



Usage of Handheld dental x-ray units in the state of Missouri

Updated: September 14, 2021

As designed and commonly used, most handheld dental x-ray units are **not in compliance** with the following Missouri Radiation Protection rule:

19 CSR 20-10.150(3): Special Requirements for Dental Radiographic Installations -- "The exposure control switch shall be provided with a cord sufficiently long so that the operator can stand at least six (6') feet from the tube housing for all exposures and well away from the useful beam."

FDA 510(k) or other approval to manufacture is largely irrelevant to this requirement. Unless a specific Missouri waiver is applied for and APPROVED, handheld dental units are NOT approved for use without the installation and use of additional equipment that will allow them to be energized from a minimum distance of six feet from the tube:

- Tri-pod/wall-mount; and
- Remote exposure switch capable of being used at least six feet from the unit.

As of the above date, only the manufacturer/representatives for certain units (approved for use in the USA by FDA) have requested and been granted a waiver of this rule for use as fully hand-held units in the state of Missouri.

Manufacturer/Distributor/ Brand	Model(s)	Fully handheld waiver approved by DHSS?
Aribex / KAVO	Nomad Series	APPROVED
Bio-Ray	PRO-X; Prox	APPROVED
Dexcowin/ Vector R&D/ Maxray	Maxray DX3000; ADX4000 Cocoon (DX7017/DX7020); ADX6000	APPROVED
Denterprise/ Digital Doc/ Digimed	Xray2Go, Xray2Go Mini MiniX-S, MiniX-V	APPROVED
Phoenix/ Remedi/ Dentrprise	Remex T-100/ MobileX	APPROVED
VaTech	EzRay	APPROVED
Carestream	CS2400P/ NP-350E	APPROVED
→Known Units Not Approved		
Genoray	Port-X II/ ZEN-PX II	NOT APPROVED as handheld
Innoden	BIOX	NOT APPROVED as handheld

A waiver above is hereby granted under the following conditions:

1. A scatter shield attachment, if a design component of the unit, **must** be in place and used at all times.
2. All operators must receive training in the proper use of this equipment prior to being allowed to use it without supervision, to include at a minimum a review of the operator's manual.
3. Manufacturer's recommendations for safe operation and maintenance must be followed.
4. It is recommended that the operator(s) of the unit(s) should be issued a radiation dosimeter for exposure monitoring and wear a leaded apron.

MO DHSS reserves the right to revoke this waiver if, in the future, additional information is found to indicate that use of the equipment violates ALARA, or new regulations are promulgated.

If you have further questions about specific units and their status on the above list, or others not on the above list, please contact our office at MRCP@health.mo.gov or by phone at 573-751-6083.

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