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The importance of the ANSI ADA Standard for digital intraoral radiographic systems—a pragmatic approach to quality assurance

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The need for quality assurance (QA) for digital dental radiography has existed since the introduction of digital imaging; however, the methods and phantoms required to achieve it were not available. This resulted in a chaotic approach to address QA based largely upon subjective analysis of image quality. The American National Standards Institute (ANSI)/American Dental Association (ADA) Quality Assurance Standard 1094 for Digital Intraoral Radiographic Systems (DIRS) presents a paradigm shift to a scientific and objective method of QA rather than one based on subjective assessments. This standard takes into account the contributions of all components of the digital imaging chain that affect final image quality rather than assessing the various components in isolation. The optimal image is determined for each DIRS through objective analysis of the image quality properties of dynamic range, spatial resolution, and contrast perceptibility. Image optimization, a critical component of a quality assurance program, is the proper balance between diagnostic image quality and radiation dose to the patient. This publication counters disseminated myths and misconceptions with scientific evidence and will help dental practitioners appreciate and understand the benefits of the new ANSI/ADA Standard on QA for DIRS. (Oral Surg Oral Med Oral Pathol Oral Radiol 2022;000:1−12)

If a dental practice uses dental X-ray sensors or photostimulable phosphor (PSP) plates to acquire digital radiographs, regulations require quality assurance (QA)/quality control (QC) procedures and records, similar to the situation for film-based dental radiography. The QA program and QC procedures are both means to measure the performance of all parts of the radiographic imaging system. The QA program ensures that this performance has not been degraded below an acceptable limit, and it is required by regulations because digital imaging systems are designed to be reused repeatedly, which gives rise to wear, degradation, and partial failure of components in the digital imaging chain.

When radiographs were acquired on film and developed with chemicals in a darkroom or film processor, regulations required X-ray film users to maintain QA/QC for films, chemicals, and darkrooms to prevent poor quality images that resulted in excessive X-ray exposure and re-exposures. Regulations for film-based radiography QA/QC were specific, and came complete with sample forms to help dental practices maintain regulatory compliance.

Today, 86% of dental practices in the United States use digital imaging systems instead of film, according to the Food and Drug Administration Nationwide Examination of X-Ray Trends (FDA NEXT) 2014-15 dental survey.[1] The regulations for digital imaging QA/QC state that the user is to follow the manufacturer's QA procedures, if they are available. No sample procedures or forms are provided by the state, and manufacturers' QA procedures are often difficult or impossible to find. If the manufacturer provides no QA resources, dentists must establish their own QA procedures. However, digital imaging QA is a technical endeavor that is not taught in many dental education programs, leaving users in a quandary.

There is a need for clear and concise QA procedures that can be implemented in any dental practice using digital intraoral radiographic systems (DIRS). The QA procedures must be universal and simple enough yet effective such that they may be implemented with any DIRS. This is where the American National Standards Institute (ANSI)/American Dental Association (ADA) Standard 1094 Quality Assurance for Digital Intraoral

Statement of Clinical Relevance

Clinical examination combined with high-quality radiographs are essential in diagnosis and treatment planning. Optimized radiographs with maximal diagnostic information and minimal exposure require an effective quality assurance program free from the myths and misconceptions that negatively influence digital radiography.

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Radiographic Systems (simply referred to as Standard 1094) fills the need.

The development of standards of dental practice is the responsibility of the ADA. ANSI is designated by Congress as the standards development organization for the United States. In turn, ANSI designates 2 ADA committees, the Standards Committee for Dental Products and the Standards Committee for Dental Informatics, to oversee the development of US standards for dental instruments, devices, materials, and information technology. Standard 1094 is one of these standards.

The QA program encompasses all of the steps required to consistently produce high-quality radiographic images and ensure maximum diagnostic yield with the lowest patient radiation exposure, a process referred to as image optimization.[2] Numerous articles describing the benefits of a DIRS QA program have been published over the past decade,[2-10] but many practices have yet to implement QA protocols.

The lack of QA in dental practices is due to a host of factors. There is simply very little information on QA for users to follow, and the technical nature of digital imaging makes it difficult for dentists to establish their own QA procedures. The absence of QA instruction in dental education programs and continuing education (CE) courses has allowed myths and misconceptions regarding DIRS to persist. In this article, we address these erroneous concepts:

1 DIRS can only fail catastrophically.
2 DIRS are self-calibrating.
3 Dose references are accurate in selecting exposure settings.
4 Software changes can compensate for inappropriate X-ray exposures.
5 Flat-field uniformity tests can assess the degree of homogeneity within a DIRS.

The purpose of this article was to dispel myths and misconceptions and encourage the reader to implement effective QA protocols for DIRS as described in Standard 1094.

