

decuCare®

# user manual

dynamic anti-decubitus hybrid mattress

decu® neo

decu® bariatric



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ver.

CE

# Manufacturer

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**Manufactured in types:**

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**decu® bariatric**

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# 1) Introduction

Dear user,

thank you for purchasing a product from our company decucare®.

The decu® Series Dynamic Anti-Decubitus Hybrid Mattress (hereinafter referred to as "hybrid mattress") consists of an air-foam mattress with cover (hereinafter referred to as "mattress") and an automatic compressor (hereinafter referred to as "compressor"). The functions are based on known mechanisms.

## **Intended purpose**

Hybrid mattresses are designed for patients with limited mobility to prevent the development of decubitus or pressure sores, up to a very high risk, and to support their treatment.

## 2) Basic product information

### 2.1 Service life and usability

The life and service life of the hybrid mattress has been determined by the manufacturer on the basis of the frequency and intensity of use to be 5-10 years, provided that the hybrid mattresses are used in accordance with the instructions for use and regular maintenance, replacement of spare parts as specified in Chapter 13 of these instructions for use and safety and technical inspections are carried out at least once a year.

### 2.2 Classification

According to Annex VIII. Regulation of the European Parliament and of the Council (EU) 2017/745 ("MDR") and taking into account its intended purpose as a non-active therapeutic product for external use only and the associated risks, hybrid mattresses are classified in risk class I, under regulation 13.

According to the criteria for electrical equipment, these are electrical equipment of protection class II, type BF.

### 2.3 Basic UDI-DI

The manufacturer has assigned a basic UDI-DI to hybrid mattresses

**8594218992DAHMF3**

### 2.4 Indications and contraindications

Mode	Indication	Contraindication
Alternative mode	Decubitus prevention and treatment support from high risk (EPUAP level III) to very high risk (EPUAP level IV).	Unstable fractures, limited contraindications with decreased sensitivity, pressure ulcer prevention and treatment.
Static mode	Decubitus prevention and treatment support up to high risk (EPUAP level III). Secondary treatment of pressure ulcers up to very high risk (EPUAP level IV), pain muscle hypertonia.	Unstable fractures, loss of sensitivity.

## 2.5 Nameplate

The hybrid mattress nameplate is located on the side of the compressor.



1. Type of mattress
2. Serial number
3. Date of manufacture in yyyy-mm format (year-month)
4. Catalogue number
5. Information about the manufacturer
6. CE marking to indicate compliance with relevant EU legislation
7. Degree of protection against the ingress of water and foreign objects into the product
8. Protecting equipment with double insulation
9. Protection against electric shock - type BF attachments
10. Warnings about safety information in the instructions
11. Follow the user manual
12. Information on waste management
13. Medical device
14. Applicable voltage
15. UDI code carrier



- A. Datamatrix code
- B. GTIN
- C. Serial number
- D. Date of manufacture

## 2.6 Law and standards

Hybrid mattresses are designed and manufactured in accordance with:

- MDR
- technical standards, in particular EN 60601-1:2006/A2:2021, EN 60601-1-2:2015+A1:2021, IEC 60695-11-10:2013, EN ISO 10993-1:2020 and other standards related to the design and development of medical devices

## 3) Equipment description

### 3.1 Description and principle

Hybrid mattresses are used in home, social, hospital and intensive care settings and are designed for patients with limited mobility to prevent and support the treatment of decubitus or pressure sores, up to a very high risk. They combine different technologies and materials to provide optimal support and relief to the patient's body, thereby minimizing pressure and friction on critical areas of the body that are prone to developing decubitus.

The mattress is made up of many air-foam cells and a polyurethane double-sided elastic waterproof and vapour permeable cover. The cells are filled with air as well as a 12 cm high safety foam core, which, among other things, prevents the patient from sinking to the level of the bed frame in the event of a system failure or long-term transport. All cells have lateral bracing to allow easy standing up and positioning with the patient.

In conjunction with the mattress and compressor, the hybrid mattress can be used in different operating modes. The cells inflate and deflate regularly, minimizing pressure on critical areas of the body such as the shoulder blades, buttocks, spine, hips, heels, etc. This prevents insufficient blood circulation that could lead to decubitus.

The use of hybrid mattresses aims to improve patient comfort, minimise pain and potentially reduce the risk of decubitus.

