A Radiation Safety Analysis of the Xray2Go MiniX-S

by

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INTRODUCTION

The use of diagnostic X-ray in dental practice has been prevalent for decades. Generally, X-ray emission devices are wall-mounted and thus permanently installed in any given room of a dental office. In the past several years, hand-held X-ray emission units have become available and are used in many dental practices throughout the world. These X-ray units are essentially no different from the wall-mounted version, except that they are portable. This portability gives rise to questions of operator safety. As with any radiation emission source, if the product is used in a manner that is contrary to that which is intended, dangerous levels of radiation exposure can occur.

From the patient's perspective, little has changed. The wall-mounted and hand-held X-ray units are technologically identical and essentially emit the same distribution of X-ray photons, with slight variation between units. For the patient, the procedural risk/benefit is the same regardless of X-ray emission technique.

The operator, however, can be affected in different ways by both units. Regardless of source, an operator who does not take advantage of shielding material (e.g., leaded apron, leaded walls) will experience higher occupational radiation dose. Likewise, an operator who purposefully stands in an area known to have high radiation fields exposes themselves needlessly. The greatest difference between wall-mounted and hand-held X-ray emission devices is that the operator can leave the room while using the wall-mounted unit, but, by definition, might hold the hand-held emission device during radiography.

Even though the hand-held devices have been engineered for safety, product testing is important for peace of mind and to ensure that levels of radiation exposure are well below those deemed safe for the industry. In this report, we explain the testing that was conducted at Oregon State University on the Xray2Go MiniX-S offered by Digital DOC in El Dorado Hills, CA, to validate its level of operational safety for dental radiography.

OBJECTIVES

There are four objectives to this work, all of which focus on the health and safety of the operator and patient:

(1) to measure the leakage radiation exposure (isodose) around the Xray2Go;
(2) to conduct a detailed analysis of the exposure from scatter radiation, demonstrating the effectiveness of the integrated backscatter shield;
(3) to evaluate the patient's entrance skin exposure (ESE); and
(4) to determine beam quality by measuring HVL.

EXPERIMENTAL STUDIES

Our study involved the use of two major instruments, the Radcal Accu-Dose[1] system and the Xray2Go[2] MiniX-S (Serial No. MS17I0376; Manufacture Date 09/28/2017; FDA K152859). A 37 m^2 (400 sq. ft.) concrete-block laboratory in the Radiation Center on the Corvallis campus of Oregon State University was used for all measurements. The room is large and excellent for these low-energy photon measurements with negligible scatter contributions. As we would do in

[1] Radcal Corporation. 426 West Duarte Road. Monrovia, CA 91016
[2] Digital DOC. 4789 Golden Foothill Parkway. El Dorado Hills, CA 95762.

any size experimental chamber, we took precautions against wall-scattered radiation during all measurements.

Radcal Accu-Dose exposure instrumentation. To measure the radiation exposure resulting from operation of the hand-held Xray2Go, we used a Radcal Accu-Dose control unit with a 10x6-180 Ion Chamber operated in the "dose accumulate" mode. This sensor allowed for high-sensitivity measurements of exposure rate as low as hundredths of micro-Roentgen (μR) per second. The Radcal was last calibrated by the manufacturer eight months prior to our use. The 10x6-180 is a 100 cm^2 parallel plate ion chamber and is ideal for leakage and low-level measurements. The Radcal ion chamber is unsealed and automatic temperature/pressure corrections, as well as background corrections, are made by the control unit. The overall accuracy is reported as +/- 5%.

All measurements were conducted for exposure times of 1 second, and results from the Radcal were provided in terms of either mR/sec or μR/sec, with units automatically adjusted by the Radcal depending on rate of exposure. In the dose accumulate mode, the Radcal provides a lowest single-measurement exposure rate of 0.4 μR/sec, with smallest increments of 0.4 μR/sec. Multiple measurements at the same location indicated that the Radcal is very stable and standard deviations are less than a few percent.

Exposure-to-dose calculation. All ionization chamber measurements provide results as exposure or exposure rate, not radiation dose. Exposure is measured in air and radiation dose is typically of importance for human tissue. The two parameters of exposure and tissue dose are closely related, but there is a fundamental difference. In order to estimate tissue dose from exposure, one should multiply the exposure value by 0.95 and then convert units (mR to mrem). For example, an exposure of 1 mR is equal to a tissue dose of 0.95 mrem. Because of this close similarity in numerical value, many times we see the (incorrect) conversion from mR to mrem as one-to-one.

Exposure factors. For this work, we analyzed the Xray2Go MiniX-S. As with the majority of hand-held units, the X-ray tube potential and tube current are fixed and not adjustable by the operator. The MiniX-S operates with a tube potential of 60 kV, a tube current of 2.0 mA, and total filtration of 1.6 mm Al equivalent. Throughout this work, all raw exposure measurements were made for exposure times ("beam-on" times) of 1 second.

Testing of wall scatter effects. Two experiments were conducted prior to leakage/scatter testing to determine the influence of the concrete walls on X-ray scatter. First, a "head-on" approach was assumed in which the ion chamber was placed directly in the X-ray beam, 11 cm from the end of the collimating cone. This configuration was maintained while moving the X-ray unit and detector toward the wall from 300 cm to 10 cm, in varying increments (see Figure 1a). The study confirmed that the exposure rate in the direct beam is so high (~115 mR/sec at that distance) that any exposure contribution from wall scatter is insignificant, resulting in a flat line response regardless of wall distance.

