

## SHORT COMMUNICATION

# Justification and good practice in using handheld portable dental X-ray equipment: a position paper prepared by the European Academy of DentoMaxilloFacial Radiology (EADMFR)

<sup>1</sup>W E R Berkhout, <sup>2</sup>A Suomalainen, <sup>3</sup>D Brüllmann, <sup>4</sup>R Jacobs, <sup>5</sup>K Horner and <sup>6</sup>H C Stamatakis

<sup>1</sup>Department of Oral Radiology, Academic Center for Dentistry Amsterdam (ACTA), Amsterdam, Netherlands; <sup>2</sup>Department of Radiology, HUS Medical Imaging Center, Helsinki University Central Hospital and University of Helsinki, Helsinki, Finland; <sup>3</sup>Department of Oral Surgery, University Medical Center, Mainz, Germany; <sup>4</sup>Oral Imaging Center, OMFS-IMPACT Research Group, Department of Imaging and Pathology, Faculty of Medicine, University of Leuven, Leuven, Belgium; <sup>5</sup>School of Dentistry, University of Manchester, Manchester Academic Health Science Centre, Manchester, UK; <sup>6</sup>Department of Orthodontics, University Medical Center of Groningen, Groningen, Netherlands

Handheld portable X-ray devices are increasingly used for intraoral radiography. This development introduces new challenges to staff and patient safety, for which new or revised risk assessments must be made and acted upon prior to use. Major issues might be: difficulties in using rectangular collimation with beam aiming devices, more complex matching of exposure settings to the X-ray receptor used (e.g. longer exposure times), movements owing to the units' weight, protection of the operator and third persons, and the use in uncontrolled environments. These problems may result in violation of the "as low as reasonably achievable", that is, ALARA principle by an increase in (re)exposures compared with the other available intraoral X-ray devices. Hence, the use of handheld portable X-ray devices should be considered only after careful and documented evaluation (which might be performed based on medical physics support), when there is evidence that handheld operation has benefits over traditional modalities and when no new risks to the operators and/or third parties are caused. It is expected that the use of handheld portable X-ray devices will be very exceptional, and for justified situations only. Special attention should be drawn to beam-aiming devices, rectangular collimation, the section of the X-ray receptor, focus-skin distance, and backscatter shielding, and that the unit delivers reproducible dose over the full set of environmental conditions (e.g. battery status and temperature).

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## Definition

This document refers to a non-standard form of dental X-ray equipment, which is battery-powered, portable and designed to be used when held in the hands of the operator during exposure. Although some equipment of this type can also be fixed to a tripod or other support

and operated at a distance with the use of either an exposure button on a cable attachment or a cable-free control, this position statement focuses on the supposed use of the devices, as the devices are designed to be used "handheld". Throughout this document, the term "handheld portable X-ray device" is used.

Handheld portable dental X-ray devices are used in dentistry for taking intraoral radiographs. The current

handheld portable X-ray devices resemble a photographic camera or have a “shotgun” design. The devices are used as a replacement for wall-mounted or semi-mobile X-ray devices (on a tripod or mobile support) and differ in two major characteristics from those:

- i. The operator holds the handheld portable X-ray devices during exposure of the patient, so the operator cannot stand back and therefore dedicated means of (scatter) radiation protection need to be provided.
- ii. The newer handheld devices have typically a lower output dose rate (set by current, waveform, filtration and cone length) than do the traditional wall-mounted direct current units.

Although the first handheld portable dental X-ray devices date back to the early 90s of the past century, those devices were intended to be used in the military field.<sup>1</sup> An increase in the marketing of handheld portable X-ray devices for intraoral radiography in general dental facilities has been recently observed.<sup>2</sup> The advertisements include both safe certified/approved units according to the International Electrotechnical Commission/European Committee for Electrotechnical Standardization (IEC/CENELEC) standards and potentially unsafe non-certified devices.<sup>3–5</sup> In Europe, there is no standard regulation across countries, with some of them adopting various restrictions or requirements for the use of the handheld equipment. It is clear that such equipment emitting ionizing radiation should be certified and operated under regulated controlled conditions by licensed personnel and in selected circumstances.<sup>6</sup> The safety requirements of these devices, including acceptability criteria and suspension levels, are the same as for other intraoral dental X-ray systems. In Europe, the “Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology” apply (European Commission, Radiation Protection series no. 162).<sup>7</sup>

## Objective

Handheld portable X-ray devices introduce new safety challenges that must be addressed for users as well as in (post)graduate teaching and training. The overriding aim when facing this challenge is to ensure that there is no additional risk to the operator, patient or third party, compared with conventional radiography, and that any perceived benefit of using this modality outweighs any increase in radiation doses.

