Handheld versus Conventional Dental X-Ray Units in Clinical Dental Practice—a Cautionary Discussion
Introduction

Originally developed for military medicine and humanitarian efforts, handheld dental X-ray units have expanded into general dentistry, raising several questions. Using handheld dental X-ray units, are operators exposed to more risk from radiation? What kind of additional safety precautions need to be adopted? What are the cost differences? To help break down the key considerations for the use of handheld units, let us examine the differences in operation, clinical workflow and safety of handheld units compared to their conventional counterparts.

Research reveals the major difference between the use of fixed and handheld dental X-ray units is in their relative safety. The higher rate of safety incidents per unit and potential for operator physical harm from malfunctions of handheld dental X-ray units in clinical practice are cause for concern. Based on the thorough analysis presented in this document, the use of handheld dental X-ray devices may be considered as a supplemental or augmenting imaging modality rather than as a replacement for conventional imaging for routine intraoral radiography in dental offices.
Handheld versus Conventional Dental X-Ray Units in Clinical Dental Practice

Dental intraoral radiography is the most common diagnostic imaging method performed in clinical dental practice. Intraoral dental X-ray sources are available in three different configurations (NCRP, 2019)—two conventional and one handheld.

- Conventional fixed—an immovable fixture attached to the wall, cabinet or ceiling of the dental operatory
- Conventional semi-mobile—supported by a mechanical stand on a tripod or with wheels
- Handheld—not supported by any mechanical fixture

Conventional dental intraoral radiography uses a socket-powered, wall-mounted or sometimes semi-mobile (stand- or tripod-mounted), dental X-ray generator positioned adjacent to the patient to produce images. Operators initiate exposures at a distance, either outside of the dental treatment room or behind a barrier, with the use of either an exposure button on a cable attachment or a cable-free control. Conventional dental X-ray units must be installed, which usually requires reinforced walls or additional electrical work. On some units, the joints in the arm mechanism may become less firm resulting in arm drift and movement of the tube head during exposures.

Handheld dental X-ray devices were originally developed for situations where fixed units could not be used, such as military field hospital and dental triage emergency facilities, as well as in forensics or disaster recovery team efforts to identify victims comparing ante- to post-mortem radiographs. Handheld units were used following both the Asian Tsunami in 2004 and Hurricane Katrina in 2005. General use of a handheld X-ray unit in dental practice was first approved by the US Food and Drug Administration (FDA) in July 2005 (ADA, 2020). Handheld units are battery powered, portable and designed to be held in the hands of the operator during exposures. They differ in two major characteristics from conventional units (Berkhout, et al., 2015):

1. Because operators hold the handheld X-ray device during exposure, they cannot distance themselves from the source of exposure and must use dedicated (scatter) radiation protection.

2. Handheld devices typically have a lower output dose rate (set by current, waveform, filtration and cone length) than current conventional units.

Handheld intraoral dental X-ray units are currently available, but not all are FDA-approved and not all FDA-approved machines have been approved for use by every state (McDaniel and Prashar, 2015).

Devices available in the US without FDA approval have failed to comply with the necessary safety standards, which can result in high radiation doses to patients and operators (Mahdian, et al., 2014). These failures to comply include the following issues:

- Short source-to-subject distance of less than 18 cm
- Inadequate collimation
- Lack of permanently attached backscatter shield
- Lower-than-acceptable kilovolt (peak) value
- Absence of basic operational safety features, such as an audible signal of X-ray generation or a dead-man switch.
Advantages and Disadvantages of Handheld Devices

Portability and flexibility are the most widely recognized advantages to using handheld X-ray generator devices. Handheld units may provide some cost benefits, such as allowing a practice to purchase only one unit for use in multiple operatories and requiring no cost for installation. However, full cost of ownership should be considered, including lifespan and battery replacement costs. Device maneuverability can help make patients more comfortable during the procedure by allowing the operator to remain chairside and perform X-rays while the patient is reclined or sitting upright.

While these advantages may be appealing, consider the possible disadvantages of incorporating handheld dental X-ray devices into clinical dental practice, which include important safety-based concerns (Image Works Corp., 2018; Rothmund, 2019):

- **Difficulty complying to optimal operator positioning** within the protection zone of the backscatter shield. Correct positioning for optimal image geometry often requires the patient’s head or chair to be altered rather than simply angling the tube head as with conventional X-ray devices. This manner of positioning may be uncomfortable for the patient and some patients may not be able to comply.

- **Interruption of clinical workflow and efficiency** for any of the following reasons:
  - The battery is completely discharged during the procedure and no replacement is available.
  - Multiple operators need access to the unit at the same time.
  - The unit must be cradled between multiple acquisitions while the intraoral detector position is adjusted to adequately cover a specific region in the mouth.

- **Risk of cross-contamination** if infection prevention measures to ensure surfaces are fully decontaminated between patients are overlooked, especially with those units that are cradled between procedures.

- **Operator arm and hand fatigue**, especially during multiple procedures, as the unit can weigh as much as 5–8 pounds.

- **Unit damage** if not handled or secured correctly during the procedure and dropped. Shipping the unit for repair may leave the office without an X-ray source unless there is an extended warranty with loaner replacement.

- **Failure in the design and operation** of the removable battery’s attachment mechanism to the body of the unit, especially the electronic connector.

- **Difficulty disinfecting the unit** due to limited choices of solutions that are appropriate for use, susceptible surfaces, such as the electronic connector, that are difficult to clean, and many areas where debris and solutions can be trapped.

- **Additional security protocols** required to prevent unauthorized use or theft.

- **Establishing the controlled perimeter required** for use in an open area. Dental personnel must stand out of the path of the X-ray beam, remain behind a protective barrier or at least six feet away from the patient, and be positioned between 90 degrees and 135 degrees to the direction of the primary beam during exposure.

- **Additional training and radiation protection measures** that may be mandatory in many states.

- **Diminished radiation output** during use as the battery charge reduces. This inconsistency in exposure may require on-the-fly adjustment of exposure timer settings and result in variable image quality.

Considering the limitations in implementation and the additional, sometimes restrictive, clinical procedures necessary to ensure consistent compliance of operator position in the zone of occupancy behind the backscatter shield, handheld dental X-ray units may not be considered a clinically equivalent replacement technology for conventional dental X-ray units. The safety risks and potentially variable image quality render the handheld units to be less advisable as imaging solutions for safe and effective routine clinical care.
SAFETY

Adoption of handheld dental X-ray technology introduces new technique challenges to operators while requiring long-term assessment of operator radiation dose risk and introduction of additional safety protocols.

Comparative Equipment Malfunctions

The potential for operators’ physical harm from malfunction of handheld dental X-ray units in clinical practice is concerning. In conventional units, malfunctions tend to be related to a part of the device detaching, often due to a structural or installation issue. Although problematic, this malfunction is not a serious danger to the operator. Malfunctions in handheld units, however, are nearly always related to the single nickel cadmium or lithium-ion battery powering the device, potentially putting the operator at much higher risk for injury.

According to the FDA Manufacturer and User Facility Device Experience (MAUDE) Adverse Events database, 85 instances of malfunction were reported with handheld intraoral X-ray devices over a five-year period beginning November of 2014. Most of these instances occurred in 2016 and 2017, with greater than 99% related to battery problems, resulting in issues like overheating, melting, charring, spontaneous combustion and one instance of an explosion of the handset containing the battery and its housing. Battery malfunctions are generally related to thermal runaway, leading to battery failure that can be harmful. A few instances of insufficient radiation output and spontaneous firing were also reported.

Over the same period, there were about half as many (43) instances of malfunction for conventional wall-mounted dental X-ray units. The most often cited report was detachment of a device or device component (e.g., separation of the arm from the wall or control unit, arm failure, separation of the tube head from the arm) and tube head oil leakage. Only one electronic malfunction (minor shock) was reported.

The medical device reports in the MAUDE database are submitted by mandatory reporters—like manufacturers, importers and device user facilities—as well as voluntary reporters such as healthcare professionals. This system has the potential to under-report events, and although the true numbers could be higher, any risk for operator physical harm from malfunctions of dental X-ray units in clinical practice is concerning. Handheld dental units are currently used in 5% to 7% of dental clinics in the United States (iData Research, 2019). Therefore, based on historical MAUDE reports, the relative number of safety incidents per unit is likely higher for handheld devices than for conventional dental X-ray units.

Operator Radiation Exposure

Occupational dose limits (ODL) are set by US federal law and accepted by most state regulatory bodies to provide acceptable levels of operator dose to minimize cancer risk and other effects of radiation. ODLs vary depending on whether the whole body or specific entities, such as the following, are considered. Current standards provide an annual maximum permissible ODL of 50 millisievert (mSv) to the whole body, 150 mSv to the lens of the eyes, 500 mSv to the skin, hands and feet, and 5 mSv to the embryo/fetus in pregnant operators (FDA, 2008). Specifically, dental workers should not receive effective doses above 1 mSv per year (NCRP, 2019).

Once X-rays are produced and exit the tube housing, they are categorized as primary radiation or secondary radiation. Primary radiation describes the useful beam that is filtered and exits in a fan shape through the collimator aperture. Secondary radiation is further categorized into leakage and scatter radiation.

Leakage radiation and back-scatter radiation potentially pose a greater risk to the operator when using a handheld X-ray source because the operator is close to the device during operation. In order to mitigate these added risks, additional shielding is incorporated into the design (NCRP, 2019).
Leakage Radiation

Leakage radiation is the radiation that escapes through the housing and its shielding. Exposure to leakage radiation is a significant safety concern for the operator of any handheld device. Since the operator is holding the X-ray source assembly, the principle of “distance” as a safety factor cannot be applied. FDA regulations state the maximum permissible radiation leakage from the X-ray source assembly is 100 milliroentgen (mR) per hour measured at a distance of 1 meter from the X-ray source. Limited available literature indicates that all FDA approved handheld units have adequate leakage control with unrecordable values 1 meter from the source and maximally 3.6 mR/hr at a distance of 5 cm (Turner et al., 2010).