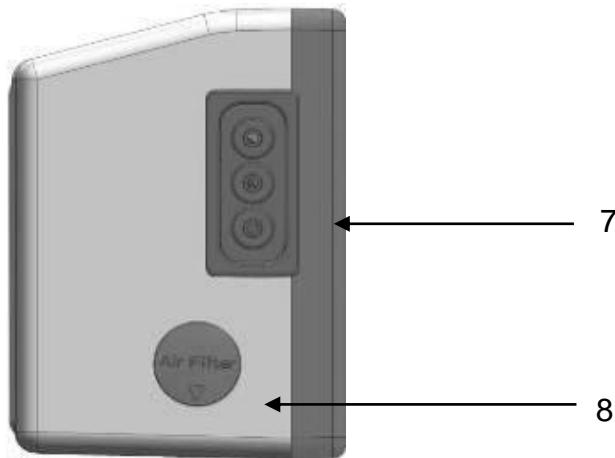
Length of hybrid mattresses: 200 cm

Width of decu® neo: 80 / 90 cm

Width of decu® bariatric: 100 / 120 cm

### 3.2 Compressor description

#### Compressor (picture from the right side)



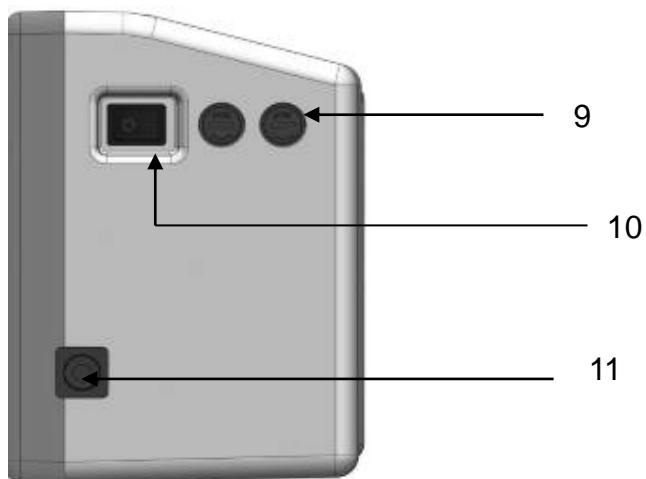
#### 7. Output air connector

Air outlet from compressor with quick connector.

#### 8. Filter

Air filter.

#### Compressor (picture from the left side)



#### 9. Two power fuses

Two separate 250 V, 500 mA fuses.

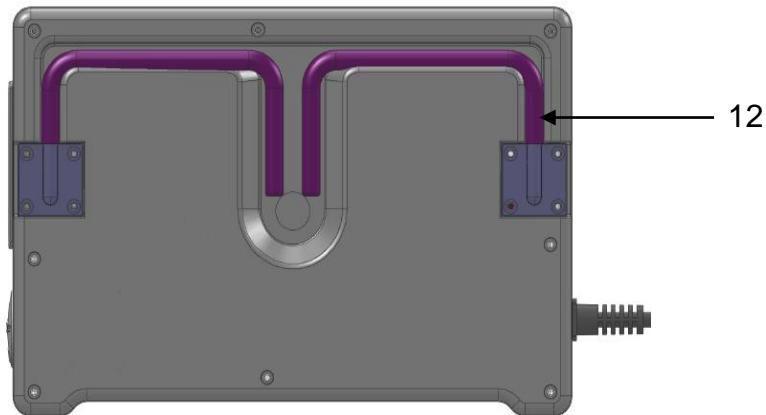
#### 10. Switch

[-] on; [o] off

#### 11. Power cable

Power cord (AC 230V / 50 Hz) for connecting the compressor to an electrical outlet.

## Compressor (picture back side)



### 12. Fixing hooks

To attach the compressor to the edge of the bed using the hooks, make sure the strap is tightened securely.

### 3.3 Materials and finishes used

Main parts of the hybrid mattress	Material	Surface finish
Compressor (cover)	PVC	Without surface treatment
Power Cables	Core – copper Sheath – PVC	Without surface treatment
Mattress cover – top part	PU	Without surface treatment
Mattress cover – bottom part	PES	Without surface treatment
CPR valve	PVC	Without surface treatment
Straps	PES	Without surface treatment
Cells	PU	Without surface treatment
Hoses	silicone	Without surface treatment

## 4) Specifications

Model	decu® bariatric	decu® neo
<b>Series</b>	hybrid mattresses	hybrid mattresses
<b>Placing</b>	for direct laying on the bed frame	for direct laying on the bed frame
<b>Degree of decubitus</b>	1 to 4 / low to very high	1 to 4 / low to very high
<b>Compressor flow rate</b>	8 (LPM)	8 (LPM)
<b>Power supply</b>	AC 230 V / 50 Hz	AC 230 V / 50 Hz
<b>Working environment</b>	20-40 °C / 68-104 °F	20-40 °C / 68-104 °F
<b>Patient Weight</b>	30~450 kg	30~250 kg
<b>Operating Modes</b>	Alternative / Static / Auto Firm / Transport	Alternative / Static / Auto Firm / Transport
<b>Alternative mode</b>	3-chamber system / A-B-C	3-chamber system / A-B-C
<b>Cycle time (alternative mode)</b>	5/10/20 min	5/10/20 min
<b>Alarm (audible and visual)</b>	Power failure alarm Service alarm Low pressure alarm	Power failure alarm Service alarm Low pressure alarm
<b>Other features</b>	Automatic pressure detector LED display Keyboard lock Memory function Ventilation system Quick connector AVS – Anti-vibration system START / STOP system CPR quick release valve	Automatic pressure detector LED display Keyboard lock Memory function Ventilation system Quick connector AVS – Anti-vibration system START / STOP system CPR quick release valve
<b>Power cable length</b>	500 cm	500 cm
<b>Compressor weight</b>	3,4 kg	3,4 kg
<b>Compressor dimensions</b>	260 x 125 x 170 mm	260 x 125 x 170 mm
<b>Weight of the mattress</b>	17 kg	12 kg
<b>Dimensions of the mattress</b>	200 x 120 x 12 cm	200 x 90 x 12 cm
	200 x 100 x 12 cm	200 x 80 x 12 cm
<b>Noise level</b>	<27db	<27db

## 5) Important safety notices

### 5.1 Important safety notices



#### DANGER

To reduce the risk from operation

- ▶ Avoid the risk of improper operation. Before using the hybrid mattress, read this user manual and follow the steps.
- ▶ It is strictly forbidden to combine this device with other devices.
- ▶ When a malfunction occurs, follow the instructions in the troubleshooting guide or contact your regional distributor. Please stop using this device.

To reduce the risk of electric shock

- ▶ Properly plug the power cord end into the electrical outlet, which must be grounded as specified in the national requirements.
- ▶ Please turn off the power to the compressor while the patient is being washed.
- ▶ Do not install or use this device in the bathroom or in an environment with high humidity.

To reduce the risk of mechanical injury

- ▶ Install this device in accordance with the user manual.
- ▶ Do not disassemble the device by unauthorized persons.



#### WARNING

- ▶ To avoid the risk of incorrect operation, it is strictly forbidden to combine this device with other devices.
- ▶ Do not use with non-standardized parts.
- ▶ To avoid the risk of fire, do not smoke near this device.
- ▶ To avoid the risk of damage to this device, place this device away from sources of heat and fire.
- ▶ The use of the device is limited to indoors only. It is strictly forbidden to install the device outdoors.
- ▶ To avoid the risk of damage to the mattress, the use of sharp objects or hairpins, metal jewellery or needles is strictly prohibited with this device.

## **5.2 Designated user profile**

Hybrid mattresses are intended for use by middle and senior medical staff or caregivers in the home or by the user themselves, who:

- ▶ has received statutory instruction, which may only be given by the manufacturer or persons demonstrably authorised by them,
- ▶ read the user manual,
- ▶ is aware of the risks associated with the use of hybrid mattresses and the risks associated with the use of electrical equipment and is able to prevent these risks.

## **5.3 Designated patient population**

Hybrid mattresses are intended for use by the user, see the designated user profile.

Hybrid mattresses can be used for patients meeting the following areas:

Weight: according to mattress type

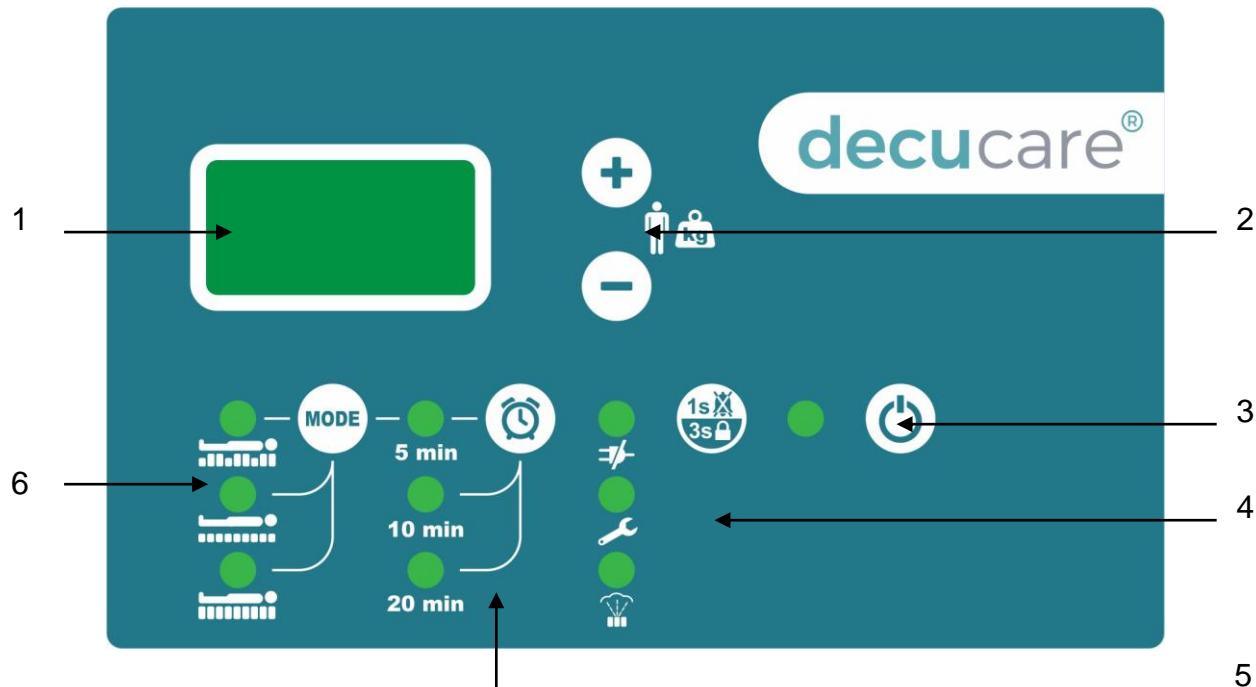
Health condition: without limits

Knowledge: no knowledge requirements

Skills: no special skills required, following the instructions in the user manual

