saniflow® p

Anti-decubitus alternating pressure system

Instructions for use

Translation of the original instructions for use

Date: 2022-01-19 | Version 01

MD

"Certified quality management system for the development, production and distribution of patient positioning and transport equipment and accessories"

Zertifiziertes QM System

DIN EN ISO 13485

CE aks

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Version history

Version	Date	Change
01	2022-01-19	Adaptations to Regulation (EU) 2017/745

1 Introduction

Dear customer,

Thank you for choosing an aks GmbH product. We appreciate your vote of confidence.

Read the instructions for use in full before using the product for the first time and before each reuse, in order to avoid damage or risks due to misuse. The instructions contain important information and notes that are necessary for proper use of the product.

If you have queries, particularly regarding the safety instructions, please contact your authorised dealer. Do not use the product until all matters have been clarified. This is to prevent injuries and damage due to incorrect use.

Keep these instructions for use within reach of the user and include them with the product if it passes to another owner.

We reserve the right to make changes and amendments. The text and illustrations may therefore not fully match the delivered product.

If you have any difficulty reading these instructions for use (e.g. due to the font size), you can always download the current version of these instructions for use as a PDF document from the aks website[1]. Open the PDF document and adjust the display on your screen according to your needs.

Using the product means a better quality of life for the patient and makes work easier for the user.

This product is not permitted for use in the **United States of America** or **Canada**. The distribution and use of the product in these countries, including any distribution or use by third parties, is prohibited by the manufacturer.

1 You can find the latest version of the instructions for use in the download area on the aks website.

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The **saniflow® p anti-decubitus alternating pressure system** (also referred to in the following as the product/products) consists of a pump unit and an alternating pressure mattress. It has been developed for decubitus prophylaxis.

Among other things, the product features the following:

- Mattress overlay system
- Individual pressure regulation according to the special characteristics of the patient
- Cycle time: 6 minutes
- Can be combined with commercially available foam mattresses
- Suitable for a mattress width of 90 cm

We hope the product fulfils your expectations and wish you every success in caring for your patients.

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1.1 Explanation of the symbols used

For ease of reading, these instructions for use employ the following symbols to indicate important information:

	**Warning of danger** Indicates safety instructions that must be observed under all circumstances in order to avoid an immediate danger to life and limb (risk of serious or fatal injury).
	**Warning of dangerous electrical voltage** Indicates safety instructions that must be observed in order to avoid danger through electrical voltage that may result in serious or fatal injury.
	**Keep dry** Keep away from spray water and do not use high-pressure jet cleaners.
	**Safety notice** Indicates information concerning safe use of and safe work on the product.
	**Information** Indicates useful and important instructions and information.

In these instructions for use, the following symbols, amongst others, are used to label medical devices:

	Observe instructions for use
LOT	Production batch number, batch
REF	Article number
SN	Serial number
SIZE	Dimensions of the product

For more information on labelling, please refer to the chapter on **Product labelling**.

2 Intended use

The products are active Class I medical devices according to Regulation (EU) 2017/745, Appendix VIII.

The products are suitable for domestic use as well as for use in inpatient[1] facilities. The products are intended for use by a trained caregiver (user). The products are only suitable for use in dry, indoor areas.

See the chapter on **Technical data** for the permitted patient weight and the climatic conditions.

The products are suitable for reuse (see chapter on **Reuse**). Intended use further includes reading and observing these instructions for use as well as performing the inspections and maintenance tasks in accordance with the maintenance schedule (see the chapter on **Maintenance**).

2.1 Intended purpose

The intended purpose of the products is sleeping/resting. To this end, they are placed on a care bed or a "standard bed" (see chapter **Commissioning**). As a mattress overlay system, the products may only be used in combination with a standard foam mattress or with a mattress underlay (minimum height 10 cm).

The products are used to prevent decubitus ulcers. With regard to decubitus prophylaxis, the products are suitable up to patients with a low risk of decubitus.

The products may only be used for decubitus prophylaxis.

Read and observe the instructions for use. Only use the products in accordance with the intended purpose as described. Any other use is prohibited.

The products are intended for long-term use under normal conditions (see chapter **Technical data**).

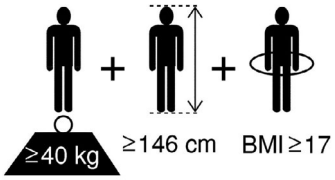
2.2 Indication

The products are intended for patients who, due to an illness, injury, disability or their age, are required to lie for long periods.

1 Use in semi-residential facilities (e.g. day/night care) is therefore also covered.

2.3 Contraindication

In combination with a care bed (EN 60601-2-52), the products are only suitable for adult patients with a body weight of at least 40 kg, a height of at least 146 cm, and a body mass index[2] (BMI) equal to or higher than 17.



Potential further **contraindications** include, for example, acute multiple traumas, unstable bone fractures, unstable spinal injuries or other spinal diseases. The products must also not be used for patients with sensory disorders.

2.4 Side effects

Please note that anti-decubitus alternating pressure systems can potentially promote or trigger spasticity. The use in these cases must be individually decided by the attending doctor.

2 Body mass index is a measurement of a person's outline based on their individual body weight and height:

$$BMI = \frac{Weight\ (in\ kg)}{Size\ x\ size\ (in\ m)}$$

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3 Safety instructions

The safety instructions apply to all and any persons who perform work in any way with or on the product (incl. accessories). Where a specific group is addressed, this does not exclude any other persons.

Read and observe the safety instructions. The safety instructions comprise text or a combination of a symbol with text. The symbols used are not substitutes for the text for the safety instructions. Read the text of the safety instructions and follow it precisely.

3.1 Explanation of the groups referred to

The operator is the person who is in possession of the medical device, i.e. any natural or legal entity whose employees operate/use the medical device. The operator does not necessarily need to be the proprietor of the medical device (e.g. medical supply store, authorised dealer, health insurer). The operator bears principal responsibility for the organisational measures and for ensuring compliance with national regulations.

The user must be trained in the safe handling of the medical devices described in these instructions for use (incl. accessories) prior to their first use and every reuse. **It is the duty of the operator (e.g. the responsible medical supply store/authorised dealer) to ensure that the user receives the proper training.**

If the medical device is to be used by relatives of the patient who are responsible for the patient's care[1], the operator must inform said relatives of the circumstances in which they should ask a health care professional for advice, e.g.:

- if they observe any health problems in the patient that are associated with the product (incl. accessories),
- if they are unsure regarding a potential use of the product (incl. accessories).

In Germany, the EU Medical Devices Adaptation Act (MPEUAnpG) applies, and in particular the Medical Devices Implementation Act (MPDG) and the Medical Devices Operator Ordinance (MPBetreibV) contained in Article 1. The corresponding national laws, regulations and requirements are applicable in other countries.

Qualified personnel are persons who, through their training and practical activities, possess the required specialist knowledge and means to properly maintain [assemble, perform commissioning, maintain, inspect, repair, treat (clean/disinfect) and dispose of] medical devices – those defined in these instructions for use – (incl. accessories) and who are capable of performing and documenting the required tasks within the necessary scope.

Qualified electricians as defined in the German accident prevention regulations DGUV Specification 3; persons who, through their specialist training, skills and knowledge as well as through knowledge of the valid regulations, are capable of performing the assigned work and assessing potential hazards.

The qualified electrician must further be trained in handling medical devices and possess knowledge of the specific product.

1 Relatives who care for the patient do **not** usually possess formal health care training.

Electrically instructed persons are persons who have been instructed and, if necessary, trained by a qualified electrician regarding their assigned tasks and the possible hazards in the event of improper behaviour, as well as regarding the necessary safety equipment and safety measures.

In the context of these instructions for use, the word **user** refers to the person who uses (operates) the medical device (incl. accessories) on the patient. The user will be taught the skills and knowledge required to do this by means of proper training provided by the operator in accordance with these instructions for use.

The user must be physically and mentally able to perform the following activities in relation to the medical devices (incl. accessories) described in these instructions for use:

- use them in accordance with their intended purpose,
- set them up in accordance with their intended purpose (e.g. carry out permissible adaptations/modifications in line with the intended use and the permissible combinations).
- in case of unusual noises or obvious damage: shut them down, mark them clearly as "Out of order" and inform the appropriate qualified personnel.

Users must be able to assess the patient's clinical condition and to take specific action to protect the patient from danger. If relatives take over responsibility for the patient's care, these relatives must be in a position to consult a health care professional when in doubt.

Prior to each use of the medical devices (incl. accessories) described in these instructions for use, the user must ensure that the products are in good condition and full working order, and observe the instructions for use.

In these instructions for use, the term **patient** is used to refer to a person who requires care due to their illness, injuries, disability or age.

For the sake of better legibility, only the male form (he/his) is used in the texts. The female form is of course always implicit in such use.

3.2 General safety instructions

Training is required in the proper handling of the product (incl. accessories). The training must be documented in an appropriate form. The training must be conducted on the product itself in accordance with the instructions for use, and must observe all the contents of said instructions for use.

Please note the minimum and maximum permitted patient weight (see chapter on **Technical data**). Undershooting or exceeding the permitted patient weight increases the risk of decubitus that is always present when the product is used. The product may only be used on adult patients when combined with a care bed (EN 60601-2-52). Failure to comply means that safe operation can no longer be guaranteed.

Do not use a damaged or heavily worn product/accessories. Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

In addition to the periodic checking by suitable qualified personnel, check that the product and its accessories are in a safe state before each use (see chapter on Maintenance, section **Maintenance schedule: Inspection by the user**). Do not continue to use the product (incl. accessories) if unusual noises or damage have occurred. If you have any doubts about the safety of the product or the accessories, do not use them. Mark the product/accessories clearly as “Out of order” and inform your authorised dealer immediately.

