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Field Safety Notice

Medtronic Reference: FA559

January 28th, 2013

Subject: Potential failure of the braking system that controls the O-arm® Imaging System gantry movement in the vertical direction, Serial Number 101 through 564

Dear O-arm Imaging System User, Radiation Safety Officer, or Risk Manager:

The purpose of this letter is to notify you of a field correction, explain what it is about and describe Medtronic Navigation's plans for implementing the correction. The company has identified a potential failure in the braking system that controls the O-arm gantry's vertical movement. We are initiating a voluntary field correction to notify you of the issue, the steps we are taking to address the issue, and what we have done to improve the O-arm system.

This potential failure exists when the O-arm gantry is in a raised position, and could result in an uncontrolled descent when the Up/Down Button is released. The gantry would stop when coming to rest on the hard stop on the horizontal frame of the device or reaching the end of travel (which could include contact with the patient and/or protruding instrumentation within the bore of the system). If this failure were to occur, it would have the potential to result in serious injury or death to the patient, or injury to users, or both. This potential failure has no impact on the amount of radiation emission delivered by the system. To our knowledge, there have been no reports of this or similar events occurring at any customer site.

Description of the issue

We believe this potential failure results from a specific transistor used in the amplifier board. The transistor is part of the motion control box that manages the gantry's vertical movement. Our internal investigation determined that during use of the O-arm the transistor could be exposed to a level of current that would damage it and could cause it to fail. If the transistor fails, the brake that holds the gantry in its vertical position could release, allowing the gantry to rapidly descend.

We are aware of only one occurrence of this failure on a single O-arm being assembled in our customary manner at our manufacturing site. This single failure prompted an internal investigation and additional testing. Our investigation concluded that it is highly improbable for this failure to occur. We assessed the probability of occurrence at approximately 1 per 6.3 million vertical movement activations. At the time of this letter, there are over 450 O-arm being used worldwide, with over 300 in the United States. There have been no reports of this event or similar events happening to O-arms installed at customers' sites. This potential condition exists on O-arm Imaging Systems with serial numbers 101 through 564. O-arm systems with serial numbers 565 and higher are not affected.

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Potential adverse conditions

If the transistor component fails, the gantry could experience an uncontrolled descent until coming to rest on the hard stop on the horizontal frame of the device or reaching the end of travel. The falling gantry could contact the patient, or protruding instrumentation within the bore of the system. This has the potential to result in serious injury or death to the patient, or injury to users, or both.

Although highly unlikely to occur, the risk cannot be completely ruled out due to variation in the use and patient size.

Action required by users

Medtronic Navigation remains confident in the reliability of your O-arm system and is not recommending discontinuing use of the O-arm. We believe the risk of the adverse health consequences described can be reduced by setting the OR table/patient height from the floor as low as possible. We ask that you please cooperate with our correction plan as described below.

Description of the correction

Medtronic Navigation has identified a correction for this potential failure by designing and implementing an improved circuit for the braking system that controls the O-arm gantry's vertical movement. This improved circuit will be implemented by replacing the motion control box on all affected O-arm Imaging systems. Replacing the motion control box with a motion control box that includes the improved design is intended to further reduce the possibility of failure of the braking system.

What Medtronic will do next

Medtronic Navigation is committed to providing the greatest possible reliability and quality in our products. As such, a Medtronic Navigation Representative will be contacting you shortly to schedule a time to conduct the motion control box upgrade.

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

If you have any questions about this notification, please contact your local Medtronic Navigation representative (insert local contact number).

Sincerely,

Signature local BU Manager