Medtronic
300 Foster St.
Littleton, MA 01460
www.medtronic.com

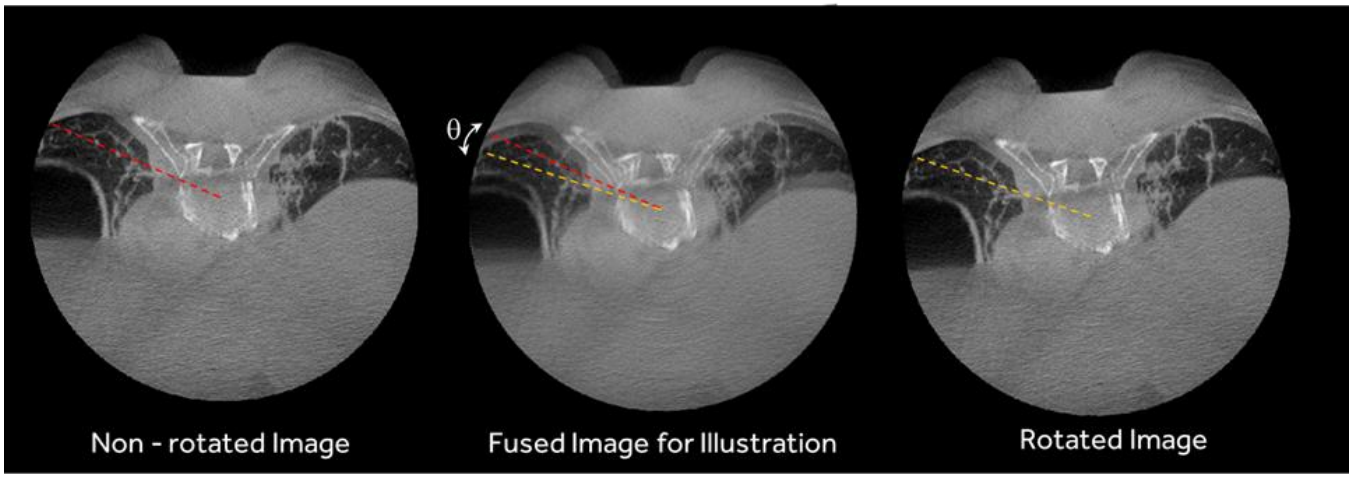
MEDICAL DEVICE CORRECTION

O-arm™ O2 Imaging System

November 15, 2019

Dear Healthcare Professional:

Medtronic has determined through internal testing that there is a potential for navigational inaccuracy when utilizing the O-arm™ O2 Imaging System's auto-registration feature, when used in conjunction with an Image-Guided Surgery System for a specific set of O-arm™ O2 Imaging System serial numbers. A list of potentially affected systems is provided in Table 1 of this letter. Due to loosening of an internal motor drive belt over extended number of uses, image rotation may occur relative to patient positioning data. Inaccuracy may occur when the O-arm registration information is transferred to an Image-Guided Surgery System to be used in navigation, utilizing the rotated images.



Navigational inaccuracies are inherent in the use of any Image-Guided Surgery System utilizing an O-arm™ O2 Imaging System, but the potential for inaccuracy may be higher if image rotation occurs in an affected system. This letter provides awareness of this issue and reinforces existing instructions within the O-arm™ O2 Imaging System User Manual (IFU) that allow for identification of the issue if it occurs. This issue does not involve the O-arm 1000 Imaging Systems.

Issue Background and Summary:

The O-arm™ O2 Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. Medtronic has determined that if the gantry tractor motor drive belt loosens over extended number of uses, it can result in rotation of 3D images about the gantry isocenter. While the 3D image is anatomically accurate within the image itself and may be used to confirm therapy, its electronic registered location may be rotated relative to the actual physical position of the patient. As a result, navigated positions may be inaccurate, with the magnitude of inaccuracy becoming more significant further away from isocenter.

If this image rotation due to a loose motor belt were to occur when auto-registration is used, it could lead to potentially significant navigational inaccuracies that may or may not be detected by the user through direct observation. The issue can be detected through navigational accuracy verification on the Image-Guided Surgery System. Unrecognized navigational inaccuracy may potentially result in serious injury.

Procedures that use intra-image fiducials or other means of registration (also known as "manual" registration) would not be impacted by this issue, because they use independent registration information, rather than the O-arm's internal auto-registration feature.

