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Mobility Monitor

Rules and Recommendations for Reprocessing

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Version 1.0

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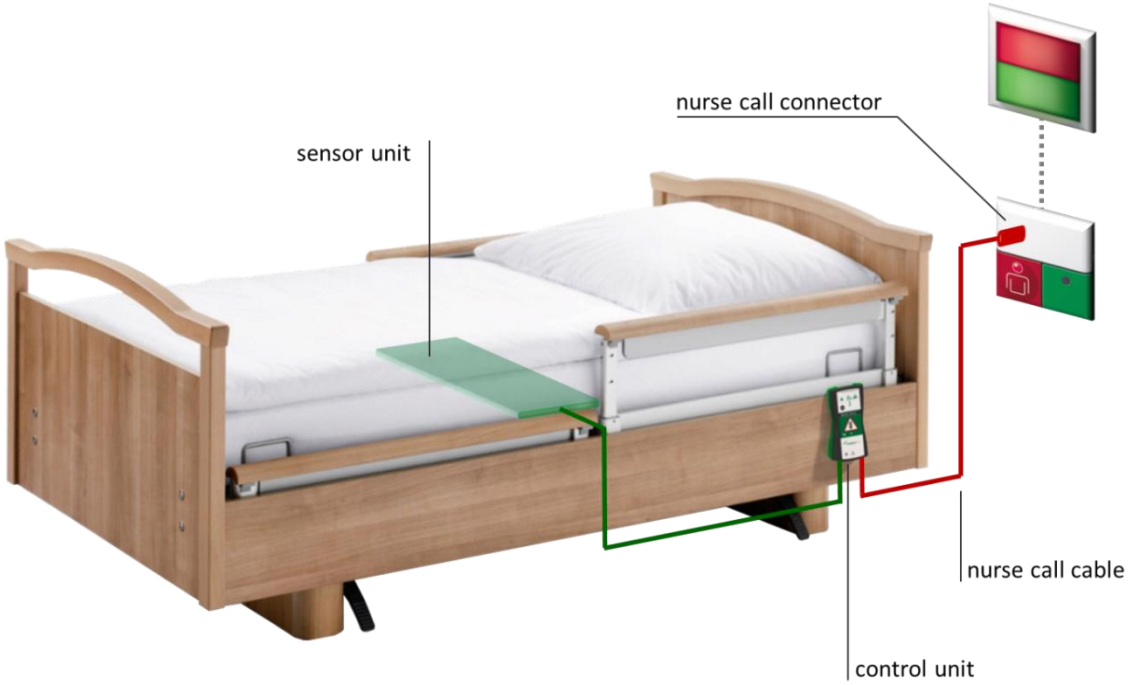
1. Introduction

1.1. Mobility Monitor by compliant concept

Mobility Monitor is an assessment instrument that, for example, makes better assessment of the risk for pressure ulcers possible. To this end, the sensor unit under the mattress, without any direct contact with the body, measures the slightest movement of the patient and displays the mobility on the control unit attached to the bed. If mobility is absent for a long period of time, the system warns the nursing staff via the nurse-call system. The mobility data is recorded and can be evaluated on the computer, so that it can be discussed at the next staff meeting.



1.2. This Document

This document describes the reprocessing of Mobility Monitor before use by the next patient. compliant concept AG recommends that the device is reprocessed for each new patient according to the recommendations in this document. Please also comply with the hygiene requirements of your facility.

The definitions in this document are based on the recommendations by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and by the Federal Institute for Drugs and Medical Devices (BfArM).

Web link to the recommendations by KRINKO

http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Medprod_Rili_2012.pdf;jsessionid=86683243A9AACDA2204D8134738EBDC3.2_cid363?__blob=publicationFile

1.3. Reprocessing of a Medical Device

This reprocessing comprises the following individual steps:

1. Preparation
2. Cleaning
3. Disinfecting
4. Examination for cleanliness and integrity
5. Function check
6. Packaging / Storage

2. Fundamentals

2.1. Annual Maintenance

We recommend taking out a maintenance contract. To maintain compliance with legal safety regulations, for maximum performance reliability and durability of the device, a technical inspection and function test must be performed on the device regularly (every 12 months).

⚠	The device must be serviced once per year. The operator is responsible for proper execution of the maintenance procedure. Maintenance may only be carried out by *compliant concept AG* or an authorized partner. The device must not be opened.

Maintenance includes at least the following services:

- ✓ Cleaning and servicing the devices
- ✓ Testing functionality using a test bench
- ✓ Testing and if necessary replacing the calibration values of the sensors
- ✓ Checking for external and internal damage by skilled technician
- ✓ Updating the firmware to the latest version
- ✓ Replacement of small parts, if necessary
- ✓ Certifying that the devices have passed all tests successfully.

