Instructions for use

Smartline plus 5
Smartline plus 8

Anti-decubitus Alternating Pressure System





novacare

Table of contents

1. General information 2
2. Safety instructions 2
3. Product information 3
4. Installation & Use 5
5. Faults & Troubleshooting 8
6. Maintenance & Repair 8
7. Disposal & Environment 9
8. Abbreviations & Symbols 10
9. Warranty 11

Read the following instructions for use carefully and observe the safety and warning information.

1. General information

The novacare® alternating pressure systems Smartline plus 5 and Smartline Plus 8 are systems for the prevention and treatment of pressure ulcers. As a medical aid, the product is mainly given to medical experts or professional users. Professional users are people who, due to their medical or comparable training, have sufficient knowledge of the product and its use. The installation and commissioning of the product should only be carried out by professional users. Commissioning by non-professional users or medical laypersons must not be carried out without adequate training. The product and the accessories identified by novacare® gmbh are only to be used in accordance with these instructions for use. Novacare® gmbh assumes no liability for the use of the product outside of the applications described in these instructions for use. Keep these instructions for use in a safe, easily accessible place and pass it on to the new owner when the product is sold. The regulatory requirements applicable to this product in the respective country of use must be taken into account.

2. Safety instructions

! Do not use the system in the immediate vicinity of heat sources.
! Do not use the system in the immediate vicinity of flammable gases or in potentially explosive areas.
! Keep away from pointed and sharp objects.
! Protect the control unit from humidity and direct exposure to fluids.
! Protect the control unit from falling or damage.
! Install the control unit at the foot of the bed and lay the power cord under the bed and away from moving parts to avoid injuries.

! Observe the correct mains voltage.
! Never pull on the cable.
! Remove the power plug when moving the bed.
! In the event of a power failure, the control unit stops working, after the power supply returns, the system returns to the last set operating mode.
! If the Smartline Plus 5 mattress is being used with a base mattress, the existing bed mattress must be removed. When using the Smartline Plus 8 the existing mattress should also be removed, no base mattress is required.
! Do not use unsuitable methods to fix the mattress in place.
! Do not use the system in an uninflated state.
! The mattress should not be exposed to direct sunlight for long periods of time. (UV radiation shortens the lifespan of the material)
! Keep the tubes free of kinks.
! If the mattress is not connected to the control unit, protect the main connection hose from ingress of dirt or dust particles by using the transport cover on the connection adapter.
! When using side rails, adhere to the specified minimum clearance, if necessary use side rail extensions.
! Use only original spare and consumable parts.
! Only have repairs carried out by the manufacturer or an authorized specialist dealer.
! Keep children away from the product and its accessories. There is a risk of injury from swallowing small parts, strangling and squeezing limbs.

3. Product information

General product description

The Smartline Plus 5 overlay mattress system is designed to be placed on standard mattresses or used as a replacement system with a novacare base mattress and is intended for use in clinical, nursing and domestic settings. Use in standard beds is possible, but hospital or nursing beds should be preferred. The system consists of a control unit with a diaphragm pump and an alternating pressure support with 17 transversely arranged air cells, whereby the three cells located in the head area are static. The cell unit is protected by a bi-elastic, anti-slip and waterproof, but water vapour permeable cover made of polyester with a skin-friendly PU coating with all-round zip.

The Smartline Plus 8 replacement mattress is a complete replacement (cell-on-cell) system intended for use in clinical, nursing and domestic settings. Use in standard beds is possible, but hospital or nursing beds should be preferred. The system consists of a control unit with a diaphragm pump and an alternating pressure support with 20 transversely arranged air cells, whereby the three cells located in the head area are static. The cell unit is protected by a bi-elastic, anti-slip and waterproof, but water vapour permeable cover made of polyester with a skin-friendly PU coating with all-round zip.

Scope of delivery:

novacare® Smartline plus from the following model series

- novacare® Smartline plus 5 alternating pressure mattress with control unit
- novacare® Smartline plus 8 alternating pressure mattress with control unit
- User manual

optional:

- novacare® base mattress (for Smartline Plus 5 system)
- novacare® carrying bag for alternating pressure systems

Intended use

The novacare® alternating pressure system Smartline plus 5 is suitable for use with decubitus ulcers of category I-III according to EPUAP/NPUAP and is intended for a maximum user weight of 160 kg. The novacare® alternating pressure system Smartline plus 8 is suitable for use with decubitus ulcers of category I-IV according to EPUAP/NPUAP and is intended for a maximum user weight of 200 kg. Use additional alternative systems of the novacare® APM series for care and treatment of heavier patients.