To date, Medtronic has not confirmed any complaints as being associated with this issue. Regardless, Medtronic would like to emphasize instructions within the O-arm™ O2 Imaging System User Manual (IFU) that allow for identification of the issue if it occurs.

Table 1: Potentially Impacted O-arm™ O2 Imaging Systems

C2155	C2180	C2193	C2203	C2213	C2223	C2233	C2243	C2257	C2267
C2157	C2181	C2194	C2204	C2214	C2224	C2234	C2247	C2258	C2268
C2165	C2182	C2195	C2205	C2215	C2225	C2235	C2248	C2259	
C2166	C2183	C2196	C2206	C2216	C2226	C2236	C2250	C2260	
C2167	C2185	C2197	C2207	C2217	C2227	C2237	C2251	C2261	
C2169	C2186	C2198	C2208	C2218	C2228	C2238	C2252	C2262	
C2172	C2187	C2199	C2209	C2219	C2229	C2239	C2253	C2263	
C2176	C2189	C2200	C2210	C2220	C2230	C2240	C2254	C2264	
C2177	C2190	C2201	C2211	C2221	C2231	C2241	C2255	C2265	
C2178	C2192	C2202	C2212	C2222	C2232	C2242	C2256	C2266	

Recommendations:

Ensure that when you are using auto-registration, follow the recommendations described under the section titled "Use of Images in Image-Guided Treatments" on page 21 of the O-arm™ O2 Imaging System User Manual (IFU):

Use of Images in Image-Guided Treatments

Images acquired on the O-arm™ O2 Imaging System may be used for image-guided surgery. When using O-arm™ images for image-guided surgery:

- Establish landmarks on the patient's anatomy that you can use to verify the accuracy of the positions displayed in images.
- Use these landmarks to verify the correct orientation of the images and the accuracy of the system during navigation.
- Verify that the line-of sight between the tracker and tracking instrument remains clear and free of obstruction.

Warning: Frequently confirm navigational accuracy and system responsiveness during live navigation. Use the probe to touch bony anatomical landmarks and confirm that the locations identified on the images match the locations touched on the patient. Failure to verify the landmark locations on the image match the landmark locations on the patient may result in inaccurate navigation. If accuracy degrades, re-register the patient.

Warning: Abort usage of the O-arm™ O2 Imaging System and contact Technical Services if images are unintentionally rotated or smeared.

If unusual or unanticipated inaccuracy occurs and cannot be corrected during a procedure, consider discontinuing use of the system, or utilizing manual registration.

Actions Required:

1) Attach the enclosed Visual Mitigation Card to the IAS of your O-arm™ O2 Imaging System, as illustrated below.

2) Please sign and date the Customer Confirmation Form enclosed with this letter to confirm that you have reviewed the information included in this notification with all users of the affected O2 system, including all physician users, and that the Visual Mitigation Card (VMC) has been attached to the affected system. Return the form to Medtronic via email at RS.NavFCA@Medtronic.com or via fax at 651-367-7075 within 30 days of receipt.

Additional Information:

Medtronic is continuing to investigate this issue, and if additional actions are identified, Medtronic will contact you accordingly. If unusual or unanticipated inaccuracy occurs and cannot be corrected during a procedure, please contact Medtronic Technical Services at 1-888-826-5603.

Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to the FDA MedWatch Adverse Event Reporting program (online, by regular mail, or by fax) and Medtronic:

- E-mail Medtronic at RS.NavTechSupport@Medtronic.com or call 1-888-826-5603.
- Online at the FDA website[1] (form available to fax or mail) or call FDA at 1-800-FDA-1088.

We regret any inconvenience this may cause. If you have any questions regarding this notification, please contact Medtronic at 1-888-826-5603.

Sincerely,

[redacted]

Lester Oestreich
Site Quality Director
Medtronic Navigation, Inc. (Littleton)

[1] Link: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm

Medtronic
300 Foster St.
Littleton, MA 01460
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MEDICAL DEVICE CORRECTION
Follow-Up to November 15, 2019 Notification
O-arm™ O2 Imaging System

January 7, 2020

Dear Healthcare Professional:

On November 15, 2019, Medtronic notified you of a potential for navigational inaccuracy when utilizing the O-arm™ O2 Imaging System's auto-registration feature, when used in conjunction with an Image-Guided Surgery System, for a specific set of O-arm™ O2 Imaging System serial numbers.

