



Circular No. 21 / 2023


نقدم بتفويض
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07-07-1444 H

29-01-2023

Field Safety Corrective Action of Airo TruCT Mobile CT Scanner from Stryker.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=18421
Product	Airo TruCT Mobile CT Scanner.
Description	Airo Mobile CT System - X-ray system, diagnostic, computed tomography, full-body.
Manufacturer	Stryker.
Local agent	Global Leading Excellence.
The affected products	Catalog Number: MOBICT-32, All Serial Numbers.
Reason	Stryker received one report of an injury to an untrained user that occurred while the untrained user was moving an Airo TruCT unit in reverse. The Airo TruCT unit at issue did not experience a malfunction.
Action	1. To increase the visibility of instructions for users to consider when transporting an Airo TruCT unit in reverse, new labels will be affixed onto the Airo units. A service representative will contact customers when labels are available. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General





To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 21 dated 29/1/2023 Regarding NCMDR Field Safety Corrective Action of Airo TruCT Mobile CT Scanner from (mfr: Stryker).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Medical Devices Sector

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- Home
- Published FSNs/Recalls
- About NCMDR
- Contact Us
- FAQ
- Login

NCMDR

National Center for Medical Devices Reporting


المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 012 01 23 000

[Back](#)

Date submitted: 1/19/2023

Manufacturer:	Stryker
Device Type:	Airo TruCT Mobile CT Scanner
Description:	Airo Mobile CT System - X-ray system, diagnostic, computed tomography, full-body.
Medical Device Identifier:	Catalog Number: MOBICT-32, All Serial Numbers.
Reason of Field Safety Corrective Action:	Stryker received one report of an injury to an untrained user that occurred while the untrained user was moving an Airo TruCT unit in reverse. The Airo TruCT unit at issue did not experience a malfunction.
Remedy Action:	To increase the visibility of instructions for users to consider when transporting an Airo TruCT unit in reverse, new labels will be affixed onto the Airo units. A service representative will contact customers when labels are available. Airo TruCT use must be limited to trained users only. As stated in Manual Sections 1.7.1 and 2.10.1.
Athorized Representative/Importer/Distributor:	Al-Faisaliah Medical System
Report Source:	NCMDR
Source Ref. Number:	682229E03D1D0
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	 Stryker.pdf

[View History](#)

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Medical Device Correction

Airo TruCT system Transport Mode Labeling Update

Attn: Risk Manager/Operating Room Director/Radiology Director

Recall number: RA2022-3159042

December XX, 2022

Catalog number	UDI-DI	Product description	Serial numbers*
MobiCT®-32	00869346000200	Airo TruCT Mobile CT Scanner	All serial numbers

Purpose of Notification

Stryker is notifying Airo TruCT customers that we will be highlighting certain information that is already in the Airo TruCT User Manual on labels affixed to the Airo TruCT unit itself. Stryker received one report of an injury to an untrained user that occurred while the untrained user was moving an Airo TruCT unit in reverse. The Airo TruCT unit at issue did not experience a malfunction.

Product description

The Airo TruCT System is a mobile computed tomography (CT) system, including a mobile base that supports the Gimbal and Ring.

Potential risks

If a user is not trained to operate the Airo TruCT in transport mode, there is a risk of injury to the user, ranging from strain/sprain, bruising and minor lacerations to fractures and other serious injuries.

Summary of Action

To increase visibility of instructions for users to consider when transporting an Airo TruCT unit in reverse, the following labels will be affixed onto the Airo unit.



When backing up the system, always monitor the route and surrounding area to avoid colliding with corners, walls, and projections.

MI-43-0359 Rev 1

MI-43-0359 Rev 1



Always place hands on holster side grips when driving



(a)

Figure 1(a) & (b)- Image of labels

(b)

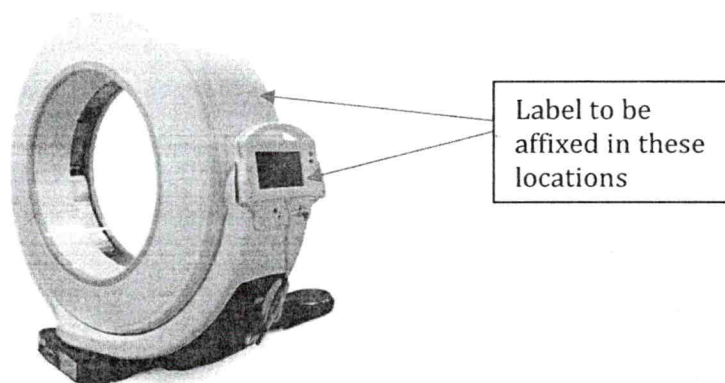


Figure 2- Image depicting location of where labels will be affixed.

Actions needed:

1. A service representative will contact your facility, when labels are available (**anticipated February 2023**), to schedule a time to affix the labeling to your Airo TruCT unit.
2. In the interim, please share this letter with Airo TruCT users as well as any other relevant personnel in your facilities.
3. Airo TruCT use must be limited to trained users only. As stated in Manual Sections 1.7.1 and 2.10.1:
 - “Users must receive and complete training from Mobius Imaging or its authorized agents before using AIRO. For training, contact your distributor or Mobius Imaging.”
 - “Cautions and Warnings: Never allow untrained persons to move or operate Airo TruCT as this creates a hazard of collision and equipment damage.”
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
 - Please provide contact details so that Stryker can inform the recipients appropriately.
 - If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
 - Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. **Complete the attached customer response form.** It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
 - Therefore, **please complete even if you no longer have any of the subject devices in your physical inventory.**
7. Return the completed form to your nominated Representative.