

Radiation Safety Characteristics of the NOMAD™ Portable X-ray System

D. Clark Turner¹, Donald K. Kloos¹, Robert Morton²

¹Aribex, Inc., 754 South 400 East, Orem, UT 84097 USA, www.aribex.com

²Quality and Regulatory Services, Lincoln, CA 95648 USA

I. Introduction

An important part of a modern dental exam is radiographic imaging. While there are risks to the use of ionizing radiation, the diagnostic benefits have been determined to outweigh the risks; thus the procedures have now become routine during regular exams.

In a recent publication on radiation safety in dentistry (NCRP 145, page 45), *"It seems reasonable to conclude that radiation-related risks to dental patients and dental x-ray equipment operators are numerically very small and may be zero."*

There are many regulations and guidelines governing the development and use of diagnostic x-ray equipment. In the USA, regulations such as 21CFR1020.30, promulgated by the FDA, provide standards for equipment performance¹. Internationally, similar standards are provided in the IEC 60601-1-3 document². Voluntary guidelines have been provided by the National Council on Radiation Protection and Measurement (NCRP) for use of radiation protection in dentistry³. Many states regulate the use of x-ray equipment per the CRCPD's Suggested State Regulations for the Control of Radiation⁴.

An important consideration is: are these older guidelines still applicable as x-ray equipment technology has continued to evolve and improve?

For example, a new handheld, battery-powered, x-ray system has been developed for use in intra-oral radiographic imaging. The NOMAD system is shown in Figure 1 below. This technology is disruptive, as it seems on first consideration to be inconsistent with the regulations and guidelines mentioned above.

There are several concerns in the guidelines that must be specifically addressed when considering the use of NOMAD as a diagnostic radiation source:

- 1) Normally, the x-ray tube assembly must be able to be mounted so that it is not held in the operators' hand (SSRCR, F4g).
- 2) The operator must trigger the x-ray exposure from a distance of 2m from the x-ray tube

assembly, preferably behind a barrier (SSRCR, F7c.2).

These concerns stem from three areas: A) Leakage radiation that is transmitted through the primary system shielding to irradiate the operator, B) Backscattered radiation from the patient (particularly the skin and teeth for dental x-rays) that can impinge on the operator, and C) Inadequate image quality will be obtained if the x-ray tube head moves during the exposure time, requiring a second irradiation of the patient.

The intent of this paper is to show that the potential risks of radiation exposure to the operator and patient from NOMAD are sufficiently small as to more than meet the regulatory standards for stationary equipment, and to meet the intent of the "as low as reasonably achievable" (ALARA) principle when considering the economic and social factors.



Figure 1. NOMAD portable handheld x-ray system.

II. Other Handheld X-ray Systems

The idea of handheld portable x-ray equipment is not new. There are a number of other x-ray tube-based handheld systems. For example, tube-based x-ray fluorescence (XRF) analyzers have been developed in the last 10 years for use in materials analysis, scrap metal sorting, lead in paint analysis, and other applications.⁵

An example of a battery-powered unit is shown in Figure 2. Systems have been developed for portable imaging, including one intra-oral dental system that is FDA cleared for marketing to the US military.⁶ A system photo is shown in Figure 3. While portable, this system still requires connection to AC electrical supply.



Figure 2. NITON handheld battery-powered XRF analyzer.



Figure 3. Dental EZ Portable HDX Intra-oral X-ray System.

III. NOMAD™ System Description

The NOMAD system is a handheld, battery-operated, portable device. It is powered by a 14.4 volt rechargeable battery. The unit is designed with reduced weight and size for easy manipulation by the operator. The system specifications typical for the unit are given in Table 1 below.

Table 1. Summary specifications for NOMAD.