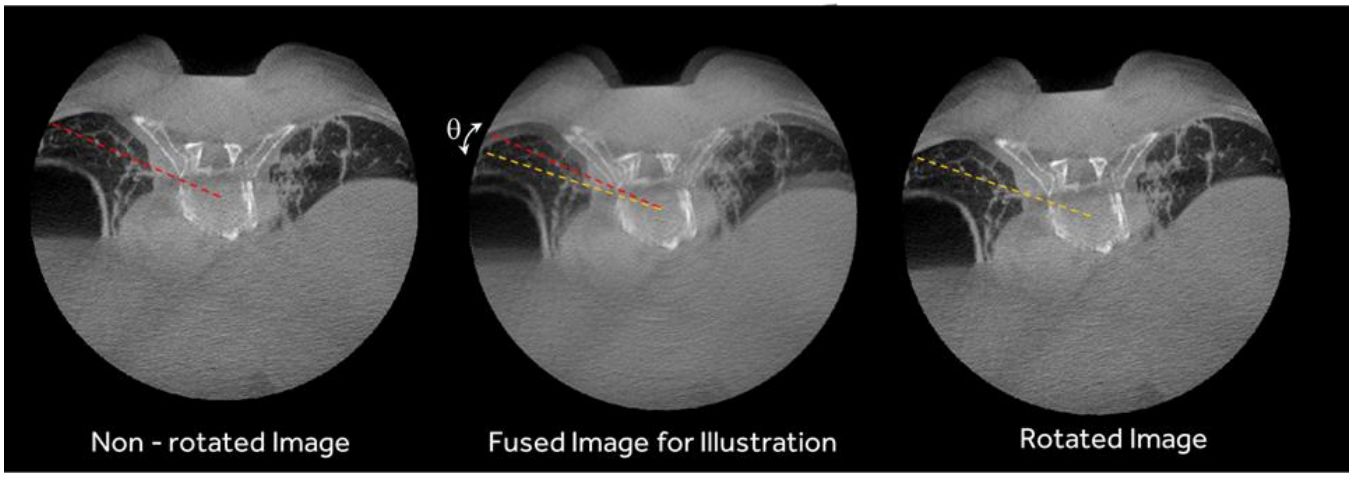
Medtronic has determined that replacement of the internal O-arm gantry tractor motor drive will resolve the issue of increased potential for loosening of the drive belt in the population of affected O-arm™ O2 Imaging Systems.

Your local Medtronic service representative will begin scheduling the system service visits as soon as possible. As the issue is related to loosening of the motor belt over an extended number of uses, where feasible, scheduling will be based on system age as well as replacement component availability. This servicing is expected to be conducted over the next nine months. In the meantime, please continue to follow the mitigation recommendations outlined in the November 15 letter (see below), as well as ensure that the visual mitigation card (VMC) provided remains affixed to your affected O-arm™ O2 Imaging System. For your convenience, an extra copy of the visual mitigation card is enclosed with this letter.

If unusual or unanticipated inaccuracy occurs and cannot be corrected during a procedure, please contact Medtronic Technical Services at 1-888-826-5603.

As Stated in the November 15, 2019, Letter:

Medtronic has determined through internal testing that there is a potential for navigational inaccuracy when utilizing the O-arm™ O2 Imaging System's auto-registration feature, when used in conjunction with an Image-Guided Surgery System, for a specific set of O-arm™ O2 Imaging System serial numbers. A list of potentially affected systems is provided in Table 1 of this letter. Due to loosening of an internal motor drive belt over an extended number of uses, image rotation may occur relative to patient positioning data. Inaccuracy may occur when the O-arm registration information is transferred to an Image-Guided Surgery System to be used in navigation, utilizing the rotated images.



Navigational inaccuracies are inherent in the use of any Image-Guided Surgery System utilizing an O-arm™ O2 Imaging System, but the potential for inaccuracy may be higher if image rotation occurs in an affected system. This letter provides awareness of this issue and reinforces existing instructions within the O-arm™ O2 Imaging System User Manual (IFU) that allow for identification of the issue if it occurs. This issue does not involve the O-arm 1000 Imaging Systems.