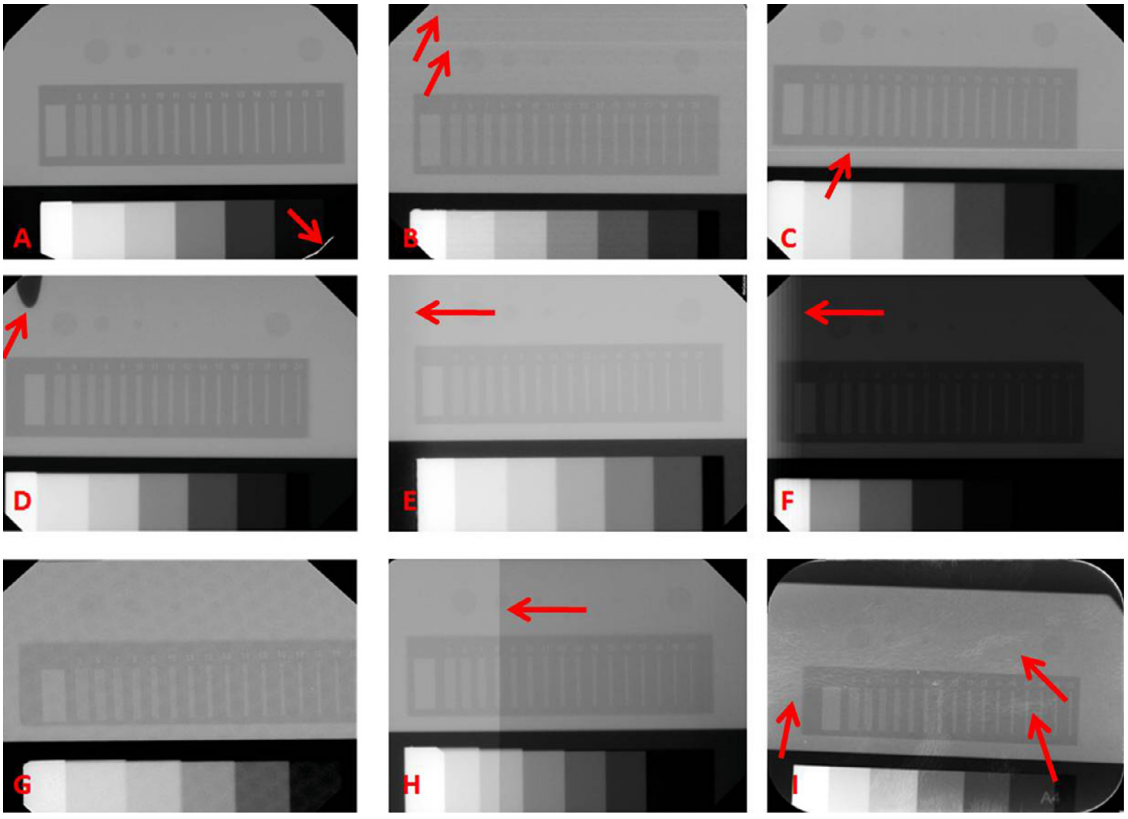

Fig. 1. Examples of image artifacts on digital intraoral radiography system images, indicated by arrows. (**A**) Delamination of the scintillation layer in the bottom right corner. (**B**) Horizontal lines across image in the region of the contrast wells. (**C**) Row of dead pixels below the spatial resolution gauge. (**D**) Incomplete delamination in the upper left corner. (**E**) Diffuse darkened non-uniformity on the left side edge. (**F**) Banding or striation pattern on the left side of the image. (**G**) Swiss-cheese pattern (present throughout the image) from the fiber-optic plate due to lack of calibration file. (**H**) Light band on the left side of the image. (**I**) Craze lines from damaged protective coating on the photostimulable phosphor plate.

MYTHS AND MISCONCEPTIONS EXPLAINED

DIRS can only fail catastrophically

The concept that a DIRS only fails catastrophically means that the system either works or does not work and thus the need for QA evaluation is not necessary. This misconception has been perpetuated to justify the failure to perform QA on DIRS. However, cases exist where image capture is possible despite a problem with a DIRS, thus refuting the catastrophic failure myth and validating the need for a QA program to detect the failure of components in the digital imaging chain. Examples are shown in Figure 1, where images were generated despite problems existing with the radiographic system. Problems include complete delamination of the scintillation layer, horizontal lines across the image, dead pixel artifacts, incomplete delamination, image nonuniformity, banding, loss or corruption of calibration file patterns; light bands, and craze lines from damage to the protective coating of PSP plates.

DIRS are self-calibrating

The belief that DIRS self-calibrate to display a proper gray level regardless of the exposure is incorrect. Although DIRS are technically sophisticated, they do not self-calibrate, and the optimal exposure must be determined for each system.

Image optimization integrates the effects of all aspects of the digital imaging chain on image quality. The misconceptions of catastrophic failure and DIRS self-calibration have hampered implementation of image optimization.[2] Therefore, it is not surprising that the FDA NEXT survey found that 30.3% of US dental facilities used the same exposure setting for all patients.[1] Image optimization has been daunting with the advent of digital intraoral imaging; nonetheless, its lack of implementation has affected clinical tasks. The difficulty of visualizing the extent of caries in intraoral radiographs has been attributed to failure to carry out image optimization to ensure diagnostic accuracy.[11]

Identical radiographic exposures have been shown to result in different responses even when using the same image receptor.[5] Table I shows X-ray output exposure measurements for 2 intraoral X-ray units, the Pro X and the Intra (Planmeca, Helsinki, Finland) using the long (30 cm) beam-indicating device (BID) made at our institution. The radiation output from the 2 models varied, even with the same exposure settings (kVp, mA, and time), due to differences in focal spot size. Additionally, the radiation output from alternating current X-ray generators may yield even larger discrepancies due to the cycling nature of alternating currents. Validating the manufacturer-supplied technique charts, even when the exposure settings are identical, is required to ensure image optimization.

Table I. Exposure output for two intraoral x-ray units using the long BID (30 cm) technique at 63 kVp, 8 mA, and varying exposure times

	Radiation exposure output			
	Planmeca Intra Focal spot 0.7 mm		*Planmeca Pro X Focal spot 0.4 mm*	
Time (s)	*mR*	*mGy*	*mR*	*mGy*
0.010	6.9	0.060	6.1	0.053
0.012	9.3	0.082	7.1	0.062
0.016	12	0.105	9.4	0.082
0.020	14.2	0.124	11.1	0.097
0.025	17.9	0.157	14.3	0.125
0.032	21.9	0.192	18.0	0.158
0.040	27.4	0.240	22.8	0.200
0.050	33.500	0.294	28.100	0.246
0.064/0.063*	42.600	0.373	35.100	0.308
0.080	53.100	0.466	45.100	0.395
0.100	66.200	0.579	56.200	0.493
0.125	82.300	0.722	70.100	0.615
0.160	104.000	0.912	89.000	0.780
0.200	131.000	1.148	111.000	0.973
0.250	163.000	1.429	139.000	1.219
0.320	208.000	1.824	177.000	1.552
0.400	259.000	2.271	222.000	1.946
0.500	324.000	2.841	277.000	2.428
0.640/0.630*	414.000	3.630	348.000	3.051
0.800	518.000	4.541	442.000	3.875

*The 2 double entries in the exposure time are a result of the different displayed exposure settings between the Planmeca Intra and the Planmeca ProX X-ray units at this particular incremental setting, with the Planmeca ProX being the latter value.*BID*, beam-indicating device; *kVp*, kilovoltage peak; *mA*, milliamperes; *mR*, milliRoentgens; *mGy*, milliGrays.The X-ray units used were the Intra and ProX models (Planmeca, Helsinki, Finland) with long cone technique (30 cm from source to end of BID).

