ekamove®

Adjustable 30° lateral positioning

Instructions for use





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2 Contents of delivery



1 x base unit comprising:

Control unit with clamping unit

Mains cable

1 SD card (2 GB) for data storage

1 x air chamber system

Air chamber with connecting hoses

Protective sleeve

Sensors with supply line

2 x stabilisation plates for sensors

- 1 x instructions for use
- 1 x brief instructions for use and brief installation instructions
- 1X packing material
- 1 x carrying bag for transport and storage

3 General

3.1 Explanation of symbols



Plus key for selection

with programme key depressed => next programme with angle key depressed => angle value is increased with time key depressed => time value is increased



Minus key for selection

with programme key depressed => previous programme with angle key depressed => angle value is decreased with time key depressed => time value is decreased



Programme key for selecting the positioning programme

(Only in combination with Plus or Minus key)



Start key for starting the system

(In programming mode for confirming values)



Stop key for stopping the system

(In programming mode for exiting the programming mode)



Angle key for selecting the positioning angle

(Only in combination with Plus or Minus key)



Time key for selecting the positioning time



Emergency relief

Identifies the emergency relief coupling



Identification for hose connection right



Identification for hose connection left

3.2 Notes on using the installation instructions and instructions for use

These operating instructions provide important information on handling the **ekamove** system. Observing all the specified safety information and handling instructions is a prerequisite for safe handling of the apparatus.

In addition, the local accident prevention regulations and general safety requirements are to be observed, which apply in the area of use of the apparatus.

Attention!

Meticulously read the instructions prior to commencing any work.

These operating instructions form part of the product and must be kept in the direct vicinity of the apparatus for the personnel / operator and be accessible at any time.

If the apparatus is handed over/sold, the operating instructions are to be included.

Images in these instructions - to illustrate the details - are not necessarily to scale and may slightly deviate from the actual apparatus design.

3.3 Guarantee, warranty and liability rules

In these operating instructions, all specifications and information are compiled with consideration of valid standards and regulations and state-of-the-art technology.

ekamed GmbH & Co. KG provides a guarantee of 24 months from the date of invoice in the case of proper handling of the apparatus. During this period, the apparatus and accessories may be repaired or replaced free of charge due to material or manufacturing faults.

ekamed GmbH & Co. KG shall not assume any liability for damages due to:

- 1. Failure to comply with the operating instructions
- 2. Improper use
- Unauthorised alteration
- 4. Technical modifications
- 5. Use of unapproved spare parts

The warranty is based on legal provisions and directives.

If any work or interventions are carried out on the apparatus or its accessories by the client or by third parties without the prior approval of ekamed GmbH & Co. KG, the warranty lapses.

For medical products within the scope of EU Directives 93/42/EEC which have to be regularly maintained or conditioned, the warranty only applies if the prescribed maintenance intervals are observed.

If claims are made on the warranty and if, after checking where applicable, it should turn out that these are based on signs of wear or other forms of damage not covered by the warranty, ekamed GmbH & Co. KG is entitled to pass any expenses incurred (testing,

transport costs and similar) on to the client.

3.4 Safety

This section provides an overview of all important safety aspects for optimum protection of the user and third parties, as well as for the safe and trouble-free operation.

The apparatus is used at home and in the care sector (commercial area). In the commercial area, the operator of the apparatus is subject to legal obligations for occupational safety.

In addition to the occupational safety instructions in these instructions, the field of application of the apparatus must adhere to valid safety, accident prevention and environmental regulations. The following apply in particular:

- The operator must clearly regulate and specify the responsibilities for operation, maintenance and cleaning.
- The operator must make sure that all staff who handle the apparatus have read the operating instructions and understood them.

Moreover, the operator is responsible for ensuring that the apparatus is in proper technical condition at all times. The following thus applies:

- The operator must make sure that the maintenance intervals described in the instructions for use are adhered to.
- The operator must make sure that only approved accessories are used in connection with the apparatus.

Warning: It is not permitted to modify the ME apparatus

Attention: In order to prevent the risk of an electric shock, this apparatus must only be connected to a power supply network with a protective conductor.

Do not use the ekamove system without safety sides.

Do not install the apparatus in the immediate vicinity of sources of interference such as microwaves or strongly emitting devices. To ensure electromagnetic compatibility, the apparatus is only to be connected to a power supply network with protective conductor.

The location of the apparatus and the routing of the power line should be selected so that accidental disconnection from the supply network is excluded. The mains cable is designed in such a way that it does not become jammed or squashed. It should be laid in such a way that it does not pose a trip hazard.

Even in oxygen enriched environments the risk of fire hazard is largely decresed, due to hardly inflammable Materials of the housing.

Attention: No smoking!

Attention: Should you wish to perform a test, the apparatus must be installed properly in a nursing bed with a suitable mattress. If not installed properly with a mattress, it may result in malfunctions.

4 Combining with other devices

The ekamove comes with an SD card that records all patient movement data. ekamove® can be used in normal operation with a PC or laptop for data storage of the positioning systems. For this purpose, a software programme from ekamed GmbH & Co. KG

can optionally be purchased. Standard commercial SD cards (2 GB) can be used for storage.

Using the ekamove system with an alternating pressure mattress

The ekamove can be used with an alternating pressure mattress under certain conditions.

In doing so, the measured angle of the lateral rotation cannot be precisely determined. This means: if 30° is set, the actual angle may deviate. The sensors must rotate/tilt so that the incline can be determined.

Prior to using an alternating pressure mattress, an **individual onsite risk assessment** must take place.

5 Indication and contraindication

5.1 Indication

ekamove® is suitable for the prevention of decubitus ulcers (prophylaxis) for patients / residents who are at risk of developing decubitus ulcers or as an auxiliary decubitus therapy for patients / residents who are already suffering from existing decubitus ulcers up to and including stage 3 (EPUAP). The system is designed for patients with a body weight of up to 300 kg. In exceptional cases the system can also be used for higher stage decubitus ulcers.

However, it is essential that a healthcare professional should be consulted for this and his approval is necessary.

The ekamove ® is suitable and recommended for:

- pre-existing decubitus ulcers (up to and including stage III EPUAP)
- people with a moderate to high risk of decubitus ulcers (as per Braden)
- people whose disability or illness means that they must spend long periods lying down
- people who cannot change their position when lying down themselves
- o people who have suffered a stroke with partial paralysis
- people with paraplegia who want to change the position in which they are lying with the use of their arms.

5.2 Contraindication

The product should not be used with:

- unstable fractures
- severe burn injuries
- equilibrium disturbances
- underlying neurological diseases which lead to anxiety behaviour in patients.

Claims of any kind for damages resulting from incorrect or inappropriate use are excluded. ekamove ® is an aid for the avoidance of decubitus ulcers and an auxiliary therapy for them. Even when using ekamove® the skin should also be regularly examined by the person himself – where possible – or by carers and/or qualified clinicians for pressure points. If no improvement occurs in the condition, a specialist clinician should be consulted.

Attention! Claims of any type for damages resulting from use other than for intended purpose are excluded. The operator shall be liable for damages associated with inappropriate use.

6 Accident and damage reports

Malfunctions or breakdowns in the apparatus which have caused personal injury must be notified without delay to the competent authority and ekamed GmbH & Co. KG.

Comment!

The competent authority may demand that the operator, at his own cost, have the notified incident assessed by an expert and submit the assessment in writing. The expert is selected in agreement with the competent authority.

The technical safety assessment, must identify the following:

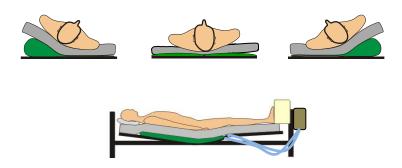
- cause of notified incident
- condition of the equipment
- the existence of any further risk.
- whether new knowledge has been gained which requires other or additional precautions

7 Operation

ekamove is a lateral positioning system which can be individually adjusted to the needs of the person or patient requiring care. The positioning is done gently with low noise. The system takes approx. 7 - 14 minutes for a partial position change. The system is based on an air chamber system which laterally lifts the person lying on it via a soft foam mattress and thus puts the reclined person into the desired lateral position.

The air chamber system is operated via the control unit. A pair of sensors on the air chamber system send a feedback signal to the control unit when the inclined position is reached.

The system can also be operated without sensors (manual mode). In manual mode (without sensors) the inclination is determined by the filling time.



7.1 Benefits at a glance

- ✓ Extensive pressure relief
- ✓ Complete healing of existing decubitus
- ✓ No disturbance at night
- ✓ Low noise level
- ✓ Lifts patients weighting up 300 KG
- Complete orientation as the patient always lies with his back on the soft orthopaedic mattress
- ✓ Gentle positioning for patients/residents in pain
- ✓ Flexible programming for patient specific care
- ✓ Care tracking via in-built SD card
- ✓ Sensor-monitored positioning change
- ✓ Improved micro-climate and circulation
- ✓ Robust, durable, reliable

Can be integrated into any nursing bed with saftey sides.

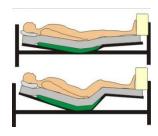
The system supports the elevated position of the healthcare bed in the head and foot parts. However, attention must be paid here to the correct position and attitude of the patient. This will depend on body shape and clinical picture. In case of doubts or questions, please ask the treating doctor or the specialist healthcare professional.

In the head-up position it is essential to make sure that the patient is prevented from falling forwards. Depending on body shape, a head support should be used as appropriately.

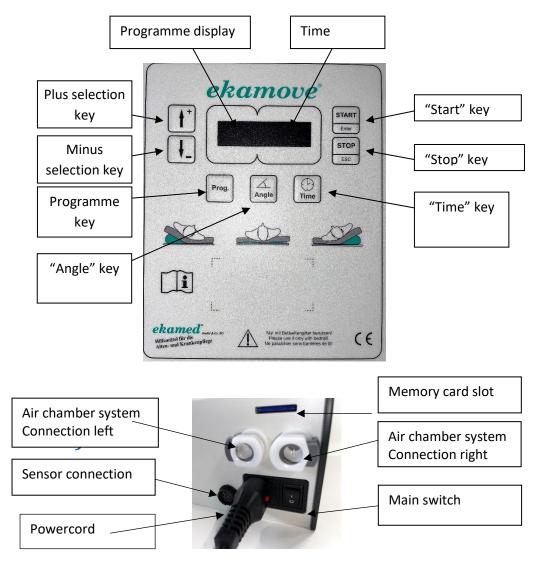
The system will emit an error code if the head-up position is too sheer. The error code disappears once the head-up position is reduced. This function can be deactivated, if required. To do so, contact your service partner or ekamed GmbH & Co.KG

Attention!

This option is only offered as a support; the maximum possible level of the head-up position must be checked and if necessary limited by the care personnel.



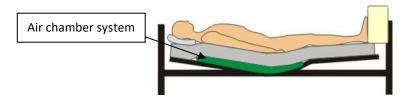
8 Operating overview



9 Installation

9.1 Installing the air chamber system

The air chamber system is installed between the bed frame and the soft orthopaedic mattress.



When doing this, attention must be paid to the correct positioning of the two air chambers. The system has a top side, which can be recognised by the "wings" of the individual air chambers. These must face the mattress. The top of the sensors can be recognised by the label (L, R) which is positioned under the protective cover. In doing so, the sensor with 2 cable outputs is to be positioned on the right patient shoulder.

The height of the assembly should be arranged so that the air chamber system starts about 5 cm above the shoulders of the person receiving care. Please be sure to check first how tall the person lying in the bed is!

When the installation height has been determined, the air chamber system is fixed to the slatted frame/bed frame using the fixing straps provided for this. In doing so, the fixing is to be selected in such a way that the function of the nursing bed is not impaired.



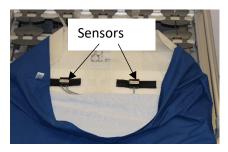
The lateral adjustment must be done centrally to the bed. Accordingly, the hose system is fixed in the bottom part of the bed, also with the fixing straps, to the slatted frame/bed frame and the supply hoses are run through the bed frame and under the foot of the bed.

The sensor line is to be run with the supply hoses under the foot of the bed.

It is important that the supply lines and the sensor line are not pinched or crushed. This should be checked with the bed functions and secured.

Before the mattress is laid on the air chamber system, the correct position of the air chamber system and its fixing should be checked once again. The position of the two sensors is also to be checked. You can see the correct position from the illustration. It is important here that the sensors are fixed firmly and at right angles to the guide arms.

The distance between the sensors must be the distance between the shoulder blades of the person lying on the bed. If necessary, adjust the distance between the sensors. Depending on the bed frame, in order for the sensors to have a firm basis, the stabilisation plates (already fixed to the air chambers) should be checked to make sure that they are correctly seated.



In the case of the mattress, it is important that this is the right size for the healthcare bed. In order to guarantee problem-free functioning of the lateral positioning system, the mattress should be able to be easily lifted from the side and not pinched by any guide rails that may be there. If the mattress is too wide, this may affect the function. Also the mattress should be produced in a high quality soft foam in order to guarantee stability of form for the mattress itself.

9.2 Installing the control unit

The control unit has a variable fixing system and can thus be fixed to any bed (preferably at the foot).

To do this, undo both of the knurled head screws and open up the fixing area so that you can push this over the foot of the bed.

If the opening is not wide enough, contact ekamed GmbH & Co.KG. or a company authorised by them.

Now press down the fixing bracket and screw down both knurled head screws tightly by hand. The apparatus should now be fixed

firmly to the bed. Please note that there is a piece of factory foam rubber between the bed and the apparatus. Please do not remove this.



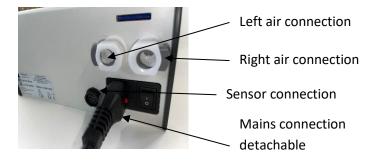


9.3 Connecting the air chamber, sensor and control unit

The connection of the air chamber is established by means of quick-fitting couplings. To do this, please plug the hose of the air chamber system marked with an R to the right-hand connection on the apparatus. Then plug the hose of the air chamber system marked with an L to the left-hand connection on the apparatus. In both cases you will hear a clear click when the coupling is in place.

The sensor is to be plugged into the socket in the base of the control unit. The plug only fits in the direction of the apparatus socket, and may need turning in order to align correctly. Now tighten the wrap. (Bayonet lock)

Please lay the cable in such a way that there is no risk of an accident or an unintentional removal.



9.4 Connection with the mains supply

The supplied mains cable with plug is connected to the contoll unit at the buttom. The plug now locked in place. To disconnect the mains cable from the control unit, press down the small red lever (on the side of the plug). The plug can be pulled out again by pressing and pulling at the same time the red lever. Lay the power

line so that it does not present any risk. Also the power line should not be damaged or pinched in any way. The power plug is connected to the mains socket (Attention: only use mains sockets with corresponding protective conductors)

The ekamove® is now ready for operation!

10 Commissioning

10.1 Switching on

The ekamove® system is switched on by activating the main switch (switch set to 1) On the base of the control unit.

The word ekamove® appears in the display and the deflation of the air chamber system begins (lasts about 5 minutes). The word "Empty" appears in the display. If the air chamber system has already been completely deflated, you can end this process by pressing the "Stop" key twice.

Now follows an automatic calibration of the sensors (whereby the sensors are adjusted). The display then changes to the last positioning programme or, in case of initial installation, to the programme set in the factory.

After switching on at the main switch, it is essential to wait **20** seconds before switching the apparatus back on.

If the ekamove is switched on and the note "!!!Service!!!" appears on the display, this means the service interval for the the product has been reached. Please inform your technican or supplier to request a service. This can be cleared from the display by pressing the STOP key, normal use can then resume.

10.2 Setting the date/time

The date and time have already been set in the factory. However, if it is necessary to change the date/time, please proceed as follows:

By holding down the "Time" key and pressing the "Prog" key once, you enter the setting mode for the date and time. The left display (program display window) shows a "D" (D=day) and the right display half shows the set day. This value can now be changed by pressing and holding the "Prog" key and operating the "Plus" or "Minus" key. When the correct day is set, the "Prog" key is released.

The next value can now be selected by pressing the "Plus" or "Minus" key. An "M" (M-month) appears in the display on the left and the month set in the right-hand side of the display. This value can be altered in the same way as for setting the day.

This process applies for the following parameters

D Day M Month Y Year

F Format (12 h or 24 h)

HH Hours MM Minute

The setting mode for date/time is ended by pressing the "STOP" key. The time set is used for logging the position changes carried out. Please note, there is no automatic switch to daylight saving time. This must be changed manually by the operator, if necessary.

10.2.1 Calling up the date and time

By keeping the "Time" key depressed, first the date (e.g. 29.03.2010) and then the time (e.g. 14:24 or 2:24 PM) is displayed

as running text in the display. This only happens in the "ready" condition.

Therefore not in running positioning operation.

10.3 Calibrating the sensors

Your system is equipped with position sensors. Calibration of the sensors is necessary after the basic parameters have been entered. This happens automatically when you switch on, after about 5 minutes.

For any recalibration which may be necessary, the bed is to be put in a horizontal position, where both head and foot sections must also be put into the horizontal position. Check that the sensors are in the correct position (see installation of air chamber system)

By holding down the "Angle" key, the current angle of the sensors is shown in the display. Keeping the "Angle" key depressed, activate the "Prog" key. "Cal.S" now appears in the display.

The sensors are now calibrated.

Important!

Calibration is always necessary if the bed is changed or the installation position of the system is altered. It is possible that calibration may need to be carried out if the person lying on the bed is repositioned.

10.4 Factory settings

When the system is delivered, the following positioning programme has been set in the factory:

Positioning programme: LR

Position time per

partial positioning stage: 20 minutes

Lateral position:

Angle mode 20°

Manual mode 6 minutes filling time (without sensors)

11 Normal operation

11.1 Starting the system

The system is started by pressing the "START" key (approx. 3 seconds). If air is still in the air chambers upon starting, the system starts deflating before the actual positioning begins. "Empty" appears on the display. The programme previously selected and set up now begins to position the person requiring care into the first partial positioning stage. In the left-hand display, the positioning stage is shown in blinking mode (L= left; R= right; N= back) and the current angle appears in the right-hand display. On systems without angle sensors, "+" appears. Depending on the parameters set, the programme takes about 6 minutes. When the selected position is reached, the pre-set positioning time appears in the right-hand display and the positioning stage (L= left; R= right; N= back) continues to blink in the left-hand display. The positioning time is shown as a "countdown" so it is possible for you to check the progress of each positioning stage.

When the positioning time has elapsed for the partial positioning stage, the changeover to the next partial positioning stage begins. To do this, the filled air chamber is now emptied in a controlled way. This is again shown in the display with the positioning stage blinking in the left-hand display and a "-" in the right-hand display.

When the next positioning stage is achieved, the representation in the display begins for this positioning stage, as described above. This means that the progress of positioning is shown on the system at all times.

The programme selected will carry out the positioning stages set continuously and the person in bed will be repositioned continuously.

11.2 Care key

By keeping the Time key depressed for approximately 2 seconds, you can put the system into care mode. In this case the person on the bed will be put into the supine position and the sensors are deactivated. The system requires 8 minutes for this. During this time, no modifications can be made (abort care function). With the care function, you can provide care for the person lying down. You are given 30 minutes time for this. If this time is not sufficient, by pressing the Time key again you can get a further 30 minutes care time. If care is completed before the allocated 30 minutes have elapsed, you can press the "Stop" key to put the system back into positioning mode. The system carries on at the point of the positioning programme where it was interrupted. In other words, repeat loading on one side of the body is avoided.

When the care time has expired, a warning signal sounds. In this way, the system tells you to stop care mode by pressing the "STOP" key and return to positioning mode.

Please note that the system does not start automatically after the care time has elapsed; instead you must put the system back into positioning mode by pressing the "STOP" key.

11.3 Calling up the values set

While the system is operating, the corresponding values for the positioning time and positioning angle can be displayed by pressing the "Time" or "Angle" key. This means that you can have the set values displayed on a change of shift or an inspection round.

11.4 Stopping the system

By holding down the "STOP" key (for at least 3 seconds) the programme is stopped. "EMPTY" appears in the display. The person requiring care is put into the N (= back) or supine position. Depending on the position state, this takes the system up to 7 minutes. At the end of the "Stop" function, "WAIT" appears in the display and the display changes to the programme set.

12 Selecting the positioning programme

The following programmes can be selected:

Programme	Description
L-N-R	Positioning between left (L), back (N) and right (R) sides (default setting)
	right (R) sides (default setting)
L-R	Positioning between left (L) and right (R)
	sides
L-N	Positioning between left (L) and back (N) sides
R-N	Positioning between right (R) and back (N) sides
L-N-R P5	Freely programmable programme

L= Left position

R = Right position

N = Neutral position (back)

Programme selection is done by pressing and holding the programming key ("PROG") and activating the "Plus" or "Minus" selection keys. The respective programme appears in the programme display window.

13 Selecting the positioning angle

System with sensor:

The positioning angle is selected by pressing and holding the "Angle key" and activating the "Plus" or "Minus" selection keys. The set positioning angle appears in the angle and time display window. The setting range is 5 - 30° and can be adjusted in 1° increments.

The positioning angle is the same for each side (right or left). Depending on local conditions, there may be discrepancies between the positioning angle selected and the angle achieved. The angle displayed is the angle on the underside of the soft orthopaedic mattress in the area of the shoulders of the person receiving care.

It is only possible to select another angle for each positioning side by using the freely programmable programme (P5).

For more details, refer to the "Freely programmable programme" section. (Page 32)

System without sensor (sensor not inserted on apparatus):

In this case, the angle is controlled via the filling time.

The filling time can be set to between 1 and 7 minutes. Here 1 minute corresponds to approx. 5°, which means that 6 minutes equals about 30°.

This is adjusted by pressing and holding the "Angle" key while simultaneously activating the "Plus" or "Minus" key.

Attention: When starting the system you should check that there is no air in the air chamber system. If there is any air remaining in the chamber system, this can be emptied by holding down the Stop key.

14 Selecting the positioning time

The positioning time is selected by pressing and holding the "Time"-key and activating the "Plus" (+) or "Minus" (-) selection keys. The positioning time set is displayed in minutes in the angle and time display window. Time setting is done in 10 minutes increments and is limited to max. 120 minutes per partial positioning. The shortest positioning time for a partial positioning stage is 10 minutes.

The positioning time is the same for all partial positioning stages in the programme selected and begins when each position is reached!

It is only possible to select another positioning time for each positioning side by using the freely programmable programme P5. For more details, refer to the "Freely programmable programme" section. (Page 32)

15 Freely programmable programme

With ekamove® you have the option of specific patient care using the freely programmable programme. To do this, the "L-NR P5" programme can be adjusted individually for each partial positioning stage. For example, you can select a different angle for each side position. Also the positioning time can be adjusted separately for each partial positioning stage. So, for example, if you have a person requiring care who has decubitus ulcers on the right trochanter and in the region of the coccyx and you want to protect these affected parts of the body, then you can programme the following setting, for example.

Left side 30° with a positioning time of 2 hours, supine position 30 minutes and right side 10° and 20 minutes.

In order to enter the individual settings for the relevant partial positioning stage, you should select the "L-N-R P5" programme. If you hold down the "Prog" key, the left-hand display side starts to flash the L.

On systems with sensors, press and hold the "Angle" key and the angle display will appear in the right-hand display side. You can now change this to the required value by activating the "Plus" (+) or "Minus" (-) keys. The value adjusted will be adopted immediately.

Attention: When starting the system you should check that there is no air in the air chamber system. If there is any air remaining in the chamber system, this can be emptied by holding down the STOP key.

In manual mode, you can set the filling time for this side. The filling time can be set to between 1 and 7 minutes. Here 1 minute corresponds to approx. 5°, which means that 6 minutes equals about 30°.

This is adjusted by pressing and holding the "Angle" key while simultaneously activating the "Plus" or "Minus" key.

You can now make the setting for the desired positioning time for this partial positioning stage.

Press and hold the "Time" key; the positioning time is displayed in the right-hand side of the display. You can now alter this by keeping the "Time" key depressed and activating the "Plus" (+)or "Minus" (-) key.

The value set will be adopted automatically when you release the "Time" key.

Once you have set the values for the left partial positioning stage, by pressing the "Prog" key you will go to the next partial positioning stage (in this case "N" for the supine position). You should proceed in the same way as for setting the left side, except that you do not select any angle here.

Now follow the same steps for the right partial positioning stage and programming is complete.

It is also possible to deselect a partial positioning stage. The "deselection" of a partial positioning stage can be done by selecting the positioning stage and pressing the "Plus" or "Minus" key. The partial positioning stage you have deselected will be represented by an X.

To leave the programming mode press the "STOP" key.

Now you can start the programme you have entered by pressing the "START" key and the positioning stages will now be executed.

The "P5" programme set up will be maintained until the system is reprogrammed!

16 Leg extension

If you have purchased an ekamove with leg extension, the system parameters need to be adjusted according to the service instructions. This should be done by a service technician.

17 Documentation

The system includes a continuous documentation function. All position changes and programme modifications are electronically saved with date, time and positioning stage.

Storage and data exchange is done by means of an SD card.

There is a separate, optional software programme available for your PC for evaluating the data. This enables you to produce positioning documentation which, together with the documentation on bedsores, will help optimise the positioning required.

18 CPR function

If a medical emergency should arise, rapid deflation can be effected. To do this, please press the grey release button for the quick couplings in the bottom of the control unit with one hand and, with the other hand, pull out the filling hoses for the air chamber system from the coupling. By releasing this connection, the air chambers will now quickly deflate and the person on the bed will be put in a horizontal position. To empty the air chambers even faster you can apply pressure on the mattress.

Before the system can be put back into operation, any programme still running should be stopped by pressing the "STOP" key. After connecting the filling hoses of the air chamber system the system can be started again normally. (Please make sure that the air chambers are completely deflated.)

19 Cleaning/Disinfiction

Cleaning

The system should be cleaned when necessary. Please observe the following points:

Before cleaning, switch off the base unit and disconnect it from the power supply.

The base unit must not be submerged under running water or in water for cleaning. (Attention danger to life !!)

The cleaning should generally be done with a suitable cleaning liquid (e.g. soap suds) and a suitable cleaning cloth or sponge. After cleaning, all components must be dried with a soft cloth.

The air chamber system should be cleaned with the utmost care and attention.

The protective cover can be easily removed from the air chamber system and washed at 95° in the washing machine.

Under no circumstances should the air chamber system be cleaned with sharp or pointed objects.

After cleaning, all components must be checked for proper condition. In case of cracks or squeezing in the supply lines, they must be replaced by a specialist authorized by ekamed GmbH & Co.KG.

Disinfection

After cleaning, the components of the system can be disinfected with a commercial wipe disinfection (preferably chlorine-free). If disinfectants containing chlorine are used, however, the color of the housing may change.

During disinfection, the instructions of the disinfectant manufacturer must be followed. If these are not followed, the disinfection is ineffective.

The air chamber system can also be cleaned with a commercially available wipe disinfection or a wipe disinfection offered by ekamed

If a patient is changed or used again, thorough cleaning with proper disinfection is required.

The system should also be reset to factory settings afterwards (before reuse). If you have any questions, please contact your authorized dealer or Ekamed itself.

20 Maintenance

The system should be inspected every 2 years by a specialist authorised by ekamed GmbH & Co. KG.

The operator is responsible for complying with the prescribed maintenance requirements.

An electrical inspection as prescribed by the law is to be carried out by the relevant operator at the legally required intervals; this is the responsibility of the operator alone.

21 Disposal

Disposal is done <u>exclusively</u> by ekamed GmbH & Co. KG or an authorised partner. This will ensure that disposal is done correctly and in an environmentally friendly way and that all resources are protected.

22 Malfunctions / error messages

If an error occurs, an acoustic signal will sound for max. 5 minutes. The alarm can be shut off by pressing the "STOP" key. The error will be displayed by means of an error code.

The error code can be deleted by switching the system off and on again.

Please note that you must wait **20 seconds** between switching on and off again.

If the power supply is interrupted during operation, the system also goes into error mode.

If the apparatus cannot be switched on, please check the power supply.

However, if the power is connected and the apparatus can still not be switched on, contact the authorised ekamed specialist or notify this problem directly to ekamed GmbH & Co. KG.

If the system is only pumping on one side, please check that the supply lines are properly located and functioning. The supply lines must not be pinched or crushed. If this is the case, eliminate this problem and start the system again. If the problem persists after restarting, restore the system to the state in which it was delivered.

To do this, switch the system off (main switch on the bottom), then hold down the "START" and "Plus" keys and switch the system on. The "-INIT-" message appears on the display. The system is back to the as delivered state

Fault display	Meaning	Possible causes	
ERR SL	Sensor left faulty	Plug pulled out during operation	
		Line damaged	
		Sensor left (L) defective	
ERR SR	Sensor right faulty	Sensor right (R) defective	
NO card	No memory card	SD card not inserted properly	
ERR TIME	Supine position not achieved within 10 minutes after stop of the system.	 Hose defective Air chamber defective Pump defective Hose pinched 	
POW off	Power supply interrupted	Mains failure on the object side	
ERR XPOS	Inclined position not achieved or not change in time.	 Hose defective Air chamber defective Pump defective Hose pinched 	
BackRst	Head end set too steeply	Adjust the head of the bed to be flatter.	

MEM< 5%	Memory on the SD- Card not enough	Renew the SD-Card
!!!!Service!!!!	Overdue maintenance	Inform technician, press "STOP" key
err offs or err poso	If a bladder is not empty or the sensor is tilt this error will appear	You have to check this, and when all is o.k. you can accept by pressing the enter key A additional question will appear, which you can accept by pressing the enter key again Finally you can switch off the system and start again to empting the air chambers

23 Warning messages

If the corresponding angle or position is not achieved within 10 minutes, an acoustic warning message is output and the apparatus goes into error mode (see Malfunctions/Error messages). Before starting the programme again you should calibrate the sensors. (see section on Calibrating the sensors)

If, during operation, the apparatus should be disconnected from the power supply or if there is a power failure, an acoustic warning message is output for approx. 5 minutes.

The warning message can be shut off by pressing the "STOP" key.

You will then need to restart the apparatus! ekamove Rev. 7 instructions for use Dated: 11/2021

24 Technical data

<u>Dimensions</u> (LxWxH)

Base unit 21 cm x 12 cm x 31 cm

Area of air chamber 110 cm x 80 cm

Weight

Base unit 2.8 kg
Air chambers incl. hoses 1.5 kg

Electrical values

Operating voltage 240 V

Frequency 50 Hz/60 Hz Power max. 18 W

Classification protection class II

Fuse (in the apparatus) M3A, 230 V micro fuse

Patient positioning

Positioning angle 5° to 30° (depending on body

shape) ±3°

The precision of the angle display depends on various factors (the properties of the bed and the mattress; correct positioning of the sensors).

Positioning times 10 minutes to 120 minutes per

partial positioning stage ±15

seconds

Contact and moisture protection

Housing and sensors IP 33

Storage conditions

Temperature range -10° to 50° Celsius

Relative air humidity 0% to 95 % no condensation

Operating conditions

Apparatus Is designed for continuous

operation

Temperature range 0° to 40° Celsius

Relative air humidity 20 % to 95 % no condensation

<u>Internal power supply for the warning system in case of power failure</u>

2 no-maintenance batteries type AA 1.2V 1900 mA

25 EMC compatibility

2 Tables concerning safe use of medical electrical apparatus - INFORMATION Please refer to English text of EN 60601-1-2

2.1 General data 2.1.1 Table 201

3	Emission	agreement	
4	RF- emissions following EN 55011	group 1	+
6	RF- emissions following EN 55011	class B	_
7	Generation of mains harmonics following IEC 61000-3-2	class A	_
8	Generation of voltage fluctuations/ flicker following IEC 61000-3-3	none	

2.1.2 Table 202

Susceptibility	IEC 60601-test level	Actual level	
ESD IEC 61000-4-2	+/-6kV cd	+/-6kV cd	
	+/-8kV ad	+/-8kV ad	
Bursts	+/-2kV mains	+/-2kV mains	
IEC 61000-4-4	+/-1kV I/O	+/-1kV I/O	
Surges	+/-1kV dm	+/-1kV dm	
IEC 61000-4-5	+/-2kV cm	+/-2kV cm	
Voltage drops etc	Reduction to	Reduction to	
	5 % for 10 ms/ positive amplitude	5 % for 10 ms/ positivee amplitude	
IEC 61000-4-11	5 % for10 ms/ negative amplitude	5 % for10 ms/ negativee amplitude	
	40 % for100 ms	40 % for100 ms	
	30 % for500 ms	30 % for500 ms	
	0 % for5000 ms	0 % for5000 ms	
H- field at 50/ 60 Hz IEC 61000-4-8	3 A/m	3 A/m	

2.2 NON life- supporting systems 2.2.1 Table 204

Susceptibility	IEC 60601-test level	Actual level	**
Conducted rf IEC 61000-4-6	3Veff 150 kHz to 80 MHz	3 V	
Radiated rf IEC 61000-4-3	3Veff 80 MHz to 2,5 GHz	3 V/m	

2.2.2 Table 206;

Output power of transmitter	f Safety distance depending on frequency/ m			
W	150 kHz to 80 MHz	80 MHz to 800MHz	800 MHz to 2,5 GHz	
0,01	0,12 m	0,12 m	0,24 m	
0,1	0,37 m	0,37 m	0,74 m	
1	1,17 m	1,17 m	2,34 m	
10	3,69 m	3,69 m	7,38 m	
100	11,67 m	11,67 m	23,34	

26 Standards

DIN IEC 60 601-1
DIN IEC 60 601-1-2
Medical product law / directive 93/42/EEC

27 Contact

ekamed Distributor UK



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We are certified according to DIN EN ISO 13485 :2016

