of the 5 DIOS. Optimal exposure was defined as the lowest radiation exposure at which the largest number of contrast wells, the highest spatial resolution, and all 7 steps on the step wedge were visible, thereby depicting the most diagnostic information while maintaining the full dynamic range. If the same numbers of contrast wells and spatial resolution were observed at a lower exposure while all 7 steps were visible, the lower exposure dose was deemed to be the optimal exposure. This was the same protocol used in the studies by Walker et al.[2] and Udupa et al.[13]

Since the radiation output was recorded with a Raysafe Unfors ThinX Intra meter, these exposures were compared with the DRL and AD for adult molar bitewing (BW) radiographs, as specified in National Council on Radiation Protection and Measurements (NCRP) Report 172, and ESE, as specified in the Radiation Control Regulations for Dental Radiation Machines Texas Administrative Code (TAC) 25 §289.232.[14,15] Since the DRL, AD, and state mandated exposure limits were for the adult molar BW radiographs, we did not include the exposure results for size 1 sensors in this comparison of exposures. However, any defects or discrepancies in the size 1 sensors that were discovered on acceptance testing were included in this study.

RESULTS

Of the 147 sensors (sizes 1 and 2) evaluated, discrepancies were documented in 35 DIOS (23.8%) and are discussed in alphabetical order by manufacturer. A summary of the discrepancies can be found in Table I. Illustrations of the discrepancies are provided for Carestream RVG 6200 (Figure 3 A1, A2, and A3), Gendex GXS-700 (Figure 3 B1, B2 and B3), and Planmeca ProSensor HD (Figures 3 C1, C2, C3, 3 D1, D2, and 3E1) sensors. Additional illustrations of discrepancies with the Gendex GXS-700 (Figure 4) and Sirona Schick 33 (Figure 5) sensors are also provided.

Carestream RVG 6200

On external physical inspection of these sensors, one size 1 sensor was found to have a damaged USB 2.0 connector, which was replaced by the manufacturer with another size 1 sensor for the study. An image defect, consisting of a subtle dark band on the end where the wire exits the sensor was noted with a size 2 sensor (see Figure 3, A1, A2, and A3). On Figure 3, A3, it was difficult to visualize this artifact near the premolar region; however, it was noticeable in the same region on the images acquired with the DDQA phantom.

Table I. Summary of discrepancies

DIOS type	*Total DIOS received*	*DIOS replaced*	*DIOS with imaging defects*
Carestream RVG 6200	25	1 USB connector defect (size #1)	1—dark band (size #2)
Gendex GXS-700	25	1 (size #2)	1—vertical striations (size #2) 1—delamination (size #2)
Planmeca ProSensor HD	25	1 (size #2)	1—latent image (size #2) with severe blooming on left 2/3's of sensor 1—linear demarcated non-uniformity (size #2) 1—delamination (size #2)
Sirona Schick 33	48	12 (size #1) 12 (size #2)	4—honeycomb pattern (size #1)
XDR Radiology	24	0	0
Total DIOS	**147**	**27**	**10***

*Two sensors (1 Gendex and 1 Planmeca) with imaging defects were also returned to the manufacturer. These sensors are listed in both the "DIOS replaced" and "DIOS with imaging defects" columns.
DIOS, digital dental intraoral sensors. *USB*, Universal Serial Bus.

