A RADIATION SAFETY ANALYSIS OF THE MaxRay Cocoon (70 kV, 1.7 mA)

by

DAVID M. HAMBY, PhD

PROFESSOR OF HEALTH PHYSICS OREGON STATE UNIVERSITY CORVALLIS, OREGON

CLINICAL PROFESSOR OF RADIATION ONCOLOGY OREGON HEALTH AND SCIENCE UNIVERSITY PORTLAND, OREGON

January 2019

INTRODUCTION

The use of X-ray in dental diagnosis has been around a long time. Historically, X-ray emission devices were mounted to the wall and thus permanently installed in any given room of a dental office. In the past decade or so, hand-held X-ray emission units have been made available and are used in many dental practices throughout the world. These X-ray units are essentially no different that the wall-mounted version, except that they are portable. This portability has given rise to questions of safety for both the patient and the device operator. 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 accumulated 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 array 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 technologist/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 the 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, must 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 MaxRay Cocoon (70 kV, 1.7 mA, Serial No. CCE180065) to validate its level of safety for dental radiography.

OBJECTIVES

Two major objectives were embarked upon at the outset of this work. Both objectives focus on the health and safety of the operator and include the measurement of leakage radiation around the unit and an analysis of the operator's exposure from radiation scattered off the patient, demonstrating the effectiveness of the integrated backscatter shield present on many hand-held units. At the end of this report, a few other additional parameters (e.g., ESE, HVL) were measured or confirmed.

EXPERIMENTAL STUDIES

Our study involved the use of the Radcal Accu-Dose¹ system and the MaxRay Cocoon². A 37 m² (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 very large compared to a dental exam room and the potential for increased exposure due to wall-scattered X rays is very low. Previous studies in our lab have indicated that wall scatter could be a contributing factor if the X-ray unit or the detector is within about 40 cm of the wall. To prevent any wall scatter from influencing measurements, all exposures were conducted at distances no closer than 1 meter from any wall/floor surface.

¹ Radcal Corporation. 426 West Duarte Road. Monrovia, CA 91016

² Iridium Dental. 6824 19th Street. University Place, WA 98466

Radcal Accu-Dose exposure instrumentation. To measure the radiation exposure caused by the handheld X-ray units, we used a Radcal Accu-Dose control unit with a 10x6-180 Ion Chamber Sensor. This sensor allowed for high-sensitivity measurements of exposure rate as low as hundredths of micro-Roentgen (μ R) per second. The 10x6-180 probe is a 100 cm² 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%.

Except for time linearity, all measurements were conducted for exposure times of 1 second, and results from the Radcal were provided in terms of either mR/sec (milli-Roentgen per second) or μ R/sec (micro-Roentgen per second), with the units automatically adjusted depending on rate of exposure. The Radcal provides a lowest single-measurement exposure rate of 0.05 μ R/sec, with smallest increments of 0.05 μ R/sec. Therefore, for very small exposure rates (on the order of 0.05 μ R/sec for some of our leakage measurements), the relative standard deviation of several measurements ("uncertainty") could be in excess of 100%. However, once exposure rates are on the order of ~1 μ R/sec or above, uncertainties drop to less than 5%.

Regarding detector orientation, previous studies have indicated that orientation is important, but its influence is only significant past an angle of about 45 degrees, and its greatest significance is shown to result in a measured reduction of only about 15%, within the uncertainty of many of the lower-level exposure measurements. Except where space was limited, all studies were conducted with the ion chamber in a perpendicular orientation to the primary source of X-rays (the focal spot for leakage, and the patient's jaw for scatter).

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.

Constancy of Exposure Rate. For this work, we analyzed the MaxRay Cocoon hand-held dental X-ray generator. As with most hand-held units, the X-ray tube potential and tube current are fixed and not adjustable by the operator. The Cocoon operates with a tube potential of 70,000 Volts (70 kV) and a tube current of 1.7 mA. The operator can change the exposure time from zero to 1.0 seconds, with the expectation that a doubling of time results in a doubling of exposure. This being the case, an experiment was conducted to determine whether the X-ray output was indeed linear with exposure time. The RadCal was used to measure total exposure for several irradiation times (Figure 1). In the plot, it is evident that all measurements fall on a straight line indicating that the Cocoon is indeed stable when adjusting exposure time (raw data are within 5%).



Figure 1. Exposure/time profile for the Cocoon. A linear fit to the data is shown (dashed blue line) demonstrating exposure linearity.

