Additional Sheet to the *sleep•safe harmony* Instructions for Use

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The following serves as additional information for the Instructions for Use *sleep•safe harmony* with software version 2.4 and software version 3.0.

This additional sheet describes the measures in the Instructions for Use taken to implement data protection.

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

2.9 Duties of the responsible organisation

Requirements

The responsible organisation must ensure that the following requirements are met:

- Compliance with the national or local regulations concerning the installation, operation, use, and maintenance of the device
- Compliance with the accident prevention regulations
- Ensuring the proper and safe condition of the device
- Ensuring the availability of the Instructions for Use at all times
- The device must only be operated under the operating conditions specified by the manufacturer.
- Patient cards must be kept in a safe place.
- The applicable data protection regulations (e.g., GDPR) must be observed.
- The measures to be taken for implementing data protection should be documented by the responsible organisation.
- When disposing of the device and patient card, disposal of the data storage devices in compliance with data protection law must be ensured.

Manufacturer's instructions on data protection (see below).

Training and instruction

Before the responsible organization can begin to operate the device, the individual responsible for its operation must have received a certificate of training from the manufacturer on how to use the device and must be thoroughly familiar with the contents of the Instructions for Use. The device must only be operated by individuals who have been trained and certified in the proper operation and handling of the device.

The manufacturer provides training for this device.

If you have any questions, please contact your local service support organisation.

Incident reporting

Within the EU member states, the user must report any serious incident that has occurred in relation to the device to the manufacturer according to the labelling ( ) and to the competent authority of the member state in which the user is established.

Data protection violation incidents may be subject to notification requirements in accordance with Art. 33, 34 of the GDPR.

Ensure that the safety seal is undamaged. If the safety seal is missing, damaged or if it looks as if it has been removed and re-affixed, this may be a data protection violation subject to notification requirements, which must be handled in accordance with defined data protection processes. In addition, the following points can be contacted:
– Responsible service support
– Manufacturer via the following e-mail address: DataProtectionOfficer@fmc-ag.com

Manufacturer's instructions on data protection (see below).

2.10 User responsibility

Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from glucose imbalance due to incorrectly entered parameters

The following must be observed when entering parameters:

– The parameters entered must be verified by the user, i.e., the user must check that the values entered are correct.

– If the check reveals a deviation between the required parameters and the parameters displayed on the device, the setting must be corrected before activating the function.

– The actual values displayed must be compared with the required values specified.

Warning

Patient hazard from overfilling of peritoneal cavity

The use of incorrect prescription data can result in an incorrect treatment for the patient.

➢ Only the patient whose name is displayed on the screen must be connected to the device.

➢ The user must check the treatment data (maximum inflow volume, treatment volume and treatment duration) for plausibility before starting the treatment.

The technical and organisational measures defined by the dialysis centre for compliance with data protection must be observed by the user. For the protection of any saved personal data, secure storage of the device, and of the patient card in particular, is recommended.

When using the device, personal data may be viewable and accessible to others via the device screen. Make sure that the device screen cannot be viewed by unauthorized persons.

Whenever the patient card is passed on, it is the duty of the responsible organisation to comply with the national or local data protection directives.

Manufacturer's instructions on data protection (see below).

◆ **The following information is in addition to the Instructions for Use provided with the device**

Data protection

Safely handling personal data

The responsible organisation or dialysis centre must disclose any data protection notices to the user or patient.

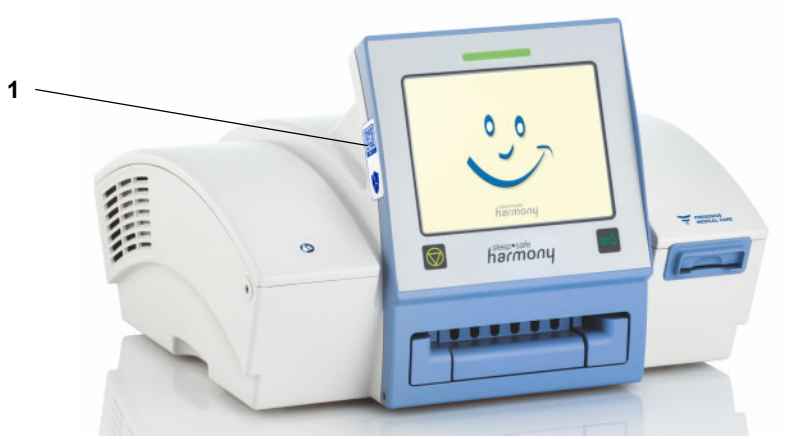
The manufacturer offers information on safely handling personal data. This is available at the following website.

https://www.freseniusmedicalcare.com/en/product-data-governance/product-privacy

Position and handling of the safety seal

To recognise any unauthorised opening of the device, the device is equipped with a safety seal with a QR code. The QR code refers to the manufacturer's website.

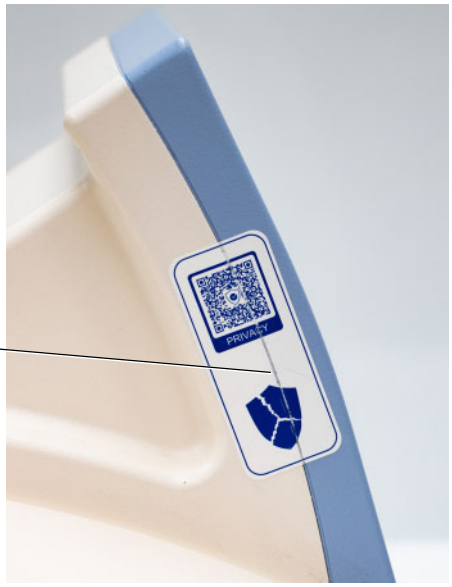
The safety seal with a QR code is located on the left of the screen (1).



Ensure that the safety seal is undamaged. If the safety seal is missing, damaged or if it looks as if it has been removed and re-affixed (2), this should be reported to the relevant dialysis centre, clinic or attending physician in accordance with the applicable data protection directives. In addition, the following points can be contacted:

– Responsible service support
– Manufacturer via the following e-mail address: DataProtectionOfficer@fmc-ag.com

These will undertake the necessary measures (see Chapter 2.9).



Processing personal data

When using the device and patient card, the following personal data is processed:

1. General personal data:
   – Name
   – First name
   – Date of birth
   – Weight (optional)
   – Gender (optional)
   – Device identification number
   – Patient identification number
   – User login information

Further information (see Chapter 4.5.1) and (see Chapter 4.6).

2. Special categories of personal data (health data) in the course of treatment:
   – Prescription data
   – Treatment report data
   – Patient parameters

3. Technical device data is required by the manufacturer for processing any malfunctions or complaints and for providing information for reporting incidents, such as for the Medical Device Directive (MDD, 93/42/EEC) or the Medical Device Regulation (MDR, (EU) 2017/745).

Further information (see Chapter 2.9) and (see Chapter 2.10).

Saving personal data

Personal data is required in the course of treatment. This data is entered into the device as part of the process for preparing a treatment during the personalisation of the device and is then stored (see "Processing personal data").

When using the patient card, personal data is imported from the card and then saved on the device.

When using the device, personal data may be viewable and accessible to others via the device screen. Make sure that the device screen cannot be viewed by unauthorized persons.

When using the patient card, the treatment report is saved along with personal data onto the patient card at the end of treatment (see Chapter 4.4.1).