⚠ **Alternating pressure systems do not replace the regular, manual change of position of the patient by the nursing staff.**

Indication:

Treatment and prevention of pressure ulcers (decubiti) according to the care plan and in compliance with national standards. In the case of patients in pain or with a low pain threshold, the system should only be operated in static mode or a more suitable novacare® system should be used.

Contraindications:

The system should not be used for patients with multiple trauma, fractures of the spine, pelvis and extremities, or intracranial injuries or concussion. For patients with neurological deficits and a lack of body awareness, a medical indication for use is required. In the event of allergies to materials used in the cover or the cells, it should also not be used.

Technical Data

Control unit	Product variant	
	996600 S Smartline plus 5	**996700 Smartline plus 8**
Weight	1,7 kg	1,7 kg
Dimensions	28 x 16 x 10 cm	28 x 16 x 10 cm
Voltage Values	AC 220-240 V 50-60 Hz max. 0.2A	AC 220-240 V 50-60 Hz max. 0.2A
Fuses	T1AL 250 VAC 1A	T1AL 250 VAC 1A
Protection classes	Type BF, class II	Type BF, class II
Mains cable length	4,5 m	4,5 m
Max. Filling pressure	20 to 55 mmHg	20 to 55 mmHg
Min. Filling pressure		
Cycle	10 Min	10 Min
Mattress topper	996600 S Smartline plus 5	96700 Smartline plus 8
Cell dimension	88 x 11 x 13 cm Ø	88 x 10 x 20 cm Ø
Cell material	Nylon / TPU coated	Nylon / TPU coated
Approved load weight	20 bis 160 kg	20 bis 200 kg
Weight	4,7 kg	7,3 kg
Dimension	200 x 88 x 13 cm	200 x 90 x 20 cm
Material (cover)	48 % Polyurethan 52 % Polyester	48 % Polyurethan 52 % Polyester
Note:	The use of a base mattress increases the total height by the height of the base mattress.	

Regulatory requirements

The alternating pressure systems of the novacare® gmbh meet the following regulatory requirements:

- Regulation (EU) 2017/745 about Medical Devices
- Testing of medical electrical devices according to DIN EN 60601-1
- Test for flammability according to BS EN 597-1 and -2, CAL-117
- The cover meets Crib 5 (BS 7175)
- Testing for biocompatibility according to DIN EN ISO 10993
- Oeko-Tex® Standard 100
- CPR emergency valve
- Optical and acoustic low pressure, cycle and mains failure alarm

⚠ **All serious adverse events that occur in relation to the product must be reported immediately to the manufacturer and the competent authority.**

Accessories

The medical products from novacare® gmbh may only be used with the accessories provided for them. The accessories are available separately from novacare® gmbh customer service.

4. Installation & Use

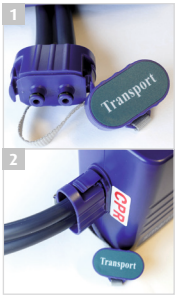
Environmental conditions

	Storage	Operation	Transport
Temperature	+5 bis +50 °C	+15 bis +40 °C	-20 to +50 °C
Relative humidity	30-75 % (non-condensing)	30-75 % (non-condensing)	-
Air pressure	795 - 1060 hPa	795 - 1060 hPa	-

The system should have the opportunity to adapt to the room temperature before it is put into operation.

Installation

1. Check the packaging and product for possible damage and completeness upon delivery.
   ⚠ **Never put a damaged product into operation.**
2. Take the control unit out of the box, fold out the retaining bracket on the back and attach the control unit to the foot end of the bed.
3. **Smartline plus 5:** Take the mattress out of the box and place it on the existing mattress or remove the existing mattress and insert a base mattress into the pocket beneath the cell holder sheet. The size of the overlay must match the size of the mattress. If the prescribed minimum distance of 22 cm between the inflated mattress and the side-rails in their highest position is not achieved, use a side rail extension.
4. **Smartline plus 8:** Remove the mattress from the packaging and lay on the bed frame. If the prescribed minimum distance of 22 cm between the inflated mattress and the side-rails in their highest position is not achieved, use a side rail extension.
5. The connection tube is located at the foot end of the mattress (printed feet) and should not be kinked.
6. **Applies to Smartline plus 5:** Secure the overlay to the mattress with the straps attached to the underside to prevent it from slipping.
7. Remove the transport lock from the connection adapter of the main connection hose 1 and connect the connection adapter to the connection socket on the control unit 2. Make sure that the coupling engages correctly.
8. **Applies to Smartline plus 5:** Check that the CPR pull tag is correctly inserted into the system to prevent air loss. **Applies to Smartline plus 8:** Check the rotating dial position of the CPR emergency valve (head end). The dial must be set to the "close" position.
9. Connect the mains plug, making sure that the mains voltage is correct.
10. Start the control unit by pressing the power button for around 3 seconds.
11. The LED display "POWER" lights up and flashes until the preset pressure is reached.



