User Manual

Smartline plus 5

Anti-Decubitus Alternating Pressure System

Product name Smartline plus 5

Item no. 996600 UK/ 996600

novacare

Thank you for purchasing the novacare® Smartline plus 5, a system for the treatment and prevention of pressure ulcers up to grade 3 according to EUPAP.

A *Smart* decision.

Please read the following operating instructions carefully and read the safety notices before using the system.

1. The system / scope of use

The novacare® Smartline plus 5 is an overlay system that is placed onto a standard mattress and is designed for use in home care, care home and hospital environments.
The system consists of a control unit with a membrane pump and a mattress replacement with 17 nylon/TPU (Thermoplastic polyurethane) air cells arranged horizontally. The three cells located at the head end are static. The cell unit is equipped with a bi-elastic and watertight but steampermeable wraparound protective cover made from PU. The materials used are biocompatible.

2. Indications / contraindications

Indications:
Treatment and prevention of pressure ulcers/decubitus. The system should be used in accordance with a care plan developed by qualified nursing staff. The national decubitus standard must be taken into account.

Contraindications:
The system should not be used for patients with multiple traumas, patients with fractures of the spine, pelvis or extremities or intracranial injuries or concussion. In the case of patients with neurological problems or a lack of body awareness, the doctor in charge must confirm that use is indicated. Alternating pressure should not be used on patients in pain or patients with a low pain threshold.
In such cases, use the static mode or another suitable mattress made from foam material or other materials such as can be found in the novacare® range. In the event of allergies to materials used in the cover or cells, the overlay system should not be used.

Patients weighing under 20 kg
Patients weighing over 160 kg

Static mode:
In the case of patients in pain or with a low pain threshold, the system should be operated in static mode.

3. Area of application

The novacare® Smartline plus 5 is suitable for use with decubitus ulcers of grade I - III (according to Seiler) or category I – III (according to EPUAP/ NPUAP). In the case of a higher risk or decubitus grade, use an appropriate system from the novacare® range.

4. Maximum load / patient weight

The novacare® Smartline plus 5 is designed for a maximum patient weight of 160 kg. For heavier patients please use a suitable alternative from the novacare® range.

5. Packaging

Check the goods and packaging for any damage upon delivery. If you need to transport the system after use, please use the original packaging. Otherwise, dispose of the packaging in accordance with national waste disposal guideline.

6. Safety precautions before use

In order to avoid any damage to the device as a result of improper use and any injury to the patient or user, please read the operating instructions carefully and fully before use. Please observe the safety notices. Use the system and accessories only in accordance with these operating instructions. Keep the operating instructions in a safe place and make sure that they are accessible to all users at all times. In the event of a change of ownership, pass on the operating instructions to the new owner.

The company novacare® gmbh accepts no liability for any use of the system other than those described in these operating instructions.

- All parts must be used as specified and may not be changed or modified.
- Settings may only be adjusted by nursing staff or other personnel who have received suitable instruction.
- Watch for changes to the skin and, if necessary, consult your physician or nurse.
- As a matter of course, the provisions of the National Medical Devices Act and the National Medical Devices Operator Ordinance must be observed.

7. Safety / preparing the system for use

1. Remove the control unit from the box, unfold the mounting brackets on the rear and attach the unit to the foot end of the bed.
2. Now remove the mattress overlay from the box and place it onto the hospital bed mattress. If the minimum clearance cannot be adhered to, use a height extension for the side rail.
3. Ensure that the connection hose is located at the foot end of the bed and does not become kinked.
4. Attach the novacare Basic overlay to the patients mattress using the straps provided at the head and foot end. This prevents the overlay from movement. Please note that the straps should not be attached to the bed frame but to the profiling frame.
5. The foot end of the mattress is marked with imprinted feet on the cover. The CPR emergency valve is located on the head end.
6. Now connect the main connection tube of the mattress to the connector on the side of the control unit (after first removing the transport securing device). Ensure that the connection hose engages properly (see section 13 Fig. 1).
7. Ensure that the CPR emergency plugs are inserted into the mattress.
8. Insert the plug into a power outlet (230 V), making sure that the voltage is correct.
9. Switch on the control unit (see section 9). The power on LED will blink green until the preset pressure has been reached. Thereafter the LED will light constant green.
10. The device is now working, and the overlay mattress will inflate. This process takes about 30 - 35 minutes.
11. Now set the regulator to the patient's weight. When doing so, refer to the weight data provided on the regulator scale.
12. The patient can now lie on the mattress. In order to improve patient comfort, a sheet can be placed over the system. When doing so, take care to avoid folds.
13. Carry out the Practical Test (see section 14) and make individual adjustments if necessary.