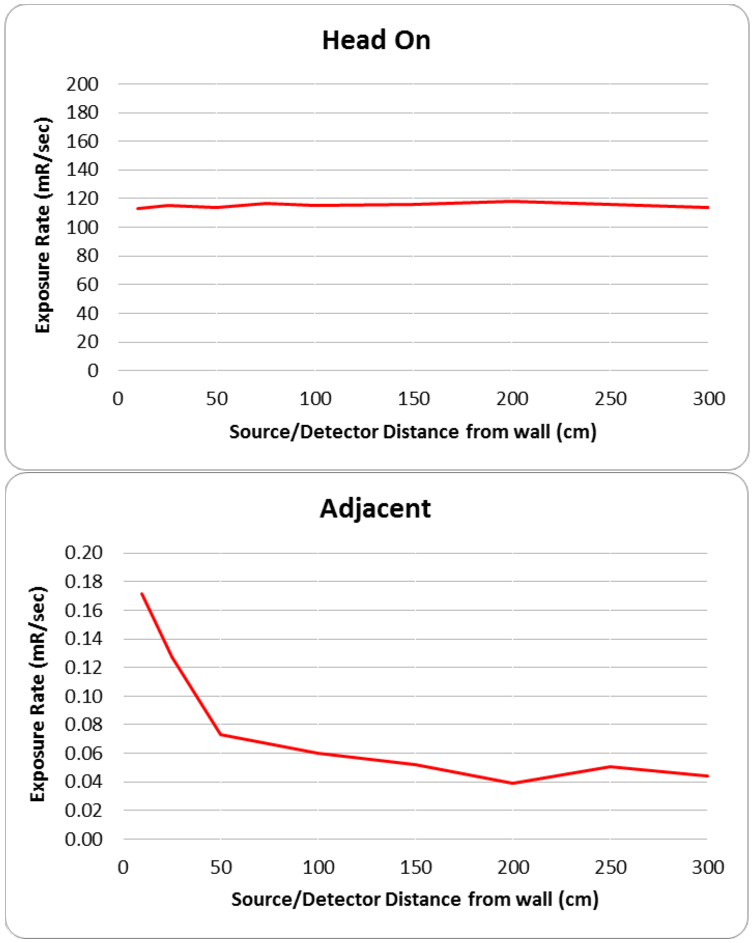


Figure 1. Influence of scatter from (a) head on and (b) adjacent measurements of exposure.

Second, we again held the source and detector in a constant configuration, but this time the two were directly adjacent to each other both facing the significant scatter wall. The two together were moved closer to the wall from 300 cm to 10 cm, in varying increments (see Figure 1b). The study suggests that the contribution of indirect wall-scatter (hundredths of mR/sec) becomes significant once if the source and detector are within about 1 meter from the beam-absorbing wall. We conclude therefore that all experiments should be conducted with at least 1 m wall clearance; easily achievable in our laboratory.

Time linearity. As stated above, the exposure factor parameter that is adjustable by the operator is beam time. This being the case, a simple experiment was conducted on the Xray2Go to determine whether the X-ray output was indeed linear with time. For example, increasing and decreasing exposure time by a factor of 2 should also increase and decrease total exposure by a factor of 2, respectively. In order to test this, we first determine the total exposure (mR) at a given location for an exposure time of 1 second. We then normalized all other measurements to that exposure. Figure 2 indicates that the device is generally linear with time, varying by only about 5% at very short time settings.

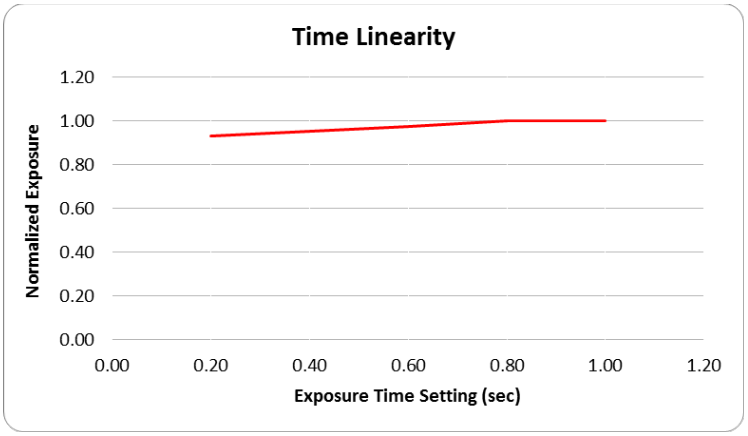


Figure 2. Linearity of exposure time.

Determination of significance of detector orientation. Based on our experience with the RadCal Accu-Dose system, we know that the orientation of the 10x6-180 ion chamber (relative to the X-ray source) can influence the exposure measurements. These influences occur only past an angle of about 45 degrees, with the greatest significance (X-ray beam oriented on detector edge) shown to result in a reduction of about 16%. Therefore, we conducted all studies in an orientation where the broad face of the ion chamber was directed perpendicular to the primary source of X-rays (either in the beam or facing the focal spot). The ion chamber is large (100 cm^2) and measurements therefore are not precise in positioning.

Cell phone interference. Some regulating agencies require that X-ray emitting devices be subjected to cell phone interference investigations. We tested the Xray2Go in various experimental settings to determine whether it would inadvertently initiate an X-ray emission due to cell phone operation in close proximity. Our tests involved both texting and phoning features of a typical smart phone. After numerous attempts, at various distances and orientations, our technicians could not cause the Xray2Go to “fire” inadvertently.

If the Xray2Go (or any other handheld unit) were controlled by a wireless system with a frequency in a similar band to that of cell phones, it could be possible to initiate an accidental emission. The Xray2Go, however, is manually operated by a pressure switch on the unit itself or a button on an extension cable. There appears to be no possibility of the Xray2Go to be accidentally discharged by wireless means.

LEAKAGE AND SCATTER STUDIES

Presentation of data. The data that are critical to operator safety are presented as estimates of annual dose (mSv/yr). The Xray2Go documentation indicates an estimate of annual usage to be 7,200 exams with the average exam requiring 0.1 seconds of exposure time (with a digital sensor). This being the case, we converted the raw exposure-rate measurement (M) collected as exposure during 1 second of beam time (μR/sec) to an estimate of annual occupational dose (D), using:

$$D\left[{}^{mSv}/_{yr}\right] = \frac{M\left[{}^{\mu R}/_{sec}\right] * 0.95\left[\frac{\mu rem}{\mu R}\right] * 0.1\left[{}^{sec}/_{ex}\right] * 7{,}200\left[{}^{ex}/_{yr}\right]}{100{,}000\left[{}^{\mu rem}/_{mSv}\right]}$$

For example, a measured exposure rate of 10 μR/sec in the laboratory (see Figure 3) results in an estimate of annual total exposure to the operator of 0.07 mSv.

