

Urgent Field Safety Notice

Subject: TotalCare® Duo®2 Therapy System

FSCA-identifier Mod 379

Type of action Information on Cleaning and Disinfection Instruction

Date: 01st October 2007

To: Facility Risk Manager and Administrator
Vigilance Manager
Biomedical Engineering

Affected devices:

TotalCare® Duo®2 Therapy System

Background:

Hill-Rom have updated the cleaning and disinfection instructions of the TotalCare® Duo®2 Therapy System to limit the risk of cross contamination.

Action to be taken by the user:

1. Follow the attached Hill-Rom cleaning and Disinfection Instructions.
2. Unzip the mattress cover. Check for any sign of fluid contamination on the mattress and damage or holes in the mattress covers.
3. Clean and disinfect the bed frame and mattress.

Transmission of this Field Safety Notice: (if appropriate)

Please 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.

Contact reference person:

If you have any questions regarding this safety notice, please contact Hill-Rom Technical Support using the attached listing for your geographical area.

Yours sincerely

Hill-Rom Technical Support



Technical Support Contact Information

Important: This is a comprehensive list of Technical Support contact information for Hill-Rom offices worldwide. If this is attached to another document or letter, it does **not** mean that every country listed below is affected by that document.

| | |
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| United States: | 800-445-3720 (8:00 a.m. to 5:00 p.m. ET*) |
| Canada: | 800-267-2337 (8:00 a.m. to 5:00 p.m. ET*) or jeff.moorehead@hill-rom.com |
| Austria: | 02243 28550 |
| France: | 0820 01 23 45 |
| Germany: | 02152 144 222 |
| Ireland: | 01 413 6005 |
| Italy: | 02 950541 |
| Netherlands: | 0347 323532 |
| Nordic Region: (Sweden, Norway, Denmark, Finland, Iceland) | +46 (0)8 564 353 60 or se.marketing@hill-rom.com |
| Spain: | 902 193 423 |
| Switzerland: | 0848 81 15 30 |
| United Kingdom: | 01530 411000 |
| All other countries requesting support for products manufactured in the U.S.: | 812-934-1348 (8:00 a.m. to 5:00 p.m. ET*) or gary.lakes@hill-rom.com |
| All other countries requesting support for products manufactured outside the U.S.: | +33 (0) 2 97 50 92 45 or leny.rodriquez@hill-rom.com |

* ET = New York time