Observe the specifications regarding cleaning/disinfecting (see the chapter on **Cleaning/disinfecting).**

When cleaning/disinfecting the product, note that the individual components could be infectious or contaminated. Take suitable precautions for your own safety. Use suitable packaging/labelling to ensure that the product/accessories can be transported without any risks to third parties.

Keep the product (incl. accessories) away from direct sunlight. Protect the product from intense heat (e.g. heating, stoves) **or open flames** (e.g. fireplace, cigarette ember, candle) **and other heat effects** (e.g. from electric blankets). It is not flame retardant. There is a risk of fire. This also applies when drying.

Note that smoking in bed (due to embers) **increases the risk of fire.**

Protect the product (incl. accessories) from pointed and sharp-edged objects and surfaces (this also includes the claws and teeth of pets). There is a risk of damage!

Check the suitability of the product (incl. accessories) for the patient at regular intervals (e.g. in case of physical changes [amputation] or weight gain/loss). In doing so, take account of the special characteristics of the patient. Evaluate the existing decubitus ulcers using appropriate means. Ensure that professional assessment in the form of a risk analysis is ensured, so that the correct size and version of the anti-decubitus alternating pressure system are used for the patient. Match the functional characteristics of the anti-decubitus alternating pressure system to the specific disabilities and functional limitations of the respective patient. Potential contraindications must be observed in this regard.

Use the product in line with its intended purpose only and always observe the instructions for use.

When using the product in a care bed with side rails, check the height of the side rail above the top of the mattress. It must measure at least 220 mm. If the distance is less than 220 mm, use a suitable side rail height extender.

Never operate the pump unit in a closed compartment (e.g. drawer) and do not cover it during operation. There is a risk of overheating.

Explain any potential risks to the patient and brief them to ensure that their behaviour does not generate any additional risks. There is a higher risk for unsupervised persons lying in a care bed / standard bed who are also mentally deranged or extremely fragile. Strictly comply with the safety instructions specified here in order to minimise the residual risk.

When using the product in a care bed with side rails, note the additional risk of crushing and shearing.

The patient should not come into direct contact with the alternating pressure mattress or the mattress cover. Only use the product with a suitable mattress cover for the alternating pressure mattress and a bed sheet.

Please note that no other overlays (e.g. fur) are to be used on the alternating pressure mattress (mattress cover).

Make sure that there is no foreign matter (e.g. food scraps) between the bed sheet and the patient.

For hygiene reasons, always use the product (incl. accessories) for the same patient.

Use only original aks accessories/spare parts in order to avoid danger (see the chapter on **Accessories/combinations**).

Do not leave children unsupervised in the vicinity of the product. The anti-decubitus alternating pressure system is not a toy.

If the mattress is not used for an extended period, observe the requirements for storage in the chapter **Storage**.

Faults due to the use of mobile communications devices cannot be completely ruled out. Note that possible electromagnetic or other influences between the product and other equipment cannot be ruled out. If there is a risk of reciprocal interference, remove the sources of interference sources. When using mobile communications equipment, maintain a safety distance of at least 3.3 m. This avoids any potential electromagnetic interference between the communications devices and product and guarantees safe operation of the product. – See position paper of the German Federal Institute for Drugs and Medical Devices (BfArM) (reference no.: 9/0508).

Avoid mechanical strains on the power supply line used. Pulling, kinking and driving over the power supply line can damage it. In the event of damage to the case or the power supply line, first unplug the mains plug and inform your authorised dealer immediately. The pressure in the alternating pressure mattress reduces in the period during which the system is not supplied with power (including in the event of a power failure). In this case, place the patient elsewhere. In the event of a brief power failure, note the information on the chapter on Operation/use, section **Power failure**.

Before moving the care bed, the pump unit must be secured against falling and the supply hoses and power supply line must be protected against being driven over. Unplug the mains plug from the mains socket (see chapter on Operation/use, section **Patient transport**).

Protect the pump unit against the ingress of liquids. There is a risk of a short-circuit and/or electric shock.

The product's electrical components have been tested by an external, independent test institute to ensure the safety of the product. Nevertheless, hazards may arise in case of unintended use.

If you experience any serious incidents[2] involving the product (incl. accessories), please contact aks GmbH and the relevant national authorities without delay.

3.3 Safety instructions for the operator

Prior to initial use and every reuse, train the user on the product itself (incl. accessories) on the basis of the instructions for use, explain the safety instructions, test the effectiveness of the training, and properly document said training. Make the user aware of the hazards that may arise in case of unintended use of the product (incl. accessories).

The product is not EX-protected and must not be operated in potentially explosive areas. It must not be operated in the vicinity of flammable, narcotic mixtures of air, oxygen or nitrogen oxides.

The product does not have any equipotential bonding and is therefore not suitable for medical electrical applications.

You as the operator must ensure (e.g. by means of corresponding instructions and precautions) that no mechanical loads are applied to the power line during use (e.g. kinking, shearing, driving over the lines with the product itself or with equipment trolleys, loads during room cleaning etc.).

Make sure that the electrical installation of the room/area in which the product is connected and operated complies with the state of the art.

2 "Serious incident" means any incident (involving the product (or its accessories) that directly or indirectly led, might have led or might lead to any of the following: (the death of a patient, user or other person, or the temporary or permanent serious deterioration of a patient's, user's or other person's state of health).

Only allow suitable qualified personnel to perform the commissioning, maintenance, treatment (cleaning/disinfecting) and repair of the product (incl. accessories).

Make sure that the user is physically and mentally able to perform the following activities in relation to the medical devices (incl. accessories) described in these instructions for use:

- use them in accordance with their intended purpose,
- set them up in accordance with their intended purpose (e.g. carry out permissible adaptations/modifications in line with the intended use and the permissible combinations),
- in case of obvious damage, unusual noises and malfunctions: shut them down, mark them clearly as “Out of order” and inform the appropriate qualified personnel.

Inform the user that, in addition to the periodic checking by suitable qualified personnel, the user themselves must check that the product and its accessories are in a safe state before each use (see chapter on Maintenance, section **Maintenance schedule: Inspection by the user**).

Make sure that the user possesses the skills and knowledge required to check the suitability of the product (incl. accessories), to assess the patient’s clinical condition, and to take specific action to protect the patient from danger.

Observe the following measures in order to prevent fires:

- Use flame-retardant mattresses and bedsheets wherever possible.
- Instruct the user and the patient that smoking in bed is not allowed.
- Instruct the user and the patient that candles are not allowed next to the bed.
- Only use electrical devices (e.g. lamps, radios) that are in full technical working order, and ensure that their power lines are not in a position where they can be damaged by the moving parts of the care bed.
- Make sure that these devices cannot accidentally end up on or under the bedsheets (risk of heat accumulation)! Use LED lamps where possible, as these generate far less heat than conventional lamps.
- Do not connect plugs to extension lines or multiple sockets underneath the bed (risk of short-circuit/fire due to penetration by water).

If relatives take over responsibility for the patient’s care, check that these relatives are in a position to consult a health care professional when in doubt. Explain to the users when they should ask a health care professional for advice, e.g.:

- If they observe any health problems in the patient that are associated with the product/accessories.
- If they are unsure regarding a potential use of the product/accessories.

Only operate the product (incl. accessories) in accordance with the combination of pump unit and alternating pressure mattress described in these instructions for use (see chapter **Scope of delivery**). A combination with any other alternating pressure mattress and/or any other pump unit is not permitted.

When using the product, comply with all the provisions of the EU Medical Devices Adaptation Act (MPEUAnpG), and in particular the Medical Devices Implementation Act (MPDG) contained in Article 1, and all additionally applicable legal regulations as well as with the applicable work health and safety regulations, accident prevention regulations and the general provisions concerning the handling of technical devices.

Note that this product is a medical device and the Medical Devices Operator Ordinance (MPBetreibV) are binding for the operator in Germany.

The corresponding national regulations apply in other countries. For use in countries other than Germany, observe the respective applicable national laws, regulations and provisions.

3.4 Safety instructions for the user

Arrange for the operator (e.g. your responsible medical supply store/authorised dealer) to train you in the safe handling of the product (incl. accessories) using the product itself, in accordance with the instructions for use.

Only use the product (incl. accessories) if you have been instructed about its handling – including the safety instructions – and you have the corresponding expert knowledge to assess the suitability of the product (incl. accessories) for the patient. If in doubt, ask a health care professional for advice. If you have queries, particularly regarding the safety instructions, please contact the operator. Do not use the product (incl. accessories) until all matters have been clarified. This is to prevent injuries and damage due to incorrect use.

When using the medical devices (incl. accessories) described in these instructions for use, ensure regularly that the products (incl. accessories) are in good condition and full working order (see chapter on Maintenance, section **Maintenance schedule: Inspection by the user**). Observe the instructions for use.

4 Scope of delivery

The product has already been inspected at the factory to ensure completeness and freedom from defects. Nevertheless, check the product immediately after receipt for possible transport damage.

After removing all individual parts, check the completeness of the scope of delivery using the delivery note. If not all the individual parts of the scope of delivery are present, contact your authorised dealer.

