



July 15, 2016

MEMORANDUM

TO: X-Ray Facilities
X-Ray Service Providers

FROM: Aaron A. Gantt, Chief 
Bureau of Radiological Health
SC Department of Health and Environmental Control

SUBJECT: HAND HELD X-Ray Devices-Guidelines of use Requirements

The Department of Health and Environmental Control, Bureau of Radiological Health has reviewed a proposal to sell and market the ARIBEX NOMAD Hand Held Portable X-Ray device in the state of South Carolina. The Bureau has determined that in certain situations this unit could be a useful diagnostic imaging tool. The following requirements must be followed for the use and sale of the unit in South Carolina to Facilities and Vendors.

- 1) In the event a facility elects to use the Aribex NOMAD Pro, the facility will be required to obtain a variance approval from the Department regarding RHB 1.2.7 and RHB 4.2.13.3.
- 2) When operating the Aribex NOMAD hand held device, the operators shall wear a 0.25 mm lead equivalent apron and thyroid collar.
- 3) In order to ensure radiation safety for the operators of the Aribex NOMAD Pro handheld x-ray device, it will be necessary that the facility establish a baseline exposure reading for the operators. This will be accomplished by having the operators wear a personnel monitoring badge for a period of six months. At the conclusion of the six month monitoring period, the use of the personnel monitoring will be left up to the discretion of the facility/Radiation Safety Officer. However, if monitoring readings of the operators show that they are likely to receive ten percent of the limits outline in RHB 3.4 & RHB 3.12.4.1.1 (500 mRem or 50mSv) then monitoring badges will be required to be worn. Personnel monitoring records must be maintained and be available for review by the Department.
- 4) A copy of this letter must be distributed with all units sold to South Carolina Facilities and any Company (Vendors) that plan to sell the device in South Carolina.

Handheld X-Ray Devices
Guidelines of Use Requirements
July 15, 2016

- 5) All literature regarding the use of the NOMAD including training CD's distributed by the manufacturer to end users must be reviewed and accepted by the Bureau of Radiological Health before the NOMAD can be sold in South Carolina.
- 6) Each operator must complete the training program supplied by the manufacturer and accepted by the Department prior to using the x-ray device. Records of the training shall be maintained on file for review by the Department.
- 7) The ARIBEX NOMAD Pro, manufactured after January 2008, is the only hand held device that is accepted for routine radiographic procedures in facilities. To ensure radiation safety, only the x-ray operator and the patient will be present in the room during the x-ray exposure(s). All other models of the ARIBEX NOMAD hand held dental x-ray device shall not be used in the State of South Carolina.
- 8) The Aribex NOMAD may only be used in conjunction with "F-speed" film, phosphorus or digital image receptors to further minimize patient and operator radiation exposure.
- 9) Facilities that wish to purchase the NOMAD device must follow all registration requirements and obtain Facility Registration Approval from this Department. Vendors that want to sell the unit in South Carolina shall be registered with this Department.
- 10) All operators of the unit must meet the requirements of the South Carolina Dental Board.
- 11) Registrants of the NOMAD must secure the device in a safe location that prevents unauthorized use of the NOMAD.
- 12) The NOMAD unit must have an Equipment Performance Test completed annually (Appendix F, Title B Regulations).

Please keep in mind, currently the ARIBEX NOMAD Portable Dental X-Ray machine is the only hand held x-ray device for human use that has been accepted by this Department. Other hand held x-ray devices will need to go through an acceptance review process.

Any person, manufacturer, dealer, or registrant who fails to abide by the requirements outlined in this document may be subject to enforcement actions including the potential for civil penalties being assessed for permitting unnecessary radiation exposure.

If you have any questions regarding this matter, please feel free to contact this Department at 803-545-4400.