## 6) Description of functions

### Compressor (picture of compressor keyboard)



#### 1. LED display

The LED display shows the selected patient weight and indicates activation of the keyboard lock function.

#### 2. Choice of weight



Use the [+] and [-] buttons to enter the patient weight in kg. The compressor will automatically adjust and maintain the most suitable pressure level in the mattress.

#### 3. Power



Turn on the power on the left side of the compressor. As soon as the power light comes on, the compressor is ready in standby mode. After pressing the [ ] button, the operator can start to control any function and use the compressor.

## 4. Device alarm and keyboard lock functions

### a. Power failure alarm



If the power failure alarm light is on, it means that the power supply (AC 230V) is not working. The power supply may have failed or the power cord may have been pulled out of the power outlet. Please check the power supply and the electrical plug.

### b. Service alarm



If the service alarm light is on, it means that the compressor has an internal fault. Please contact our sales representative for repairs. Never attempt to repair the compressor yourself.

### c. Low pressure alarm



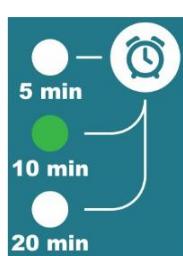
If the low pressure alarm light is on, it means that the mattress is leaking air. Follow the „troubleshooting“ procedure when checking the mattress.

### d. Keyboard lock



The keypad lock is automatically activated after 30 seconds of inactivity. An acoustic warning sounds and "LC" appears on the display. To unlock the keypad, press the button for 3 seconds. An acoustic warning will sound and the display will show the set patient weight.

## 5. Cycle time in alternative mode

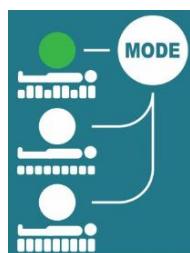


The compressor offers three cycle time options (5/10/20 min). The operator should follow the physician's instructions when selecting the rotation period.

**[NOTE]** Unless instructed by a physician, we recommend setting the cycle time to 10 min in the alternative mode to reduce patient pressure and maximize energy savings.

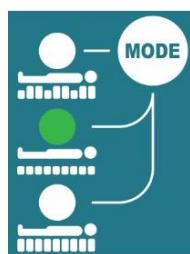
## 6. Operating mode

### a. Alternative mode



When the "Alternative Mode" is set, the pressure in all cells in the three-chamber system (A-B-C) will change repeatedly during the selected time interval of 5/10/20 minutes. The cell pressure value will be automatically set and maintained according to the specified patient weight.

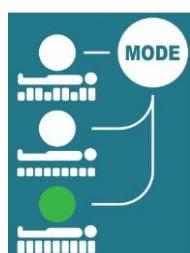
### b. Static mode



When "Static Mode" is set, the pressure in all cells will be the same and will be automatically adjusted and maintained according to the specified patient weight. The mode will promote a firm surface and maintain a specific low pressure that will allow the patient to sleep well.

**[Note]: When the compressor is switched on with the "ON" button, the "Static Mode" function starts automatically, and when the pressure reaches the specified patient weight, it automatically switches to the alternative mode.**

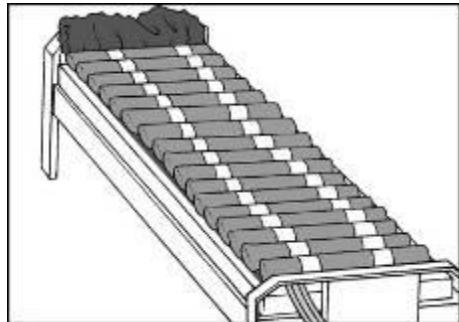
### c. Auto Firm mode



When "Auto Firm" mode is set, the pressure in all cells will be the same and a specific high pressure will be automatically set and maintained to provide safe support for the patient.

**[Note]: To maintain normal blood circulation function and effectively prevent decubitus, the compressor switches to "Alternative Mode" after 30 minutes of using the "Auto Firm" mode.**

## 7) Installation



STEP 1: Place the mattress flat directly on the bed frame. The hoses for connection to the compressor must be in the leg area so that they can be connected to the air outlet connector on the compressor.

