

Getinge - MAQUET GmbH | Kehler Str. 31 | 76437 Rastatt

Urgent Field Safety Notice

Please forward this notice to all relevant staff and potential users of the device!

Preventive Field Corrective Action

Emergency Room Examination Table 42039602

Reference CP2018-002

Dear customer,

with this letter we inform you about a potential issue concerning the Emergency Room Examination Table 42039602.

Description of the problem including the determined cause:

As part of our Post Market Surveillance Getinge – MAQUET was informed by BfArM of the following issue with the Emergency Room Examination Table (42039602). It has been reported that screws that hold the reclining surface on the frame have loosened or completely fallen out. The screws that hold the reclining surface on the frame are not secured against unintentional loosening. Through years of daily use of the Emergency Room Examination Table (42039602), screws can come loose or fall out completely. If all screws loosen / become detached and the reclining surface is just lying on the frame with this is not noticed by the user and the patient, the reclining surface together with the patient could fall down. To prevent such eventuality, we have started this field action.

Such a situation has not been reported to Getinge - MAQUET GmbH to date

No case of injury of a patient or user has been reported to Getinge - MAQUET GmbH to date.

Identification of the affected medical devices:

Potentially affected by this issue are all manufactured Emergency Room Examination Table (42039602).

Which measures are to be taken by the user?

Our sales records indicate that you own one or several of the potentially affected products.

To ensure that there will be no incident in the future due to a loosened reclining surface the screws are replaced and new screws will be secured with detent edge discs.

Until replacement of the screws the Emergency Room Examination Table (42039602) should be inspected for loose or lost screws at least once per day.

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 passed the product on to third parties, please forward a copy of this notice or inform the Getinge - MAQUET contact you are aware of.

Please keep this notice together with the instructions for use of the device at least until the corrective measure has been performed.

Contact person:

For further queries please do not hesitate to contact your Getinge - MAQUET contact person. Should more information being required please contact our safety officer for medical devices during normal business hours (refer to contact data on the first page).

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

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

With kind regards

Getinge - MAQUET GmbH