The product's scope of delivery includes:

- 1 x anti-decubitus
  alternating pressure pump unit
- 1 x flow air® small-cell anti-decubitus
  alternating pressure mattress
- 1 x instructions for use

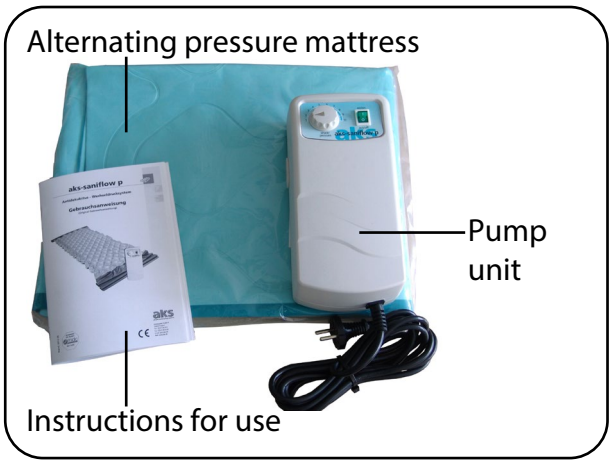

Abb. 4.01 - Lieferumfang

The saniflow® p alternating pressure mattress is 6.35 cm high and is available in the following dimensions:

SIZE		REF
W [cm]	L [cm]	
90	192	22110

5 Product overview

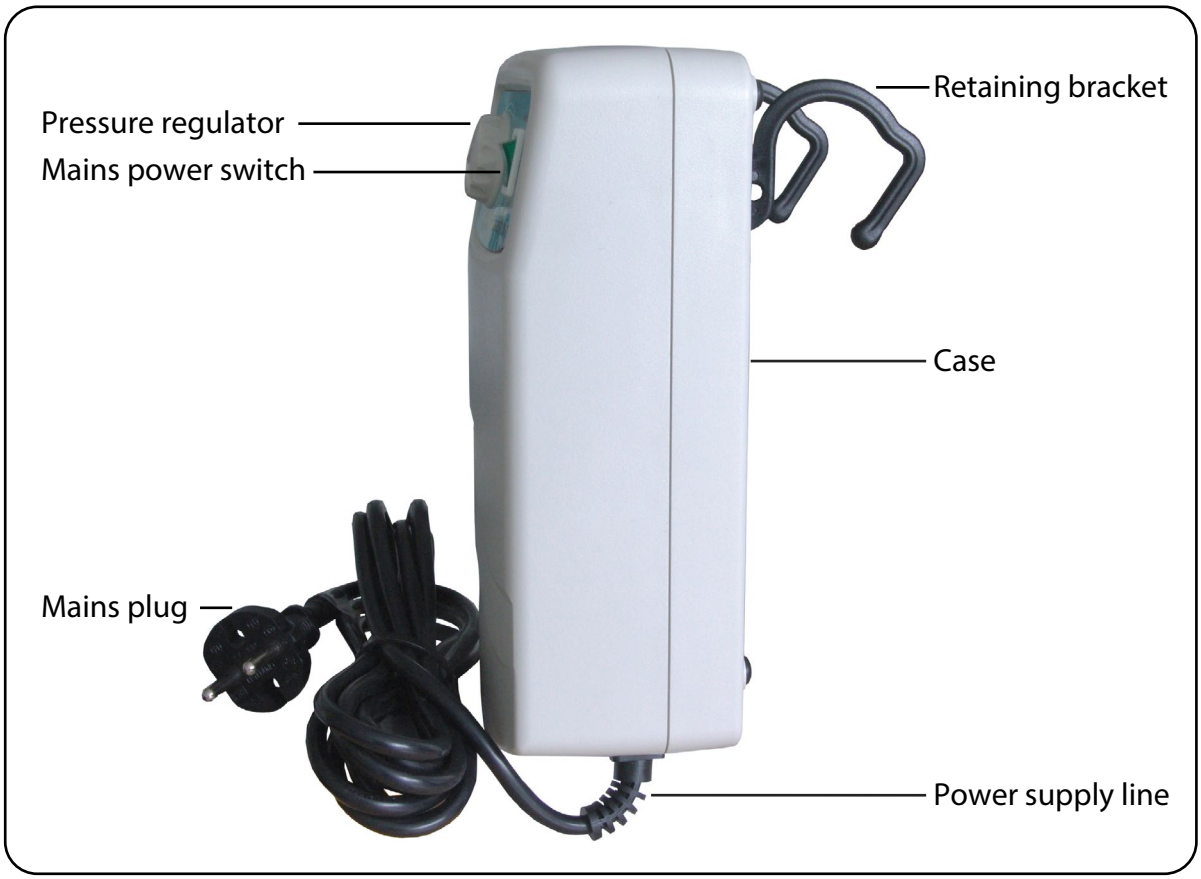

Fig. 5.01 - Side view of saniflow® p pump unit

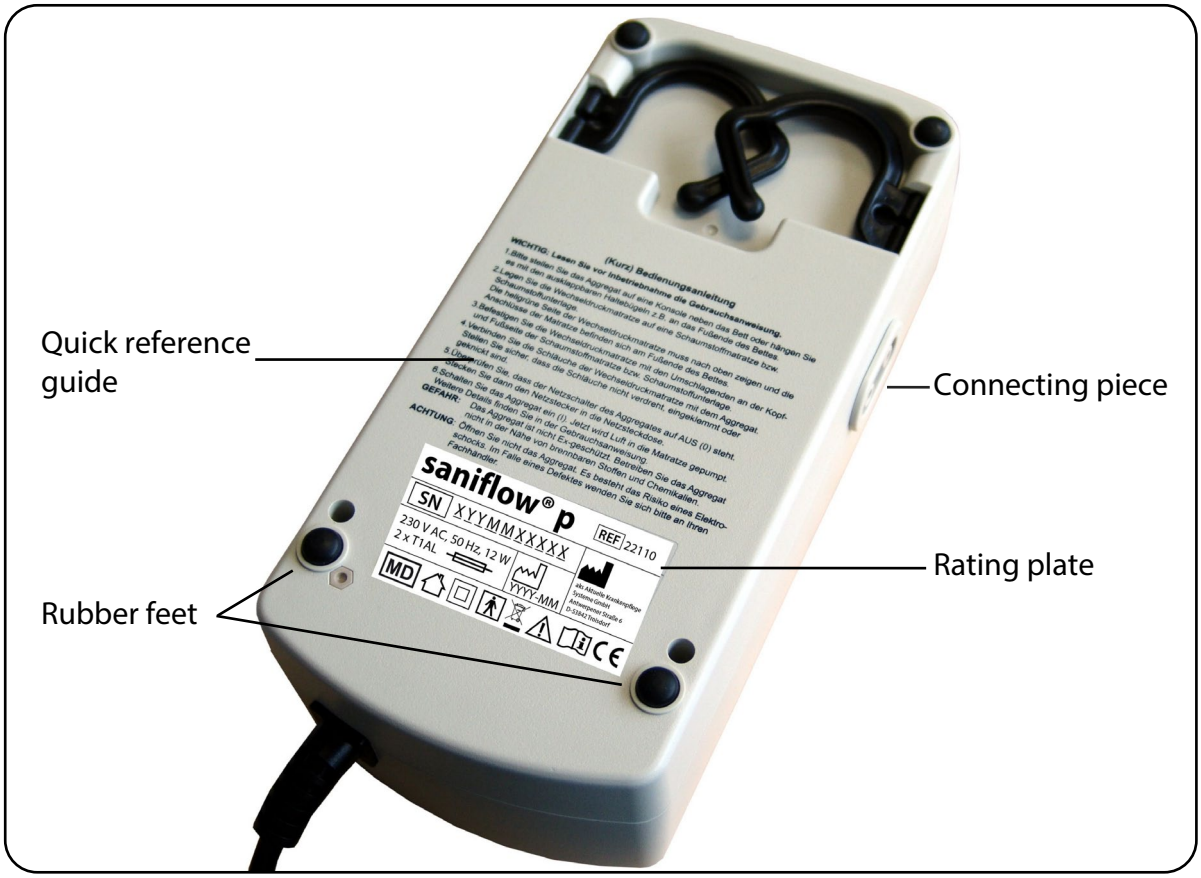

Fig. 5.02 - Rear view of saniflow® p pump unit

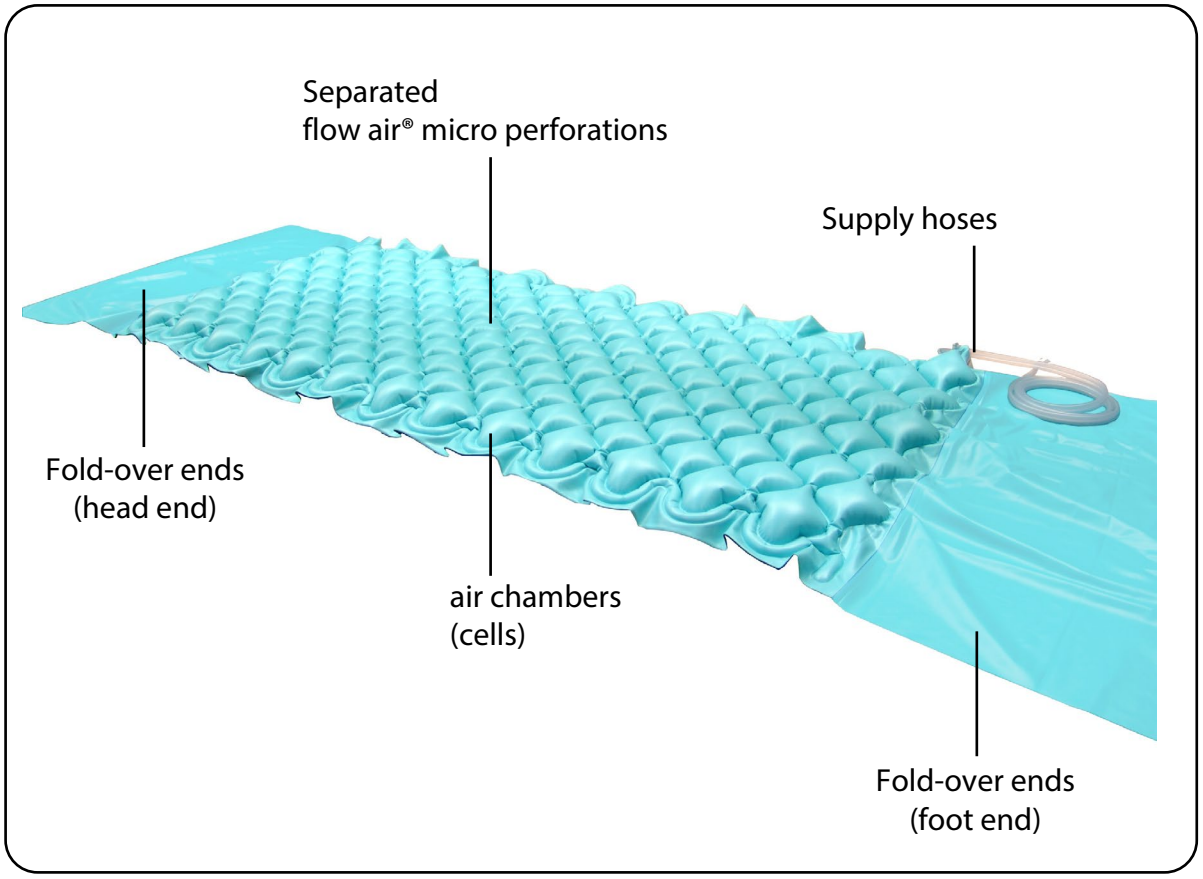

Fig. 5.03 - Small-cell alternating pressure mattress, top side

5.1 Functional description

Fig. 5.1.01 – Control panel for saniflow® p pump unit

Explanation of the controls for the pump unit		
No.	**Element**	**Function**
1	Pressure regulator	You set the optimum pressure for the patient here.
2	Mains power switch	You switch the device on and off here. If the pump unit is switched on, the green operation indicator lamp in the mains power switch lights up.

The product is a small-cell, air-filled anti-decubitus alternating pressure system with automatic regulation of the filling pressure. It functions according to the principle of intermittent relief of the support pressure for the patient and is intended for decubitus prophylaxis on the whole body. The anti-decubitus alternating pressure system is used as a mattress overlay system, i.e. a separate foam mattress with a height of at least 10 cm is required as a mattress underlay for the alternating pressure mattress in the bed.

The product consists of a pump unit and an air-filled alternating pressure mattress that are connected to each other by two supply hoses. The pump unit contains an electrically operated pump, a control valve and a synchronised air distributor which function together as a control unit. The alternating pressure mattress consists of a total of 124 air chambers (cells), divided into two air chamber circuits. Micro perforations that produce a continuous air flow (flow air®) are integrated in the reclining surface of the alternating pressure mattress.

The control unit of the pump unit inflates and deflates the two air chamber circuits of the alternating pressure mattress intermittently in a cycle of six minutes. This alternating inflation and deflation of the cells relieves pressure alternately on individual parts of the body. The alternating pressure mattress also adapts to the contours of the body, which results in a more even distribution of the body weight and a reduction of the support pressure. Due to the intermittent relief and the reduction of the support pressure, the blood circulation in the tissue areas is improved and the risk of decubitus development is reduced.

The pressure regulator on the pump unit's control panel (Fig. 5.1.01) is used to adjust the filling pressure in relation to the patient's weight, using a diagram (Fig. 8.1.01) as a guideline. The pressure can be adjusted continuously in a scale range of 1 to 10 to the individual patient's weight or current load situation. An inspection of the patient and readjustment of the filling pressure, if necessary, ensures optimum adjustment to the patient's specific characteristics (see chapter on Operation/use, section **Normal operation**).

The alternating pressure mattress is fastened to the standard foam mattress or the foam underlay by means of fold-over ends that are located at the head and foot ends of the alternating pressure mattress (Fig. 5.03).

The product is protected from soiling by a liquid-impermeable aks-inkocover stretch cover. The aks-inkocover stretch cover is available as an optional accessory (see chapter on **Accessories/ combinations**). It has an elastic strap all around its edge and it is stretched over the mattress. In the event of soiling, it can be removed and washed in a washing machine using normal household washing agents (see chapter on **Cleaning/disinfecting**).

6 Commissioning

The product (incl. accessories) was developed for use on a care bed or a “standard bed”.

Do not use a damaged or heavily worn product. Inspect the relevant product (incl. accessories) before and during set-up for damage and defects. The power supply line, the pump unit case as well as the connections and the alternating pressure mattress must not be damaged. Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

The bed must have a mattress holder or a frame construction that prevents the product from slipping out.

Ensure that the reclining surface of the bed is stable and that the external dimensions of the reclining surface are appropriate for the product. The product can be used on all adjustable or rigid slatted frames and lattice support surfaces. The reclining surface must not have any sharp edges and corners which could damage the mattress.

Please note that the anti-decubitus alternating pressure system is only optimally effective if the reclining surface is level.

If you have established that the delivery is complete based on the **Scope of delivery** chapter in this manual and that the delivery is undamaged, proceed with the commissioning as follows:

1. Check whether the reclining surface is suitable for use with the mattress. Note the safety instructions for the user (see chapter on Safety instructions, section **Safety instructions for the user**).
2. Place a commercially available standard foam mattress or a mattress underlay (minimum height 10 cm) which corresponds to the dimensions of the alternating pressure mattress on the bed’s reclining surface.
3. Remove the small-cell alternating pressure mattress from the packaging.
4. Retain the packaging for future transport or storage of the product.
5. Lay the alternating pressure mattress on the reclining surface of the standard foam mattress or mattress underlay and unfold it completely.
6. Position the alternating pressure mattress on the mattress/reclining surface of the bed so that the connections are located at the top at the foot end of the bed.
7. Fasten the alternating pressure mattress by tucking both fold-over ends at the head and foot ends (Fig. 5.03) under the standard foam mattress or the mattress underlay. Fixing the alternating pressure mattress is required in order to prevent slippage. In the case of beds with an adjustable reclining surface, all movement functions of the bed must be able to be performed without damaging the alternating pressure mattress. The supply hoses of the alternating pressure mattress must be placed so that they are not kinked, crushed or twisted.

8. Next, place a separate mattress cover on the alternating pressure mattress, e.g. aks-inkocover stretch cover (see chapter on **Fitting the aks-inkocover stretch cover to the product**) and fit a bed sheet over the mattress cover. Make sure that the sheet is fitted without creases.

9. Check the reclining surface of the alternating pressure mattress for possible pressure points caused by creases. Also make sure that the mattress is secure on the reclining surface of the bed.

10. The pump unit has a suspension attachment (two retaining brackets) and four rubber feet on the reverse (Fig. 5.02). Attach the pump unit to the foot end of the bed using the two folding retaining brackets, or place it on a flat surface next to the bed with its reverse facing down.

11. Connect both the supply hoses of the alternating pressure mattress to the connecting pieces of the pump unit (Fig. 5.02). Make sure that the supply hoses are not twisted, pinched or kinked.

12. Check that the mains power switch (green) of the pump unit is set to “off” (0). The mains power switch is located on the front of the pump unit (Fig. 5.01 and Fig. 5.1.01).

13. Connect the pump unit to the mains supply.
Connected load: see chapter on Technical data, section **Pump unit**. When connecting the pump unit, the power supply cable must be laid so that it cannot be dragged, driven over or endangered by moving parts during operation of the care bed.

Connect the mains plug directly to the mains supply. Only use mains sockets that have been installed properly and are suitable for use with the mains plug. Do not use a multiple socket. Ensure that the mains plug is always accessible so that the pump unit can be disconnected from the mains supply in an emergency.

If the product is used on a care bed with side rails, ensure that the function of the side rails is not impaired in any way.

Note the safe working load of the care bed.

6.1 Fitting the aks-inkocover stretch cover to the product

The aks-inkocover stretch cover is available as an optional accessory (see chapter on **Accessories/ combinations**). We recommend only fitting the stretch cover after the mattress has been pumped up (see chapter on Operation/use, section **Normal operation**, item 4). Note the following in this context:

- The stretch cover has to be stretched over the alternating pressure mattress and the standard foam mattress or foam underlay.
- The soft polyester side of the stretch cover is the patient’s side. This means that the seams should be on the inside of the stretch cover and the smooth PU-coated side of the stretch cover is in contact with the alternating pressure mattress.
- After it has been stretched over the mattress, the stretch cover should have a crease-free surface.

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7 First time use

Before using the product for the first time and every time it is reused, check that the product (incl. accessories) is in safe condition based on the maintenance information in the chapter on **Maintenance**. Before the product (incl. accessories) is reused, always clean and disinfect it in accordance with the instructions given in the chapter on **Cleaning/disinfecting**.

Observe the safety instructions (see chapter on **Safety instructions**).

8 Operation/use

Before and during each use of the product, note the following information:

If the product is to be used on a care bed, also read and observe the instructions for use for the care bed.

Inspect the product (incl. accessories) regularly, especially after cleaning/disinfecting (see the chapter on Maintenance, section **Maintenance schedule: Inspection by the user**).

Do not use a damaged or heavily worn product/accessories. Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

Keep the product (incl. accessories) away from intense heat or open flame. It is not flame retardant. There is a risk of fire. This also applies when drying.

Observe the specifications regarding cleaning/disinfecting (see the chapter on **Cleaning/disinfecting).**

Avoid placing the patient directly on existing wounds.

Note that the use of the product does not completely replace the need for regular repositioning of the patient.

