You have purchased the novacare® Smartmove wheelchair cushion, a product for the treatment and prevention of pressure ulcers.

A good decision.
Your novacare® – Team

Please read the following instructions carefully and observe the warning instructions before using the system.
Table of contents:

1. The System / Area of application  page 4
2. Severity of decubitus / Pressure sores  page 4
3. Safety before use  page 4
4. Maximum load / Patient weight  page 4
5. Indication / Contraindication  page 5
6. Unpacking and disposal of packing material  page 5
7. Preparation before use  page 5
8. Caution  page 8
9. Static mode / Alter mode  page 8
10. Alarm function  page 8
11. Pressure check  page 8
12. Maintenance / Inspection  page 9
13. Storage after use / Repackaging  page 9
14. Surrounding conditions  page 9
15. Classification of information  page 10
16. Combination with other products  page 10
17. Hygiene  page 10
18. Care, cleaning, disinfection  page 11
19. Safety Tests  page 11
20. EMC  page 11
21. Technical data  page 12
22. Disposal  page 12
23. Warranty  page 12
24. Warning notice for private, non-professional operators  page 13
25. Box contents  page 13
26. Identification / item no.  page 13
27. Explanation of symbols  page 14
28. Declaration of conformity  page 15
1. The System / Area of application

The novacare® Smartmove wheelchair cushion is a cushion for the use on wheelchairs as well as on normal chairs. It features a digital control unit and an foam-molded seat cushion, which can be vented alternatively and is made up of 6 TPU cells.

The cells are protected by a bi-elastic and waterproof but steam-permeable PU cover with an all-around zipper.

2. Severity of decubitus / Pressure sore

The novacare® Smartmove wheelchair cushion is recommended to be used for decubitus / pressure ulcers I – III (high risk). They are recommended to be used to prevent pressure ulcers in a sitting position.

3. Safety measures before use

Please read the operating instructions carefully before use, to prevent damage to the system or endangerment of patient and operator. Observe the warning notices! Use only as described in the operating instructions.

Keep the manual on hand so that the particular user or a possible new owner can access it at any time if needed.

novacare® gmbh does not assume liability for the use of the cushion if the applications described in this manual are not being met.

- All parts must be used as intended and should never be changed or modified.
- Make sure the batteries are charged 12 hours before first use to ensure proper function and a long life span.
- The adjustments should only be made by assigned personnel
- Pay attention to skin changes, ask your doctor if necessary.
- In general, the rules of the medical product act and the medical product manufacturing regulations are to be followed.

4. Maximum load / Patient weight

The novacare® Smartmove wheelchair cushion is recommended for patients weighing up to 130kg.
## 5. Indication / Contraindications

| Indication: | Treatment and prevention of pressure ulcer and decubitus. The system should be used according to the care plan. |
| Static mode: | Pain or pain (pressure)-sensitive patients require system operation static mode. |
| Contraindication: | Alternating pressure should not be applied to pain or pain-sensitive patients. Patients with neurological problems or lack of body awareness require an indication for use from their attending physician. In these cases the static mode setting is recommended as well as other suitable foam overlays or other materials which can be found in ample supply in the novacare® product range. The novacare® Smartmove wheelchair cushion should not be used if there is an allergic reaction present. |

## 6. Unpacking and disposal of packing material

Please inspect upon delivery the product and the packaging for damage. Use the original packaging should the novacare® Smartmove wheelchair cushion be transported after use. If not, dispose in accordance with national waste management regulations.

## 7. Preparation before use

1. Remove any other cushions from the chair.
2. Take the novacare® Smartmove wheelchair cushion out of the box and place it into the chair. The blue cover surface on top and the novacare® logo in the front.
3. Take the control unit out of the box and open the battery cover (pic.1) located on the back of the unit and connect the battery cables (pic. 2). Close the cover when done.
4. Choose the right adapter for your region (EU/UK) and attach it to the plug (pic 3).