Scatter Radiation

Scatter radiation is produced in all directions by interactions with matter in the patient. Backscatter radiation refers to the scatter radiation directed backwards, towards the X-ray tube head. Based on available data, operator exposure using handheld X-ray units originates from backscatter sources.

When the operator places the X-ray collimator adjacent to the patients face, the backscatter protection zone of occupancy (operator safety zone) is optimal with a 150-degree to 160-degree arc, depending on the diameter of the shield. In this situation, backscatter shielding is effective at reducing annual exposures behind the backscatter zone to less than 10 mrem with annual exposure values outside the backscatter zone of occupancy ranging from 500 to 700 mrem (Hamby, 2015). However, when the X-ray collimator is moved away from the patient and the image receptor, increasing the source to object distance, two things happen (Fig. 1):

1. The arc of the backscatter safety zone decreases as the gap between the end of the X-ray collimator and the patient’s face increases. Note that annual exposures in the safety zone are still less than 10 mR, but the zone is narrower and smaller, possibly exposing the operator’s head or lower body to higher radiation levels.
2. Exposure time must increase as the distance increases to compensate for the reduced X-ray beam intensity. This increase will, over time, contribute to a decrease in the life span of the X-ray tube.

Figure 1. Diagrammatic depiction of the effect of increasing the source-to-object distance (b) of a collimator on the arc of the backscatter occupancy zone for a representative handheld dental X-ray device (MaxRay DX 3000) compared with placement adjacent to the patient’s skin surface (a). The bubbles indicate the magnitude of scatter exposure (mR in 1 hour operated at 2.0 mA) relative to their surface area [Hamby, 2015].
Factors Affecting Operator Exposure with Handheld Dental X-Ray Units

Handheld dental X-ray operators must follow very specific operating procedures to minimize exposure. When followed, these procedures position the operator within the protective zone of occupancy behind the backscatter shield. In certain clinical situations, complying with these requirements can be difficult or impossible to achieve, putting the operator at risk. Some of these situations include the following examples.

Example 1. When the backscatter shield is close to the patient, the device must be held as close as possible to the patient’s skin surface (Fig. 2). This positioning can be impractical if the backscatter shield interferes with the arm of a positioning device and prevents placement of the collimator, the patient is unable to adjust their head position, or the operator can’t physically extend his/her arms and hold the collimator against the skin. In these situations, the skin surface entrance diameter may be greater than the 7 cm allowable (NCRP, 2019).

Example 2. When the device is held away from the patient, often because the operator is physically unable to extend their arms and hold the collimator adjacent to the skin, the backscatter protection zone is decreased by reducing the backscatter arc (Fig. 2).

Example 3. When operators remain within the significant zone of occupancy immediately behind the device shield (Fig. 3), they must hold the unit at exactly 90 degrees. In many intraoral projections, especially the anterior maxilla and mandible, the device cannot be supported this way. Patients are seated in the dental chair and cannot turn their head to the correct position to the side of the chair. The position of the device relative to the operator has been reported to have a significant effect on the overall operator’s radiation exposure (Makdissi et al., 2016).

Example 4. When the paralleling technique is used, the operator will often use a positioning device. With the use of standard sensors, the arm of the positioning device supporting the collimator is typically too long and forces the backscatter device to be retracted towards the X-ray generator even though the backscatter shield must be fully extended and positioned at the outer end of the collimator cone to be fully effective.

In clinical situations like these, where the operator is outside the protection zone or the protection zone is diminished, most handheld unit user manuals clearly outline that proper precautions should be used according to requirements of local jurisdictions. These may include the use of a lead apron and thyroid collar for the operator.

Figure 2. The diagram demonstrates clinical operating conditions under which the operator’s protection from the backscatter shield of a handheld dental X-ray unit is reduced and, therefore, operator radiation dose is increased. The zone of maximum protection is shown in green and backscatter radiation shown in red (NOMAD Pro 2 Operator Manual, 2013).

