RESEARCH ARTICLE

Operator safety during the acquisition of intraoral images with a handheld and portable X-ray device

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Objectives: The present study aims at investigating different radiation protection issues and dose values while acquiring intraoral images with a handheld X-ray device.

Methods: An Aribex NOMAD Pro 2^{TM}, a RANDO® male head phantom, a consistency testing body, a PTW NOMEX® Multimeter, and a PTW Farmer® Ionization Chamber Type 30,010 were used to investigate: (1) dose area products; (2) the expansion of the control area (CA); (3) the scattering pattern and (4) the potential risk for operators of the X-ray device.

Results: Dose area products at different exposure times were distributed linearly with a high correlation factor (>0.9). At 4000 simulated exposures, the greatest extent of the CA was 42 cm (mean = 16.7 cm, SD = 10.8 cm). The highest occurrence of scattering radiation resulted between the RANDO® phantom and the X-ray device. No scattered radiation was measured at the dorsal part of the phantom or on the operator site of a virtual vertical plane through the focal spot of the X-ray.

Conclusions: Through this study, we could demonstrate that the application of an Aribex NOMAD Pro 2 device for intraoral imaging does not increase the risk for the operator if the device is controlled according to the manufacturer's specifications. Furthermore, we were able to show that the CA was significantly smaller than specified by European and other international radiation protection standards.

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Introduction

A portable and handheld X-ray device can help to reduce acquisition and maintenance costs of multiple and wall mounted X-ray units. Transportation of bedridden people can be complicated and inconvenient for the patient. Hence, an important application of handheld and portable systems is the dental treatment of patients in retirement homes. Patients often must be treated without the reliability of intraoral (IO) X-rays. Additional fields of applications for mobile X-ray systems are their use in field (humanitarian aid) and forensic science.

Systems were successfully used by Federal Criminal Police Offices and Interpol for identification purposes after the massive Tsunami catastrophe in southeast Asia in December 2004. In countries outside the European Union, these handheld devices are used in daily practice. [Figure 1](#) displays a system intended to acquire IO X-rays.

Most IO X-ray systems are wall-mounted or coupled with a dental examination chair. These systems work between 50 and 70 kV, 2 and 5 mA and exposure times between 0.1 and 0.5 s. In some dental practices, an IO X-ray system is installed in all examination rooms so that the patient can stay in the chair during individual treatment steps.

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Figure 1 NOMAD Pro 2™ handheld and portable X-ray system.

What kind of difficulties may surface when we want to operate a handheld and portable system in European countries? In Germany, we have to take a look into the “ordinance on the protection against risks arising from X-ray” (XRO).¹ The control area (CA) is specified in § 19. Each person can collect an effective Dose (E) of equal or higher than 6 mSv within the CA if he/she permanently remains there. Ideally, the extent of the CA must match the extent of the X-ray room. During the acquisition of X-rays, the CA must be clearly recognizable to prevent unauthorized persons from entering the area by mistake. Further, it is stated in the XRO in § 20 that any X-ray system should only be used in a room that is enclosed on all sides. For portable X-ray systems, these are the first obstacles to overcome. Exception may only be accepted if required by the health of the patient, as stated in § 4 Paragraph 4 of the XRO.

Another hurdle is that the operator is not allowed to enter the CA throughout the time of exposition. Only if required, a person may enter the CA (§ 22 No. 2a). In such cases, this person must be equipped with appropriate protection against hazards rising from radiation.

The “Guideline for the radiation expert’s examination according to the German X-ray ordinance” (German: Richtlinie für Sachverständigenprüfungen nach der Röntgenverordnung)² is an important document; it includes an inspection report (2.2.5: Dental X-ray systems with tube) that has to be taken into account. It defines the minimal metrical extension of the CA independent of any kind of dose measurements. In Section D No. 3 (05D01), the establishment, delineation, and labeling of the CA are claimed in accordance with § 19 Paragraphs 1 and 2 of the XRO. Further, the release switch must be situated at least 1.5 metres away from the X-ray source or behind a mobile radiation shield. This leads to obscurities and gives room for different interpretations of the issue. The phrasing in this section could stop the admission examination for a handheld and portable X-ray system.