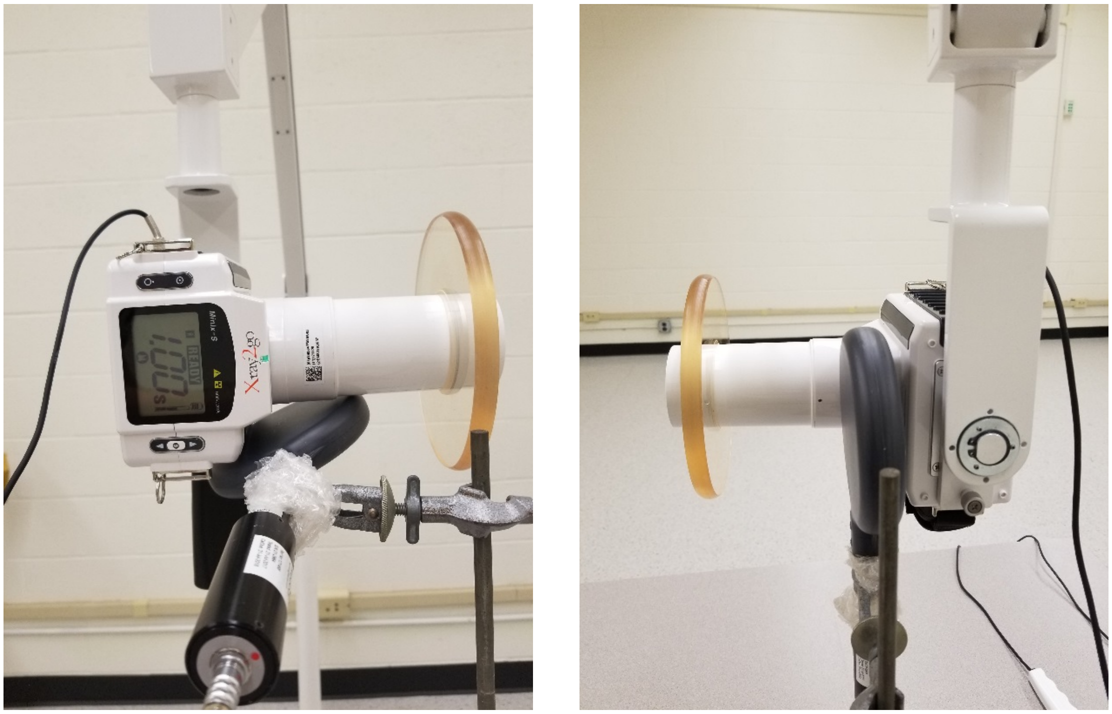


Figure 3. Demonstration of contact leakage-exposure measurement.

Leakage radiation measurements. Exposure to leakage radiation, the X-rays that escape through the housing and its shielding, is an important safety concern for the operator of any hand-held device. Prior to using similar devices, it is paramount to determine how much leakage radiation exists and if there is potential for significant radiation dose simply by being near the unit as it generates X rays. Our experiments were conducted on the Xray2Go to ensure its operational safety. We collected numerous measurements at various locations around the Xray2Go in order to map its leakage radiation exposure field.

As stated above, raw measurements of exposure rate (μR/sec) were converted to annual occupational estimates of extremity dose (mSv/yr) and are presented below in all three dimensions (Figures 4a – 4c) for the Xray2Go. The representation of annual dose is plotted as a bubble (sphere) with its surface area proportional to its numerical value. For all leakage radiation plots, relative bubbles are drawn such that a bubble that is twice the surface area of another bubble represents a leakage exposure (converted to dose) that is twice its value. All bubbles plotted in Figure 4 are on the same scale so that they are all visually comparable. Plotting relative to surface area (proportional by the power of 2) gives the ability to show a greater range of data values on the same plot.

On examination of the three plots, we can see that internal shielding is very good and that the maximum annual dose to the operator from leakage would be about 0.05 mSv/yr (5 mrem/yr). This dose is ten-thousand times lower than the dose to extremities (500 mSv) allowed by the federal government[3]. Looking at Figure 4a, we see that doses are essentially symmetrical around the unit in the front-view plane; this layout can be thought of as an isodose mapping of leakage exposure in the front-view plane. An exponential decrease in dose with distance from the focal

[3] 10CFR20.1201

spot is expected, however, we attribute the fairly constant dose rates to detector size and location imprecision. From the top and side views, Figures 4b and 4c indicate that internal shielding is very good in all directions and that additional shielding is apparently present in the back of the unit. As expected, dose rates along the collimating tube and near the output end are significantly higher than that which is leaked through the device.

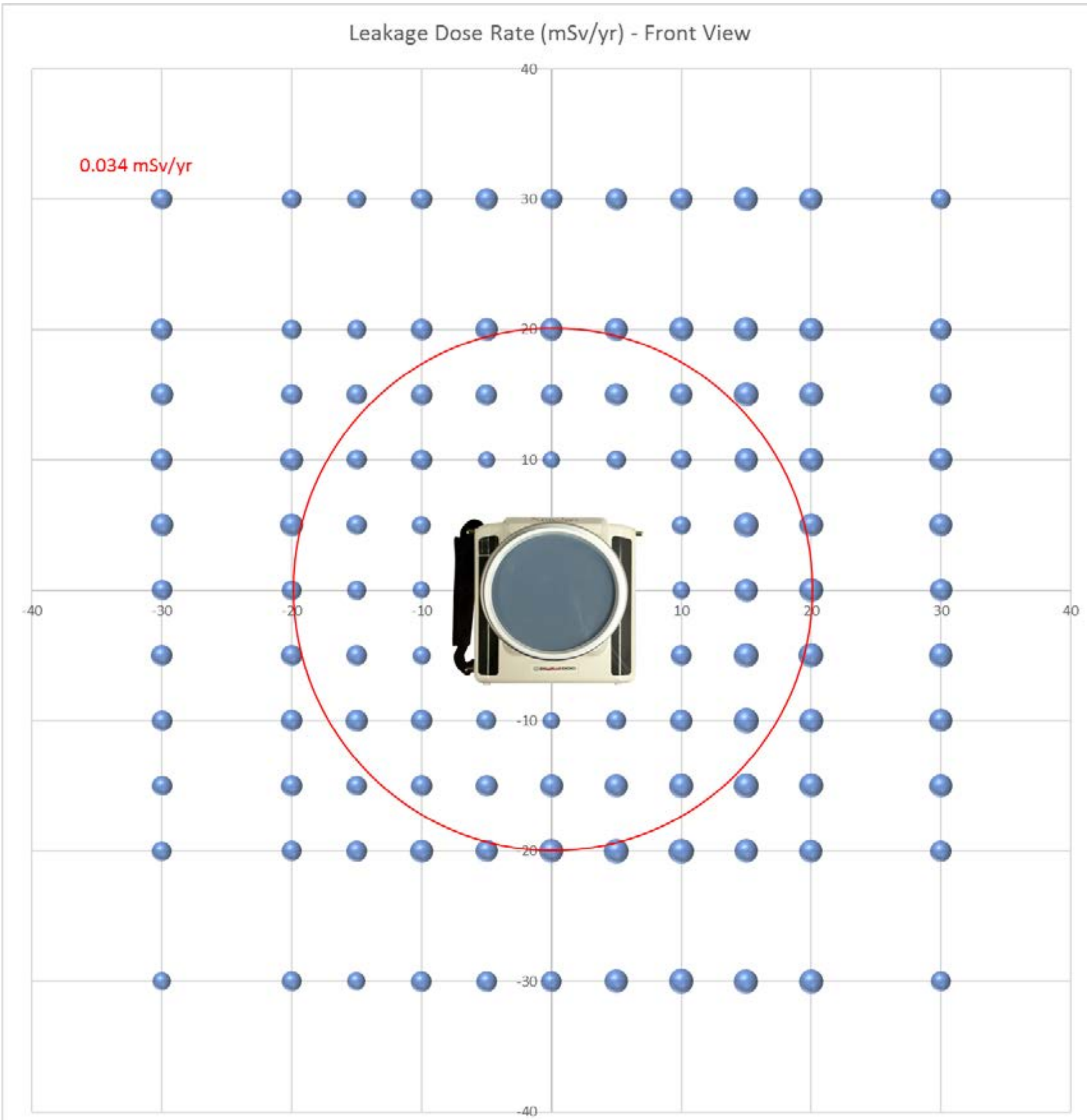


Figure 4a. Front view where the primary beam of X-rays is coming out of the page. Bubbles indicate the magnitude of exposure relative to their area. The red circle simply indicates a distance of 20 cm from the focal spot, and the value provided in red gives the reader an indication of relative dose rates for all other measurements.