PARAMETER	VALUE
Anode voltage	60kV
Anode current	2.3 mA
Exposure time range	0.01 – 0.99 s
Focal spot size	0.4mm
Minimum inherent filtration	1.5mm Al equivalent
Source to skin distance	20cm
X-ray field	60mm round
Maximum duty cycle	1s:60s
Total weight	<4kg

There are several features of the NOMAD that address the safety concerns mentioned in the introduction. Refer to Figure 4 for graphical interpretation of these features as they are discussed.

First, the high-voltage power supply is a high-frequency DC unit, which reduces the dose to the patient. More will be said about this later. Second, the x-ray tube is surrounded by compounds of heavy metals to reduce the leakage radiation from the tube. (These compounds are not Pb, but a proprietary mixture designed to provide equivalent or better shielding.) The beam limiting device (exit cone) is lined with Pb. This would not normally be required in a dental unit, as the exit cone is defined by Pb apertures closer to the tube. However, in our case, backscattered radiation from the patient could travel through the exit cone and impinge on the operators' hand. This backscattered radiation is absorbed in the lead-lined cone.

Backscattered radiation is also absorbed in a Pb-filled acrylic shield attached at the end of the exit cone. This shield has a Pb-equivalent of 0.5mm thickness, and protects the operators' torso, hands, face, and gonads from backscattered radiation from the patient's face and teeth.

NOMAD has the other beam quality and safety features normally specified for dental intra-oral systems. The minimum inherent filtration in the x-ray beam is at least 1.5mm Al equivalent. The source-to-skin distance is a minimum of 20 cm. The radiographic technique factors of peak potential and anode current are both fixed at 60kV and 2.3mA respectively. The only operator-adjustable parameter is the irradiation time, which varies from 0.01 to 0.99 seconds.

IV. Radiation Protection of the Patient

The main consideration in any radiographic procedure involving live patients is to reduce the dose to the patient as much as possible while still achieving the diagnostic goals. Intra-oral dental radiography has been shown to be safe and effective, and the radiation risks are low relative to the patient benefits.⁷ NOMAD was designed to operate with technique factors that help to maintain this safe operating region:

- High-frequency, constant potential, has been shown to reduce patient dose by up to 1/3 per image.⁸
- System is optimized for digital sensors at 60kV. Digital sensors reduce the dose per image by 1/4th to 1/10th compared with conventional film.
- Beam is limited to 6cm diameter, rather than the allowed 7cm. This smaller irradiation area reduces the patient dose by 25% without significantly compromising the beam aiming capability.