Finally, a glance at the relevant sections of the DIN 6815 (Medical X-ray equipment up to 300 kV: Rules

Table 1 Results of blank measurement

System	NOMEX®	Farmer®
Air KERMA (μGy)	2078	2090
Air KERMA rate ($\mu\text{Gy s}^{-1}$)	2027	
Exposure time (s)	1.03	
Average kVp (kV)	61.1	
Max kVp (kV)	61.1	
Filtering (mm Al)	1.5	
Pulses (n)	1	

for testing of radiation protection after installation, maintenance, and essential modification)³ is necessary. The delineation of the CA is defined in Section 4.1 of the document. It is claimed that the boundaries of the CA should be congruent with the size of the X-ray room. According to this phrasing, the use of a mobile system in the field is forbidden. The most critical point, however, can be found in Table 1 of the document (minimal extent of the CA for specific X-ray systems). In row 1, the minimal radius of the CA is specified as 1.5 metres or more with the X-ray source or the patient as the centre.

Although mobile and handheld systems are used frequently in some countries, radiation protection parameters have not been assessed in detail. One of the first publications dealing with handheld and portable X-ray devices was a statement paper formulated by a workgroup within the European Academy of Dentomaxillofacial Radiology in 2015.⁴ To the best of our knowledge, only two more publications are available to approach this topic. Both studies evaluated the E accumulated by the operator while using a handheld and portable X-ray device.^{5,6} Both papers did not find a significant increase of the E for the operator.

Therefore, the aim of the present study was to measure radiation protection and dose values when acquiring IO images with a handheld and portable X-ray system. Precisely, operator safety during the acquisition, the real extent of the CA and technical specifications given in the X-ray system’s manual were evaluated.

Methods and materials

A NOMAD Pro 2 (Aribex Inc., Charlotte, NC), as shown in Figure 1, was employed in this study. It was equipped with a lithium polymer battery with 22.2 V and 1.25 Ah, a tube voltage of 60 kV DC, and a tube current of 2.5 mA. Exposure times could be set between 0.02 and 1 s. The size of the focal spot was 0.4 mm and the total filtering was >1.5 mm of aluminium-equivalent. The primary beam had a circular diameter of 6 cm and the minimum focus skin distance was 21 cm. A lead-filled acrylic ring with a diameter of 16 cm, which had 0.5 mm lead-equivalent, was attached at the patient’s end of the tube.

For all examinations, the NOMAD PRO 2™ was mounted on a tripod and the beam angulation was set horizontally where the focal spot F and the centre of the tube opening T were at a height of 110 cm.

The cable-run triggering of exposures was realized with a setting servo (Graupner, Kirchheim unter Teck, Germany), which was mounted onto the shutter release button of the X-ray device and controlled via an open source ARDUINO UNO Board microcontroller (Arduino S.r.l., Strambino, Italy). The code was written in the ARDUINO software v. 1.6.6 and transferred to the board by using a USB 2.0 type A/B cable.

A RANDO® male head phantom type SK 150 (The Phantom Laboratory, Salem, NY) mounted on a tripod was used to simulate a patient's head. The phantom consisted of a real skull embedded in X-ray soft tissue-equivalent material. For the simulation of a left bitewing image, the phantom was placed in front of the NOMAD Pro 2 system.

A consistency test body (CTB) (SOREDEX®, Tuusula, Finland) was used as a second phantom to imitate a scattering body. It had a height of 8.5 cm, a diameter of 14 cm and consisted of PMMA for the approximate simulation of homogeneous soft tissue-equivalent material. The CTB was situated directly in front of the tube opening T at a height of 110 cm.

