
Urgent Field Safety Notice

Subject: ClinActiv® Therapy Surface—Instructions in Case of Accidental Release of Silicone Oil

FSCA-identifier: Mod 1207

Type of action: Customer Notification

Date:

To: Chief Executive,
Facility Administrator,
Facility Engineer,
Vigilance Manager,
Biomedical Engineering,
Medical Device Liaison Officer

Affected Devices:

Models: ClinActiv® and ClinActiv® Plus Therapy Surface
Models N02050, N02051, P02062, P02063,
P02064 and P02065

Range of serial numbers affected: All

Background:

Hill-Rom has become aware of a possible hazardous situation when silicone oil contained in the Vario® sensor within the ClinActiv® Therapy Surface is accidentally released. When the pocket of silicone oil is subjected to excessive mechanical stress it may disconnect and leak oil outside the mattress enclosure and onto the floor. This may create a hazardous situation where the patient or caregiver may slip and fall. One health consequence has been reported related to this issue.

Action to be taken:

Hill-Rom has developed additional cleaning instructions on how to clean the floor if silicone oil is accidentally released to help avoid potential injury.

Please complete and return the attached Customer Response Form/Receipt within 30 days of receipt.

After receipt of your Response Form, Hill-Rom will send you a copy of the “Accidental silicone oil release measures” cleaning instructions. In the case of accidental silicone oil release, you should follow these cleaning instructions.

It is important for ClinActiv® users to adhere to maintenance instructions provided by Hill-Rom, and to inspect mattresses and accessories at least once a year. The Vario® sensor is a wearable part of the ClinActiv® mattress, and ClinActiv® users should consider replacing the Vario® sensor at least every 3 years. Beyond that, any mattress maintenance program must be adapted to its actual conditions of use.

Important: The *Customer Response Form/Receipt* provides Hill-Rom with the means to monitor the progress of Field Corrective Actions. It is imperative that you return this form/receipt for our records.

Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Hill-Rom confirms that the relevant Competent Authorities have been informed of this Urgent Field Safety Notice.

If you have sold/loaned your mattress and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner. Please inform your local Hill-Rom representative about the new owner to avoid any unnecessary reminder.

Contact reference person:

If you have any questions concerning this notification, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Regards,

Hill-Rom Technical Support

Attachment: Customer Response Form/Receipt



Customer Response Form/Receipt

Subject: ClinActiv® Therapy Surface—Instructions in Case of Accidental Release of Silicone Oil (Mod 1207)

It is imperative that you return this form/receipt for our records.

Please complete and **return this Response Form** within 30 days to Hill-Rom. See specific instructions at bottom of page. Thank you.

Hill-Rom account number: _____

Name of the facility: _____

Address of the facility: _____

City: _____ Country: _____

Facility Authorized Name: _____

Please print legibly

Signature: _____ Date: ___/___/___

Title: _____ Phone: _____

Email: _____ Fax: _____

Check action(s) taken:

- We acknowledge receipt of this notification, and it has been forwarded to those who need to be aware within our organization and/or to any organization where the affected devices have been transferred.
- We need _____ copies of the cleaning instructions.
- We do not have any affected products.

As soon as possible, please FAX or email this form to: