Field Safety Notice / Avis de sécurité

sleep•safe harmony (article no. M206001) – Risque potentiel de surcharge hydrosodée en mode de traitement pédiatrique

Date: 03 Juin 2026

Cher(e) client(e),

Dans le cadre de notre surveillance continue du marché, Fresenius Medical Care (FME) met à jour la notice d'utilisation (IFU) de notre dispositif sleep•safe harmony (SSH). Cette mise à jour inclura un avertissement concernant le risque potentiel de surcharge hydrosodée pouvant survenir en mode de traitement pédiatrique avec des volumes d'injection compris entre 100 ml et 500 ml, typiquement utilisés pour le traitement des nourrissons et des jeunes enfants.

L'interaction des paramètres patient liés au volume, tels que le volume résiduel intra-péritonéale autorisé et la gestion du temps, peut influencer la génération d'ultrafiltration, le volume drainé et *in fine* l'efficacité du traitement. Une rétention hydrosodée peut entraîner une surcharge hydrosodée, conduisant à une prise de poids et à des complications cliniques potentielles associées liées à cette surcharge hydrosodée, telles que l'hypertension artérielle, l'œdème pulmonaire et d'autres complications cardiovasculaires.

Afin de minimiser le risque de surcharge hydrosodée pour cette catégorie de population sensibles à toute dysrégulation du métabolisme hydrosodée avec des volumes d'injection faibles, les mesures suivantes doivent être appliquées :

1 . **Renforcer la surveillance du patient :**
   - Surveiller étroitement le poids du patient, la pression artérielle et l'état hydrosodée en vous aidant si besoin d'une bio impédance en sus de la clinique et la biologie
   - Surveiller attentivement les variations du volume d'ultrafiltration attendu
   - Mettre en œuvre immédiatement des actions cliniques en cas de diminution significative de l'ultrafiltration ou de signes cliniques de surcharge hydrosodée.

2. **Ajuster le paramètre de volume résiduel autorisé**
    - Modifier le paramètre par défaut de 35 % pour le « volume résiduel autorisé » vers une valeur plus faible (par exemple 15 % ou 10 % selon le cas) sur l'appareil sleep•safe harmony

3. **Envisager un drainage manuel et/ou supplémentaire**
    - Envisager l'utilisation d'un « drainage manuel » ou la mise en œuvre d'une stratégie de « drainage supplémentaire » conformément aux recommandations cliniques établies et aux besoins du patient

Veuillez transmettre ces informations à tous les professionnels de santé de votre établissement qui traitent des patients avec sleep•safe harmony en utilisant l'option PÉDIATRIQUE.

Fresenius Medical Care est en cours de mise à jour de la notice d'utilisation. En complément un document additionnel à l'IFU vous sera transmis prochainement.

Un représentant FME vous contactera prochainement afin de vous transmettre cette fiche complémentaire et de proposer une formation dédiée.

Nous vous présentons nos sincères excuses pour tout désagrément que cela pourrait occasionner. Le bon fonctionnement de l'appareil sleep•safe harmony est confirmé et son utilisation reste sûre.

Fresenius Medical Care s'engage à garantir que ses produits et services répondent en permanence aux normes les plus élevées de qualité et de sécurité pour les patients et les professionnels de santé.

Veuillez diffuser cet avis de sécurité à toutes les personnes concernées au sein de votre organisation.

Pour toute question complémentaire, n'hésitez pas à contacter :

Lamia BELARBI

affaires.pharmaceutiques@freseniusmedicalcare.com

Bien cordialement,

Lamia BELARBI

LOCAL SAFETY OFFICER FRESENIUS MEDICAL FRANCE

Additional sheet to the Instructions for Use

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The following points serve as additional information for the following Instructions for Use:

Device concerned	*sleep•safe harmony*
Software version	2.4, 3.0, 3.1, 3.2

The following chapters replace the corresponding chapters in the Instructions for Use provided with the device.

◆ 7.3 Therapy options

The following options must be individually adapted to the respective patient and prescribed by an appropriate healthcare professional. The prescribed settings can be set in the “Patient options” menu by a specially trained healthcare professional. They influence the volume and time management of the treatment.

● Volume and time management

The flexible volume and time management is implemented to improve patient’s sleep quality by reduced drain alarms, to retain treatment time and to maximize the contact of the peritoneum with fresh dialysis solution to obtain the best treatment efficacy. This volume and time control tailored for the individual patient is an interplay of five parameters. Volume and time are controlled and adjusted by variable settings. These settings are automatically adapted by the device within the defined limits set by the healthcare professional of the Responsible Dialysis Center (see Instructions for Use chapter 4.6.1.3).

