

INFORMATION ON DATA PROTECTION & PRIVACY

Protection of personal data when using the *sleep•safe harmony* automated peritoneal dialysis device for home dialysis or in a clinical environment¹

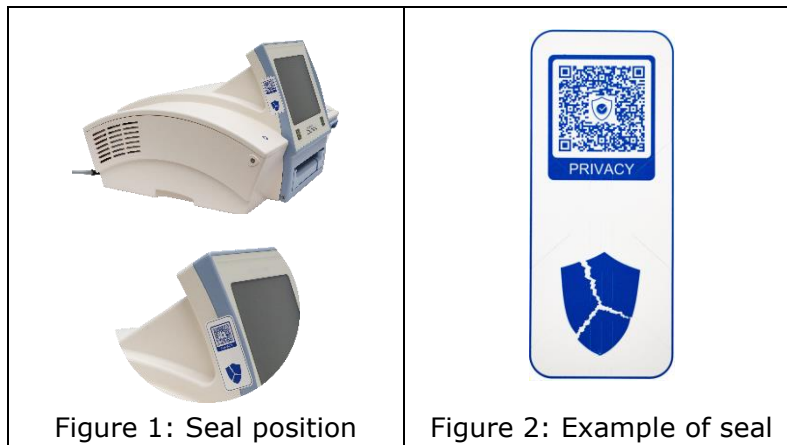
1. Personal data on the *sleep•safe harmony* device

Personal data is stored on the peritoneal dialysis device upon initial setup and personalisation of the device. Personal data includes but is not limited to treatment data and other sensitive information that may allow conclusions about the patient's health. Please ensure the peritoneal dialysis device and the data stored on it are always protected against access by unauthorised persons. This can be done, for example, by placing the peritoneal dialysis device in a lockable or supervised room that is not accessible by the public, or by taking other suitable measures to prevent unauthorised access to the data stored on the device.

The PatientCard^{Plus} (patient card) provided with the peritoneal dialysis device should also be protected against access by unauthorised persons and stored in a safe place after personalisation and when not in use, since this card provides access to the patient's device and therefore to the patient's treatment data. The patient card should only be shared with authorised persons involved in the patient's treatment (such as the patient's physician).

2. Authorised use of the *sleep•safe harmony* device

Only the patient and authorised persons should be allowed to view the display and have access to the peritoneal dialysis device and the data stored on it. To indicate unauthorised opening of the peritoneal dialysis device, the device is equipped with one (1) security seal with a QR code on the left of the display. See Figure 1 for the seal position and Figure 2 for an example of the seal with a QR code. Always make sure the seal is intact.



If the seal is missing, damaged, or if it looks as if it has been removed and re-affixed, report this immediately to the relevant dialysis centre, clinic, or attending physician. You may also contact the local service organisation listed in the Instructions for Use for the peritoneal dialysis device or the device manufacturer, Fresenius Medical Care, at DataProtectionOfficer@freseniusmedicalcare.com.

¹ The following notes are provided by us in our capacity as manufacturer (Fresenius Medical Care AG, Else-Kröner-Strasse 1, 61352 Bad Homburg, Germany) and do not constitute a privacy notice. The responsible body for data protection is the relevant clinic, dialysis centre, or attending physician.

3. Shipping and transport of the *sleep•safe harmony* device

Observe the local applicable data protection and privacy regulations for the handling of patient data when shipping the peritoneal dialysis device and preparing for transport. If you have questions about data protection when shipping or transporting the peritoneal dialysis device, contact the relevant dialysis centre, clinic, attending physician, or the local service organisation listed in the Instructions for Use for the device. Via your local technical service organisation, you can also arrange for internal storage media on the peritoneal dialysis device to be removed before returning it.

Always remove the patient card from the peritoneal dialysis device before packaging and store the patient card in a suitable, safe place. If the patient card is no longer needed by the patient, it should be returned to the relevant dialysis centre, clinic, attending physician, or local technical service support organisation. The establishment should observe local applicable data protection and privacy procedures when handling or disposing of the card.

Important!

If a data breach or loss of data due to unauthorised access is suspected, please report it to the relevant dialysis centre, clinic, or attending physician. You may also contact the local service organisation listed in the Instructions for Use for the peritoneal dialysis device or manufacturer, Fresenius Medical Care, at DataProtectionOfficer@freseniusmedicalcare.com.