



تقدم بثقة
Moving Forward
with Confidence



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. 278.. dated 25/12/23. Regarding NCMDR Field Safety Corrective Action of Luminos Select from (mfr: SIEMENS).

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



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control





Circular No. 278/2023

11 -06-1445 H
25 -12-2023

لتقدم بثقة
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Field Safety Corrective Action of Luminos Select from SIEMENS

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19818
Product	Luminos Select.
Description	Radiological technology - stationary radiological equipment.
Manufacturer	SIEMENS.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Luminos Select.
Reason	Potential risk of footrest detaching from the patient table during an examination.
Action	1. The user must check that the footrest is locked into position and attached firmly every time before allowing a patient to set or stand on it. 2. The footrest must only be attached and removed when the table is horizontal. 3. For attaching the footrest, please follow the instruction in the attachment (Addendum – Supplementary Information) 4. Contact the local agent for remedial action.
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



How will the issue finally be resolved, and the corrective action be implemented?

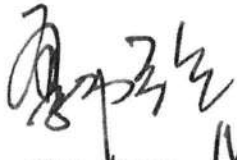
This advisory letter is distributed to all affected customers together with an addendum to the operator manual. The addendum contains additional details and illustrations on how to securely attach the footrest to further improve the understanding of handling the foot rest.


Please make sure that all persons operating the system are informed about the content of this letter and the addendum to the operator manual.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately inform your personnel accordingly. Please ensure that this safety advisory notice and the addendum to the operator manual are placed in the system's instructions for use.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely yours,
Shanghai, November 6th 2023


Nov. 6th 2023
Guo, Qiang
Head of Business Line
SSME X-Ray Products











Nov. 6. 2023
Wu, Jinyu
Head of Quality Management
SSME X-Ray Products



Footrest

Addendum – Supplementary Information

Legend

	Indicates a hint Is used to provide information on how to avoid operating errors or information emphasizing important details
	Indicates the solution of a problem Is used to provide troubleshooting information or answers to frequently asked questions
	Indicates a list item
	Indicates a prerequisite Is used for a condition that has to be fulfilled before starting a particular operation
	Indicates a one-step operation
	Indicates steps within operating sequences
<i>Italic</i>	Is used for references and for table or figure titles
	Is used to identify a link to related information as well as previous or next steps
Bold	Is used for screen outputs of the system
Menu > Menu Item	Is used for the navigation to a certain submenu entry
Text	Is used to identify inputs you need to provide
Orange	Is used to emphasize particularly important sections of the text
 CAUTION	<p>CAUTION</p> <p>Used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage.</p> <p>CAUTION consists of the following elements:</p> <ul style="list-style-type: none"> • Information about the nature of a hazardous situation • Consequences of not avoiding a hazardous situation • Methods of avoiding a hazardous situation
 WARNING	<p>WARNING</p> <p>Indicates a hazardous situation which, if not avoided, could result in death or serious injury.</p> <p>WARNING consists of the following elements:</p> <ul style="list-style-type: none"> • Information about the nature of a hazardous situation • Consequences of not avoiding a hazardous situation • Methods of avoiding a hazardous situation

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1 Area of application

This document describes the extensions to the Operator Manuals for the following systems:

- AXIOM Iconos MD
- AXIOM Iconos R100
- Luminos RF Classic
- Luminos Fusion
- LUMINOS Impulse

2 Footrest

Application

Positioning aid for examining patients when standing or sitting and for additional use with the foot holder for recumbent patients in Trendelenburg position.

The maximum permissible patient weight on the footrest is 180 kg.

WARNING

Foot rest overloaded

Foot rest disconnects or breaks resulting in patient injury

- ◆ Do not load the foot rest with more than 180 kg.
- ◆ If the patient weighs more than 180 kg, do not tilt the table more than 45°.
- ◆ Take care that the patient can stand securely on the foot rest.
- ◆ The maximum permissible weight for the patient table is 200 kg.

WARNING

Footrest not firmly attached

Patient slides off table with risk of cuts and other injuries

- ◆ Make sure that the footrest is attached firmly by pulling and pushing it and lifting it up.
- ◆ Check that the two green bars on each side of the footrest are visible.
- ◆ Attach and remove only when table is horizontal.

CAUTION

Attaching or detaching the footrest

Risk of injury

- ◆ Consider the heavy weight when handling the foot rest. Weight of the foot rest: ~ 15 kg.



The footrest can also be attached to the head end of the patient table, if the patient has to be turned for positioning (left-hand side head end).