The specific objective of this position statement is to raise awareness on the importance of establishing clear regulations and guidance regarding the indications, the specifications, the radiation protection demands and the safe use of certified handheld portable X-ray devices. The statement is aimed at use by qualified personnel in clinical dental practice or for forensic purposes, excluding

applications in the industrial and research field, which are not in the scope of this document.

## Indications for the use of handheld portable dental X-ray device

The use of handheld portable X-ray devices can be divided into patient-related situations and forensic situations. For forensic work, radiation safety procedures should be designed specifically for the operator of the handheld portable X-ray device, whereas in patient care protection of the patient should also be taken into account. In both situations, the use shall always be justified on a case-by-case basis.

### *Use in intraoral dental radiography of patients*

As a general rule, a handheld portable X-ray device should only be used in scenarios where an intraoral radiograph is deemed necessary for a patient and the use of a fixed mounted or semi-mobile X-ray device is proven impractical. In such cases, the published European guidelines on the safe use of X-rays in dental radiography should be followed (Radiation Protection no. 136, European Guidelines on Radiation Protection in Dental Radiology, European Commission, 2004).<sup>8</sup>

Despite the low patient doses associated with dental examinations, the second basic principle of radiation protection “ALARA” (doses should be kept as low as reasonably achievable) should be always restricted. Therefore, the general use of handheld portable X-ray devices are not justified. The handheld portable dental X-ray device shall not be used for routine dental radiography in dental offices.

Handheld portable X-ray devices should only be used in specific cases where it is impractical or impossible to transfer the patient to a fixed mounted X-ray installation, and use of mobile devices are not practicable, such as in:

- i. Operation theatres where no fixed mounted X-ray unit is available and the patient is under general anaesthesia or sedation. The first choice in this case should be a semi-mobile device.
- ii. Emergency rooms, surgical suites, patient rooms or other hospital facilities for immobile patients. The first choice in this case should be a semi-mobile device.
- iii. Nursing homes, residential care facilities or homes for persons with disabilities, which compromise mobility or their general health and who are thus unable to attend a healthcare facility. In this case, the follow-up treatment should be considered before justification of the X-ray procedure is made. If follow-up treatment is not available at the site, the patient might need to be moved to a healthcare facility, and X-ray imaging can be performed at the healthcare facility.
- iv. Detention centre facilities where persons are physically confined and cannot easily be moved or transferred.

- v. Work in remote areas without dental facilities, such as military operations abroad.<sup>9</sup>
- vi. Dental support in rural areas in developing countries or isolated areas without dental facilities.

Although (i) and (ii) will be environments that are well used to radiation safety requirements and associated risk assessments, locations (iii) and (iv) usually will not be. Where a dentist is visiting such a location, he/she should undertake a risk assessment with the host to identify the most suitable room, to arrange the conduct of the examination so that unsuitable barriers (*e.g.* ground floor windows, doors) are avoided and to arrange so that third parties cannot inadvertently enter the room and other host staff are informed of X-rays being used. Unless the dentist is suitably trained and confident in the risk assessment, the involvement of a radiation protection adviser/medical physics expert (MPE) should be arranged.

Also for situations (v) and (vi), the responsible dentist, radiation protection adviser and/or MPE should undertake a risk assessment to identify the most suitable set-up for radiation protection of operator, staff and the general public.

#### *Use in forensic odontology*

Handheld portable X-ray devices may be used in applications of forensic odontology, for example, in mass disasters or fatal accidents, where a multitude of individuals have to be identified on site, or in facilities lacking fixed mounted units. Also, the electricity supply might be cumbersome or even absent in mass disaster areas or fixed X-ray units may get damaged by constant line fluctuation. In those circumstances, a handheld portable X-ray device may be of benefit for the identification process.<sup>10</sup>

Although perhaps in contradiction with the aforementioned issue of electricity supply, the use of digital image receptors is advocated by Interpol (see the Image quality section).

In such mass disaster cases where no living persons are irradiated, only the radiation protection demands for the operator and the general population apply (see the Radiation protection section).<sup>11</sup>

#### **Good practice recommendation in patient exposures**

For each case a handheld portable X-ray device is used, complete documentation in the patient records should be filled in by a licensed operator, stating the device used; the clear reasoning for the use of a handheld X-ray unit; the number of taken exposures; and the radiation protection measures taken.