Figure 3. Operator, patient and handheld X-ray unit positioning for optimal operator radiation back-scatter protection is achieved when the operator remains within the significant zone of occupancy immediately behind the device shield (NOMAD Pro 2 Operator Manual, 2013).
Additional Operator Protection Requirements

Due to the possibility of additional whole body or extremity (particularly fingers) radiation exposure to operators from backscatter radiation using handheld dental X-ray units, each state has its own approval requirements for use. These requirements may include the following:

- Unit-specific attestation/certification of additional specific training, retained for each operator
- Additional personal protective measures such as a personal dosimeter or even whole-body protective apron and thyroid collar
- Safety policy ensuring no bystanders come within a radius of at least six feet from the patient being examined
- Adequate shielding for the rooms in which handheld units are being used
- Equipment secured against unauthorized access and use

In Washington state, for example, operators must wear a leaded apron of 0.25 mm lead equivalent under certain conditions (Table 1) (Department of Health of Washington State, 2011). Operators in Oregon must use a protective whole-body lead apron with thyroid collar and personal dosimetry (Oregon Health Authority, 2013). Exemption is possible if operators demonstrate compliance with specific conditions, including that they have received appropriate training and can operate the equipment properly, and that the dosimetry records indicate no operator has received a radiation dose greater than 10% (500 mrem) of their annual dose limit (5,000 mrem).

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<table>
<thead>
<tr>
<th>Annual predicted whole-body dose rate</th>
<th>Annual predicted shallow dose rate (fingers)</th>
<th>Operator use modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 mSv.yr⁻¹</td>
<td>&lt; 1 mSv.yr⁻¹</td>
<td>None</td>
</tr>
<tr>
<td>&gt; 1 mSv.yr⁻¹</td>
<td>&lt; 1 mSv.yr⁻¹</td>
<td>Shall wear a leaded apron of 0.25 mm lead equivalent</td>
</tr>
<tr>
<td>&lt; 1 mSv.yr⁻¹</td>
<td>&gt; 1 mSv.yr⁻¹</td>
<td>As above, plus shall use equipment for special needs patients outside of routine dental office settings only</td>
</tr>
</tbody>
</table>

Recent recommendations from the National Council on Radiation Protection and Measurements (NCRP) support these guidelines, allowing operators to use US FDA-cleared handheld X-ray units without a personal radiation protective garment as long as the whole-body effective dose to the operator is less than 1.0 mSv.y⁻¹ (NCRP, 2019). They suggest operators wear personal monitors when first using these devices to confirm radiation exposure levels.

Office Shielding Structural Requirements

The NCRP outlines shielding and radiation protection requirements for dental X-ray facilities. NCRP Report #19, “Radiation Protection in Dentistry and Oral & Maxillofacial Imaging: Recommendations of the National Council on Radiation Protection and Measurements,” (NCRP, 2019) defines these two areas within dental facilities:

- Controlled Area—anywhere within the dental practice an X-ray unit is used. In these areas, dental X-ray operators have a significant potential for exposure to radiation in the course of their work or are directly responsible for or involved with the use and control of radiation. The NCRP recommends an annual limit for effective dose (E) for these individuals of 50 mSv y⁻¹ (1 mSv week⁻¹) with the cumulative E not to exceed the product of 10 mSv and the radiation worker’s age in years (exclusive of medical and natural background radiation).

- Uncontrolled Area—areas adjacent to but not part of the X-ray facility occupied by individuals such as patients, visitors to the facility, and employees who do not work routinely with or around radiation sources. NCRP shielding designs shall limit exposure of all individuals in uncontrolled areas to an effective dose (in air kerma) that does not exceed 0.2 mSv week⁻¹ (10 mSv y⁻¹).

Controlled areas are easy to identify in dental facilities that use wall-mounted dental X-ray units because the X-ray units are located in specific places. Because all dental X-ray exposures are performed here, the workload is higher and shielding requirements may be increased. However, even practices using handheld dental X-ray units need to consider dental office shielding in dental design.

In fact, if a handheld X-ray device is used in an open area, the operator must establish a controlled perimeter. This controlled perimeter ensures dental personnel do not stand in the path of the X-ray beam, that they remain behind a protective barrier or stand at least six feet away from the patient, and are positioned between 90 degrees to 135 degrees to the direction of the primary beam during exposure.
Handheld versus Conventional Dental X-Ray Units in Clinical Dental Practice

Most handheld X-ray units operate at a fixed, lower kilovoltage (kVp) of 60 kVp. Conventional units will operate at a fixed 70 kVp or a variable 60–70 kVp, with some units operating at up to 90 kVp.

Over time, X-ray units operating at a lower kVp, such as handheld units, produce less radiation. However, the average photon energy is also reduced, requiring longer exposure times that can negatively affect image quality, skin entrance and deep dose.

Handheld units, like most conventional units today, operate using direct current (DC) power, which provides a continuous X-ray beam. While DC power allows for a higher image quality (mean keV) and shorter exposure times in conventional units, DC power benefits handheld units by allowing a lower kVp, but with moderate increases to exposure times.

Handheld dental X-ray units use a battery, which depletes in charge over time. Available commercial literature indicates more than 100 exposures can be performed using one charge. However, they may not all be obtained at optimal exposure in regards to kVp.

A 2011 study investigated the relationship between the amount of battery charge and the tube voltage in seven different handheld dental X-ray systems—Rextar, AnyRay, Nomad Pro, Point-X, Prox, DX 3000 and Port X-II (Kim, 2011). The tube voltages of all tested units were decreased as the residual amount of the battery charge decreased. This finding is in contrast to conventional dental X-ray units where tube voltage is consistently maintained.