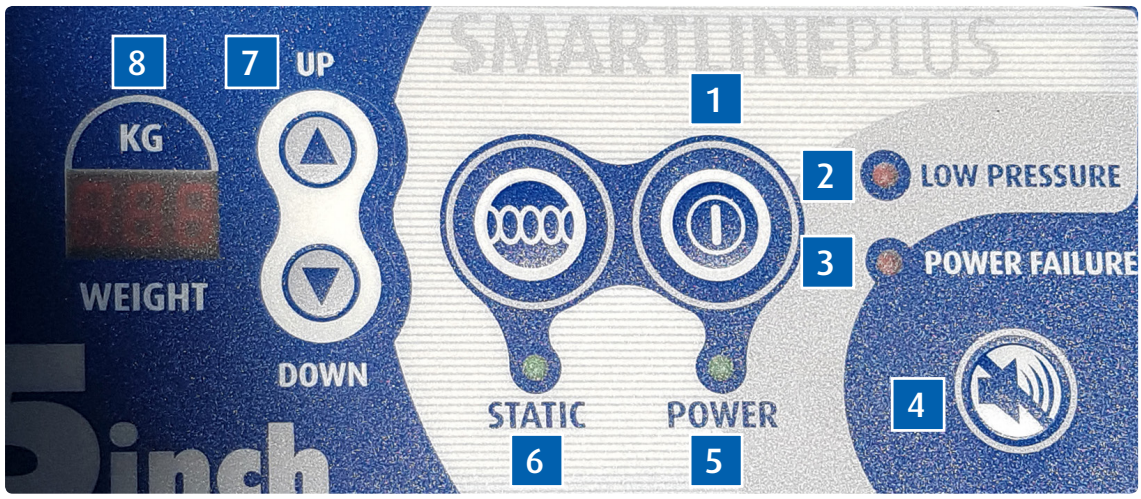
N.B.: The alternating pressure system can also be used on beds with profiling surfaces. If the bed head is raised or positioned vertically, increase the mattress pressure by 1 - 2 settings. If possible, avoid adjusting the surface by more than 30°. Carry out the Practical Test (see section 14).

The cells at the head end are not alternating, but static. The setting selected for the alternating pressure also affects the pressure in the cells at the head end.

8. Alternative positioning of the control unit

The control unit of the novacare® Smartline plus 5 should be hung onto the foot end of the bed. Alternatively, if space is an issue, the unit can also be hung on the lower of the two bedside rails. Please check that the tubing leading to the pump doesn´t get kinked.

9. Control unit / operating panel



1. Power On/Off switch
2. Low pressure LED
3. Power Fail LED
4. Alarm mute
5. Power on LED
6. Static on LED
7. Weight Setting up/down
8. Weight LED

10. Weight setting

Please consult the settings provided on the regulator scale in order to achieve the appropriate cell pressure for your patient.

Please note that these are default settings given as guidance only. You should always conduct the Practical Test (see Section 14) and make individual adjustments until you determine the correct setting for the patient in question.

11. Static mode

The system can be operated in static mode for certain applications (for example patients in pain and transport of patients). In static mode, all cells are inflated with the same pressure and the alternating effect is stopped. Please note that due to the cyclic adjustment of the drive, switching to static mode may take up to a maximum of 6-12 minutes. Press the static button on the touch pad until the LED lights green. The static mode is activated.
In static mode we recommend that the pressure is lowered by 1-2 settings. You should carry out the Practical Test here, too (see section 14).

12. Alarm function

The novacare® Smartline plus 5 is equipped with an alarm system. Low pressure is indicated visually and audibly. Any power failure or interruption in the power supply is indicated by an acoustic signal and the „Power LED“ flashes. During installation the system remains in low pressure until fully inflated and the visual low pressure indicator is activated. The audible alarm features a delay function which takes the inflation time into account. The audiable alarm is automatically activated after about 45 minutes. Should internal cell pressure fall below 20 mm/Hg for a short time (for example during repositioning or during a cycle change, the low pressure LED will be activated). If there is low pressure for a longer duration, the acoustic alarm will be activated.

13. Connections

Connection mattress to air pump

Transport Cap. Used during transport or repositioning of patients (please refer to 15 b)

14. Practical test

At the optimum and correct pressure, you should be able to pass your hand between the patient and a deflated cell without any difficulty. The patient should not be lying on the bed frame.