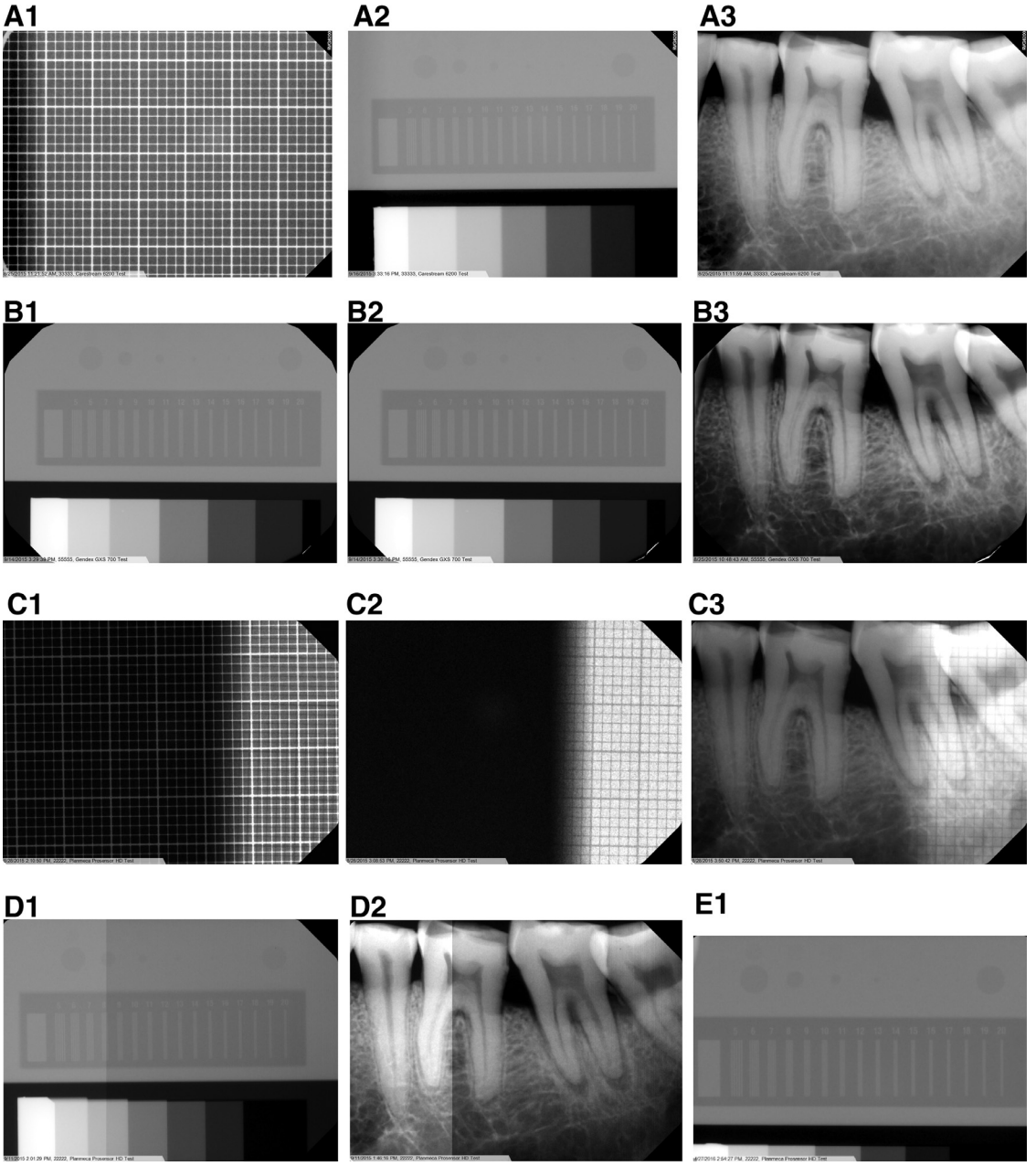

Fig. 3. Sample images of defects on digital dental intraoral sensors (DIOS). *A1, A2, A3*, Dark band on the mesial end of a Carestream RVG 6200 size 2 sensor. *B1, B2, B3*, Delamination or white void at the bottom right corner of a Gendex GXS-700 size 2 sensor. *C1, C2, C3*, Dark area characteristic of saturation, light and dark non-uniform regions, and a latent image of a grid pattern on a Planmeca ProSensor HD size 2 sensor. *D1, D2*, Light and dark regions causing non-uniformity in another Planmeca ProSensor HD size 2 sensor. *E1*, Delamination artifact in the upper left corner Planmeca ProSensor HD size 1 sensor.

Gendex GXS-700

External physical inspection of these sensors did not reveal any defects. Upon image acquisition, one size 2 sensor had internal delamination, which could only be detected on the radiograph. This white region appeared on the bottom right corner of the radiographic image and increased in size as the exposure time increased. The white region was visualized on the image with the DDQA phantom but was not easily identified on the image with teeth (see Figure 3, B1, B2, and B3). At a higher exposure, the same Gendex GXS-700 DIOS developed a vertical striation or banding pattern after the optimal exposure time was exceeded (see Figure 4A). For clarity, this sensor was counted twice in Table I, once in the "DIOS replaced" column and again in the "DIOS with imaging defects" column. The number of DIOS with defects was adjusted so that this sensor was not counted twice in the study. A second size 2 sensor also

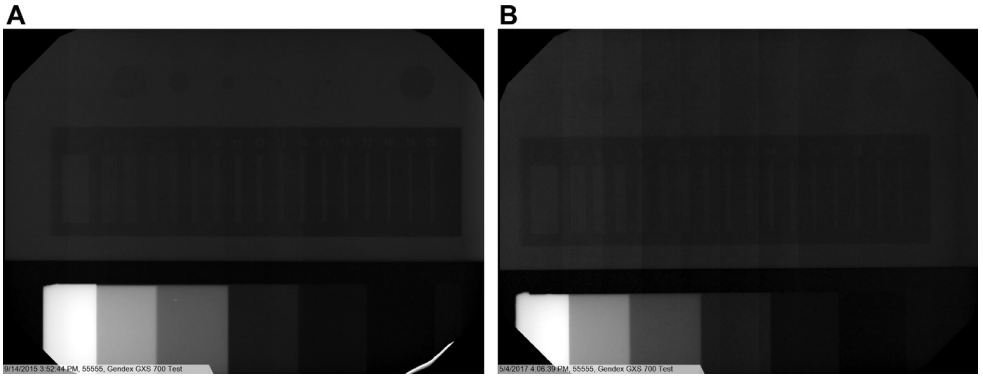

Fig. 4. Banding pattern. (**A**) Delamination and vertical striation pattern at high exposure; Gendex GXS-700 size 2 sensor. (**B**) Vertical striation or banding pattern after optimal exposure time was exceeded; Gendex GXS-700 size 2 sensor.

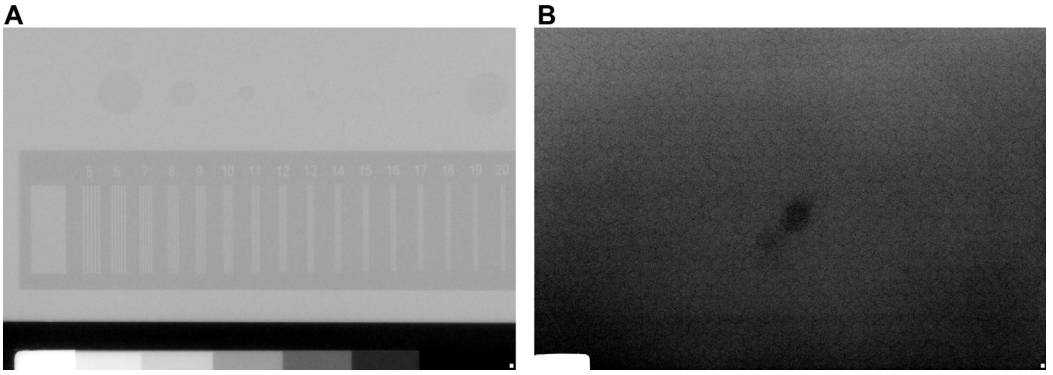

Fig. 5. Honeycomb appearance. (**A**) (**B**) Honeycomb appearance on a Sirona Schick 33 size 1 sensor.

developed a similar vertical striation or banding pattern when a higher exposure time was used (see Figure 4B).

Planmeca ProSensor HD

External physical inspection of the sensors did not reveal any defects. Three sensors each displayed a different imaging artifact. On the end of the sensor where the cord exits, one sensor had a dark, poorly delineated area, which was a "burned in" or latent image of a previously imaged grid pattern (see Figure 3, C1, C2, and C3). The images produced by this sensor were not readable. To clarify, this sensor was counted twice in Table I, once in the "DIOS replaced" column and again in the "DIOS with imaging defects" column. The number of DIOS with defects was adjusted so that this sensor was not counted twice in the study. Another sensor had a linearly demarcated light and dark region causing nonuniformity (see Figure 3, D1 and D2). The third sensor had a light area immediat'ely adjacent to the dark triangle at the upper right and left corners, characteristic of delamination (see Figure 3, E1). The Planmeca ProSensor HD size 2 sensor had severe blooming on the left two-thirds of the sensor, resulting in a loss of uniform appearance of the grid pattern. The saturation of pixels in the CMOS detector created a dark region on the radiographic image.

Sirona Schick 33

External physical inspection of the Sirona Schick 33-DIOS did not reveal any defects. However, the first batch of these sensors (n = 24), identified as Generation 1, did not consistently generate images after radiographic exposure. Upon exposure, there was a random disconnection of the sensors from the software while acquiring radiographs, which necessitated restarting the computer each time. These events were software-related and significant because they would contribute to patient radiation dose without diagnostic benefit. As a result, all 24 Generation 1 sensors (12 size 1 and 12 size 2) were replaced with Generation 2 sensors, along with new intermediary hubs and software.

Subsequent evaluation of the Generation 2 Sirona Schick 33 sensors revealed that 4 size 1 sensors displayed a honeycomb appearance in the radiographic images. At low exposures the radiographs did not display a flaw, but as the exposure times approached 500 ms and higher, the presence of a honeycomb pattern appeared on the radiographs (see Figures 5A and 5B).

Table II. DIOS median optimal exposure values (with the full dynamic range) and performance specifications

DIOS type	*Contrast perceptibility*		*Actual spatial resolution lp/mm*	*Theoretical spatial resolution lp/mm*	*Latitude of sensor*	
	No. of varying depth wells	*No. of varying diameter wells*			*Lowest exposure mGy*	*Highest exposure mGy*
Carestream RVG 6200	1	5	11	24.0*	0.09	1.15
Gendex GXS-700	2	6	12	25.6	0.07	1.79
Planmeca ProSensor HD	3	6	12	33.3	0.09	1.43
Sirona Schick 33	1	4	11	33.3	0.09	1.43
XDR Radiology	3	6	11	26.3	0.09	1.15

DIOS, digital dental intraoral sensors; *lp/mm,* line pairs per millimeter.
*From: http://pdf.medicalexpo.com/pdf/carestream-dental/rvg-6200/70654-116689.html.

XDR Radiology

No defects were found when evaluating the sensors in this DIOS.

In summary, there was a total of 35 DIOS with discrepancies: 1 physical problem (a damaged USB 2.0 connector); 26 related to software and hardware; and 10 related to imaging. Since a Gendex GXS-700 and a Planmeca ProSensor HD both had imaging defects, they were replaced; they are listed twice in Table I as "DIOS replaced" and "DIOS with imaging defects." Table totals of 27 and 10 were adjusted in the report to show that there were 35 DIOS with discrepancies and not 37 DIOS.

After removal and replacement of the defective sensors, exposure data were gathered, analyzed, and tabulated, as shown in Table II. The median optimal exposure value for each of the 5 DIOS and performance specifications results of the aggregated data, as well as the number of contrast wells, spatial resolution at the optimal exposure, and latitude of each DIOS system, are shown in Table II. The optimal exposure and latitude of the DIOS system are essential components in the balance between the radiation dose and diagnostic information. Respecting the latitude of the sensor prevents radiographic exposures outside the range of useful clinical parameters.

Exposure dose

The optimal exposures determined in this study are listed in Table III. This allows for a comparison with the DRLs for the intraoral radiographic examination, which is the radiation dose that 75% of the dental facilities use for an adult molar BW radiograph. NCRP 172 recommends a DRL of 1.6 mGy with an AD of 1.2 mGy for an adult molar BW radiographic examination.[14]

The AD is the dose derived from National Evaluation of X-Ray Trends (NEXT) survey data, where a median dose was selected and 50% of facilities were at or below this dose. AD is an optimization goal, based on survey data, and typically defined as the median value (50th percentile) of the dose distribution of standard techniques and technologies in widespread use. NCRP Report 172 states that it is inappropriate to disregard clinical image quality for dose sparing to the patient if the AD is exceeded.

The ESE from DIOS at the optimal exposure determined in this study are listed in Table III. In many regulatory statutes, there are limits on the exposure dose for the adult molar BW radiograph that are set by various state administrative codes or similar legislation. According to the Texas Administrative Code (TAC) 25§289.232(i)(6)(M), "the in-air exposure for the average human adult patient thickness for routine intraoral

Table III. Comparison of the study results of optimal exposures to published values for DRL, AD, and state-mandated ESE

DIOS type	*Study results optimal exposure (mGy/mR)*	*DRL as specified in NCRP 172 (mGy/mR)*	*AD as specified in NCRP 172 (mGy/mR)*	*ESE State of Texas (mGy/mR)*
Carestream RVG 6200	0.83 / 94.5	1.6 / 183	1.2 / 137	4.5 / 513
Gendex GXS-700	0.66 / 75.8	1.6 / 183	1.2 / 137	4.5 / 513
Planmeca ProSensor HD	0.83 / 94.5	1.6 / 183	1.2 / 137	4.5 / 513
Sirona Schick 33	0.41 / 46.9	1.6 / 183	1.2 / 137	4.5 / 513
XDR Radiology	0.83 / 94.5	1.6 / 183	1.2 / 137	4.5 / 513

AD, achievable dose; *DIOS,* digital dental intraoral sensors; *DRL,* diagnostic reference level; *ESE,* entrance skin exposure; *NCRP 172*, National Council on Radiation Protection and Measurements Report 172.

Table IV. Comparison of the study results of optimal exposures to the X-ray generator: manufacturer recommended exposure settings for the Planmeca ProX used in this study

	Study results optimal exposures (mGy/mR)	*Planmeca ProX X-ray Firmware 4.03 Recommended exposure settings 63 kV / 6 mA / 0.20 s at 30 cm (mGy/mR)*
Carestream RVG 6200	0.83 / 94.5	0.66 / 75
Gendex GXS-700	0.66 / 75.8	0.66 / 75
Planmeca ProSensor HD	0.83 / 94.5	0.66 / 75
Sirona Schick 33	0.41 / 76.9	0.66 / 75
XDR Radiology	0.83 / 94.5	0.66 / 75

(bitewing) dental radiography shall not exceed 450 millirem (mR) for dental intraoral at 60 kilovolt peak and above."[15] Since regulatory documents are not always expressed in SI units, we decided to include both mGy and mR in our report to allow the reader to compare values without performing the necessary mathematical calculations (see Table III).

In each instance, the optimal exposure for every brand of DIOS was within the DRL and AD specified in NCRP Report 172. The optimal exposure for each DIOS, determined by using the DDQA phantom, was well below the allowable ESE as established by the State of Texas. The ESE will vary, depending on the state or jurisdiction under which the dental facility operates; readers are advised to consult the appropriate legislation for ESE for the adult molar BW radiograph in their region.

For comparison, Tables IV and V list the suggested exposure parameters for each DIOS compared with the optimal exposure for each DIOS. Table IV lists the X-ray generator manufacturer's recommended exposure parameters for an adult molar BW radiographic examination, and Table V states the DIOS manufacturer's suggested parameters or comments for radiographic examinations.

DISCUSSION

A universal QA protocol, as described in the recently published ANSI/ADA TR 1094 methodology, was used in this study. This QA testing for dental intraoral sensors establishes a baseline against which periodic assessments are made to compare the image quality over time to the baseline reference. The results of this study support the need for acceptance testing with DIOS as a key component of a QA program. Additionally, this study confirms that diagnostic intraoral radiographs can be acquired with DIOS at exposure doses that comply with the principles of the DRL, the AD, and the legislated ESE for an adult molar BW radiographic examination.

The defects or problems found through these acceptance tests of DIOS varied from one manufacturer to another. There was no consistent pattern of problems leading to a failure of the DIOS. For example, the Carestream RVG 6200 had 2 issues: (1) a damaged USB connector and (2) a discrepancy in image uniformity from one end of the sensor image to the other, whereas one Gendex

Table V. Comparison of exposure doses by DIOS manufacturers

DIOS	*X-ray generator*	*Exposure settings (kV/mA/s)*	*Exposure comments*
Carestream RVG 6200	Carestream Dental CS2200 20 cm	70 kV/ 7 mA/ 0.40 s	Follow the user instructions of the X-ray source
Gendex GXS-700	Compatible with any dental X-ray unit; follow the X-ray source manufacturer's recommendations	Sensor is designed for use in a wide range of dose settings according to diagnostic task	Can capture a noisy image at low incident exposure of 40 μGy
Planmeca ProSensor HD	PlanmecaProX X-ray 30 cm Firmware 4.03* Firmware 4.13†	63 kV /6 mA/ 0.20 s* 60 kV/8 mA/0.25†	0.66 mGy/75 mR*
Sirona Schick 33	See the kV and mA settings on the X-ray generator in use, and compare to the settings listed in the Schick 33 Factor Guidelines	Other X-ray manufacturer model pre-sets may not be amenable to the settings required by Schick 33 sensor	Manual settings may need to be selected for use with Sirona Schick 33 sensors because CDR may use 85% less dose than D speed film
XDR Radiology	XDR offers support in establishing exposure settings for the X-ray generator used with their product	XDR offers support in establishing exposure settings for the X-ray generator used with their product	Exposures up to the equivalent of F speed film

*Planmeca ProSensor HD User Manual.
†Planmeca ProSensor User's and Install Manual v.2.
From: Carestream RVG 6200 Quick User and Installation Guide (SM856) Ed01 2013; Gendex GXS-700 User Manual; Schick 33 System User Guide and Schick 33 Technique Factor Guidelines; The Dental Company Sirona; USER Manual for XDR Digital X-Ray System Version 3.2.13.
CDR, Computed Dental Radiography; *DIOS,* digital dental intraoral sensors.

GXS-700 sensor had a problem with delamination, which caused a white void on the corner of the sensor, and a striation and banding problem on another sensor.

Delamination occurs when the layers of the DIOS become detached from each other and light is no longer transmitted from the scintillator through the fiberoptic layer to the CMOS detector, leaving a void or white region on the radiographic image. When delamination is incomplete, some light is still transmitted to the CMOS detector; the defect is a lighter shaded area relative to the normal adjacent pixels. Delamination is most common along the edge but the central part of the sensor can delaminate when the cesium iodide layer becomes detached from the fiberoptic plate.

The problems we encountered with the Sirona Schick 33 sensors in this study included failure to capture a radiographic image. Artifacts occurred at exposures of 500 ms, but this exposure time would not be an unreasonably high exposure for an occlusal view to visualize an impacted canine.

Typically, a DIOS will not allow the user to capture a radiograph after it has become saturated or overwhelmed by the built-in mechanisms of the imaging system. However, we noted that under exactly the same exposure conditions, some of the sensors from the same manufacturer performed differently, although identical exposure conditions, software, computer, and display monitor were used.

An effective quality assurance radiographic phantom must be used for acceptance testing. The phantom must be able to evaluate the imaging parameters mentioned in ANSI/ADA TR 1094. More importantly, these test parameters must be evaluated within a single radiographic image acquisition, with exceptions for measurements of sensor latitude and patient radiation dose. These exceptions are also designated as the air kerma value or ESE for an adult molar BW radiograph. In addition, an effective QA phantom should be easy to use, replicate the source to sensor distance, ensure parallel alignment, and allow for repeatable positioning of the intraoral sensor for comparison of radiographic images.

The test phantom used in this study simulated the clinical use conditions of the DIOS in terms of attenuation, geometry, and alignment to provide clinically relevant data and aid in the development of a technique chart. The parameters for optimal exposure for one DIOS brand may not be the same as the parameters suggested by a different manufacturer; therefore, a QA assessment of image optimization is required. Table V shows the ambiguity of DIOS manufacturers on recommended exposure parameters for the same radiographic examination. Although DIOS manufacturers understand that each clinical combination of DIOS, X-ray generator, and software is unique, most offer minimal or unclear instructions for use with image optimization exposure parameters. This emphasizes the importance of the use of a test phantom in QA image optimization.

In the absence of established QA protocols for radiographic imaging, the International Commission on Radiological Protection introduced the concept of comparing radiographic exposure doses in a particular examination with other users and facilities as a self-assessment of ionizing radiation doses. DRL is defined as the upper exposure limit that the 75th percentile of users for a radiographic examination would use. Similarly, AD is defined as the exposure limit that the 50th percentile of the users of that radiographic examination would use.

DRL is neither the ideal exposure for a particular radiographic examination nor the absolute upper limit. It is used as part of a QA program to ensure the radiation doses used are consistent with other facilities performing the same radiographic examination. If the DRLs in a facility routinely exceed those of other facilities, a review of the imaging protocols is justified.

NCRP Report 172 has determined that the DRL for adult molar BWs is 1.6 mGy (183 mR) and the AD is 1.2 mGy (137 mR). In Table III, we compared the optimal exposures for each DIOS with these values. In each case, we were able to obtain optimal exposures below the stated DRL and AD for the adult molar BW radiographic examination.

Other methods to limit and control radiation doses in dentistry in some U.S. states have been to enact statutes that specify maximum ESE or air kerma limits for adult molar BW radiographic examinations as an alternative to DRL and AD. ESE represents an absolute limit and must not be exceeded. In Texas, ESE is set at 4.5 mGy (513 mR) because the state does not differentiate between film-based imaging and digital imaging. Since this study was performed in Texas, the applicable ESE values for Texas were compared with the optimal exposure for each DIOS.

As part of the requirements of the U.S. Food and Drug Administration (FDA) for the sale and use of ionizing radiation equipment in the United States, manufacturers are required to provide suggested exposure parameters. However, the difficulty with setting exposure parameters for intraoral radiography is that the manufacturer of the X-ray generator does not know what DIOS, computer hardware and software, and display monitor combination will be used in the digital imaging chain or the imaging technique. Therefore, the suggested exposure parameters may be quite different from the optimal exposure determined by using a QA phantom that evaluates the entire imaging chain.

Table IV identifies the differences between the recommended exposure parameters of the X-ray generator manufacturer and the optimal exposures resulting from the above mentioned combination of equipment in the imaging chain and different imaging techniques, such as long-cone paralleling or short-cone bisecting angle.

Although DRL, AD, and ESE may be helpful in limiting or controlling radiographic exposures, they do not replace or circumvent the need for image optimization. In reality, the optimal image exposure may be at or slightly above the DRL or AD, as reported by Walker et al.[2] and Udupa et al.[13] Simply having radiographic exposures at values lower than the DRL, AD, and ESE is insufficient to ensure that diagnostic radiographs are being acquired. This was demonstrated in the study by Walker et al.,[2] which found that it was necessary to increase the radiographic exposures in some offices to obtain the optimal radiographic exposure.

In fact, inadequate exposure in digital intraoral radiography is now a more common problem than overexposure. Too low an exposure results in a nondiagnostic radiograph that is filled with quantum mottle and noise, obscuring the clinician's ability to discern subtle details, such as the presence of incipient caries, early periodontal bone loss, and the presence of a lamina dura. The ability to identify these important details at an early stage allows the dentist to treat or prevent the progression of oral health problems at the lowest cost, with the least invasive intervention and greatest benefit to the patient.

Both overexposure and underexposure of digital intraoral radiographs may cause loss of diagnostic information and incorrect treatment decisions. Dose monitoring by using DRL and AD or dose regulation by using ESE is insufficient to ensure that diagnostic radiographs will be acquired. Image optimization as part of the acceptance testing for digital intraoral systems is the key to ensuring that high-quality diagnostic radiographs will be generated.

