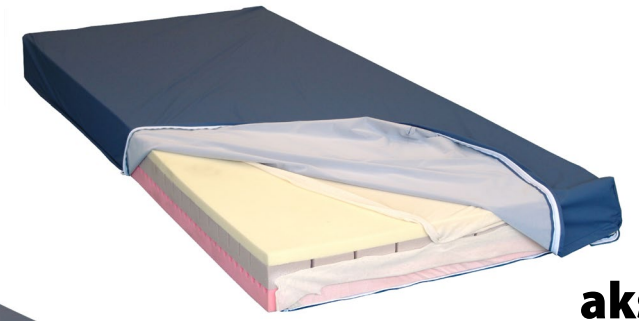
aks-HD 85

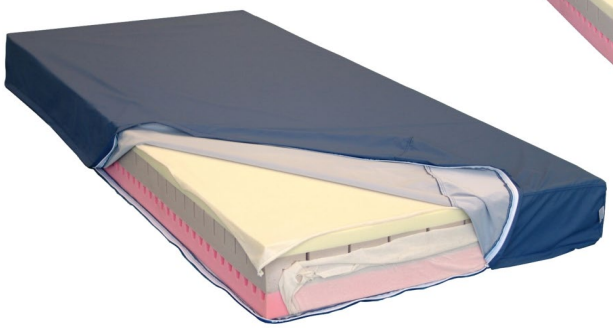
Anti-decubitus pressure-reducing support mattress

Instructions for use

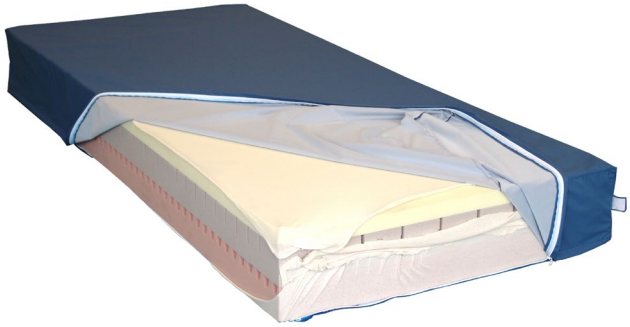
Translation of the original instructions for use



aks-HD 85 L



aks-HD 85 XL



aks-HD 85 XXL

Zertifiziertes QM System

aks®

DIN EN ISO 13485

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

MD CE

Date: 2022-02-10
Version 01

TABLE OF CONTENTS

z4200137_GA_Decu_HD85_220210_Rev01_EN

Version history

Version	Date	Change
01	2022-02-10	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 **aks-HD 85 L, XL and XXL foam pressure-reducing mattresses** (hereinafter also referred to as the products) have been developed for decubitus prophylaxis and therapy.

Among other things, the products feature the following:

- Microclimate regulation in the mattress thanks to incisions under the reclining surface
- CFC-free foam
- Available in many different sizes
- Includes liquid-impermeable inkoair® mattress cover

We hope the products fulfil 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).
	**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 Class I medical devices according to Regulation (EU) 2017/745, Annex VIII.

The products are suitable for domestic use as well as for use in inpatient[1] facilities. The products are only suitable for use in dry, indoor areas.

See the rating plate or the chapter on **Technical data** for the permitted patient weight.

See the chapter on **Technical data** for 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 to be used for sleeping/resting. To this end, they are placed on a care bed or a "standard bed" (see chapter **Commissioning**).

The products are used to prevent, treat and alleviate decubitus ulcers. They can be used for decubitus prophylaxis as well as for decubitus therapy. With regard to decubitus prophylaxis, the products are suitable up to patients with up to a medium risk of decubitus.

The products must only be used for decubitus prophylaxis and for therapy of decubitus ulcers up to and including Grade II (according to EPUAP).

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 on **Technical data**).

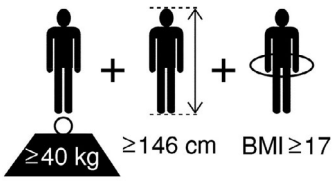
2.2 Indication

The products are intended for patients who, due to an illness, injury, disability or their age, have to lie down for long periods of time. They are particularly suitable for cachectic and pain-sensitive patients.

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.



2.4 Side effects

Note that permanent pressure-reducing support can have may cause the patient to lose his or her body scheme, mobility is restricted and a reduction of spontaneous movement may occur. This makes activating care more difficult.

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. 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.
- If they are unsure regarding a potential use of the product.

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.

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

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 in the use of the product 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 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. 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 damage has 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). The foam core is not flame retardant. There is a risk of fire.

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

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 foam mattress are used for the patient. Match the functional characteristics of the aks foam mattress to the specific disabilities and functional limitations of the respective patient. Potential contraindications must be observed here.

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.

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 mattress, mattress cover or incontinence stretch cover. Only use the product with a suitable mattress cover or incontinence stretch cover and a bed sheet.

Please note that no other overlays (e.g. fur) are to be used on the mattress (mattress cover/incontinence stretch 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 for the same patient.

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

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

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

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).

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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).

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: 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 cables 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 cables 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.

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 pressure-reducing mattress made of foam
- 1 x inkoair® mattress cover
- 1 x instructions for use

Fig. 4.01 - Scope of delivery

The product is available in the following variants/dimensions:

W [cm]	L [cm]	REF		
		aks-HD 85 L H = 14 cm	aks-HD 85 XL H = 18 cm	aks-HD 85 XXL H = 22 cm
80	190	39169	–	–
	200	39159	39172	–
90	140	39140	39620	–
	200	39141	39156	39158
	220	39157	39164	–
100	190	39170	–	–
	200	39142	39147	39168
	220	39143	39148	39171
120	200	39144	39149	39152
	220	39145	39150	39153
	240	–	39151	–
140	190	39177	–	–
	200	39146	39162	39167
	220	–	39478	39154
	240	–	–	39155

5 Product overview

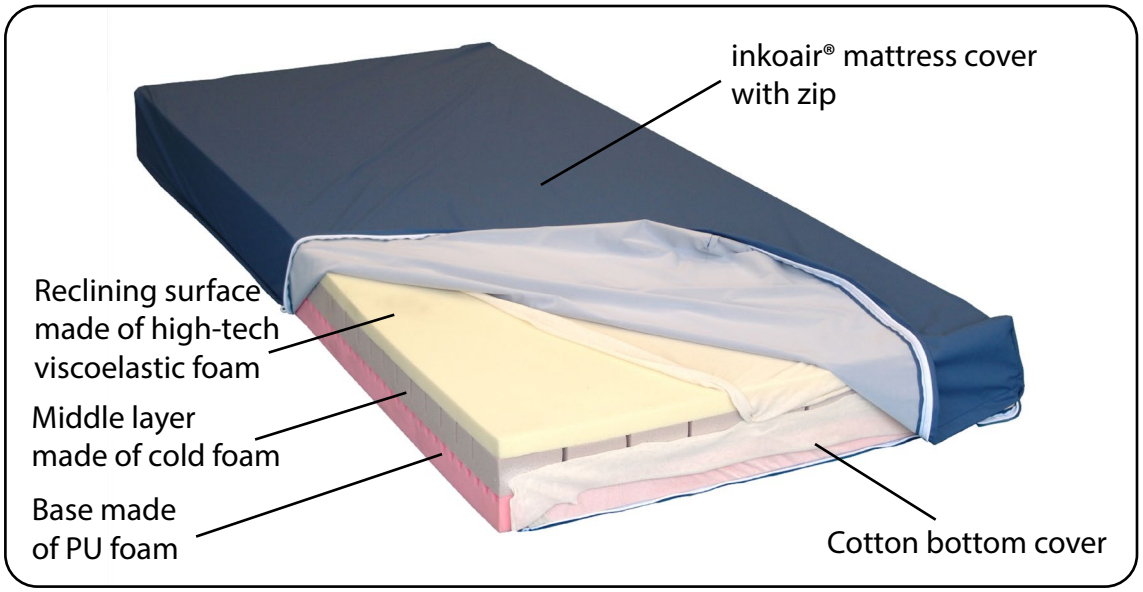

Fig. 5.01 - aks-HD 85 L

The product is a foam mattress with a single-section reclining surface. It functions in accordance with the pressure-reducing support principle and reduces the support pressure and shear forces. It is used for decubitus prophylaxis and to support decubitus therapy for the entire body.

The bottom layer is the base and it consists of a high-quality PU foam with a high density and high compression hardness. To provide a softer transition to the middle layer, the top side of the base has an undulating design.

The middle layer consists of cold foam. The top side of the middle layer has incisions in the longitudinal and lateral directions, which creates a cube structure that partially relieves pressure and improves the microclimate.

The top layer has a smooth, unstructured surface that acts as the reclining surface. It consists of a high-tech viscoelastic foam. The viscoelastic foam becomes softer as it is warmed up by body heat, which causes it to adapt optimally to the contours of the body. The patient's body is distributed across a larger support area, which reduces the support pressure. This improves blood circulation in the tissue regions and reduces the risk of developing decubitis.

The combination of the three foam layers prevents bedsores in obese patients (see chapter on **Technical data**).

The product is protected from soiling by the liquid-impermeable inkoair® mattress cover. The mattress cover is closed with a zip fastener and it can be removed. In the event of soiling, it can be washed in a washing machine using normal household washing agents (see chapter on **Cleaning/disinfecting**).

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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. 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 mattress 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**).

You must train the user and make them aware of the hazards that may arise in case of improper use of the product, e.g.:

- Damage to the product (incl. accessories) due to incorrect cleaning/disinfecting, including washing/drying at too high temperatures, using additional brighteners/ bleach (see chapter **Cleaning/disinfecting**)

2. Carefully open the packaging film at one end (e.g. using a safety cutter with blade guard). Take care not to damage the product.
3. Remove the product from the packaging film. Retain the packaging film for future transport or storage of the product.
4. Before fitting it, allow the product to lie for approximately one hour so that the foam can sufficiently expand and acclimatise.

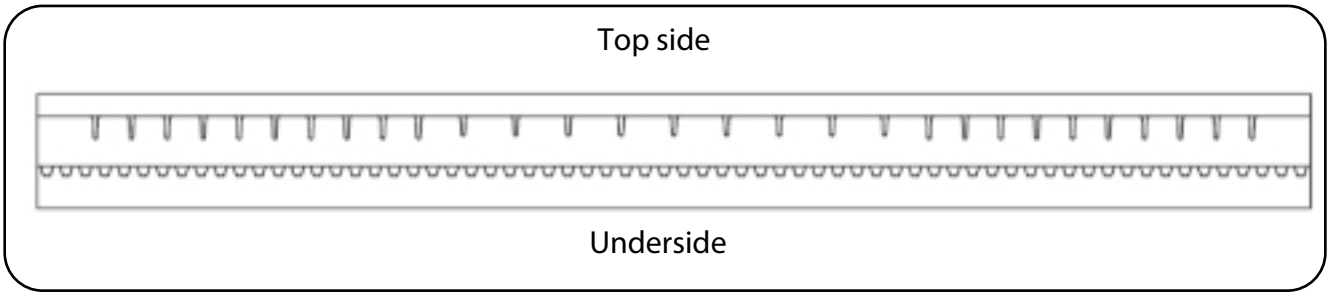

Fig. 6.01 - aks-HD 85 top side/underside

5. Fit the inkoair® mattress cover onto the product (see Commissioning chapter, section **Fitting the inkoair® mattress cover to the product**).
6. Place the product on the reclining surface of your bed. The viscoelastic foam layer is facing up and it is the reclining surface of the mattress.
7. Secure the product on the reclining surface of your bed to prevent it from slipping. In order to do so, wedge the pressure-reducing support mattress between the mattress holders or in the frame construction.
8. Ensure that the product is not compressed here and no bulges are created in the mattress.
9. Next, fit a bed sheet over the pressure-reducing support mattress or the inkoair® mattress cover. Make sure that the sheet is fitted without creases.
10. Finally, check the reclining surface of the mattress for possible pressure points due to the creation of creases and check that the product is seated securely before laying the patient on the pressure-reducing support mattress.

