

Urgent Field Safety Notice
Ref.: HCH - 2014 - 01

ULTRAFILTER U9000

17 July 2014

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Dear Customer,

Gambro is sending you this communication to advise you of the possibility of external fluid leakage with its Ultrafilter U9000 as a result of multiple disinfections using a sodium carbonate-based solution. The Ultrafilter U9000 is used on Gambro/Hospal Hemodialysis Delivery Systems to purify incoming water as well as to obtain high quality dialysis fluid that meets microbiological requirements.

Various disinfection procedures are available to support the use of the Ultrafilter U9000 with a Gambro/Hospal dialysis machine (see also Instructions for use of Ultrafilter U9000) including:

- Heat disinfection
- Heat disinfection combined with citric acid (max. concentration of 2%)
- Heat disinfection combined with sodium carbonate (max. concentration of 0.5%)
- Chemical disinfection with peracetic acid (max. concentration of 0.1%)
- Chemical disinfection with sodium hypochlorite (max. concentration of 0.5%),

The housing of the Ultrafilter U9000 is made of polycarbonate, a material that is known to undergo slow chemical degradation during long term exposure to alkaline substances. Intensive use of sodium carbonate-based disinfection programs over several months may, therefore, cause degradation of the ultrafilter housing leading to an external fluid leakage at the position of the welding seal between the filter housing and the header cap.



Position of potential leakage



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The user will generally be alerted to this condition during the machine's disinfection program or during function check prior to a patient treatment, either by observing a visible external leakage of fluid or through an alarm issued by the dialysis machine. However, if the leakage is slow developing, there is a remote probability that it will not be noticed until the dialysis treatment has started.

If a leakage is observed during treatment, the user should immediately stop the treatment and change the U9000 Ultrafilter to avoid excessive fluid removal from the patient.

Actions to be taken

The use of sodium carbonate-based disinfection programs has been broadly validated for the U9000 Ultrafilter. However, to minimize the risk of an external fluid leak, Gambro strongly recommends adhering to the following instructions, when using sodium carbonate based disinfection programs with U9000:

1. Do not exceed the recommended disinfectant concentration given in the Operator's Manual of the respective Gambro/Hospital dialysis machines.
2. Do not use more than eight sodium carbonate disinfection cycles over the lifetime of the U9000.
3. Do not use sodium carbonate disinfection cycles more than once a week.
4. Include daily disinfection with citric acid in the disinfection protocol.
5. Avoid periods of machine inactivity (e.g. weekend storage) directly after disinfection with sodium carbonate based agents.
6. The recommended process of combined "Heat + CleanCart-A" disinfection shall be followed by a "Heat + CleanCart-C" disinfection on the same day and ideally be performed in the middle of the working week.

Please, bring this notice to the attention of all who need to know or be aware of it within your facility, and to any third party to which any products may have been transferred.

Attachment

- Customer Reply Form

We kindly ask you to provide the requested information in the attached Customer Reply Form and return it to your Gambro sales office

Should you have any questions or require any further assistance, please contact your Gambro sales office:

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Sincerely yours

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