# HealthCo Supreme Pump & Mattress

Mattress Overlay & Replacement System

# USER MANUAL

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**IMPORTANT SAFEGUARDS**
When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:
HOUSEHOLD USE ONLY

**DANGER - READ ALL INSTRUCTIONS BEFORE USING THE APPLIANCE**

**DANGER** – To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for product that has fallen into water. Unplug immediately.

**WARNING** – To reduce the risk of burns, electrocution, fire or injury to persons:

1. A product should never be left unattended when plugged in.
2. Close supervision is necessary when this product is used by, on, or near children or physically challenged individuals.
3. Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
4. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it is has been dropped or damaged, or dropped into water. Return the product to a service centre for examination and repair.
5. Keep the cord away from heated surfaces.
6. Never block the air opening of this product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
7. Never drop or insert any object into any openings.
8. Do not use outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered.
9. DISCONNECT FROM SUPPLY CIRCUIT BEFORE OPENING.
10. The product has no user serviceable parts except for fuse replacement.
11. Keep the pump and sleeve away from sources of liquid and open flames.
12. Keep the pump and sleeve away from sharp objects.
13. If pain, irritation, numbness, swelling, or redness occurs discontinue use and contact a healthcare professional.
14. Power cable & pump shall be placed at the foot-side of the patient to prevent any risk of strangulation due to cable.
15. Do not obstruct the mains plug or position the equipment where the connection to the mains line can be accidentally disconnected.
16. No modification of this equipment is allowed.
17. Operators of the system are to be professionally trained or certified to handle and care for patients of pressure ulcer symptoms and not to be controlled or adjusted by the patients.

## 1. THE PURPOSE OF THIS MANUAL

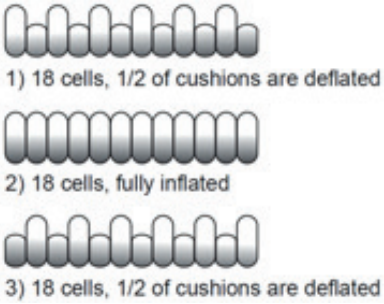
This operation manual is mainly focused on the set-up, cleaning and routine maintenance of the HealthCo Supreme Air Pump with Mattress overlay and replacement system. We recommend you keeping this manual handy to answer most of the question related to the system.

## 2. PRODUCT DESCRIPTION – INTENDED USE

The HealthCo Supreme system is a unique and innovative specialised mattress system. Which provides pressure management for pressure ulcers prevention. The 1 in 2 alternating function also provides active prevention for pressure relief, especially for those in long term care and homecare patients (the cells inflate and deflate in a 1 in 2 cycle, meaning 1/2 of the body is always supported and 1/2 the body is relieved of ANY pressure at any one time).

The HealthCo Supreme system is a compact design with an easy self-explanatory control in mind to help caregiver to monitor the softness and hardness of the air mattress according to a patient's comfort through 8 scales.

**2-1 Alternation Cycle Illustration**


**Master Control Unit Features**

- Alternation time is preset to 12 minutes cycle
- Equipped with a Low Pressure visual alarm to indicate a low pressure status
- The foot board mounting rack provides convenient placement on the bed

**Mattress Features**

- Individual air cushion design for maximum pressure distribution.
- Stretchable top cover provides friction and shear protection.

## 3. GENERAL SAFETY

It is important to read the information in this user manual before you use your HealthCo Supreme system.

Please follow the guidelines below for your added safety and maintaining system performance.

- Maximum patient weight is 150kg for overlay and 180kg for replacement
- Avoid exposing pump to liquids.
- When cleaning do not use of Phenol based substances.
- Use HealthCo Supreme pump with HealthCo Supreme mattresses only.
- This HealthCo Supreme Overlay alternating system must be used on top of mattress on a bed frame.

## 4. CONSTRAINTS FOR USE

The HealthCo Supreme Alternating System should not be applied to patients suffering from polytrauma with fractures of spine, pelvis, extremities and skull. Patients with neurological impairments and missing body perception need their physician's prescription. Alternating pressure should not be applied to pain or pain-sensitive patients. People who suffer from allergies against any of the substances used for mattress or cells body should not be positioned on the mattress.

