

2020-09-08 | 2020-010

Please forward this information to all relevant users, [biomedical staff for capital equipment, materials management and/or purchasing for consumables] and risk management department concerned in your facility

Corrective Action: mobile OR-Table MEERA, YUNO and YUNO II

Products affected:

Product	Article No.	S/N No.
MEERA EU with Drive Unit	720001B2	SN 417 to SN 503
MEERA EU w/o Drive Unit	720001B0	SN 1417 to SN 1689
MEERA US with Drive Unit	720001F2	SN 92 to SN 119
MEERA US w/o Drive Unit	720001F0	SN 221 to SN 226 and SN 701 to 711
MEERA ST EU Drive Unit	710001B2	SN 9 to SN 14
MEERA ST EU w/o Drive Unit	710001B0	SN 12 to SN 88
Mobile OR-Table YUNO OTN EU	143301B0	SN 1 to SN 267
Mobile OR-Table YUNO OTN US	143301F0	SN 1 to SN 90
Mobile OR-Table YUNO II EU	143302B0	SN 1 to SN 62
Mobile OR-Table YUNO II US	143302F0	SN 1 to SN 13

Dear Customer

The purpose of this letter is to inform about a potential issue concerning the mobile OR-Table MEERA, YUNO and YUNO II.

Our records indicate that your facility has received one or more of these devices.

Normal use and indications

The mobile OR-Tables MEERA, YUNO and YUNO II are designed to support and position the patient immediately before, during and after surgical interventions as well as for examination and treatment.

The following has been discovered

As part of our post market surveillance, cases with pulled-out plastic sockets (IEC 60320-1) of mobile OR-Tables MEERA, YUNO and YUNO II were reported to Getinge. Electric parts and / or wires were exposed. See Figure 1 below.

Potential hazards

If the mains cable (power cord) is still connected to the mains socket (power source), there is a risk of electric shock to user or third parties when touching exposed, electronic components.

Six cases have been reported to Getinge where the user received an electric shock. No permanent injury was reported to Getinge in any of these cases.

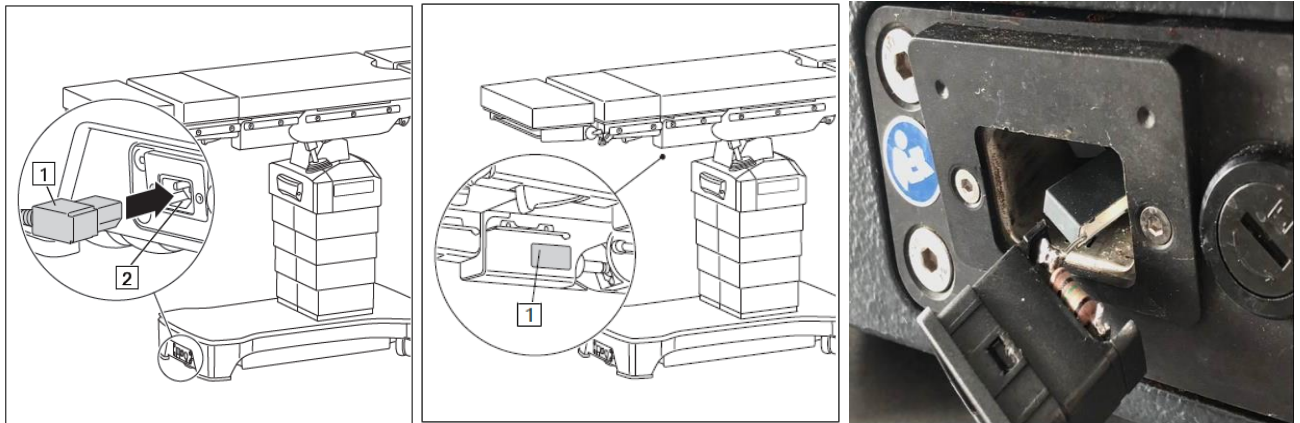


Figure 1: Position mains connection on **OR-Table MEERA** / position of product label on **OR-Table MEERA** including SN / pulled out mains connection with exposed electronic components