Volume optimization is realized by the permitted patient volume (100 to 120 % of the maximum inflow volume), permitted residual volume (10 to 50 % of the prescribed inflow volume) and permitted reduction of inflow volume (18 to 19 %, for software version 2.4: 10 to 30 %, of the prescribed inflow volume).

Time optimization is achieved by the permitted reduction of dwell duration (0 to 19 %, for software version 2.4: 0 to 30 %, of prescribed dwell duration) and catheter performance (100 to 200 % of the calculated outflow duration).

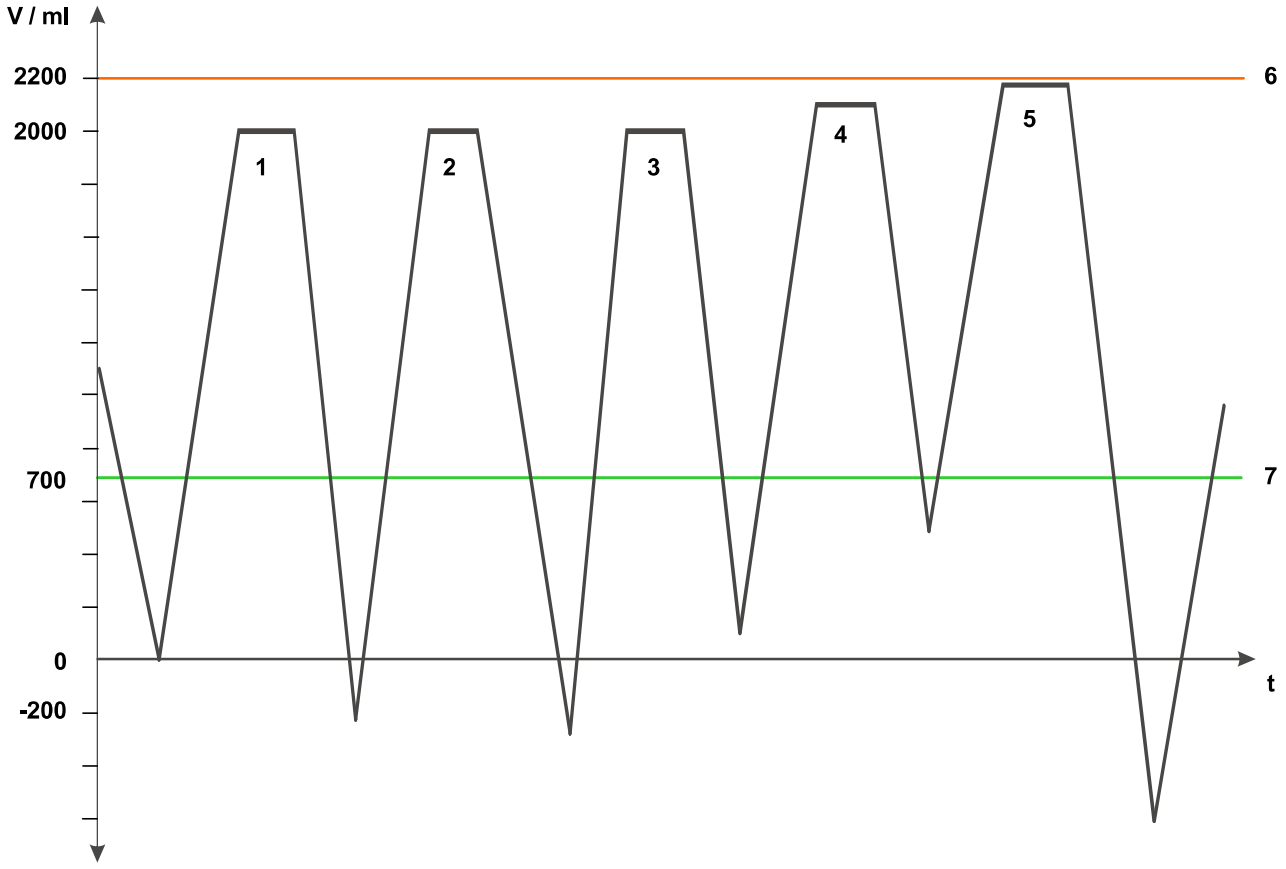
◆ 7.3.1 Volume optimization

● 7.3.1.1 Permitted residual volume

The parameter “permitted residual volume” can be set in the range of 10 to 50 % of the prescribed inflow volume. The default setting of this parameter is 35 %. In case of a prescription with variating inflow volumes the highest prescribed inflow volume is the basis for this calculation. The result of this calculation is a value for the “permitted residual volume” applied for the entire treatment.

When setting this parameter, it must be considered that it can impact the achieved outflow volume.

Fig.: Example



1 Cycle 1
2 Cycle 2
3 Cycle 3
4 Cycle 4
5 Cycle 5
6 Permitted patient volume
7 Permitted residual volume

During each outflow phase the devices’ goal is to drain the maximum available amount of fluid that can be achieved.

Under certain circumstances the device might switch into the next inflow phase when the volume in patient is within the “permitted residual volume” (see cycle 3 and 4 in the picture above). This premature outflow interruption can be caused, for example, by an exceeded negative pressure limit due to retained or not accessible fluid in the peritoneal cavity.

Assuming a prescribed inflow volume of 2000 ml and a permitted residual volume of 35 % corresponding to 700 ml the outflow of cycle 3 shown in the picture above is prematurely ended and 100 ml of fluid will remain in the patient when the device switches to the inflow of phase 4. This behavior is accordance with the selected settings of device, as the remaining 100 ml of fluid is below the permitted residual volume of 700 ml.

In such cases, the outflow volume is reduced as a result, as a certain amount of fluid remains in the patient. However, if the fluid is accessible within one of the following cycles, the device will drain it. As a consequence of remaining residual volume in patient the amount of fresh dialysis solution transferred into the peritoneal cavity within the next inflow might be reduced depending on the set value for the “permitted patient volume” (see chapter 7.3.1.2).

Using less fresh dialysis solution as prescribed for the specific inflow cycles will lead to a reduced total inflow volume which might lead to a reduced ultrafiltration and reduced efficacy of the treatment. Adjust the “permitted residual volume” setting according to the patient's clinical condition.

7.3.1.2 Permitted patient volume

The parameter “permitted patient volume” can be set in the range of 100 to 120 % of the prescribed inflow volume. The default setting of this parameter is 110 %. The “permitted patient volume” is calculated based on the prescribed inflow volume. In case of a prescription with variating inflow volumes the highest prescribed inflow volume is the basis for this calculation. The result of this calculation is a value applied for the entire treatment.

Assuming a prescribed inflow volume of 2000 ml and a selected value of 110 % for the “permitted patient volume”, the permitted patient volume would be 2200 ml.

Due to individual patient related circumstances, an outflow may occasionally not be fully completed. As a consequence, a certain residual volume will remain in the peritoneal cavity (see chapter 7.3.1.1). In such cases, the "permitted patient volume" option will be applied. The device tries to administer the prescribed inflow volume. The permitted patient volume limits the inflow volume of specific cycles.

Assuming a residual volume in the patient of 100 ml after the premature outflow interruption after cycle 3 (see picture in chapter 7.3.1.1), the next inflow of cycle 4 will be completed as prescribed and 2000 ml can be administered as the resulting volume in the patient is 2100 ml (below the “permitted patient volume” of 2200 ml) after inflow of cycle 4. After the outflow in cycle 4 the resulting residual volume in patient is 500 ml. When switching into the next inflow phase of cycle 5 the administered inflow volume will be reduced to 1700 ml as the overall volume in the patient cannot exceed the set limit of 2200 ml.

Using less fresh dialysis solution as prescribed for the specific inflow cycles will lead to a reduced total inflow volume which might lead to a reduced ultrafiltration and reduced efficacy of the treatment.

7.3.1.3 Permitted reduction of the inflow volume

Under certain circumstances, the total solution volume (connected to the device) may not be entirely available for the treatment (due to the solution volume required to prime the line set, for example). In such cases, the inflow volume will be slightly reduced.

Assuming an inflow volume of 2000 ml and a selected value of 18 % for the “permitted reduction of the inflow volume”, the inflow volume may be reduced by up to 360 ml, as required. The volume will only be reduced as required and within this specified limit. The reduction is performed automatically by the device. This device behavior ensures that the treatment can be completed even if the originally prescribed treatment volume was not available and therefore not completely administered.