While the first images performed using handheld X-ray units with a 60 kVp are acquired at this setting, subsequent images are obtained at values up to 10% less (down to 54 kVp) as the battery discharges. Although still technically within operational compliance limits (10% of the nominal line voltage), this value indicates that handheld dental X-ray systems are often used with lower-than-recommended and inconsistent kVp, potentially leading to more retakes due to underexposure. This issue could be one of the most serious factors when considering the general adoption of handheld X-ray devices for dental radiography. (Kim, 2011)
Milliamperage

Also consider that handheld units operate at a fixed and markedly lower milliampere (mA), with a range of 1.7 to 2.5 mA, in comparison to conventional units, which operate with either a higher fixed amperage of approximately 7 mA or a variable amperage of 4 to 7 mA. The lower amperage of handheld units, together with the reduced and possibly inconsistent kilovoltage of handheld units, necessitates marked increases in exposure time of handheld units to provide the necessary radiation to produce acceptable diagnostic images.

Exposure Time

Handheld X-ray devices that operate at a lower fixed voltage and amperage require longer exposure times than conventional X-ray devices (Table 2). Exposures longer than one second are inadvisable as they run a greater risk of resulting in blur artifacts caused by patient or operator movement. Such exposures can result in unusable images and more retakes.

While tube head movement can occur with conventional X-ray devices, unlike patient movement, tube head movement increases the effective size of the focal spot with little clinical significance (Wotzke et al., 1991; Clark and Zalsman 1991).

<table>
<thead>
<tr>
<th>Sensor</th>
<th>KaVo NOMAD™ Pro 2&lt;sup&gt;(a)&lt;/sup&gt; Handheld X-ray (60 kVp/2.5 mA)</th>
<th>Dexcowin DX-3000&lt;sup&gt;(b)&lt;/sup&gt; Handheld X-ray (70 kVp/1.7 mA)</th>
<th>Midmark Preva DC&lt;sup&gt;(c)&lt;/sup&gt; Conventional X-ray (65 kVp/7 mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital</td>
<td>0.17</td>
<td>0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>PSP</td>
<td>0.21</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Film</td>
<td>0.4</td>
<td>0.9</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Table 2. Comparable Default Exposure Times for Adult Bitewing in Representative Handheld and Conventional Wall-Mounted Dental X-Ray Devices among Various Intraoral Dental Sensors


PSP, Photostimulable storage phosphor; Film, F-speed

Duty Cycle

Ninety-nine percent of the energy used in the production of X-rays is generated as heat in the tube head. To avoid damage from overheating, both conventional and handheld X-ray devices will automatically shut off if overloaded. The duty cycle is a description of the time necessary between exposures for cooling of the tube head and depends on the exposure settings and frequency of exposure. If a unit is operated continuously, with no cooling intervals, this operation is termed “continuous duty.”

The maximum exposure (relationship between duration and frequency of exposures taken over a sixty-second period) for a typical handheld dental X-ray unit is 1:60, which means a one-second exposure time requires a sixty-second cooling down period before the next exposure (NOMAD Pro 2 Operator Manual, 2013).

The duty cycle depends on the exposure duration. For example, for a half-second exposure on a handheld unit, the hypothetical time between exposures is thirty seconds and, therefore, two exposures can be performed per minute. A full mouth series of twenty images will take at least ten minutes. This duty cycle can severely limit clinical efficiency as exposure times approach one second. By comparison, the duty cycle for a conventional wall-mounted dental X-ray unit is just 1:15 (Preva Dental X-ray System User Manual, Midmark Corp, 2019), meaning four exposures can be performed per minute, and a full-mouth series of twenty images will take five minutes.
Clinical Considerations

Workflow Similarities, Differences and Limitations

Benefits of Handheld Use
The Christensen Clinical Report describes considerations for the clinical implementation of handheld units into dental practice (CRC, 2019). The biggest benefit of handheld devices is their portability. They can be used in any dental operatory and, being mobile, require a very small footprint. Only handheld units can be used both inside and outside the dental office. Freehand aiming is purported to simplify radiograph acquisition without leaving the room.

Similarities between Handheld and Conventional Wall-Mounted Units
Despite the many differences, handheld and conventional units share some workflow similarities:
• The exposure settings of both handheld and conventional units are adjustable to be compatible with existing X-ray detectors.
• Potential tube head drift associated with conventional devices is comparable to the potential for operator motion during acquisition with handheld devices, particularly with longer exposure times.
• Neither type of unit requires specific detector or device technique—bisecting angle and paralleling techniques are still used.

