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Medical

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# USER MANUAL NAUSIFLOW 2S PUMP


Very high prevention
Alternating and static modes
Mechanical pressure management
Weight capacity: 130 kg
Class 1 medical device

# Contents

## USER MANUAL / PRESSURE CARE SYSTEMS: NAUSIFLOW 2S PUMP

# Introduction

PACKAGE CONTENT
- 1 pump
- 1 power cable
- 1 user manual

OPERATING PRINCIPLES:
Alternating mode:
- The system performs a regular and alternating discharge of each area of the body in contact with the support.
- This alternating pressure avoids a prolonged pressure at the same area, source of pressure ulcers, and stimulates the vasodilator reflex.

Static mode:
- The patient immersion in the support reduces pressure (continuous low pressure) and increases comfort.
- The patient penetrates into the support thus increasing its contact surface.

Low pressure:
- The system restores the lowest interface pressures allowing maximum distribution of the patient weight.
- It is obtained by increasing the positive pressure of the contact surface.
- It depends of the mode used, of the patient position and of the deformation capacity of the cells.

INFORMATIONS:
This care system is primarily intended for high-risk patients (score 5-9 on the NORTON scale - score below 12 on the BRADEN scale), or for patients suffering from pressure ulcers up to stage 3.

Risk factors are related to the patient condition: age, poor skin condition, neurological diseases, complications (intercurrent diseases), incontinence and nutritional status.

CONTRAINDICATIONS:
- The system is not indicated in some cases such as an unstable fracture of the vertebrae.
- Using the system does not exempt from regular repositioning and nursing of the patient by the medical staff.

# Specifications

| |
|---|
| Alternating mode |
| Static mode / low pressure |
| Standard pressure setting |
| Self management of seating positions |
| Visual and audible alarm |
| Power supply 230 V / 50 Hz |
| Fuse T1A / 250V |
| Class 2 type BF |
| CE certificate of conformity |
| 3 years warranty against manufacturing defects |
| Lifespan: 3 years |

CE

Environmental conditions of use and storage:
- Temperature: 5°C - 45°C
- Humidity: 15% - 60%

Electrical Classification:
- Class II Type B, double insulation with or without ground wire.
- IPX0, do not immerse the pump in a liquid, do not spray liquid directly on the pump.
- This pump is not protected AP / APG (AP = flammable anesthetics in the air), (APG = flammable anesthetics with oxygen or nitrous oxide).

Standards: EN 60601-1, EN 60601-1-2, EN 61000-3-2, EN 61000-3-3, UL-2601-1

Electromagnetic compatibility: EN 60601-1-2: 1993

Consumption: in normal use, max 12 W

Power Cable: H05VV-F3x0.75mm²

This product complies with the requirements for the safety and health of the Directive 93/42/EC concerning medical devices and the basic requirements of Directive 86/336/EC on electromagnetic compatibility.

# Safety

SECURITY PROVISIONS:
- To ensure proper use, check that everything is properly installed and secured. Do not put anything on the pump. Be sure that the power cable is located under the bed frame of the mattress and risks nothing.
- Do not use the system near unprotected flames, lighters or cigarettes. There is a fire hazard. The unit draws the surrounding air and therefore, cigarette smoke may damage the internal components.
- This system must be carefully decontaminated between patients to prevent contamination.
- Verify that the patient's weight is not above the allowed weight for the bed, the bedrails and this system.

SAFETY INSTRUCTIONS:
- Use this system with the appropriate bedrails to ensure that the space between the bedrail and the top of the mattress is sufficient to prevent the patient from introducing his head in this space. Not to ensure that could lead to a serious injury of the patient.
- Do not open the pump if you are not trained or authorized to do so. Contact your local distributor.
- This product does not have AP / APG protection (against explosive gas).
- Environmental conditions of use and storage: Temperature: 5°C - 45°C / Humidity: 15% - 60%

• Under conditions of good maintenance, a NAUSIFLOW 2S pump has a lifespan of at least three years.
• In case of destruction, do not burn or discard in the environment, please follow the law.

# Installation

WARNING: check the good state of the electrical installation (wires, plugs and fuses). If the slightest alteration (wear, shearing and deterioration) is detected, immediately replace the questionable element or postpone installation.
It is imperative to check the cleanliness of the air filter and to clean it or change it once a month to ensure optimal operation of the pump.

- Remove the existing mattress from the bed.
- Position the new mattress with air connections pointing toward the footboard.
- Fix the mattress by bordering the elastic flap.
- Check for proper functioning of the bed before proceeding to the next step.
- Position the pump on the panel at the footboard and make sure of the correct fixation.
- Check that the CPR of the mattress is closed.
- Connect the hoses of the mattress to the pump with the connectors.
- Cover the mattress with its cover by a sheet as thin as possible.


CAUTION: Bordering the sheet too tight reduces the efficiency of the system.

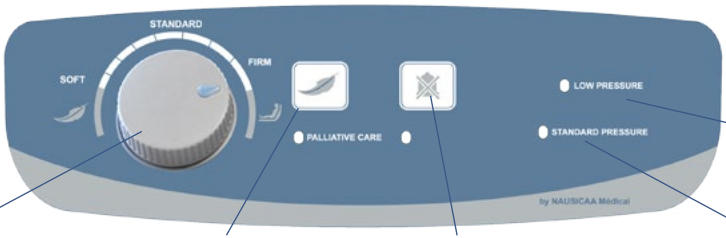
- Connect the pump to the power sector (220V-50Hz grounded outlet).
- Switch on the pump (side green button 0/I)
- The LED (low pressure warning) will first flash in red until the required pressure is not reached.
- During the inflation phase, disable the audible alarm by using the «stop alarm» button.
- Turn the pressure adjustment button in the manner shown on the side to allow faster inflation.


CAUTION: During inflation (about 15 minutes), do not lie down the patient on the sys-

- When the pressure is reached, the «normal pressure» LED (required pressure indicator) turns green. Reactivate the audible alarm by using the «stop alarm» button.
- Turn the adjustment button to the middle position.
- Lie down the patient on the system.


CAUTION: This pressure is approximate and depends on the patient's morphology.
You must check the optimal pressure (see page 7).

# Instruction




Low pressure indicator

Pressure setting

Palliative care

Alarm stop button

Normal pressure indicator

Power switch:
Turns the pump on and off

Alarm stop button:
This button turns off the alarm tone.
Each modification or selection (settings or functions) is indicated by a BEEP sound.


Normal pressure indicator:
It is displayed when the required pressure is reached


Low pressure indicator:
When insufficient pressure is detected, the indicator lights up and the audible alarm sounds.


Palliative care mode:
Activates the static mode


Pressure setting:
Ability to manually adjust the pressure to optimize patient comfort

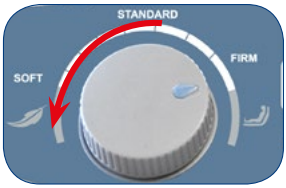
# Optimal Pressure

• Caregivers should always check the optimal pressure setting by using the following process:

- Wait until a chamber system is deflated and insert your hand flat between the heaviest part of the patient's body (usually the buttocks) and one of the deflated cells.

- The goal is to make the patient rest exclusively on the alternating pressure system to provide maximum prophylaxis.

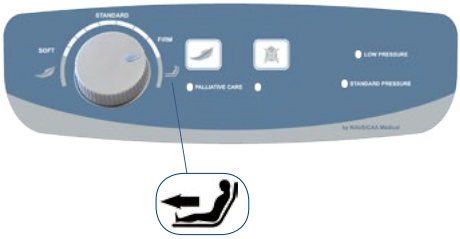
• If the hand can not be inserted: the pressure is too low. Increase it.
• If the hand can be inserted without resistance: the pressure is too strong. Reduce it.
• If the hand may be inserted with a slight resistance, the patient is lying optimally.