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.

The viscoelastic foam on the mattress surface reacts to the patient's body heat, i.e. as it gets warmer, the viscoelastic foam gets softer and starts to take effect.

6.1 Fitting the inkoair® mattress cover to the product

The products are delivered without a cover. It is absolutely necessary to cover the mattress cover with the separately included inkoair® mattress cover before commissioning. It may be necessary to remove and then re-fit the cover for cleaning (see chapter **Cleaning/disinfecting**). To fit the cover, proceed as follows:

- Place the product (without mattress cover) on the reclining surface of your bed.
- Make sure that the thin viscoelastic foam layer on the product is facing upwards and the foam layer with the structuring at the sides is facing towards the bed's reclining surface (Fig. 6.1.01).
- There is no need to differentiate between the head and foot ends of the mattress when positioning it.
- Check once again that the product is lying on the bed with the thin viscoelastic foam layer facing up.

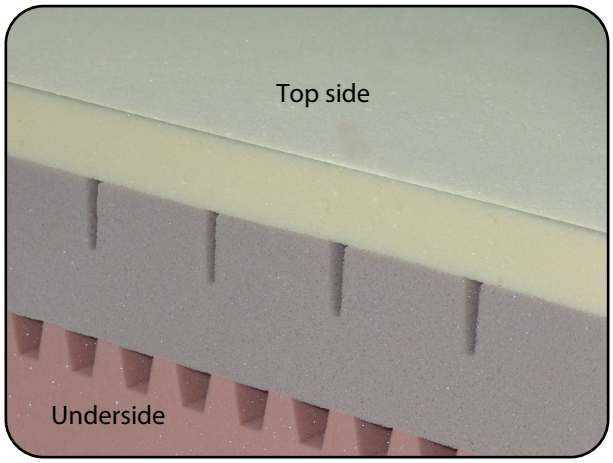

Fig. 6.1.01 - Top/bottom section

- Fit the inkoair® mattress cover over the mattress, taking care to prevent any creases. Make sure that the corners of the foam core are fitted into the corners of the mattress cover.
- Make sure that the zip fastener's protective overlap runs from the top to the bottom, i.e. liquids must not be able to penetrate into the mattress cover from above through the zip fastener (Fig. 6.1.02).

The inkoair® mattress cover must be fitted onto the mattress so that the label "Oberseite/Kopfseite / top/head" can be seen from above. This label is attached to the middle of the front side of the mattress cover (the side without a zip, Fig. 6.1.03). Make sure that the direction of the arrow matches the direction of the arrow on the rating plate (printed on the side of the mattress, see chapter **Product labelling**).

- Now proceed as described in point 7 in the chapter on **Commissioning**.

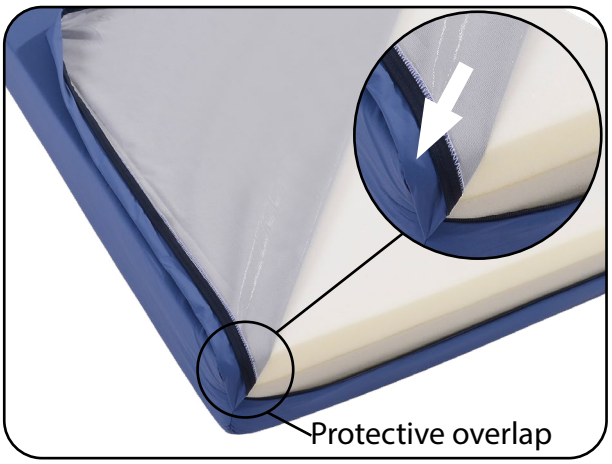

Fig. 6.1.02 - Protective overlap of the zip fastener

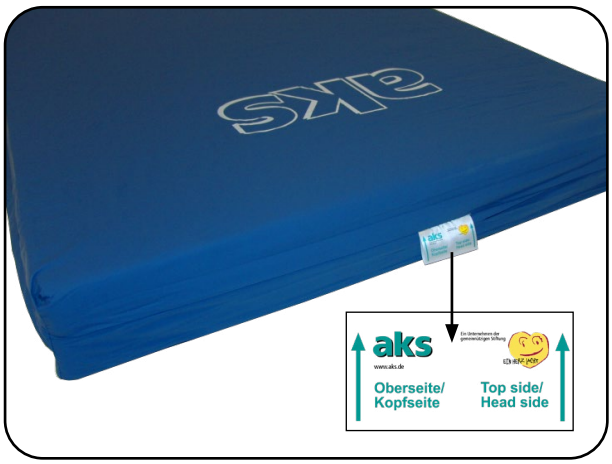

Fig. 6.1.03 - Mattress cover with label

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 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. The foam core is not flame retardant.

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 foam mattress in the right size and right version is always used for the patient in question. Match the functional characteristics of the aks foam mattress 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.

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9 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.

SIZE W x L [cm]		inkoair® mattress cover REF		
		H = 14 cm	H = 18 cm	H = 22 cm
80	190	49038	–	–
	200	49025	49029	–
90	140	49006	49051	–
	200	49007	49022	49024
	220	49023	49027	–
100	180	49044	–	–
	190	49039	–	–
	200	49008	49013	49037
	220	49009	49014	–
120	200	49010	49015	49018
	220	49011	49016	49019
	240	–	49017	–
140	190	49045	–	–
	200	49012	49026	–
	220	–	49049	49020
	240	–	–	49021

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.

10 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 microorganisms (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.

10.1 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.

All products are equipped with a rating plate (see chapter on **Product labelling**).

Please observe the relevant washing and care instructions on the rating plate 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.

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)

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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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 safe use 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.

10.2 Cleaning by the user/operator

The inkoair® mattress cover or aks-inkocover stretch cover can be cleaned by hand with a mild, alcohol-free cleaning agent and a cloth. Alternatively, the inkoair® mattress cover or aks-inkocover stretch cover can be washed in a washing machine using normal household washing agents. Observe the washing and care instructions on the rating plate (see the chapter on **Product labelling**) and choose 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 mattress protection must not be bleached and it must not be ironed. It is possible to dry it in a tumble dryer if a low temperature is set.

To ensure a longer service life, avoid drying in a tumble dryer.

The foam core is suitable for manual cleaning with a damp cloth, when necessary.

Before refitting the inkoair® mattress cover or aks-inkocover stretch cover (see the section **Fitting the inkoair® mattress cover to the product** in the Commissioning chapter) both the foam core and the mattress cover or stretch cover must be completely dry. Otherwise, there is a risk of mould. Do not use any hot air (e.g. a hairdryer) for drying purposes.

10.3 Disinfection by the user

Please note: it is important to clean the product thoroughly prior to disinfection! To disinfect the inkoair® mattress cover or aks-inkocover stretch cover by hand, use a wipe disinfection method. For regular disinfection by the user, domestic disinfectants can be used.

The inkoair® mattress cover is a full cover that completely encloses the foam core. The protective overlap of the zip fastener prevents any liquids that run down the sides from entering into the cushion.

The aks-inkocover stretch cover is a cover that is pulled over the mattress and held in place by a bordered elastic strap; the underside is only partially enclosed. The sides are protected against liquids running down.

For this reason, it is sufficient to disinfect the mattress cover or stretch cover if it has been used as intended. If the foam core has become contaminated, contact your authorised dealer.

10.4 Disinfection by the operator

Please note: it is important to clean the product thoroughly prior to disinfection! To disinfect the inkoair® mattress cover or aks-inkocover stretch cover by hand, use a wipe disinfection method. In case of disinfection carried out by the operator – e.g. during treatment for reuse – only validated disinfectants[2] may be used.