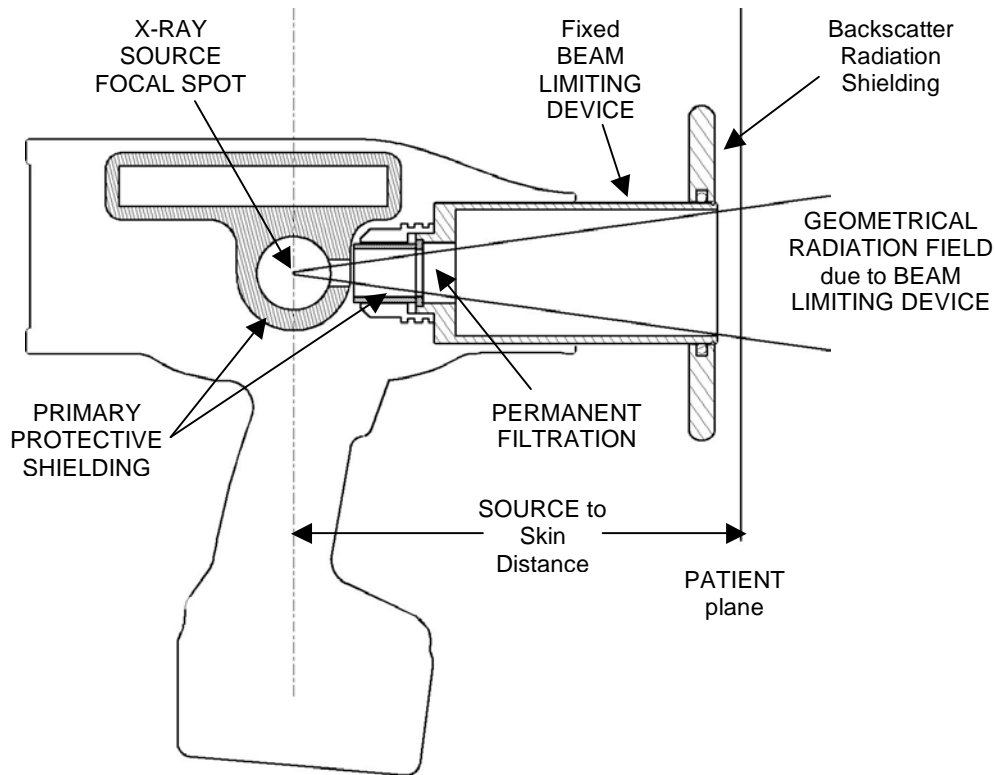


Figure 4. Cross-section of the NOMAD showing the relevant safety features.

V. Radiation Protection of the Operator

The effective radiation exposure to the operator is the sum of any radiation that is leaking from the x-ray tube source assembly (Leakage Radiation) and any radiation that scatters from the patient or any objects in the room that are in the x-ray field (Backscattered Radiation) and gets back to the operator's body.

The normal practice is to provide a means for the operator to trigger the x-ray irradiation from a position outside the room with the x-ray source. Alternatively, another approach is to provide a physical barrier between the operator and the source. These barriers are specified to be 2 meters in height to protect the tallest operators.

a. Leakage Radiation

This is the highest concern. Since the operator is holding the x-ray source assembly the principle of "distance" as a safety factor cannot apply. The USFDA regulations state that the maximum permissible radiation leakage from the x-ray source assembly is 100mR/hour measured at a distance of 1 meter from the x-ray source. To find possible "hot spots" of leakage, the limit is specified to be averaged over an area of 100cm², and it should be measured at enough sites to approximate a sphere around the instrument. The IEC specification is even more rigorous at 0.25mGy/hr (25mR/hr) as the limit.

To characterize the NOMAD, measurements of leakage radiation were made at 11 different sites to approximate a sphere around the instrument. These sites are shown in Figure 5 below. All exposure measurements were made using a RadCal MDH Model 1015 x-ray monitor S/N: 1535 (last NIST-traceable, MQSA required calibration on July 30, 2004). Leakage exposure measurements were made using a pancake probe S/N: 5464 with the probe placed at 1 meter from the focal spot of the x-ray source. Measurements were made on 3 different NOMAD instruments.

As can be seen from the first 3 columns in Table 2, no x-radiation could be detected at 1 meter distance. The probe was then positioned at 5 cm from the case housing, and the leakage radiation measurements were performed on two of the instruments. These data are reported in the next section of Table 2. The results are still significantly below the FDA and IEC limits (100mR/hr and 25mR/hr respectively), even at this short distance.

Finally, to verify this result on a statistically significant sample, 10 NOMAD instruments were tested for leakage at the case with a Victoreen 451 Survey Meter with a 20cm² lead aperture over the detector. The results were normalized to 100cm² area, and the average and maximum at each of the 11 sites are reported in the last columns of Table 2. These results suggest that there is no significant leakage radiation from the NOMAD design.

