

URGENT FIELD SAFETY NOTICE

Commercial name of the affected product: *AIRO Mobile CT Scanner (model# MobiCT-32)*
EU FSCA Identifier: 2018-FSCA-001 / US FCA Number: 3010151377-0080118-001C

Type of action: *Advice regarding the use of the AIRO / Device Modification*

- **Date:** August 2, 2018

- **Attention:**

- Brainlab AG, Device Distributor and EU Representative
- User sites with the AIRO Mobile CT Scanner with software version 2.0.0.0

- **Details on affected devices:**

This recall applies only to AIRO systems with software version 2.0.0.0.

- **Description of the problem:**

The Tube Current Modulation feature (Modulated Scans) is not working in AIRO systems with software version 2.0.0.0, and operators would not be able to detect this fault until after a scan is completed.

Due to an error in AIRO software version 2.0.0.0, a non-modulated scan may be performed in place of a selected modulated scan because the window of time for an operator to select either non-modulated or modulated scan is less than 1 second before the default selection (non-modulated) is selected by the system.

If the operator selected a modulated scan ("Modulated Tube Current", see figure #1), the system would display the modulated scan parameters and the operator would believe that a modulated scan was being performed (see figure #2) and would only know that a non-modulated scan was actually performed by reviewing the scan slice data after the scan was completed (see figure #3). The amount of dose displayed (in figure #3) and recorded for each slice of the scan correctly reflects the actual delivered dose.

NOTE: Modulated scans are part of the AIRO's Automatic Exposure Control (AEC) system. AIRO systems with SW version 1.2 and higher have the Z-axis X-ray Tube Current Modulation feature (modulated scans). Based on a scout scan, this feature modulates tube current automatically as the Ring moves along the specified length of the scan. The dose is limited to not exceed that which would normally be applied based on the selected patient weight and exam region, but may reduce dose in areas of the patient with a smaller cross section based on the scout scan.