The inkoair® mattress cover is a full cover that completely encloses the foam core. The protective overlap of the zip fastener prevents any liquids that run down the sides from entering into the cushion.

The aks-inkocover stretch cover is a cover that is pulled over the mattress and held in place by a bordered elastic strap; the underside is only partially enclosed. The sides are protected against liquids running down.

In addition, the inkoair® mattress cover and the aks-inkocover stretch cover can be cleaned separately using validated mechanised processes[2]. Observe the washing and care instructions on the rating plate (see the chapter on **Product labelling**) and choose the right settings / process parameters.

If the foam core is contaminated, a validated mechanised process[2] can be carried out. We recommend steam disinfection at 105 °C. Please note that the cover must be removed prior to disinfection in an autoclave, so that only the foam core is in the autoclave.

After autoclaving, the foam core should acclimatise at room temperature without a cover for 24 hours to remove any remaining moisture from the foam core. If the product is put on immediately, this can cause mould both on the cover and on the foam core, and thus damage the product.

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 that has been validated by the operator/treatment personnel.

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10.5 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)
inkoair® mattress cover/ aks-inkocover stretch cover	Ecolab	Incidin™ Rapid[3]	A

Mechanised disinfection

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

Component	Manufacturer/system	Method	Effectiveness* (degree of disinfection)
Foam core	Belimed Sauter	Fractional vacuum process: 105 °C programme	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)

11 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).

The maximum stacking height (when unrolled) specified in the chapter on **Technical data** must not be exceeded.

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, dry and unfolded 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.).

12 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**).

13 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**), a service life/useful life of around **three years** is possible.

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.

Do not carry out any repairs or modifications to the product.

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 **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.

14 Disposal

The products described in these instructions for use are made of plastic and, in some cases, metal (zip of the mattress cover). 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 risk 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 product is compliant with Regulation (EU) 2020/171, known as the REACH Regulation of the European Parliament and of the Council from 6 February, 2020 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

15 Warranty

The products described in these instructions for use are distinguished by their long service life and high reliability. If a problem arises, inform your authorised dealer. The authorised dealer will assist you as quickly as possible.

We guarantee the faultless condition of our products in accordance with our sales and delivery conditions. In respect of material defects, we provide a manufacturer's warranty for **24 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**).

16 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 development of the products, the applicable parts of the following standards were taken into account:

- 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.

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17 Maintenance

17.1 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 at regular intervals by appropriate qualified personnel, every time the product is returned to use and after every repair, in accordance with the maintenance schedule.

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, do not use the product any longer. Mark the product clearly as “out of order” and inform your authorised dealer immediately.

Do not carry out any repairs or modifications on the product that would alter the product characteristics. If this instruction is not observed, safe care can no longer be guaranteed and there is an increased risk of decubitus. In addition, any warranty claims and product liability are excluded.

Maintenance may only be carried out when the mattress is unoccupied.

Only original aks spare parts and aks accessory parts that are approved for these products 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 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 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

17.2 Maintenance schedule: Inspection by the operator

Service the product at regular intervals[1], every time it is returned to use after storage 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 (…)."*

The following maintenance schedule provides help for this inspection:

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: _____

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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Model	Cover	Dimensions W x L (cm)	UDI-DI	
aks-HD 85 L	inkoair®	80 x 190	04251818**00835**	☐
		80 x 200	04251818**00781**	☐
		80 x 220	04251818**00972**	☐
		90 x 190	04251818**00590**	☐
		90 x 200	04251818**00606**	☐
		90 x 220	04251818**00767**	☐
		100 x 180	04251818**00873**	☐
		100 x 190	04251818**00842**	☐
		100 x 200	04251818**00613**	☐
		100 x 220	04251818**00620**	☐
		120 x 200	04251818**00637**	☐
		120 x 220	04251818**00644**	☐
		140 x 190	04251818**00880**	☐
		140 x 200	04251818**00651**	☐
aks-HD 85 XL		80 x 200	04251818**00866**	☐
		90 x 190	04251818**00927**	☐
		90 x 200	04251818**00750**	☐
		90 x 220	04251818**00804**	☐
		100 x 200	04251818**00668**	☐
		100 x 220	04251818**00675**	☐
		120 x 200	04251818**00682**	☐
		120 x 220	04251818**00699**	☐
		120 x 240	04251818**00705**	☐
		140 x 200	04251818**00798**	☐
		140 x 220	04251818**00903**	☐
aks-HD 85 XXL		90 x 200	04251818**00774**	☐
		100 x 200	04251818**00828**	☐
		120 x 200	04251818**00712**	☐
		120 x 220	04251818**00729**	☐
		140 x 200	04251818**00811**	☐
		140 x 220	04251818**00736**	☐
		140 x 240	04251818**00743**	☐

