

## Urgent safety notice

### Disinfection and cleaning of hypothermia and hyperthermia devices

**Legal Manufacturer:** Medos Medizintechnik AG  
Obere Steinfurt 8-10  
52222 Stolberg  
Germany

To all users of the hypothermia and hyperthermia devices from Medos.

In this letter we would like to draw your attention to a problem, which could occur with the hypothermia and hyperthermia devices listed below. At the same time, we also want to inform you about our planned interim measures.

#### Affected hypothermia and hyperthermia devices

Product number	Designation
ME DPHC 0001	deltastream HC, 230V
ME DPHC 0002	deltastream HC, 115V
4000122	NovaTherm, 230V
4000127	NovaTherm, 115V
5000100	i-cor TCU, 230V
5000101	i-cor TCU, 115V

#### Description of problem

Medos has been informed of cases of nontuberculous endocarditis caused by mycobacteria or infections after cardiac surgery, in which a hypothermia or hyperthermia device was used. As part of our ongoing quality control and improvement, we would like to inform you about the changes we have made to the cleaning procedures, as well as the safety notices of the BfArM.

Please note the following in terms of precautionary health protection and as an interim measure to reduce the risk:

- In future please clean the device every 14 days with Sanosil solution (3% H<sub>2</sub>O<sub>2</sub>). Since there may be an excess pressure during the cleaning process the tank lid must remain open during the cleaning process. Furthermore, we recommend that the water is changed daily and after each patient.
- Change least once a year, the hose assembly.
- Please ensure that your employees are informed about mycobacteria, as well as their effect.
- All relevant hypothermia and hyperthermia devices should be operated in a separate room from the operating theatre. If this is not possible, another suitable measure should be found to ensure the risk of infection is effectively minimised. This is possible, for example, by increasing the disinfection frequency of the surfaces of the devices and changing gloves after cleaning the equipment.
- Note the cleaning and disinfection instructions for the equipment with the higher concentration of hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) to 3%, as mentioned above.

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- Nursing staff and doctors, who look after patients after an operation with a connected hypothermia or hyperthermia device, should pay greater attention to the symptoms caused by mycobacteria and, if necessary, carry out examinations for infection.
- Perform regular checks for contamination of equipment. We recommend monthly intervals to determine the quality of the water.

Please direct any questions you may have to our Customer Service department:

**Customer Service +49 7131 2706 133**

***Notice!***

Please do not hesitate to contact us should you have any other questions in relation to this safety information and the recommended measure.

Please ensure that all affected individuals within your organisation or other related organisations are informed about this safety information.

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Heilbronn, 09.02.2016



Dr. Torsten Rinne  
Director of Regulatory and Quality Affairs

Allegato A – feedback relativo a FSN

Xenios AG  
Alla C.A. del Dott. Torsten Rinne  
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Germania

## FSN: Disinfezione e pulizia dell'apparecchio per ipo-/ipertermia

Con la presente, confermiamo che l'informativa di sicurezza è stata inoltrata a tutti i reparti interessati e l'avvertenza di sicurezza è stata letta, compresa ed attuata.

Numero di serie: \_\_\_\_\_

Clinica: \_\_\_\_\_

Reparto: \_\_\_\_\_

Responsabile: \_\_\_\_\_

\_\_\_\_\_  
Luogo, data

\_\_\_\_\_  
Firma

Potete inviarci l'allegato A nei seguenti modi:

E-mail: [FSN@xenios-ag.com](mailto:FSN@xenios-ag.com)

Per posta: Xenios AG, alla C.A. del Dott. Torsten Rinne, Im Zukunftspark 1, 74076 Heilbronn, Germania

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