Issue Background and Summary:

The O-arm™ O2 Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. Medtronic has determined that if the gantry tractor motor drive belt loosens over an extended number of uses, it can result in rotation of 3D images about the gantry isocenter. While the 3D image is anatomically accurate within the image itself and may be used to confirm therapy, its electronic registered location may be rotated relative to the actual physical position of the patient. As a result, navigated positions may be inaccurate, with the magnitude of inaccuracy becoming more significant further away from the isocenter.

If this image rotation due to a loose motor belt were to occur when auto-registration is used, it could lead to potentially significant navigational inaccuracies that may or may not be detected by the user through direct observation. The issue can be detected through navigational accuracy verification on the Image-Guided Surgery System. Unrecognized navigational inaccuracy may potentially result in serious injury.

Procedures that use intra-image fiducials or other means of registration (also known as "manual" registration) would not be impacted by this issue, because they use independent registration information, rather than the O-arm's internal auto-registration feature.

Since the initial letter was sent to you, Medtronic has received one complaint due to this issue, which did not result in patient injury. Medtronic would like to emphasize instructions within the O-arm™ O2 Imaging System User Manual (IFU) that allow for identification of the issue if it occurs.

Table 1: Potentially Impacted O-arm™ O2 Imaging Systems

C2155	C2180	C2193	C2203	C2213	C2223	C2233	C2243	C2257	C2267
C2157	C2181	C2194	C2204	C2214	C2224	C2234	C2247	C2258	C2268
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C2177	C2190	C2201	C2211	C2221	C2231	C2241	C2255	C2265	
C2178	C2192	C2202	C2212	C2222	C2232	C2242	C2256	C2266	

Recommendations:

Ensure that when you are using auto-registration, follow the recommendations described under the section titled "Use of Images in Image-Guided Treatments" on page 21 of the O-arm™ O2 Imaging System User Manual (IFU):

Use of Images in Image-Guided Treatments

Images acquired on the O-arm™ O2 Imaging System may be used for image-guided surgery. When using O-arm™ images for image-guided surgery:

- Establish landmarks on the patient's anatomy that you can use to verify the accuracy of the positions displayed in images.
- Use these landmarks to verify the correct orientation of the images and the accuracy of the system during navigation.
- Verify that the line-of sight between the tracker and tracking instrument remains clear and free of obstruction.

Warning: Frequently confirm navigational accuracy and system responsiveness during live navigation. Use the probe to touch bony anatomical landmarks and confirm that the locations identified on the images match the locations touched on the patient. Failure to verify the landmark locations on the image match the landmark locations on the patient may result in inaccurate navigation. If accuracy degrades, re-register the patient.

Warning: Abort usage of the O-arm™ O2 Imaging System and contact Technical Services if images are unintentionally rotated or smeared.

If unusual or unanticipated inaccuracy occurs and cannot be corrected during a procedure, consider discontinuing use of the system, or utilizing manual registration.

Actions Required:

Your local service representative will contact you to schedule replacement of the tractor motor drive. In the meantime:

1) If you have not already done so, please attach the enclosed Visual Mitigation Card to the IAS of your O-arm™ O2 Imaging System, as illustrated below.

2) Please sign and date the Customer Confirmation Form enclosed with this letter to confirm that you have reviewed the information included in this notification with all users of the affected O-arm™ O2 Imaging System, including all physician users, and that the Visual Mitigation Card (VMC) has been attached to the affected system. Return the form to Medtronic via email at RS.NavFCA@Medtronic.com or via fax at 651-367-7075 within 30 days of receipt.

3) Work with your Medtronic representative to schedule the drive replacement and subsequent removal of the Visual Mitigation Card.

Additional Information:

If unusual or unanticipated inaccuracy occurs and cannot be corrected during a procedure, please contact Medtronic Technical Services at 1-888-826-5603.

Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to the FDA MedWatch Adverse Event Reporting program (online, by regular mail, or by fax) and Medtronic:

- E-mail Medtronic at RS.NavTechSupport@Medtronic.com or call 1-888-826-5603.
- Online at the FDA website[1] (form available to fax or mail) or call FDA at 1-800-FDA-1088.

We regret any inconvenience this may cause. If you have any questions regarding this notification, please contact Medtronic at 1-888-826-5603.

Sincerely,

[redacted]

Lester Oestreich
Site Quality Director
Medtronic Navigation, Inc. (Littleton)

[1] Link: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm