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User Guide

Mobility Monitor

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compliant concept AG

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User Guide

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1. Introduction

1.1. *Mobility Monitor* by *compliant concept AG*

Mobility Monitor is an assessment instrument that allows for better assessment of, for example, the risk for pressure ulcers. To this end, the measuring unit under the mattress measures, without any direct contact with the body, 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.

Mobility Monitor was developed over the course of several years by experts from various fields of medicine, nursing and engineering together with ETH Zürich and Empa. The result is an aid that is revolutionizing everyday nursing care through objective mobility data.

Clear representation of drug interactions, detailed mobility analysis for pressure ulcer risk assessment, recording of sleep behavior, and prevention of falls with a 360-degree bed-exit alert via the nurse-call system are possible with *Mobility Monitor*.

Whether for visualizing, documenting (pdf export), or in daily communication with colleagues, relatives or authorities - *Mobility Monitor* is a valuable, useful tool for the modern nursing practice.

1.2. The Modular Care Solution

The functions of *Mobility Monitor* are available as modules.

Bed-exit Module

Supports fall prevention with 360° bed-edge and bed-exit alert. It's an ideal alternative to the floor mats and other systems.

Mobility Module

Supports your pressure ulcer prophylaxis with immobility alert in the absence of pressure relieving movements by the resident / patient.

Assessment Module

Mobility analysis allows for efficient assessment and more targeted planning of nursing care measures. It helps to improve sleep behavior and more.

LiveView Module

Monitor all the data collected by Mobility Monitor clearly and in real-time on the computer in the ward.

The modules can be purchased separately or they can be combined in any configuration. On the back of the *Mobility Monitor* operating unit, you can see which modules are enabled on your device.

1.3. This Document

This handbook only applies to the *Mobility Monitor* device, and therefore includes the **mobility module** and **bed-exit module**. The other modules, **Assessment module** and **LiveView module** relate to the evaluation software *Mobility & Care Manager*. They are covered in separate instructions.

Please read this manual carefully and keep it for your reference. Please contact our customer support (→ page 34), if you are unsure.

2. Security

2.1. Symbols

The following information ensures safe usage of the device, so that neither the user nor the product will be compromised. The following warning symbols are used for this product:

Statement that prevents serious injury to personnel or to the user.

Important information that will ensure proper use of the product.

Must read and follow the user manual carefully!

This device must not be disposed of with normal household waste. Please contact an authorized representative of the manufacturer for obtaining information concerning the proper decommissioning of your equipment.

2.2. Warnings and Safety Recommendations

	Please contact the distributor or manufacturer for help with the installation and operation of the device, or if you notice any unexpected behavior by the device.
	The device must be installed and placed into operation according to the user manual. Additionally, users must be trained and familiarized with using the device.
	The data collected by *Mobility Monitor* must be evaluated by qualified and trained healthcare professionals only.
	**The actual pressure ulcer risk assessment is not handled by the device, but is the responsibility of the nursing staff.**
	**To correctly detect movements the system must be calibrated after each initial installation and after each change of bed or mattress** (→ see Chapter 4.4).
	**Mobility Monitor is not suitable for patients with a body weight below 40 kg**. With these patients, there is a danger that warnings (bed-exit or immobility alert) are not triggered correctly.

⚠	**Mobility Monitor is not suitable for patients with a body weight over 180 kg.** Using the system with these patients could lead to malfunctioning of the sensor unit.
⚠	Manipulations in the bed should be avoided as this can distort the measurements. Exception: registered repositioning by the nursing staff.
⚠	During the measurement, no other people or pets are allowed to be on the bed. An exception is the repositioning of the patient. Use of the bed by more than one person can affect the effectiveness of the system and the accuracy of the measurements.
⚠	In combination with water or air mattresses the device can only be used with limitations.
⚠	The device must be serviced once a year. Servicing may only be performed by *compliant concept AG* or an authorized partner. The device must not be opened.
⚠	The device may only be used under the specified operating conditions (→ Chapter 8.1). Do not drop the device, and do not expose it to strong impact. If the general operating conditions were violated, e.g. the sensor plate was exposed to too much pressure; the device may only be used after it has been serviced by *compliant concept AG* or an authorized partner.
⚠	Choose your cable and connector routing carefully, to reduce stumbling or strangulation hazards.
⚠	The device is only protected against spray water! If dirty, the device should only be wiped with a damp cloth. Otherwise there is danger of electric shock.
⚠	The device (operating unit and sensor plate) must not be opened. Otherwise there is danger of electric shock.
⚠	A defective device must not be used and must be professionally serviced by the manufacturer. Otherwise there is danger of electric shock.
⚠	The device meets the requirements of EN 60601-1-2 Electromagnetic Compatibility for medical electrical equipment and / or systems. This standard was developed to ensure reasonable protection against harmful interference in a typical medical installation. Because of the proliferation of radio transmission equipment and other sources of electrical noise in healthcare and other environments, it is possible that a high level of such interference negatively affects the performance of the device, due to the close proximity or power of the interference source. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed according to its instructions.
⚠	Only the parts supplied by the manufacturer are to be used. Any other parts can have a negative impact on the properties of the electromagnetic compatibility (EMC).

3. Purpose

3.1. Intended Use

Scope: hospital, long term care, home care

Users: nursing staff, persons with medical training

Mobility Monitor is a detection system for mobility and activity of a person lying in bed as well as for bed occupancy. *Mobility Monitor* consists of a sensor unit, which is installed under the mattress, and a control unit that can be attached to the edge of the bed. The operating principle is based on force measurement elements whose signals are recorded and evaluated with the help of algorithms.

Mobility Monitor includes the following essential functions

- Display on the device, if the time since the last relevant change in position exceeds the manually adjustable period of time (2, 3, or 4 hours). Optionally, *Mobility Monitor* can be connected to the nurse call system.
- Manual registration options of position changes. These are recorded as relevant repositioning's that were carried out by the nursing staff.
- Display on the device, if the person has left the bed. Optionally, *Mobility Monitor* can be connected to the nurse-call system.
- Recording of data on mobility and bed occupancy, which can then be visualized on a computer.
- Error display on the device, if a malfunction is detected.

The information on mobility contributes to the assessment of pressure ulcer risk. The detailed assessment of the overall pressure ulcer risk is inherently the responsibility of the nursing staff.

Mobility Monitor by itself cannot prevent pressure ulcers, nor falls or accidents. *Mobility Monitor* does not replace the regular check-ups by the care staff. The *Mobility Monitor* device may only be installed and placed into operation by a trained person.

	Please contact the distributor or the manufacturer, if you need help with the installation and operation of the device, or if you notice any unexpected behavior of the device.

Operating Conditions	Requirements
Operating Temperature	5…40 °C
Storage Temperature	-20…60 °C
Relative Humidity	15% to 93% relative humidity
Ambient Pressure	700 hPa to 1060 hPa
Maximum person weight	180 kg
Minimum person weight	40 kg
Maximum direct load	90 kg

3.2. Indications

Mobility Monitor provides support for the following specialized topics

- **Pressure ulcer prevention**; *Mobility Monitor* provides a fact-based decision basis according to the latest scientific findings. It can be used both for risk assessment and for the monitoring of a patient's own mobility, to make it possible to only reposition if it is necessary. Risks and the number of repositionings are minimized in favor of the resident.

- **Fall prevention**; *Mobility Monitor* continuously records sleep and getting-up behavior and helps with optimizing it. If the resident leaves the bed or wants to leave the bed, *Mobility Monitor* warns the nursing staff and helps to prevent falls.

- **Sleep behavior/medication**; by utilizing data-based "before and after" analysis, the effects of sedatives, analgesics and neuroleptics on the sleep profile can be evaluated. Good sleep behavior - especially in patients with dementia - reduces conflicts and difficult situations.

Mobility Monitor can be utilized for the following symptoms, e.g. for

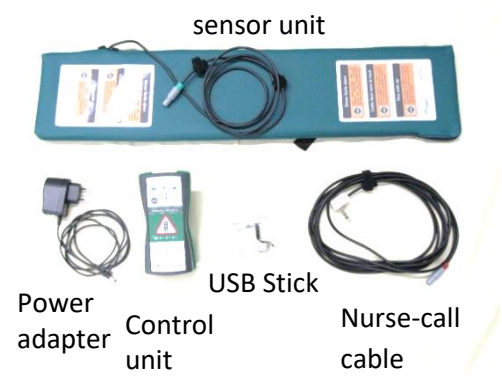
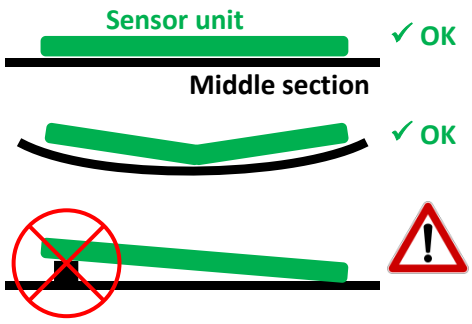
- Immobility or decreased mobility
- Increased risk for pressure ulcers
- Sensitivity deficits or loss of sensitivity
- Acute confusion
- Dementia, decreased drive
- Neurological and motor impairments and paralysis
- Frequent getting-up at night
- Danger of falls caused by uncontrolled getting-up in patients with impaired standing and walking ability
- Pain, including in patients who suffer from pain, but cannot verbalize it
- Neurological and gerontological-psychological illnesses
- Motor and mental restlessness
- Muscle tone too high or too low
- Sleep disorders and / or behavioral abnormalities (e.g. restlessness, aggressiveness, concentration problems, fatigue, weakness ...)
- Suspected paradoxical or adverse reactions to medications
- Perception of negative side effects, which are due to other repositioning systems
- Determining the patient's mobility to validate the use of repositioning systems

3.3. Contraindications

There are no known contraindications.

4. *Mobility Monitor* Installation

4.1. Attaching the Sensor Unit

	Before installing, please check for completeness of the *Mobility Monitor* set. The USB stick and the nurse-call cable are optional.
	Remove the mattress. Check, which is the non-movable middle section of the bed (at pelvic level).
	Using the straps attach the sensor unit to the non-movable middle section of the bed. **Important**: Make sure that the label of the sensor unit is facing up, and that the plate cannot slip.
	Nothing can stick up from the middle section of the bed, because it could impair the function of the sensor plate!

4.2. Checking the cable routing

	Attach the sensor unit cable to the bed frame that nothing can pinch it. Use the cable straps attached to the cable for this. **Important:** Make sure that nothing can jam by moving the bed into all possible positions.
	**Important:** Please place the mattress back on the bed.

4.3. Connecting the Cables and Testing the Nurse-Call

	Attach the control unit to the bed and connect the sensor unit cable. Now connect the device to the power supply. Connecting to the nurse-call system is optional. **Important:** You can check whether the nurse-call works by unlocking the keypad and pressing the buttons "bed-exit alert" and "immobility alert" (+) simultaneously for 2 seconds

⚠	**Important**: *Mobility Monitor* cannot verify that the nurse-call alert is actually delivered. Therefore, check regularly and after every installation, if a nurse-call is sent to the nurse-call system correctly, and is processed properly (How to carry out the tests is described in Chapter 4.3)

4.4. Calibration / Adjust to the Bed

For *Mobility Monitor* to be able to detect movements correctly, the system must be adjusted/calibrated to the bed and the mattress. First unlock the keys .

Then press the "key lock" and the "repositioning key" simultaneously and hold for 4 seconds (+), until the traffic light is flashing and the device is calibrating.

The following points must be observed:

- The bed must be empty and the mattress has to be on the bed during calibration.
- Calibration must be performed after every new installation and after each change of patient.
- Calibration must be done, if the control unit or the sensor plate is replaced.
- Calibration must be done when the red light of the traffic light is flashing.

Calibration successful

Calibration failed

After successful calibration, the green light on the traffic light briefly flashes up.

Possible causes of a failed calibration:

- There is a person in the bed
- A person touches the bed during calibration
- During calibration, something was placed on the bed

In the event of a failed calibration, it must be repeated.

⚠	Perform calibration only when the mattress is on the bed, and thus rests on top of the *Mobility Monitor* sensor unit.
⚠	Perform calibration only when the bed is not occupied.

4.5. Mobility Monitor Wireless-868

This section only applies to devices with wireless technology. These control units are marked with this symbol.

To ensure optimal radio connection, the control unit should not be placed in the vicinity of large metallic surfaces. If possible, do not mount the control unit to a metal bed frame, but preferably on an area of the bed made of wood or plastic. Check, if a wireless connection is made, as described in Chapter 5.11.2.

⚠	Be sure to also connect the nurse-call cable, even with *Mobility Monitor Wireless-868*! The radio transmission only relates to the measured data for the modules **Assessment module** and **LiveView module** in the Software *Mobility & Care Manager.* For bed-exit and immobility alerts, the nurse-call cable is essential.

5. Functions and Operating Mobility Monitor

5.1. Controls - Overview

Calibration keys (→5.5):
After unlocking, press „key lock“ and “repositioning key” simultaneously and hold for 4 seconds to calibrate the device.

Key Lock (→5.4)
Press and release to unlock the keys.

Bed-exit Alert Key (→5.6):
Turn bed-exit alert on/off (press and release key) or switch from bed-exit alert to bed-edge alert (press and hold key for 2 seconds).

Immobility Alert Key (→5.7):
Turn immobility alert on/off (press and release key) or set tolerance period (press and hold key for 2 seconds).

Repositioning Key (→5.8/5.9):
For registering a repositioning performed by nursing staff (press and release key). The LED flashes green once, when the repositioning is registered.
During bed occupancy check (traffic light blinks green) nursing staff can confirm with this key that the patient is in the bed.

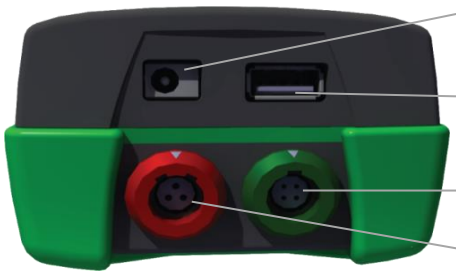
Mobility Display (→5.3):
The traffic light changes to red, when the set tolerance period has passed (see Immobility Alert).

Power On Light:
Lights up when the device is attached to power.

Error Notification Light (→7.1):
Lights up when a problem or error is detected. Chapter 7 describes possible special situations and their solutions.

Data Transmission Light (→5.11):
Remains on when wireless connection exists. Blinks together with the Error Notification Light when connection interruption is detected. Blinks during saving data to USB Stick.

Acoustic Alert Light (→5.10):
Light is on, when the audible alert option is turned on.



Electrical power

USB Port:
For data transfer via USB Stick (→5.11.1).

Sensor Unit cable connector

Nurse-call cable connector

5.2. Default Settings

At commissioning all alerts are set to "OFF" by default, the acoustic alert is active.

After each calibration the alerts (bed-exit and immobility alert) will be reset to "OFF". The setting for the acoustic alert is retained.

After a power failure, or if the power cord is unplugged and plugged in again, all the settings are retained.

5.3. Mobility Display 

The mobility display indicates whether the resident has made a relevant movement in the last 2, 3 or 4 hours (adjustable, see →5.7).

If the bed is unoccupied, the traffic light is turned off.

Red	The traffic light changes to red when the set tolerance period limit is reached.
Orange	The traffic light changes to orange 30 minutes before the set tolerance period limit is reached.
Green	The traffic light remains green when the resident has moved enough during the set tolerance period limit.

	Setting the tolerance period limit is the responsibility of the nursing staff. The specified value must be checked constantly and adjusted if necessary. The patient must always be subject to daily examinations and skin checks.
	The traffic light does not indicate whether someone is developing pressure ulcers or not. It shows only if the patient has made relevant movements during the preset tolerance period.

5.4. Key Lock 

To avoid incorrect operation and prevent accidental change of settings, the device has an automatic key lock. Press the key lock to unlock the keys. In general, the keys must always be unlocked before using.

The keys lock automatically after a few seconds.

To unlock the keys:

1. Press the key lock.
2. The key lock lamp **lights up green** when the keys are **unlocked.**
3. By pressing the button again, the keys are locked again**.**

Keys unlocked **Keys locked**

5.5. Calibration +

In order for *Mobility Monitor* to detect movements correctly, *Mobility Monitor* sensors must be adjusted/calibrated to each bed.

⚠	**After** *Mobility Monitor* has been **installed**, it **must be calibrated**. Please note that the **mattress** has to be **on the bed, and that nobody should be in the bed** during calibration. Calibration must be carried out again after the control unit or the sensor unit is replaced.
⚠	**Calibration must be carried out at every change of bed, mattress or patient.**

Calibrating *Mobility Monitor:*

1. Please unlock the keys first
2. Then press the repositioning key and the key lock simultaneously and hold for 4 seconds.
3. The traffic light starts blinking - the unit is being calibrated.
4. After successful calibration, the traffic light flashes green for 2 seconds.
5. If the calibration was not successful, the traffic light flashes red and stays red. In this case, you must repeat the calibration; the device won't be ready for use otherwise.

Calibration successful (blinks green)

Calibration failed (blinks red)

ℹ	**Possible causes of a failed calibration:** - A person is in the bed - Somebody touches the bed during calibration - Something was placed on the bed during calibration
⚠	After each calibration the alerts (immobility and bed-exit alert) will be reset to "OFF".
ℹ	After every calibration, the settings are reset to their default values: - Immobility alert tolerance period: 3h - Bed exit: setting for alert at bed-exit - Alerts are disabled after calibrating (setting "OFF“)

5.6. Bed-Exit Alert

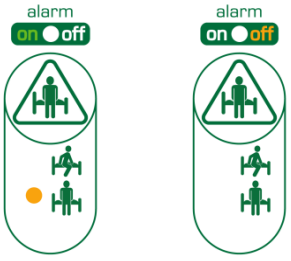
⚠	Verify regularly, if the chosen setting is correct for the resident or patient.
⚠	The bed-exit alert is only active if bed occupancy is detected. That means, that the green traffic light stops blinking and lights solid green.
ℹ	During bed occupancy check (traffic light flashes green), the user can press the repositioning key and confirm that a patient is lying in the bed (see Chapter 5.9). The device then terminates its own checking whether a patient is in the bed, and immediately switches to monitoring mode (traffic light switches to solid green). The bed-exit alert is active, assuming that the alert is switched on.

When the bed-exit alert is activated, the system detects if a resident leaves the bed and sends an alert to the connected nurse-call system.

The bed-exit alert has **two settings options** available: The first alert option is triggered as soon as the patient sits on the **edge of the bed**. The second alert option triggers once the patient has left the bed **completely**. The alert is activated by briefly pressing the button. The setting can be changed by pressing and holding the button.

Turning the Bed-exit Alert On and Off:

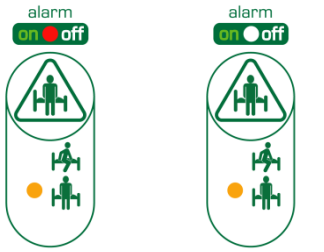
1. Please unlock the keys first. .
2. Press the bed-exit alert key to toggle it On or Off.
3. The "ON" LED lights up when the bed-exit alert is **activated.** The "OFF" LED lights up when the alert is turned off.



On **Off**

Acknowledge the Bed-exit Alert (optional):

1. The light flashes red (=bed-exit alert).
2. Please unlock the keys first .
3. Now press the bed-exit alert key .
4. The flashing red light turns off, the "On" lamp lights green. This means the alert is acknowledged and the bed-exit alert is still active.

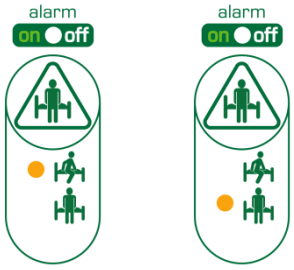


Alert **Acknowledged Alert**

ℹ	The bed-exit alert is acknowledged automatically after 15 minutes.

Changing Settings:

1. Please unlock the keys first .
2. Press the key and hold for 2 seconds.
3. The bed-exit setting light flashes yellow when the setting can be changed.
4. Now press the key repeatedly, until the desired bed-exit setting flashes yellow.
5. When the bed-exit setting light stops flashing and remains on, the setting has been changed. This happens automatically after a short period of time. Alternatively, the setting can be accepted by pressing the key lock .



Bed Edge **Bed Exit**

	If the bed-edge alert is triggering all the time (e.g. because the patient sleeps on the edge of the bed) we recommend using the "bed-exit" setting.

5.7. Immobility Alert

When the immobility alert is activated it sends a signal to the nurse-call system, if the resident has not made a relevant movement in **2, 3, or 4 hours (tolerance period adjustable)**. The alert is activated by pressing briefly, by **pressing and holding** the **setting can be changed**.

	The nursing staff is responsible for setting the tolerance period for the immobility alert. The specified value must be checked constantly and adjusted if necessary. Daily skin checks must not be neglected.

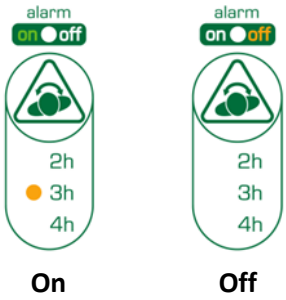
Setting tolerance period for Immobility Alert:

1. Please first unlock the keys
2. Press the immobility alert key and hold for 2 seconds.
3. The LED setting light flashes yellow when the tolerance period can be adjusted.
4. Now press the key several times , until the desired tolerance period flashes yellow.
5. Once the setting light stops flashing yellow and remains on, the setting has been adopted. This happens automatically after a certain time. Alternatively the setting can be accepted by pressing the key lock.

Alert after 3 hours

Turning the Immobility Alert On and Off:

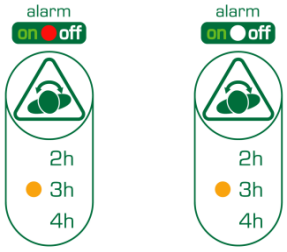
1. Please unlock the keys first
2. Press key to turn the immobility alert On or Off.
3. The "ON" LED lights up when the immobility alert is **activated.**
   The "OFF" LED lights up when the alert is turned off.



On **Off**

Acknowledge the Immobility Alert (optional):

1. The light flashes **red** (= **immobility alert).**
2. Please first unlock the keys .
3. Now press the key .
4. The flashing red light turns off, the "On" lamp lights green, which means the alert is acknowledged and the immobility alert is still active.



Alert **Acknowledged Alert**

⚠	After the immobility alert has been acknowledged, the alert will not go off again until after the set tolerance period has passed. This is true even if no repositioning was performed.
ℹ	The immobility alert is acknowledged automatically if the resident moves independently or when a repositioning by the nursing staff has been registered (see Repositioning → 5.8).

5.8. Registering / Documenting a Repositioning

The nursing staff can register a performed repositioning directly at the device.

Pressing the repositioning key causes the traffic light, if it was on red or orange, to turn green again. The repositioning is recognized by the device as a relevant change in position and treated as such.

In addition, the repositioning is specially marked and displayed in the Software *Mobility & Care Manager* and enables seamless documentation of care measures.

Registering a Repositioning:

1. Please first unlock the keys
2. Press the Repositioning key , to register the repositioning
3. The LED blinks green, which means that the repositioning has been registered.

⚠	The repositioning key affects the immobility alert and the mobility display. The button must not be pressed if a sufficient repositioning has not been performed first.

5.9. Confirming Bed Occupancy

If the repositioning key is pressed during the bed-occupancy check (traffic light flashes green), this is detected as a confirmation that a patient was placed in the bed.

The device then terminates its own checking for whether a patient is lying in the bed and immediately switches to monitoring mode (traffic light solid green). The bed-exit alert is active, assuming that the alert is switched on.

⚠	The bed-exit alert only activates if bed-occupancy has been detected. This means that the green traffic light stops blinking and turns to solid green.

5.10. Acoustic Alert

A short beep sounds during a power failure and after every hour during which an immobility alert was not acknowledged.

As a control measure a short beep sounds when the device is turned on, if the acoustic alert is activated.

Turning the Acoustic Alert On and Off:

1. Please first unlock the keys
2. Press the keys "Immobility Alert" and "Repositioning" simultaneously and hold for 2 seconds.
3. The LED lights up green when the acoustic alert is **activated.** The LED does not light up when the alert is turned off.

On **Off**

5.11. Data Transfer

5.11.1. Data Transfer via USB Stick

To be able to import the data into the *Mobility & Care Manager* (PC software), it must be transferred to the USB stick. Plug in the included USB stick into the slot provided on the device. During the data transfer to the stick, the data transmission LED flashes green. Once the LED stops flashing, the data transfer is complete and the USB stick can be removed.

ℹ	Only remove the USB flash drive after the data transfer LED has stopped blinking. After the successful transmission of data you will also hear a short beep.

	If the USB drive is removed too early, no beep sound can be heard, and the error notification light flashes briefly. In this case, repeat the data transfer.
	Mobility Monitor can store data for up to 7 days of measurements. If the data is not removed within this time frame, the oldest data will be continually overwritten with new data.
	The USB drive has a capacity of 1.86 GB. The mobility data for a 24 hour period uses 72 kBytes of space. Therefore approximately 27,000 measured days could be stored on the USB flash drive.
	For performance reasons, it is recommended to regularly delete old data from the USB stick. This is most easily achieved via the option "delete data from USB flash drive after importing" in *Mobility & Care Manager,* after the data has been transferred from a USB stick into *Mobility & Care Manager.*

5.11.2. Data Transfer for Devices with Wireless 868

If your *Mobility Monitor* comes with Wireless 868 radio transmission, the data is transferred automatically when the device is connected. The connection status is displayed on the device via the data transmission light:

Good Connection		Remains on
No Connection		Is off
Device searches for a connection		Flashes
Connection interruption		Flashes together with error light (After a period of time, they will stop flashing and the "no connection" will appear)

5.12. Testing Nurse-Call +

The nurse-call can be triggered manually for testing purposes. To do this press the keys "bed exit alert" and "immobility alert" simultaneously and hold for 2 seconds. At the control unit the nurse-call is signaled by a flashing bed-exit or immobility alert (depending on the configuration and design of your device).

Acknowledge the test alert with the corresponding key, before a new test alert can be triggered.

6. Maintenance and Care

6.1. Annual Maintenance

We recommend taking out a maintenance contract. To maintain compliance with legal safety regulations, for maximum operational safety 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 a 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 the functionality using test benches
- ✓ Testing and if necessary replacing the calibration values of the sensors
- ✓ Checking for external and internal damage by specialist
- ✓ Updating the firmware to the latest version
- ✓ Replacement of small parts if necessary
- ✓ Certifying that the devices have passed all tests successfully.

6.2. Cleaning and Disinfecting

compliant concept recommends cleaning and disinfecting the equipment after each resident change. Please also comply with the hygiene requirements of your facility.

The device surfaces can be cleaned and disinfected by wiping and surface disinfecting. The control unit housing and the cover of the sensor unit should be wiped with a soft, slightly damp cloth or with wipes containing antiseptics. Use a listed, commercially available disinfectant. Observe the reaction time and allow the device to dry thoroughly.

⚠	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.
ℹ	The surfaces of *Mobility Monitor* can be destroyed by improper cleaning agents or disinfectants.

6.3. Storage

To prevent the battery of *Mobility Monitor* from becoming completely discharged, the unit must be **connected to a power source for 2 hours at least once every 6 months**.

If the battery has been completely discharged, this is indicated by continuous illumination of the error notification light. In this case the device can only be made operational again by *compliant concept AG*.

	*Mobility Monitor* should always be stored at room temperature. Extreme Temperatures cause the unit to age faster and the internal battery will be discharged quicker. Be especially careful that the device is not unnecessarily exposed to strong sunlight or other heat sources (e.g. heating radiators).

Please also note the maximum storage temperatures in Chapter 8.

7. Troubleshooting and Technical Support

7.1. Error Light 

Error Description	Possible Cause	Solution
The error light **flashes** together with the **orange mobility indicator light (traffic light).**	The sensor cable is not plugged in.	Please connect the sensor cable into the green port. If the cable is already connected, unplug it and plug it back in. If the error light is still flashing, please try to restart the device, by unplugging the power cord and plugging it back in again.
The error light is **flashing** together with the **red mobility indicator light (traffic light).**	The device must be calibrated.	Please calibrate the *Mobility Monitor*. First unlock the keys. Then press the "key lock" and the "repositioning key" simultaneously and hold for 4 seconds, until the traffic light flashes and the device is calibrated. After successful calibration, the traffic light briefly lights up green. **Important**: The bed has to be unoccupied, and the mattress has to be on the bed. No one is allowed to touch the bed or lay on the bed.
The error light flashes when a USB stick is inserted.	Not an original *compliant concept* USB flash drive or USB drive is defective.	Please always use a *compliant concept AG* USB stick. If you are using an original USB flash drive, try to unplug it and plug it back in again. Please contact support if the problem persists.
The error lamp flashes for a few sec. immediately after a USB drive was unplugged.	The USB stick was unplugged too early and not all data could be transferred.	Plug the USB stick into the control unit again and wait until the green data transfer LED stops flashing rapidly.
The error light **lights up permanently.**	A system error was detected.	Please remove the sensor cable, the nurse-call cable, the USB stick, and **then** the power cord. Then insert the sensor cable and the nurse-call cable again, and **after that** please connect the power cord. Please contact support if the problem persists and the light remains lit.
The error light flashes together with data transfer light (without USB stick)	The wireless connection of the wireless device is interrupted	Unplug the power cord and plug it in again. This triggers a new connection attempt. If there is still no connection, please check whether other devices also don't have a connection. If not, you should check whether the receiver or repeater are still working. Do not place the handset in the vicinity of metal structures (e.g. a metal cabinet, metal bed frame.)
A nurse call was triggered, but neither the bed-exit alert nor the immobility alert are blinking. The device displays an error.	An error occurred while a patient was lying in the bed, and an alert was activated. For safety reasons, the nurse call was triggered, because correct monitoring of the patient is no longer possible due to the error.	Check if the sensor cable is plugged in. If the error light remains on continuously, remove the sensor cable, the nurse-call cable, the USB stick and then the power cord. Then insert the sensor cable and the nurse-call cable again, then plug in the power cable. Please contact support if the problem persists and the error light is still on.

7.2. Device and Device Functions

Error Description	Possible Cause	Solution
The lights are off and the device does not respond.	No power	Please check whether the power cord is properly plugged into the unit or into the outlet. Please check if it works plugged in to a different outlet (may not have power at the outlet).
All functions are **impaired.** Mobility is displayed incorrectly, bed-exit alert is not working correctly, etc.	The device was not calibrated when the bed or patient was changed.	Please calibrate the *Mobility Monitor*. First unlock the keys. Press the "Key Lock", and the "repositioning key" simultaneously and hold for 4 seconds until the traffic light flashes and the device is calibrated. After successful calibration, the traffic light briefly lights up green. **Important**: The bed has to be empty, and the mattress has to be on the bed. No one is allowed to touch the bed or put something on the bed.
The **traffic light** is **activated** even though **no one** is lying in the **bed.**		
The **bed-exit alert** trips too often.	The bed-exit alert is set to bed-edge alert while the patient is sleeping on the edge of the bed.	Set the alert to "bed-exit" . 
Calibration of the device fails.	Someone is lying in the bed or someone is touching the bed.	Please ensure that during calibration no one is in the bed and nobody is touching the bed. The mattress must be on the bed. Should calibration fail repeatedly, even though all conditions are met, remove the sensor unit and then place it again and repeat the calibration process.

8. Technical Specifications

8.1. General Technical Specifications

Control Unit	
Models	*02x* und *03x*
Operating voltage	9 Volt DC
Max. Power	300 mA
Data storage	7-day data storage
Power Supply	100-240 V / 50-60 Hz, for medical applications Protection class II, according to safety standard IEC60601-1
Expected life	5-10 years
Housing protection	IP33 Protected against solid foreign objects with diameters from 2.5 mm Water resistant against falling water up to 60 ° against the vertical
Connection for nurse call	max. 50V AC/DC max. 100 mA continuous current max. 200 mA peak current for a maximum of 0.2 s
Wireless data transmission (with Wireless-868)	869.525MHz / 27dBm

Sensor Unit	
Model	01x
Operating voltage	5 Volt DC
Max. power	150 mA
Protection class	B
Expected life	5-10 years
Housing protection	IP23 Protected against solid foreign objects with diameters from 2.5 mm Water resistant against falling water up to 60 ° against the vertical
Size	730x20x160mm

Operating Conditions	Requirements
Operating temperature	5…40 °C
Storage temperature	-20…60 °C
Relative Humidity	15% to 93% relative humidity
Ambient pressure	700 hPa to 1060 hPa
Maximum person weight	180 kg
Minimum person weight	40 kg
Maximum direct load	90 kg

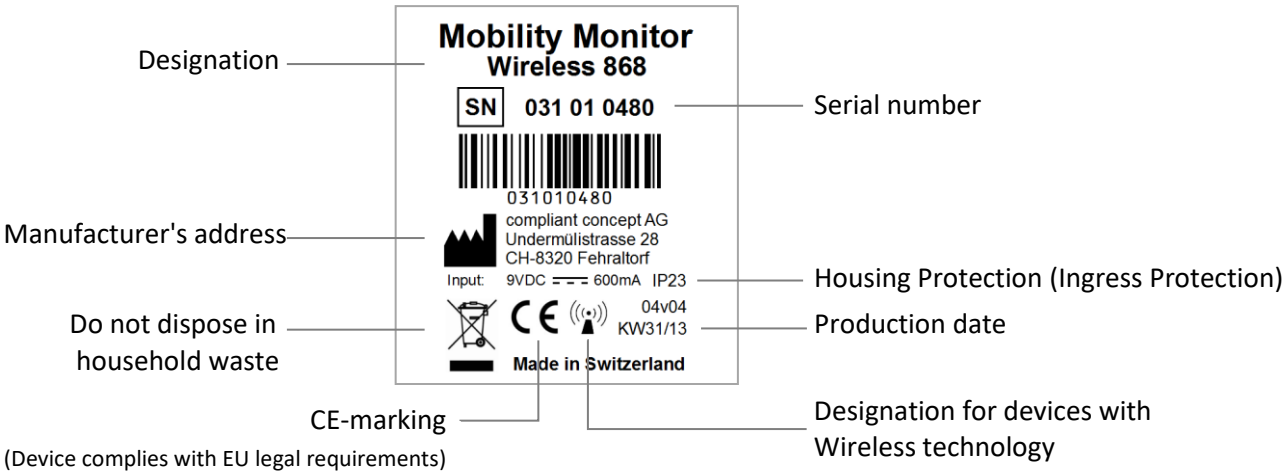
8.2. Compliance with Standards

Mobility Monitor has been tested and conforms to the requirements of the following standards:

Directive / Standard	Description
EN 60601-1 / 2005-12	med. electrical equipment: General requirements for basic safety and essential performance
EN 60601-1-2 / 2007-12	Collateral Standard: Electromagnetic disturbances - Requirements and tests

See Declaration of Conformity Chapter 10.

8.3. Type Plate Control Unit



8.4. Guidance and manufacturer's declaration – electromagnetic emissions

The *Mobility Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Mobility Monitor* should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The *Mobility Monitor* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *Mobility Monitor* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

8.5. Guidance and manufacturer's declaration – electromagnetic immunity

The *Mobility Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *Mobility Monitor* should assure that it is used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance
			Portable and mobile RF communications equipment should be used no closer to any part of the *Mobility Monitor*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 kHz bis 80 MHz	3 V	$d = (0.12)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz bis 2.5 GHz	3 V/m	$d = (0.12)\sqrt{P}$ 80 MHz bis 80 MHz $d = (2.33)\sqrt{P}$ 800 MHz bis 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,(a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Mobility Monitor* is used exceeds the applicable RF compliance level above, the *Mobility Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Mobility Monitor*

b *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.*

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% UT (0,5 cycle) 40% U T (5 cycles) 70% U T (25 cycles) <5% UT for 5 s	<5% UT (0,5 cycle) 40% U T (5 cycles) 70% U T (25 cycles) <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment. When the user of the *Mobility Monitor* requests the continued operation during interruptions of energy supplies, it is recommended to feed the *Mobility Monitor* from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

8.6. Recommended separation distances between portable and mobile RF communications equipment and the *Mobility Monitor*

Recommended separation distances between portable and mobile RF communications equipment and the *Mobility Monitor.*

The *Mobility Monitor* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Mobility Monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Mobility Monitor* as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz bis 80 MHz $d = 0.12\sqrt{P}$	**80 MHz bis 800 MHz** $d = 0.12\sqrt{P}$	**800 MHz bis 2500 MHz** $d = 2.33\sqrt{P}$
0.01 Watt	0.012 m	0.012 m	0.233 m
0.1 Watt	0.038 m	0.038 m	0.737 m
1 Watt	0.120 m	0.120 m	2.330 m
2 Watt	0.170 m	0.170 m	3.295 m
10 Watt	0.379 m	0.379 m	7.368 m
100 Watt	1.200 m	1.200 m	23.300 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. Warranty Provisions

9.1. General

The warranty applies to both materials and production faults of any kind that may occur during normal usage. The warranty period is 2 years.

Please contact our support team before you send in the device (→ see Chapter 11).

9.2. Scope

In the case of a defect with your device, under this warranty *compliant concept AG* guarantees either the repair or replacement of the device. The decision if to repair or replace the device is made by *compliant concept AG*. To this extent, *compliant concept AG* may decide at its discretion to replace the device sent in for warranty repair with an identical unit of the same quality.

The warranty does not apply to wear and consumables materials, i.e. parts that need to be replaced at regular intervals during regular use of the device, such as batteries.

For damages caused by improper use of the device, *compliant concept AG* assumes no warranty. For the exact procedures for operating your device, please refer to this manual.

If it turns out during the repair, that the error is not covered by the warranty, *compliant concept AG* reserves the right, to bill the customer for the costs incurred in the form of a processing fee and the fee-based service for parts and labor according to a cost estimate provided to the customer.

9.3. Exclusion

compliant concept AG provides no warranty for failure and damages due to external influences, accidental damage, improper use, changes, conversions, extensions, use of non-original parts, neglect, viruses or software errors, improper transport, improper packaging or loss when returning the device to *compliant concept AG*.

The warranty is void if the error on the device occurred from maintenance or repair, which was not carried out by *compliant concept AG* or one of *compliant concept AG* authorized service partners. The warranty also is void if labels or serial numbers of the device or a component of the device have been changed or made illegible.

9.4. Support Helpline

See → Chapter 11 "How to Reach Us"

10. Declaration of Conformity

compliantconcept
innovations for a better life

CE

EC-Declaration of conformity
CE-Déclaration de conformité
EG-Konformitätserklärung

We / Nous / Wir — **compliant concept AG**, Undermülistrasse 28, 8320 Fehraltorf, Switzerland — declare under our sole responsibility that the products / déclarons sous notre seule responsabilité que les produits / erklären in alleiniger Verantwortung, dass die Produkte

Mobility Monitor	•	Version 2	•	Models 022
Mobility Monitor	•	Version 3	•	Models 031

to which this declaration relates, are in conformity with the requirements of the following directives
auxquels se réfère cette déclaration, sont conformes aux prescriptions des directives
auf die sich diese Erklärung bezieht, konform sind mit den Anforderungen der Richtlinien

- **Low Voltage Directive 2006/95/EC**
- **Electromagnetic compatibility Directive 2004/108/EC**

Furthermore, the products comply with the following standards and recommendations
De plus les produits sont conformes aux normes et recommandations suivantes
Weiter entsprechen die Produkte den folgenden Normen und Empfehlungen

- **EN 60601-1 / 2005-12**
- **EN 60601-1-2 / 2007-12**

compliant concept AG, Fehraltorf, 20.05.2015

Eric R. Perucco Brandenburger
General Manager

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Quality Manager

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11. How to Reach Us

Questions about *Mobility Monitor* and *Mobility & Care Manager*? We provide technical support via phone or Email.

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

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

Change History

Version	Language	Release Date	Change	Translated from		Prepared	Reviewed	Approved
				language	revision			
2.0	EN	14.07.2015	Adjustments for *Mobility Monitor* Wireless / without software *Mobility & Care Manager* / Based on BG FW 5:12	DE	2.0	kgi	utu	kst
2.1	EN	03.04.2017	New Design	DE	2.1	Jdo		