5. Attach control unit to the power cord (pic. 4).

6. Attach air hoses to the control unit (pic 5).
7. Insert the power plug into an outlet of appropriate voltage. The unit is now charging and can be used during this time also. Charging is complete when the LED light ‘charging’ turns off.

8. Switch on the pump by pressing the ‘power’ button (pic 6) until you hear a beeping sound.

9. Choose between static and alternating mode (pic 8) by pressing the “Alter/Static” button.

10. While in alternating mode the cycle time (5 min / 10 min) can be changed by pressing the therefor shown button (pic 7) on the display of the pump.

11. The novacare® Smartmove wheelchair cushion can now be used.

12. The pressure/comfort can be adjusted (pic 9) by choosing the right pressure mode. (soft/medium/firm).

13. Place the pump into the carry bag and attach it to the handlebar of the wheelchair in the back.
8. Caution

- Protect control unit from humidity and direct wetness
- Keep tubes free of bends
- Do not use system in the immediate proximity of a heat source.
- Never pull the cord.
- Sharp objects must be kept away.
- Do not operate system in the immediate proximity of flammable gases (risk of explosion)
- Repairs should only be performed by authorized personnel and using original replacement parts.

9. Static mode / Alternating mode

Set the system to static mode by pressing the “alter/static” (pic 8) button. The LED “Static” lights up. All cells are vented with the same pressure. The alternating mode is overridden.

Set the system to alter mode by pressing the “alter/static” button (pic 8). The LED “Alter” lights up. Choose between 5 min or 10 min cycle time by pressing the button (pic 7).

10. Alarm function

The novacare® Smartmove wheelchair cushion is equipped with a visual and acoustic low pressure alarm system. The alarm will activate in case the pillow is wrongly connected or in case of leaking.

Deactivate audible alarm
Once the acoustic alarm has been activated, deactivate it by pushing the “Low pressure” button (pic 10).

11. Manual check

An ideal and correct setting permits the insertion of a hand between patient and a low pressure cell without any problems.
12. Maintenance / Inspection

The novacare® Smartmove wheelchair cushion is a medical product in accordance with RL 93/42/EWG. Use and applications are subject to these legal foundations.

Systems are suitable for reuse. However, hygiene directives must be observed (topic 17 & 18) and flawless operation must be ensured.

Maintenance at regular intervals (mandatory every 2 years) is necessary to preserve the function of the novacare® Smartmove wheelchair cushion.

Maintenance / inspection is conducted by the producer or a firm authorized by the producer at the client’s expense.

If maintenance / inspection is not conducted at all or in due time or not by an authorized firm, the guarantee or warranty claims are no longer valid. Damages or any other loss of function arising from lack of maintenance or untimely maintenance / inspection or interferences by an unauthorized party, likewise lead to loss of guarantee and warranty claims (see warranty).

Maintenance / inspection carried out by the novacare service department is recorded and documented.

13. Storage after use

Store the novacare® Smartmove wheelchair cushion always indoors. Make sure that water cannot penetrate the electric parts. The novacare® Smartmove is best stored in its original packaging. Before next use, recharge the batteries.

14. Surrounding condition

Storage:
Temperature -10 °C to +40 °C
Humidity 20 % to 90 % at 30 °C – non-condensing
Pressure 700 to 1060 hPa

Operation:
Temperature +10 °C to +40 °C
Humidity 20 % to 90 % at 30 °C – non-condensing
Pressure 700 to 1060 hPa

Transport: Don’t subject the cushion to bumps or shocks.
Don’t use a damaged cushion.
15. Classification of Information

The novacare® Smartmove systems are medical care products. They are sold by novacare gmbh primarily to medical experts (care-taking personnel, specialized medical dealers, users, medical facilities, etc.) and put at the disposal of professional users. Experts and professional users are defined as persons who, based on their medical or comparable training, have sufficient knowledge about the condition intended to be treated with the system or its prevention, in order to enable the patient and/or the non-professional user and medical layman to sufficiently operate the alternating pressure (pressure care) system.

