

# **Urgent Field Safety Notice**

**Subject:** Thermo contour mattress

**FSCA:** BAR0902

**Type of action – Revised instructions for use/maintenance**

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**Date:** 18<sup>th</sup> December 2009

**To:** Chief Executive  
Facility Risk Manager  
Nursing Directors  
Infection Control Managers  
Tissue Viability Nurses  
Vigilance Manager  
Biomedical Engineering  
Medical Device Liaison Officer

**Affected devices:**

Thermo contour mattresses.

**Background:**

In 2009 following an increased level of inspection, some hospitals in England reported an increasing number of contaminated Thermo contour mattresses as a result of mechanical damage to covers in use, presenting a risk of cross infection between patients.

Polyurethane covers as used by all producers and suppliers of all brands of mattresses are frequently damaged in use. In many cases the damage is not visible to the naked eye, and only revealed after the cover is unzipped. A greatly increased level of inspection by some hospitals has revealed contamination of the inside.

A previous Field safety Notice (BAR0901) released on August 3 2009 is now cancelled and replaced by this current Field safety Notice because subsequent multiple laboratory testing and examination of damaged Thermo contour covers has revealed no manufacturing fault.

All Thermo contour products are certified to Quality Assurance standard ISO 13485-2003 by Veritas Denmark.

In line with these findings the Instructions for Use sent with all Thermo contour mattresses have now been updated to clarify the routine inspection and maintenance requirements in order to reduce the risk.

**Action to be taken by the user:**

The new leaflet provides the following information:

**Daily:** Visually inspect the surface for any evidence of damage. Replace damaged covers.

**Weekly:** Unzip the cover of each Thermo Contour mattress.

Inspect the inside of the top cover and the top of the foam for visible signs of contamination from fluids that may have leaked into the mattress.

If contaminated:

- Remove the mattress from service.
- Contact your local distributor (see the attached list of contacts) quoting reference BAR0902 to purchase replacement Thermo contour mattresses and covers.

Ensure that spare mattresses and covers are readily available.

**Transmission of this Field Safety Notice:**

Please acknowledge receipt and pass this notice on to all those who need to be aware within your organisation and/or to any organisation 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.

Yours sincerely,

Michael B. Allaway  
Managing Director  
Barrington Healthcare International Ltd  
26 Old Gloucester Street  
London WC1N 3XX

## List of contacts

<b>Country/Region</b>	<b>Telephone</b>	<b>Distributor</b>
Austria:	+43 (0)2243 28550	Hill-Rom
France:	+33 (0)2 97 50 92 12	Hill-Rom
Germany:	+49 (0)211 16 45 00	Hill-Rom
Italy:	+39 02-950541	Hill-Rom
Netherlands:	+31 (0) 347 32 35 32	Hill-Rom
Nordic Countries:	+46 (0)8 564 353 60	Hill-Rom
Republic of Ireland:	+353 (0)1 459 6585	Keaney Medical Ltd
Spain/Portugal:	+34 (0) 93 6856000	Hill-Rom
Switzerland:	+41 (0) 21/706 21 30	Hill-Rom
United Kingdom:	+44 (0) 1530 562167	Hill-Rom
Rest of the World:	+44 (0) 20 7629 9787	Barrington Healthcare International Ltd