#### *Good practice*

Complete documentation is required whenever a handheld portable X-ray device is used inside or outside the designated facilities, allowing for controlled and justified use of handheld equipment and discouraging potential misuse.

#### **Use/handling/storage**

The published European guidelines on the safe use of X-rays in dental radiography and the Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy (Radiation Protection series no. 136 and 162) should be followed when using a handheld portable X-ray device, just as with fixed mounted units.<sup>7</sup> Conformité Européenne (CE) marking is mandatory, but not sufficient. Any unoptimized use should not be allowed. Specifically for the handheld portable X-ray devices, special attention is given to the following.

#### *Patient*

*Beam-aiming devices:* Special attention is drawn to the recommended use of image receptor holders, beam-aiming devices and rectangular collimation, since it is not always evident that handheld devices support their use. In particular, the backscatter shield may obstruct the arm of the image receptor holder, increase the distance between the X-ray source and the skin and increase the area of the patient irradiated by the inverse square law. Note should be taken of “Radiation Protection 162”, which states that a rectangular field  $>40 \times 50$  mm is unacceptable. This situation will either mean higher doses than reasonably achievable or abandonment of image receptor holders, with the latter giving a loss of image quality. While the specifications of some handheld devices may be certified as “safe” for clinical use, it is equally important that good radiation practices are not abandoned. Therefore, where the design of a handheld X-ray device does not facilitate the use of image receptor holder/beam-aiming devices and rectangular collimation, it should not be adopted for clinical use.

*Image receptor:* According to the above, the image receptor should also satisfy the good radiation practice principles. Therefore, only films with speeds designated as E or ideally F-speed or faster, or digital image receptors (sensors or phosphor plates) should be used to minimize the required dose.

*Exposure time:* Compared with fixed mounted X-ray devices, longer exposure times are needed for handheld portable X-ray devices operating with low tube current. It should be noted that exposure times over 1 s must never be used in patients, even when employing a tripod, because of movement artefacts caused by patient or operator movement. The risk of unusable images, and as a result of that retakes, will be higher owing to longer exposure time and movement of the device.

*The battery:* Because the devices are portable and thus battery operated, they should be charged up each day. Battery power will reduce during successive operations and the quality of the tube output may also degenerate, comprising image quality and/or radiation safety.<sup>12</sup> The

device should have a clear indication when the battery power is low and tube current or operating potential is below the intended level. The Criteria for Acceptability of Medical Radiological Equipment (Radiation Protection no. 162) apply as much to handheld portable X-ray devices as they do to conventional equipment. Devices that cannot meet the criteria, in particular suspension levels (notably operating potential deviation >10% from set value and repeatability of radiation output greater than +20% of mean values of measurements) should not be used.

*Weight of the device:* It should be noted that the weight of some of these devices is considerable (2.2–5.0 kg). This may increase the risk of movement during exposure and misalignment. The use of a tripod stand, where available, is therefore desirable. A risk assessment is advised in relation to handling and use, particularly in situations where the patient is in the supine position such as in an operating theatre, to consider the risk of dropping the unit onto the patient's head.

#### *Operator*

*Backscatter shielding:* The operator (and any other staff involved in the radiographic examination or members of the public other than the patient) must be adequately protected from backscattered radiation. To comply with this, the handheld portable X-ray device must be equipped with some form of shielding against backscatter. This is currently achieved most effectively by a backscatter shield installed at the end of the position-indicating device of specific lead equivalent thickness and diameter. According to Food and Drug Administration requirements, this shield should have a minimum specification of 0.25-mm lead equivalent, be 15.2 cm in diameter and be capable of being positioned no further than 1 cm from the end of the position-indicating device so that backscatter radiation is sufficiently blocked.<sup>13</sup> The handheld portable X-ray device must always be used with the backscatter shield in place.<sup>14–16</sup>

*Licensing and authorization:* Depending on national requirements, handheld portable X-ray devices should be individually registered by the regulatory authorities and regularly inspected by authorized medical physicists, just as their fixed mounted counterparts are. They should only be operated by licensed/registered dentists or appropriately educated dental staff.

*Storage:* Operators using handheld portable X-ray devices should care for the security and safe storage of the unit by not allowing access by unauthorized persons while not in use, for example, by storage in a locked place (room, locker, container, case).