The following maintenance schedule provides help for this inspection:

Inspection of anti-decubitus foam mattress – inspection points*	**OK**	**NOK**	**n/a**
Check of the basic requirements			
Appropriate use (see chapter Intended use, section **Intended purpose**)			
Permitted combinations of mattresses and mattress protection (see chapter **Accessories/combinations**)			
Instructions for use available, legible and accessible to user			
No unauthorised interventions, modifications or improper handling			
Inspection of the foam core/ foam cubes with mounting frame *(aks-varioplus)* – The mattress cover/stretch cover must be removed			
Labelling is present and legible (product designation, serial number, CE marking, date of manufacture, manufacturer's details, bottom marking etc.) (see chapter **Product labelling**)			
No deformation, formation of depressions			
No damage (tears, cuts)			
No soiling of the foam layers			
No soiling of the foam cubes with mounting frame			
Reclining surface (and edge zones) undamaged (no tears, holes, hardening etc.)			
No wear, no worn/abraded areas			
Adhesive bond between the foam layers is intact			
All foam cubes present and completely inserted in the mounting frame (see chapter on **Technical data**)			
Mounting frame undamaged (no cracks etc.)			
Inspection of the mattress cover/stretch cover			
Labelling inside the mattress cover/stretch cover present, attached and legible (see chapter **Product labelling**)			
No damage (e.g. tears, holes, cuts, separating seams, scorch marks)			
No soiling			
No wear, no worn/abraded areas			
Mattress cover: Zip fastener functional and complete (slider, slider grip)			
Mattress cover: "Top/head" label on the front side present and legible (see chapter on **Product labelling**)			
Stretch cover: Elastic strap sufficiently elastic and tight			

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

Data for anti-decubitus foam mattress					
Product	Type	Dimensions L x W (cm)	SN / LOT	Date of manufacture (YYYY/MM)	Next maintenance/ inspection
Mattress					
Mattress cover/ stretch cover					

(*)

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 not present, e.g. stretch cover

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17.3 Maintenance schedule: Inspection by the user

In addition to the periodic inspections by suitable qualified personnel, the user must check at regular intervals that the product is in a safe state. Do not use the product if you are concerned about the safety of using it. Contact you authorised dealer immediately.

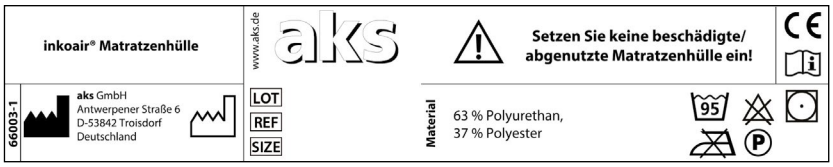
The following table provides help for this inspection:

Inspection of the mattress/mattress protection – inspection points
No deformation, formation of depressions
No damage (tears, holes, cuts, separating seams, scorch marks)
No soiling of the mattress protection
No wear, no worn/abraded areas
Mattress cover: Zip fastener functional and complete (slider, slider grip)
Stretch cover: Elastic strap sufficiently elastic and tight

If any of these checks indicate defects/damage, the product must no longer be used. Mark the product clearly as “out of order” and inform your authorised dealer immediately.

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.