Acceptance testing serves the following purposes:

1. Ensures that dental providers receive what they ordered, including features and accessories
2. Validates that installation or set up is correct
3. Ensures compatibility of all components in the imaging chain
4. Ensures that radiographic image quality is adequate
5. Validates that dental staff and radiographers are properly trained to operate the radiographic equipment
6. Ensures that radiographic exposures are in compliance with state-mandated maximum exposure limits
7. Allows comparison to diagnostic reference levels (DRL) and achievable doses (AD) that are suggested in NCRP Report 172[14]
8. Provides guidance for a technique chart to use with the DIOS, X-ray generator, software, computer, and image display monitor as required for most state radiation protection program regulations
9. Ensures compliance to meet the standard of care and QA as specified in ANSI/ADA TR 1094[3]
10. Establishes a baseline reference for longitudinal comparison.

This study is the first of its kind in that an Internet search of acceptance testing of DIOS yielded few results. One finding from the Internet search was the American Association of Physicists in Medicine Report 175 (AAPM Report 175) Acceptance Testing and Quality Control of Dental Imaging Equipment, which states that acceptance testing should be performed.

We found another study we believe confirms the need for acceptance testing of intraoral image receptors in digital imaging. However, this study was a report on "fish scale" artifacts and was not listed under the search terms of acceptance testing as a QA protocol. Buchanan et al.[16] identified inherent fish scale artifacts on 46.7% of new PSP plates before clinical use. The impact that these artifacts may have on diagnostic decisions is of concern. Nevertheless, the report by Buchanan et al. brought awareness of the need for acceptance testing with PSP plates. The study by Buchanan et al. was different from the present investigation in that the former evaluated PSP plates and only from one manufacturer. The incidence of fish scale artifacts on 46.7% of the new PSP plates is alarming. Many intraoral radiographic examinations are performed worldwide on an annual basis. A medical device with a failure rate approaching 25%, as in the present study, is excessive but not unexpected, given the recent publication by Buchanan et al.[16]

This study also disproves the popular misconception that because DIOS are solid-state image receptors, they only fail catastrophically. Catastrophic failure is an easily identifiable problem. However, failures occur when DIOS acquire a radiographic image, even when there is a defect with the DIOS, as was demonstrated in this study. It is the potential loss of image fidelity that is difficult to detect without a proper QA program.

We surmise that the internal corporate QA aspects of each manufacturer vary greatly. We discovered that one DIOS manufacturer had a far greater share of

discrepancies compared with the others and that another DIOS manufacturer's sensors had no discrepancies. This is surprising, given that the FDA requires every DIOS manufacturer to have an internal QA protocol to validate and ensure that diagnostic radiographs will be produced with their products. These internal QA protocols are considered proprietary and confidential and, thus, are not shared with the end user of these DIOS products. This leaves one to wonder what these QA programs entail.

To the best of our knowledge, other studies on acceptance testing of DIOS have not been published despite almost 1.2 billion intraoral radiographic examinations performed annually in the United States alone.[17] Many more intraoral radiographic examinations are performed worldwide on an annual basis.

Although AAPM Report 175 indicates that acceptance testing should be performed on all digital radiographic imaging systems, it does not specify a protocol for intraoral radiography.[4] Other research papers have discussed QA for digital intraoral systems, but they have not mentioned acceptance testing as part of their QA protocols.[18,19] Acceptance testing is an important aspect of a QA program because it can be initially used to ensure compatibility of the components of the imaging chain, and over the long term, it establishes a baseline reference for longitudinal comparisons of the digital imaging systems' performance and deterioration over time.

CONCLUSIONS

This study demonstrates that acceptance testing is a necessary part of a comprehensive QA program for digital intraoral systems. Without acceptance testing, defective or faulty products may lead to nondiagnostic radiographs, unnecessary exposure of patients, or an incorrect diagnosis. As indicated by the findings of this study, upon the delivery of a new DIOS, there is a 1-in-4 chance that the product may be defective.

Digital intraoral acceptance testing must be implemented with a phantom that objectively tests the relevant parameters: contrast perceptibility, spatial resolution, dynamic range, and latitude. Acceptance testing provides a baseline reference to compare image quality as the DIOS is used throughout its lifespan in clinical practice. An effective acceptance QA program will go a long way to ensure that dental care providers have a proper functioning DIOS, with which they can make their diagnoses and treatment plans for their patients. Finally, when discrepancies in performance are discovered during acceptance testing, the manufacturer of the particular DIOS brand should be consulted to see if product replacement or repair is warranted.

DISCLOSURES

This study was conducted at the United States Air Force Dental Evaluation & Consultation Service, San Antonio, Texas.