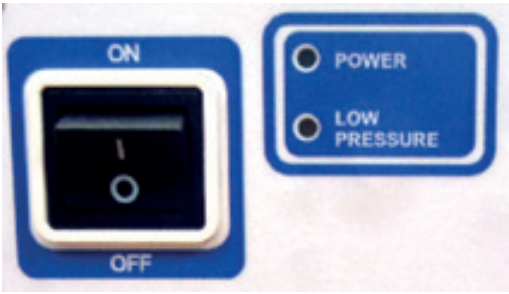
This product is designed for users whose age is above 12 years.

## 5. INTENDED USER PROFILE

- Education/Knowledge: 12 years+
- Language understanding:
  - Read and understand 'Westernised Arabic' numerals when written in Arial font
  - Understands hygiene
- Experience Requirement: Professional nursing support
- Permissible impairments: Except for constraints listed
- User cannot be the operator.
- This device can be used in home and professional healthcare environment.

## 6. INSTALLATION GUIDE

1. Place HealthCo Supreme mattress overlay on top of the existing mattress and orient the overlay so the umbilical tube is at the foot of the bed. Secure HealthCo Supreme mattress overlay to existing mattress with the elastic straps underneath the base cover. If the HealthCo Supreme mattress has had foam added below the cells to create a replacement mattress - Do NOT place on top of existing mattress. Remove mattress from bed frame and replace with HealthCo Supreme Replacement system.
2. Hang the control unit on the foot board of the bed frame.
3. Attach umbilical air tube connector to the socket on side panel of the control unit.
4. Verify that air hoses are not kinked under the mattress. Ensure the CPR valve is set to "CLOSE" position.
5. Attach cover to mattress.
6. Plug in the control unit and turn on the power.




7. Please turn the dial to "FIRM" and allow for an approximately 40 minutes time for full mattress inflation. After the mattress is fully inflated, the caregiver can then transfer the patient on to the mattress.
   **NOTE: Low Pressure visual alarm will always be triggered for each initial inflation. This is normal and the visual alarm will turn off by itself when mattress is fully inflated.**
8. Use pressure adjustment dial to set mattress pressure comfort level according to patient's weight and comfort needs.

9. Low Pressure Alarm: The Control Unit is equipped with a low pressure visual alarm. This function enable the Control Unit generates a visual alert to remind the caregiver of a low pressure issue with the mattress system.


⚠ **Caution: Response by the operator is required when a low pressure alarm is present.**

**10. CPR Deflation:** For an emergency mattress deflation is required, turn the CPR valve to "OPEN" position (Fig. 1). The mattress should deflate within 30 seconds. To close CPR valve simply turn the valve to the "CLOSE" position (Fig. 2).


Fig. 1 Turn the dial to **OPEN** position to release air.


Fig. 2 Turn the dial to **CLOSE** position to inflate air mattress.

**IMPORTANT: Please ensure that all care staff are trained and familiarised with the mattress and this function.**

⚠ **CAUTION: During EFT interference, pump LED indicator may be flashing, this is normal.**

⚠ **Caution: During power outage, pump will stop functioning and the POWER LED indicator may be flashing as well as the power failure alarm may be triggered if equipped, these are normal. The pump will return to its normal operation when power is resumed.**

## 7. MAINTENANCE & TROUBLESHOOTING

No daily maintenance is required. It is intended this equipment should only be serviced by qualified and authorised technical personnel. In case of minor trouble please refer as following Troubleshooting.

| Symton | Inspection Procedure | Possible Solution |
|---|---|---|
| Air is pumping out from the control unit but mattress is not inflating. | 1. Is the power source correct? Improper voltage may cause the pump to function abnormally and damage the control unit.<br>2. Is there any kinking tube?<br>3. Is there any air leakage from the air cells?<br>4. Is there any air leakage from air tube between mattress and control unit?<br>5. Has the air tube connector been connected properly?<br>6. Is CPR valve sets to "CLOSE" position? | 1. Use power regulator.<br>2. Adjust the air tubes to enable smooth air flow.<br>3. Replace with new air cells.<br>4. Replace with new air tubes.<br>5. Re-connect the air tubes.<br>6. Turn CPR valve to "CLOSE" position to stop deflation. |
| The Control Unit is not functioning. | 1. Check the power cord and the power voltage.<br>2. Check the fuse. | 1. Use a power regulator.<br>2. Replace with a new fuse. |
| Some of the air cells are not properly inflated. | 1. Is the connection between air cells and the air manifold kinked?<br>2. Is there any air leakage from the air cells? | 1. Check for any kinking<br>2. between air cells and air manifold.<br>3. Replace new air cell if faulty. |

**5. CLEANING & DISINFECTION PROTOCOL**

It is very important to have a strict cross infection, cleaning and disinfection policy in line with current Hospital/Nursing Home infection control guidelines.