• If the patient's bust has been raised to more than 30° in alternating mode and the patient is heavy, there is a risk of crushing the mattress cell below the sacrum when the latter is deflated.

• To avoid this, position the weight/pressure setting on the sitting position.

CAUTION:
When returning to a position where the bust goes up to less than 30°, it is very important to put the pressure setting on its previous position.



# Warnings

• Alarm trigger in alternating mode:

WARNING: When the device is on, if the LED flashes in red and a beep «sounds off», the alarm warns of a low pressure malfunction. You must check the optimal pressure (see page 7).

• The triggering of an alarm can be generated by:
- The patient has just been moved: the alarm went off because there were movements of oscillation in the system. There is nothing to do.

• Leakage in the mattress or in the air hoses:
1) Check the connection of the air hoses to the pump.
2) Open the cover and check the connections of the air hoses and cells.
3) Check that the deflation caps are in place.
4) Once the points 1, 2 and 3 checked and/or repaired, if another alarm trigger occurs, it means that an air hose or a cell is pierced. Find the leak and repair it.

• Turning off the alarm: Press the «stop alarm» button. The beep sound is interrupted and the button lights.

# Cleaning & Maintenance

• DAILY MAINTENANCE:
- Who? Personal of the using service.
- What? Cleaning of the cover on a daily basis and after every defilement.
- With what? Detergent disinfectant, diluted at 1 dose per 5 litters of water.
- How? Wear gloves and eye protection, take a single use paper (cellulose wadding type) and soak it with the detergent disinfectant. Rub the entire cover in contact with the patient and check the integrity of the cover (a hole or a gap should cause an immediate change of the cover or a mattress change). Repeat the process if necessary.

• COVER WASHING: in a washing machine, up to 95°C.

• MAINTENANCE BETWEEN 2 PATIENTS:
- Who? Personal of the using service.
- What? Cleaning and disinfection of the mattress cover before storing it.
- With what? Detergent disinfectant, diluted at 1 dose per 5 litters of water – ready to use disinfectant spray.
- How? Wear gloves and eye protection for the entire procedure of cleaning and disinfection.

• CLEANING PROCEDURE:
1. Verify the integrity of the mattress cover (if it is damaged, exchange it with a new one), take a single use paper (cellulose wadding type) and impregnate it with detergent disinfectant. Rub the entire surface of the mattress cover, pass a humidified paper with detergent disinfectant on the pump (do not use a too soaked paper and do not spray, otherwise there is a risk of damaging the electrical connections). Wipe with a clean and dry cellulose wadding paper.
2. Disinfection procedure: take a disinfectant spray and apply it to the entire surface of the cover. Let it dry and protect the result of the disinfection operations with a sheet.
3. Mattress:
- PHASE 1: Using a disinfectant spray, pulverize the cells and the mattress.
- PHASE 2: Using a slightly humid sponge, clean the cells and the mattress.
Rinse with a slightly humid sponge and wipe.
- PHASE 3: with a spraying decontamination product, reprocess the cells and the mattress.

• PREVENTIVE MAINTENANCE:
- Check that there aren't any abrasions on the electrical outlet and on the plug, due to excessive use.
- Check that the mattress cover is not worn or damaged.
- Check the air hoses to see if there are wrinkles or cuts.
- Check the connectors between the mattress and the pump.