Limitations of Handheld Devices
Apart from the perceived benefits and similarities to conventional machines, use of handheld X-ray units introduces workflow limitations not encountered by use of their wall-mounted counterparts. These workflow limitations can include the following:
• Difficult positioning can expose the operator to additional radiation. For several intraoral image projections (e.g., maxillary/mandibular anterior, maxillary posterior premolars and molars) the patient may have difficulty tilting or adjusting their head adequately for the device to be positioned perpendicular to the operator, thereby maximizing the occupancy zone of the backscatter shielding.
• Angulation of the device relative to the position of the detector using either parallel or bisecting technique requires holding a heavy device at various positions, which may be difficult for some operators with limited physical arm strength.
• Handheld units are susceptible to being dropped and damaged. Due to the possibility of internal shielding being fractured, some manufacturers specifically require units that have been dropped to be returned to the factory for analysis. This requirement results in the dental practice not having that unit available for use during the period of inspection.
• Specific dental radiographic image series (e.g., full mouth X-ray series, bitewing series) may take longer as the device must be placed on a stable surface or cradled between repositioning of the image sensor to perform multiple images. Neck straps are available for some models, but these may introduce infection control challenges.
• Constant repositioning of the sensor between multiple image acquisitions requires the operator to repeatedly handle the device, leading to potential cross-contamination issues.
Intraoral Technique Complications

Current NRCP recommendations state that the parallel technique with rectangular collimation is preferred for intraoral radiography (NCRP, 2019). This technique demands the use of a beam-aiming or position-indicating device (PID). Use of handheld X-ray units does not always facilitate the use of this device. Specifically, the backscatter shield may obstruct the arm connecting the receptor holder to the external aiming ring.

In this instance, the handheld unit must be positioned farther away from the aiming ring, increasing the distance between the X-ray source and the skin, along with increasing the area of the patient’s skin surface irradiated. For example, for a 6-centimeter-diameter round collimator, the skin surface area should be 7 cm or less. Increasing the distance between the X-ray source and the skin will also require using higher exposure times than reasonably achievable or adopting techniques that do not use image receptor holders, such as the bisecting angle technique.

The introduction of handheld dental X-ray devices does not appear to affect the precision of aiming compared with conventional X-ray devices (Hoogeveen, et al., 2019). Therefore, errors due to geometric distortion (e.g., horizontal overlap, foreshortening and elongation) are not anticipated to increase with use of handheld devices.

Estimated 5-Year Use Cost

Handheld dental X-ray unit battery life is finite. The listed use life for handheld batteries varies. The literature provided by one manufacturer indicates that 100 exposures to a maximum of 600 exposures can be performed with one charge, and that each battery can be safely recharged 300 times (NOMAD Pro 2 Operator Manual, 2013; MAUDE, 2019). Similar assertions for the MaxRay indicate 200 exposures are possible per charge and batteries can be recharged 300 times. The NCRP provides estimates for average intraoral radiography for low (25 images per week), medium (100 images per week) and high (200 images per week) workloads. Based on these definitions, the estimated cost for 5-year use can be calculated (Table 3).

<table>
<thead>
<tr>
<th>Line item</th>
<th>Nomad Pro 2</th>
<th>Preva</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase price ($) (a)</td>
<td>$7,960</td>
<td>$6,070</td>
</tr>
<tr>
<td>5-year extended protection warranty (b)</td>
<td>$495 + (4 yrs @ $895) = $4,075</td>
<td>$1,470</td>
</tr>
<tr>
<td>Individual battery*</td>
<td>$395</td>
<td>0</td>
</tr>
<tr>
<td>Estimated number of exposures per battery*</td>
<td>30,000</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of years per battery (normalized exposures)**</td>
<td>2.89</td>
<td>N/A</td>
</tr>
<tr>
<td>Total additional batteries over 5 years***</td>
<td>0.73</td>
<td>N/A</td>
</tr>
<tr>
<td>Total projected battery cost (c = a x b)</td>
<td>$288</td>
<td>N/A</td>
</tr>
<tr>
<td>Total cost (a + b + c)</td>
<td>$12,323</td>
<td>$7,540</td>
</tr>
</tbody>
</table>

Table 3. Estimated Five-Year Cost of FDA-Approved Handheld Dental X-Ray Units (Nomad Pro 2) vs. Conventional Wall-Mounted Units (Preva) for High-Volume Workload (10,400 Intraoral Images per Year)

*Assume 100 exposures can be performed with one charge and that each battery can be safely recharged 300 times
** Number of years per battery = [Estimated No. of exposures per battery (30,000) / high volume intraoral workload (10,400)] = 2.89
*** Total additional batteries over 5 years = 1 - [5 yrs / number of years of battery] = 1 - [5/2.89] = 0.73
Published Recommendations For Use

Not all FDA-approved equipment has been approved for use by every state in the United States (McDaniel and Prashar, 2015). In the US, there are no standard federal regulations regarding the use of handheld X-ray devices. Therefore, individual states vary in their approval and requirements for handheld X-ray devices, including device storage, use of protective apron, and radiation monitoring. Some states provide cart blanche approval for the use of handheld units, while others give approval on a case-by-case basis, usually by an exemption.