Installation and system set up at the patient’s as well as putting into service and instruction of the non-professional user or the medical layman respectively are carried out by medical experts.

These are to be carried out within the scope of the usual instruction obligations, for example the description of functions, explanation of operating features, as well as cleaning and system effectiveness, and the indication of potential risks.

Operation by non-professional users or medical laymen is possible but should not be implemented without sufficient instructions.

Special training concerning function and operation of the system are not necessary but can be offered upon request.

16. Combination with other products

The novacare® Smartmove can also be used with the control unit of the novacare® Smartline 1 pressure system.

17. Hygiene

Systems designed for reuse must be prepared on the basis of locally valid directive, laws or regulations “for Hospital hygiene and Infection prevention“.

Already validated procedures and hygiene schedules, if any, must be applied for this preparation.

Please act according to your locally valid hygiene directives and the respective list of disinfectants for disinfecting the products and use only disinfectants listed in them. Follow the instructions for use prescribed by the respective manufacturer.

Guarantee claims become null and void if inappropriate and unlisted preparations are used or are used inappropriately.

We recommend our cleaning service. Prices applicable from time to time are mentioned in the valid service price list.

**Do not use any phenolhaltigen Mittel or such that consist of Diethylene Glycol Monoethyl Ether. The cover will be damaged.**
18. Care, cleaning, disinfection

The novacare® Smartmoves all-around protective cover can be cleaned chemical-thermally by machine up to 60°. For disinfection we recommend the use of an approved disinfection cleaning additive. To increase the life span, clean cells by spray/wipe disinfection. In special cases chemical-thermal cleaning is possible as well.

Please ensure that the cell body opening is shut when cleaned by machine.

For use, follow the recommendations of the respective manufacturer.

This measure might not replace hygiene regulations currently valid in your country and should be applied only in special cases (i.e. interim cleaning of acute contamination during applications).

19. Safety tests

- Testing in accordance CE EMC DIN EN 60601-1-2-2007
- California – fire test class 1 (cover)
- Fire test according to DIN EN 597/1 and DIN EN 597/2(cells)
- Audible low pressure alarm
- Optical low pressure alarm
- DIN EN ISO 10993-1:1998
- ASTM F 963-96a

20. EMC

Electric devices may interact due to electro-magnetic radiation. We recommend a safety distance of at least 1 meter distance especially for sensitive equipment.

Upon request we will provide you with a table for more detailed information.
21. Technical data

- **Control unit:**
  - Weight: 1.6 kg
  - Dimension: 19 x 9.5 x 6 cm
  - Length power cord: 1.5 m
  - Rated speed: AC 100-240 V / 50-60 Hz
  - Max. 0.4 A
  - Protection class: Type BF / Class II
  - Battery type: Lipo 11.1V, 4300mAh

- **Cushion:**
  - Weight: 1.3 kg
  - Dims (w/o base): 44 x 45 x 8 cm
  - Material (cover): PU / Polyester

- **Cells:**
  - Dims: 38 cm wide / 6 cm (6 inch) Ø
  - Material: TPU

- **Cycle:**
  - 5/10 minutes

22. Waste Disposal

**Pillow**

The materials used do not pose any danger for the environment. They may be disposed with the household waste. Disposal via official waste incineration is preferred.

**Control units**

Control units are considered electric waste. Please contact the proper waste disposal officials.

Novacare gmbh electric equipment is registered (see symbol)

**WEEE – Reg.- No. DE – 89 403 200**

23. Warranty

- The warranty is based on statutory regulations.
- Furthermore a warranty is ruled out, if the goods supplied by us are processed, handled or modified by other parties without our consent or if our operating instructions are not followed. If the seals are damaged, it will be assumed that the aforesaid activities have been carried out.
- For medical devices as understood by the EU-Directive 93/42, whose usage (also operations) is subject to regular service and maintenance, a warranty can be offered only if the service intervals prescribed by the manufacturer are adhered to.
- As far as warranty claims are asserted and if during the subsequent inspection it is found that the damages are of wear and tear or are not subject to warranty, we are empowered to claim the expenses (inspection, transport costs etc.) from the client.
• The use of parts or individual components of other systems or products or combinations thereof are not permissible. Warranty claims cease to exist for any damage resulting from this, which must be borne by the user.