Various methods have been advocated for determining the optimum exposure for DIRS. These methods include the use of human participants[12]; stepwedges[13]; various objects—a bib chain clip or alligator clip,[1] paper clip, coins, keys, printed circuit boards, and pencils; noise evaluation (whether it be noise alone, signal-to-noise ratio [SNR], contrast-to-noise ratio [CNR] or some other variant of noise level)[5,6,14-18]; uniformity tests[5,6,17]; and radiographic phantoms.[2-4,8-10,17-23]

The acquisition of multiple radiographic images of the same area on a person to optimize image quality is prohibited by standards of practice and violates fundamental radiation safety protocols.[12] Comparing radiographs among patients is fraught with problems due to differences in attenuation, positioning, and other technical factors. Figure 2 shows a series of radiographic images of the same human jaw phantom with teeth at increasing exposures, with the largest exposure 80 times greater than the smallest exposure. It is, however, difficult if not impossible to discern which of

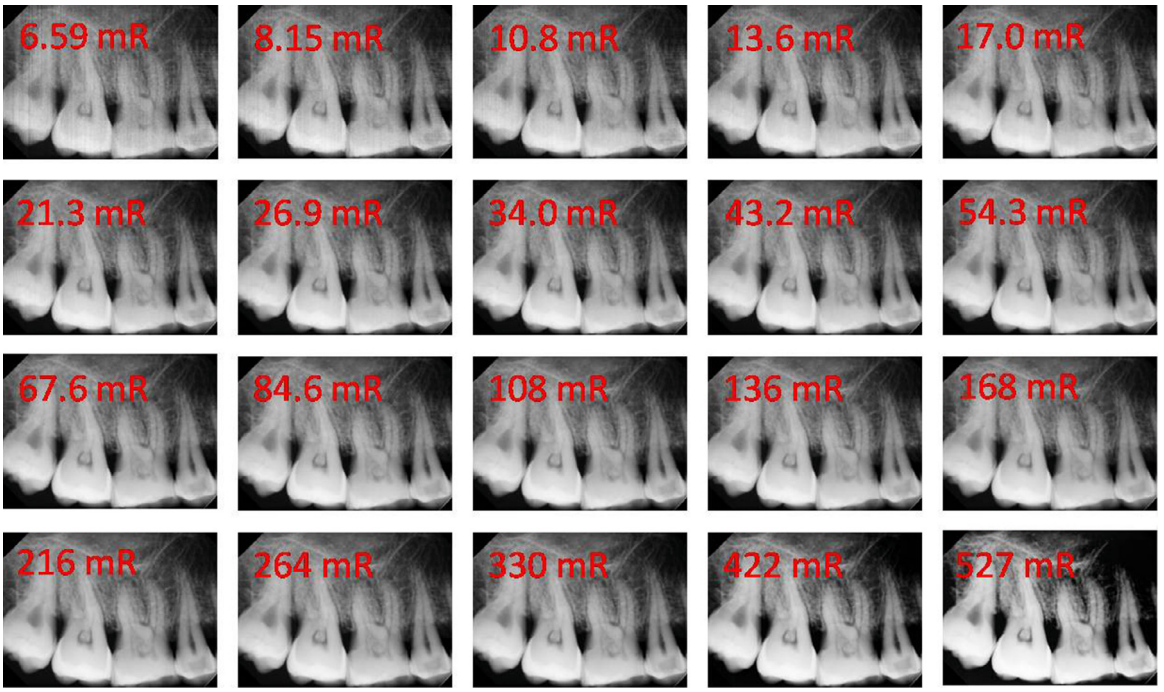

Fig. 2. Radiographs of a human maxilla at incrementally increasing exposures over a range of 20 exposures. *mR*, milliRoentgens.

these radiographic images is properly exposed to select the optimal exposure.

Similarly, the use of a step-wedge alone does not provide adequate evaluation of image quality. In Figure 3, although gross under- and overexposures are apparent, it is impossible to identify the optimum exposure using only a step-wedge due to the lack of spatial and contrast resolution assessments. Table II indicates that the measured gray-scale values on each of the 7 steps of a step-wedge pattern on a digital

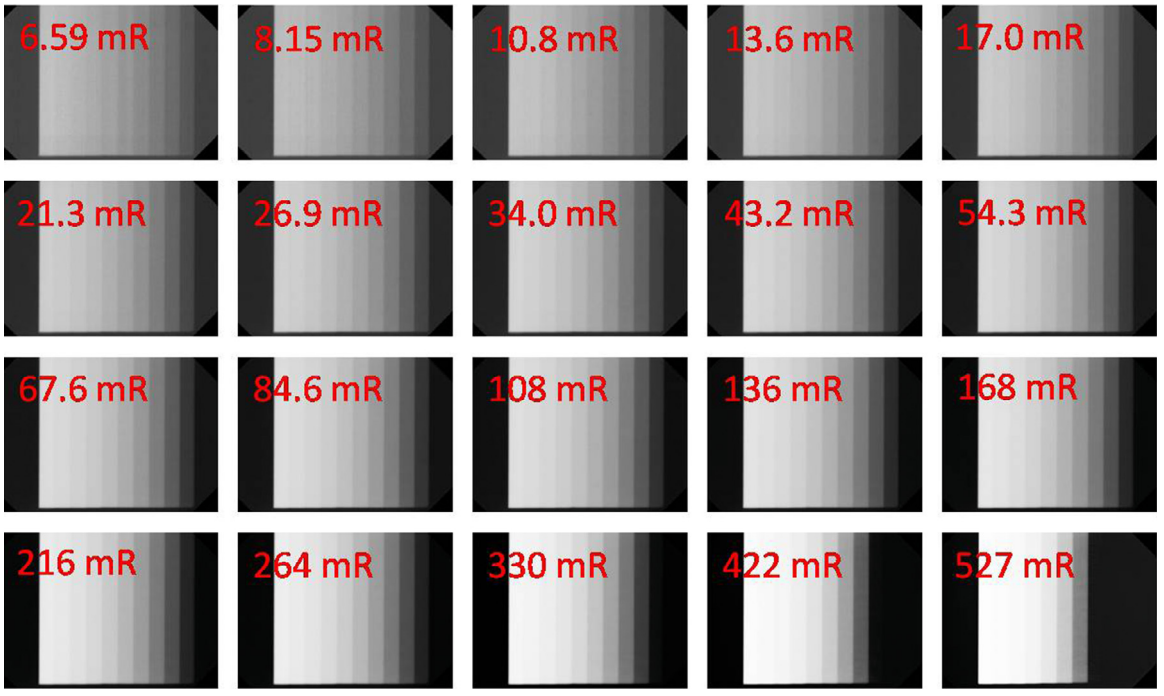

Fig. 3. Radiographs of an aluminum step-wedge at incrementally increasing exposures over a range of 20 exposures. *mR*, milliRoentgens.

Table II. Gray-scale values at incrementally increasing exposure settings using a 7-step step-wedge ranging from full attenuation to no attenuation

Exposure (mR)	*No. of visible steps*	*Step 1 (lead)*	*Step 2*	*Step 3*	*Step 4*	*Step 5*	*Step 6*	*Step 7 (air)*
101.98	7.00	233	198	168	116	62	17	0
150.29	7.00	235	200	171	117	61	16	0
206.94	7.00	234	198	168	113	56	14	0
249.33	7.00	230	193	161	103	47	11	0

Image analysis performed with NIH software (National Institute of Health, Bethesda, MD, USA).
mR, milliRoentgens.

radiographic image do not change with each incremental increase in X-ray generator exposure as they do with film-based imaging. This is due to the fact that manufacturers apply image processing or autoleveling (adjustment to a preset median gray level) to digital radiographs; therefore, a change in exposure does not equate to an observable change in gray levels as with films. The statement that DIRS self-calibrate is not entirely false in that the software alters gray levels in the radiograph to some preset level, but this adjusted gray level is not reflective of the actual or optimal exposure.

One sensor manufacturer's QA protocol entails the placement of an alligator clip or paper clip onto the imaging surface of the receptor, positioning the BID 3 inches away, and then acquiring a radiograph at an exposure value "that correspond(s) to a typically-used minimum dosage."[13] The problem with this protocol is that there are no criteria on what constitutes a diagnostic radiograph of these clips, and the changes in appearance can be so minimal that it is impossible to determine which radiographic image represents the optimum exposure for the image receptor. There is no method to confirm that the full dynamic range (i.e., gray-scale) has been captured, which may result in loss of diagnostic information. To illustrate the shortcomings with an alligator clip QA test, 20 images with incrementally increasing exposures were acquired using a constant potential X-ray unit set at 63 kVp and 6 mA. The relatively indistinguishable images are shown in Figure 4. The exposures were increased until the sensor was saturated, as evidenced by the dark shadow between the upper and lower sets of teeth on the alligator clip. It is also difficult to verify perpendicular alignment, even though it was used, by ascertaining changes in the sharpness of the teeth of the alligator clip. It is worth mentioning that establishing a perpendicular alignment between the BID and the image receptor was difficult without a holder for the image receptor.

Others have suggested the imaging of objects with varying densities such as the eraser end of a lead pencil, a printed circuit board, a coin, or a key in a similar manner to a step-wedge. However, these objects are also ineffective in evaluating digital radiographic image quality for the same reason as for the alligator clip: they do not span the complete dynamic range from full to no attenuation, thereby failing to ensure that the entire dynamic range is acquired.

Although the evaluation of noise, SNR, or CNR is also suggested in the evaluation of image quality and optimization,[5,6,15-18] there is scant scientific research suggesting that measuring noise is adequate to determine optimal exposure. There is no evidence to suggest that noise above a certain threshold renders the radiograph nondiagnostic. On the other hand, increasing the radiation dose to reduce noise to a hypothetical level, or to improve the SNR or CNR that has not been clinically validated, leads to unnecessary radiation dose to the patient and is contrary to image optimization. Noise is ubiquitous and its effects are never completely eliminated, but when using the protocol specified in Standard 1094, noise can be minimized such that it does not interfere with diagnostic quality. Standard 1094 includes the measurement of dynamic range, spatial resolution, and contrast perceptibility, which are the attributes required to ensure optimal diagnostic quality. Accordingly, a separate noise, SNR, or CNR evaluation is not required for image optimization when following Standard 1094.

Dose references are accurate in selecting exposure settings

The exposure parameters and latitude for a DIRS are dependent upon the components within the imaging chain and cannot be based upon preset generalized values. Dose limits and the use of diagnostic reference levels (DRL), achievable doses (ADs), and even some manufacturer-provided technique charts are not applicable to a specific DIRS with different components than those the manufacturer used to create the technique chart. One cannot assume that the exposure parameters will automatically be significantly reduced. Unfortunately, claims of $\leq$90% dose reduction over film-based radiography have led to this improper assumption.[24] Studies using QA protocols as specified in Standard 1094 have shown that although there may be dose reductions with solid-state DIRS compared