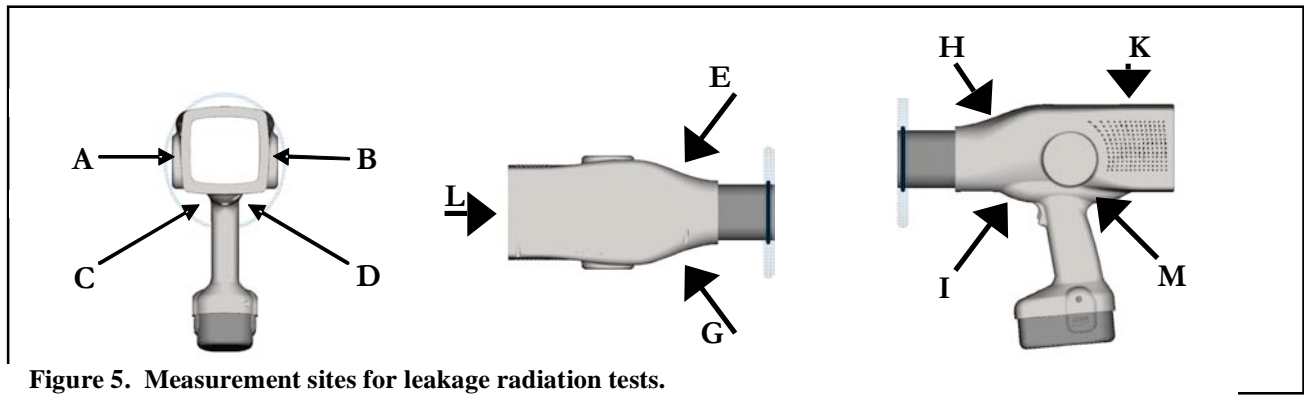


Figure 5. Measurement sites for leakage radiation tests.

Table 2. Radiation Leakage Measurements. (See Figure 2 for measurement sites.)

Site	021405-01	021405-02	021405-03	Serial #	021405-02	021405-03	10 Units - Average	10 Units - Maximum
	100 cm from source	100 cm from source	100 cm from source	Distance from source	5 cm from case	5 cm from case	5 cm from case	5 cm from case
	mR/hr	mR/hr	mR/hr	Units	mR/hr	mR/hr	mR/hr	mR/hr
A	ND	ND	ND		0.84	0.12	ND	ND
B	ND	ND	ND		0.48	0.72	ND	ND
C	ND	ND	ND		1.44	0.72	0.72	0.90
D	ND	ND	ND		1.32	1.92	0.80	1.20
E	ND	ND	ND		0.84	2.28	2.38	3.60
G	ND	ND	ND		1.32	2.16	2.11	3.00
H	ND	ND	ND		2.16	2.28	2.11	3.30
I	ND	ND	ND		2.88	2.04	1.18	3.00
K	ND	ND	ND		0.12	ND	ND	ND
L	ND	ND	ND		ND	ND	ND	ND
M	ND	ND	ND		ND	ND	0.58	0.90
Max	ND	ND	ND		2.88	2.04	2.38	3.60

ND – None detected. Detection limit is 0.001mR per exposure (0.06mR/hour at 1:60 duty cycle and maximum exposure time of 0.99 seconds.)

Table 3. Radiation Leakage Measurements from traditional stationary dental systems.

Site	A	A	Unit #	B	B
	100 cm from source	5 cm from case	Distance from source	100 cm from source	5 cm from case
	mR/hr	mR/hr	Units	mR/hr	mR/hr
A		8.28		1.44	12.6
B		1.08			0.18
C					
D					
E	1.44	39.6			
G		24.0			
H		27.5			6.48
I		3.21			6.30
K		6.12		0.36	5.58
L		1.26			ND
M		4.26			6.30
Max	1.44	39.6		1.44	12.6

An interesting consideration is how NOMAD compares to conventional stationary x-ray systems with respect to leakage radiation. Two different stationary dental intra-oral x-ray systems were measured with the Victoreen survey meter at 5 cm from the case. The location showing the highest leakage was measured again at a distance of 1 meter from the focal spot. The results are reported in Table 3 above. It is interesting to note that the readings are generally higher than those of the NOMADs, and that the highest reading recorded, almost 40mR/hr at the case, was on one of the stationary systems.

b. Backscatter Radiation

An important consideration, not addressed in the FDA regulations, but included in the Annex of the IEC60601-1-3 standard, is the level of backscatter radiation incident on the operator of an x-ray system. The IEC standard defines a "zone of significant occupancy" within which the operator can be standing. This standard is specifically designed for fluoroscopic applications where the operator would be standing next to the patient, but it can be applied to NOMAD since the operator will be holding the source and standing next to the patient.

Figure 6 shows the geometrical definition of the zone of occupancy. Based on the size of the backscatter shield, a cone of protected space envelopes the NOMAD instrument and the area where the operator is standing. To test this zone, measurements of the backscattered radiation were made at the plane defined by the back of the NOMAD instrument (marked with a scale in Figure 6.) The sample was a dental phantom prepared for the NEXT test protocol⁹ by Cardinal Health, catalog #76-025. The density and composition of the plastic in this phantom is designed to permit an accurate simulated clinical image evaluation. Measurements were made with and without the backscatter shield in place. The chart in Figure 6 shows the recorded radiation measurements as a function of height from the floor, with the NOMAD positioned at 1 meter above the floor. The measurement probe was the Radcal MDH pancake probe with active area of 100cm².

The scattered radiation recorded in a 1 second exposure was normalized to one hour of operation by multiplying the result by 60 exposures per hour at the maximum duty cycle of 1:60. It can be seen from Figure 6 that the backscatter shield reduces the exposure by almost 1 order of magnitude compared with the results without the shield. This result is consistent with the Pb-equivalence of the plastic, which is 0.5mm thickness of Pb equivalent. Since the half-value thickness for 60keV x-rays in Pb is about 0.2 mm, the measured result is consistent with about 2.5 half layers, or 0.5mm thickness. It should also be noted that the level of backscattered

radiation at the back of the instrument, with no shield, is on the same order as the leakage radiation at the case. It is also significantly below the 100 mR/hr "safe" limit. With the shield in place, the backscattered radiation is sufficiently attenuated that the leakage radiation becomes the primary contributor to the operator dose.