Numerous organizations worldwide have provided guidance regarding appropriate use of handheld X-ray units in clinical dental practice.

American Dental Association (ADA)
The ADA provides limited guidance on the use of handheld dental X-ray devices (ADA, 2020). They support the position of the FDA in that they advise dentists to use devices legally marketed for this purpose and to check that they are properly labeled to indicate this is the case (FDA, 2008). They also acknowledge that radiation exposure is within safety limits and cite limited data indicating operator exposure is significantly less than for wall-mounted systems (Gray et al., 2012), concluding there is no need for additional shielding.

California Dental Association (CDA)
The guidelines published by the CDA (CDA, 2014) indicate that specific exemptions to the regulatory prohibition that “neither the tube housing nor the position indicating device (cone cylinder) shall be handheld during exposure” were enacted for handheld X-ray units in March 2013 and modified in January 2016. Operators are exempt from this requirement if the following conditions are met:
- The portable dental X-ray system is FDA approved and is being used in a manner consistent with that approval.
- A permanent backscatter shield of not less than 0.25 mm lead equivalent is permanently affixed to the unit.
- Personnel monitoring devices are worn by all individuals operating portable dental X-ray systems, monitored monthly and stored. (Some exceptions may apply.)
- All personnel receive training in the safe use of these X-ray systems and these records are available for review.

An operator may wear a lead apron for additional protection; however, this measure is not required.

National Council on Radiation Protection and Measurements (NCRP)
In December 2019, the NCRP published Report #177, Radiation Protection in Dentistry and Oral & Maxillofacial Imaging (NCRP, 2019). It did not provide specific guidance on selection criteria for use, but did make these five recommendations regarding the use of handheld X-ray units in dentistry:
1. When portable or handheld X-ray machines are used, all individuals in the area other than the patient and operator shall be protected as members of the public (Recommendation #28).
2. Operators of handheld X-ray equipment shall have the physical ability to hold the system in place for multiple exposures (Recommendation #43).
3. Operators shall store handheld X-ray equipment so that it is not accessible to members of the public when not in use (Recommendation #44).
4. The operator of a US FDA-cleared handheld X-ray unit shall not be required to wear a personal radiation protective garment (Recommendation #45).
5. Rectangular collimation shall be used with handheld devices whenever possible (Recommendation #46).
The FDA provided a guidance document for manufacturers of X-ray equipment designed for handheld use (US Department of Health and Human Services; FDA, 2008). This guidance describes specific radiation safety considerations, such as shielding the unit housing as required by the federal standard, providing either external shielding or a means to increase distance between the operator and the unit, and measuring typical exposures near and around the unit.

The guidance also requires manufacturers to identify necessary safety precautions as required by the federal standard (21 CFR 1020.30(h)(1)(1)) and provide adequate instructions to operators concerning radiological safety procedures and precautions that may be necessary because of unique features of the equipment. The FDA recommends these user precautions:

- Designate a significant zone of occupancy.
- Provide information on exposure levels near and around the device near the unit.
- Possibly adopt additional precautions like a personnel monitoring device and protective equipment (e.g., lead-lined gloves and gowns).
- Apply procedural controls to limit the number of exposures initiated by a single operator over a period of time or limit use of the handheld unit without an equipment stand or remote switch as necessary.
- Provide information describing exposure hazards and radiation safety precautions appropriate for patients and other individuals present in the area during examination.

In addition, the FDA specifies the following operational considerations:

- A minimum of E or F speed film or a digital sensor should be used.
- The use of lead aprons with thyroid collars should be considered for patients when optimal rectangular collimation is unable to be incorporated because of design or choice.
- The backscatter shield should not be placed any farther than 1 cm from the end of the cone to sufficiently block backscatter radiation and create a protective zone.
- Dentists should only use devices legally marketed for this purpose. In addition, dentists have a fiducial responsibility to check that handheld devices are properly labeled and FDA approved.

The European Academy of Dento-Maxillo-Facial Radiology (EADMFR)

In Europe, the EADMFR recognizes the challenges of incorporating handheld devices into contemporary clinical dental radiographic practice (Berkhout, et al., 2015). This group acknowledges that these challenges may result in violation of the “as low as reasonably achievable” (ALARA) risk-reduction principle by an increase in (re)exposures compared with conventional intraoral X-ray devices. To use handheld devices, practices must address these difficulties:

- Incorporation of rectangular collimation with beam aiming devices
- More complex matching of exposure settings to the X-ray receptor used (i.e., longer exposure times)
- Movements owing to the unit’s weight
- Protection of the operator and third persons
- Use in uncontrolled environments

Hence, the EADMFR concludes and recommends the general use of handheld portable X-ray devices is not justified and should not be used for routine dental radiography in dental offices. Handheld portable X-ray devices should only be used when:

- An intraoral radiograph is deemed necessary for a patient and the use of a fixed mounted or semi-mobile X-ray device is proven impractical. This includes operating theaters, emergency rooms, nursing homes, residential care or detention facilities, remote areas, and mobile military facilities.
- Evidence suggests that handheld operation has benefits over traditional modalities.
- No new risks to the operators and/or third parties are caused.
Public Health England (PHE)

Perhaps the most comprehensive document published so far detailing the use of handheld dental X-ray devices has been by PHE in 2016 (Gulson and Holroyd, 2016). This guideline was produced by the health authorities in the United Kingdom in response to a noted steady increase in both the number of handheld X-ray sets used in general dental practice for routine intraoral radiography and the number of models of handheld X-ray units available to dentists. Based on internal investigations and data reported in the literature, the authors came to several conclusions about image quality and operator exposure.

First, they found that handheld units provided similar clinical efficacy and diagnostic image quality to wall-mounted versions. PHE acknowledged the added potential for reduced image quality due to movement, the technical difficulties in obtaining certain radiographic projections and using rectangular collimation, the need for longer exposure times, the effect of battery discharge on X-ray beam quality and quantity, and the use of handheld devices in “uncontrolled” environments. They found no difference, however, between handheld and wall-mounted units in image quality or clinical efficacy. PHE noted that projection errors were most likely to occur with upper and lower anterior periapicals and that, while all projections were clinically practical, these periapicals necessitated greater manipulation and head position—particularly problematic for patients with restricted neck movement or short necks.

Second, PHE reported that there was a wide variation in the standard of radiation protection afforded by the different designs. Doses to operators of well-designed and constructed handheld X-ray equipment were comparable to doses received by operators of wall-mounted X-ray units, provided certain additional precautions were observed. On the other hand, poorly designed and constructed equipment may place the operator at risk of exceeding statutory dose limits and incurring potential radiation injuries.

The authors also noted the difficulty in placing the backscatter shield against the surface of the patient’s skin, increasing both the size of the X-ray beam incident on the patient and the exposure time required. This issue results in an overall increase in patient dose of 50%–100% (in terms of dose area product). PHE concluded that while it may be clinically practicable to use handheld dental X-ray equipment for many radiographic examinations commonly undertaken with wall-mounted X-ray equipment, this use is only acceptable under specific conditions.

- Rectangular collimation must be used.
- The unit must have a feature that disables exposures to unauthorized users.
- Operators must be knowledgeable in and adopt procedural adjustments such as patient positioning.
- Additional advice from health physicists (referred to as radiation protection adviser) must be sought in regard to personal dosimetry, the selection and use of personal protective equipment, equipment selection, a review of previous office shielding designs, the need for additional training and instruction, and the introduction of a quality assurance program amongst other controls.
Conclusion

Handheld dental X-ray units were originally introduced in dentistry as a supplemental modality for specific circumstances outside of the dental office. They have been an unquestionable asset for military use in the field, in forensics and especially following mass disasters for obtaining post-mortem radiographs. In recent years, their use has expanded into general dental practice with the promise of becoming a substitute X-ray source for conventional fixed dental X-ray units. However, to consider handheld X-ray units a replacement for conventional radiographic units in clinical dental practice, their use and operation must satisfy specific requirements:

• The operator, patient and public should face no additional risk compared with conventional radiography.

• Any perceived potential benefit for using handheld units must outweigh any potential risk of increase in radiation dose or re-exposure.

Conventional and handheld X-ray units are technologically identical and emit similar X-ray spectra, with slight variation between units, and produce diagnostically acceptable images. So, for the patient, the procedural risk/benefit is the same regardless of which X-ray unit is used.

Handheld dental X-ray units have some benefits from the operator’s perspective. Compared to fixed dental radiographic units, handheld units are portable and flexible since one unit can be used in multiple operatories. However, there are numerous limitations to using handheld X-ray units.
Operators who use handheld devices assume a higher occupational risk from radiation exposure because the technique they use does not take advantage of additional shielding material (e.g., leaded walls) or the benefits of distance. While most studies report operator radiation dose levels well below the maximum permissible dose, it must be acknowledged that the use of handheld X-ray devices can expose operators to levels higher than fixed units.

In addition, handheld dental X-ray unit dose studies often assume perfect compliance with somewhat restrictive clinical technique procedures. Perfect compliance is not what typically occurs in the real world of clinical dental practice where users may have to compromise operating guidelines especially in relation to technique. They are then potentially exposed to a small but greater radiation risk compared to the use of conventional dental units.

This increased risk is acknowledged by numerous regional regulatory agencies, which mandate the adoption of supplemental radiation protection protocols and controls.

Based on thorough analysis, the use of handheld dental X-ray devices is best considered as a supplemental or augmenting imaging modality rather than as a replacement for conventional imaging for routine intraoral radiography in dental offices. Dental professionals can reevaluate when additional data is available to fully substantiate assertions of diagnostic and operator radiation safety equivalency using handheld units compared with the use of conventional fixed X-ray units.
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