



08 MAY 2020

FDA ADVISORY
No. 2020-793

TO: ALL MEDICAL RADIATION FACILITIES

SUBJECT: PROHIBITION OF THE OPERATION OF PORTABLE /
HANDHELD DIAGNOSTIC X-RAY MACHINES

Despite the increased demand to utilize innovations in diagnostic x-ray devices brought about by the COVID-19 pandemic, the Food and Drug Administration (FDA) reminds the general public and all radiation facilities to refrain from using **portable/hand-held diagnostic x-ray machines** pursuant to Section 5.3.25 of DOH Administrative Order (AO) No. 35 s. 1994 or the “Requirements for the Control of Radiation Hazards from Clinical Diagnostic X-ray Facilities”. These handheld x-ray devices are configured to have a single peak kilovoltage (kVp) and low tube current (mA) settings insufficient for x-ray procedures of varying body dimensions. Basic radiation protection and safety principles are compromised with the use of such devices because of the increased probability of committing errors caused by the following:

- Unstable rectangular collimation of areas of interest due to hand movement/tremors which can cause unwanted exposure of adjacent body parts.¹
- Questionable image quality and increased patient radiation dose due to the use of single kVp and low mA settings.²
- Vulnerability to unauthorized use due to accessibility and portability.

The FDA fervently supports measures that will help in the prevention and diagnosis of COVID-19 and other communicable diseases without compromising other aspects of the public health. For questions, clarifications and/or reports regarding this matter, please contact the Center for Device Regulation, Radiation Health, and Research (CDRRHR) through the hotline (02) 8815-9600 or email at cdrhr@fda.gov.ph or cdrhr.rrd@fda.gov.ph.

For strict compliance.


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Director General



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¹ Requirements for Practices, Chapter II of the Manual on Basic Radiation Protection and Safety of X-ray Sources / DOH Department Circular No. 323 s. 2004

² FDA Circular No. 2014-005 or “Prohibition of the Operation of Radiographic X-ray Machines with Tube Currents below 100 mA in Diagnostic Radiology.”

