

2019-04-02 | 2018-025 |

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

## Preventive Corrective Action: mobile OR-Table MEERA

### Products affected:

Product	Article No.	S/N No.
MEERA EU with Drive Unit	720001B2	SN 1 to SN 416
MEERA EU w/o Drive Unit	720001B0	SN 1 to SN 1416
MEERA US with Drive Unit	720001F2	SN 1 to SN 91
MEERA US w/o Drive Unit	720001F0	SN 1 to SN 220
MEERA ST EU Drive Unit	710001B2	SN 1 to SN 8
MEERA ST EU w/o Drive Unit	710001B0	SN 1 to SN 11
MEERA ST US w/o Drive Unit	710001F0	SN 1

Dear Customer

The purpose of this letter is to inform about a potential issue concerning the mobile OR-Table MEERA. Our records indicate that your facility has received one or more of these devices.

### Normal use and indications

The mobile OR-Table MEERA is 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 were reported to Getinge involving a mobile OR-Table MEERA, and in which the plastic socket of the IEC 60320-1 socket was pulled out of the metal cage and electronic parts were exposed. See Figure 1 below.

### Potential hazards

In cases where the socket was pulled out and main cable is still connected to the main socket (power source), there is a risk that a user or third person may suffer an electric shock when coming in contact with the exposed electronic components.

Three 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 / pulled out mains connection with exposed electronic components / position of product label on mobile OR-Table MEERA 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 2 below.

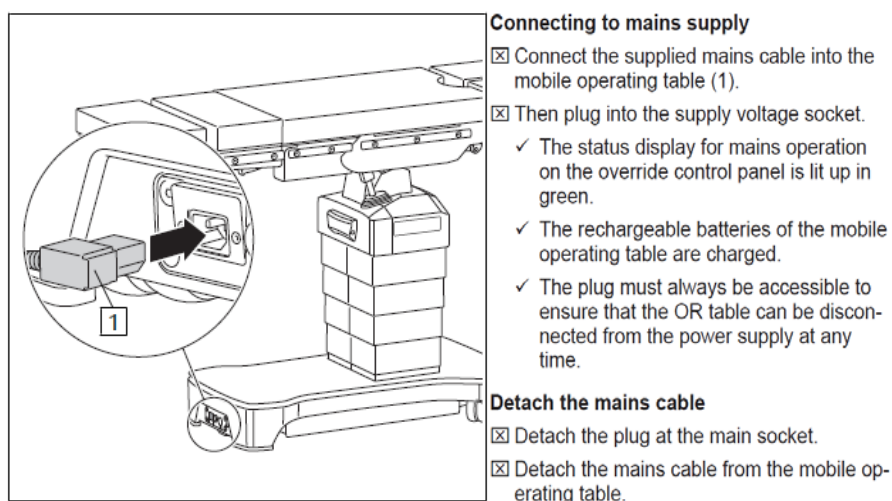


Figure 2: Abstract form IFU (establishing / separating the mains connection)

If the plastic socket of the cold-device plug is pulled out do not try to put it back into the housing and if there are any exposed electronic components: do not touch them. Call your in-house technical service and arrange the repair of the table.

### **Corrective action**

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

Getinge will initiate an immediate field action of all affected MEERA OR-Tables with the serial numbers listed above. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

### **Passing on the information described here**

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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 has been updated, to ensure effectiveness of the corrective action.

### **Contact person**

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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

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Holger Ullrich

Director Product Compliance  
SW

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Mario Mühe

Safety Officer for Medical Devices