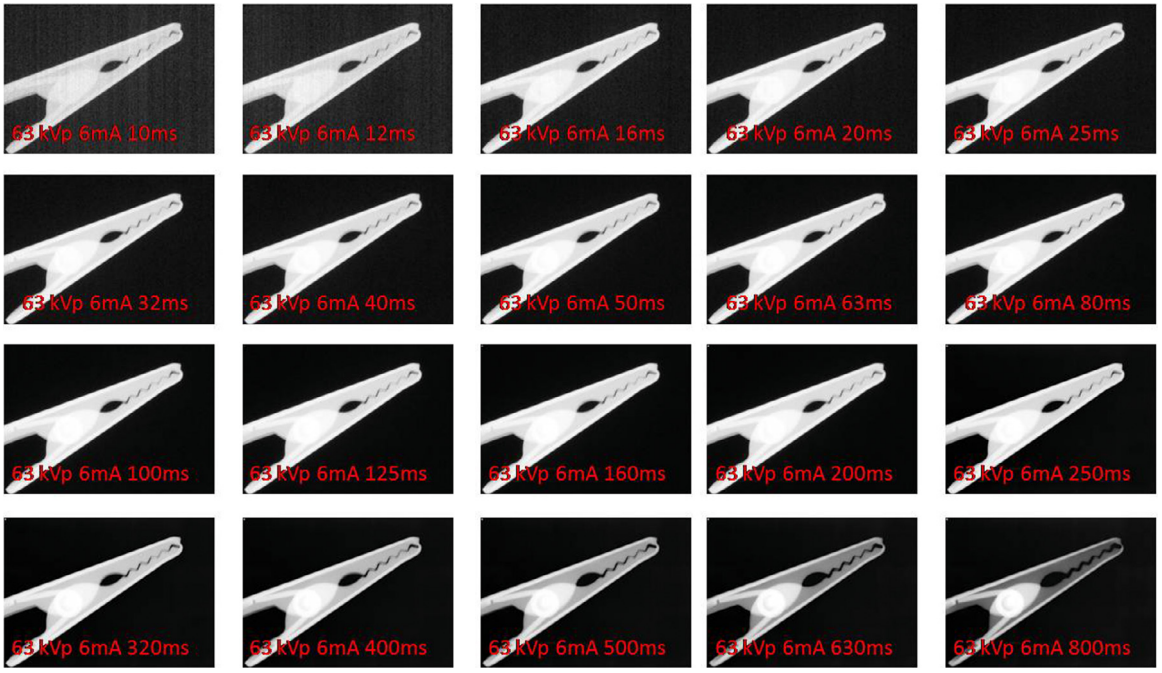

Fig. 4. Radiographs of an alligator clip at incrementally increasing exposures over a range of 20 exposures. *kVp*, kilovoltage peak; *mA*, milliamperes; *ms*, milliseconds.

with film-based imaging, they are not at the exaggerated reduction of 90%.[3-5,9,25]

DRLs are typically set at the 75th percentile of the dose distribution from a survey conducted across a broad user base. A DRL is not the suggested or ideal dose for a particular procedure or an absolute upper limit dose. It represents the dose level at which the appropriateness of the dose should be reviewed for QA. The Image Gently website includes a proposed a range of 50 to 100 mR (0.44-0.88 mGy) for adult molar bitewing radiographs using direct digital CMOS sensors.[26] However, the FDA NEXT 2014-15 dental study reported a DRL of 1.56 mGy for the adult molar bitewing radiograph.[1] The National Council on Radiation Protection and Measurements NCRP Report No. 172 recommended a DRL of 1.6 mGy for intraoral imaging.[27] In comparison to these 2 sources, doses of 0.44 to 0.88 mGy are low and may result in loss of diagnostic information.

Other attempts to use dose as a means of QA involve the concept of using a single AD exposure. AD is typically set at the 50th percentile of the dose distribution from a survey conducted across a broad user base. With DIRS, exposure settings are not readily discernible and are affected by many factors in the imaging chain. In fact, a single value for AD is not practical for DIRS.[16] NCRP Report No. 172 suggested an AD of 1.2 mGy for intraoral imaging, which is significantly higher than the inaccurate dose reference of 0.44 to 0.88 mGy for adult molar bitewing radiographs mentioned above.[27] Not surprisingly, digital intraoral techniques were found to be more difficult to comprehend and optimize than film-based imaging.[25] Image optimization is a fundamental aspect of a QA program and, when implemented correctly, determines the best exposure for the digital radiographic system.[20] The optimal exposure for a given DIRS varies with the different mix of components within the imaging chain; therefore, a blanket exposure dose is untenable.

Software changes can compensate for inappropriate X-ray exposures

The belief that one can correct for the problems of a poor radiographic exposure by simply adjusting brightness and contrast within the software is incorrect. It is often claimed that one of the greatest benefits of digital radiography is the ability to optimize the radiograph after the image has been acquired.[24,28] This myth has existed since the introduction of digital imaging to dentistry and regrettably has contributed to the lack of image optimization in practice. As an example, the International Atomic Energy Agency website states: "Intraoral digital radiography offers a potential for significant dose reduction; some studies report that, depending on the diagnostic task, a lower exposure may be used when density and contrast is adjusted using the software features. This is one of the benefits of digital radiography where image quality can be optimized after the image has been taken."[29] In reality, no amount of image processing can restore diagnostic

Table III. Proposed uniformity tests along with frequency, method, and type of evaluation

	Modality	*Frequency*	*Method*	*Uniformity evaluation*
QUALITATIVE				
Greenall et al.[6] Dental	PSP receptors; digital sensor	Monthly to quarterly	Capture one image at a fixed distance using short exposure	Visual inspection for areas of gross nonuniformity
AAPM Report 175[21] Dental	Digital receptors, CCD, CMOS, PSP, and film	Monthly to quarterly	Follow instructions provided by the phantom manufacturer	No significant nonuniformity is observed
AAPM Report 93[17] Medical	PSP imaging systems	Acceptance test and periodic checks	Follow phantom manufacturer's instructions	Visualize a uniform image
QUANTITATIVE				
Hellén-Halme et al.[5] Dental*	Digital sensors based on CMOS technology	Acceptance test and periodic checks	Capture 1 flat-field image using a 30 mm acrylic glass plate in front of the sensor at a distance to mimic the clinical situation	Measure the uniformity of 5 circular ROIs, expressed in pixel value deviation peripherally/centrally at exposures of 0.05 s and 0.16 s
AAPM Report 93[17] Medical†	PSP Imaging Systems	Acceptance test and periodic checks	ROI covers 80% of the image	Average digital value of each ROI should be within 10% of the global average; standard deviation should be similar in each of the 5 ROIs

*This test was unable to be performed on the Gendex GXS-700 imaging system.
†Specified 80 kVp and 5 mA exposure parameters and a distance of 1.8 m from the source to image receptor. The raw data were used for medical radiology assessments.*AAPM*, American Association of Physicists in Medicine; *CCD*, charge-coupled device; *CMOS*, complementary metal oxide semiconductor; *PSP*, photostimulable storage phosphor; *ROI*, region of interest.

information lost during image acquisition due to insufficient X-ray exposure or saturation of the sensor. Kal et al. compared endodontic file lengths, as measured from the radiographic apex to the endodontic stopper, to the true file lengths. They found that the actual lengths of the endodontic files could not be established radiographically because the images were not acquired at the optimal exposure despite using 5 different post-processing algorithms. In all cases, the actual working length or length of the endodontic files appeared shorter than the true file length.[30]

This use of software adjustments in an attempt to compensate for underexposed and overexposed radiographs has led to the creation of esthetically pleasing images; however, esthetic images do not equate to diagnostic images. Many vendors display esthetically pleasing radiographs in marketing and advertising brochures to satisfy the expectations of dental providers to see crisp demarcations between cavitated lesions and the rest of the tooth, but this is unrealistic. Carious lesions spread diffusely and do not have clear, distinct boundaries. An improperly exposed radiograph cannot be corrected using software algorithms to display the anatomic truth after the fact.