 **CAUTION:**

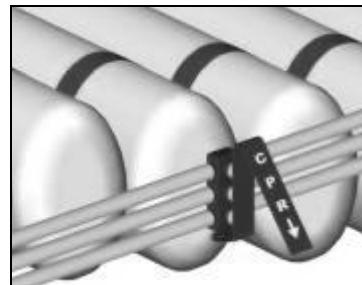
- 1. For easy connection of the mattress hose to the compressor, keep both the mattress hose and compressor in the footwell.**
- 2. Please remove the original foam mattress and place the mattress directly on the bed frame, the function of the bed rails will be maintained to prevent the patient from falling off the bed.**

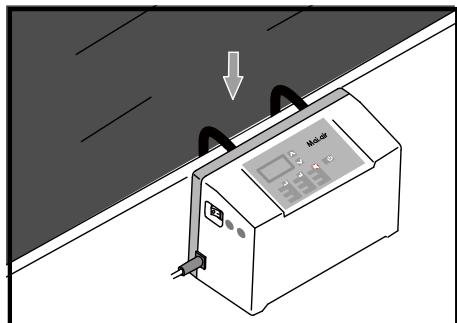


STEP 2: Unzip the cover and check the arrangement of all cells and the air hose connections to the cells. Secure the mattress to the non-moving part of the bed frame using the 3 straps on each side of the mattress to prevent the mattress from shifting.

 **CAUTION:**

- 1. Unzip the cover and check that all hoses are firmly attached to each cell.**
- 2. Check that the CPR valve is closed.**

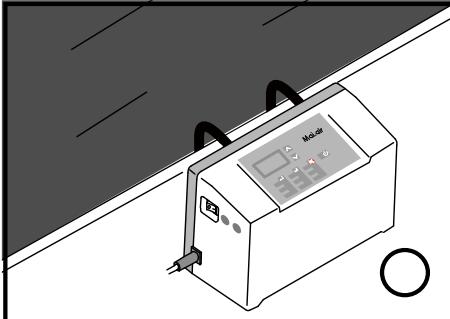




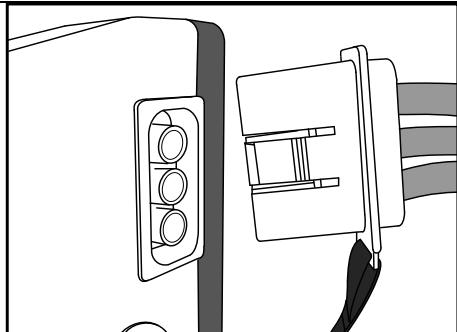
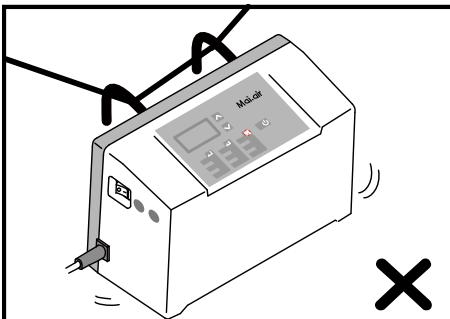
STEP 3: Hang the compressor using the integrated hooks on the headboard or bed frame at the foot end of the bed.

**⚠ CAUTION:  
CORRECT compressor INSTALLATION**

**Correct:** use the integrated hooks to hang the compressor on the headboard or bed frame.



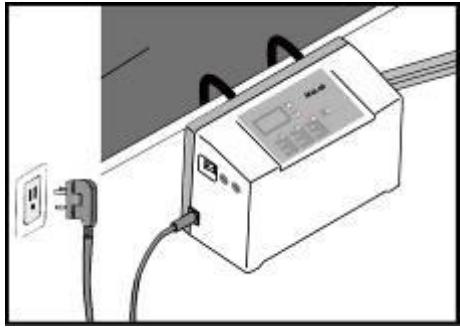
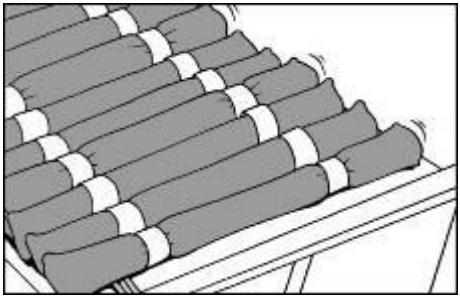
**Incorrect:** do not hang the compressor on a wire or unstable place.

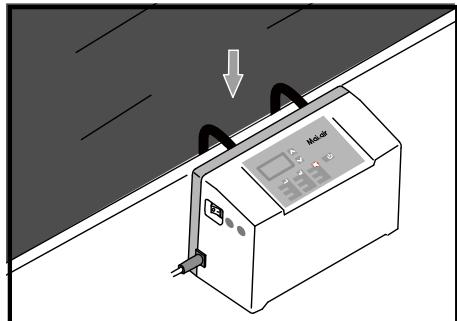


STEP 4: Connect the hose connector to the air outlet connector on the compressor. Push gently until you hear a "click".

**⚠ CAUTION:**

- 1. Method of pulling out the hose connector:** with your thumb and forefinger, gently press on the locking tabs on the hose connector while holding the compressor with your left hand, and then gently pull the hose connector out of the air outlet connector on the compressor.