c. Total Dose calculations

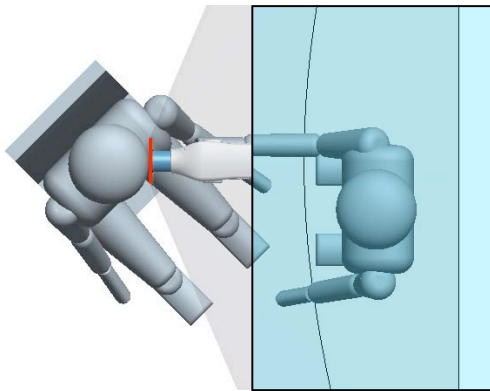
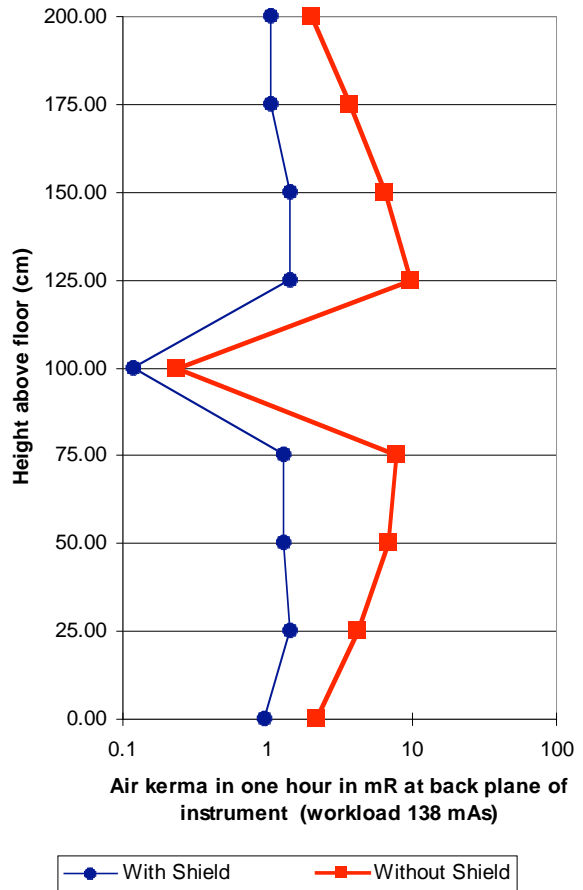
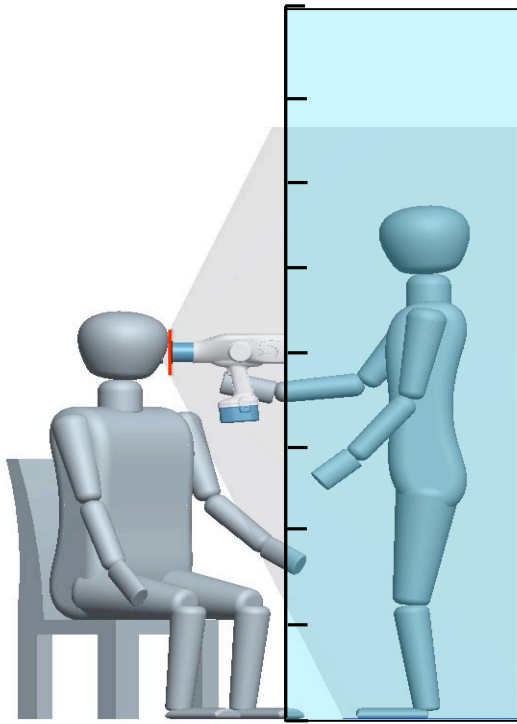
Given the Leakage Radiation and Backscatter Radiation measurements at the instrument backplane, it is possible to estimate the maximum dose that would be received by an operator using the NOMAD. The typical whole body exposure to the operator can be estimated using the measured sum of backscatter and leakage radiation level at the control panel of approximately 1 mR/hr. This is at the maximum duty cycle of 60 images per hour. NCRP reports that a high-volume dental practice would take 300 images per week. This would then produce 5mR of operator exposure per week, if each image required a full 1 second dose of radiation. However, typical Kodak D speed film requires an irradiation time of only 0.5 seconds, reducing the weekly exposure to 2.5mR. If digital sensors are used, the typical exposure time is only 0.1 second, reducing the weekly exposure to 0.5mR. This suggests annual exposures of 130mR in an operatory using film, and 26 mR in an office using digital sensors, *if* only one operator takes all the images. In a typical practice this workload would be shared between 2 or more operators, so the results reported in Table 4 assume 2 operators in the practice.

Exposure to the hand is even more benign relative to the recommended exposure limits. The highest leakage data was 3.6mR/hr. Table 4 shows the cumulative hand exposure for the same 300 films per week, at reduced exposure times for film and digital sensors and 2 operators sharing the load.

NCRP gives a recommended annual occupational dose limit at 50mSv, with an exposure limit to the skin, hands, and feet of 500mSv. These levels are easily achieved with the NOMAD.

Table 4. Total Annual Operator Exposures

Hand/Extremity Exposure	mR	mSv
NCRP recommended limit	50,000	500
Typical NOMAD used with film	240	2.4
Typical NOMAD used with digital	47	.47
Whole Body Exposure		
NCRP recommended limit	5,000	50
Typical NOMAD used with film	65	0.65
Typical NOMAD used with digital	13	0.13
Average annual background in USA	295	2.95



ZONE OF SIGNIFICANT OCCUPANCY

Figure 6. Example of the "zone of significant occupancy" for the NOMAD system.