Flat-field uniformity tests can assess the degree of homogeneity within a DIRS

Flat-field uniformity tests have been promoted as an additional method to validate intraoral digital image receptor performance.[5,6] Uniformity tests are used in medical radiology to reveal inconsistencies of X-ray exposure in the image receptor. Medical radiology uniformity test protocols include the parameters for an accurate execution of the test, and to date, there are no similar parameters designated for uniformity tests in dentistry. Examples of the parameters used in medical radiology include centering the X-ray beam to ensure uniform exposure of all pixels, using a fixed distance of 1.8 meters between the X-ray unit and the image receptor, and attaining a reproducible geometry of the X-ray beam and sensor position.[17]

Uniformity testing may be accomplished by qualitative and/or quantitative methods. The qualitative tests are performed by visual examination of the image for the presence of nonuniformity and artifacts. The quantitative tests involve an analysis with software and mathematical calculation to derive a numerical value or score to compare with a predetermined threshold in most cases. Table III lists qualitative and quantitative uniformity tests along with the frequency, method, and type of evaluation. Medical radiology QA for computed radiography (referred to as the PSP imaging system in dentistry) has a 10% standard of variance.[17]

At present, no similar criteria exist to define what level of nonuniformity constitutes a failure with dental intraoral image receptors. There is also insufficient research to validate a universally suitable method for a dentist to perform a quantitative uniformity test on these receptors. Uniformity testing is carried out with raw unprocessed radiographic images in medical radiology,

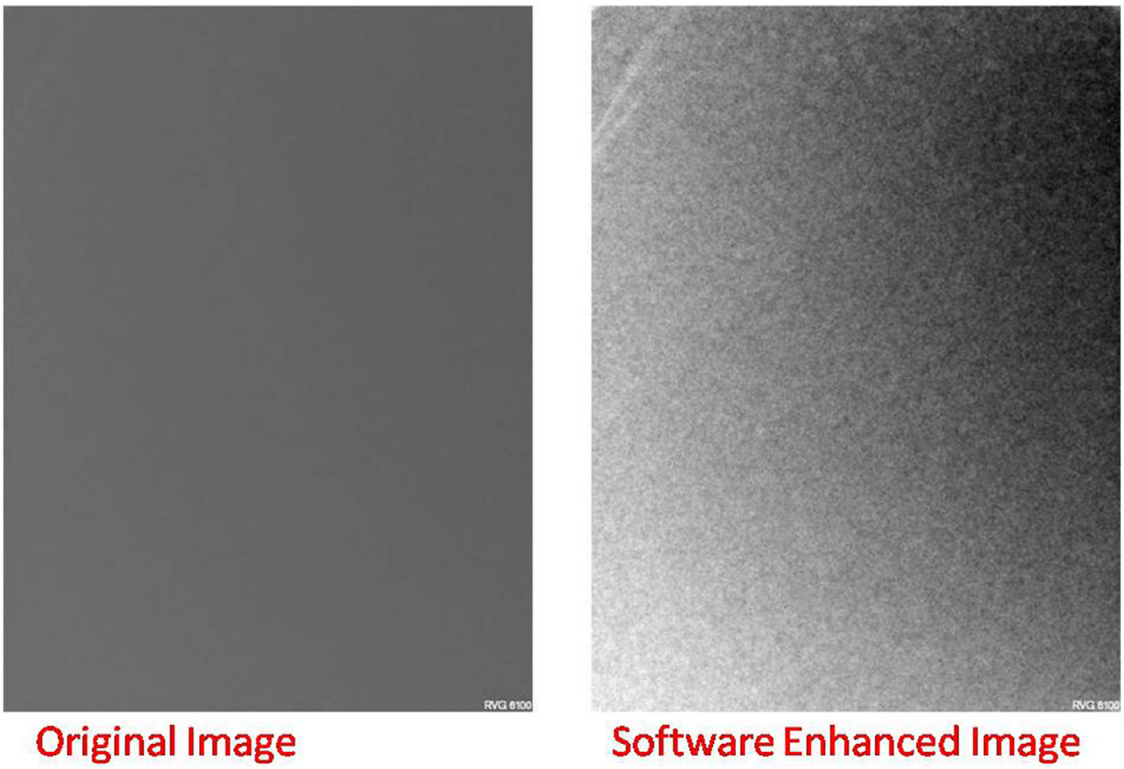

Fig. 5. Software applications accentuating minor nonuniformity disparities. The image on the left depicts minor discrepancies in uniformity on the original. The image on the right highlights the effect of additional software post-processing applications that exaggerate the differences in uniformity.

whereas in DIRS the user has no access to these images. Furthermore, the user has little or no control over automated proprietary software processing protocols used in dental radiographic systems. As mentioned earlier, many manufacturers of DIRS employ image processing or auto-leveling to maintain a median or average gray level within the image. These automated image processing algorithms may exaggerate subtle nonuniformities when present, as seen in Figure 5.

Several sources of nonuniformities in intraoral dental radiography do not allow for the performance of quantitative uniformity tests. Dental X-ray units produce a beam that is more intense in the center where the focal spot is located and less intense at the periphery. In Figure 6, an increased photon signal intensity or hot spot is noted around the central area on the grid pattern, which aligns with the central ray and apparent focal spot of the X-ray unit. A similar problem of signal intensity exists in medical radiology, but in medicine the effects are mitigated by positioning the X-ray source 1.8 m away from the image receptor to minimize effects of variations in beam intensity.[17] Because the concentrated effect of a point source of energy dissipates with distance, the increased source to image receptor distance results in a more uniform X-ray beam at the level of the image receptor. The dental source to image receptor distance is only 0.2 m with a short BID or 0.3 m with a long BID, and thus the X-ray beam itself may be a cause of nonuniformity. However, deviating from the clinical use conditions in dentistry may lead to erroneous results, so increasing the distance in uniformity testing would not be appropriate.

The presence of the fiber-optic plate in DIRS may also affect image uniformity. The purpose of the fiber-optic plate is to channel the visible light, produced when X-rays interact with the scintillator, onto the sensor below. The photons in the central ray strike the scintillator in a perpendicular manner and the light generated is better transmitted through the fiber-optic plate.[9] Conversely, the X-rays at the periphery of the X-ray beam are divergent and not as easily transmitted through the plate.[7] The nature of X-ray beam divergence leads to nonuniform intensity on the sensor. To obtain a more uniform dispersion of light through the fiber-optic plate, the X-ray source would need to be placed farther away from the image sensor, but this would not simulate the use of the sensor in a clinical dental environment.

For the reasons and limitations discussed, there are no universal quantitative uniformity tests for digital dental intraoral sensors similar to those in medical uniformity testing.[17] However, a visual qualitative

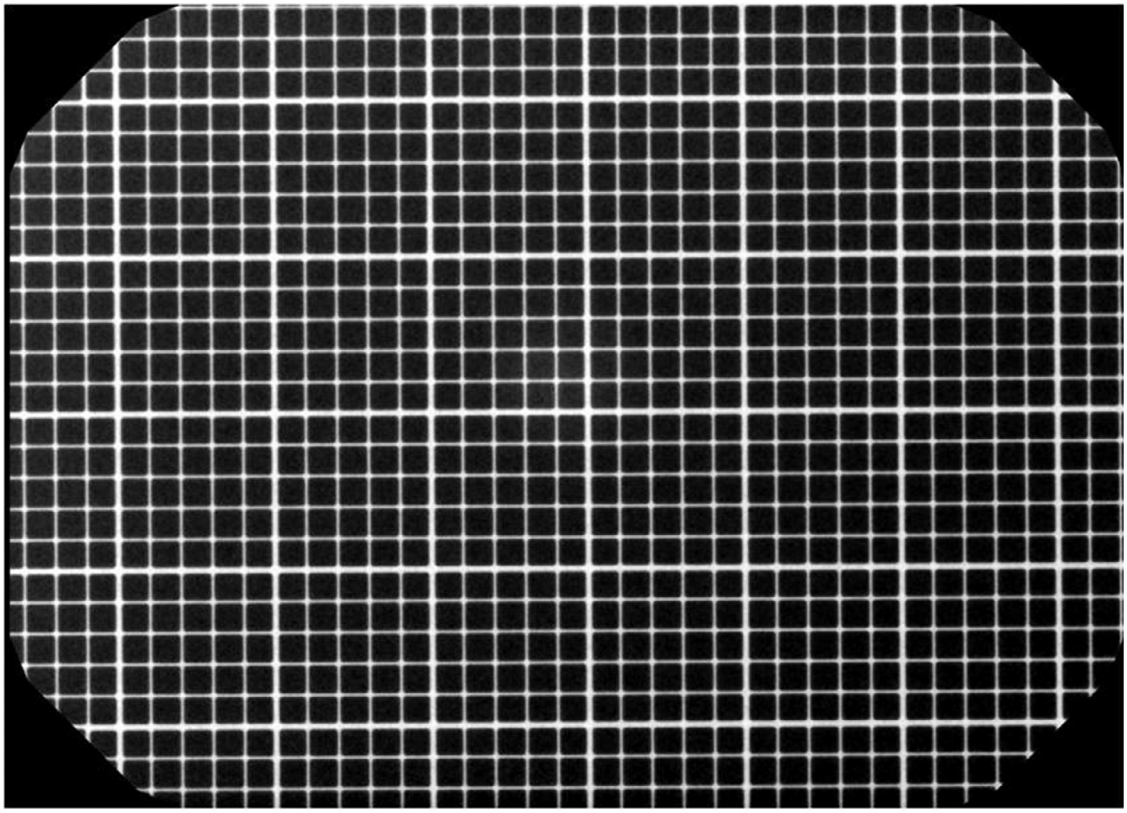

Fig. 6. Increased intensity in the central region in alignment with the central beam.

uniformity assessment may be performed using a radiographic phantom in conjunction with other QA tests.[2] The purpose of a visual qualitative uniformity assessment is to establish a baseline reference upon initial acceptance and to determine whether the image receptor is failing over time or if the calibration has been corrupted, as seen in the examples of digital imaging artifacts in Figure 1.

Although many radiographic phantoms have been devised for intraoral imaging, the suitability and effectiveness of these phantoms for digital radiographic systems are not equal. Accordingly, it is critical to select a radiographic QA phantom that complies with Standard 1094 and is designed specifically for digital intraoral imaging. The radiographic phantom must measure the full dynamic range and contrast perceptibility, as well as spatial resolution that extends to 20 lp/mm at a geometry that replicates clinical use. This will allow the user to identify the maximum diagnostic yield at the lowest radiation dose for the digital image receptor. As a qualitative uniformity assessment, the acquired radiographic QA image should also be reviewed for the presence of nonuniformities and artifacts, as seen in Figure 1. This enables the user to determine the optimal exposure and visualize uniformity of the image receptor with a single radiographic image. Reeves et al. identified nonuniformities simultaneously with other QA parameters using the Digital Dental Quality Assurance phantom.[2,22] The nonuniformities identified by Reeves et al. were delamination and banding.[2] The presence of a variety of nonuniformities on direct capture and PSP plates was also presented by Mah et al. in a publication with the Digital Dental Quality Assurance phantom.[22] Therefore, a QA phantom that meets the specifications in Standard 1094 can be used for both image optimization and qualitative uniformity assessment.

DISCUSSION

The introduction of Standard 1094 in December 2020 highlighted the importance of QA and image optimization in dentistry. Intraoral radiography constitutes the most prevalent radiologic examination in medicine and dentistry combined.[1,31] According to the FDA NEXT data, 296 million intraoral dental X-ray examinations were performed in the US in 2014.[1] Approximately 10% of these examinations consisted of a single radiographic image, whereas 80.7% involved 2 to 6 images; 9.2% of these exams included 7 or more radiographs.[1] Taken together, dentists in the US acquire approximately 1.1 billion intraoral radiographic exposures annually. Without a doubt, the need for QA in digital intraoral imaging is paramount.[2,3,4,10,16]

Standard 1094 presents a universal method and a step-by-step process whereby image optimization and

longitudinal QA can be accomplished for DIRS by dentists with any intraoral radiographic system (long vs short and circular vs rectangular collimation as well as fixed vs handheld X-ray generators). This is comparable to the QA protocols available with film-based imaging, which have helped dental practices maintain regulatory compliance. The method is simple to follow and describes the tools necessary for its implementation. As mentioned above, however, although several radiographic phantoms have been promoted as suitable for QA tests with intraoral radiographic systems, they lack the ability to optimize the DIRS.[5,6,14,15,17,18]

Although Figure 1 provides a number of cases where radiographic images were generated despite the presence of system failures, these are not exhaustive cases. Other situations exist where there may be a damaged fiber-optic plate in the direct capture sensor, causing lines on the radiographic image similar to the appearance of broken glass, and failures in the X-ray generator itself that may produce very light radiographic images. Furthermore, the loss or corruption of calibration files may cause a Swiss-cheese appearance or Moiré pattern. In Figure 1G, the Swiss-cheese pattern is shown. It is not possible to list or illustrate all possible situations of partial failures with a DIRS, and thus the reader is advised to consult with an oral and maxillofacial radiologist familiar with the imaging technology and/or the manufacturer of an intraoral imaging system when in doubt.

Figures 2, 3, and 4 demonstrate the limited value of 3 of these devices, as differences in exposure up to 80-fold were required before perceivable changes were detected among the exposures. It is difficult to compare radiographic image quality among patients, and small losses in quality are not easily detected. Although the cost of step-wedges, paperclips, alligator clips, bib chains, and lead pencils may be small, their effectiveness as QA phantoms for digital intraoral radiography is lacking.

Standard 1094 specifies the requirements of a radiographic phantom that are needed for image optimization. Specifically, the radiographic phantom must measure the full dynamic range from 0 to 255 gray levels in an 8-bit system or 0 to 4095 gray levels in a 12-bit system. A sufficiently wide dynamic range is required because only information that has been captured and contained on the original digital radiograph can be enhanced or extracted. Because periodontal disease and dental caries are displayed in 2 different ranges of contrast density (periodontal disease in darker areas and dental caries in lighter areas) a sufficiently wide dynamic range is required. This is the primary reason for ensuring that all diagnostic information spanning from full to no attenuation limits are captured along with the varying thicknesses of an aluminum step-wedge on the QA phantom. The radiographic phantom must also measure spatial and contrast resolution in order to properly identify the optimal image. With direct observation and scoring of the dynamic range, spatial resolution, and visible number of contrast wells, the required training can be minimized. This allows for easy application of Standard 1094 in dental practices. Sample worksheets are provided with the phantom that allow the user to perform the measurements and complete a QA maintenance record.

CONCLUSION

In this article, we have shown that DIRS may have partial failures with image quality issues using a QA phantom, as illustrated in Figure 1, where different components of the imaging chain were defective but images were produced.

Because DIRS do not self-calibrate and dose references can be misleading, it is important to evaluate each imaging system. Image optimization is one of the most important processes in an effective QA program. Failure to perform image optimization properly may result in reduced image quality and increased patient dose. Image optimization integrates the effects of all aspects of the digital imaging chain and can only be performed accurately using the protocol listed in Standard 1094. The optimal image with a proper QA phantom serves as a baseline reference to discern longitudinal changes in image quality. If the components of the DIRS are replaced or changed, the baseline reference will need to be re-established following the method described in Standard 1094. The standard is universally applicable on any DIRS, so changing any component of the imaging chain is not an issue with its implementation.

Software enhancements only allow the user to enhance or extract information that is contained within the image when captured. Information lost at the time of image acquisition cannot be restored with software adjustments. Thus, there is a necessity to ensure that the full dynamic range is captured on a digital radiograph.

The qualitative evaluation of uniformity in a DIRS along with the use of a phantom that meets the specifications in Standard 1094 are sufficient to maintain diagnostic quality images. There are currently no quantitative uniformity tests that may be universally applied to DIRS.

In a radiology update to its members, the ADA stated that “dentists should consider developing and implementing a radiation protection program in their offices. In addition, practitioners should remain informed on safety updates and the availability of new equipment, supplies and techniques that could further improve the diagnostic ability of radiographs and

decrease exposure."[32] Though its importance has been recognized by the ADA, the adoption of digital imaging QA procedures has been slow due to misconceptions and a lack of resources and education.

In order to overcome misinformation and gain the ability to implement an appropriate QA protocol, dental schools should provide a better understanding of how digital radiographic imaging systems function and teach the QA procedures specified in Standard 1094. Commission on Dental Accreditation (CODA) standards for dental educational programs include a QA requirement, but it is nonspecific. Perhaps a specific requirement of QA relating to imaging should be considered. Likewise, education on Standard 1094 must be disseminated in advanced education training programs and CE courses. Given the importance of radiology to the practice of dentistry, perhaps a digital radiology CE requirement for all dental personnel should be considered in the CODA standards. To assist with this endeavor, the ADA Standards Council, through its university outreach program, has recently provided free access to Standard 1094 and other standards for dental university faculty to use in their curricula.[33]

DISCLOSURE

The views expressed are those of the author(s) and do not reflect the official views or policy of the Department of Defense or its Components. Peter Mah is the President of Dental Imaging Consultants, LLC, which holds a patent for the Digital Dental Quality Assurance phantom. Peter Mah has no financial interest in the other companies whose materials are discussed in this paper. Allison Buchanan and Teresa Reeves do not have any financial interest in the companies whose materials are discussed in this paper.

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