	<p>2. Without properly squeezing the locking tabs on the hose connector and holding the compressor with your left hand, you could break or damage the hose connector if you apply too much force. Please note that if removal of the hose connector from the air outlet connector on the compressor is not done in accordance with the instructions, any damage to the hose connector will not be recognized by the manufacturer as a warranty repair.</p>
	<p>STEP 5: Connect the power cord of the compressor to an electrical outlet (AC 230 V / 50 Hz). Use the integrated power cord holders on the left side of the mattress to secure the power cord to the mattress so that it does not lie on the floor and prevent possible damage.</p> <p><b>⚠ CAUTION:</b> <b>Before plugging the power cord into an electrical outlet, make sure that the voltage is compatible with the compressor as specified in the user manual.</b></p>
	<p>STEP 6: Turn on the main switch on the right side of the compressor. The green power indicator light comes on. The compressor is in standby mode. Press the power button on the compressor keyboard, the compressor will turn on and you can select any function and use the compressor.</p>
	<p>STEP 7: The mattress will be inflate for approximately 20 minutes.</p> <p>STEP 8: Straighten the mattress cover.</p> <p><b>⚠ CAUTION:</b> <b>The first full inflation will take about 20 minutes, depending on the different mattress sizes.</b></p>



#### STEP 9:

Use the [+] and [-] buttons to enter the patient weight in kg. According to this value, the compressor will automatically adjust and maintain the most suitable pressure level in the mattress. The set pressure weight value is displayed on the LCD display.



#### CAUTION:

- 1. For proper function and highest possible effectiveness against decubitus, set the correct weight of the patient.**
- 2. Do not put too heavy or thick a blanket on the mattress, this can reduce the relief of ulcers.**
- 3. The hybrid mattress is designed to reduce the occurrence of skin pressure and prevent ulcers. We strongly recommend that patients turn over or get out of bed daily and use the mattress to relieve or relieve pressure on the skin.**

## 8) Operating instructions

### 8.1 Start of operation

#### STEP 1 :



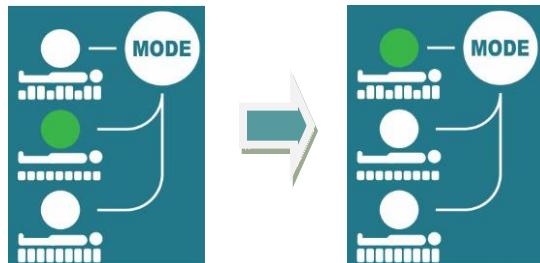
Turn on the power on the left side of the compressor. As soon as the power light comes on, the compressor is ready in standby mode. After pressing the power button on the compressor keyboard, the operator can start to control any function and use the compressor.

#### STEP 2 :



Use the [+] and [-] buttons to enter the patient weight in kg. The compressor will adjust and maintain the most suitable pressure level in the mattress.

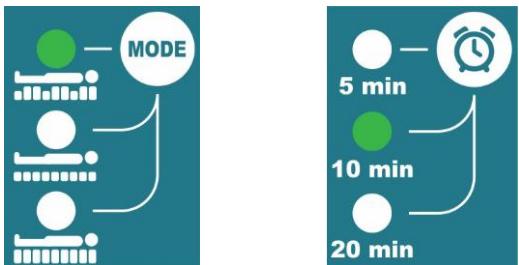
#### STEP 3 :



To check for damage or air leakage from the cells, the compressor switches to "Static Mode" when switched on. The pressure in all cells will be the same and will automatically adjust according to the selected patient weight. If the air pressure from the cells reaches the pressure limit, the compressor automatically switches to "Alternative Mode".

### 8.2 Alternative mode

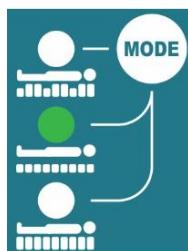
#### STEP 1 : Select [Alternative mode]



When the "Alternative Mode" is set, the pressure in all cells in the three-chamber system (A-B-C) will change repeatedly during the selected time interval of 5/10/20 minutes. The cell pressure value will be automatically set and maintained according to the specified patient weight.

## 8.3 Static mode

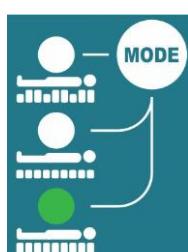
STEP 1 : Select [Static mode]



When "Static Mode" is set, the pressure in all cells will be the same and will be automatically adjusted and maintained according to the specified patient weight. The mode will promote a firm surface and maintain a specific low pressure that will allow the patient to sleep well.

## 8.4 Auto Firm mode

STEP 1 : Select [Auto Firm]



When "Auto Firm" mode is set, the pressure in all cells will be the same and a specific high pressure (100%) will be automatically set and maintained to provide safe support for the patient.

# 9) Other features

## 9.1 Ventilation system

The cell aeration system effectively dissipates heat and moisture between the patient and the mattress. This significantly helps to reduce the risk of decubitus ulcers and their treatment..

## 9.2 Memory function

After switching off and then on, the compressor automatically adjusts to the last set values. This applies even in the event of a power failure.

## 9.3 START/STOP function

The "START/STOP" mode to save compressor energy is controlled by a microcomputer that limits further inflation while inflation by air rises above the initial high cell pressure limit. If the air pressure drops below the initial low air pressure limit, the compressor automatically detects insufficient air pressure and starts inflating.

## **9.4 CPR valve**

For easy and immediate release of air from the mattress, use the CPR valve located on the right side of the mattress in the head area.

## **9.5 Keyboard lock**



The keypad lock is automatically activated after 30 seconds of inactivity. An acoustic warning sounds and "LC" appears on the display. To unlock the keypad, press the button for 3 seconds. An acoustic warning will sound and the display will show the set patient weight.

## **9.6 AVS – Anti-vibration systém**

The air unit housing system in the compressor eliminates vibration and helps reduce the operating noise level to less than 27 dB.

## **9.7 Safety quick connectors**

Safety quick connectors allow easy disconnection of selected cells (all or 6 pcs - depending on specification). This achieves zero pressure in at-risk areas, which helps to reduce the risk of decubitus and its treatment. This parameter is optional.

## 10) Troubleshooting

If the compressor is working properly, no LED fault light will illuminate on the panel.

If:

Problem	Possible cause	Solution
<p>The [power] light is not on.</p> 	Burnt fuse	Replace one of the two fuses (damaged) on the left side of the compressor.
	Motherboard failure	Please contact your distributor.
The [Power Failure Alarm] light is yellow.	Power failure (AC 230 V / 50 Hz)	<ol style="list-style-type: none"><li>1. Press button  off acoustic alarm.</li><li>2. Check that the power cord has not been pulled out of the power socket.</li><li>3. Check that the power supply at the power outlet is normal and/or that there is no power failure.</li></ol>
The [service alarm] light is yellow.	Failure of the internal system	<ol style="list-style-type: none"><li>1. Press button  off acoustic alarm.</li><li>2. Please contact your regional distributor.</li></ol>
The [pressure drop alarm] light is yellow.	Air leakage, pressure drop below the limit automatically set according to the specified patient weight.	<ol style="list-style-type: none"><li>1. Press button  off acoustic alarm.</li><li>2. Check the black rubber oil seal on the hose connector for damage.</li><li>3. Check that the hose connector is correctly connected to the compressor.</li></ol>

	Air leakage from the hoses on the side of the mattress	<ol style="list-style-type: none"> <li>1. Press button  off acoustic alarm.</li> <li>2. Check that the hoses are not cracked.</li> <li>3. Check that the hoses are well connected to the individual cells.</li> </ol>
	Air leakage from the CPR valve	<ol style="list-style-type: none"> <li>1. Press button  off acoustic alarm.</li> <li>2. Check that the CPR valve is closed.</li> <li>3. Check that the CPR valve is connected to the air hoses.</li> </ol>
	Air leakage from cells	<ol style="list-style-type: none"> <li>1. Press button  off acoustic alarm.</li> <li>2. Check for air leakage from cells.</li> </ol>

## 11) Cleaning

Please follow the recommendations for regular cleaning and maintenance of the compressor and mattress.

### Compressor

- DO NOT overload or soak the compressor, serious damage could occur.
- Place the compressor on the work surface and spray or wipe the outside of the housing with quaternary ammonium solution. (If the cleaning solution gets inside, damage will occur.)
- It is recommended to change the compressor air filter every 3 months to ensure normal air flow and pressure from the compressor.

### Mattress

- To protect patient health, it is recommended to wash at least once a week with warm water and a low-irritant detergent.
- After cleaning, dry the mattress. Do not use a tumble dryer to dry the cover. This can easily cause separation of the coating layers, affecting the normal functions of waterproofing and vapour permeability.
- To protect patient health, wash the cover and clean up soiling as soon as the mattress is contaminated with urine, blood, body fluids, excrement or food.

## 12) Handling and storage

### Compressor

- Disconnect the compressor. Place the compressor in a suitable plastic bag. Comply with statewide compressor disposal requirements.

### Mattress

- When storing the mattress, avoid environments with high temperatures, humidity, direct sunlight and strong pressure.

## 13) Maintenance and replacement of spare parts

PARTS	FUNCTIONS	Recommended replacement time
Air Filter	Cleans the inlet air to the compressor.	Replace once every 3 months.
Cover	Protects hoses and cells during operation. Keeps patients in a waterproof and breathable environment.	Replace the cover if it is damaged.
Cell	The supporting part of the mattress.	Replace cells if damaged.
Hose on the side of the mattress	They provide air distribution from the compressor to the individual cells.	Replace the hoses if they are damaged.
Seal	It ensures the airtightness of the cells.	Replace the seal if it is damaged.

The manufacturer reserves the right to make adjustments and recommendations based on the current situation.

In accordance with legal requirements, the manufacturer determine that during the entire period of use of the hybrid mattresses, a periodic safety and technical inspection to be carried out once a year.

The electrical installation must be inspected at least once every two years in accordance with the applicable standards or other similar locally applicable regulations relevant to electrical equipment.

## 14) Warranty

Please keep the following information for possible service and maintenance.

1. Product nameplate (with model name and product serial number)
2. Proof of purchase - invoice (with date of purchase and seller's stamp)

If you have any questions about the product, please provide us with proof of purchase and we will be happy to offer you immediate after-sales service.

### **2-year limited warranty**

covers any defects in material or workmanship under normal use and specified conditions for a period of two years from the date the hybrid mattress was purchased new, regardless of who the current owner is.

We will repair any defect in material and workmanship and send it back to you, all free of charge, no later than the time required by current legislation after you hand over the compressor/mattress to us.

We will not repair a compressor or mattress free of charge if it has been misused or damaged by accident.

You must send the compressor or mattress to us with the original proof of purchase and you must pay all delivery costs. It must be sent to decucare s.r.o. or a regional distributor. Failure to present the original proof of purchase will void this warranty.

decucare s.r.o. shall not be liable for incidental or consequential damages with respect to economic loss or injury to persons or property, whether due to breach of warranty, negligence or otherwise. decucare s.r.o. shall not be liable for the consequences of careless handling or improper use.

Any warranties enforced by law will be limited in time by the terms of this warranty. This warranty gives you specific legal rights and you may have other rights that vary from state to state.

## 15) Disposal

### 15.1 Disposal of hybrid mattresses

The user must assess whether the hybrid mattresses have been contaminated with hazardous substances as a result of their use and take into account any contamination when disposing of them.

If the hybrid mattress contaminated with hazardous substances:

- a) **were not**, the user disconnects the compressor from the mattress and follows the applicable legislation of the country for waste disposal. ATTENTION – the compressor falls under electrical and electronic equipment (see Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)). 
- b) **were**, dispose of hybrid mattresses as hazardous waste.

Do not dispose of hybrid mattresses with mixed municipal waste.

### 15.2 Environmental protection

The manufacturer is aware of the importance of protecting the environment and the role it plays for future generations.

Hybrid mattresses are manufactured in accordance with Directive 2011/65/EU restricting the use of certain hazardous substances.

The packaging materials used are manufactured in accordance with the relevant Directives and MDRs.

Ensure that packaging materials are disposed of in accordance with their labels.

## 16) Declaration of conformity



### EU DECLARATION OF CONFORMITY

decucare®

Declaration number:

**EUDOC2DAHM**

**Manufacturer**

decucare s.r.o.

with the headquarters

Slezska 1281,  
756 61 Roznov pod Radhostem  
Czech Republic

SRN:

**CZ-MF-000038224**

**declares under his sole responsibility that**

**products:**

dynamic anti-decubitus hybrid mattress

manufactured in types

decu®neo, decu®bariatric

with the basic UDI-DI:

**8594218992DAHMF3**

**are in agreement with the requirements of the Regulation of the European Parliament and the Council on medical devices (EU) 2017/745.**

Additional information:

**Classification of the object of the declaration:**

- According to Annex VIII of the Regulation of the European Parliament and of the Council (EU) 2017/745 and taking into account the intended purpose as active therapeutic product which is only used externally use only and the associated risks are classified in Class I, according to Rule 13.
- According to the criteria for electrical devices, these are electrical devices of protection Class II, type BF.

Conformity assessment procedure:

The manufacturer assessed conformity according to point 7 of Article 52 of the Regulation of the European Parliament and of the Council (EU) 2017/745 and developed technical documentation according to Annexes II and III of this regulation.

Roznov pod Radhostem 15. 09. 2023

Frantisek Skronicek – Managing director

  
decucare®  
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EUDOC2DAHM, ver.

[www.decucare.eu](http://www.decucare.eu)

decucare s.r.o., Slezska 1281,  
756 61 Roznov pod Radhostem,  
Czech Republic. info@decucare.eu

ID: 19710623, VAT: CZ19710623,  
reg. at the regional court in Ostrava  
under file number C 93658

Fio Bank, a.s. (CZK)  
IBAN: CZ77 2010 0000 0027 0265 6844  
SWIFT/BIC: FI0BCZPPXXX

Cifin, společné družstvo (EUR, USD)  
IBAN: CZ86 2080 0000 0000 0118 6476  
SWIFT/BIC: CITFCZPPXXX

## 17) Contact information

Contact our customer service department for further information:



decucare s.r.o.

Slezska 1281, 756 61 Roznov pod Radhostem, Czech republic

[info@decucare.eu](mailto:info@decucare.eu); [www.decucare.eu](http://www.decucare.eu)



## 18) Notes





development and production of anti-decubitus mattresses

**decucare s.r.o.**

e-mail: [info@decucare.eu](mailto:info@decucare.eu)

Address:

Slezska 1281

756 61 Roznov pod Radhostem

Czech Republic