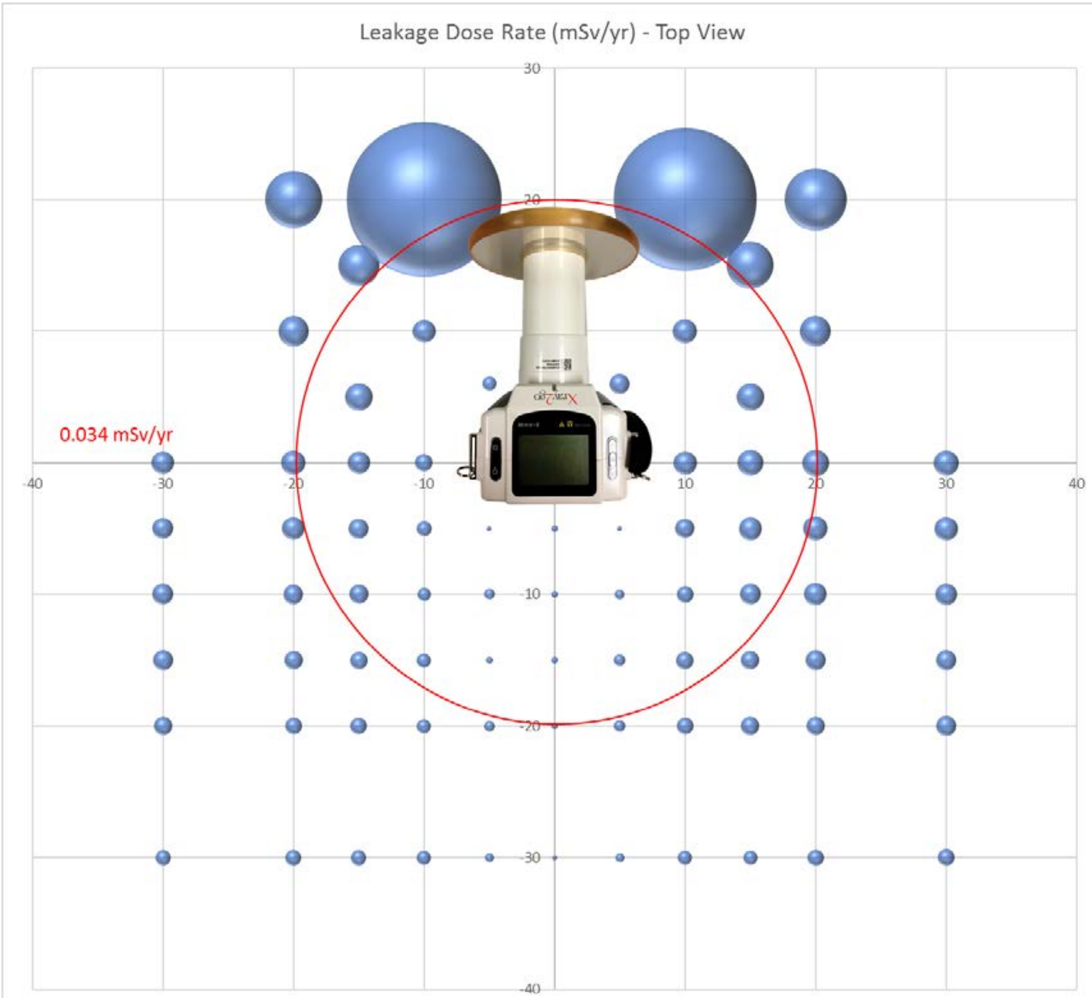


Figure 4b. Top view. Bubbles indicate the magnitude of exposure relative to their area. The red circle simply indicates a distance of 20 cm from the focal spot, and the value provided in red gives the reader an indication of relative dose rates for all other measurements.

