AMS – Active Mobilisation System

Operating Manual

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Imprint

Active Mobilisation System (AMS)
Operating Instructions
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Table of Contents

1. General Information

1.1. About this manual

This manual is part of the AMS (Active Mobilisation System) by *compliant concept AG* and provides important instructions for commissioning, safety, intended use and care of the appliance.
All pictures and drawings in this manual are for general illustration only and are not binding for its construction details.
The operating instructions must always be available; their best location is in the vicinity of the device. It should be read by every person and be applied by all who are tasked with:

- Commissioning,
- Operation,
- Cleaning,
- Maintenance,
- Troubleshooting

of the AMS.

1.2. Limitation of liability

All technical information, data and installation, operation and care instructions included in this manual reflect the latest status at the time of printing and are based on our previous experience and knowledge to the best of our knowledge.
No claims can be derived from the details, illustrations, and descriptions in this manual.
The manufacturer assumes no liability for damages due to:

- Not adhering to the manual
- Improper use
- Improper repairs
- Technical changes
- Use of unauthorized replacement parts
- Unauthorized conversions and changes

Translations are carried out in good faith. We do not assume any liability for translation errors, even if the translation was carried out by us or on our behalf. The original German text is the solely binding version.

1.3. AMS features

The following features distinguish the AMS:

- Continuous repositioning/side positioning with additional, intermittent pressure relief on the patient's body
- Extremely low noise and low vibration
- Very easy to use
- Good transfer properties for entering and exiting
- When the back rest is raised too high (>30° or optionally >50°), the AMS stops its movements
- The adjustment options of the bed remain: the knee and foot section should not be adjusted while the AMS is running. The back rest can however be raised to a maximum of 30° (or optionally 50°).
- CPR function (Cardiopulmonary resuscitation)
- Tapered heel zone for additional pressure relief

1.4. Scope of delivery

The Active Mobilisation System comprises:

- Protective carrying bag
- Control unit (CU)
- Active mattress (MS - Moving System), consisting of:
  Carrier cover, Foam mattress, Active modules, Mattress protection cover, and Tube connector
- Power cable
- Operating manual and Quick guide

2. Purpose

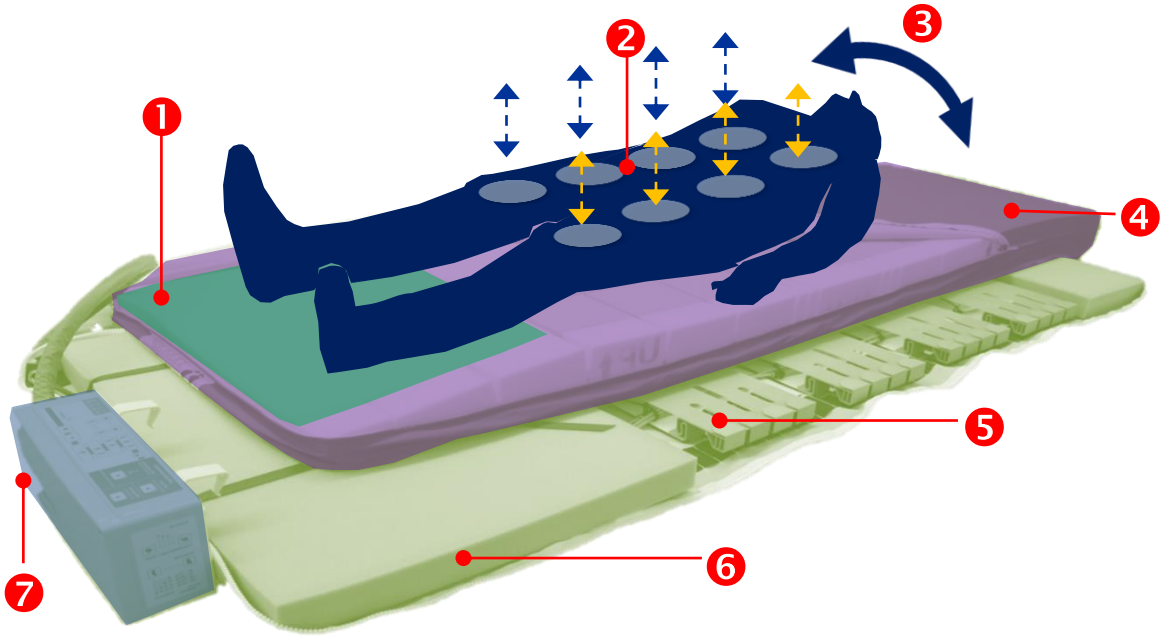
The AMS is a hybrid, dynamic mattress that combines continuous lateral repositioning with additional intermittent pressure relief to support the prevention and treatment of pressure injuries.

2.1. Intended use

Scope for use: hospital, long term care, home care, the private sector within the EU and EFTA
Users: health care workers, people with medical training, any trained individuals

2.2. Operating principle of the AMS

The operating principle of the AMS combines lateral repositioning with intermittent pressure relief. The device mobilises or turns the patient at periodic intervals into a slight left and/or right lateral position, depending on the user's choice and the needs of the patient. In the lateral position, the patient experiences additional, intermittent pressure relief in the shoulders, upper back, hips/sacrum and thighs. The rotations and reliefs are intended for patients in the supine position.



2.3. Structure and essential functions of the AMS

The upper part of the mattress ❹ consists of a high specification reactive pressure injury prevention foam surface with a reinforced edge zone and a bevelled foot part for heel relief ❶. The lower part ❻, the mobilising part, consists of four transverse mounted lamellae ❺, which deform in a wave-like manner and thus reposition the patient from one side to the other, and additionally provide intermittent relief at critical pressure points and body parts ❷. The on/off and programme selection are done via push buttons on the control unit ❼, which is mounted at the foot end of the bed by means of the hooks supplied.

The AMS includes the following essential functions:

- Starting and stopping of mobilisation
- Setting of the repositioning **intensity**
- Setting of the repositioning **interval** (speed)

The system does not decide when and how a patient needs to be mobilised. This is determined by the user, who starts the system manually and stops it again and who must choose the correct intensity and intervals. The information displayed only serves to identify which mobilisation parameters are activated.

If the mobilisation of the patient by the AMS is not possible due to a technical defect, malfunction, or improper manipulation, this is signalled. (Always visually. Acoustic signalling can be turned off.)

The AMS by itself does not prevent pressure injuries. It can be used as a supportive measure for preventing pressure injuries in the case of moderate, medium, and high risk, and as support for the treatment of pressure injuries. It does not replace prophylactic / therapeutic measures, as well as regular inspections by the nursing staff.

When the AMS is used in beds with side rails the upper edge of the side rail must be fixed at least 22 cm above the surface of the unloaded mattress.

2.4. Indication

The AMS is suitable as a *supporting* device…

- for pressure injury prophylaxis in patients with a low to very high risk according to Norton or Braden or a high immobility measured with the Mobility Monitor
- the therapy of pressure injuries of all categories according to EPUAP.

The AMS is designed for use with people with a **height of 146 cm and taller** and **weighing between 40 and 150 kg.**

With patients who may not lie on their back due to their physical condition, the mobilization function of the AMS must be deactivated.

2.5. Contraindication

When the mobilization function of the AMS is activated, the patient is rotated in his longitudinal axis. Thereby, the rotation angle for the upper body is greater than that for the legs.

With due consideration of the intended use, the function and mode of operation of the product, the AMS is with the prior approval of the responsible surgeon, suitable for use following certain types of surgery such as shoulder, back, pelvis, spinal cord, and visceral surgery in the abdomen area prior to complete wound healing.

The AMS is **not suitable** for patients with the following diagnoses:

- Unstable spinal fractures
- Cervical extensions

- Manière's disease
- Intolerance towards the product

2.6. Side effects

- The unaccustomed movements of the AMS may initially cause unease. However, this usually disappears after a settling-in period of up to 3 days.
- The small turns of the AMS can lead to a kind of "seasickness" in patients, depending on their pre-disposition. This "seasickness", also called travel or motion sickness (the technical term is kinetosis from the Greek word kinein = to move), is accompanied by physical reactions such as paleness, dizziness, headache, nausea and vomiting, caused by the unaccustomed movements.

If the patient / resident refuses or rejects the AMS, or if a decline in health can be observed, the use of the AMS should be discontinued.

2.7. Clinical benefit

- Effective pressure relief for both the treatment of existing pressure injuries and prevention of new pressure injuries occurring.
- Relief for the care persons by assuming the physical work of repositioning the patient.
- An improvement in quality of sleep for the patient due to lack of sleep interruptions for repositioning.

2.8. When used by lay persons trained on the AMS

In the event that the skin condition of the patient deteriorates or in the case of uncertainty of the suitability of the device based on the indication given, a medically trained person should be consulted (see chapters → **2.4,** → **2.5,** → **2.6).**

3. Safety

3.1. Symbols

The following information is provided for the safe use of the device, so that neither the user is endangered, nor the product is damaged. The following warning signs are in use:

	**Instructions** that prevent injury to personnel or the user.
	**Important information** that will ensure proper use of the product.
→ 7	**For more information**, see the chapter number indicated (→ **Link**).

3.2. General warnings

	Please contact the manufacturer or distributor for assistance with installation and operation of the device, or if you notice an unexpected malfunction of the device.
	The device must be installed and commissioned according to the operating manual. In addition, the user must be instructed in the operation of the device.
	The pressure injury risk assessment is not performed by the device but is the responsibility of the nursing staff.
	The AMS is designed for use with people with a height of 146 cm and up and weighing between 40 and 150 kg. The intensity of the repositioning must be adapted to the patient's weight (see chapter → **7.9**).
	Continuing care measures: the AMS does not replace the prophylactic / therapeutic measures nor the regular inspections by the care personnel. The AMS alone cannot prevent pressure injuries. It can be used as a supportive measure for preventing pressure injuries in the case of moderate, medium, and high risk.
	The control unit (CU) may not be loaded with more than 5 kg (50 N). It does not serve as shelf space.
	The device is subject to special EMC precautions (See EMC declaration)
	Portable and mobile RF communications equipment can affect medical electrical equipment.
	The AMS may only be operated with accessories supplied by *compliant concept AG*.

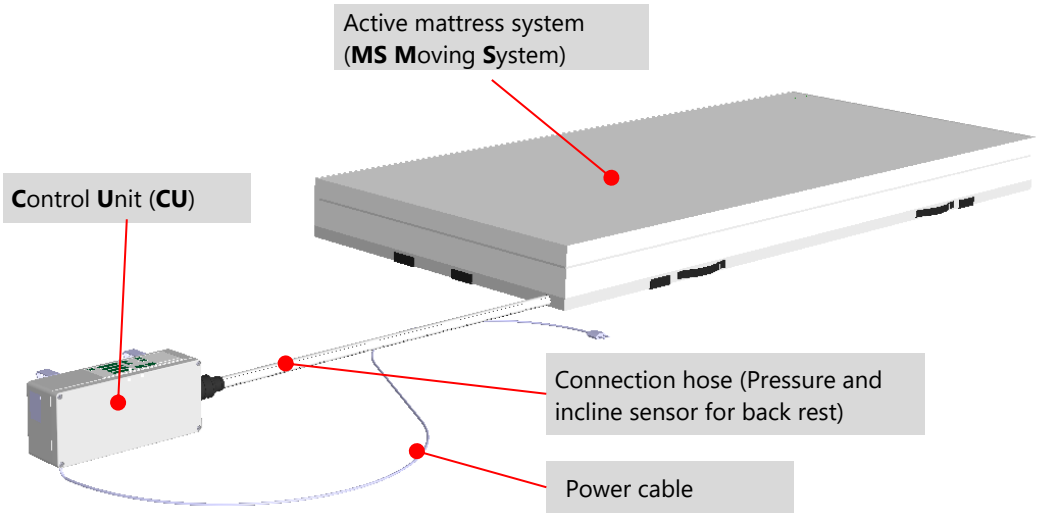
	The AMS may not be serviced during operation.
	The maintenance intervals must be observed to ensure safe operation. See maintenance indicator on the CU.
	All modifications to the AMS are prohibited.
	The battery must be replaced by trained personnel only.
	Place all cables carefully to reduce the hazards from tripping or strangulation.
	We urgently recommend cleaning and disinfect the system at least after each patient change.
	The device is only water resistant to splashes! If dirty, the device should only be wiped with a damp cloth. Otherwise, there is danger of electric shock.
	The control unit 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.
	In the unlikely event that someone is injured in connection with the use of the device, this should be reported immediately to the responsible authorities and the manufacturer. For further information on steps to be taken contact us via the contact details in chapter → **16** of this manual.

4. Overview

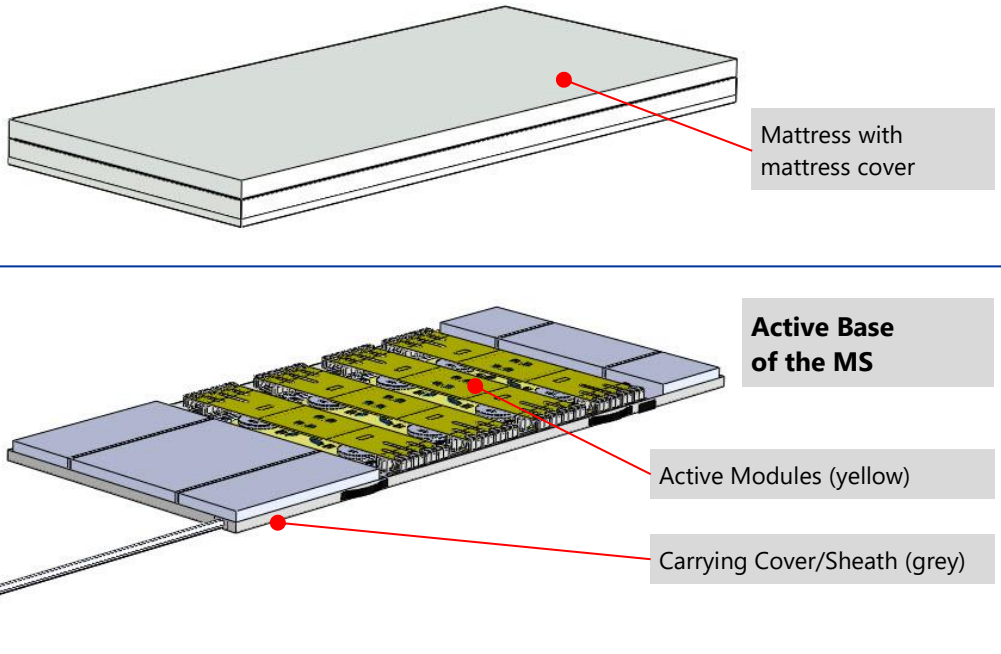
4.1. AMS components

Before installing, please check that all parts of the AMS are included:

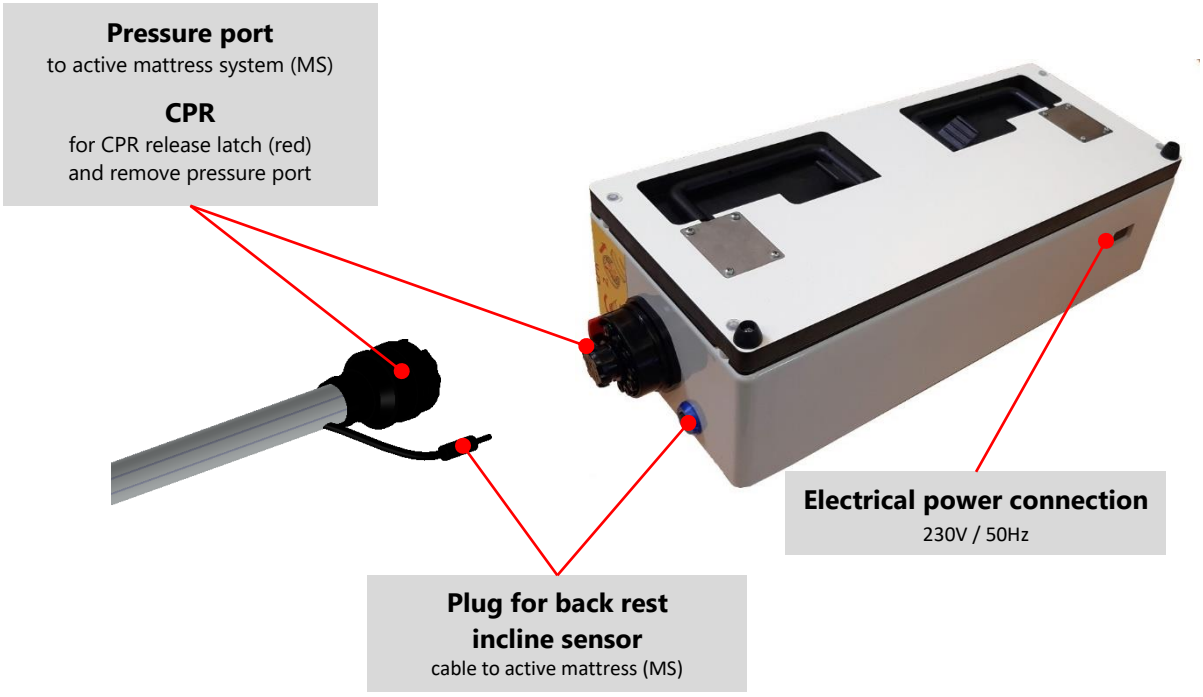
- Protective carrying bag
- Control Unit (CU)
- Active mattress MS (Moving System) consisting of:
  Carrier cover, Foam mattress, Active modules, Mattress protection cover, and Tube connector
- Power cable
- Operating manual and Quick guide



4.1.1. Active Mattress System (MS)

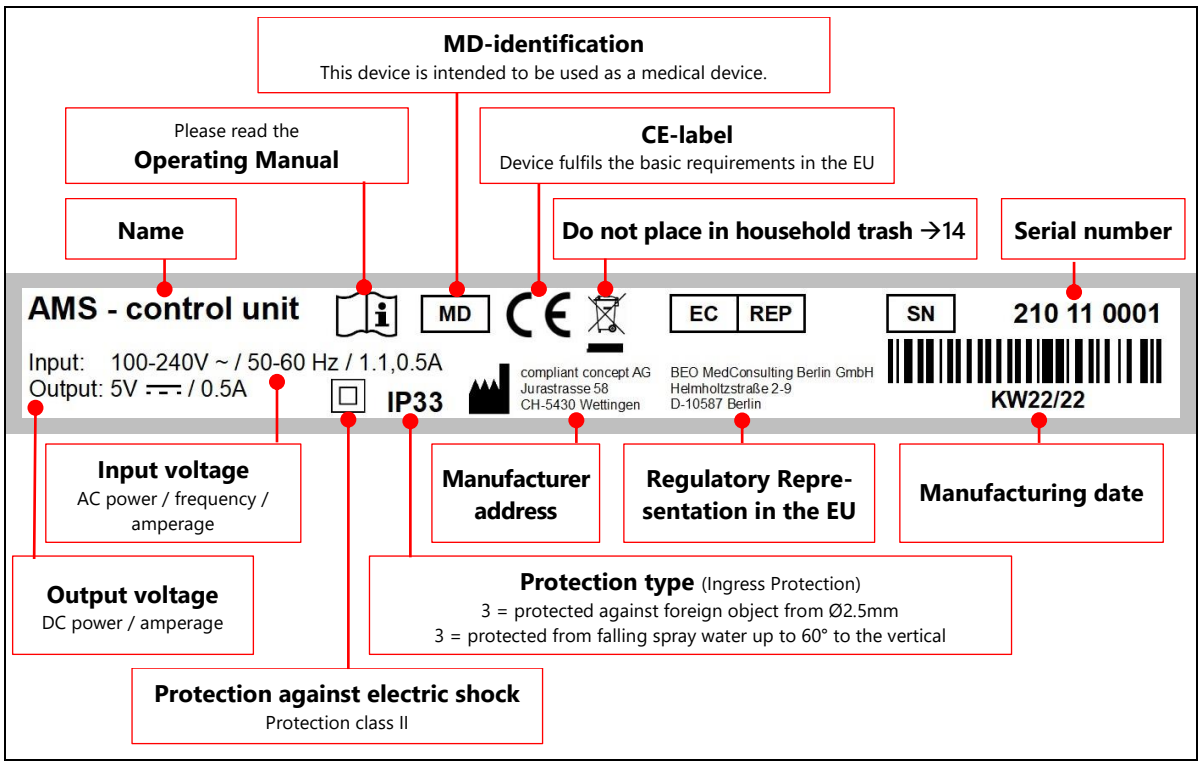


4.2. Connections

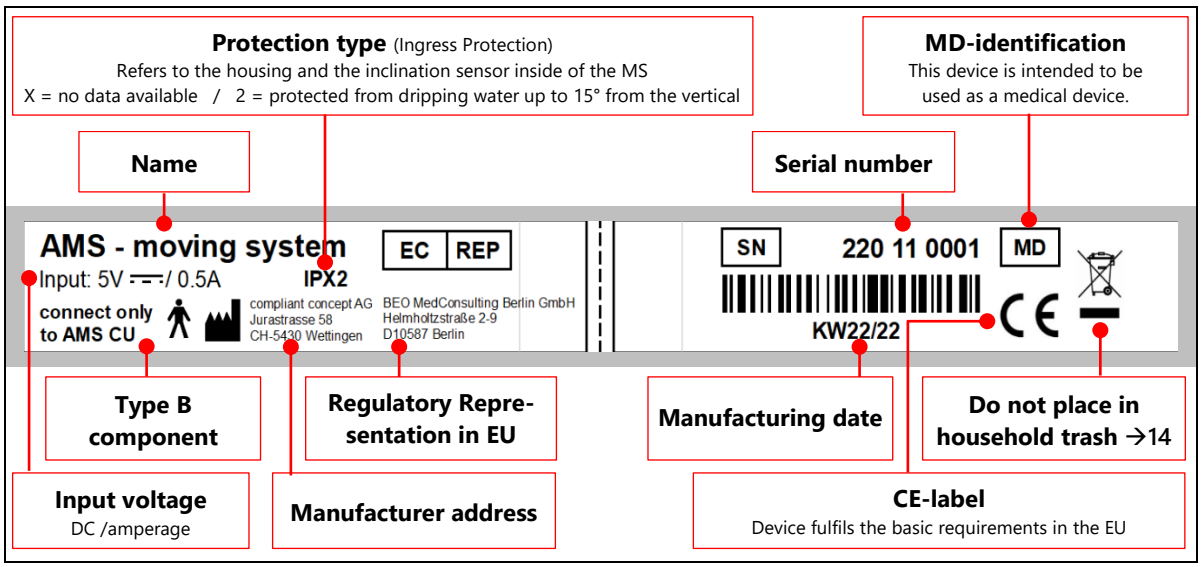


On a new device plugging the connector of the inclination sensor into the control unit (CU) will need some force. Make sure that it is inserted all the way in.

4.3. Type plate Control Unit (CU)



4.4. Type plate Moving System (MS)



5. AMS Installation

5.1. Commissioning

The Active Mobilisation System (AMS) must only be commissioned and adjusted for the bed by properly instructed personnel.

We recommend that the AMS be set up in one specific bed and remain there, in particular, if several different types of beds are in use.

The AMS is installed directly on the support surface of the bed, and thus replaces the original mattress.

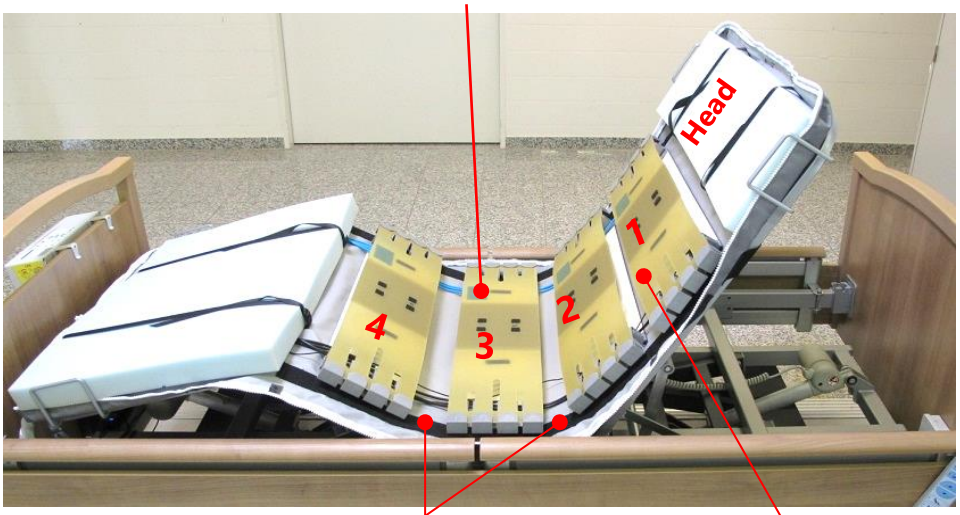
- Remove the existing mattress.
- Place the Moving System (MS) on the surface of the bed. Attach the MS using the belt loops of the carrier cover across the corners to the back rest of the bed.

The belt loops on the carrier cover serve to secure the mattress additionally so that it is optimally positioned on the bed and cannot slide down the bed.
Situations may arise whereby the technical characteristics of the bed do not permit the use of the belt loops. In such cases care should be taken to secure the position of the mattress on the bed by other means such as an elevated bed frame at the foot of the bed.

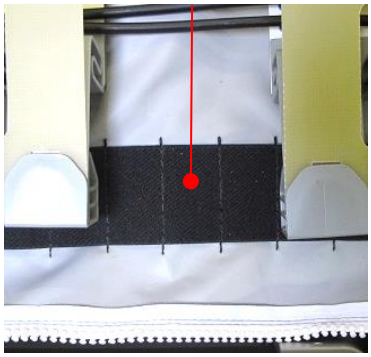
Important: Make sure that the mattress is properly oriented (labelling on the mattress oriented correctly, logo and hose/air pipe positioned at the foot of the bed)

- Remove the mattress of the MS (large white zipper. Start in the centre of the foot end) and make sure that the following points are adhered to:
  - **a.** The active modules are correctly positioned: (This can be checked by raising and lowering the back rest and leg support)
    1. **3rd active module** in the fixed section of the bed
    2. 3 visible loops distance to the **modules 2 and 4**
    3. **Module 1** approximately in the middle between **module 2** and the "head" foam and at least 1 visible loop distance to **module 2**

Active module no. 3 in fixed area (should remain level when bed is adjusted



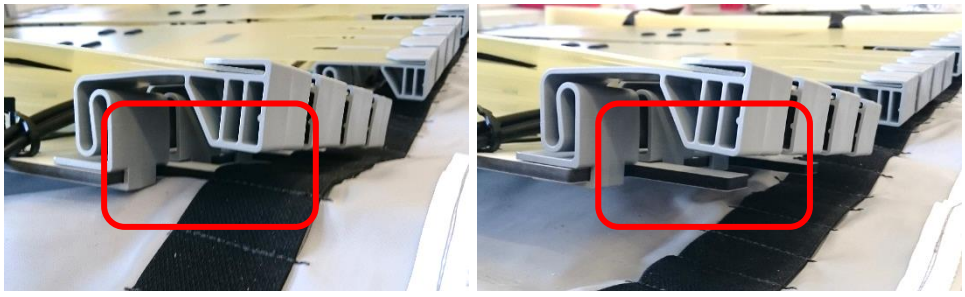
Distance: 3 visible loops



Module 1
approximately
centered between
Module 2 and foam
"head" and
at least
1 visible loop distance
to Module 2

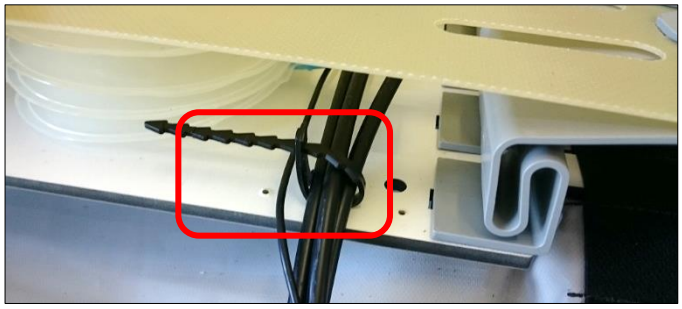
If the positioning is not correct, you will find a step-by-step guide in chapter → **5.2**.

b. that the active modules on both sides (left and right) are hooked into the loops



Correct **Wrong**

c. that the hose/cable clips are closed.

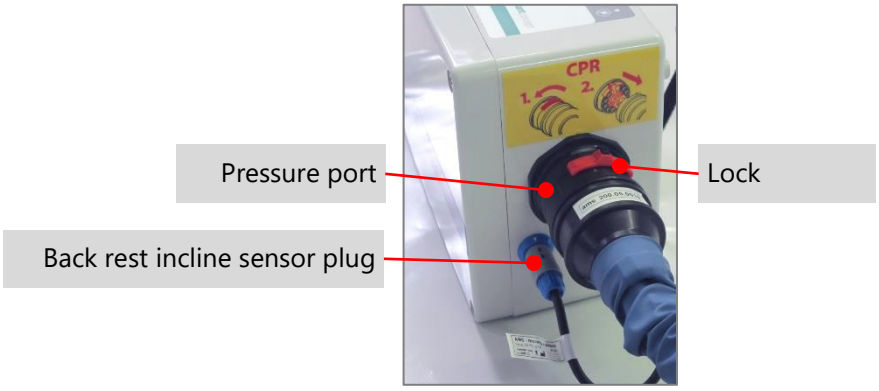


Before initial installation, and when **changing bed type**, the active modules must be properly positioned, → **5.2.**

- Hang the control unit (CU) at the foot of the bed
- Connect the pressure port. Pay attention to the label on the red connector.
  - Turn the red connector completely to the left (OPEN)
  - Connect the pressure port of the MS.
  - Turn the red connector **FULLY** to the right to close it (LOCK)

Important: the lock should not be left in an intermediate position!

- Plug in the backrest incline sensor cable.
  Make sure that the plug is pushed all the way into the socket.



- Position the cables (connecting air pipe and power cable) so that nothing can pinch them.

Important: Check that nothing can be pinched by testing the leg and back sections in all positions. Check also that the side rail cannot be blocked by the air pipe.

- Put the mattress of the MS on top of the carrying cover/sheath and close the zipper.

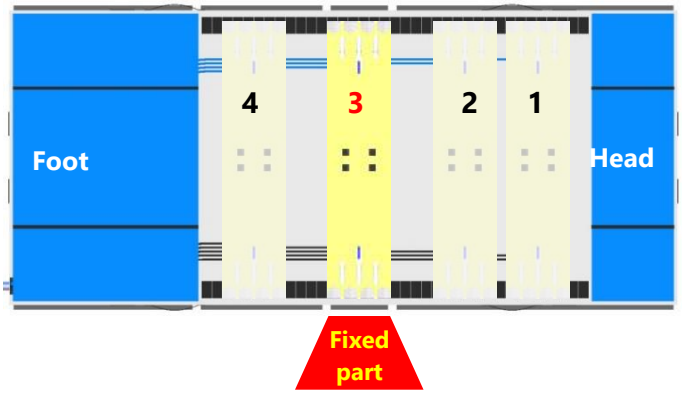
After commissioning the AMS, it is recommended to make the bed as usual with fitted sheet, incontinence protection, etc.

Important: It is important to ensure that the sheet is not too tight or sufficiently stretchable, so that the movements of the AMS are not hindered.

5.2. Positioning the Active Modules

Step by step instructions for positioning the active modules (AM):

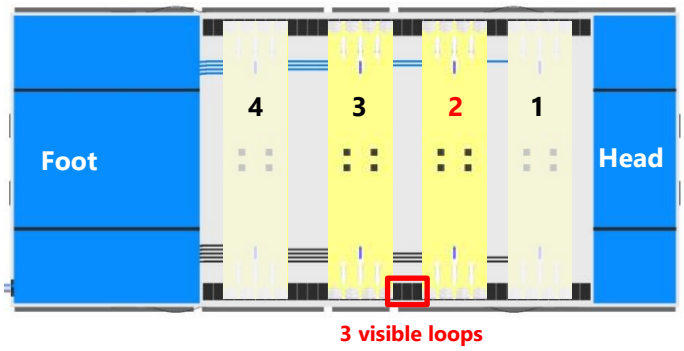
1. Place the MS on the surface of the bed (after the conventional mattress has been removed) for which it should be fitted.
2. Use the belt loops to fasten the MS to the corners of the back rest. **Make sure** that the back rest is still movable, and that the loops don't block anything.
3. Remove the mattress from the active base using the zipper that goes all the way around
4. Remove the active modules (AM) from the belt loops
   a. Slide the AM in the belt loop to one side as much as possible
   b. On the other side unhook the AM from the loops
   c. Now pull the AM out of the loops on the other side also
5. Check that the **carrying cover/sheath is located centrally** on the bed (the same amount of space at the top and at the bottom. It tends to slide towards the top slightly, because of the belt loops).
6. Position the AM in the pelvic area (3rd module) such that it is located exactly on the fixed, i.e., non-movable part of the bed.
   a. Once the AM is in this position, hook it into the belt loops again.
   b. Make sure that the AM is sitting straight.



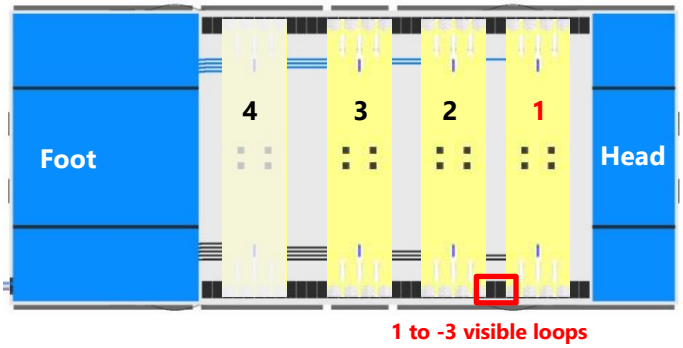
If the fixed part is narrower than the active module, please proceed as follows:

- Check if the upper leg support part retreats when lifting.
- If so, the thigh section (upper leg support) may no longer be raised.
- If not: position the active module on the fixed part with an overlap to the thigh part (upper leg support).

7. Position the AM in the lower back part (2nd module) so that the **distance to the** 3rd module **is such that 3 are visible from above.**
   a. Hook in the AM

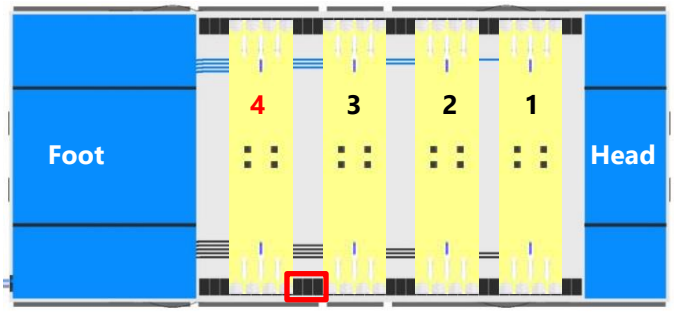


8. Position the AM in the upper back / shoulder area (1st module) with 1 to 3 loops distance to the 2nd module.
   a. Select the distance such that the 1st module is centred between the 2nd module and the foam in the head area
   b. Hook the AM in



1 to -3 visible loops

9. Position the AM in the thigh area (4th module) with 3 loops distance to the 3rd module
   a. Hook the AM in



3 visible loops

10. Move the back rest and leg support of the to their respective stops and check that the pipes cannot become trapped.
11. Make sure that the foam pieces at the head and foot part are tightened and that the bands are stowed such that they cannot interfere with the active modules.
12. Place the mattress back on top and close the zipper

Checklist before closing up the mattress:

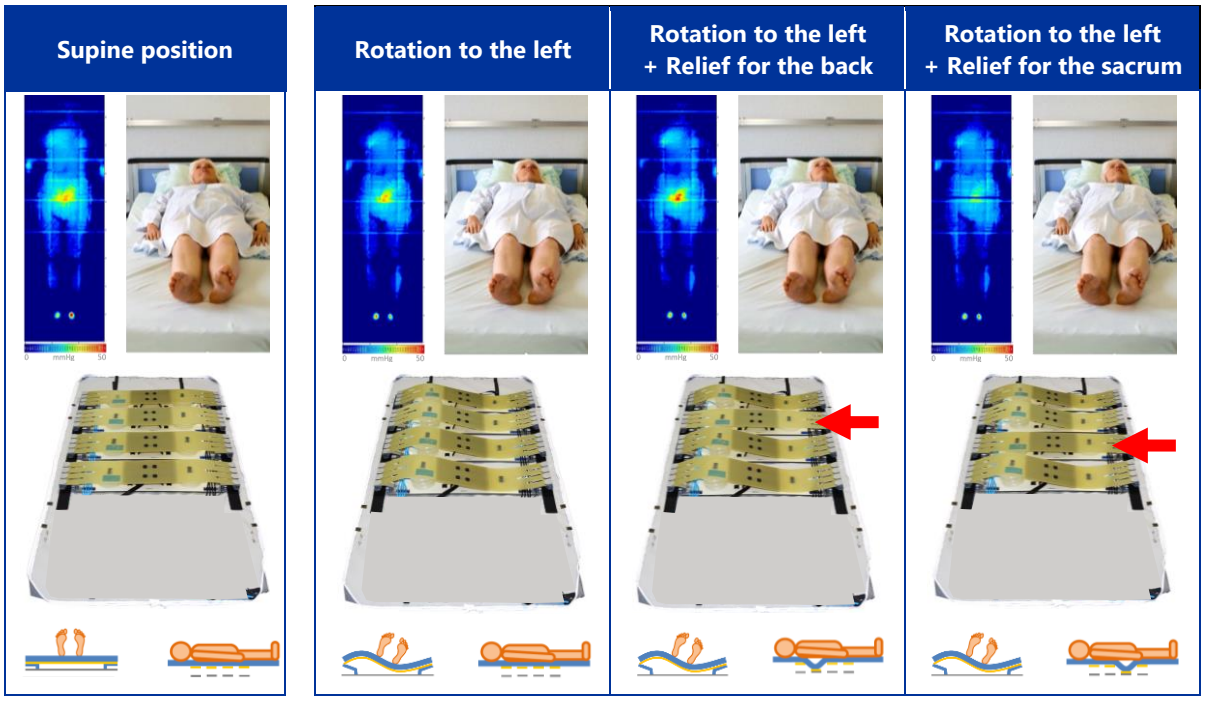
- Is the MS attached to the back with the belt loops?
- Are the active modules positioned correctly?
- Are the active modules hooked in correctly?
- Are the tubes/hoses mounted in the guides/clips?
- Are the pipes not jammed anywhere? (Even if the bed gets adjusted)
- Are the foam pieces of the head and foot sections properly positioned and tightened and the straps stowed such that they cannot interfere with the active modules?

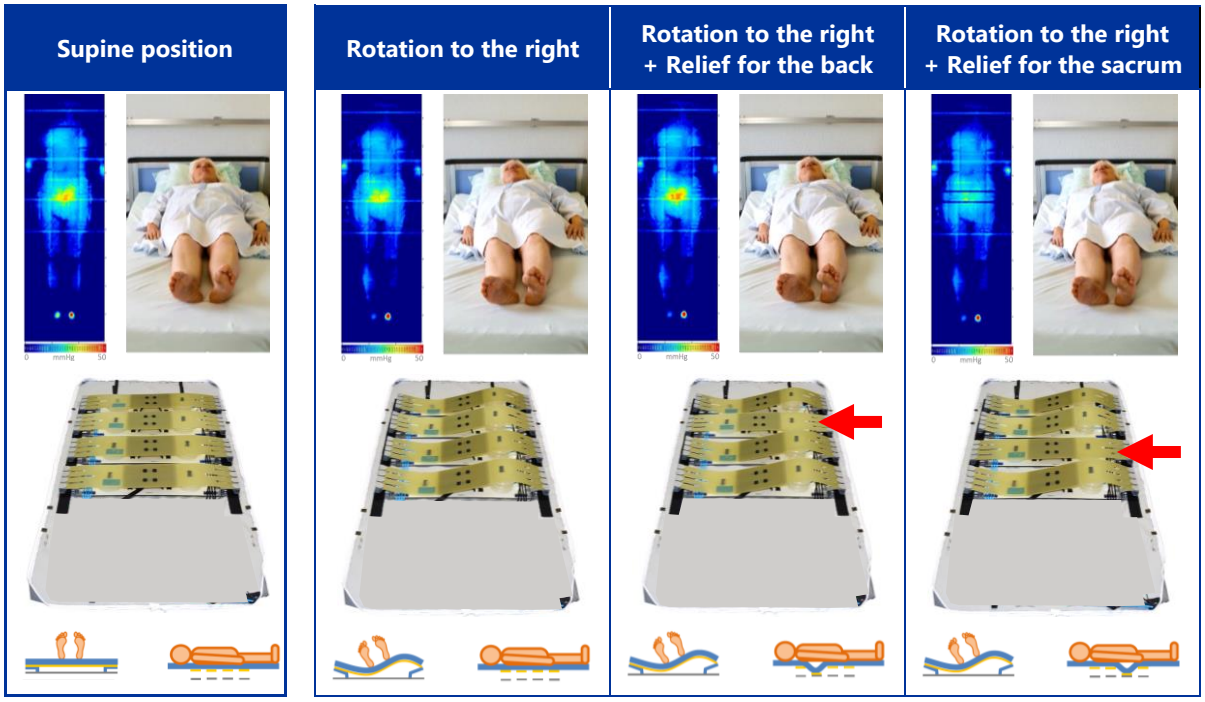
6. Function of the AMS

The AMS rotates and relieves the patient by deforming the 4 active modules as a wave. The active modules are positioned approximately under the following parts of the patient's body:

Module 1: Shoulder area
Module 2: Upper back
Module 3: Hips / sacrum
Module 4: Thighs

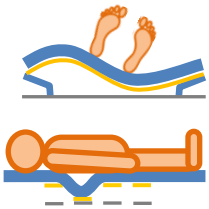
In addition, during the cycle, individual active modules are lowered, thereby providing additional, intermittent pressure relief for the respective area.





6.1. Overview of programmes

The indications **rotation to the left** or **rotation to the right** are always meant **from the patient's point of view.**

Programme 1  Mobilisation: **Rotation** to the **left** and to the **right** with intermittent pressure reliefs	 Supine position	 Rotation to the **right** and intermittent pressure reliefs	 Supine position	 Rotation to the **left** and intermittent pressure reliefs
Programme 2  Mobilisation: **Rotation** to the **right** with intermittent pressure reliefs	 Supine position	 Rotation to the **right** and intermittent pressure reliefs		
Programme 3  Mobilisation: **Rotation** to the **left** with intermittent pressure reliefs	 Supine position	 Rotation to the **left** and intermittent pressure reliefs		
Programme 4  Stimulation: Intermittent pressure reliefs, without any rotation	 Supine position	 Intermittent pressure reliefs at the upper body	 Intermittent pressure reliefs at the pelvic area	

6.2. Programme 1 – Rotation with pressure relief to the left and right

Programme 1 turns the patient alternately onto the left and right side of the body and provides intermittent pressure relief on the opposite side of the body. It is used as a standard.

			Speed / Interval			
Repositionings per hour			**1**	**2**	**4**	**6**
Supine position			240 mins	120 mins	60 mins	40 mins
Rotation to the right and intermittent pressure reliefs						
Supine position						
Rotation to the left and intermittent pressure reliefs						

6.3. Programme 2 – Rotation to the right with pressure relief on the left

Programme 2 turns the patient to the right side only and provides intermittent pressure relief on the opposite side of the body.

			Speed/Interval			
Repositionings per hour			**1**	**2**	**4**	**6**
Supine position			120 mins	60 mins	30 mins	20 mins
Rotation to the right and intermittent pressure reliefs						

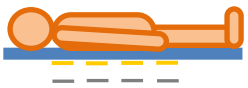
6.4. Programme 3 – Rotation to the left with pressure relief on the right

Programme 3 turns the patient onto the left side only and provides intermittent pressure relief on the opposite side of the body.

			Speed/Interval			
Repositionings per hour			**1**	**2**	**4**	**6**
Supine position			 120 mins	 60 mins	 30 mins	 20 mins
Rotation to the left and intermittent pressure reliefs						

6.5. Programme 4 – Stimulation

There is no rotation in programme 4 and the patient remains in supine position. The upper body and pelvic areas are relieved one after the other.

		Speed/Interval			
Relief events per hour *		**1.3**	**2.7**	**5.5**	**8**
Supine position without relief		 90 Min.	 45 Min.	 22 Min.	 15 Min.
Relief for the upper body					
Supine position without relief					
Relief for the pelvic area					
Supine position without relief					

* In programme 4 no mobilisation takes place but rather only the illustrated relief events.

Since the stimulation programme does not provide any mobilisation, the patient should be turned additionally manually – as long as he/she is at risk for pressure injury.

6.6. Pressure redistribution for heels

The feet of the patients are turned together and follow the continuous turning of the torso. Thus, the pressure on the heels is actively redistributed. For most patients this is sufficient.

Since the heels of every patient are different attention should be paid to the skin condition of the heels during regular check-ups, particularly at the start of the use of the AMS. Additional offloading should be ensured if there are any signs of redness.

For patients at particularly high risk or in the case of recurring complication in the heels area we recommend applying an additional suspension of the heels or other recognised prophylactic and therapeutic measures as required.

7. Operating the AMS

7.1. General information and default settings

As soon as the power cord is connected...,

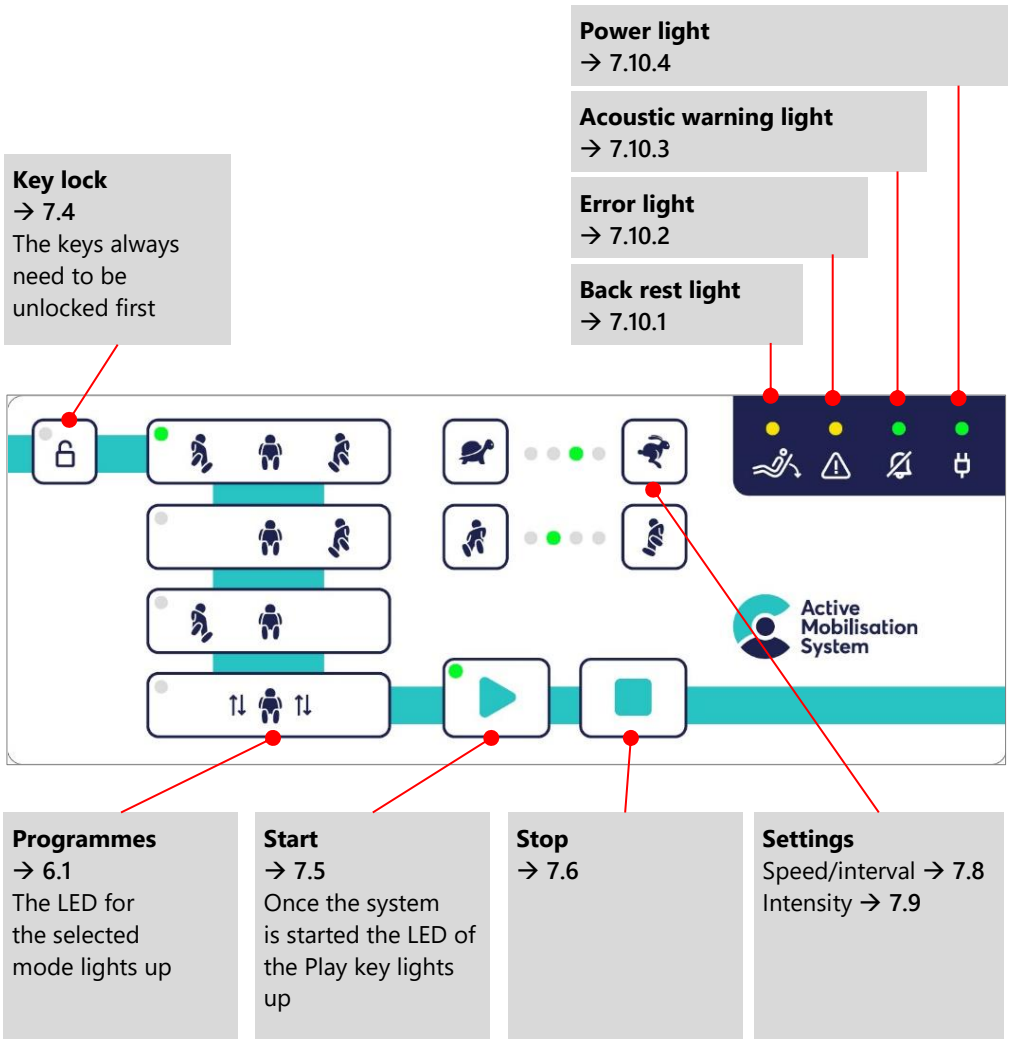
- all indicators light up briefly, the warning sound is heard, and the pumps start up to bring the system to the initial pressure.
- The LEDs (lights) indicate the current settings.
- The most recent settings are saved and will be displayed again when the system is restarted.
- At first use, the audible alarm is switched on.

After a short power failure ...

- of less than 30 seconds, the most recently selected programme automatically starts up again with the most recent settings.
- If the device was without power for longer than 30 seconds, the programme must actively be started again.

The system should remain plugged in even when no program is running, so that the mattress surface always maintains the desired firmness. If at any time it is not plugged in, the mattress will sink in slightly. The patient, however, is still lying comfortably on the foam mattress.

7.2. User interface – Overview



7.3. Turning the AMS on / off

To turn the AMS on, connect the power cables to the CU. To turn it off, unplug the power cord.

AMS turned **ON**

AMS turned **OFF**

Stop the AMS before turning it off, → **7.6.**

7.4. Key lock

Before a key can be activated, the keys must be unlocked using the Key Lock key. Once the key lock key is pressed, the corresponding LED lights up and all LEDs become brighter. The keys can now be used.

Keys operable

Keys locked

After a few seconds the keys lock automatically.

The key-lock is used to protect against accidental changing of the settings. Nevertheless, it cannot be excluded that the settings are changed, for example by a child. Therefore, the settings should be checked regularly to see if they are still correct.

7.5. Starting the device

Make sure that the system is turned on. (Power indicator light on)

1. Unlock the keys
2. Check whether the programme and the settings are correct. If not:
   a. Select the desired programme (→ **6.1**)
   b. Select the desired settings (→ **7**)
3. Start the system by pressing the Play key. The Play key lights up.
4. Lock the keypad by pressing the key. If the keypad is not locked manually, it will lock automatically after 10 seconds.

The LED in the Play key shows if the AMS is running or not.

AMS is **running**

AMS not running/ **is stopped**

Due to the fact that several minutes pass until the AMS starts to move and that the movements are very slow and there is hardly any noise, it is difficult to discern whether the AMS is running. Therefore, always make sure that the indicator LED on the Play key is lit.

7.6. Stopping the device

To stop the system, proceed as follows:

1. Unlock the keys
2. Press the Stop key

The Play key flashes until the system has returned to a neutral position. Then, the Play key light will turn off. The system is stopped.

AMS **stopped / goes into flat position**

AMS is not running / **stopped**

Always stop the system before you disconnect it from electrical power.
If power to the system is suddenly interrupted during operation, it will remain in the current position. This could be uncomfortable for the patient / resident.

Always stop the AMS before transferring the patient in and out of bed.

7.7. Selecting the programme

You can choose from four different programmes. (For details on the programmes see → **6.1**)

Rotation to the **left** and to the **right** with pressure reliefs (programme 1)

Rotation to the **left** with pressure relief to the right (programme 2)

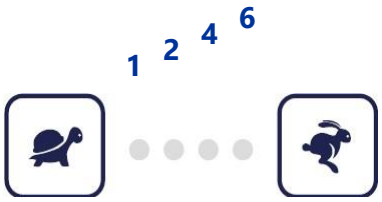
Rotation to the **right** with pressure relief to the left (programme 3)

Stimulation (programme 4)

1. Unlock the keys .
2. Select the desired programme by pressing the appropriate key. The LED of the selected programme lights up.

3. Lock the keypad by pressing the lock key. If the keypad is not locked manually, it will lock automatically after 10 seconds.

7.8. Interval / Speed settings



Repositionings per hour

You can choose between four different interval speeds. The lowest level makes one reposition per hour and the highest level six repositionings per hour. Repositioning is defined as a rotation from the centre to the side or vice versa. See also the programme sequences in chapters → **6.2,** → **6.3,**→ **6.4,** →**6.5.**

The interval speed can be set as follows:

1. Unlock the keys
2. Select the desired settings by pressing the following keys until the desired level is reached.
3. Lock the keypad by pressing the lock key. If the keypad is not locked, it locks itself after 10 seconds, if no key is pressed.

Setting the interval speed is the responsibility of the nursing staff. The setting must be monitored continuously and adjusted if necessary. Daily skin checks should be carried out as always.

A programme or interval speed setting change will take effect immediately.

7.9. Intensity setting

The intensity setting can be adjusted in 4 steps. The higher the intensity, the stronger the patient is rotated.

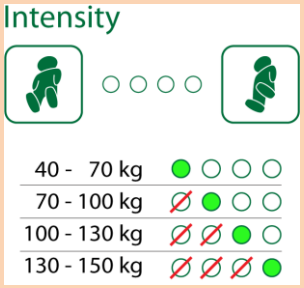
The selected intensity also influences the firmness of the AMS in the flat state. The higher the intensity, the firmer the support of the mattress.

The intensity can be set as follows.

1. Unlock the keys
2. Select the desired settings by pressing the following keys until the desired level is reached.
3. Lock the keypad by pressing the lock key. If the keypad is not locked, it locks itself after 10 seconds, if no key is pressed.

The intensity must be adapted to the patient's weight. The heavier the patient, the higher the intensity must be set. See the table on the right:

All intensity levels may be used for patients **under 70 kg**.
For patients **over 130 kg** it is recommended to set to the highest intensity.



Setting the intensity level is the responsibility of the nursing staff. The specified value must be checked constantly and adjusted if necessary. Daily skin checks must not be neglected.

It is recommended to adjust the intensity according to the weight. If the intensity is set higher, it may happen that the rotation is experienced as too strong and unpleasant.

The intensity setting change does not take effect until the end of a cycle is reached.

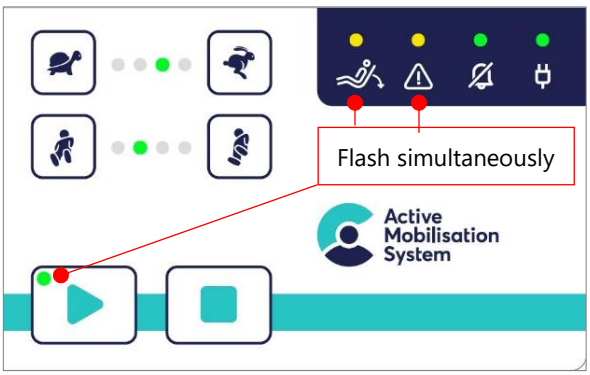
7.10. Indicators

7.10.1. Back Rest Incline

If the AMS is started and at the same time the back rest of the bed is raised more than 30° (or optionally 50°), the AMS stops the movement and assumes a level position. This is a safety precaution of the AMS. It should prevent on the one hand that a patient without muscular tension can be tipped out of the bed on the other hand a steeper back rest causes greater shear forces on the sacrum.

Optionally and after consultation with the institution, depending on the bed used the maximum angle of inclination of the back rest can be adjusted to 50° by installing a special firmware.

In this state, the LEDs of the Play key flash to signal that the AMS programme is interrupted. As a further warning the LED on the symbol for back rest and the warning LED flash simultaneously. In addition, every 10 seconds a warning sound (double beep) is given, as long as the audible warning is not disabled (→ **7.10.3**). As there are situations in which for short nursing or therapy measures the back rest is raised and this warning would disturb, it stops initially after 3 signals and starts warning again after a further 30 minutes.



The AMS was running but has been interrupted by the back rest being raised steeper than 30° (or optionally >50°) .

Once the back rest is lowered to below 30° (or optionally 50°), the AMS will recommence the movements. The AMS can be operated/set up normally with elevated back rest.

7.10.2. Error Indicator Light

The error indicator light displays technical errors.

When an error occurs, the error indicator lights up yellow. Proceed as follows:

1. Turn off the system by unplugging the power cord.
2. Wait until all LEDs have turned off.
3. Make sure that all connections are plugged in properly (→ **4.2**)
4. Turn the system on again (plug in the power cable)
5. If the warning light comes on again, please contact *compliant concept AG* (→ **16**)

If the error indication light is lit up or blinks, then the warning is according to the international standard IEC 60601-1-8 of medium priority. **This means that immediate action is necessary** in order not to put the patient in danger of acquiring a pressure injury.

7.10.3. Acoustic Alert/Alarm Off

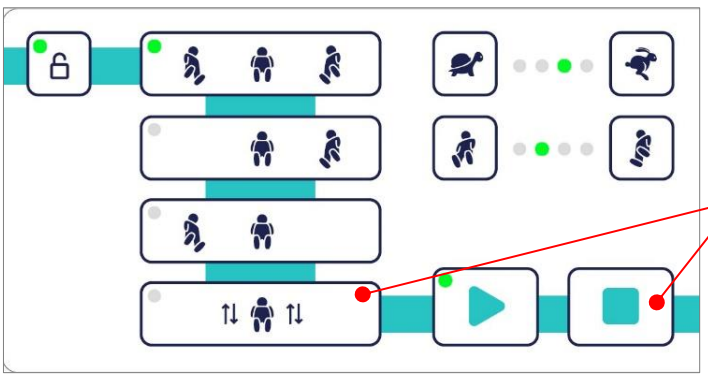
If the LED for "acoustic alarm off" is lit , no audible alarms will sound.

Acoustic alarm
on

Acoustic alarm
off

It is recommended **not to** disable the acoustic alarms.

The acoustic alarm can be switched on and off as follows.



Press both keys simultaneously for 5 seconds * until the green LED "Acoustic alarm" goes out or lights up again.

* On earlier AMS, the acoustic warning is switched on and off by pressing and holding the "key lock" button for about 4 seconds.

An acoustic alarm sounds in the following situations:

- The AMS is disconnected from electrical power while it is running.

- A technical error occurs – the Error LED is lit
- The back rest is too high (**>30° or optionally >50°**) while the AMS is on (**→7.10.1**)
- When the AMS is turned on (1 beep)
- The function of the acoustic alarm can be tested (as for reconnecting) by disconnecting from the power and reconnecting (see above)

7.10.4. Power Light

As soon as the system is connected to electrical power, the power LED lights up.
If the current is interrupted while a programme is running, the LED flashes for 30 seconds and an acoustic alarm sounds (→ **7.10.3**).

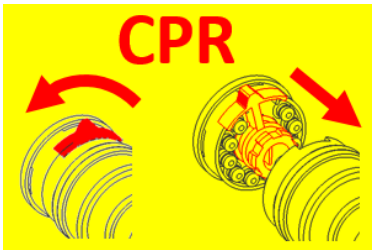
not connected to power

connected to power

7.11. CPR – Cardiopulmonary Resuscitation

In the event that a CPR (cardiopulmonary resuscitation) must be performed, the system can be brought into a level position within a matter of seconds using the following 2 steps:

1. Opening the connection → Turn the red latch completely to the left (OPEN)
2. Remove pressure connection → Pull the coupling out of the CU

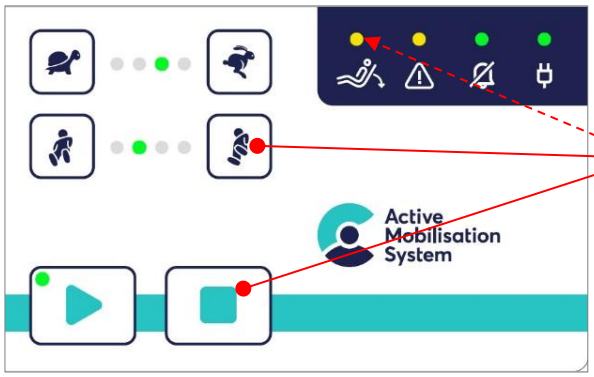


It is possible that the backrest incline sensor in the system is damaged after performing CPR with an AED (defibrillator) and an error is displayed. In this case, please contact *compliant concept AG* → **16.**

7.12. Special functions

7.12.1. Deactivation of back rest incline sensor

The following key combination can be used to deactivate the back rest incline sensor.



Press both keys simultaneously for 5 seconds until the LED "back rest incline" lights up continuously.

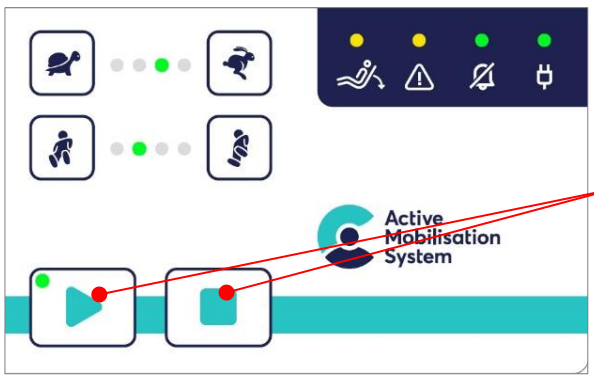
If the backrest incline sensor lights up continuously this means that the sensor has been deactivated. To reactivate the sensor, repeat the button combination or disconnect the AMS from the power.

⚠	The sensor should normally not be deactivated!
⚠	If the incline sensor is deactivated the AMS will not stop automatically due to the backrest being raised too steeply! If the AMS is run with a steep back rest a patient with little muscle tension could be tipped out of the bed. In addition, increased shear forces may have a negative impact on the skin condition i.e., increased risk for pressure injury.
⚠	If the incline sensor is deactivated no warning (neither acoustic nor visual will be given when the back rest is raised higher than 30° (or optionally >50°).

7.12.2. Test mode

A test of the pneumatic circuits can be started using the following button combination. During the test 2 of the programme lights will blink simultaneously. The test lasts about **5 minutes**. Once the test is completed the last chosen programme setting will be automatically started.

⚠ **Important!** During the test mode the AMS must be unoccupied!



Press and hold both keys for 5 seconds until the LEDs of two programme selection buttons flash simultaneously.

If the error indicator LED lights up during or after the test, then the AMS should be checked by *compliant concept AG* or an authorised Partner. If the error indicator does not light up, then the system passed the test and can continue to be used.

8. Cleaning Instructions

8.1. Responsibilities

Two separate use cases are distinguished for cleaning and disinfection of the AMS:

- Use in a hospital or nursing home: see chapter → **8**
- Use in private homes. All instructions for this case are found in chapter → **9**

For cleaning and disinfection of the AMS in private households, see chapter → **9**

8.2. Instruction for cleaning and disinfection

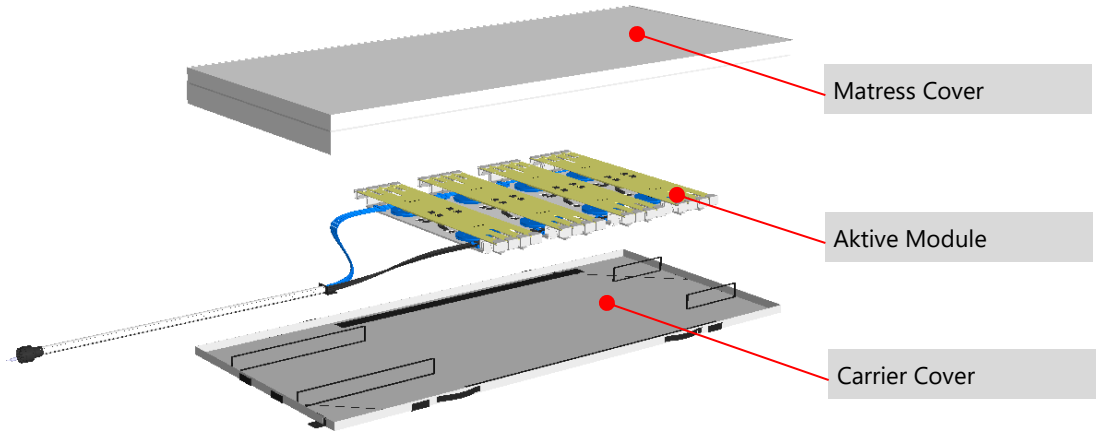
We strongly recommend cleaning and disinfecting the system at least after each patient change.

The surfaces of the AMS can be destroyed by improper cleaning or disinfectant agents.

The manufacturer instructions for the disinfectants must always be observed.

Unplug the power cord before you begin cleaning and disinfecting the unit!

Never let liquids get into the Control Unit. Before re-using, all parts of the system must be completely dry.



8.3. Approved disinfectants

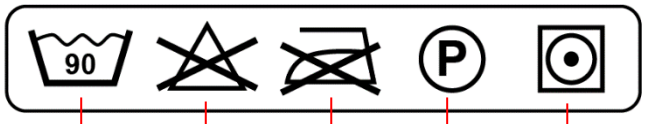
The following cleaning and disinfectant agents have been tested and approved by *compliant concept AG*. A more extensive document on this subject can be found on our website → **16**.

Manufacturer	Products	Products
Ecolab	Incidin® OxyFoam S / OxyWipe S	Incidin® Pro
	Incidin® Rapid	Sani Cloth® Active
Hartmann	Dismozon® plus	
Schülke	mikrozid® sensitive liquid / wipes	mikrozid® universal liquid / wipes
	perform®	terralin® protect

8.4. Mattress cover

The mattress cover is resistant to cleaning at boiling temperature, dryer safe, dry-cleanable and can be steam sterilized* (* = not recommended for private households)

Always keep the mattress cover as clean as possible and regularly clean it by wiping with disinfectant.



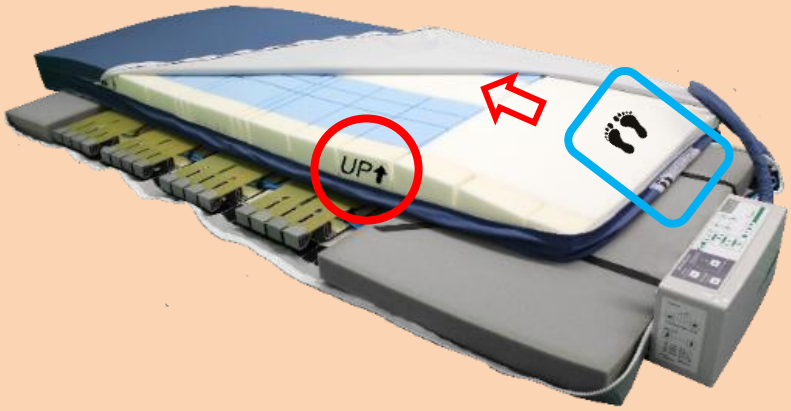
Drying in a clothes dryer possible, low temperature (60 °C)

Professional Dry-cleaning with Perchloroethylene, Hydrocarbon, regular process

Do not iron

Do not iron

Regular laundry cycle up to 90°C



Be careful to ensure that after cleaning the mattress should put back in the cover/sheath with the light **middle stripe** (see arrow) facing upwards. Please also note the UP (up) markings on the side of the mattress. Also, make sure that the foot symbols on the mattress and the one on the on the label of the blue protective cover are on the same side.

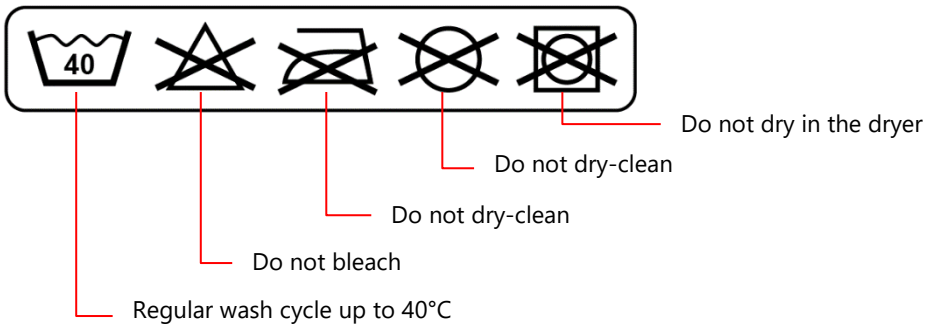
8.5. Active modules (AM) and tubing

After removing the mattress, the active base is accessible and can be disinfected by wiping with common disinfectants. Only soft cloths or sponges may be used for cleaning with common disinfectants. For heavy soiling, the active modules and the tubing/cables can be removed and cleaned.

Only authorised trained persons may disassemble the MS – moving system – for cleaning.

8.6. Carrier cover

The grey carrier cover (base of the mattress system) can be washed at 40 ° C:



8.7. Control Unit (CU)

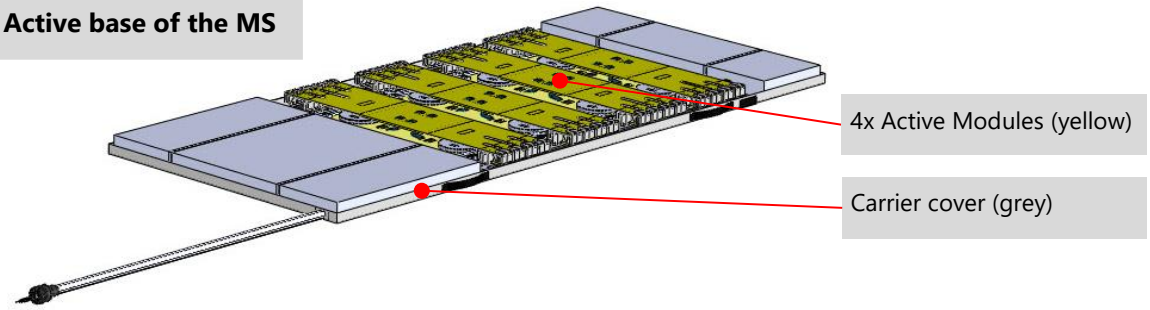
Wipe the control unit with a damp cloth, use conventional cleaning agents. If necessary, it can also be disinfected with a disinfectant.

9. Cleaning and Disinfecting for Private Households

9.1. Please note

Only technically trained persons should disassemble for cleaning purposes the active base of the MS (Moving System), that contains the moving mechanism (Active Modules, sensors, pneumatic pipes, and carrier cover.

Active base of the MS



Unplug the power supply before beginning with the cleaning and disinfection of the device!

The manufacturer's specification for cleaning and disinfection agents should always be followed

Do not let liquids ingress into the control unit (CU).

All parts of the system should be completely dry before reusing.

9.2. Cleaning of surfaces

Apart from the agents listed in chapter → **8.3** the following may also be used for daily cleaning of surfaces:

- mild soap suds
- mild acetic cleaner
- commercially available window cleaning agent (Ajax etc)
- allrounder cleaning agent (Meister Proper etc.)

Ensure that the cloth used for cleaning **is not dripping.**

These agents are for cleaning purposes and not suitable for disinfection. → **8.3**.

9.3. Disinfecting of surfaces

For disinfecting the surfaces, in addition to those listed in chapter → **8.3**, the following agents may also be used:

- Alcohol-based disinfectants (Ethanol, Propanol, Isopropanol)

Ensure that the cloth used for disinfecting **does not drip**.

9.4. Cleaning and disinfecting the mattress cover

Please see chapters → **8.4**, → **9.2**, → **9.3** for cleaning and disinfecting the blue mattress cover. In order to remove the mattress cover for cleaning in a washing machine, open the correct zip over the whole length.

9.5. Cleaning and disinfecting the mattress

The foam mattress can as needed be wiped with a microfiber cloth that has been steeped in disinfectant spray, but not dripping. After a minimum drying time of 10 minutes, it can then be replaced on the MS. If necessary, the foam mattress can be cleaned with a cleaning cloth covered with mild soap, though not dripping. Afterwards the mattress should be left open to dry for at least 30 minutes. If you remove the mattress from the MS for cleaning or disinfecting, please take care on reintroducing the mattress, that the arrow (**UP**↑) placed on the side of the mattress points upwards and that the tapered foot end of the mattress should be at the end where the piping connection is. Also, make sure that the foot symbol 👣 on the mattress and the one on the on the label of the blue protective cover are on the same side. Further information can be found in chapter → **8.4**.

9.6. Cleaning and disinfecting the Active Modules and the piping/cables

Please consult also chapter → **8.5** for the cleaning and disinfection of the Active Modules, the pneumatic piping and the electrical components.

The Active Modules, pneumatic piping and the electrical components should only be removed and correctly replaced **by authorised technically trained persons**.

9.7. Cleaning and disinfecting the carrier cover

Please consult also chapter → **8.6** for the cleaning and disinfection of the carrier cover.

All elements mounted on the carrier cover (Active Modules, piping, electrical components) may only be removed and replaced by **authorised technically trained persons**.

9.8. Cleaning and disinfecting the Control Unit (CU)

Please consult also chapter → **8.7** for the cleaning and disinfection of the Control Unit.

9.9. Recommissioning the AMS

Following use for a patient in a private household the AMS in question must be reconditioned by a partner that has been authorised by *compliant concept AG* before it can be used for another patient. The following instructions should be followed:

1. Everything that was supplied in the protective carrying cover or in the box should be disinfected: Control Unit (CU), Mobilisation System (MS), laminated user manual, the protective carrying bag inside and outside.
2. Packaging material and non-laminated user information delivered from the last patient, should be disposed of.
3. The protective carrying bag in which the AMS was carried, should be cleaned with a disinfectant spray and microfiber cloth.
4. The AMS is removed from the protective carrying bag and checked for visual soiling. If no soiling is visible, continue to **step 9**.

5. In the case of soiling (discoloured etc.) the mattress cover should be removed from the mattress and submitted for reconditioning (laundry).
6. The interior mechanisms (Active Modules, piping and cables, foams etc. should be sprayed generously with disinfectant spray and wiped down with a fresh microfiber cloth.
7. The mattress is wiped down on both sides with a soaked microfiber cloth and replaced back on the MS (after 10 minutes drying).
8. After drying the foam mattress should be introduced into a fresh mattress cover and re-joined with the lower part of the MS.

9. The AMS should be wiped down all over with a fresh microfiber cloth and disinfectant spray.

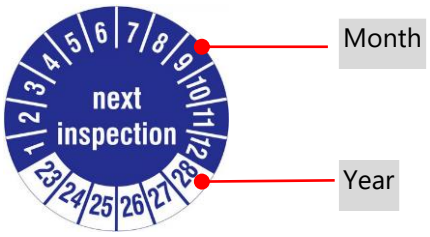
10. Control Unit (CU) power cable and the laminated user manuals should be wiped down with disinfectant.
11. Clean the inside of the protective carrying bag with disinfectant spray and a microfiber cloth.
12. Once all parts are completely dry reintroduce them into the protective carrying bag.
13. Transfer for repairs or maintenance where necessary or for storage ready for the next use.

10. Servicing and Maintenance

10.1. Servicing

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 operation time on the pneumatic pumps is checked during maintenance and replaced at the specified intervals. Note the sticker on your device.

The device must be serviced once a year. The operator is responsible for proper execution of the servicing procedure.
The device must only be serviced by *compliant concept AG* or an authorized service partner.



Please contact *compliant concept AG* to arrange servicing → **16**.

10.2. Storage

For storage of the AMS the following conditions must be met:

- Store the mattress flat without rolling, folding or similar.
- Store the MS and the CU in the protective and transport bag supplied.
  If this is not possible, connect the CU with the MS to prevent dirt from getting into the system.
- The AMS may not be stored at more than 60° C and higher than 75% relative humidity.
- Do not store the AMS for more than 8 months without connecting to electricity (the internal battery for operating data can otherwise be completely discharged)

10.3. Replacement parts

The following parts can be ordered as standard spare parts from compliant concept:

Item number	Description	Comments
B-000063	Power cable	2-pole, 5 m long
P-000010	Foot-end foam	
P-000011	Head-end foam	
P-000015.4	Foam mattress	It is recommended to change out the mattress at least every 5 years
P-000108	Carrier cover	Base of the AMS
P-000112	Mattress cover	
P-000048	Protective carrying bag	

If other components are defective, please contact *compliant concept AG* → **16**.

11. Errors and Troubleshooting

Description of Error	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 and into the outlet. Please check if it works plugged in to a different outlet (maybe there is no power at the outlet).
The **keys** do not respond	The keys are not unlocked.	Unlock the keys → **7.4**
The **error light** is permanently lit	There is an error in the system	Turn off the system by unplugging the power cord. Wait until all LEDs have turned off. Make sure that all connections are plugged in properly (→**4.2**) Turn the system on again (plug in the power cable) If the warning light comes on again, please contact compliant concept AG (→ **16**)
+  The LED of the **"Play key" flashes** together with the **"Back Rest Incline"-LED**	AMS is running while the backrest is elevated >30° (or optionally >50°)	Once the back is lowered to below 30° (or optionally >50°), the AMS will begin its movements again → **7.10.1.** The LED "Back Rest Incline" turns off. The "Start button" light is on continuously.
 **No acoustical signal** is audible despite an error	The acoustical signal is deactivated	Reactivate the acoustical signal → **7.10.3**

If the problem could not be resolved, please contact our support department. → **16**

12. Technical Specifications

	CU - Control Unit	MS - Moving System
Model	21x.xx.xxxx	22x.xx.xxxx
Operating voltage	100-240V/50-60Hz	5 Volt DC
Max. power	1.1 A	50 mA
Electrical power	120 W	---
Operating pressure	Up to 320 mbar	Up to 320 mbar
Max. pressure	650 mbar	650 mbar
Ingress Protection	IP33	IPX2
Size	350×150×150 mm	2000×900×170 mm
Weight	3.0 kg	22 kg
Volume	27 dBA	---
Patient weight	---	40 to 150 kg
Patient height	---	from 146 cm
Back rest incline	---	Standard max. 30° Optional max. 50°
Lateral inclination	---	20°
Operating temperature	5...35 °C	
Storage Temperature	-20...60 °C	
Relative Humidity	up to 75%	
Classification	Class I	Application part Type B
Complies with	CE MDR 2017/745	EN 60601-1 EN 60601-1-2

Item	Material	Characteristics
Mattress foam	Core (blue): Select 4339 Insert (white): Visco 5043 Edge area (white): Base 5672	RG 43 kg/m^3: compressive strength: 3.9 kPa RG 50 kg/m^{3}Compressive strength: 4.3 kPa RG 56 kg/m^{3}Compressive strength: 7.2 kPa All foams used are free of CFC, HCFC and formaldehydes. Burning rate of all foams used: <100 mm/min.
Mattress cover medilind	Textile base: 100% Polyester Moisture barrier: 100% PU	Bi-elastic special knitwear, adaptable, soft, skin-friendly, waterproof, bacteria-proof, boil-proof (hot water to 90°C), dryer safe, dry-cleaning safe, steam sterilisable Resistant to blood, urine, oils, greases, and disinfectants Flame retardant according to BS 6807 crib 5

12.1. Emission

Guidelines and MANUFACTURER's declaration - ELECTROMAGNETIC RELEASE		
The AMS is intended for use in the electromagnetic environment specified below. The customer or the user of the AMS should ensure that it is used in such an environment.		
Emission measurements	**Fulfilment**	**Electromagnetic environment - guidelines**
RF emissions according to CISPR 11	Group 1	The AMS uses RF energy only for its internal FUNCTION. Therefore, its RF emissions are very low, and it is unlikely that nearby electronic devices will be interfered with.
RF emissions according to CISPR 11	Class B	The AMS is intended for the use in all facilities, including living areas, and such that are connected directly to a PUBLIC POWER SUPPLY that also supplies buildings used for domestic purposes.
Harmonic Oscillations according to IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker according to IEC 61000-3-3	Met	

Guidelines and MANUFACTURER's declaration - ELECTROMAGNETIC INTERFERENCE Immunity			
The AMS is designed for operation in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user of the AMS should ensure that it is used in such an environment,			
Immunity Checks	**IEC 60601 Test level**	**Fulfilment Level**	**Electromagnetic Environment – Guidelines**
Discharge of static electricity (ESD) According to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient Electrical Disturbances / bursts According to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and Output line	± 2 kV for power lines ± 1 kV for input and Output line	The quality of the supplied voltage should be that of a typical commercial or hospital environment.

Surges According to IEC 61000-4-5	± 1 kV Voltage external conductor – external conductor ± 2 kV Voltage external conductor – grounding	± 1 kV Voltage external conductor – external conductor ± 2 kV Voltage external conductor – grounding	The quality of the supplied voltage should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and fluctuations in the supply voltage According to IEC 61000-4-11	<5% U_T for ½ period (> 95% dip 40% U_T for 5 periods (60% dip) 70% U_T for 25 periods (30% dip) <5% U_T for 5 s (> 95% dip)	<5% U_T for ½ period (> 95% dip 40% U_T for 5 periods (60% dip) 70% U_T for 25 periods (30% dip) <5% U_T for 5 s (> 95% dip)	The quality of the supplied voltage should be that of a typical commercial or hospital environment. If the user of AMS needs continued OPERATION even upon the occurrence of dis-ruptions in power supply, it is recommended that the AMS be connected to an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) According to IEC 61000-4-8	3 A/m	30 A/m	
NOTE U_T is the AC mains voltage prior to application of the test level.			

12.2. Immunity

Guidelines and MANUFACTURER's declaration - ELECTROMAGNETIC IMMUNITY			
The AMS is designed for operation in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user of the AMS should ensure that it is used in such an environment.			
Immunity Checks	**IEC 60601 Test level**	**Fulfilment Level**	**Electromagnetic Environment – Guidelines**
			Portable and mobile radio equipment should be used no closer to the AMS including cables, than the recommended safety distance, calculated according to the applicable equation for the transmission frequency.

Conducted RF disturbances According to IEC 61000-4-6	3 V 150 kHz to 80 MHz	6 V	**Recommended safety distance:** d = (0.06) $\sqrt{P}$
Radiated RF disturbances According to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	d = (0.035) $\sqrt{P}$ 80 MHz to 800 MHz d = (0.7) $\sqrt{P}$ 800 MHz to 2.5 GHz where P is the nominal line of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in meters (m). The field strength of stationary radio transmitters for all frequencies should be, in accordance with a site survey, less than the CONCORD LEVEL. In the vicinity of equipment marked with the following symbol, interference is possible. 

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

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

a. The Field strengths from fixed transmitters, such as for example, base stations of cordless telephones and mobile terrestrial radio equipment, amateur radio, AM and FM radio and TV stations, theoretically cannot be predetermined exactly. To determine the ELECTROMAGNETIC ENVIRONMENT of stationary transmitters, a study of electromagnetic phenomena of the location should be considered. If the measured field strength at the site where the AMS is used, exceeds the above CONCORD levels, the AMS should be observed to verify the intended FUNCTION. If abnormal performance is observed, additional measures may be required, such as reorienting or relocating the AMS.

b. For the frequency range of 150 kHz to 80 MHz field strength should be less than 10 V/m.

12.3. Recommended safety distances

Recommended safety distances between portable and mobile RF telecommunications equipment and the (ME device or ME system)

The AMS is designed for operation in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the AMS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AMS - dependent on the output power of the communications equipment as indicated below.

Rated Capacity of the transmitter	Safety distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 0.035\sqrt{P}$	80 MHz to 800 MHz $d = 0.06\sqrt{P}$	800 MHz to 2500 MHz $d = 0.7\sqrt{P}$
0.01 W	0.04 m	0.06 m	0.07 m
0.1 W	0.01 m	0.2 m	0.2 m
1 W	0.35 m	0.6 m	0.7 m
10 W	1.1 m	1.8 m	2.2 m
100 W	3.5 m	0.6 m	7 m

Transmitters for which a maximum rated output is not specified in the above table, the recommended safety distance *d* in meters (m) can be determined using the equation for the respective column, 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 higher frequency range applies.

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

Recommended distance between AMS and other electronic devices

The AMS has been designed and tested such that it should influence its environment electromagnetically as little as possible. The customer or user of the AMS can help to avoid electromagnetic disturbances by keeping to the minimum distance to other electronical devices of 0.3m and not placing it on top of other such devices.

13. Warranty Conditions

13.1. General information

The warranty applies to both materials and production damages of any kind that may occur during normal usage. The warranty period is 2 years.
Please contact our support team before you send the unit (→ **16**).

13.2. Scope

In the case of a defect with your device under this warranty, *compliant concept AG* guaranties the repair or replacement of the device. The decision if repair or replacement of the equipment is made by *compliant concept AG*. In that regard, *compliant concept AG* can decide at its discretion to replace the device submitted for warranty repair with an identical unit of the same quality.
No guarantee is given for wear and tear materials and consumables, 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 guarantee. For exact procedures for operating your device, please refer to this operating manual.
If it turns out during the repair, that the issue is not covered by warranty, *compliant concept AG* reserves the right to charge the customer for the costs incurred in the form of a processing fee and the fee-based service for parts and labour after a cost estimate has been provided.

13.3. Exclusion

compliant concept AG assumes no guarantee for failure and damage caused by external influences, accidental damage, improper use, changes made to the compliant concept device, conversions, extensions, use of outside parts, neglect, improper transport, improper packaging, or loss during return of the unit to *compliant concept AG*.
The warranty is void if the failure of the product is caused by service or repair, which was carried out by someone other than *compliant concept AG* or a service partner authorized by *compliant concept AG* for this device. The warranty also expires if labels or serial numbers of the device or a component of the device have been changed or made illegible.

14. Disposal Instructions

Electrical and electronic devices frequently still contain valuable materials. But they also contain harmful substances, which were necessary for their function and safety. In residual waste or handled incorrectly these can cause harm to human health and the environment. This device may not be disposed of in general commercial or household waste! The AMS, particularly the CU (Control Unit), is not permitted to be disposed of in commercial or household waste. The manufacturer takes back your used device. Please contact *compliant concept AG* → **16.**

15. Revision History

Version	Release	Change	Prepared	Reviewed	Approved
1.14.0	09.11.2018	Chapter 7.10.3: key combination for switching on and off the acoustical signal changed. CE-DOC updated to October/18. Several minor updates	oca	men	bhu
2.5.1	31.01.2022	Updated to match version 2.5.1 of the German instructions.	oca	bhu	kst
2.6.0	28.02.2023	Ch. 17 CE Declaration of Conformity updated to V1.7.0. Wettingen company address added. Title of ch. 2.6 clarified. Ch. 12 Technical data adapted. Ch. 16.1 added. New cover image. Various small details changed.	oca	oca	kst
2.8.2	31.08.2023	Ch. 2 Definition of “Purpose” clarified, Ch. 2.2 "Operating principle of the AMS" and Ch. 2.3 "Structure and essential functions" added, Ch. 4.1 Scope of delivery adapted, Ch. 4.3 and 4.4 Type plates CU and MS with Wettingen company address, Ch. 6 “Function of the AMS” enhanced with graphics, Ch. 6.1 Working principle clarified, Ch. 6.2 und 6.3 Working principle clarified and enhanced with graphics, Ch. 6.5 “Upper body and pelvic area relief during lateral position" removed. Ch. 7.10.1 and throughout the document references to option "50°" integrated, Ch 8.4 and 9.5 reference added to matching the "feet" when reinserting the mattress, Ch. 17 Declaration of Conformity updated to V1.8.0. Ch. 12 Tech specs adapted. Membrane keypad changed to new design in whole document. Various small details changed.	oca	bhu	kst

16. How to Contact Us

You have questions regarding the AMS (Active Mobilisation System)? Our support team is available to help via phone or e-mail.

Switzerland	
Telephone	+41 44 552 15 00
Phone AMS Support:	+41 44 552 15 03
E-mail:	support@compliant-concept.ch
compliant concept AG Jurastrasse 58 CH-5430 Wettingen www.compliant-concept.ch	
International	Support- and Contact Addresses Distributors https://compliant-concept.ch/de/support

16.1. Ensuring conformity in the EU

EC REP	BEO MedConsulting Berlin GmbH Helmholtzstraße 2–9 D-10587 Berlin

17. Declaration of Conformity

Compliant Concept

DOC-000011.en – 1.8.0

CE EC Declaration of Conformity

Manufacturer:

compliant concept AG
Jurastrasse 58 • 5430 Wettingen • Switzerland SRN: CH-MF-000018990

We declare under our sole responsibility that the product

Product:

Active Mobilisation System	**AMS**	(Trade name and product name)
Article Number:	A-000001	
Basic UDI-DI:	PP 12312 AMS01 41	
Product Classification:	I Medical Device	Classification rule(s) 1 & 13
Sterility Status:	non-sterile	
Measuring Function:	no	
Conformity Assessment Procedure:	Annex VIII	

to which this declaration relates, are in conformity with the requirements of the following regulations

- **Medical Devices Regulation (EU) 2017/745 and MepV**

Furthermore, the products comply with the following standards and recommendations

- **EN 60601-1**
- **EN 60601-1-2**
- **EN 62353 VDE 0751-1**
- **EN 12182**
- **EN 597-1**
- **EN 597-2**

Intended Use of the Product:

The AMS is a hybrid, dynamic mattress that combines continuous lateral positioning with additional intermittent pressure relief to support the prevention and treatment of pressure ulcers.

European Representative:

EC REP
BEO MedConsulting Berlin GmbH
Helmholtzstraße 2–9
D-10587 Berlin

SRN: DE-AR-000006764

compliant concept AG, Wettingen, 19.06.2023

Stéphane Kaus
Head of Research and Development

Orazio Castelletto
Tech Product Manager

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