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Therapeutic Products Directorate
Medical Devices Bureau
2934 Baseline Road, 3rd Floor
Qualicum Building, Tower B
Address Locator: 3404A
Ottawa, Ontario
K1A 0K9

March 14th, 2012

Dear Health Care Professional,

Subject: Licence Suspension of the Digital Motion X-ray system

On December 20th 2011, Health Canada suspended the medical device licence for the Digital Motion X-ray System, manufactured by DMX-Works Inc., because it presents significant safety risks to patients and users. The licence suspension means that DMX-Works Inc. may no longer sell the device in Canada. Health Canada strongly recommends that healthcare professionals stop using the Digital Motion X-Ray system immediately.

The Digital Motion X-ray system (DMX) is a fluoroscopic X-ray system which allows clinicians to view X-ray images of the body in real-time motion.

The following issues have been identified:

- Compliance with the Canadian Radiation Emitting Devices Regulations, Schedule II, Part XII could not be verified.
- The X-ray system does not provide quantitative information regarding the radiation output of the device, leading to unknown radiation doses to patients, operators and surrounding staff.
- The instructions for use fail to provide information necessary for optimizing the radiation exposures to patients and minimizing exposures to operators and surrounding staff, consistent with the principle that radiation exposure should be as low as reasonably achievable.
- The indications for use include headaches, blurred vision, throat swelling, neck pain and a negative previous imaging test. These relatively minor conditions do not justify the radiation exposure involved with this device.

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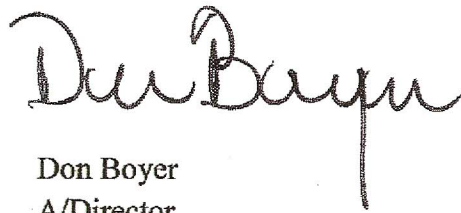
- The device's user manual is deficient in essential information to mitigate certain risks to patients, operators and surrounding staff.

Health Canada is unable to conclude that the diagnostic benefits of this medical device outweigh its risks.

Health Canada strongly recommends that healthcare professionals who own or operate a Digital Motion X-Ray system stop using it immediately.

Should you have any further questions or require clarification with respect to the content of this letter, please contact: Dr. Philip Neufeld, Acting Manager, Device Evaluation Division at (613) 954-0298 or by e-mail at philip.neufeld@hc-sc.gc.ca.

Sincerely,

A handwritten signature in cursive script that reads "Don Boyer". The signature is written in black ink and is positioned above the printed name and title.

Don Boyer
A/Director,
Medical Devices Bureau