VI. Protection of the Public

NOMAD is intended to be used in the same settings, and with the same protocols, as stationary dental x-ray equipment. Since the instrument is ambulatory, training must be provided about good radiation practice in areas outside the dental office. In general, if standard radiology protocols are utilized, there is no reason that this portable instrument should be less safe than a stationary unit.



Figure 7. Postmortem image collected with a digital sensor.

VII. Image Quality

An important safety consideration is the ability to take a quality image with a handheld system. One of the reasons that existing standards require the x-ray tube assembly to be mounted in a stationary position is so that stability of the instrument can be assured. Any blurred or sloppy pictures require another irradiation of the patient. These should be avoided whenever possible.

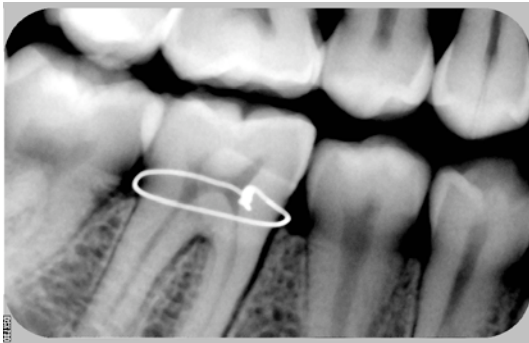


Figure 8. Skull phantom imaged with a

We have taken a significant number of images using both conventional dental film and several different brands of digital sensors. In all cases - with reasonable care to steady the instrument with both hands - the operator has been successful in creating dental images of comparable quality to stationary systems. Examples of digital and film-captured images are shown in Figures 7-10. (These samples were primarily on full-head phantoms, although NOMAD units have been in use in dental clinics in Thailand since December, 2004.)



Figure 9. Implant check using D speed film.



Figure 10. Root canal monitoring using D speed film.

VIII. Summary

We have shown that use of NOMAD in its intended applications presents no more risk to the operator or the patient than using stationary x-ray equipment. With moderate care, the operator can prevent any risk to the public. We have also shown that the image quality rivals that of stationary equipment, even when the x-ray source is handheld – particularly in cases using digital sensors with correspondingly short exposure times.

IX. Acknowledgements

The authors wish to thank Ann M. Jones of Medical Physics Consultants, Jason McCeighen, and Khoi Nguyen for the leakage radiation measurements and backscattered radiation measurements on the NOMAD devices.

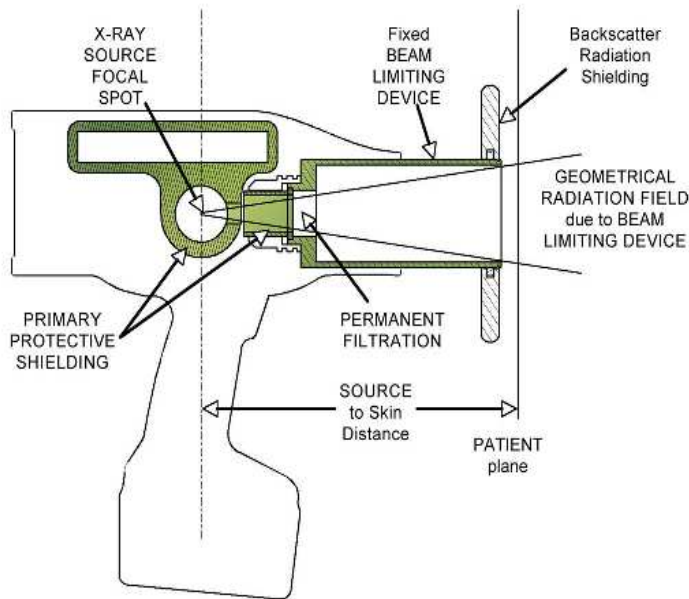
X. References

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6. "DentalEZ Portable HDX Intraoral X-ray," User's Manual, Flow X-ray Inc., 03/2000.
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8. Compendium Report, May 1993, Vol. XIV, No. 5, "X-Radiation: Potential Risks and Dose Reduction Mechanisms."
9. NEXT (Nationwide Evaluation of X-Ray Trends) is a committee of the Conference of Radiation Control Program Directors (CRCPD) that oversees quality control procedures for diagnostic radiology

ARIBEX INC.

