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Urgent Field Safety Notice

O-arm® 1000 Surgical Imaging System

Model numbers BI-700-00027 and BI-700-00028

Important Device Information

July 2016

Medtronic reference: FA726

Dear OR /Risk Manager,

It has come to our attention that your O-arm® system requires updates in order to maintain compliance with applicable performance standards. Specifically,

1. Certain aspects of the technical information in the Instructions for Use document require clarification. The information to be updated includes system's specification for x-ray technique factor accuracy, filtration strength, leakage technique factors, air kerma reference location, and tube housing cooling curves.
2. Radiation measurement methodologies associated with confirming the accuracy specifications of the air kerma displays do not fully comply with requirements.
3. The O-arm System X-ray technique factor display accuracy related to mA and mAs might not be compliant to the system specifications.
4. X-ray generator and motion batteries require inspection to insure they are free from damage during shipment.

Please note that items 1 and 2 do not affect the safety or performance of your system. Item 3 does not increase the safety risk of the product to users or patients, but could affect performance related to image quality. Item 4 addresses possible shipping damage to the batteries. Damaged batteries may result in odors/fumes, smoke, and the system not functioning as intended.

To bring the affected O-arm® systems into compliance, we are providing to you the attached errata sheet with the correct information. We will be following up this errata sheet with an update to your system software that corrects this information in the on-system Instructions for Use. In addition, we will be performing the appropriate measurements of air kerma rate, as well as testing the X-ray technique factor display accuracy for compliance. We will also be visually and electrically inspecting the batteries for potential damage. Your local service representative will contact you to schedule the update when it becomes available.

The Competent Authority of your country has been notified of this action.

Medtronic Navigation regrets any inconvenience that this matter may cause. However, we want to insure that the products and services we provide are of the highest quality. If you have any questions, please contact your Medtronic Representative directly or via tel no:+353 1 5111 400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland

Appendix: Errata Sheet