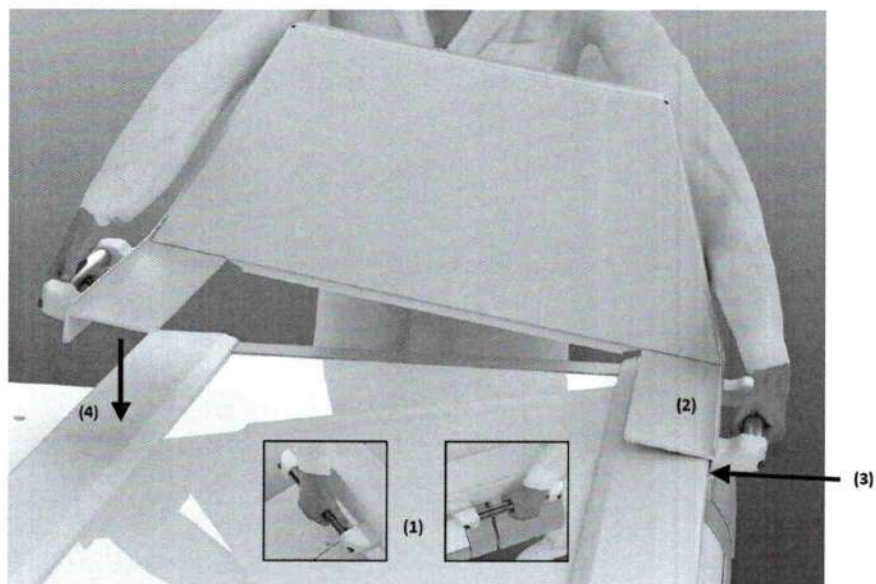
Three lock-in positions every 20 cm at the head end and foot end are available.

The room height calculator does not consider the footrest attached at the head end.

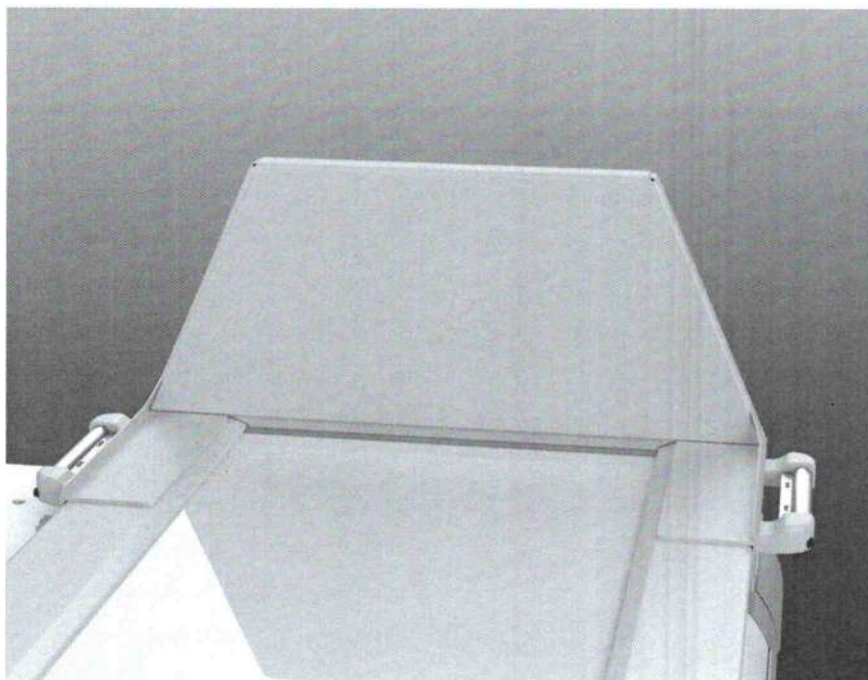
Be extremely careful when tilting the unit with the footrest attached at the head end and extended tabletop.

2.1 Attachment

- ✓ Patient table in horizontal position

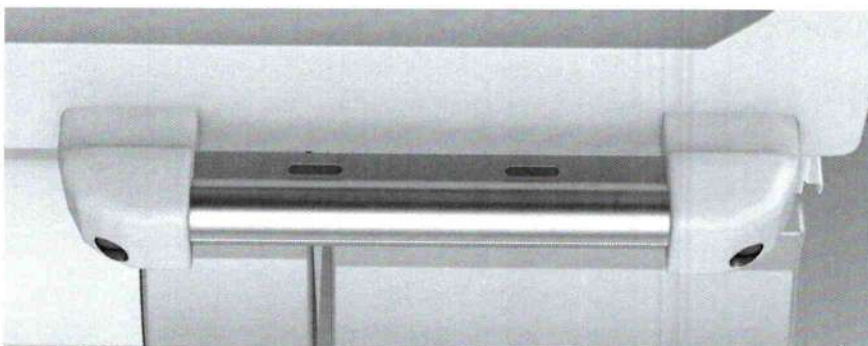


- 1 Hold footrest laterally on the handgrips and press the spring-loaded parts of the handgrips.
The two red buttons (1) on each side must be visible.
- 2 First, tilt the foot rest to the left and hook it in the left-hand side accessory rail (2). Press the left hand grip firmly to the accessory rail and release the spring-loaded part of the left hand grip (3).
- 3 Then lower the right side onto the accessory rail and release the spring-loaded part of the right hand grip (4).



- 4 Move the foot rest firmly back and forth until you hear it click into place.

The two red buttons must be flush with the hand grip and the two green bars must be visible on both hand grips.



- 5 You can shake the foot rest vigorously by grasping the foot rest itself (rather than the hand grips). Make sure that both sides of the foot rest are securely attached to the table.
- 6 Position the patient.



Be sure to check that the footrest has locked into position every time before allowing a patient to sit or stand on it.

Make sure that patients standing on the footrest hold onto the handgrip or the handgrip strip.

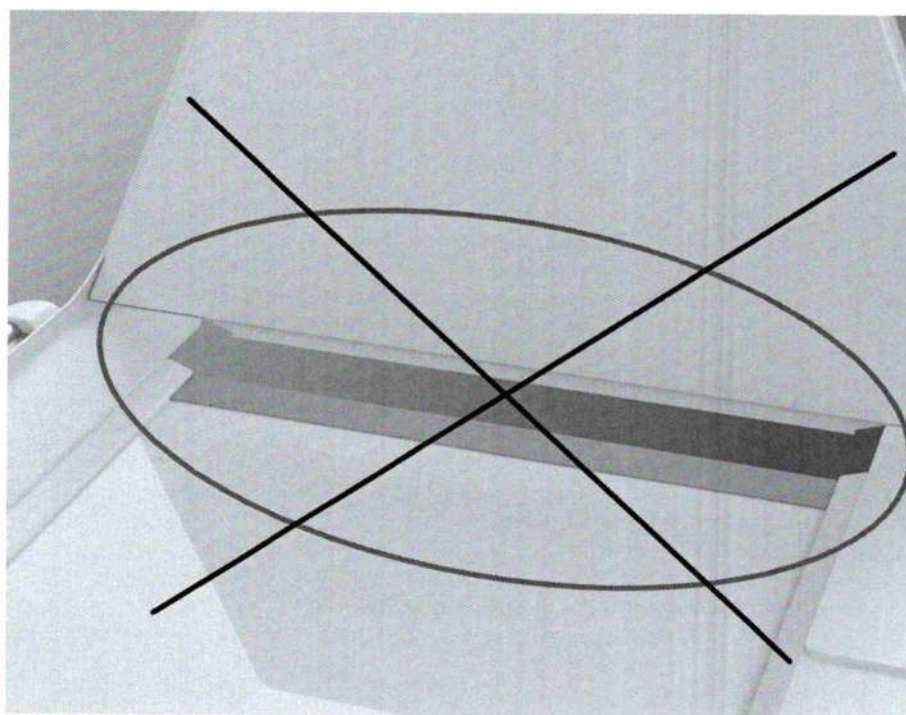
⚠ WARNING

Table tilted in Trendelenburg (head-down) position

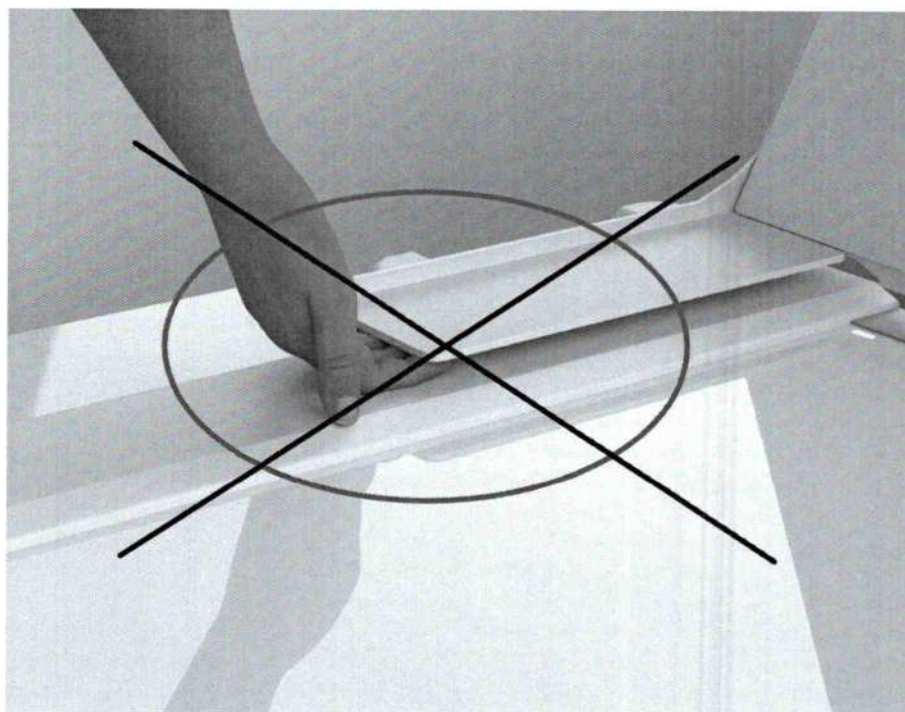
Patient slides off table head-first

- ◆ Use shoulder supports to prevent the patient from sliding off the table.
- ◆ If the table must be tilted more than 15° Trendelenburg (head-down), use the foot holder in addition to the shoulder supports.

2.2 Examples of incorrect attachment



There should be no visible gap between the end of the tabletop and the foot rest.



The foot rest must be flush with the tabletop. If there is too much play (like in the Figure above) the attachment is not secure. You should not be able to get your fingers between the foot rest and the table.

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