

July 18, 2016

Dear Customer

RE: Corrections for the O-arm® O2 Surgical Imaging System (model number BI-700-02000)

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 the system's specification for x-ray filtration strength, leakage technique factors, tube housing cooling curves, technique factor measuring criteria, and air kerma reference location.
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 might not be compliant to the system specifications.

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.

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. Your local service representative will contact you to schedule the update when it becomes available. These corrections are being made at no charge to you in order to bring your system into compliance with applicable federal standards in accordance with a plan approved by the Secretary of Health and Human Services.

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. Please do not hesitate to contact your local Medtronic Representative if you have any questions or concerns regarding this matter.


Shirley Loh
Marketing Director, RTG SEA

Encl.