

# Medical Device Alert

Ref: MDA/2013/086 Issued: 19 December 2013 at 15:30

## Device

Pressure reducing air mattresses: ClinActiv and ClinActiv Plus Therapy Surface. Manufactured by Hill-Rom.

Models N02050, N02051, P02062, P02063, P02064 and P02065.

All serial numbers are affected

## Problem

Silicone oil may leak out of the pressure sensor of the mattress and spill onto the floor. Patients or carers may slip in the oil and injure themselves.

The manufacturer has developed instructions on how to clean up these leaks but they were not included in the [Field Safety Notice](#) dated 22 July 2013.

In addition, the manufacturer has not received sufficient confirmation from users that they have received and acted upon this information.

The MHRA remains in discussion with Hill-Rom about its corrective actions and sensor replacements.

## Action by

Those responsible for the use, service and maintenance of these devices.

## Action

- Ensure all staff are aware of the instructions on how to clean up any silicone oil leakage (see appendix).
- Ensure the sensors are:
  - checked annually
  - replaced at least every 3 years
  - included in your maintenance programmes.
- Return the customer response form to Hill Rom.

## CAS deadlines

Action underway: 07 January 2014

Action complete: 19 February 2014

**Note: These deadlines are for systems to be in place to ensure that staff are aware of the instructions and to check that maintenance programmes are updated.**

## Contact

### Manufacturer

Bhaveeka Dattani  
Hill-Rom

Tel: 01530 562 129

Email: [mdd@hill-rom.com](mailto:mdd@hill-rom.com)

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- Social services in England (directors)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All wards
- All clinical area
- Community hospitals
- Community nurses
- EBME departments
- Equipment libraries and stores
- Maintenance staff
- Medical directors
- Medical libraries
- Nursing executive directors
- Risk managers

### NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Risk managers

### Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Equipment stores
- Equipment supplies managers
- Maintenance staff
- Risk managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing personal care (adults)
- Care homes providing nursing care (adults)
- Further education colleges registered as care h
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

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Ashby Park  
Ashby de la Zouch LE65 1 JG  
Tel: 01530 562 129  
Fax: 01530 441 555  
Email: [mdd@hill-rom.com](mailto:mdd@hill-rom.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/086** or **2013/006/011/401/002**.

### Technical aspects

Andy Marsden or Ian Sealey  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7205 / 6691  
Fax: 020 8754 3965  
Email: [andy.marsden@mhra.gsi.gov.uk](mailto:andy.marsden@mhra.gsi.gov.uk)  
[ian.sealey@mhra.gsi.gov.uk](mailto:ian.sealey@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
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London SW1W 9SZ  
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Fax: 020 8754 3965  
Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings, Stormont Estate  
Dundonald BT4 3SQ  
Tel: 02890 523 704  
Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

## How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 5801

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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Appendix

## Accidental silicone oil release measures

The user is instructed that if he experiences accidental release of silicone oil, the following measures shall be followed:

### Environmental precautions

Do not discharge into drains, water courses or onto the ground. Collect spillage. For a large spillage, contain the spillage by bunding.

### A Methods for containment and cleaning up the floor

#### 1. Recovery

Instruct the staff NOT TO REMOVE AFFECTED MATTRESS FROM BED SPACE (to prevent spreading the silicone over a greater area).

Collect up contaminated products and place it in a spare container:

- suitably labeled;
- with a closing device.

Keep the recovered product for subsequent disposal.

#### 2. Neutralisation

Absorb with dry sand, dry sawdust or other dry inert absorbent. Neutralisation step length should be adapted to permit all silicone that penetrated the floor to be absorbed: the longer silicone oil remained on the floor, the longer the neutralization should last. If unknown, neutralization should last at least half a day.

#### 3. Cleaning / Decontamination

**WARNING:** Do not clean with the following product: Water, ethanol, acetone.

Hill-Rom recommends the following product: Cillit Bang - Power Cleaner with bleach from Reckitt Benckiser.

Ready to use - Contact time: 15 min

Use cleaning/disinfection products safely: Always read the label and product information before use.



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Finally, flush area with plenty of cold water or your usual cleaning products.

If necessary, repeat cleaning / decontamination with the recommended product until the ground gets free of silicone oil.



\* Based on information provided by the manufacturer of the silicone oil  
(Source: Bluestar Silicone – Rhodorsil 47 V 100, MSDS rev 7.0 issued on July 19, 2011).



### Personal precautions, protective equipment and emergency procedures:

**WARNING:** Contaminated surfaces may be slippery. A hazard warning sign shall be used to make sure that everyone is safe and alert as long as measures have not been implemented. Contaminated area should be delimited.

The Use of personal protective equipment is encouraged during all steps.

**Eye/face protection:** Safety Glasses.

**Hand protection:** Use protective gloves made of: Nitrile or Polyvinyl chloride (PVC).

**Other:** It is a good industrial hygiene practice to minimize skin contact. *Wear suitable protective clothing.*

### B Method for cleaning covers of the mattress

Covers of the mattress if contaminated can be machine washed.

Follow the instructions below to prepare for machine washing:



Maximum temperature : 70°C  
Delicates



Only clean with oxygenated agents



Do not iron



Do not dry clean



Can be tumble dried  
Moderate temperature: 50°C

### C Disposal

Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Incinerate in suitable combustion chamber.

Contaminated packages should be as empty as possible. Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Recycle following cleaning or dispose of at an authorised site.

European Waste Codes:  
Unused product: 07 02 17

Hill-Rom

Hill-Rom Industries S.A. - 188, Rue du Caducée - 7000 Courmoulogne - 34195 MONTPELLIER Cedex 5 - FRANCE  
Hill-Rom reserves the right to make changes to the design, characteristics and models without prior notice.  
The only warranty Hill-Rom makes is the express written warranty attached on the sale or rental of its products.  
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