To measure the air KERMA K_a , two different dose-meters were utilized to compensate for system specific errors. The first dosimeter was a PTW NOMEX® Multimeter (PTW-Freiburg, Freiburg, Germany) for absolute dosimetry and quality assurance. This dosimeter was designed for K_a measurement, that ranges from 50 nGy up to 500 Gy, with a possible deviation of $\pm 3.5\%$, and K_a rate ranging from $5 \mu\text{Gy s}^{-1}$ up to 500 mGy s^{-1} , with a possible deviation of ± 3.5 . The trigger level was at least 10 nGy s^{-1} . Within the measurement range between $0.1 \mu\text{Gy s}^{-1}$ and 500 mGy s^{-1} , a possible deviation of up to $\pm 5\%$ was indicated. The PTW NOMEX Multimeter was also able to determine the filtering of the tested X-ray systems that ranges from >1.5 to 40 mm aluminium-equivalent, with a possible deviation of $\pm 10\%$. The tube voltage of a tested X-ray system could be determined between 40 and 150 kV, with a possible deviation of $\pm 1.5\%$.

The PTW NOMEX Multimeter was connected via an USB 2.0 type A to mini-B cable to a MacBook Pro Retina 13", mid 2014 (Apple, Cupertino, CA, USA), with Mac OS X v10.11.3. On a virtual Windows 10 Pro machine under Parallels Desktop® 11 for Mac, v. 11.1.3 (Parallels® Inc., Seattle, WA, USA), the PTW-NOMEX software was installed as v. 2.0.

As a second dosimeter, a PTW Farmer® Ionization Chamber Type 30,010 (PTW-Freiburg, Freiburg, Germany) with a sensitive volume of 0.6 mm^3 was applied. The dosimeter was also designed for absolute dosimetry of K_a within a span of photon radiation from 30 kV to 50 MV. It was calibrated with ^{60}Co reference radiation. The required operating voltage was provided by a UNIDOS®

E (PTW-Freiburg, Freiburg, Germany) to which the PTW Farmer Ionization chamber was connected.

A PTW DIAMENTOR® E2 DAP Meter (PTW-Freiburg, Freiburg, Germany) with an appropriate measuring chamber was applied to quantify the DAP.

The evaluation and graphical representation of data were performed in MATLAB® (MathWorks Inc., Natick, MA, USA) vR2014b. The surface plots depicted for the measurements have been processed in part through a 4/16 finite-impulse-response (FIR) filter. Therefore, data were interpolated, which led to a smoothed representation of the final result.

As a preliminary point, the NOMAD Pro 2 was tested for radiation leakage from the housing. In addition, the information provided by the manufacturer regarding the adjacent tube voltage, the tube current, as well as the filtering and the selected exposure time, were confirmed with the PTW NOMEX Multimeter located in front of the tube opening T and around the housing.

Determination of the DAP

The measuring chamber attached to the PTW DIAMENTOR E2 was positioned directly in front of the tube opening T . As the tube voltage and current were fixed, only different exposure times t_e were tested. The measurements were repeated five times and averaged afterwards.

Determination of the CA

To define the true CA, a blank measurement without a scattering body was taken at a distance of 35 cm from the focal spot F with both dosimeters and with the K_a determined at an exposure time t_e of 1 s, a tube voltage of 60 kV, and a tube current of 2.5 mA. The results are presented in Table 1. Then, the CTB was placed directly in front of the tube opening T mounted on a tripod. To reduce scattering radiation from the tripod, the CTB was placed on several layers of thin wood. To measure the radius R_{CA} of the CA, a plumb line was fixed directly above the centre of the CTB at the point C_{CTB} , which could be rotated horizontally in a full 360° around the CTB. The PTW Farmer Ionization Chamber was now moved in circular sections of 10 degrees around the CTB body and the point C_{CTB} . The sensitive volume of the chamber was 110 cm above the ground and, thus, at the same level as the focal spot F . At the exposure time t_e of 1 s, the distance from the PTW Farmer Ionization Chamber to the point C_{CTB} was decreased and the measurement was repeated until the UNIDOS® E showed a value of exactly $6 \mu\text{Gy}$. Each radius R_{CA} between 0 and 350° from the PTW Farmer Ionization Chamber to the point C_{CTB} was recorded and is displayed in Table 2 and Figure 2.

An exposure time of 0.25 s would be rarely exceeded in real life. If the measured $6 \mu\text{Gy s}^{-1}$ are multiplied by 0.25 s, it is possible to derive a total number of 4000 acquisitions with a measured K_a of $1.5 \mu\text{Gy}$ per acquisition at the determined distance R_{CA} .

Table 2 Distance of the ionization chamber from the centre of the CTB

Degree (°)	Distances (cm)
0	35
10	42
20	13
30	15
40	15
50	17
60	16
70	15
80	18
90	20
100	21
110	25
120	22
130	17
140	29
150	0
160	0
170	0
180	0
190	0
200	0
210	0
220	28
230	17
240	22
250	26
260	21
270	19
280	17
290	15
300	15
310	17
320	14
330	15
340	13
350	42

Evaluation of the scattering pattern

Plumb lines were attached at the housing near and below the focal spot *F* and the tube opening *T* of the NOMAD PRO 2™. On the floor, a marking on a fixed piece of paper for each plumb line indicated their corresponding positions and defined the respective tube opening *T* and the focal spot *F* in a two-dimensional plane. The RANDO® phantom was positioned for the acquisition of a left bitewing, as shown in Figure 3, in front of the NOMAD PRO 2.

A grid pattern was set over the entire floor below the X-ray device, which had a resolution of 1 cm for measurements with the PTW NOMEX® Multimeter

and a resolution of 2 cm for measurements with the PTW Farmer Ionization Chamber. Both dosimeters were also mounted holders on a tripod and aligned with the sensitive volume located at a height of 110 cm. The plumb lines were also attached as close as possible to the smallest horizontal distance to the sensitive volume. All measurements carried out were mapped with sufficient accuracy.

Initially, the PTW Farmer Ionization Chamber was placed at 90 different sites around the RANDO® phantom. The *K_a* reached at the exposure time *t_e* of 1 s, the tube voltage of 60 kV, and the tube current of 2.5 mA was recorded and registered in the corresponding grid.

Then, to determine a scattered radiation pattern, the experimental set-up, as described above, was performed with the PTW NOMEX® Multimeter. Furthermore, the number of measurement sites was reduced and confined to an area directly ventral to the RANDO® Phantom. Fewer measurements could be acquired in the area between the RANDO® head phantom and the protection shield because of the dimensions of the dosimeters.

Measurement of the *K_a* on the focal spot plane and on the z-axis of the RANDO® head phantom

In a virtual plane *P_F* through the focal spot *F*, which was set perpendicular to the beam direction, *K_a* was determined at different measurement points in an applied grid with a resolution of 20 cm with the PTW Farmer Ionization Chamber. The exposure time *t_e* was 1 s.

Subsequently, further measurements were performed with the PTW NOMEX® Multimeter on the z-axis of the phantom. Each measurement was taken from above and below the RANDO® head phantom, while the distance to the phantom was increased until the display of the PTW NOMEX Multimeter indicated that no further values after an exposure were recorded. One second was selected as the exposure time *t_e*. The tube voltage and tube current remained at 60 kV and 2.5 mA. The results for the region below the chin are displayed in Table 3.

Additional measurements were carried out directly at the edges of the scattering radiation shield of the NOMAD Pro 2 system. From the operator’s view, the measurements were conducted at 0, 90, 180, and 270°.

Results

No dose values could be detected neither on the handle nor directly on the housing of the NOMAD Pro 2™ X-ray system.

Determination of the DAP

The results of the measurements of the DAP at an exposure time between *t_e* 0.02 and 1 s, a tube voltage of 60 kV, a tube current of 2.5 mA, and a total filtration of 1.5 mm of aluminium-equivalent showed—as expected—a high correlation coefficient of 0.999.

Figure 2 Plot of distances RCA. View from top, where the CTB is located in the centre of the plot.