15. Transportation of patients / dust cover

If the power supply is interrupted (e.g. patient transportation), pressure within the alternating pressure mattress can be maintained for a certain amount of time. Two options apply. First switch the system to static mode.

a. Remove the power plug. System pressure is maintained for 15-20 minutes and is then gradually reduced.
b. Separate the control unit from the alternating pressure mattress by releasing and removing the mattress air socket from the control unit. Put the transport cap onto the socket and ensure that it engages correctly. This should be done quickly in order to avoid loss of pressure. The system maintains the pressure for several hours. We recommend checking the overlay for sufficient pressure at regular intervals.

16. CPR valve

The novacare® Smartline plus 5 is equipped with a CPR emergency tab pull system. It allows deflation within seconds, for example, to carry out resuscitation. Quick deflation is achieved by pulling on the red tab marked “CPR”
This CPR pull tab is located at the head end of the mattress system.

17. Safety notices

- Protect the control unit from humidity and from direct exposure to fluids.
- Keep the tubes free of kinks.
- Do not use the system in the immediate vicinity of a source of heat.
- Ensure that the mains voltage is correct.
- Do not use the system in an uninflated state.
- Remove the power plug when moving the bed.
- Never pull on the cable.
- Keep away from sharp objects.
- Do not use unsuitable methods to fix the overlay in place.
- Do not use the system in the immediate vicinity of inflammable gases or in areas where there is a risk of explosion.
- Use only genuine spare parts and expendables.
- When using side rails, adhere to the specified minimum clearance. If the minimum clearance cannot be adhered to, use a height extension for the side rail.
- The provisions of the National Medical Devices Act and the National Medical Devices Operator Ordinance must be observed.
- Only allow repairs to be carried out by the manufacturer or an authorised dealer.
- The novacare® plus 5 is a mattress overlay system. Always place the overlay onto the hospital bed mattress.
- If desired, use a mattress base, then you can place it onto the slatted bed frame (optional accessory).
- If used outside Germany, the national regulations pertaining to medical devices should be observed.
- The cover should not be exposed to direct sunlight for long periods of time. UV radiation shortens the lifespan of the polyurethane.

18. System failure / notes for the user

Error	Possible cause	corrective
Bottom out	The alternating pressure mattress is not or insufficient ventilated.	Inform your specialist dealer.
	Leak	
	CPR-valve open	Close CPR-valve
	The main connection tube is not connected	Connect main connection tube
System failure	No power supply	Establish the power supply / Check house fuse
	Device is off	Turn device on
	Power cord is not properly connected	Connect power cord Connect power cord
	Plug is not inserted correctly	Insert plug

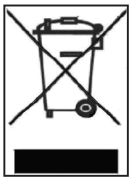
If these measures are unsuccessful, contact the relevant supplier or operator. Never try to repair the system yourself. Fuses may only be replaced by qualified and authorised personnel. In the event of any damage, remove the plug.

19. Environmental conditions

Storage	
Temperature:	0 °C to + 50 °C
Relative humidity:	30 % to 75 % at 30 °C – non-condensing
Air pressure:	795 to 1,060 hPa
Operation	
Temperature:	5 °C to + 40 °C
Relative humidity:	30 % to 75 % at 30 °C – non-condensing
Air pressure:	700 to 1,060 hPa
Transport	Do not drop the compressor or damage the housing during dismantling or transport. Avoid using any damaged compressors.

20. Technical data

Control unit		Cells	
Weight	1.7 kg	Dimensions	88 x 11 x 13 cm
Dimensions	28 x 15 x 10 cm	Material	Nylon / TPU
Length of power cord	4.5 m	Max. inflation pressure:	w/o weight 30 – 60 mm Hg
Electrical ratings	AC 220-240 V/ 50-60 Hz. Max. 0.2 A	Cycle	10 min
Fuses	T1AH 250 VAC 1A	Acceptable patient weight	20 - 160 kg
Protection class	Typ BF / Class II		
		Three cells located at the head end are static. Please note that when using a safety mattress, the total height increases by the height of the safety mattress.	
Mattress			
Weight	3.8 kg		
Dimensions	200 x 88 x 13 cm		
Material (cover)	48 % Polyurethane 52 % Polyester		



21. Maintenance / inspection

The novacare® Smartline plus 5 is considered to be a medical device according to Directive 93/42/EEC and the German Medical Devices Act (MPG). These statutory regulations should be observed during use.
The system is suitable for repeated use. However, the hygiene regulations (see Section 22 and 23) must be observed and it must be ensured that the system is in proper working order.

In order to maintain functionality of the novacare® Smartline plus 5, regular maintenance and safety inspections must be carried out. This does not apply to any safety tests carried out in accordance with DGUV Regulation 3.