EXPOSURE STUDIES

Presentation of Data. The leakage and scatter data that follow are presented as cumulative exposure to a single operator over an assumed working year (with units of mR/yr). We have used a conservative estimate of beam exposure time given that a typical exposure is 0.1 seconds in digital radiography and an operator performs 7,200 exposures over the course of the working year. Therefore, the raw exposure measurement (M), collected as exposure during 1 second of beam time, in units of μ R/sec, is converted to an estimate of annual occupational exposure (E), using the following calculation:

$$E \left[\frac{mR}{yr} \right] = \frac{M \left[\frac{\mu R}{sec} \right] * 0.1 \left[\frac{sec}{ex} \right] * 7,200 \left[\frac{ex}{yr} \right]}{1000 \left[\frac{\mu R}{mR} \right]}$$
$$E \left[\frac{mR}{yr} \right] = 0.72 * M \left[\frac{\mu R}{sec} \right]$$

For example, a measured exposure rate of exactly 2.00 μ R/sec in the laboratory results in an estimated annual total exposure to the operator of 1.44 mR. If desired, the annual exposure could be converted to annual dose by multiplying by 0.95, i.e., 1.40 mrem in this example. Due to inherent uncertainties in all radiation measurements, we will present the data that follow to only two significant digits.

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 Cocoon to ensure its operational safety. We collected measurements at several different locations around the X-ray unit (Figure 2) in order to map its leakage radiation exposure fields. All measurements were conducted in a way that kept any potential wall scatter to a minimum. As seen in the pictures of Figure 2, the ion chamber is always positioned with its surface facing the focal spot.



Figure 2. Experimental arrangement of the Cocoon for leakage measurements

As described above, raw measurements of exposure rate (μ R/sec) were converted to annual occupational exposure estimates (mR/yr) and are presented below in all three dimensions (Figures 3a – 3c). The representation of exposure is plotted as a bubble (sphere) with its surface area proportional to its numerical value. For all leakage radiation plots, bubbles are drawn relative in size to surface area, e.g., a bubble that is twice the surface area of another bubble represents a leakage exposure that is twice its value. The bubbles in all plots of Figure 3 are sized relative to each other so that a quick examination is possible to determine comparative exposure rates and total annual exposure due to leakage.



Figure 3a. Front view of the Cocoon where the primary beam of X-rays is coming out of the page. Bubbles indicate the magnitude of exposure relative to their surface area. The units of printed values are mR/yr, exposure to the operator in an assumed working year.



Figure 3b. Top view. Bubbles indicate the magnitude of exposure relative to their surface area.



Figure 3c. Side view. Bubbles indicate the magnitude of exposure relative to their surface area.

In an examination of all three plots, we see that the greatest exposure rate for an entire working year is about 1 mR/yr (i.e., 0.95 mrem/yr to extremities). This dose is extremely small and is more than 20,000 times lower than the extremity dose allowed by the federal government³. Looking at Figure 3a, we see that exposures are generally the same all around the device, increasing slightly (within the bounds of measurement uncertainty) as the detector is moved away from the unit. This unexpected increase is likely because the detector is large relative to the size of the source, and due to its proximity, the entire detector is not exposed. Figure 3b and 3c indicate similar results with a slight increase toward the front of the unit, as expected.

³ 10CFR20.1201

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 jaw of the patient. This scatter radiation is called "backscatter" in that it is scattered back toward the operator. The MaxRay Cocoon provides a fixed leaded-plastic backscatter shield designed to provide a cone of protection in which the operator stands for maximum radiation shielding. As part of this safety analysis, we collected several of measurements 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 jaw of a human while obtaining dental radiographs. The most accurate assessment of scatter will be obtained by tests on humans. This obviously isn't possible in the laboratory, therefore we looked for the nearest surrogate. We have chosen to use an alpaca skull (Figure 4a) in water to simulate the human skull with its surface tissue. The modified skull (Figure 4b) was placed inside a plastic bag filled with water (Figure 4c) and shaped so that about 0.5 cm of water covered the surface of the bone (approximate cheek thickness).







Figure 4. (a) Original alpaca skull, (b) the modified skull, and (c) demonstration of scatter measurements.

The X-ray emission cone from the Cocoon was aimed directly at the alpaca teeth, in one experiment nearly touching the plastic bag, and then 10 cm from the bag surface to evaluate the change to operator safety. 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 5 and 6. Exposure values are again presented as spheres relative in size by surface area.



Figure 5a. Top view of the Cocoon safety zone as provided by the backscatter shield. Bubbles indicate the magnitude of exposure relative to their surface area.



Figure 5b. Side view of the Cocoon safety zone as provided by the backscatter shield. Bubbles indicate the magnitude of exposure relative to their surface area.



Figure 6. Side view of the Cocoon safety zone being reduced as the X-ray unit is moved away from the patient's jaw Bubbles indicate the magnitude of exposure relative to their surface area.

Figures 5a (top view) and 5b (side view) show the backscatter field and protected area when the operator places the X-ray cone very close to the patient's face. The backscatter shield does an excellent job of protecting the operator from higher radiation fields. The plots show that the annual exposure values are in the hundreds of mR outside the backscatter zone, but that the shielding is quite effective at keeping

total annual exposure rates within the backscatter zone to about 2 mR/yr or less (i.e., < 2 mrem/yr). The federal government maintains an occupational dose limit of 5,000 mrem⁴ to the whole body.

Figure 6 shows what can happen to the backscatter zone when the X-ray cone is moved away from the patient's jaw. As the gap between the end of the X-ray cone and the patient's face is increased, the backscatter safety zone decreases. Annual exposure rates in the safety zone are still low, but the zone is physically smaller, meaning that the operator's head or lower body could be exposed to higher radiation levels. This shows the importance of keeping 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.

Measured exposure rate and entrance skin exposure. The exposure rate was measured directly at the end of the collimation tube (21.5 cm from the focal spot) using the RadCal in accumulated-dose mode. The exposure rate at the face of the Cocoon was 111 mR/sec. A typical exposure time of 0.1 seconds would therefore result in an entrance skin exposure (ESE) of about 11 mR.

Measured HVL. The HVL of the Cocoon X-ray beam was determine by examination of attenuation in varying thicknesses of aluminum. Three aluminum filters were used with thickness of 1.27, 1.65, and 1.78 mm. Measurements of exposure for a 1 second beam with no filtration and the three filters provided the data necessary to generate an exponential attenuation equation, with an exponential coefficient of 0.29 mm⁻¹ (see Figure 7). This coefficient is the attenuation coefficient (μ) of aluminum calculated for the Cocoon beam. The HVL refers to the thickness of filtration (aluminum in this case) required to reduce the intensity (exposure rate) of the beam by a factor of two, i.e., the HVL is equal to $\ln(2)/\mu = 2.4$ mm Al.



Figure 7. Exposure rate at the face of the Cocoon as a function of attenuation filtration thickness.

Measured kV. The tube potential is measured, confirmed and specified by the manufacturer (stated as 70 kV for the MaxRay Cocoon). The tube potential cannot be measured directly without opening the device. We can, however, make a direct assessment of the effective (average) energy of the X-ray beam

⁴ 10CFR20.1201

at the same time we measured HVL. Born out of that measurement is a very specific attenuation coefficient. With this coefficient, we can estimate the beam's effective energy. As shown below, the aluminum attenuation coefficient (μ) measured for this Cocoon is 0.29 mm⁻¹. Converting this value to a mass attenuation coefficient ($\mu/\rho = 1.07 \text{ cm}^2/\text{g}$) and comparing it to the appropriate tabulated data (Johns & Cunningham, <u>The Physics of Radiology</u>, 4th ed, pg 732), we see that the effective energy of the Cocoon beam is about 31 keV. This effective energy is reasonable given the labeled 70 kV of the MaxRay device.

Measured mA. The tube current (mA) is measured, confirmed and specified by the manufacturer. The tube current cannot be measured directly without opening the device. We can, however, conduct other measurements to provide confidence in the labeled tube current. As stated above, the exposure rate at the end of the Cocoon collimation tube (21.5 cm) is 111 mR/sec. Given this, a reported tube current of 1.7 mA, and a tube potential of 70 kV, we estimate an exposure at 100-cm SID of 3.0 mR/mAs. Using Bushong's nomogram (<u>Radiologic Science for Technologist</u>, 9th ed, page 599) the estimated total filtration in the device is 3.6 mm Al, a value greater than the reported 2.3 mm Al total filtration. This result suggests increased safety (lower dose to the patient) by further hardening of the beam.

CONCLUSIONS

A safety analysis of the MaxRay Cocoon (70 kV, 1.7 mA, Serial No. CCE180065) has been conducted. The data confirm that the Cocoon 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 hundreds of times lower than those stipulated in federal law. Within our current state of knowledge, the unit is deemed safe for the operator when used as intended.