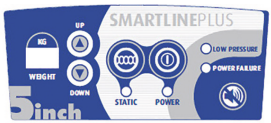
12. The inflation process takes approx. 30 minutes. When the preset pressure is reached, the pump switches off automatically. The LED display "POWER" now lights up constantly.
13. Set the desired operating mode by pressing the STATIC key. In static mode the LED display "STATIC" lights up, in alternating pressure mode it does not.
14. To set the system to the patient's weight, press the "up" or "down" button until the LED field to the left of it shows the selected weight.
15. Place the patient on the system.
16. It should be possible to slide a hand between a deflated cell and the person lying on the bed with just slight resistance (= practical test). Correct settings if necessary.

The Smartline plus alternating pressure system can also be used for beds with a profiling lying surface. The head cells are static, but the setting selected for the alternating pressure also affects the pressure in the head cells. If the bed is raised at the head end, the mattress pressure should be increased by 1 to 2 levels and a practical test carried out. Adjusting the lying surface by more than 30° should be avoided.

Normal Use

Adjustments must only be made by trained nurses or trained other adults. Pay attention to skin changes and consult a doctor or nurse if necessary. In alternating pressure mode, every second cell is alternately filled with air while the other cells are deflated. The pressure on the skin is reduced and stimulates blood circulation. When switching to static mode, the alternating inflation and deflation is stopped and all cells are filled with the same pressure. This can take up to 12 minutes. The pressure range should be set one to two levels lower in static mode. If it is necessary to move the person lying on the bed, switch the mattress to static mode.





Interruption of the power supply (transport)

If it is necessary to interrupt the power supply, the system should be switched to static mode before disconnecting the mains plug. The inflated system usually maintains pressure for 15 to 20 minutes and then deflates slowly. Alternatively, the connection adapter on the control unit can be pulled out and the transport cap quickly put on. The pressure is thus maintained in the system for several hours, but should be checked regularly.

⚠ **Applies to Smartline plus 5:** In the event of a system failure, the use of the mattress without an underlying mattress or a base mattress inserted into the system can lead to the person lying on the slatted bed base.

Error displays and warning signals

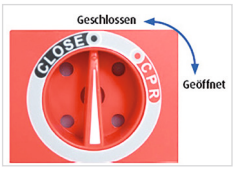
The product is equipped with an alarm system and reacts to low pressure, cycle error and power failure with an acoustic signal. In the event of lowpressure and cycle error, the "POWER" indicator POWER FAILURE also flashes. If there is low pressure in the system, the LED low pressure indicator "LOW" LOW PRESSURE lights up. For the ventilation time when the system is started up, the acoustic negative pressure alarm has been equipped with a delay function and activates automatically after about 45 minutes. Short-term low pressure, due to e.g. repositioning or cycle change, is only indicated by a visual signal, the low pressure indicator LOW lights up. If the low pressure persists for more than five minutes, the acoustic alarm is also activated.

Exceptional situations - emergency situations

The system Smartline plus 5 is equipped with a CPR emergency valve on the right side of the head section, which enables spontaneous ventilation within a short time in the event that resuscitation is required. Pull the red CPR emergency tab. In addition, loosen the connection adapter on the control unit.



The System Smartline plus 8 is equipped with a CPR emergency valve on the right side of the head section, which enables spontaneous ventilation within a short time in the event that resuscitation is required. To do this, turn the CPR emergency dial to "CPR".



5. Faults & Troubleshooting

Malfunction	Possible causes	Solution
Person lying down due to	Support is not properly or insufficiently ventilated Leak	Inform specialist shop
	CPR valve open	Close the CPR valve
	Main connection hose not connected properly	Connect the main connection hose
System failure	No power supply	Connect power supply (check fuse)
	Unit fuse on the connection plate is not fully screwed in	Tighten the fuse with a screwdriver
	Unit is not switched on	Switch on the unit
	Mains cable not connected correctly	Connect the mains cable correctly
	Mains plug not inserted correctly	Plug in the mains plug

If these measures are unsuccessful, contact the service technician.

⚠ **Do not repair the system yourself.**
⚠ **Have fuses replaced only by qualified and authorised personnel.**
⚠ **In case of damage, disconnect the mains plug. Do not use a damaged product.**

6. Maintenance & Repair

Reprocessing
This product is suitable for repeated use on additional persons. In general, the applicable national regulatory requirements for hygienic reprocessing must be observed and fault-free functioning must be ensured.