2.2. Classification according to the KRINKO Recommendation

Mobility Monitor is classified in the **non-critical** medical device category, since during normal use it only comes into contact with intact skin.

It follows that Mobility Monitor does not need to be sterilized and does not require special labeling for this.

3. Reprocessing Recommendations

compliant concept recommends cleaning and disinfecting the device after each occupant / patient change. Please also comply with the hygiene requirements of your facility.

3.1. Preparation

Making sure that the product is complete. Mobility Monitor includes the following components:

- Control Unit
- Sensor Unit
- Power Supply
- Storage Bag
- compliant concept USB-Sticks
- Optional Nurse-Call Cable

All plugs must be unplugged for reprocessing. However, disassembling the components is not part of the procedure.

3.2. Cleaning

All components must be checked visually for any traces of dirt. Any signs of dirt must be removed with a damp (H_2O) cloth.

Caution: Components must not be immersed in any liquid. Cleaning in an ultrasonic bath is not possible.

3.3. Disinfecting

The device surfaces can be cleaned and disinfected by wiping and surface disinfecting. The housing of the control unit and the outside of the sensor unit can be wiped with a soft, slightly damp cloth or with wipes containing antiseptics. Use a listed, commercially available disinfectant. Also note the exposure time and let the device dry thoroughly.

Caution: Thermal disinfecting processes are not possible, because the electronic equipment would be damaged.

3.4. Check for Cleanliness and Integrity of the Surfaces

After cleaning and disinfecting with optical control (with normal or normal-corrected vision) no contamination should be visible on any parts of the medical device (e. g. encrustations, plaque film).

Check if the surfaces of the components are intact. Particular attention should be paid to the enclosing cover of the sensor unit. When the cover is damaged by cracks, there is a risk that contamination can get stuck at the damaged site or penetrate into the device. Any damage needs to be repaired / replaced by the manufacturer.

Check if the zipper of the sensor unit is sealed. If the seal is missing, the device must be checked by an authorized service center.

3.5. Function Control Check

The technical functioning of Mobility Monitor must be checked before use as follows:

	Control Check	Default	OK?
1.	Connect control unit with power supply unit to the electrical power	Green power LED on the control unit lights up	
2.	Optical Control check	When the device is switched on, all the lights (LED) light up briefly.	
3.	Acoustic Control check	When the instrument is turned on, a beep will sound. For this test activate the audible alarm according to the manual.	
4.	Connect the sensor unit to the control unit	On the traffic light on the control unit the yellow light does NOT blink after the sensor unit has been connected.	
5.	Check the fault light on the control unit	The error light on the control unit is off or blinking, but is NOT PERMANENTLY on.	
6.	With the nurse-call cable, connect the control unit to the nurse call system and trigger a test alarm. [1] Alternative method: Connect the nurse-call cable with the control unit and with a suitable testing device[2] check whether the contacts of the internal relay open / close (depending on configuration) when a test alarm is triggered.	On the control unit a red alarm LED blinks and the test alarm is shown on the external device (nurse-call system, test instrument, electrical continuity tester or).	

3.6. Packaging / Storage

After the disinfectant has dried, all the components are packed in the provided carrying bag. Store in a clean, dry and disinfected storage room at room temperature and normal humidity (see technical specifications for more details).

[1] See Mobility Monitor User Manual for how a test alarm can be triggered

[2] compliant concept AG can provide a special testing device, with which the internal relay can be checked. But an electrical continuity tester can be used as well, or the method described whereby the device is connected to the nurse-call system

3.7. Warnings

	Unplug the power cord before you begin cleaning and disinfecting the unit!
	Never let liquids get into the control unit or the sensor unit. Before re-using all parts of the system must be completely dry.
	Disinfecting or cleaning under pressure and heat, or in a bath is strictly prohibited.
	The surfaces of Mobility Monitor can be destroyed by improper cleaning agents or disinfectants.
	Mobility Monitor should always be stored at room temperature. Extreme temperatures cause the unit to age faster and the internal battery will discharge quicker. Be especially careful not to unnecessarily expose the device to extreme sunlight or other heat sources (e.g. heating radiators).

4. How to Reach Us

Do you have questions about Mobility Monitor and Mobility & Care Manager? Our support team will gladly assist you by phone or email.

Switzerland

Phone, main:	+41 44 552 15 00
Phone Support:	+41 44 552 15 03
Fax:	+41 44 552 15 09
Email:	support@compliant-concept.ch

compliant concept AG
Undermülistrasse 28
CH-8320 Fehraltorf
www.compliant-concept.ch

International Support and contact addresses, distributors
http://www.compliant-concept.ch/de/support

Change History

Version	Language	Release Date	Change	Translated from		Prepared	Reviewed	Approved
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