Valid for software version 3.0, 3.1 and 3.2

If a value less than or equal to 18 % was prescribed via the associated medical software application for the patient parameter “permitted reduction of the inflow volume”, this preset value is automatically adapted by the device to a value of 18 %. If a value greater than or equal to 19 % was prescribed via the associated medical software application for the patient parameter “permitted reduction of the inflow volume”, this preset value is automatically adapted by the device to a value of 19 %. The data on the patient card and the data saved on the device will remain unchanged.

Using less fresh dialysis solution as prescribed for the entire treatment will lead to a reduced total inflow volume which might lead to a reduced ultrafiltration in the patient and reduced efficacy of the treatment.

To mitigate this scenario, it should be assured that sufficient solution volume is connected to the device. Otherwise, the prescription should be adjusted to ensure the prescribed total volume is achievable based on the available solution volume connected to the device.

7.3.2 Time optimization

7.3.2.1 Permitted reduction of the dwell duration

The goal of the “permitted reduction of the dwell duration” option is to prevent the exceedance of the calculated total treatment duration. In case of an outflow taking longer than calculated, the device attempts to save the additional time required for this outflow. This is achieved by a dynamic adaptation of the dwell duration over the remaining dwells.

Assuming a dwell duration of 100 min and a selected value of 15 % for the “permitted reduction of the dwell duration”, this dwell duration may be reduced by up to 15 min. In case of frequent reductions of the dwell duration, the parameter “catheter performance” (see chapter 7.3.2.2) can be used to influence the expected treatment duration.

Valid for software version 3.0, 3.1 and 3.2

If a value greater than 19 % was prescribed via the associated medical software application for the patient parameter “permitted reduction of the dwell duration”, this preset value is automatically adapted by the device to a value of 19 %. The data on the patient card and the data saved on the device will remain unchanged.

A reduced dwell duration compared to the prescribed dwell duration of the entire treatment might lead to a reduced ultrafiltration and reduced efficacy of the treatment.

7.3.2.2 Catheter performance

The patient parameter “catheter performance” aims to provide a realistic expected outflow duration by taking patient's individual outflow characteristics into account. The parameter can be set in the range between 100 to 200 % of the expected outflow duration. The expected outflow duration is calculated based on the expected outflow volume and the maximum allowed flow rate of the patient (see Instructions for Use chapter 4.6.1.3).

A catheter performance of 100 % represents a high performance of the catheter.

A catheter performance of 200 % represents a low performance of the catheter.

Assuming a maximum outflow rate of 200 ml/min and a calculated outflow volume of 2000 ml the calculated outflow duration would be 10 minutes. With a catheter performance of 130 % the recalculated outflow duration is 13 minutes plus a certain outflow initiation time of a few minutes.

The catheter performance influences the calculated outflow duration and thus the expected total treatment duration. In case of frequent reductions of the dwell duration (see chapter 7.3.2.1), the expected treatment duration can be adapted to the actual treatment duration using the parameter “catheter performance”. Increasing this parameter will increase the expected treatment duration.

The parameter “catheter performance” will only adapt the expected treatment duration and does not influence or adjust the pumping performance of the device.

14.1 PAEDIATRIC option

Warning

Risk of overhydration for paediatric patients

The PAEDIATRIC treatment option enables the use of inflow volumes from 100 to 500 ml to treat paediatric patients. This patient group is considered as a vulnerable patient group.

It is therefore important to closely monitor the patient's status based on the dynamic development of small patients.

Patient parameters linked to 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 excessive weight gain and potential clinical complications associated with overhydration.

➢ Enhance patient volume monitoring (e.g. frequent weight measurements, blood pressure monitoring and assessment of fluid status with additional analysis equipment, for example BCM).

➢ Assess the patient condition and if necessary, adjust volume and time management settings accordingly (see chapter 7.3.1 and chapter 7.3.2).

➢ Assess if necessary, the usage of a manual outflow during the treatment (see Instructions for Use chapter 4.7.3) and/or adjust the additional outflow settings (see Instructions for Use chapter 7.3.4).

Recommendation

1. Enhance patient volume monitoring

When treating the above-mentioned vulnerable patient group, it is imperative to closely monitor their volume status. This includes, but is not limited to, frequent weight measurements, blood pressure monitoring, and assessment of the fluid status. Any significant decrease in ultrafiltration or signs of excessive fluid overload should prompt immediate clinical evaluation. Close monitoring is required to ensure that expected ultrafiltration is achieved.

2. Adjust permitted residual volume setting

To mitigate the risk of decreased ultrafiltration in paediatric patients with low inflow volume, it is recommended to change the "permitted residual volume" setting on the device from default of 35 % to a lower value (e.g. 15 % or 10 % as appropriate) (see chapter 7.3.1.1).

