# Q.A. COLLECTIBLE

*Sponsored by CRCPD's Committee on Quality Assurance*
*In Diagnostic X-Ray (H-7)*

# HAND-HELD DENTAL X-RAY UNITS

## INTRODUCTION

Currently, there are several manufacturers who make hand-held dental x-ray units. Of those, several of these units have received U.S. Food and Drug Administration (FDA) clearance to be marketed for human use in the United States. One manufacturer/unit is designated for non human use (veterinary unit). At least two systems of hand-held dental x-ray devices have been cleared for marketing in the United States. FDA has a website for all device approvals and clearances:

> http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm

The main advantages of a hand-held dental x-ray device are mobility and positioning. One device can be used in multiple dental operatories or easily transported to remote locations like nursing homes or temporary health clinics. The operator isn't limited to how far a support arm can move or if the dental chair must be positioned in a specific direction or orientation. They also allow for easy adjustments for limited patient flexibility.

## RADIATION DOSE / EXPOSURE

Two potential negative issues arise from the use of hand-held x-ray devices: operator dose and increased patient dose.

### Operator Dose

Sources of operator dose include: tube leakage radiation to the operators' hands and back-scatter dose to the operators' hands and body. Because the operator is holding the device, their ability to use distance as a protection factor is limited to the length of their arm. Time of exposure is defined by the anatomy (exposure factors kVp and mA are fixed). That leaves shielding as the default means of operator protection.

Like most dental units, the x-ray tube, x-ray control circuitry, and high voltage generator (transformer) are all contained in a single, lead-shielded housing. All FDA cleared units have shielding sufficient to meet the leakage radiation requirement under 21 CFR 1020.30(k) (0.88 mGy or 100 mR in an hour). The dose to the operator varies based on the unit's design.

Back-scatter from the patient also adds to the potential operator dose. A properly deployed lead acrylic disk surrounding the exposure aperture cylinder absorbs virtually all back-scatter and limits this unnecessary dose.

**Patient Dose**

Increased patient dose could come from: inconsistent source-to-image distances, central ray angles (image cut off), repeated exams due to motion of the operator, or errors in central ray angles (image quality-elongation or foreshortening). Another potential issue is movement. If the tube moves due to length of exposure time or the operator moving (breathing or the fatigue related to unit weight), there is loss of image detail. This may be minimal due to the amount of motion and the relative geometry of the film and anatomy, but could lead to repeated exams. Motion can be minimized by using F-speed dental film, or solid state digital imaging systems, and with units using higher tube current (mA).

Technique charts are established based on an x-ray unit's radiation output, patient anatomy to be imaged, image receptor system, and source-to-image distance (SID). The anatomy, output, and image system, once established, generally remain consistent. In general, the SID for dental units is operator dependant. For hand-held dental units, SID is totally operator dependant. Dental assistants are taught during their training that the end of the cylinder should not touch the patient. Positioning arms and aiming rings (a film or digital sensor holder with a ring for positioning the x-ray tube cone) are available to assist in proper positioning of the x-ray tube relative to the image sensor and in avoiding cone cutting or misalignment of the x-ray tube with the image sensor. If properly used, these also assure that a consistent source-to-image distance is maintained by the operator. These should be used for hand-held units also.

Any hand-held unit sold in the U.S. must meet the minimum 18 cm source-to-skin (end of cylinder) distance required by the FDA. It should be stressed that some hand-held devices significantly reduce the patient (and staff) dose through optimized design. This is accomplished by using

direct current to the x-ray tube, smaller cylinder diameters, and fully lead shielded cylinders.

## DESIGNS FOR HAND-HELD DENTAL DEVICES

The hand-held dental x-ray units approved for sale in the United States have two basic design shapes. The first design has a handle and trigger device similar to a hand-held "cutie pie meter."

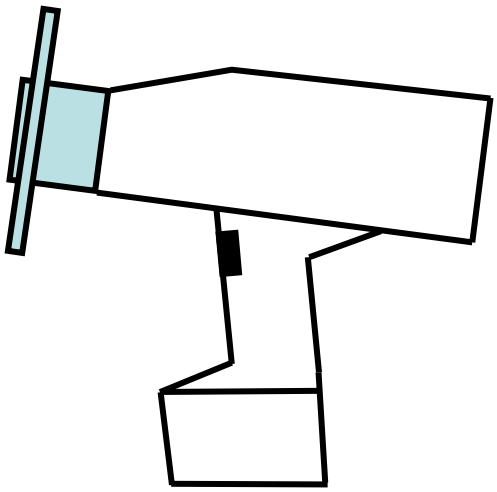

Figure A. Design similar to a cutie-pie meter with an integral back-scatter shield.

The second design resembles a digital camera:

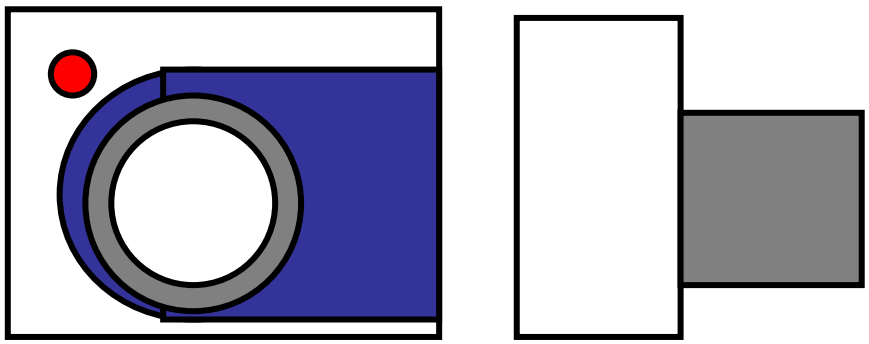

Figure B. Digital camera design hand-held x-ray unit. There can be some variation in cylinder aperture (cone) length. At least one of the manufacturers using the camera body design offers an optional back-scatter shield.

Although the hand-held dental x-ray units operate at fixed kVp and mA factors (all units use 60 kVp and mA varies by manufacturer from 1.0 – 2.5 mA), the exposure times have a range from 0.03 – 2.0 sec. All utilize focal spots comparable to traditional dental units that have their tube heads affixed to a support arm. Focal spot sizes range from 0.4 to 0.8 mm, which is similar to that used in wall-mounted units. The hand-held x-ray units are also comparable to traditional dental units in radiation output.

## X-RAY UNIT SAFETY

Radiation tests conducted on four hand-held dental x-ray devices by Washington State x-ray inspection personnel demonstrated that operator exposure varies widely from one device to another. The testing also demonstrated that while no hand-held dental device exceeded established occupational dose limits for extremities, the tested leakage exposure to the hands ranged from minimal to 270 mrem (2.7 mSv) from a total of 750 exposures. All tested units had exposure factors adjusted to equivalent radiation output of 130 mR (1.14 mGy) ESE (within 10%).

> The highest dose observed was at the exposure switch location (i.e., right finger)
>
> 270 mrem (2.7 mSv)/750 exposure = 0.36 mrem (0.0036 mSv) /exposure
>
> 750 exp/by 22 work days = 34 exp/day (22 works days equivalent to one month);
>
> 8-9 patients if 4 exposures per patient or 17 patients if two bitewings only
>
> 34 exp/day X 0.36 mrem (0.0036 mSv)/exposure = 12 mrem/day {this is to the finger and would not exceed the maximum permissible dose (MPD) of 50 rem (500 mSv) per year})

For a given month, the worst possible scenario for hand-held units would not exceed occupational limits. However leakage dose to the hands may be a concern.

### Radiation Dose to the Operator

Measurements of operator dose from back-scatter were taken for various parts of the body. Back-scatter shields are available for some units

(may be integral or optional). All measurements with the back-scatter shield in place were minimal.

The highest dose (to the operator's abdomen) was measured without a back-scatter shield.

60 mrem (0.6 mSv)/750 exp = .08 mrem (0.008 mSv)/exp

34 exp/day X .08 mrem (0.008 mSv)/exp =
2.72 mrem (0.0272 mSv)/day

2.72 mrem/day X 250 working days = 680 mrem/year

Again, no unit tested would exceed occupational dose limits. However, ALARA (as low as reasonably achievable) guidelines would be better followed if a back-scatter shield is utilized/required. A back-scatter shield is most effective when positioned at the end of the cylinder (closest to the patient) because that provides a larger protective area for the operator.

## QUALITY CONTROL TESTING

Quality control testing is not addressed specifically by all manufacturers. Ideally, prior to use on humans, some quality control should occur. The facility should contact the manufacturer for an appropriate quality control procedure.

## SUMMARY

In summary, there are several hand-held x-ray units available in the United States. These have some distinct advantages for the users but also have drawbacks with regard to user radiation safety. It should be noted that each model of hand-held x-ray units should be evaluated individually for safety purposes as the design characteristics vary significantly from one manufacturer to another.

The following points should be stressed for the users of hand-held dental, or other types, of x-ray units:

- Some units result in radiation doses to the hands on the order of 3,000 mrem per year, and to the body of 680 mrem per year. Although this is below regulatory limits, use of a

shield significantly reduces the amount of back-scattered radiation received by the user.

- Higher tube current (mA) reduces exposure time and the potential for motion blur.
- Reducing exposure time by using a high speed image receptor, (F-speed dental film, or solid-state digital imaging systems), significantly decreases patient exposure and the potential for motion blur. In addition, use of F-speed film, or solid state digital imaging systems, significantly reduces the dose, i.e., by a factor of two, to the patient and staff
- Use of an aiming ring will minimize cone cutting and x-ray tube image receptor misalignment.