Use in the domestic area (without changing patients):
Wipe the cover regularly and if necessary with commercially available cleaning agents or disinfectants and a soft cloth. Do not use abrasive products, products containing phenol or diethylene glycol monoethyl ether. Remove the cover of the system regularly and wash in the washing machine at up to 70°C with commercially available detergents and then dry gently at low temperatures.

Use in the nursing area (change of patients):
Reprocess according to national regulatory requirements. novacare® gmbh expressly recommends reprocessing in accordance with the recommendations of the German Robert Koch Institute on hygiene requirements for the reprocessing of medical devices. If necessary, clean the cover of the system chemothermally by machine at up to 70°C. Disinfect the cell body by wiping, only reprocess chemothermally if necessary.

⚠ **Disconnect the mains plug before cleaning the control unit.**
⚠ **Do not clean the cells in a washing machine.**
⚠ **Disinfection measures are only to be carried out with suitable disinfectants that have been tested for effectiveness.**
⚠ **Disinfectants that can damage the materials of the system should be avoided.**
⚠ **The instructions for use of the disinfectant manufacturer must be observed.**

The use of unsuitable disinfectants or disinfectants that have not been tested for effectiveness or their incorrect application will invalidate the warranty and guarantee.

Maintenance
To maintain the function of the system, maintenance and a safety check by qualified personnel is required every two years at the latest. For continuous use, we recommend an annual safety check and maintenance interval. The maintenance or inspection is carried out by the manufacturer or by a company authorised by the manufacturer and is subject to a charge.

⚠ **All service, repair and inspection work may only be carried out by competent and instructed personnel.**
⚠ **Only original spare parts and consumables may be used.**

7. Disposal & Environment

Disposal mattress

The mattresses can be disposed of with household waste (residual waste). The respective valid disposal guidelines must be observed.

Disposal control unit



The control unit is electrical waste and must not be disposed of in household or residual waste. It must be handed over to the responsible disposal point.

The electrical devices of novacare® gmbh are registered: WEEE reg. no.: DE-89403200.
The batteries in the system are registered: GRS contract number: 109101377.

Disposal packaging

No special types of packaging are used. The respective valid disposal guidelines must be observed.

8. Abbreviations & Symbols

List of abbreviations

CPR	Cardiopulmonary resuscitation
EPUAP/NPUAP	European Pressure Ulcer Advisory Panel / National Pressure Ulcer Advisory Panel
PU	Polyurethane
TPU	Thermoplastic polyurethane
UV	Ultraviolet

Symbol directory

	Manufacturer
	Date of manufacture
	Reference to information in or location of the instructions for use.
	Safety note: The instructions for use must be observed.
CE	CE mark, confirms conformity with relevant standards.
MD	Medical device
SN	Serial number
LOT	Lot number
CH REP	Indicates the authorised representative in Switzerland
	Attention, a warning notice follows.
	Attention: Device and batteries must not be disposed of in household waste.
	Insulated housing class II, degree of protection against electric shock
	Applied part type BF - degree of protection against electric shock
IPXX	Protection against harmful penetration of water and certain substances, protection against vertically falling water drops

	Maximum washing temperature XX°C
	do not bleach
	tumble dryer can be used. Maximum output temperature 60°C.
	do not iron
	Cl 1000 ppm
	NaClO Sodium hypochlorite
	manual cleaning
	fragile, Handle with care
	keep dry
	not dry clean

9. Warranty

Novacare® gmbh assumes a guarantee on every mattress in the novacare® product range that is defective due to manufacturing and / or material defects within 24 months of purchase. If an examination by novacare® gmbh shows that warranty claims have been made that relate to one of the following reasons for exclusion, novacare® gmbh is entitled to pass on expenses incurred (e.g. testing and transport costs) to the claimant.

novacare® gmbh does not assume any guarantee:

- for defects that can be traced back to improper handling and / or disregard of the intended purpose and the application or behavioral rules described in these operating instructions.
- for damage and malfunctions caused by natural wear and tear or during transport.
- for the replacement of wearing parts.
- for delivered goods that have been modified, treated or changed without the consent of novacare® gmbh.
- in the event of maintenance and servicing measures not carried out, not carried out on time, improperly or by unauthorized persons, or damage resulting therefrom.
- when using parts or individual components of other products, other makes and / or their combination with the present product.
- if the regulatory requirements with regard to regular maintenance and servicing measures for medical devices are disregarded.
- if the instructions for use are not observed.
- if the seals are damaged or opened.

Operators of the present product must observe the regulatory requirements for medical devices applicable at the place of use.

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