FRESENIUS MEDICAL CARE

Field Safety Notice

sleep•safe harmony (article no. M206001) – Potential risk of overhydration in pediatric treatment mode

Date: May 28th, 2026

Dear Valued Customer,

As part of our ongoing market surveillance Fresenius Medical Care (FME) is updating the Instruction for Use (IFU) to our *sleep•safe harmony* (SSH) device. The IFU update will include a warning regarding the potential risk of overhydration that may occure in pediatric treatment mode with inflow volumes from 100 ml to 500 ml, typically used in treatment of infants and young children.

The interplay of patient parameters linked to volume, such as permitted residual volume, and time management can influence the generation of ultrafiltration, the outflow volume as well as the treatment efficiency. Reduced removal of fluid may result in fluid overload, leading to weight gain and potential clinical complications associated with overhydration, such as hypertension, pulmonary edema, and other cardiovascular issues.

To reduce the potential risk of overhydration in this vulnerable patient population with low inflow volumes, the following recommendations should be applied:

1 . Enhance patient monitoring

- Closely monitor e.g. patient weight measurement, blood pressure and fluid status
- Closely monitor changes in the expected ultrafiltration volume
- Immediate clinical actions must be taken in case of any significant decrease in ultrafiltration or clinical signs of fluid overload

2. Adjust the setting for the allowable residual volume

- Change the default setting of 35 % for "*permitted residual volume*" to a lower value (e.g., 15% or 10% as appropriate) on the sleep *sleep•safe harmony* device

3. Consider manual and/or additional outflows

- Consider using a "*manual outflow*" or implement an "*additional outflow*" strategy on the cycler as per established clinical guidelines and patient needs

Please provide this information to all Health Care Professionals in you organization who treat patients with *sleep•safe harmony* using PEADIATRIC option.

Fresenius Medical Care is in the process of updating the IFU and an additional sheet to the IFU will be provided to you soon.

A FME representative will contact you shortly to provide the additional sheet and to offer dedicated training.

We sincerely apologize for any inconvenience this may cause. The functionality of the *sleep•safe harmony* device is confirmed and safe for use.

Fresenius Medical Care is committed to ensure that our products and services consistently meet the highest standards of quality and safety for patients and healthcare providers.

Please provide this Safety Notice to all those who need to be aware within your organization.

In case of any further questions do not hesitate to contact Susanne Renner (susanne.renner@freseniusmedicalcare.com).

Sincerely yours,

Susanne Renner

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