18 Product labelling

Product labelling	
	**Rating plate** Mattress imprint (on side)
	**Rating plate** Mattress cover label (inside)
	**Top/head marking** Mattress cover label (outside)

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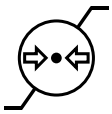
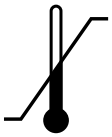
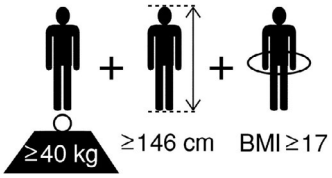
Explanation of the symbols	
CE	CE marking – this product satisfies the applicable requirements of the Regulation (EU) 2017/745 on Medical Devices (MDR) and other legal requirements of the European Union regarding affixing the relevant marking.
SIZE	Dimensions of the product
MD	Medical device as per Regulation (EU) 2017/745 on medical devices
class I	Class I according to Annex VIII of Regulation (EU) 2017/745 on medical devices
UDI	Unique Device Identifier (UDI) – refers to a sequence of numeric or alphanumeric characters that allows unambiguous identification of specific products on the market
= kg	Permitted patient weight
Explanation of the symbols	**EN ISO 15223-1**
	Observe instructions for use
	Attention
	Manufacturer
	Date of manufacture
LOT	Production batch number, batch
REF	Article number
SN	Serial number
	Air pressure, limit
	Humidity, limit
	Temperature, limit
	Keep dry/store in a dry place
	Protect against heat/sunlight

Explanation of the symbols	IEC 60417
	Stacking limit by quantity

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
	Professional dry cleaning, normal process
	Do not dry clean

19 Technical data

General information on the product				
Classification	Class I medical device according to Regulation (EU) 2017/745, Appendix VIII			
Basic UDI DI	425181871240118DW			
Permitted patient weight [kg]	**aks-HD85 L**	40 to 150 kg		
	aks-HD85 XL	40 to 200 kg		
	aks-HD85 XXL	40 to 300 kg		
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		
Storage	Max. stacking height [pcs]	6		
Mattress				
Model	SIZE [cm]	**aks-HD 85 L H = 14 cm**	**aks-HD 85 XL H = 18 cm**	**aks-HD 85 XXL H = 22 cm**
Weight [kg] (examples)	90 x 190	7.1	7.6	7.6
	90 x 200	approx. 7.5	approx. 8.0	8.0
	100 x 200	8.6	8.7	8.7
Material	PU foam			
Reclining surface foam	Density: 85 kg/m³ Compression hardness: 1.6 kPa; 40% (ISO 2439)			
Foam middle layer	Density: 58 kg/m³ (aks-HD 85 L and XL), 80 kg/m³ (aks-HD 85 XXL) Compression hardness: 8.0 kPa (aks-HD 85 L and XL), 11 kPa (aks-HD 85 XXL); 40% (ISO 2439)			
Base layer foam	Density: 50 kg/m³ Compression hardness: 3.9 kPa; 40% (ISO 2439)			
inkoair® mattress cover				
Material	63% polyurethane, 37% polyester Weight: 150 g/m² Flame-retardant acc. to BS 7175 (Crib 5)			

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 REACH Regulation, 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.

Notes:

Enter the data for your product here:

Type:

- ☐ aks-maxiplot
- ☐ aks-microplot plus
- ☐ aks-varioplus
- ☐ aks-duoplot
- ☐ aks-duoplot RV
- ☐ aks-duoplot plus
- ☐ aks-duoplot plus RV
- ☐ aks-memoplot
- ☐ aks-memoplot RV
- ☐ aks-theraplot
- ☐ aks-viscoplot
- ☐ aks-HD85 L
- ☐ aks-HD85 XL
- ☐ aks-HD85 XXL

Mattress protection: ☐ inkoair® ☐ aks-inkocover

UDI (01)042518187 __ __ __ __ __

SN _____

SIZE **[cm]**

- ☐ 90 x 200
- ☐ 100 x 200
- ☐ 90 x 190
- ☐ _____ x _____

Year _____ month _____

First time use: year _____ month _____

Authorised dealer:

Name _____

Street _____

Postcode/town _____

Telephone number _____

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