24. Warning notice for private, non-professional operators

In case of system failure check:
• Is the unit turned on?
• Is the power cord connected properly and is the power plug inserted correctly into the socket?
• Is the connection tube connected properly?
• Is one or more air cells defect
• If this measure fails to be successful contact the responsible supplier or user (authority responsible for the use and maintenance of the equipment).
• Never attempt to repair the system yourself. Fuses may only be exchanged by qualified and authorized personnel.
• In case of damage pull the power plug and contact service personnel.

25. Box contents

• novacare® Smartmove control unit
• novacare® Smartmove seat cushion
• Adapter
• Operating instructions

26. Identification / Item no.

• Identification : novacare® Smartmove System
• Item no.: 996900 (with battery) 
  996950 (with SL 1 control unit)
### 27. Explanations of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schutzisoliertes Gehäuse Klasse II, Schutzart gegen elektrischen Schlag. (siehe Technische Daten)</td>
<td></td>
</tr>
<tr>
<td>Beachten Sie die Gebrauchsanweisung! (siehe Lifter-Etikett)</td>
<td></td>
</tr>
<tr>
<td>Achtung! Das Gerät und die Batterie dürfen nicht mit dem Hausmüll entsorgt werden! (siehe Gebrauchsanweisung)</td>
<td></td>
</tr>
<tr>
<td>Anwendungsteil Typ BF - Schutzgrad gegen elektrischen Schlag. (siehe Technische Daten)</td>
<td></td>
</tr>
<tr>
<td>Wechselstrom</td>
<td></td>
</tr>
<tr>
<td>Achtung! Warnhinweise beachten! (siehe Gebrauchsanweisung)</td>
<td></td>
</tr>
<tr>
<td>Hersteller novacare® gmbh, 67098 Bad Dürkheim, Germany (siehe Etikett)</td>
<td></td>
</tr>
<tr>
<td>Gebrauchsanweisung befolgen! (siehe Etikett)</td>
<td></td>
</tr>
<tr>
<td>IPXX</td>
<td>Schutzart gegen das Eindringen von Wasser.</td>
</tr>
<tr>
<td>Gibt den Temperaturbereich an, in dem das Gerät betrieben oder gelagert werden kann.</td>
<td></td>
</tr>
<tr>
<td>Gibt an, dass das Gerät vor Feuchtigkeit geschützt werden soll.</td>
<td></td>
</tr>
</tbody>
</table>
KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

novacare® gmbh
Bruchstrasse 48
D-67098 Bad Dürkheim
Deutschland / Germany

Wir erklären in alleiniger Verantwortung, dass das/die nachstehend aufgeführte/n Produkt/e den „einschlägigen Bestimmungen“ der RL 93/42/EWG, Anhang I, entsprechen.

Das Konformitätsbewertungsverfahren wurde gemäß Anhang VII durchgeführt.

We declare under our sole responsibility that the product(s) meet(s) all the relevant provisions of the MDD 93/42/EEC, annex I.

The conformity assessment procedure was carried out in accordance with annex VII.

Das/die Produkt/e sind nach Anhang IX, Regel 12, RL 93/42/EWG, klassifiziert und der Klasse - I - zugeordnet

The product(s) has been classified in accordance with annex IX, rule 12, MDD 93/42/EEC and categorized as class - I -.

Produkt: novacare® Smartmove

Bad Dürkheim: ........................................
Joachim Köhm
CE-Bevollmächtigter /
MP - Sicherheitsbeauftragter
MDD – Safety Officer