#### *Other considerations*

*National regulations:* Regarding the clinical use and handling of the equipment, various national restrictions

apply across Europe that should be followed by the operator. A national regulation has been brought to our attention where a safety license for the device, the clear reasoning for the use of handheld portable X-ray unit, the number of taken exposures, and the radiation protection measures taken are required.<sup>17</sup> This is recommended as good practice even in areas where no such obligation applies, allowing the regulatory bodies to control the exposure load.

In some countries, the use of a tripod stand is obligatory, whereas others also add a requirement for an exposure switch cable to increase the distance of the operator from the unit and the patient. In some national regulations, the use of the device outside a designated dental facility is prohibited. It should not be overlooked that even if the device has been certified as “safe” for the operator and patient for use without the above additions, the national regulations should be followed until future amendment of the legislation.

## **Radiation protection**

#### *Patient*

The same requirements apply as with fixed intraoral X-ray unit (see European Commission, Radiation Protection series no. 136 and 162).<sup>7,10</sup>

#### *Operator*

A radiation risk analysis should always be available for the location in which the handheld portable X-ray device is used. The device should be equipped with a backscatter shield and, depending on the radiation risk analysis, personal monitoring of the radiation dose is recommended. If handheld devices are used, operator's exposure shall be monitored (whole body and finger dosimetry) unless it is demonstrated that dose limits for the general public are not liable to be exceeded.

#### *General population*

A radiation risk assessment should always be available for the location in which the handheld portable X-ray device is used. The radiation risk assessment should include a minimum clearance distance (“controlled area”) around the X-ray device and shielding requirements if applicable.

## **Image quality**

The same image quality requirements apply to handheld portable X-ray devices as do to fixed intraoral X-ray units.

Acceptable image quality can be obtained with some handheld portable X-ray devices. However, image quality might be lower than wall-mounted devices.<sup>18</sup> Image quality depends on the interaction of X-ray device, exposure time, exposure geometry and image receptor. In the study of Pittayapat *et al*,<sup>19</sup> it was

concluded that handheld portable X-ray devices produce satisfactory image quality for use in forensic odontology.

In forensic use, for reasons of image quality and ease of access, Interpol recommends to use digital radiographic systems to record the (dental) data of victims in a disaster victim identification procedure.<sup>20</sup>

### Quality assurance

The Holder (natural or legal person who has the legal responsibility under the national law for a given radiological installation) shall arrange quality assurance procedures for practices involving exposure to radiation, and a quality assurance programme is required. The programme shall define the necessary quality assurance functions and must also include the principles for preventing errors and accidents from which radiation doses may arise unintentionally. Quality assurance practices shall be assessed regularly and, when appropriate, changed. Quality assurance can be categorized as assurance of the technical quality and assurance of the operational quality.<sup>10</sup> Amongst the quality assurance activities, users should undertake image reject analysis to check that reject rates do not exceed normal quality standard for intraoral radiography.<sup>7</sup>

### Equipment specification requirements and medical physics tests (CE approval)

CE approval and labelling according to the Medical Devices Directive is required. All criteria of the report of the European Commission, Radiation Protection no. 162—criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy—should be adhered to.<sup>10</sup>

Special attention should be drawn to the focus–skin distance that should be at least 200 mm. Additional conditions (or special justification for non-application of these conditions) apply regarding image detector sensitivity (minimum class E film) and beam collimation resulting in a field size not more than 40 × 50 mm.

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As stated in the Backscatter shielding section (above), the handheld portable X-ray device must be equipped with a backscatter shield of no less than 0.25-mm lead equivalent and 15.2 cm in diameter that can be positioned to within 1 cm of the end of the position-indicating device. The handheld portable X-ray system must always be used with the backscatter shield in place.<sup>21</sup>

### Medical physics support

In line with the new proposed European Basic Safety Standard, medical physics (a MPE/radiation protection expert) expertise is required, and the MPE should be involved in acceptance testing and testing throughout the lifetime of the equipment, at a level specified in a national legislation.<sup>22</sup>

### Training

Users of handheld portable X-ray devices shall provide proof of training for the safe use of radiation sources so that he/she understands the risks involved when using the handheld portable X-ray device and radiation protection measures to be taken.

### Review of this position statement

This statement shall be reviewed in 5 years, or earlier if the evidence underlying it is judged to have changed significantly.

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