Determination of the CA

A blank measurement of K_a was carried out with both dosimeters at a distance of 35 cm from the focal spot F . The results of this test series are shown in Table 1. The measured K_a differed only slightly when using both dosimeters. Furthermore, the measurements validated

the information given in the manufacturer's manual of the device. In Table 2, the distances R_{CA} from the PTW Farmer Ionization Chamber to the point C_{CTB} are listed according to the rotation angle. Furthermore, the distances R_{CA} are plotted in Figure 2.

Evaluation of the scattering pattern

In Figure 4 and in Figure 5, the isodose lines for the K_a measured with the PTW Farmer Ionization Chamber

Figure 3 RANDO® phantom positioned to acquire a left bitewing.

Table 3 Measurements below the chin of the phantom

Air KERMA (μGy)	Measured exposure time (s)	Position below chin surface (cm)
14.6	1.009	0
13.5	1.009	2.5
11.9	1.008	5
3.4	0.1825	7
1.9	0.0695	8
0.9	0.001	10

Figure 4 Isodose lines for the K_a measured with the PTW Farmer® Ionization Chamber.

and with the PTW NOMEX® Multimeter are shown from a top view with the X-ray device at the bottom border of the illustration. The closer together and darker the isodose lines are printed the higher the measured energy was.

For these illustrations, it is notable that measurement values were processed with a 4/16 FIR filter for interpolation. Therefore, no units can be specified for the displayed graphics. These figures are for illustrative purposes only. Furthermore, the RANDO® phantom and the NOMAD Pro 2 X-ray system are not shown in the illustrations.

Measurement of the K_a on the focal spot plane and on the z-axis of the RANDO head phantom

No measurements could be recorded with the PTW NOMEX® Multimeter. Thus, if scattered radiation reached the focal spot plane P_f , according to the sensitivity of the dosimeter, it did not exceed a K_a rate of 10 nGy s⁻¹.

Measurements directly above and posterior to the phantom yielded no results. Energy was detected below

the phantom's chin skin surface up to a distance of 10 cm.

Finally, no energy was detected at the four specified sites around the scattered radiation shield of the NOMAD Pro 2™ with the PTW NOMEX® Multimeter.

Discussion

In the present study, different radiation protection and dose values of an Aribex NOMAD Pro 2 System were evaluated. The unit was equipped with rechargeable storage batteries. Technical characteristics were comparable to conventional wall-mounted X-ray systems.

The linear results of the DAP measurements showed that the evaluated system works within the range of adjustable exposure times. This is an important parameter for mobile X-ray devices with rechargeable batteries, whereas voltage variations can lead to X-ray spectrum changes.

The results of this and earlier studies showed, that the operator is not exposed to leakage or scattering radiation, in case the operator is located behind the focal spot

Figure 5 Isodose lines for the $K\alpha$ measured with the PTW NOMEX® Multimeter.

plane and uses the device according to the manufacturer's instructions.^{7,8} Therefore, one of the biggest critical points of this handheld and portable X-ray devices for IO imaging could be defused.

The Compton effect should be considered predominating at a soft X-ray spectrum like diagnostic radiation. With energies lower than an electron's rest energy (511 keV) photons lose only little energy after their first interaction with an external shell electron. Furthermore, the photon's rest energy depends only a little on the scattering angle. Therefore, the correct application of the device is highly important, in particular, considering scattering radiation, which mainly arises from the investigated object. At a diagnostic X-ray spectrum of 60–90 kV, the scattering angles symmetrically spread around the vertical tier of the photon's invasion angle. It can be assumed that a significant part of the scattering radiation from the object eventually returns into the direction of the operator.⁹ As the amount of backscatter is also depending on the angle of the device, it is essential to operate the system according to the manufacturer's instruction.¹⁰ Finally, the backscatter angle is influenced by the distance of the object from the system's tube opening and should be kept as small as

possible in order to reach the maximum shielding effect behind the system's scattered radiation shield. Hence, the manufacturer or reseller of the system should offer proper courses on how to operate the device correctly to decrease the risks.