# Spare Parts

| REFERENCES | DESIGNATIONS |
|---|---|
| NAUS-CP-FAC | HOUSING FRONT |
| NAUS-CP-VARP | PRESSURE DIMMER AVEC SETTING BUTTON |
| NAUS-CP-PAN | REAR HOUSING |
| NAUS-CP-CRC | HANGERS (by pair, right and left) |
| SAN-2S-CP-CA | DISPLAY AND CONTROL ELECTRONIC BOARD |
| SAN-2S-CP-VM | MOTORIZED VALVE |
| AUF-CP-CNT | PUMP CONNECTOR |
| SAN-2S-CP-CE | ELECTRONIC BOARD |
| SAN-2S-CP-REGP | PRESSURE REGULATOR |
| SAN2-CP-PMP | AIR PUMP |
| SAN2-CP-CRD | POWER CORD |
| SAN2-CP-INT | ON / OFF SWITCH |
| ENT-CP-FUS-1A | TIMED FUSE 5 x 20 / 1A / 250V (by 5) |
| SAN2-CP-FLT-EXT | EXTERNAL AIR FILTER (by 5) |
| NAUS-CP-PFS-BL | FUSEHOLDER BLUE CABLE |
| NAUS-CP-PFS-MR | FUSEHOLDER BROWN CABLE |
| SAN2-CP-CPT-FA | EXTERNAL AIR FILTER COVER |

# Troubleshooting Guide

| Problems | Origins | Solutions |
|---|---|---|
| The pump does not work. | 1. Check the power outlet and its power.<br>2. Check that the internal terminals of the power cord are not disconnected.<br>3. 1 or 2 fuses are out of service. | 1. Change the outlet or restore the power supply.<br>2. Position the power cord.<br>3. Change the fuse or fuses (accessible from the outside). |
| There is little or no air output from the pump. | 1. Out of service pump.<br>2. 50 mbar minimum pressure on max position.<br>3. Check the internal air connections. | 1. Change the pump.<br>2. Set up again the disconnected hoses or change the broken hoses. |
| Clicking noise. | 1. If the noise is slow, the motorized valve is «dry».<br>2. If the noise is fast and weak, it comes from a failure of the valve motor.<br>3. If the noise is fast and strong, it comes from an air pump malfunction. | 1. Remove the valve, clean it with a dry cloth and grease it with silicone grease.<br>2. Change the motorized valve.<br>3. Change the air pump. |

CAUTION:
- This system is not a maintenance-free product. Maintenance and repairs must be made by an authorized person. All systems must be cleaned and disinfected before being returned. Soiled or dirty products will be refused without repair.
- It is imperative to check the cleanliness of the air filter.

# Warranty

• Article 1: NAUSICAA Médical S.A.S. warrants this product against any defects in manufacturing and assembly of mechanical and electronic components. This warranty is for devices used only in accordance with NAUSICAA Médical S.A.S. terms of use.
The warranty covers all mechanical and electrical parts, except filters and breakage.
This warranty whose terms of use are defined below is valid for 36 months from the date of first departure from NAUSICAA Médical S.A.S..

• Article 2: The warranty entitles the free labour and the free replacement of defective parts.

• Article 3: The original out-going shipping costs of the device and all associated costs are the responsibility of the distributor. The goods always travel at the risk and the responsibility of the distributor.
Under warranty: return costs after intervention will be borne by NAUSICAA Médical S.A.S..
Out of warranty: return costs are at the expense of the distributor whether or not he accepts the repair estimate.

• Article 4: The warranty does not apply if the claims are consecutive to:
- accident, misuse or neglect of the unit by the end customer.
- shipping performed without adequate protection.
- alteration or transformation not validated by NAUSICAA Médical S.A.S..
- the impact of external elements (natural disaster, fire, shock, humidity, flood, lightning, ...).
- installation and/or use in a non-compliant way with technical standards and safety (in case the unit would work in a country other than the country of origin) ; and/or if the electrical power is not suited for the operating voltage of the device.
- a lack of routine maintenance.

• Article 5: The distributor may not invoke the benefit of the warranty:
- if the device serial number has been removed, altered or rendered illegible.
- if the device under warranty has been modified without the approval of NAUSICAA Médical S.A.S..

• Article 6: During the repair of any defective equipment, no loan will be made.

• Article 7: All warranty claims must be exercised through the distributor.

• Article 8: Sending spare parts under warranty will be made after consultation with the distributor customer service.

• Article 9: Defective parts changed under or out of warranty will be guaranteed for 6 months from the date of repair or sending of the spare parts.

• Article 10: No distributor can unilaterally change the terms of this warranty.

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