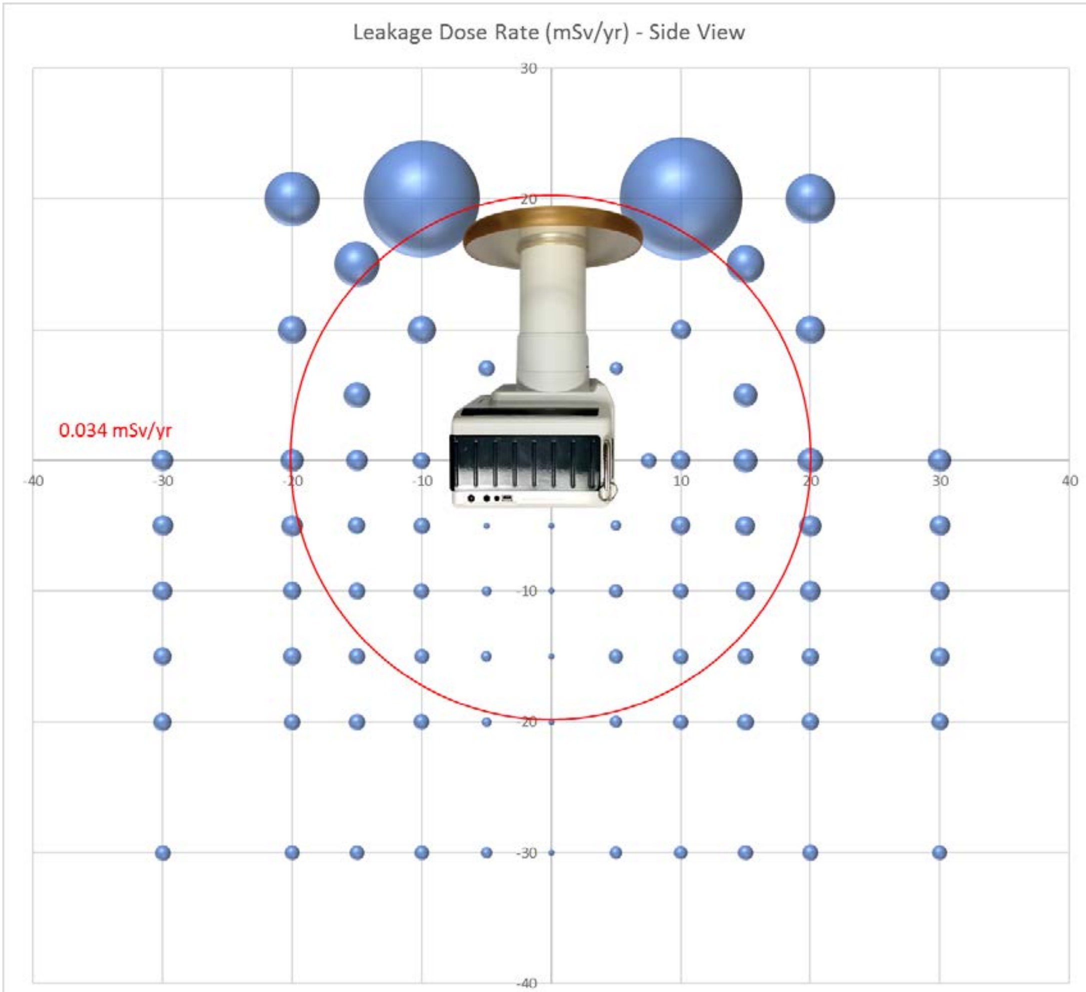


Figure 4c. Side view. Bubbles indicate the magnitude of exposure relative to their area. The red circle simply indicates a distance of 20 cm from the focal spot, and the value provided in red gives the reader an indication of relative dose rates for all other measurements.

Scatter radiation measurements. In terms of dose to the operator, radiation leakage from the device is quite small compared to the amount of radiation scattered off the patient's jaw. This scatter radiation is called "backscatter" in that it is scattered back toward the operator. The Xray2Go MiniX-S contains a backscatter shield designed to provide a cone of protection in which the operator stands for maximum radiation protection. As part of this safety analysis, we collected exposure-rate data in and around the backscatter-shielding zone to assess the effectiveness of the safety design.

In any study where scatter radiation is the central factor, the material from which scatter is assessed is of utmost importance. For example, we are interested in the X-ray field scattering off the skull of a human while obtaining dental radiographs. The most accurate assessment of scatter will be obtained by tests on humans. This obviously is not possible in the laboratory; therefore, we look for the next nearest surrogate. We have chosen to use an alpaca skull (Figure 5a) submerged in water to simulate the human skull with its surface tissue. The modified skull (Figure 5b) was placed inside a plastic bag filled with water and shaped so that about 5 mm of water covered the surface of the bone (approximate cheek thickness).

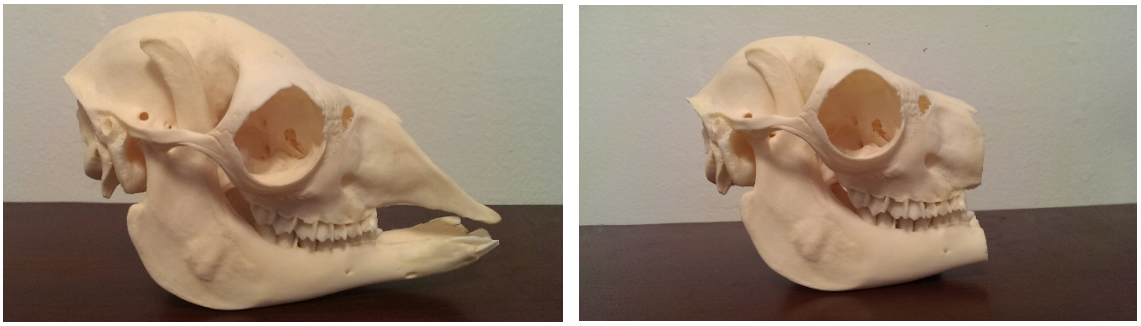


Figure 5. (a) Original alpaca skull, and (b) the modified skull

The X-ray emission cone from the Xray2Go was aimed directly at the alpaca teeth (see Figure 6), in one experiment nearly touching the plastic bag, and then 10 cm from the bag surface. The ion chamber was placed at various locations around the backscatter shield to provide an exposure map and delineate the operator's backscatter protection zone. The results are provided in Figures 7 and 8. Again, annual dose rates (mSv/yr) are presented as bubbles (spheres) proportional by surface area.

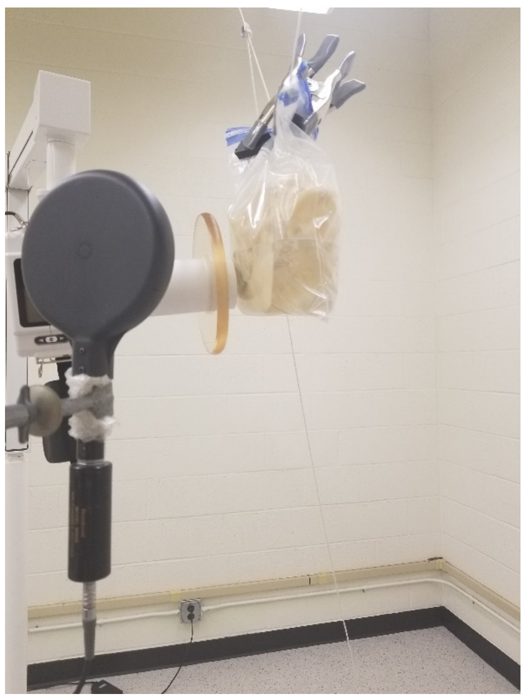


Figure 6. Orientation of the Xray2Go, the alpaca skull, and the ion chamber during backscatter measurements.

Figures 7a (top view) and 7b (side view) show the backscatter field present when the operator places the X-ray cone very close to the patient's face (the largest measured value is labeled for reference). The backscatter shield is very effective at keeping higher radiation fields off the operator. The plots show that the annual dose rates outside the backscatter zone can be rather high (tens of mSv/yr), but that the shielding is quite effective at keeping total annual doses to the operator within the backscatter zone to less than 1 mSv. Additionally, it is evident that the shield provides a protection factor of at least a factor of 10 with measurements shown in the plots. The federal government[4] maintains an occupational total effective dose equivalent limit of 50 mSv.