Maintenance/inspections are carried out by the manufacturer or by a contractor authorised by the manufacturer and are subject to a charge.

If maintenance / inspections are carried out late or not at all, or are performed by an unauthorised agent, then any claims made under the warranty or guarantee are no longer valid. Any damages or other loss of function arising from lack of maintenance or untimely maintenance / inspection or intervention by an unauthorised agency likewise leads to loss of warranty and guarantee/liability claims (see Warranty).

The following measures are to be implemented during maintenance / inspection:

- Replace air chamber set with membrane
- Replace the timing motor
- Conduct function test / function inspection
- Sealing of the case and attachment of an inspection sticker
- Test according to EN 62353
- Safety inspection

Maintenance and inspections undertaken by the service department of novacare gmbh are recorded and documented.

The year of manufacture is determined by the first two didgets of the serial number.

22. Hygiene

For application at domestic location:
The removable wraparound cover of novacare® Smartline plus 5 Alternating Pressure System can be machine washed up to 95 °C with commercial detergents. The alternating pressure mattress and wraparound cover can be cleaned with commercial detergents and disinfectants. For this, use a soft cloth and no abrasive detergents.

Do not use any agents containing phenol or diethylene glycol monoethyl ether.

Change of patient:
If there is a change of patient or the system is reused, then it must be prepared in accordance with the recommendation of the Robert Koch Institute on hospital hygiene and infection prevention and the „Recommendations for preparing medical devices“, and all other relevant regulations must be observed. Please observe the provisions of the National Medical Devices Act and its ordinances or the appropriate national legislation. If any validated procedures and hygiene schedules are already in place, then these must be applied during preparation.

When disinfecting the products, observe the list of disinfectants and the recommendations of the RKI (Robert Koch Institute) or other valid regulations and use only the products listed or approved therein. Follow the instructions provided by the respective manufacturer of any preparation used; Obtain confirmation from the manufacturer of the disinfectant that it will not attack the materials used in the system.

Do not use any agents containing phenol or the substance diethylene glycol monoethyl ether.

Warranty and guarantee claims become null and void if inappropriate and unlisted preparations are used or if preparations are used incorrectly. We recommend you use our equipment inspection and/or service check.

23. Preparation by qualified personnel

All service work, repairs and inspections must be carried out by trained and qualified personnel.

The wrap-around protective cover of the novacare® Smartline plus 5 can be cleaned in a machine using a chemical/thermal process up to 95° C. For the cells, we recommend wiping with a disinfectant. In order to prolong their service life, do not put the cells in a washing machine. In certain cases, however, chemical/thermal cleaning is also possible.

Wiping with a disinfectant:
The surface on which the patient lies should be disinfected regularly and always after cleaning. By preference, use a wipe-on disinfectant. Follow the instructions issued by the manufacturer of the disinfectant or seek advice from the relevant nursing staff or suppliers.
In special or urgent cases, for example for incidental cleaning in the event of heavy soiling during use, an alcohol based wipe-on disinfectant may be used. This does not replace the validated process described in the RKI hygiene recommendations and should only be carried out in special cases.

24. Safety

- Test according to EN 60601-1-2
- Test according to 60601-1
- Test according to 60601-1-11
- BS EN 597-1, BS EN 597-2 (cells)
- BS7175 (cover)
- Power failure alarm visual & audiable
- Low pressure alarm Visual & audiable
- CPR emergency valve

25. Toxicological safety and biocompatibility (fulfilment of standards)

ISO 10993-5

26. Disposal

Mattress / overlay:
The materials used in the mattresses/overlays are not harmful to the environment. They can be disposed of as domestic waste. Preferably, they should be disposed of at the appropriate official refuse incineration plant.

Control units:
The control units are electrical waste. They should be disposed of via the appropriate waste management centre.

Electrical devices from novacare gmbh are registered (see symbol)
WEEE – Reg. No. DE – 89 403 200

The batteries contained in the system from novacare gmbh are registered (see symbol)
GRS contract number 109101377

Ni-MH battery

27. Explanation of symbols

Follow the operating instructions! (see label)

The CE marking indicates that all standards relevant to the product and all EU directives are complied with. (see operating instructions and packaging)

Control unit:

Insulated housing Class II,protection against electric shock (see technical data)

Caution! The device and battery must not be disposed of as house-hold waste! (see operating instructions)

Application part Type BF - protection against electric shock (see technical data)

Matress cover:

Manufacturer novacare® gmbh, 67098 Bad Dürkheim, Germany (see label)

Maximum washing temperature 95 °C

Do not bleach

Tumbler drying possible
Low temperature, maximum starting temperature 60 °C

Do not iron

Professional chemical purification regular process

Lot number

28. EMC

Electromagnetic radiation can cause electrical devices to interfere with one another. We recommend a safety distance of at least 1 metre, especially for sensitive equipment.