A DISCUSSION ON LEAKAGE RADIATION June 2006

The **primary protective barrier** for leakage from the NOMAD™ is the shielding that surrounds the x-ray tube. The x-ray tube is potted with heavy metals impregnated in silicone for radiation shielding and the collimator is shielded with a lead lining so that it is safe even if the operator has their hand on the collimator. This construction limits any leakage radiation from the device to be considerably below the maximum allowable exposure limits called out by both the state and federal requirements.



In the study published by ARIBEX summarizing data collected by both ARIBEX and Underwriters Laboratory (UL), *Radiation Safety Characteristics of the NOMAD™ Portable X-ray System*, it is shown that in “worst case” situation that an operator has a potential of receiving an exposure of 3.6 mR/hr leakage at the hand. This is based on worst case use of the NOMAD™, taking 60 exposures per hour at a maximum exposure of .99 second each. It could be argued that this does not represent the actual potential exposures since it is not practical that a dentist would take 60 exposures in an hour and the slowest film only requires an exposure time of .5 seconds. Taking this into account, the actual exposure per hour will be much lower than recorded. The typical leakage exposure for an operator doing a maximum of 300 images per week is shown in the last column of Table 1.

However, to remove the possibility of exposure from any potential use that may approach the worst case situation used in our study, ARIBEX has enhanced the primary shielding to reduce the leakage even further. This modification has just recently been completed and the NOMAD™ has been revised to include the additional shielding in all systems that are now being manufactured and shipped. Since the modification, 36 NOMAD™ systems have been shipped to customers. The leakage levels measured at the case for the 36 systems that have been shipped are summarized in the following table.

Table 1 - Leakage Radiation – Comparison

JUNE 2006 – ARIBEX INC.

	Test Results Original – Worst Case					Test Results New – Worst Case		Test Results New - Typical	
	Serial # 02145-02	Serial # 021405-03	10 Units Average	10 Units Maximum	10 Units Maximum	36 Units Maximum	36 Units Average	36 Units Maximum	36 Units Average
	5 cm from case - UL	5 cm from case - UL	At case ARIBEX	At case ARIBEX	1 meter UL	At case ARIBEX	At case ARIBEX	At case ARIBEX	At case ARIBEX
	mR/hr	mR/hr	mR/hr	mR/hr	mR/hr	mR/hr	mR/hr	mR/hr	mR/hr
Exp / wk	2400	2400	2400	2400	2400	2400	2400	300	300
Exp Time	.99 sec	.99 sec	.99 sec	.99 sec	.99 sec	.99 sec	.99 sec	.50 sec	.50 sec
A	0.84	0.12	ND	ND	ND	ND	ND	ND	ND
B	0.48	0.72	ND	ND	ND	ND	ND	ND	ND
C	1.44	0.72	0.72	0.90	ND	0.3	0.3	.019	.019
D	1.32	1.92	0.80	1.20	ND	0.6	0.2	.038	.013
E	0.84	2.28	2.38	3.60	ND	0.6	0.18	.038	.011
F	1.32	2.16	2.11	3.00	ND	0.6	0.06	.038	.004
G	2.16	2.28	2.11	3.30	ND	0.9	0.52	.056	.033
H	2.88	2.04	1.18	3.33	ND	0.6	0.05	.038	.003
I	ND	ND	0.58	0.90	ND	0.6	0.08	.038	.005
MAX	2.88	2.04	2.38	3.60	ND	0.9	0.52	.056	.033

Note Improvement with
new design

Typical with High
Volume Usage

SITE WHERE MEASUREMENTS TAKEN