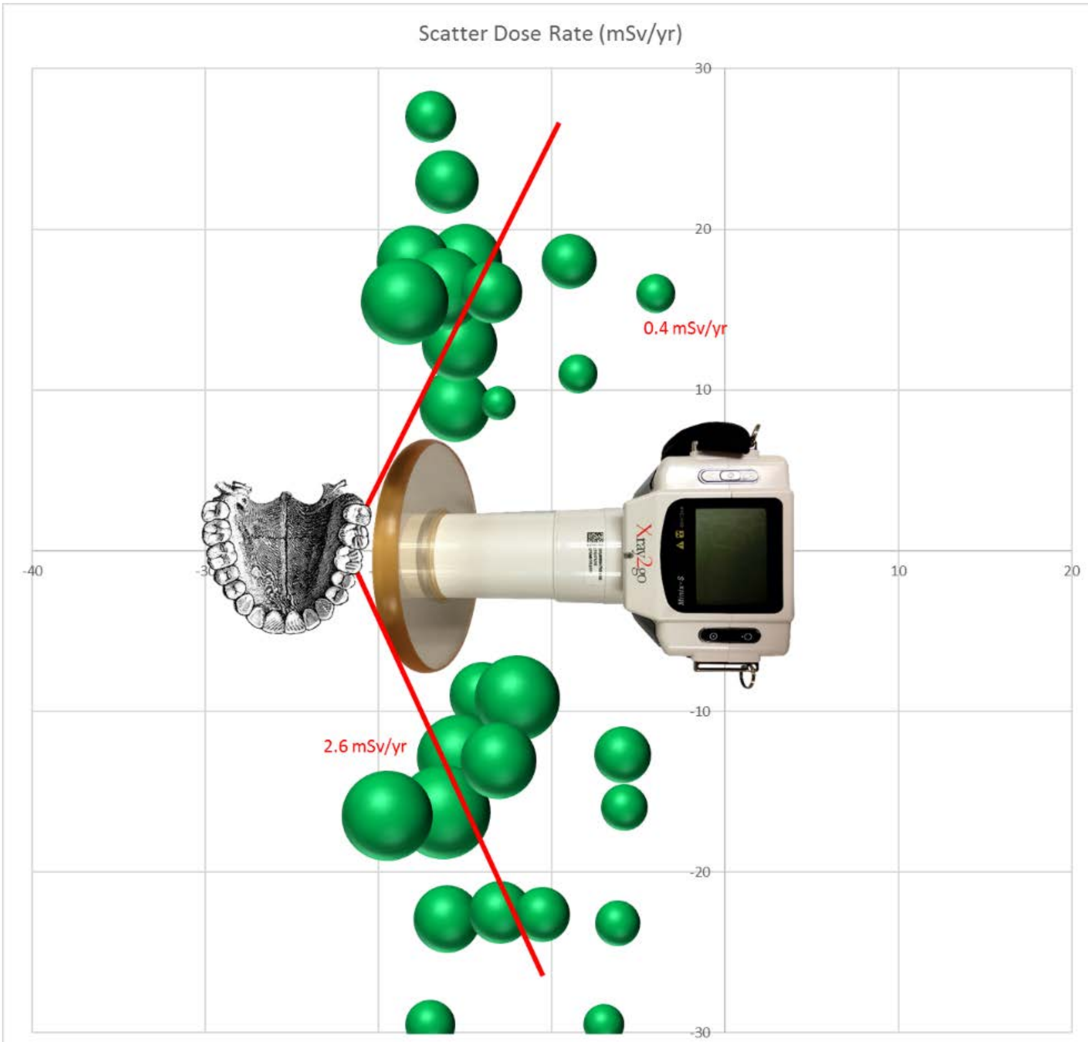


Figure 7a. Top view with dose rates of 2.6 and 0.4 mSv/yr labeled for comparison. Bubbles indicate the magnitude of dose rate relative to their surface area.

[4] 10CFR20.1201

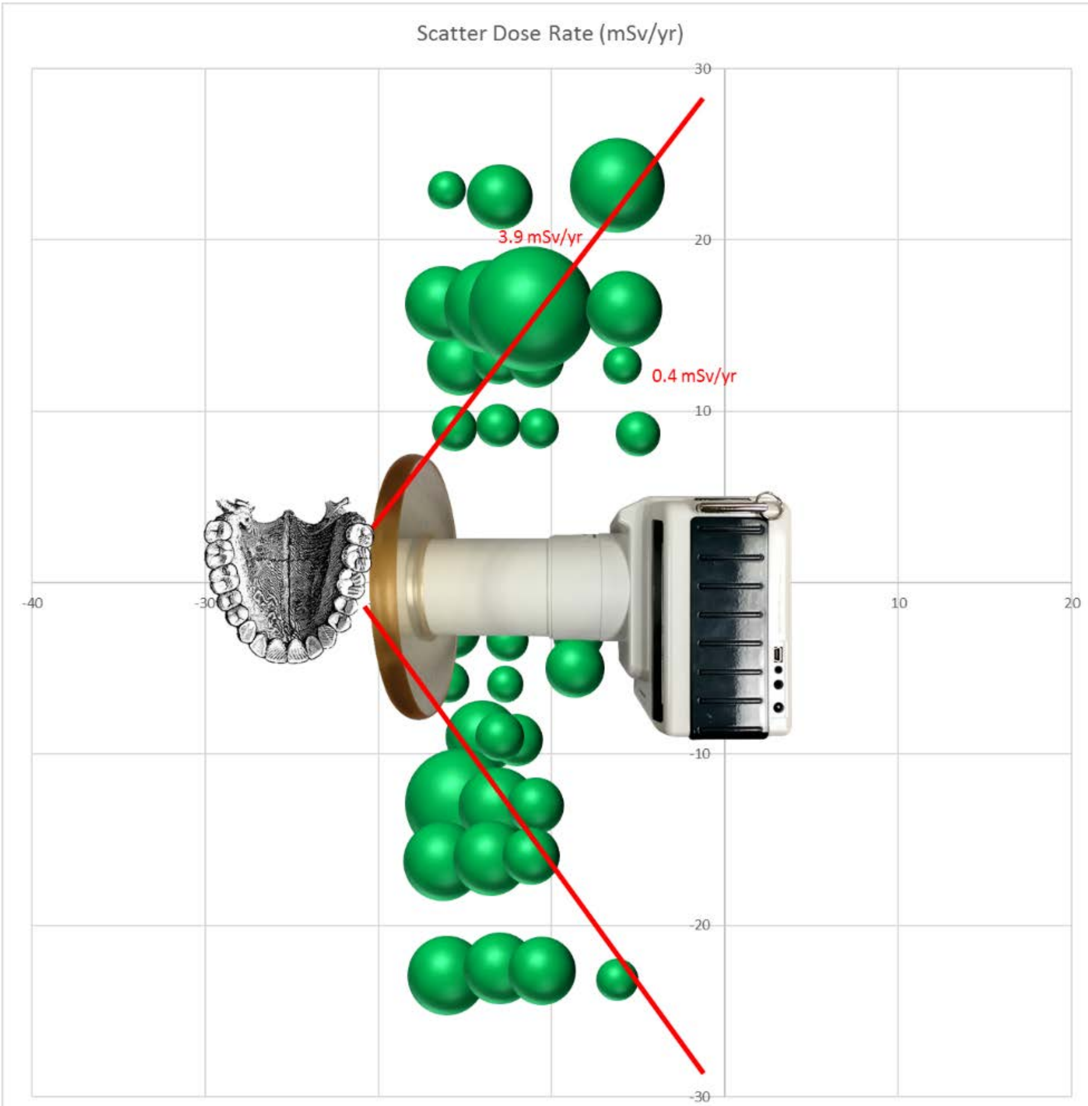


Figure 7b. Side view with dose rates of 3.9 and 0.4 mSv/yr labeled for comparison. Bubbles indicate the magnitude of dose rate relative to their surface area.