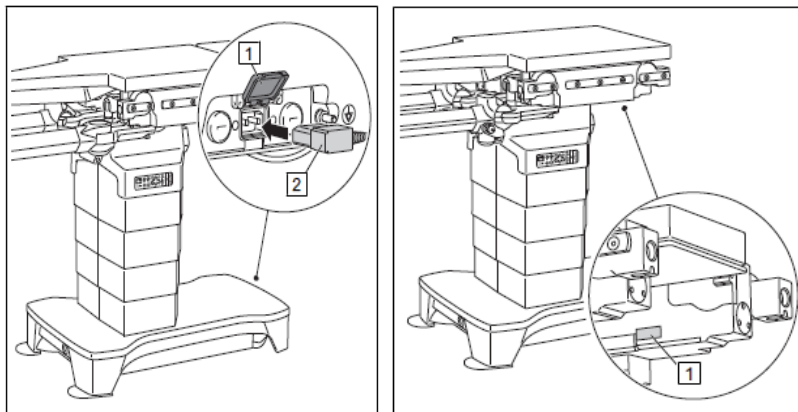
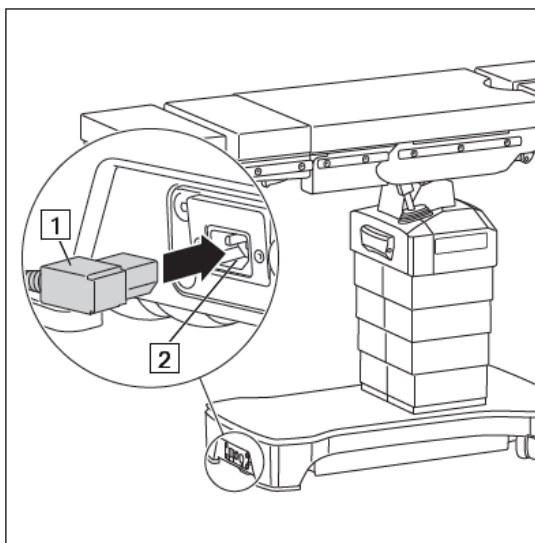


Figure 2: Position mains connection on **OR-Table YUNO** / **OR-Table YUNO II** / position of product label on **OR-Table YUNO** / **OR-Table YUNO II** including SN

Precautions

Until all actions have been accomplished, a visual and functional check is required to be performed by a trained person before operation. Furthermore, the information in the instructions for use (IFU) regarding connection to and disconnecting from the mains socket (power source) should be observed as a matter of urgency. See figure 3 for OR-Table MEERA and figure 4 for OR-Table YUNO.



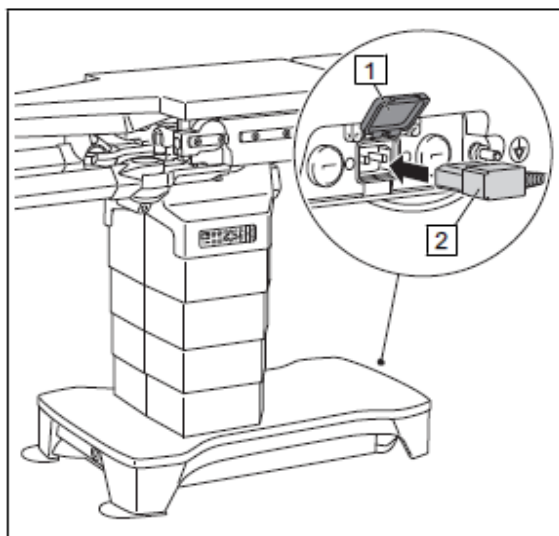
Connecting to mains supply

1. Connect the supplied mains cable **1** to the mains connection **2** of the OR table.
2. Plug into the supply voltage socket.
 - The status display for mains operation on the override control panel is lit up in green.
 - The rechargeable batteries of the OR table are charged.
 - The plug must always be accessible to ensure that the OR table can be disconnected from the power supply at any time.

Detach the mains cable

1. Detach the plug at the main socket.
2. Detach the mains cable from the operating table.

Figure 3: Abstract form IFU (establishing / separating the mains connection) for **OR-Table MEERA**



Connecting to mains supply

- Open the cover of the mains connection (1).
- Connect the supplied mains cable into the mobile operating table (2).
- Then plug into the mains socket.
 - ✓ The green LED on the override control panel flashes.
 - ✓ The rechargeable batteries of the mobile operating table are charged.
 - ✓ The plug must always be accessible to ensure that the OR table can be disconnected from the power supply at any time.

Detach the mains cable

- Detach the plug at the main socket.
- Detach the mains cable from the operating table.

Figure 4: Abstract form IFU (establishing / separating the mains connection) for **OR-Table YUNO / OR-Table YUNO II**

If the plastic socket of the cold-device plug is pulled out, do not try to put it back into the housing. If electronic parts or wires are exposed, do not touch them. Disconnect/detach the cable from the main socket and call your in-house technical service and arrange the repair of the table.

Corrective action

A technical solution that will correct this issue has been developed.

Getinge will initiate an immediate field action of all affected mobile OR-Tables MEERA, YUNO and YUNO II with the serial numbers listed above. You will be contacted by your Getinge sales or service representative to schedule the update of your device(s).

Passing on the information described here

Please ensure that all persons within your organization who use the above-mentioned devices - and anybody else who needs to know - receive this field safety notice. If you have distributed the product on to third parties, please forward a copy of this notice or inform the Getinge contact you are aware of.

Please complete & return the attached acknowledgement form and maintain awareness of this notice and related actions until your mobile OR-Table MEERA, YUNO and / or YUNO II has been updated, to ensure effectiveness of the corrective action.

Contact person

Should you have questions or require additional information, please contact your local Getinge representative.

The competent authorities concerned have received a copy of this field safety notice.

We apologize for any inconvenience. However, please consider this action as a preventive action to increase quality.

With kind regards

MAQUET GmbH

Holger Ullrich

Director Quality Regulatory Compliance

Mario Mühe

Safety Officer for Medical Devices