3. Consider manual and/or additional outflow

In cases where ultrafiltration remains insufficient despite adjusting the "permitted residual volume", clinicians should consider using a manual outflow and/or implementing additional outflow strategies as per established clinical guidelines and patient needs (see Instructions for Use chapter 4.7.3 and Instructions for Use chapter 7.3.4).

14.1.1 Pre-requisites for paediatric treatment

A paediatric treatment performed with *sleep•safe harmony* means that the prescribed maximum inflow volume is in the range between 100 ml up to 500 ml.

Any prescription including an inflow volume equal to or higher than 501 ml cannot be performed with the PAEDIATRIC therapy mode. Instead, the DEFAULT therapy mode must be chosen.

Main differences between the both therapy modes

	Treatment from 100 to 500 ml inflow volume	**Treatment from 501 to 3500 ml inflow volume**
To be considered for the user		
Device	PAEDIATRIC therapy mode (needs to be enabled by Service)	DEFAULT therapy mode
Disposable and tubing set	*sleep•safe* Set Paed	*sleep•safe* Set *sleep•safe* Set Plus
sleep•safe harmony **Patient**Card *Plus*	PAEDIATRIC therapy mode	DEFAULT therapy mode
Technical differences implemented by the device*		
Target inflow rate	50 to 150 ml/min	50 to 350 ml/min
Target outflow rate	50 to 100 ml/min	50 to 230 ml/min
Maximum (negative) allowed pressure during outflow (at patient access with closed patient line)	-80 mbar	-100 mbar

*overview on the entire prescription parameter can be found in (Instructions for Use for software version 2.4, 3.0 and 3.1 chapter 12.11, for software version 3.2 chapter 12.12).

Note

When a paediatric patient is treated in both therapy modes, the relevant preconditions (the two patient cards, different *sleep•safe* Set, see table above) must be considered.

Preconditions

The PAEDIATRIC therapy mode can be selected during personalisation on the screen for entering the date of birth if the device has been enabled for paediatric treatment.

The patient card must be configured for the PAEDIATRIC therapy mode to provide paediatric treatment.

A patient card or device must be personalised.

If the patient card is enabled for the paediatric treatment, the device must be enabled for paediatric treatment, too.

Preparing for treatment

A *sleep•safe* Set Paed must be used for paediatric treatment.

The solution bag, *sleep•safe* Set Paed, and *sleep•safe harmony* used must have a temperature of +20 to +35 °C for paediatric treatment.

Identification of a paediatric treatment

When switching on the device the text “PAEDIATRIC option enabled” will appear beneath the smiley on the bottom edge of the screen.

The “Teddy” paediatric symbol appears next to the patient name and in the top right corner of the screen instead of the **Help** key to indicate operating steps for paediatric treatment.

Changing the inflow flow rate

The inflow flow rate can be set in increments of 50 ml between 50 and 150 ml/min. The factory setting is 150 ml/min

◆ 15.6 Training Record

Scope, purpose

The proper training of the users is one of the duties of the responsible organization. Training is based on this additional sheet. The manufacturer recommends using this Training Record to document the training performed.

Significance of warnings

Compliance with all warnings in this additional sheet is essential for the safe use of the device and therefore for proper training.

● Explanations on the Training Record report

General information

- The report header logs framework conditions for training.
- The report footer records the trainer and participants.
- The chapters of the additional sheet are listed on separate lines up to the second level.

Y/N/NA

- ❑/–/– Chapter required for proper training.
- ❑/❑/– Chapter recommended for proper training.
- ❑/–/❑ If the option is available: Chapter required for proper training.
- ❑/❑/❑ If the option is available: Chapter recommended for proper training.

➢ Record the instruction of the relevant content and warnings completed by marking ✔ in field **Y**.

➢ Record chapters or options that have not been instructed with ✔ in field **N**.

➢ Record unavailable options with ✔ in field **NA**.

FRESENIUS MEDICAL CARE	Training Record	*sleep•safe harmony*
Customer name:		Start date:
Address:		End date:
		Software version:
		Serial number:

Description	Y/N/NA
7 Functional description	
7.3 Therapy options	❑/❑/–
14 Options	
14.1 PAEDIATRIC option	❑/–/❑
15 Appendix	
15.6 Training Record	❑/❑/–

Comments:

Trainer

Date	Name	Signature

Participant

Date	Function	Name	Signature