Figure 8 shows what can happen to the backscatter zone when the X-ray cone is moved away from the patient. As the gap between the end of the X-ray cone and the patient's cheek is increased, the size of the backscatter safety zone decreases. Annual doses in the safety zone are still less than 1 mSv, but the zone is smaller, meaning that the operator's head or lower body could be exposed to higher radiation levels. This shows the importance of keeping the end of the X-ray cone very close to the patient's face during radiography to ensure image quality while maintaining a safe work zone for the operator.

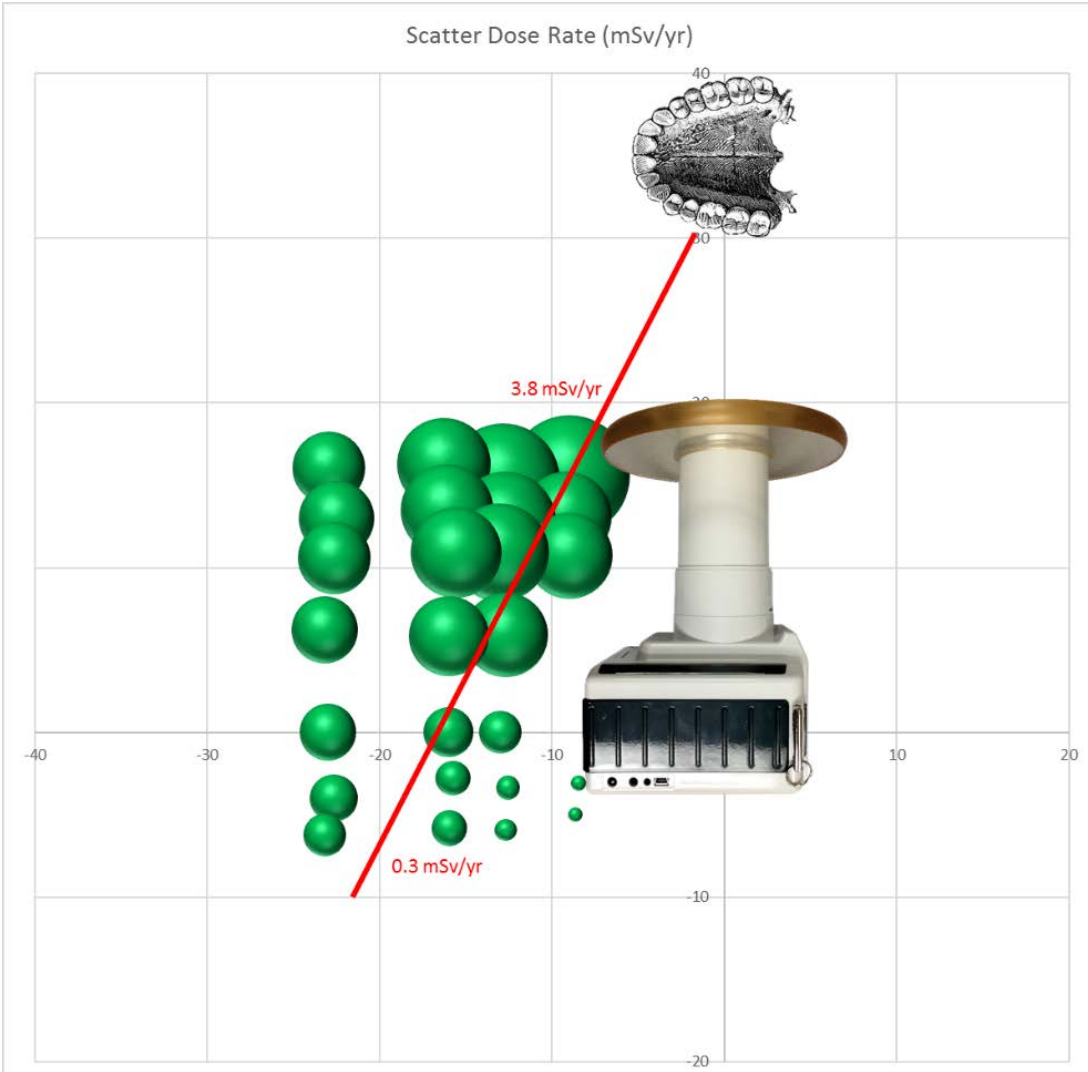
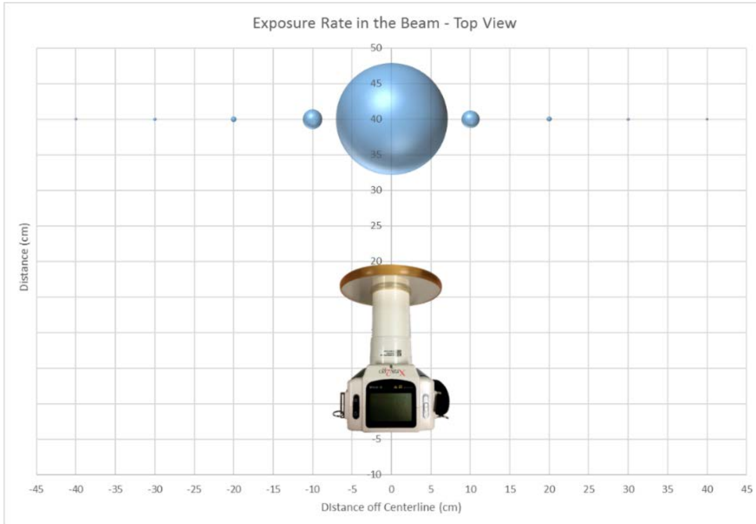


Figure 8. Side view with dose rates of 3.8 and 0.3 mSv/yr labeled for comparison. Bubbles indicate the magnitude of dose rate relative to their surface area. There is now a 10 cm gap between the end of the collimating tube and the patient's cheek.

IN-BEAM EXPOSURE RATES

We also examined exposure rate (mR/sec) directly in the beam and adjacent to the beam. These studies were carried out to determine the general shape and symmetry of the beam cone and to estimate the total filtration equivalent (in mm Al); the Xray2Go documentation states that total filtration is 1.6 mm Al.

Shape of the beam cone. Figures 9a and 9b show exposure rate at a distance of 40 cm from the plane of the focal spot, from a top view and side view, respectively. It is apparent that exposure rate along the centerline is significantly higher than the exposure rate only 10 cm off centerline. Inspection of the two plots indicates that exposure rate at 10 cm on either side of the centerline is slightly higher to the left, and significantly higher (factor of 3) toward the bottom of the beam. This may suggest that filtration is thinner toward the left/bottom of the collimating tube (as also seen in Figure 4b).



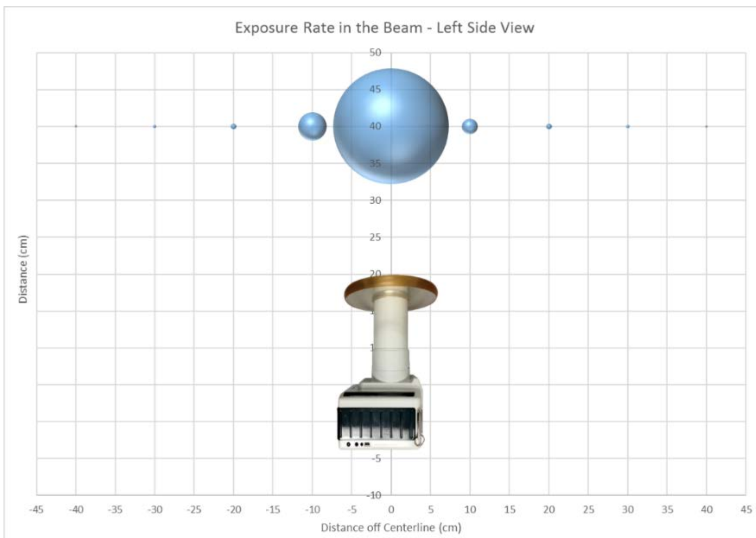


Figure 9. (a) Top view and (b) side view. Beam exposure rate at a distance of 40 cm from the focal spot is 62 mR/sec. Bubbles indicate the magnitude of exposure relative to their surface area.

Entrance skin exposure and total filtration estimate. The exposure rate is expected to drop exponentially with distance from the focal spot, both in the beam as well as other locations. We measured exposure rate at various positions directly in the beam to determine Entrance Skin Exposure (ESE) as a function of distance and to predict the total filtration equivalent (in mm of aluminum) offered by the X-ray emission device. The instructional literature for the Xray2Go states that the total filtration for the model under evaluation is 1.8 mm Al.

The ESE for this 60 kV X-ray tube, operated at 2 mAs, measured at the end of the collimating tube (20.5 cm) was 114 mR. Given this and a few other measurements (Figure 10), we determined an exponential loss equation to predict ESE at any other distance from the focal spot. Additionally, the use of Bushong's nomogram[5] (Fig. 39-1, pg 599) suggests a total filtration equivalent of 3.0 mm Al for this particular unit.

[5] S.C. Bushong. Radiological Science for the Technologist. 9th ed. Mosby Elsevier. St. Louis, Missouri. 2008.

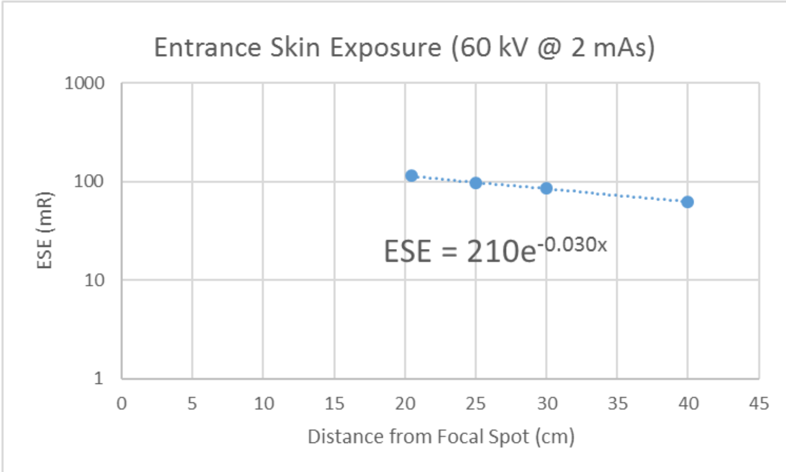


Figure 10. Entrance Skin Exposure (ESE) for 60 kV @ 2 mAs from the Xray2Go (MiniX-S) as a function of distance from the focal spot.

Measurement of beam quality (HVL). We estimated the equivalent half-value layer (HVL) of aluminum for the Xray2Go by placing different aluminum filters into the X-ray beam and measuring exposure rate. The data are shown in Figure 11. The equation fit to the data shows that the linear attenuation coefficient (μ) has a value of 0.312 mm^{-1}, indicating that the HVL is 2.2 mm Al, well in excess of the minimum 1.5 mm Al required by law (21 CFR 1020.30(m)) for an x-ray tube potential of 60 kV in specified dental systems.

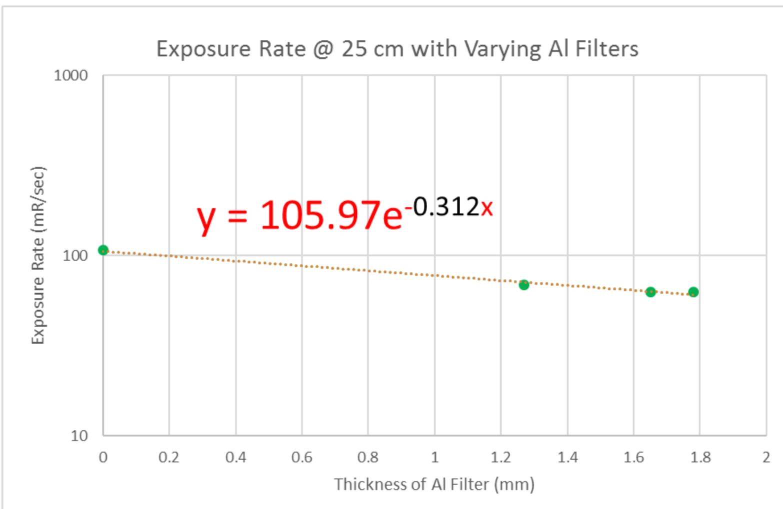


Figure 11. Exposure rate in the beam for 60 kV @ 2 mAs from the Xray2Go (MiniX-S) as a function of aluminum thickness placed into the beam. Distance from focal spot to detector is constant.

CONCLUSIONS

A safety analysis of the Xray2Go (MiniX-S) has been conducted. The data confirm that the Xray2Go is a safe device, is comparable to other hand-held X-ray units, and has design features that protect the operator keeping their occupational radiation dose to values that are thousands of times lower than those stipulated by federal law. Within our current state of knowledge, the unit is deemed safe for the operator when used as intended.