Guidelines and MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC RADIATION for all ME DEVICES and ME SYSTEMS which are not LIFE SUPPORTING.

Guidance and Manufacturer's Declaration - Electromagnetic emissions		
The Smartline plus 5 is intended for use in the electromagnetic environment specified below. The customer or the user of the the Smartline plus 5 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Smartline plus 5 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR11	Class B	The Smartline plus 5 is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions lEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions lEC 61000-3-3	Complies	

Guidance & Declaration — Electromagnetic immunity			
The Smartline plus 5 is intended for use in the electromagnetic environment as specified below. The customer or the user of the Smartline plus 5 should assure that It is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) lEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge lEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smartline plus 5 require continued operation during power mains interruptions, it is recommended that the Smartline plus 5 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field lEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The Smartline plus 5 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Smartline plus 5 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF lEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the model Smartline plus 5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[3,5/V_1]\times P^{1/2}$
	6 Vrms in and amateur radio bands	6 Vrms in and amateur radio bands	

Guidance & Declaration - Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7GHz	d=1.2×P$^{1/2}$ 80 MHz to 800 MHz d=2.3×P$^{1/2}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	**385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)**	

NOTE 1 At 80 MHz and 800 MHz. the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smartline plus 5 are used exceeds the applicable RF compliance level above, the Smartline plus 5 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the the Smartline plus 5.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Smartline plus 5

The Smartline plus 5 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the Smartline plus 5 help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the the Smartline plus 5 is recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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

29. Warranty

- The warranty is based on statutory regulations and is valid for 24 months from transfer of ownership.
- Every warranty is deemed void if the goods supplied by us are processed, handled or modified by another party without our consent or if our operating instructions and prescribed maintenance intervals are not followed. If the seals are damaged, it will be assumed that such improper handling has taken place.
- For medical devices as understood by Directive 93/42/EEC whose usage (National Medical Devices Act) is subject to regular service and maintenance, a warranty can only be given if the service intervals prescribed by the manufacturer are adhered to.
- As far as warranty claims are accepted and if during the subsequent inspection it is found that the damages are a result of wear and tear or are not subject to warranty, then we are entitled to claim the expenses incurred (inspection, transport costs, etc.) from the buyer.
- The provisions of the National Medical Devices Act and the National Medical Devices Operator Ordinance must be observed.
- The use of parts or individual components of other systems, other makes or combinations thereof is not permissible. Any damages arising therefrom invalidate all warranty claims and costs must be borne by the user.
- We offer a guarantee on every alternating pressure system in the Smartline series, covering defects occurring within 24 months of purchase and arising from faults in manufacturing and/or materials. This guarantee covers repair or (if repair is impossible) replacement, free of charge.
- The guarantee will not apply where the defect in the device is due to inappropriate use and/or use outside the device's intended purpose or contrary to regulations contained in these instructions for use.
- We will not be liable for damage or faults arising from fair wear and tear or during transportation.
- Replacement of wear parts is not included in the guarantee.
- The guarantee on batteries is six months.

30. General information

The novacare® Smartline plus 5 is a medical aid. It is supplied by novacare® gmbh primarily to medical specialists (medical nursing staff, medical stockists, operators, medical institutions, social institutions, etc.) and to professional users.

Specialists and professional users include persons who by virtue of their medical or other equivalent training possess suitable knowledge of the condition to be treated with the system and its prevention, in order to enable the patient and the nonprofessional user or medical layperson to use the alternating pressure system properly.

Installation and set-up of the system at the patient's home and handover and instructions for the non-professional user or medical layperson should be carried out by medical specialists.
These steps shall all be carried out in accordance with the usual obligation to provide instructions, e.g. description of the functions, explanation of the controls, cleaning and operation of the system, and information about potential risks.

It is possible for non-professional users or medical laypeople to operate the system, but not without adequate instruction.

31. Scope of supply

Control unit novacare® Smartline plus 5
Alternating pressure overlay system
Operating Instructions

32. Name / item No

Name: Novacare® Smartline plus 5
Item No.: 996600 UK / 996600

33. Notes

novacare® gmbh
ISO CERTIFIED
DIN EN ISO 13485
CE

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AH 11 V2 · Instructions for use

novacare