The product (incl. accessories) may only be used after careful consideration of the individual patient. The suitability of the product (incl. accessories) for the patient must be checked at regular intervals (e.g. in case of weight gain/loss). Consider the special requirements of the patient to ensure that a anti-decubitus alternating pressure system in the right size and right version is always used for the patient in question. Match the functional characteristics of the anti-decubitus alternating pressure system to the specific disabilities and functional limitations of the respective patient. If a patient has restless legs syndrome, for example, we recommend positioning them so that their heels are not in contact with the mattress. Potential contraindications must be observed in this regard. Failure to comply with these instructions can result in a shorter service life/ useful life for the product. In addition, the increased strain from shear forces increases the risk of decubitus that is always present when the product is used.

8.1 Normal operation

Before operation, ensure that the alternating pressure mattress is securely attached by the fold-over ends to the reclining surface of the bed and that the supply hoses are not kinked, pinched or twisted.

While using the product, check at regular intervals that the patient is not at risk of developing bed sores.

1. Switch on the pump unit using the mains power switch (Fig. 5.01 and Fig. 5.1.01). The operation indicator lamp in the mains power switch lights up green.
2. Turn the pressure regulator (Fig. 5.1.01) to the scale value 1 so that the operating pressure in the alternating pressure mattress can build up.

No load may be applied to the alternating pressure mattress while the operating pressure in the alternating pressure mattress is being established. This process lasts approx. 15 minutes.

3. Check again that the alternating pressure mattress is fitted correctly and check the alternating pressure system for possible leaks.
4. Fit a separate cover such as the aks-inkocover stretch cover to the alternating pressure mattress. Unfolding of the alternating pressure mattress must not be obstructed.
5. Next, fit a thin bed sheet over the alternating pressure mattress or over the aks-inkocover stretch cover. Make sure that the sheet is fitted without creases.
6. Now place the patient on the alternating pressure mattress.
7. Next, adjust the power level. The optimum power level depends on several factors. These primarily include the weight of the patient and the patient's support area. The diagram (Fig. 8.1.01) can provide an initial guide value for the setting. This value is only a guide value for approximate pressure setting and it is not a precise value for the yield behaviour of the body.
8. After about six minutes, the system has settled down and the operation is stable.
9. Now check how the set pressure is affecting the patient. The patient must not be at risk of bed sores, i.e. there must be a small pocket of air between the patient and the mattress / mattress underlay underneath.

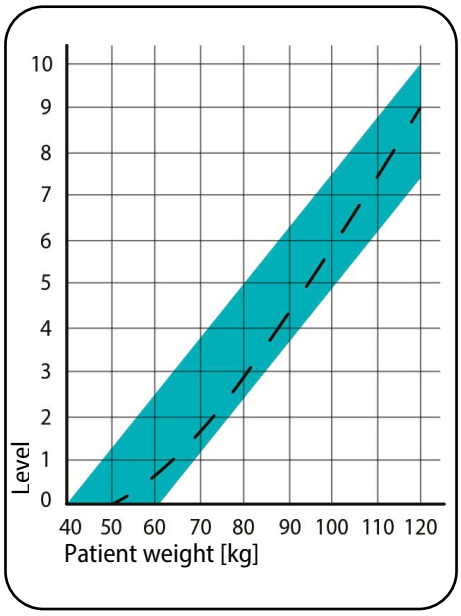

Fig. 8.1.01 – Power level setting

10. If necessary, use the pressure regulator to change the pressure setting. Repeat this procedure at the end of the cycle time until the optimum positioning has been achieved. This is the only way to ensure that the patient is sufficiently supported while simultaneously ensuring maximum pressure relief.

Note that a higher pressure in the alternating pressure mattress is necessary in the sitting position, particularly in the area of the buttocks, than in the lying position to prevent any development of bed sores of the patient.

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8.2 Cycle time

The product's cycle time is six minutes. Using the control unit of the pump unit, both air chamber circuits of the alternating pressure mattress are inflated and deflated intermittently in a cycle of six minutes.

8.3 Power failure

In the event of power failure, there is the risk of rapid pressure loss in the alternating pressure mattress.

The pressure can drop very quickly due to the ventilation openings (flow air®) in the alternating pressure mattress.

The patient must be placed elsewhere for the duration of the power failure.

8.4 Patient transport

The power supply cable and the supply hoses must not be driven over.

Note the information in the instructions for use for the care bed in question.

If the patient is transported on the alternating pressure mattress in a reclining position, the interruption to the power supply can cause rapid pressure loss in the alternating pressure mattress. Proceed as follows for any patient transport:

1. Switch off the pump unit using the mains power switch (Fig. 5.01 and Fig. 5.1.01) and disconnect it from the mains supply by unplugging the mains plug from the mains socket.
2. Disconnect the two ends of the supply hoses from the connecting pieces on the pump unit (Fig. 5.02).

Note that the alternating pressure mattress now deflates completely. The patient is now supported only by the standard foam mattress or the foam underlay.

3. Attach the pump unit to the foot end of the bed using the two retaining brackets. Secure the pump unit to prevent it falling.

Secure the power supply cable and the supply hoses of the alternating pressure mattress against being driven over by the bed castors.

4. After completion of the patient transport, attach the ends of both supply hoses to the connecting pieces on the pump unit (Fig. 5.02) and connect the pump unit to the mains supply.
5. Place the patient elsewhere and refill the mattress as described in the chapter on Operation/ use, section **Normal operation**.

9 Troubleshooting

Not all malfunctions are caused by product faults. The following table provides assistance for troubleshooting in case of malfunctions. If you are unable to rectify the malfunction using the information in this table, please contact your authorised dealer.

Repairs to and measurements of the electrical components may only be performed by suitably qualified personnel (see chapter on **Maintenance**)**! Other persons (e.g. users) are not under any circumstances permitted to attempt to resolve defects by themselves.**

Malfunctions and their causes		
Malfunction	**Possible causes**	**Remedy**
The pump unit is not operating	Mains plug is not or only partially plugged into the mains socket	Fully insert mains plug into the mains socket
	Mains power switch is not switched on	Switch on the mains power switch (indicator light in the mains power switch must light up) (Fig. 5.01 and Fig. 5.1.01)
	If the mains plug is completely inserted, the mains power switch is switched on and the pump unit is still not operating, inform your authorised dealer	
The small-cell alternating pressure mattress is not or insufficiently filled (the patient is at risk of decubitus)	Supply hoses are kinked, pinched or twisted	Check supply hoses and remove kinks, pinch points or twists
	Supply hoses are damaged (e.g. cracks, holes)	Inform your authorised dealer
	Supply hoses are not completely attached to the connecting pieces of the pump unit	Push both ends of the connection hoses completely onto the connecting pieces of the pump unit.
	Mattress is defective (holes, cracks etc.).	Inform your authorised dealer

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10 Accessories/combinations

Only original aks accessory/spare parts may be used as accessories/spare parts because only these have been tested by aks GmbH and thus guarantee faultless and safe function. Accessories/spare parts that have not been approved by aks GmbH can cause hazards.

Accessories/spare parts	SIZE		REF
	W [cm]	L [cm]	
flow air® small-cell anti-decubitus alternating pressure mattress	90	192	02101
aks-inkocover stretch cover	90/100	200	04104
Pump unit			22111

Further accessories / spare parts available on request.

We reserve the right to make changes and amendments. As a result, the specifications for REF may vary. Latest REF available on request.

Combination

The product can be combined with other aks GmbH products. These include the aks-inkocover stretch cover, for example.

As a mattress overlay system, the product may only be used in combination with a standard foam mattress or with a mattress underlay (minimum height 10 cm). Only use mattresses with dimensions corresponding to the dimensions of the alternating pressure mattress.

11 Cleaning/disinfecting

Cleaning: Achieving a state of cleanliness (visible). Removal of contamination to the extent required for the intended purpose of the product.

Disinfection: Reducing the number of or destroying micro-organisms (not visible). Procedure designed to reduce the number of viable micro-organisms to a pre-defined acceptable level appropriate to the intended purpose of the product.

When cleaning/disinfecting the product, note that the individual components could be infectious or contaminated. Take suitable precautions for your own safety. Use suitable packaging/labelling to ensure that the product/accessories can be transported without any risks to third parties.

Note the difference between cleaning/disinfecting for use by "**the same patient**" and cleaning/disinfecting for "**reuse**". Note that, for reuse in particular, only disinfection methods that are performed according to a validated procedure[1] with the suitable process parameters are permitted.

The product must always be disconnected from the mains supply for cleaning and disinfection in order to prevent risk of electric shock, fire hazard and functional failure. The plugs and sockets on the product are only protected against spray water when plugged together.

At minimum, the product's electrical components are protected against water drops falling vertically as per IP21 (see chapter on Technical data, section **Pump unit**)**.** Failure to comply means that safe operation can no longer be guaranteed.

The electrical components must show no external signs of damage. In case of damage, water and cleaning agents may get into the electrical components. This can cause malfunctions and damage to the electrical components. Before putting the product back into use, make sure that there is no residual moisture on the electrical contacts. This can be done by wiping or blowing the contacts dry.

Never spray the electrical components of the product with liquids (water, disinfectant etc.) and do not perform machine cleaning/disinfecting of the electrical components. Never submerge the product in liquid.

1 E.g. in accordance with the requirements of the Robert Koch Institute (RKI) or another procedure that has been validated by the operator/treatment personnel.

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11.1 General cleaning and disinfecting instructions

The product is suitable for reuse (see the chapter on **Reuse**). The product is manufactured subject to the highest quality standards. The following manufacturer information on cleaning/disinfecting must always be observed to ensure that the characteristics stated by the manufacturer do not change. This is the only way to guarantee that the product is safe and effective for its intended purpose.

Please observe the washing and care instructions indicated below for cleaning and disinfection. The table "Explanation of the care symbols" in the chapter **Product labelling** explains what these symbols mean. **Failure to observe the care instructions, for example by washing/drying at too high temperatures, or using additional brighteners/bleach, will damage the product.**

Both domestic and professional cleaning agents and disinfectants can be used to clean and disinfect the product. The following points must be observed:

Never use

- Abrasive agents or cleaning materials containing ammonium chloride
- Basic/alkaline cleaning agents
- Aggressive cleaning materials, e.g. solvents and hard brushes etc.
- Oil-based furniture polishes for the electrical components

If possible, use

- Environmentally and dermatologically tested cleaning agents
- Alcohol-free and chlorine-free disinfectants and methods for wipe disinfection from the Robert-Koch Institut (RKI) list or the disinfectants list of the Verbund für Angewandte Hygiene e. V. (VAH)

Observe the instructions and safety precautions from the manufacturers of the cleaning and disinfectant materials.

Clean and disinfect the product at regular intervals and whenever there is evident soiling and keep a proper log of the cleaning/disinfection.

In addition to regular maintenance, regular cleaning helps to identify loose and/or worn parts. This ensures trouble-free operation and extends the product's service life.

Wear gloves during cleaning/disinfection to prevent the cleaning agents/disinfectants from coming into direct contact with your skin.

Keep the surface disinfectants you use in sealed containers and note that these will need replacing at regular intervals in accordance with the manufacturer's specifications. We recommend using re-sealable pump dispensers to apply cleaning agents/disinfectants to cleaning cloths.

Make sure the room is ventilated sufficiently, or air it out thoroughly after wipe disinfection.

11.2 Cleaning by the user/operator

The pump unit and the alternating pressure mattress together with the aks-inkocover stretch cover can be cleaned by hand with a mild, alcohol-free cleaning agent and a cloth. In addition, the aks-inkocover stretch cover for the alternating pressure mattress can be washed in a washing machine using normal household washing agents. Note the care symbols (see section **General cleaning and disinfecting instructions**) and select the right settings / process parameters.

Note that washing at 95°C with normal household washing agents is a type of cleaning that is only effective for the same patient. Note that, when the product is used by a different patient (=reuse), only disinfection methods that are performed according to a validated procedure with the suitable process parameters are permitted.

The aks-inkocover stretch cover for the alternating pressure mattress must not be bleached and it must not be ironed.

Before refitting the cover, make sure all product components are completely dry. Otherwise, there is a risk of mould. Do not use any hot air (e.g. a hairdryer) for drying purposes.

11.3 Disinfection by the user

Please note: it is important to clean the product thoroughly prior to disinfection! To disinfect the pump unit and alternating pressure mattress by hand, use wipe disinfection. For regular disinfection by the user, domestic disinfectants can be used.

The pump unit and the alternating pressure mattress together with the aks-inkocover stretch cover can be disinfected using a mild antiseptic solution and a wipe disinfection method.

11.4 Disinfection by the operator

Please note: it is important to clean the product thoroughly prior to disinfection! To disinfect the pump unit and alternating pressure mattress by hand, use wipe disinfection. In case of disinfection carried out by the operator – e.g. during treatment for reuse – only validated disinfectants[2] may be used.

In addition, the aks-inkocover stretch cover can be cleaned separately using validated mechanised processes[2]. Note the care symbols (see section **General cleaning and disinfecting instructions**) and select the right settings / process parameters.

2 e.g. from the Robert-Koch Institut (RKI) list or the disinfectants list of the Verbund für Angewandte Hygiene e. V.(VAH) or another disinfectant/method validated by the operator/treatment personnel.

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11.5 Approved disinfectants and disinfection methods

When using disinfectants and disinfection methods, always observe the corresponding information from the manufacturer, particularly the specifications regarding concentration (dosage) and exposure time. Always use cold water (max. 30°C) when diluting disinfectants.

The following disinfectants and disinfection methods have been tested and approved by aks GmbH.

Wipe disinfection

Component	Manufacturer of disinfectant	Designation / active ingredient	Effectiveness* (degree of disinfection)
Alternating pressure mattress including aks-inkocover stretch cover	Ecolab	Incidin™ Rapid[3]	A

Mechanised disinfection

Component	Manufacturer of cleaning agent / disinfectant	Designation / active ingredient	Effectiveness* (degree of disinfection)
aks-inkocover stretch cover	Ecolab	Ozonit method: Ecobrite Magic Emulsion (cleaning agent) + Ozonit super[4] (disinfectant)	AB

* A: Suitable for killing vegetative bacteria, including mycobacteria and fungi including fungal spores

B: Suitable for inactivation of viruses

We recommend the certified treatment unit at aks pura GmbH for cleaning and disinfection of the product.

3 According to the Verbund für Angewandte Hygiene e. V. (VAH) – Active ingredient basis: Aldehyde(s), quaternary compound(s)

4 According to the Verbund für Angewandte Hygiene e. V. (VAH) - Active ingredient basis: peroxide compound(s)

12 Shutdown

If the products described in these instructions for use will no longer be used and should be shut down, proceed as follows:

1. The patient must no longer be lying on the alternating pressure mattress when removing it from service. The patient has to be relocated elsewhere.
2. Switch off the mains power switch (Fig. 5.01). The green operation indicator lamp in the mains power switch must be off (see chapter **Product overview**).
3. Unplug the mains plug from the mains socket.
4. If the alternating pressure system is to be transported and/or put into storage, the supply hoses must be disconnected from the pump unit (see chapter Operation/use, section **Patient transport**, and chapter **Storage**).
5. Remove the two fold-over ends at the head and foot ends from under the standard foam mattress or the mattress underlay (Fig. 5.03); see chapter **Product overview**.
6. After the alternating pressure mattress has been completed deflated, the pump unit, the alternating pressure mattress and (if applicable) the mattress underlay must be packed for transport or storage.
   Note the information in the chapter **Storage**.

13 Storage

The storage location should be as cool and dry as possible and not exceed normal room temperature. The climatic conditions are described in the chapter on **Technical data** and must be complied with.

Ensure damage and continual strain are ruled out during the storage period.

Do not place anything on the product that could damage it (e.g. pointed objects with sharp edges).

Do not drag the mattress along the floor when transporting it. Also avoid contact with walls, door frames, door locks or handles etc.

For long-term storage, the product should be stored in a clean and dry state. Use the original packaging for storage to protect the product against dust and/or cover the product with foil or a sheet.

Keep the product away from direct sunlight, fire and heat sources (e.g. heating, stoves etc.).

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14 Reuse

The products described in the instructions for use are suitable for reuse. Before reusing the product in question (e. g. in the event of a change of patient), make sure that it has been cleaned and disinfected as described in the chapter on **Cleaning/disinfecting** and serviced as described in the chapter on **Maintenance**, and that any defects or damage found has been repaired by the appropriate qualified personnel and/or the components in question replaced.

Observe the safety instructions (see chapter on **Safety instructions**).

15 Service life

If the product is used as intended, cleaned and disinfected as described in the chapter on **Cleaning/ disinfecting** and maintenance work is carried out at regular intervals as defined in the maintenance schedule (see chapter on **Maintenance**), the following service lives/useful lives are possible:

Component	Service life/useful life
Anti-decubitus alternating pressure pump unit	approx. **three years**
Small-cell alternating pressure mattress	approx. **one year**

Do not use a damaged or heavily worn product/accessories. Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

Please note the permitted patient weight (see chapter on **Technical data**). Exceeding the permitted patient weight not only reduces the service life/useful life of the product, it also increases the risk of decubitus that is always present when the product is used.

The service life/useful life of the products is affected by the patient's specific characteristics. These characteristics include restless legs syndrome, among others. Note the information in the chapter on **Operation/use**.

The product's service life/useful life is of course dependent on how it is used. Frequent transportation, cleaning and disinfection reduce the service life/useful life as do improper handling, improper storage and irregular maintenance.

If the products are treated properly and handled carefully, and they are cleaned/ disinfected as described in the chapter on **Cleaning/disinfecting**, they can also be used for longer.

The fact that aks GmbH specifies an expected service life/useful life for the products does not represent an additional guarantee.

16 Disposal

The products described in these instructions for use are made of metal and plastic parts along with electrical components. These must be disposed of properly, separately and in accordance with the statutory requirements.

Sort the packaging materials according to the parts that are recyclable, and recycle these in accordance with the applicable environmental regulations. Properly dispose of the parts that are not recyclable in your country.

When disposing of the product, note that the individual components could be infectious or contaminated. Take suitable precautions for your own safety. Use suitable packaging/labelling to ensure that the product/accessories can be disposed of without any risks to third parties.

Contact your local disposal company. For disposal in countries other than Germany, observe the respective applicable national laws, regulations and provisions.

The products are compliant with Regulation (EU) 2020/171, known as the REACH Regulation of the European Parliament and of the Council dated 6 February 2020 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

These products are classed as an item of electrical and electronic equipment intended for professional use (b2b) in accordance with the WEEE Directive 2012/19/EU (Waste Electrical and Electronic Equipment). The electrical components must be treated as waste electrical equipment in accordance with the WEEE Directive and disposed of properly. This is indicated by the symbol in Fig. 16.01.

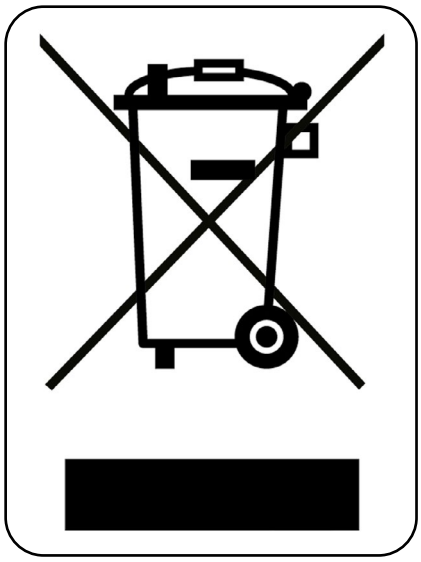

Fig. 16.01 – WEEE marking

The products comply with EU Directive 2011/65/EU, known as RoHS II of the European Parliament and Council dated 8 June 2011 for the Restriction of the use of Certain Hazardous Substances in electrical and electronic equipment.

In the case of electrical equipment brought into circulation after 13 August 2005, the owner is legally obligated not to hand over electrical components to municipal collecting points but to send them directly to the manufacturer for disposal. The general terms and conditions of aks GmbH apply to these returns.

17 Warranty

The products described in these instructions for use are distinguished by their long service life and high reliability. Should a fault occur and the product cease to operate correctly, check the malfunction using the table in the chapter on **Troubleshooting**. If the fault cannot be cleared in this way, contact your authorised dealer. They will provide a remedy as quickly as possible and procure the required spare parts.

We guarantee the faultless condition of our products in accordance with our sales and delivery conditions. We provide a manufacturer's warranty for the pump unit for **24 months** from the date of purchase and a manufacturer's warranty for the alternating pressure mattress for **6 months** from the date of purchase (soiling and normal wear are not covered by the warranty).

Non-observance of the instructions for use, improper use, improperly carried out maintenance work, and technical modifications and additions (e.g. attachments) without the permission of aks GmbH render the warranty and general product liability void.

We reserve the right to make technical changes for the purpose of improvement. For the product designation and information for clear identification (e.g. SN, LOT), refer to the rating plate (see chapter on **Product labelling**).

18 Declaration of conformity

The products described in these instructions for use comply with all the applicable requirements of Regulation (EU) 2017/745 on Medical Devices (MDR). During the development, the applicable parts of the following standards were taken into account:

- EN 60601-1 — Medical electrical equipment - Part 1:
  General requirements for basic safety and essential performance
- EN 60601-1-2 — Medical electrical equipment - Part 1-2:
  General requirements for basic safety and essential performance –
  Collateral standard:
  Electromagnetic disturbances - Requirements and tests
- EN ISO 10993-5 — Biological evaluation of medical devices – Part 5:
  Tests for in vitro cytotoxicity

The full Declaration of Conformity is available on request.

19 Maintenance

19.1 General maintenance instructions

The service life of the products (incl. accessories) described in these instructions for use is of course dependent on the type of use.

In order to ensure safe operation, the product in question must be visually inspected and functionally checked at regular intervals by appropriate qualified personnel, at least once a year, every time the product is reused and after every repair, followed by an electrical check, in accordance with the maintenance schedule. Shorter inspection cycles may be necessary if the product is used more frequently than normal.

If the product is not regularly and properly serviced, safe use is no longer guaranteed. Wear, damage as well as loosening of connecting elements can therefore not be detected.

If any checks indicate defects/damage, immediately disconnect the product from the mains supply and do not operate it again. Mark the product clearly as “Out of order” and inform your authorised dealer immediately.

Unplug the product from the mains supply before the visual inspection to prevent danger, e.g. from damaged power line insulation. If no damage is detected during the visual inspection, reconnect the product to the mains supply to perform a function test.

Defective/damaged electrical components must be replaced by suitable qualified personnel. Electrical components must not be opened and must be replaced as complete units.

Removed, defective/damaged electrical components may only be checked and evaluated by a qualified electrician or aks GmbH.

Do not carry out any repairs on the product that would alter the product characteristics. If this instruction is not observed, safe care can no longer be guaranteed and the risk of decubitus associated with using the product will increase. In addition, any warranty claim and product liability are excluded.

Maintenance may only be carried out when the anti-decubitus alternating pressure mattress is unoccupied.

Only original aks spare parts and aks accessory parts that are approved for this product may be used (see chapter on **Accessories/combinations**). Otherwise, any warranty claims and product liability are excluded. You must not make any technical modifications and additions without permission from aks GmbH.

In Germany, the EU Medical Devices Adaptation Act (MPEUAnpG) applies, including the Medical Devices Implementation Act (MPDG) and the Medical Devices Operator Ordinance (MPBetreibV). The corresponding national laws, regulations and requirements are applicable in other countries.

The latest versions of EN 62353 and the maintenance schedule must be used as test specifications for the products (incl. accessories) described in these instructions for use, and this must be properly documented.

Perform all tests under normal indoor ambient conditions (humidity and temperature). Perform the tests in the specified order (visual inspection first, then functional check). Perform all the tests on the same product and document your results. The following information must be provided as a bare minimum:

- Name and address of testing company
- Name of tester
- Test date
- Information on the product, incl.: Type, size, date of manufacture/production, serial/LOT number, catalogue umber where applicable
- Permitted patient weight
- Name and address of the manufacturer
- Test results
- Indication of next test date

19.2 Maintenance schedule: Inspection by the operator

Perform maintenance of the product (incl. accessories) at least once a year[1], before every reuse, and after every repair.

Article 7 of the MPBetreibV specifies the following:
*"Maintenance measures refer to inspections and **maintenance tasks** that are necessary in order to continuously ensure safe and proper operation of medical devices. The maintenance measures shall be performed taking the **manufacturer's instructions** into consideration (…)."*

If an error rate of less than 2% is identified and properly documented during inspections **of the electrical components**, the inspection interval for the electrical components can be extended accordingly (max. two years); see also the latest version of DGUV Specification 3; § 5; Table 1B. Regardless of the error rate, a full inspection as described in the maintenance schedule must be performed by suitable qualified personnel before each reuse and after each repair.

Application area	
☐ Private household ☐ In-patient facility	☐ _____
Client: _____	First time use (YYYY/MM) _____/_____
Last inspected on: _____	by: _____
Inspection prior to initial commissioning conducted on: _____	by: _____
Data for the anti-decubitus alternating pressure system	
Date of manufacture (YYYY/MM) _____/_____	SN _____
Inventory number: _____	

UDI-DI of the anti-decubitus alternating pressure system		
Model	Dimensions of mattress W x L [cm]	**UDI-DI**
saniflow® p (pump unit and mattress)	90 x 192	04251818700002

1 Article 11 of the MPBetreibV specifies the following for technical safety inspections for the medical devices specified in Annex 1 of the MPBetreibV:
"The owner shall schedule inspection intervals accordingly to ensure that the defects that are to be expected on the basis of past experience can be identified in good time."
Technical safety inspections do not apply to the products described in these instructions for use. The wording specifies the owner's responsibility.

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The following table provides help for this inspection:

Item	Inspection of the aks anti-decubitus alternating pressure system – inspection points*	OK	NOK	n/a
1	**Check of the basic requirements**			
1.1	Appropriate and safe use (see chapter Intended use, section **Intended purpose**)			
1.2	Permissible combination of pump unit and alternating pressure mattress (see chapter **Accessories/combinations**)			
1.3	Secure positioning of the pump unit			
1.4	Secure positioning of the alternating pressure mattress			
1.5	Instructions for use available, legible and accessible to user			
2	**Visual inspection of the pump unit** - The mains plug must be disconnected from the mains socket			
2.1	No unauthorised interventions, modifications or improper handling			
2.2	No contamination			
2.3	Rating plate present on the rear side of the case and legible			
2.4	Quick reference guide present on the rear side of the case and legible			
2.5	No damage to the case (no cracks, ruptures etc.)			
2.6	Both retaining brackets present and undamaged			
2.7	Rubber feet are present on the rear side of the case and not damaged			
2.8	Top part of case is firmly connected to bottom part of case; all four screws present and tightened			
2.9	Mains power switch with green operation indicator lamp not damaged			
2.10	Power supply cable with mains plug available and undamaged			
2.11	Lettering on the control panel is present and legible			
3	**Visual inspection of the alternating pressure mattress / stretch cover**			
3.1	**Alternating pressure mattress**			
3.1.1	No unauthorised modifications or improper handling			
3.1.2	No soiling			
3.1.3	All honeycomb (cells) undamaged			
3.1.4	Mattress cover present and undamaged			
3.1.5	Supply hoses not kinked, twisted, pinched, no fractures			
3.1.6	Connecting pieces for the supply hoses undamaged			
3.1.7	Both fold-over ends on the mattress underside are present and not damaged			
3.1.8	Mattress underlay with cover present and undamaged			
3.2	**aks-inkocover stretch cover**			
3.2.1	No tears, holes, cuts, separating seams, scorch marks			
3.2.2	No soiling			
3.2.3	No wear, no abrasion			
3.2.4	Labelling inside the stretch cover present, attached and legible (see chapter **Product labelling**)			
3.2.5	Elastic strap sufficiently elastic and tight			

Maintenance schedule continues on next page.

(*)

OK	in order	The condition or the function complies with the requirements
NOK	not in order	The condition or the function does not comply with the requirements. The defect has to be rectified by a repair or replacement
n/a	not applicable	Property/component/function not present, e.g. care function

4	Electrical inspection according to EN 62353	OK	NOK	n/a
4.1	Device leakage current – alternative measurement method: max. 500 µA Note: Insulation resistance measurement must not be performed. Voltages of more than 1 kV can result in damage.			
4.2	Leakage current of the user part - alternative measurement method: max. 5,000 µA			
5	**Functional check of the pump unit** - The mains plug must be connected to the mains socket			
5.1	Mains power switch with operating indicator lamp is functional			
5.2	Cycle time (6 minutes) is complied with			
5.3	The pressure can be adjusted; pressure regulator functioning			
5.4	Pressure regulator is not damaged and is fixed on the shaft			
5.5	The switch between inflation and deflation of the two air chamber circuits takes place once per cycle time			
5.6	Both retaining brackets are functional (can be folded)			
5.7	No abnormal operating noises present			
6	**Functional check of the alternating pressure mattress**			
6.1	Inspection of the alternating pressure mattress for leaks (honeycomb (cells), supply hoses etc.)			