The authors Teresa Reeves and Wen Lien do not have any financial interest in the companies whose materials are discussed in this paper. The author Peter Mah is the President of Dental Imaging Consultants, LLC, which holds a patent for the Digital Dental Quality Assurance (DDQA) phantom and is an authorized distributor for RaySafe Unfors products. This author has no financial interest in the other companies whose materials are discussed in this paper.

DISCLAIMER

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Air Force.

The views of Carestream Health, KaVo Kerr Group, Planmeca USA, Sirona Dental, and XDR Radiology are not necessarily the official views of, or endorsed by, the U.S. Government, Department of Defense, or Department of the Air Force. No Federal endorsement of any manufacturer is intended.

FUNDING

No financial support was received from any external source or vendor for this project. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors, although all sensor manufacturers provided all their products to the USAF Dental Evaluation and Consultative Services at no cost to the USAF and signed Memoranda of Technology Agreement to that effect. Upon completion of the study, all products were returned to the various manufacturers.

REFERENCES

1. Walsh C, Gorman D, Byrne P, Larkin A, Dowling A, Malone JF. Quality assurance of computed and digital radiography systems. *Radiat Prot Dosimetry*. 2008;129:271-275.
2. Walker T, Mah P, Dove SB, McDavid WD. Digital intraoral radiographic quality assurance and control in private practice. *Gen Dent*. 2014;62:22-29.
3. American Dental Association. ADA Technical Report No. 1094 Quality Assurance for Digital Intra-Oral Radiographic Systems. Available at: https://ebusiness.ada.org/productcatalog/33770/Informatics/ADA-Technical-Report-No-1094-Quality-Assurance-for-Digital-I/P. Accessed November 1, 2018.
4. American Association of Physicists (AAPM) Task Group 175. *Acceptance Testing and Quality Control of Dental Imaging*

Equipment AAPM Report No.175. Alexandra, VA: AAPM; 2016.
5. RaySafe. Available at: http://www.raysafe.com/en/Products/Equipment/RaySafe%20ThinX. Accessed April 29, 2019.
6. Gray J. Use of the SMPTE test pattern in picture archiving and communication systems. *J Digit Imaging*. 1992;5:54-58.
7. Mah P, McDavid WD, Dove SB. Quality assurance phantom for digital dental imaging. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2011;112:632-639.
8. Carestream Dental. RVG 6200. Available at: http://www.carestreamdental.com/us/en/rvgimaging/6200#Features and Benefits. Accessed November 1, 2018.
9. KaVo Dental. Gendex GXS-700. Available at: http://www.gendex.com/gxs-700. Accessed November 1, 2018
10. Planmeca USA. Planmeca ProSensor HD. Available at: https://www.planmeca.com/na/Imaging/Intraoral-imaging/planmeca-prosensor-hd/. Accessed November 1, 2018
11. Sirona. The Dental Company. Available at: https://www.dentsplysirona.com/en-us/categories/imaging-systems.html. Accessed December 5, 2019.
12. Dental Compare. XDR Anatomic. Available at: https://www.dentalcompare.com/4448-Dental-Digital-Radiography-Digital-Dental-X-Ray-Intraoral/42334-XDR-Digital-Radiography/. Accessed November 1, 2018
13. Udupa H, Mah P, Dove S, McDavid W. Evaluation of image quality parameters of representative intraoral digital radiographic systems. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2013;116:774-783.
14. National Council on Radiation Protection and Measurements (NCRP). *Reference Levels and Achievable Doses in Medical and Dental Imaging*: Recommendations for the United States, NCRP Report No. 172. Bethesda, MD: NCRP; 2012.
15. Texas Administrative Code (TAC) 25 §289.232. Radiation Control Regulations for Dental Radiation Machines. Available at: https://www.dshs.texas.gov/radiation/laws-rules.aspx. Accessed April 29, 2019.
16. Buchanan A, Morales C, Looney S, Kalathingal S. Fish scale artefact on an intraoral imaging receptor. *Dentomaxillofac Radiol*. 2017;46:2017224.
17. U.S. Food and Drug Administration (FDA). Nationwide Evaluation of X-Ray Trends (NEXT). Available at: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/NationwideEvaluationofX-RayTrendsNEXT/default.htm. Accessed November 1, 2018.
18. Hellen-Halme K, Johansson C, Nilsson M. Comparison of the performance of intraoral X-ray sensors using objective image quality assessment. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2016;121:e129-e137.
19. Greenall C, Drage N, Ager M. Quality assurance tests for digital radiography in general dental practice. *Dent Update*. 2014;41:126-134.

Reprint requests:

Teresa E. Reeves
Diplomate ABOMR
United States Air Force Postgraduate Dental School
Lackland Air Force Base−Joint Base San Antonio
1615 Truemper Street
San Antonio
TX 78236
USA
Teresa.e.reeves.mil@mail.mil