Only a few more studies were found to have evaluated the exposure for the operator^{5–8} and are based on a statistical analysis only. Thus, the found studies were not comparable due to different study designs.

Another aim of this study was to determine the real CA of the system while acquiring IO radiographs. The values for the CA radius in legal documentation have not been modified within the last 50 years, and the development and the modification of modalities, combined with a reduction of radiation exposure have not been taken into account. Nevertheless, according to the results of our study, a CA radius of 1.5 metres is not reasonable. The extent of the real CA evaluated in this study differs from the regulations and DIN standards. The maximum radius of 45 cm is just a third of the claimed distance. Although operator safety and patient protection are very important, the results of this study suggest reconsidering the extend of the CA for specified X-ray devices. Even if the results were conceded to be

strongly inaccurate (e.g. by a factor 2), the required CA would be twice as big as the real CA.

The graphs show the expected distribution of the scattering pattern: peak values behind the object, where the penetration of radiation was at the highest level, at the phantom's, and in between the phantom and the scattering radiation protection shield of the device. No scattered radiation was detected dorsal and above the phantom because the relatively soft radiation, resulting from a 60 kV tube, was not able to penetrate the bony parts of the phantom. With the given specific tissue attenuation coefficient for X-rays generated with 60 kV this result is acceptable.

On the other hand, small dose values were detected directly inferior of the phantom's chin, decreasing disproportionately to the distance from the chin. This can be easily explained by the inverse square law. Although the radiation exposure is not very high patient protection equipment should be applied. Accordingly, the results of an earlier study by Hoogeveen, where the protective effect of a thyroid shield during the acquisition of an IO radiographs, were confirmed. Following Hoogeveen's study, thyroid shielding can reduce the thyroid organ dose by 75 %.¹¹ Organs located below the thyroid level have not been evaluated in this study.

Further, for statistically stable results, multiple repetitions of a measurement series were performed in our study. The series for DAP measurements were performed five times and the results were then averaged. The comparison of the measurement series revealed acceptable results with only small SD and indicated a high reproducibility of the generated spectrum of the investigated X-ray device.

The technical radiation protection value determined in this study is K_a . Guidelines and DIN standards, however, use E as the standard unit. On the basis of the evaluated data, the conversion of the units was not possible¹² because no absorbed doses in soft tissues were investigated in this study. Hence, organ doses could not be calculated, which would be the basis for calculating the E . If there is a homogenous distribution of the K_a over the entire range of the examined patients, the calculation of the E would lead to a massive overestimation. Taking this fact into account, our results include a very high safety range.

As critical aspects of this study, the following should be mentioned. The active volumes of the two used

ionization chambers varied in size. Depending on the total number of photons that reached the active volume, the results of the K_a measurements can differ from one dosimeter to another.

Regarding the positioning of the ionization chambers, a more precise method could be investigated in future studies. The positioning of the chamber and their tracking may be solved in a better way. The results of this study would probably be the same, but the realization might have been much easier.

In our study design circular collimation was used. We believe that, although rectangular collimation should be used and is even mandatory in some countries, many operators refrain to use it. While the reasons for the aforementioned operating mode cannot be unraveled, we decided to use the presented study design, even though it might not be in accordance to valid radioprotection guidelines.

Finally, the graphic representations of the measurements only serve the visualization of the results. The FIR filtering lead to interpolation of the data. Likewise, no dose values were illustrated within the phantom because data scaling would have been necessary.

An estimate of the significance of the present study in the context of already existing studies is multifaceted because of the availability of only a very small number of comparable studies.

Conclusion

According to the results of this study and with regard to the study design, the investigated handheld X-ray system cannot be rated in a disadvantageous manner in comparison with a wall mounted system, with reference to the radiation exposure to the operator, as long as the device is handled according to the manufacturer's instruction. In addition, it has been shown that the actual CA of the investigated systems is notably smaller than (German) regulations and DIN standards demand. Nonetheless, a wider evaluation of the question is needed to strengthen such fundamental statement.

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