

Medical Device Safety Notice

O-arm™ O2 Surgical Imaging System
High-power cable connector short while servicing O2 system

October 2017

Dear Customer:

Problem Description:

The purpose of this letter is to inform you that Medtronic will be installing a service kit for your O-arm O2 surgical imaging system (model number BI-700-02000) to further enhance the safety of field service personnel. During servicing of certain internal components of the O-arm O2, it is possible that the high-power cable connector may come in contact with surrounding metal (toggle switch or corner of battery tray) during the disconnecting/reconnecting process. If this occurs, it may result in an electrical short and a shock to the field service technician. Medtronic became aware of this issue via a complaint reported by a Medtronic field service technician.

O-arm 1000 surgical imaging systems are not affected by this issue.

Required Actions:

No actions are required of you. Our investigation has determined that the issue will only occur when service personnel (Medtronic field service representative or 3rd party service provider) services internal components of the system. Normal clinical use of the system will not cause the issue to occur.

Medtronic Actions:

Medtronic has provided field service personnel with a Safety Notification reminding them to follow servicing procedures. In addition, Medtronic is developing a retrofit service kit that will be installed during the next service visit for each O-arm O2 system, no later than 15 months from service kit availability. The user can continue to use the system prior to installation of the service kit.

Medtronic will also implement the same changes in the manufacturing process for newly manufactured O-arm O2 systems.

Medtronic regrets any disruption and thanks you for your cooperation. We believe that safety is of the utmost importance and we are committed to addressing this issue. Please do not hesitate to contact Medtronic Sales Representative if you have any questions or concerns regarding this matter.

Sincerely,



Diana Teo
QA Supervisor, Medtronic