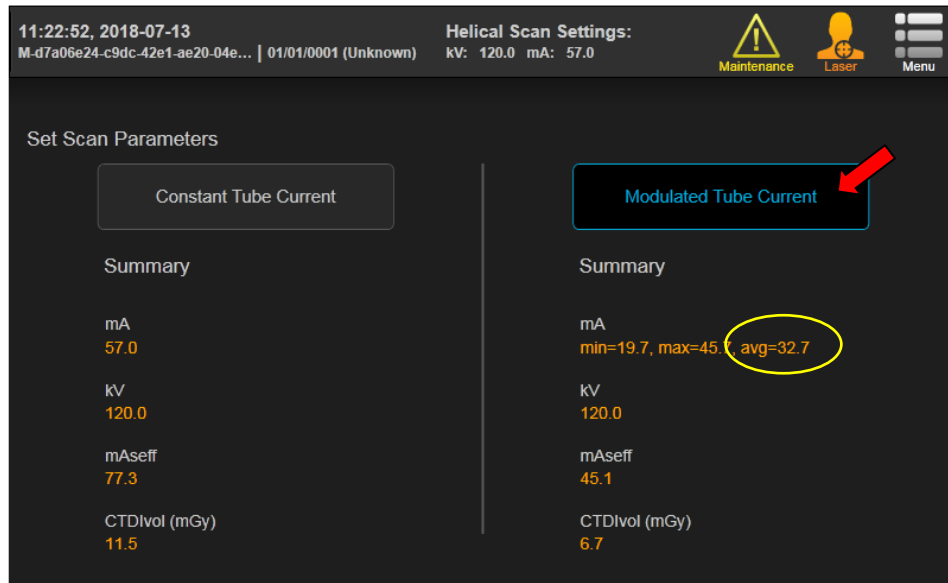


Figure #1

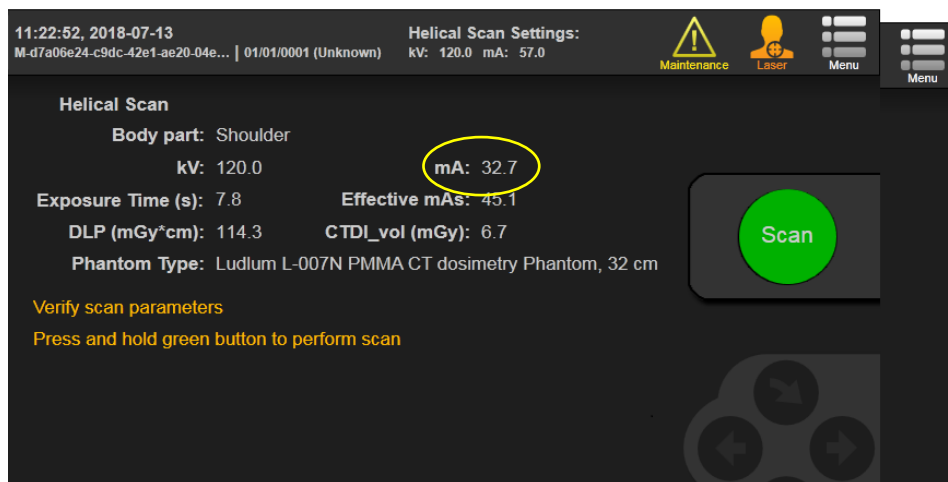


Figure #2

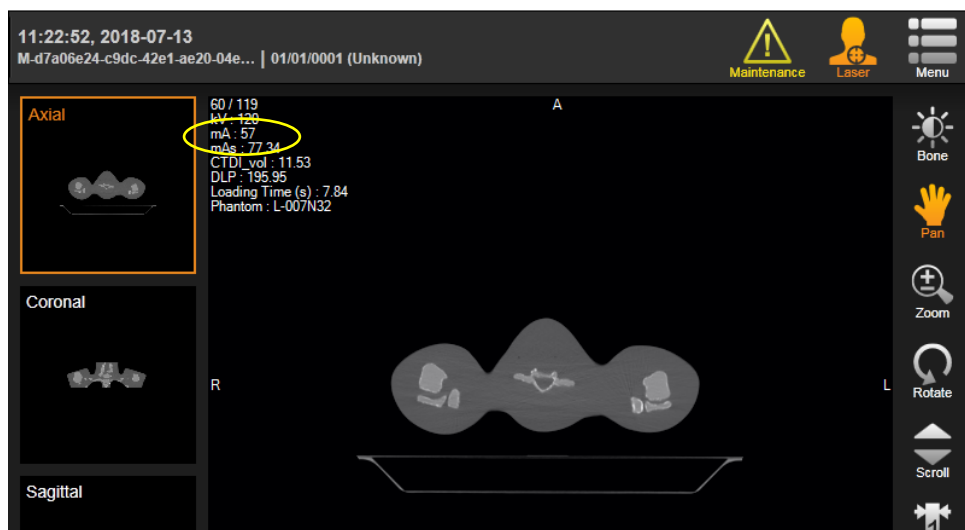


Figure #3

- **Associated risks to patients and potential hazards associated with the continued use of the device:**

The associated risk to patients would be extra dose/radiation. The patient would receive the non-modulated dose for the selected body region rather than the selected modulated scan dose, which may be lower.

This extra dose is more of a concern for the pediatric population because pediatric patients are more radiosensitive than adults and have a longer expected lifetime, putting them at higher risk of cancer from the effects of radiation exposure. The specific amount of deviation depends on the body region scanned.

The potential hazard associated with the continued use of the device is that if an operator selects a modulated scan, the system may perform a non-modulated scan and the operator would not be aware that a non-modulated scan was performed and more dose was delivered to the patient than intended.

- **Advise on actions to be taken by the user:**

CONTINUE USE OF AIRO ONLY IF USING NON-MODULATED ("CONSTANT TUBE CURRENT") SCANS (AS APPROPRIATE)

Mobius Imaging is advising all customers using AIRO systems with software version 2.0.0.0 to not select the modulated scan option, since scans will not be performed according to the parameters displayed for this option. Customers shall only select the non-modulated scan option until the software patch has been installed on their system.

Note that due to above described issue and the resulting non-availability of the modulated scan option, radiation protection is not optimized in regard to individual dose for the exposed person, and AIRO systems with software version 2.0.0.0 may not fulfill country-specific regulatory requirements in markets where Modulated Scans are required.

- **Please provide a copy of this Field Safety Notification to all AIRO operators that use the AIRO system.**

- **Transmission of this Field Safety Notice:**

At this time Mobius Imaging is requesting that Brainlab:

Contact all customers with AIRO systems with software version 2.0.0.0, and make the customers aware of the potential safety issue and to discontinue the use of Modulated Scans.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been distributed.

- **Mobius Imaging Contact (manufacturer):**

Michael Flynn
VP of Quality
Mobius Imaging, LLC
Phone: 978-615-5025
Email: mflynn@mobiusimaging.com

- **Brainlab Contact (distributor):**

If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

Customer Hotline: +49 89 99 15 68 1044 or +1 800 597 5911 (for US customers) or by

E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)

Fax Brainlab AG: + 49 89 99 15 68 5033

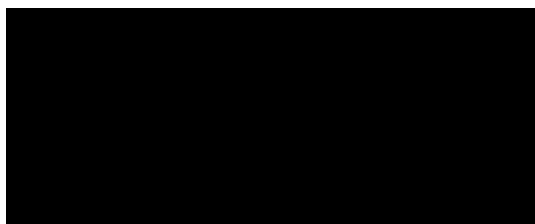
Address: Brainlab AG (headquarters), Olof-Palme-Straße 9, 81829 Munich, Germany.

- **Potential Fix and Timing:**

Mobius Imaging is currently working on an update to the software (software patch), to correct the issue and ensure that the type of scan selected by the operator will be performed. The software patch is tentatively planned to be available for AIRO systems by the end of August 2018. Brainlab will actively contact affected customers immediately to schedule the installation of the update once it is available.

The undersigned confirms that the appropriate EU Authorized Representative and Regulatory Agencies will be notified.

Sincerely,



Mobius Imaging, LLC

AIRO Field Safety Notification (FSN) Acknowledgement Page

I acknowledge, as a representative of the Hospital or Institution listed below, that I have received the Mobius Imaging Field Safety Notification (FSN# 2018-FSCA-001) concerning the risk associated with the use of the modulated scan feature on the AIRO.

(Please Check all that apply)

- ☐ I have read and understood the information in the Field Safety Notification;
- ☐ I have passed the information on to all people in my organization that need to be aware of the potential risk;
- ☐ We are aware not to select Modulated Scans at our facility until the AIRO software has been updated.

Site Name: _____

City: _____

State/Region: _____

Country: _____

System Serial Number: **AIRO -**

Hospital Representative: _____
(Name + Title)

(Signature)

Date Performed: _____