Overall assessment: Anti-decubitus alternating pressure system			
aks anti-decubitus alternating pressure system and accessories are in order: ☐ YES ☐ NO			
Remark:			
Test date	Company	Inspector	Signature

Data for the anti-decubitus alternating pressure system				
Product	Model	SN	Date of manufacture	Next maintenance/ inspection
Pump unit	saniflow® p			
Alternating pressure mattress	90 x 192 cm			

We recommend the certified treatment unit at aks pura GmbH for the periodic monitoring, cleaning and disinfection of the products.

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19.3 Maintenance schedule: Inspection by the user

In addition to the periodic checking by suitable qualified personnel, the user must check that the product (incl. accessories) is in a safe state before each use. Do not use the product/accessories if you are concerned about the safety of using them. Contact your authorised dealer immediately.

Regularly and at short intervals check the power supply line for mechanical damage (e.g. monthly and after any mechanical strains that occur).

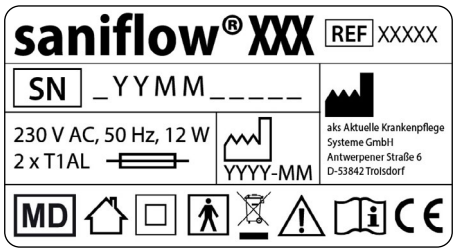
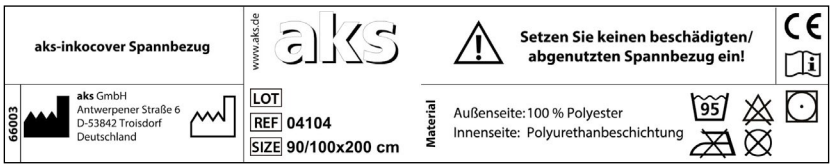
Do not use a damaged or heavily worn product/accessories. Failure to observe this requirement will increase the risk of decubitus that is always present when the product is used.

The following maintenance schedule provides help for this inspection:

Inspection of the alternating pressure mattress/pump unit – inspection points
Alternating pressure mattress - incl. supply hoses – shows no obvious damage or wear
Mattress underlay with cover present and undamaged
Alternating pressure mattress – air-filled honeycomb (cells) cannot be pressed together fully by hand
Switch between inflation and deflation takes place once per cycle time
aks-inkocover stretch cover: No soiling
aks-inkocover stretch cover: Elastic strap sufficiently elastic and tight
Pump unit incl. power supply cable – shows no obvious damage or wear
Pump unit – fully functional
All controls on the control panel functioning and reacting according to their corresponding functions
No unusual noises

If any checks indicate defects/damage, immediately disconnect the product from the mains supply and do not use it again. To do so, unplug the mains plug from the mains socket. Mark the product clearly as “Out of order” and inform your authorised dealer immediately.

20 Product labelling

Product labelling	
	**Rating plate** Pump unit Sticker (rear of case) see chapter on **Technical data**
X Y Y M M X X X X X	**Marking** SN YY – year of manufacture MM – month of manufacture
	**Rating plate** aks-inkocover stretch cover Label (inside)

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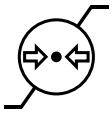
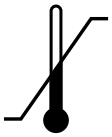
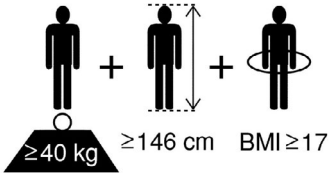
Explanation of the symbols	
CE	CE-Marking – this product satisfies the applicable requirements of the Regulation (EU) 2017/745 on Medical Devices (MDR) and other legal requirements of the European Union regarding affixing the relevant marking.
	WEEE marking (the device must not be disposed of with domestic waste)
SIZE	Dimensions of the product
MD	Medical device as per Regulation (EU) 2017/745 on medical devices
class I	Class I according to Regulation (EU) 2017/745 on medical devices, Annex VIII
UDI	Unique Device Identifier (UDI) – means a series of numeric or alphanumeric characters that allows unambiguous identification of specific devices on the market

Explanation of the symbols	EN ISO 15223-1
	Observe instructions for use
	Attention
	Manufacturer
	Date of manufacture
REF	Article number
SN	Serial number
	Air pressure, limit
	Humidity, limit
	Temperature, limit
	Keep dry/store in a dry place

Explanation of the symbols	EN ISO 15223-1
	Protect against heat/sunlight
	Fragile, handle with care

Explanation of the symbols	IEC 60417
	For indoor use only
	Protection class II against electric shock
	Application part type BF
	Device fuse
	Top

Explanation of the symbols	EN 60601-2-52
	Min. patient body weight = 40 kg Min. patient height= 146 cm Min. patient BMI = 17 Body mass index (BMI) is a measurement of a person's outline based on their individual body weight and height: $BMI = \frac{Weight\ (in\ kg)}{Size\ x\ size\ (in\ m)}$ BMI calculation: Example 1: $BMI = \frac{40\ kg}{1.46\ m\ x\ 1.46\ m} = 18.8 =$ *in order!* Example 2: $BMI = \frac{40\ kg}{1.56\ m\ x\ 1.56\ m} = 16.4 =$ *not in order!*

Explanation of the care symbols	EN ISO 3758
	Hot wash (normal washing cycle) Washing temperature 95 °C, normal process
	Do not bleach Use bleach-free detergents
	Dry with reduced thermal load Dry at low heat setting (maximum approx. 60 °C)
	Do not iron
	Do not dry clean

Protection type of the enclosure acc. to EN 60529	
IP21	First digit: Level of protection against contact and foreign objects **2** – protection against ingress of solid foreign objects, diameter ≥12 mm Second digit: Level of protection against water **1** – protection against vertically falling drops of water

20.1 Quick reference guide

Quick reference guide (extract from the instructions for use)

Read the instructions for use in full before using the product for the first time and before each reuse.

1. Attach the pump unit to the foot end of the bed using the retaining brackets, or place it on a flat surface next to the bed.
2. Place the alternating pressure mattress (APM) on a foam mattress / foam underlay.
   Please note: APM connections should be on top at the food end.
3. Fasten the APM with the fold-over ends at the head and foot ends.
   To do so, slide the fold-over ends under the foam mattress/underlay.
4. Connect the hoses of the APM to the pump unit.
   Please note: Do not twist, wedge or kink the hoses.
5. Check the following: Pump unit is switched off, mains power switch (green) is set to “off” (0).
6. Insert the mains plug into a mains socket. Switch the pump unit on by switching the mains power switch (green) to “on” (1); air flows into the APM.
7. For further details, see the instructions for use.
   In the event of a defect, contact your authorised dealer without delay.

Do not operate the APM in the vicinity of flammable substances or chemicals. This could cause an explosion.

Do not open the pump unit and do not immerse it in liquids.
Failure to comply with these instructions could result in electric shock.

MEDIZINPRODUKT Klasse I
MEDICAL DEVICE Class I
IP21
Application part: saniflow® p small-cell alternating pressure mattress

aks
www.aks.de

Fig. 20.1.01 - Quick reference guide (rear of pump unit case)

21 Technical data

General information on the product			
Classification	active class I medical device according to Regulation (EU) 2017/745, Appendix VIII		
Basic UDI DI	425181871**22111D8**		
Permitted patient weight [kg]	45 to 120		
Climatic conditions	Ambient temperature [°C]	Use	10 to 40
		Transport/storage	0 to 40
	Humidity [%]		30 to 75
	Air pressure [hPa]		800 to 1060
			Normally composed atmospheric air
Pump unit			
Input voltage	230 V AC, 50 Hz		
Power consumption	max. 12 W		
Protection type	IP21		
Device fuse (on the floor side):	2 x glass microfuse T1AL/250 V		
Power supply cable (length)	3 m		
SIZE [cm]	W	H	D
	11	23	8.1
Weight [kg]	approx. 1.1		
Max. filling pressure:	approx. 140 mbar		
Cycle time	6 minutes		
Alternating pressure mattress			
SIZE [cm]	W	L	H Cell height
	90	192	6.35
Weight [kg]	approx. 2.3		
Number of cells	124		
Material	PVC		
Air filling time	approx. 15 minutes		
aks-inkocover stretch cover (optional)			
Material	100% polyester with polyurethane membrane Weight: 100 g/m²		

All specifications regarding dimensions and weights are approximate specifications. The sizes of the mattresses are affected by manufacturing tolerances; this means that deviations in the stated dimensions of up to 2 cm are possible.

The product fulfils the requirements of the RoHS, REACH and WEEE regulations/ guidelines, among other requirements.

All parts and data are subject to constant further development and can thus be different from the information shown in this document.

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Enter the data for your product here:

Type: saniflow® p

Mattress protection: ☐ aks-inkocover ☐ _____

UDI (01)042518187 __ __ __ __ __

SN _____
Pump unit

_____
Small-cell alternating pressure mattress

SIZE **[cm]** 90 x 192

Year _____ Month _____ (pump unit)

Year _____ Month _____ (small-cell alternating pressure mattress)

First time use: Year _____ Month _____

Authorised dealer: Name _____

Street _____

Post code/town _____

Telephone number _____

Notes:

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