1. Remove the bedding.
2. If necessary, inflate the mattress.
3. Ensure that the power unit is off.
4. Unplug the power cord from the wall outlet.
5. Ensure that the underside of the mattress is clear of all sharp objects.
6. Examine the surface of the power unit and mattress assembly components for visible blood or body fluids.
7. Perform one of the following:
   - If blood is present, decontaminate the whole mattress product in line with current Hospital or Nursing Home Guidelines.
   - If blood is not present, remove any soil from the cover with paper towels.
   **NOTE:** Check underside of cover for 'strike-through'. If grossly soiled, the cover should be removed, cleaned and decontaminated.
8. Using a clean sponge or paper towel, wipe down the cover surface and cells with a diluted detergent solution or recommended cleaner disinfectant or other germicidal detergent solution.
9. Cleaning and disinfection may be carried out on the cover with hand hot water and a neutral detergent or with a sodium hypochlorite solution (0.1% or 1000 parts per million available chlorine).
10. Alternatively remove the cover and launder, 70° C (160° F), using normal detergents. It is essential that articles be thoroughly dried after all cleaning procedures and before storage.

11. Perform the following steps to clean the power unit and hose fittings:
    - Wipe all controls, chassis and hose fittings with a damp cloth and a mild detergent.
    - Using a nylon brush, gently clean all crevices as they can contain microorganisms.
    - Air dry all treated surfaces.

**WARNING:**

- **Switch off the electrical supply to the pump and disconnect the power cable from the mains before cleaning and inspection.**
- **Protective clothing should be worn when performing cleaning procedures.**
- **Do not use Phenol based cleaning solution.**

All equipment should be inspected. Any item that is visibly soiled with the patient's blood or other body fluids should be properly cleaned or removed. It is recommended that the system is clean regularly and after each patient use.

In many cases it will be only be necessary to remove the mattress cover for cleaning. If there is obvious soiling a complete cleaning or decontamination will be required.

**Replace Air Filter**

1. Remove Air filter and Replace a new Filter.
2. Use a soft bristle brush to remove dust and difficult dried-on soil.

## 6. SPECIFICATION

**Control unit (Air Pump)**

| | |
|---|---|
| Model No. | M26-4 |
| Size L x W x H | 265 x 120 x 95 |
| Weight (Kg) | 1.8 |
| Phase Time | 12 Minutes |
| Max/Min Operating Pressure | 25 ~ 60mmHg |
| Rated Voltage | AC 220-240V / 50Hz |
| Max Current | 0.1A |
| Fuse Rating | T1AL 250V |
| Classification | Class II Type BF, Not AP or AGP type |
| Ingress of Water Protection | IP21 |
| Operation Temperature | 15° C to 40° C (59° F to 104° F) |
| Operation Humidity | Operation: 30% to 75% non-condensing |
| Operation Atmospheric Pressure Range | 700 hPa to 1060 hPa |
| Safety Standard | IEC/EN60601-1, IEC/EN60601-1-2<br>IEC/EN 60601-1-11 |

**Mattress Overlay/Replacement (WITHOUT foam)**

| | |
|---|---|
| Size L x W x H | 2000 x 880 x 130 |
| Weight (Kg) | 7 |
| Material | Top Cover: PU laminated Nylon<br>Base Cover: PVC laminated Polyester<br>Air Cell: PU laminated Nylon |

**Symbol Definition**

| | | | |
|---|---|---|---|
| | Type BF<br>Protection Against Electronic Shock | | Class II Equipment |
| | Operating Instructions | | Waste Disposal |
| | Caution, Consult accompanying documents | | Alternating Current |

## 7. WASTE DISPOSAL

This Product has been supplied from an environmentally aware manufacturer that complies with the WEEE.

This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according the legislation. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.

## 8. STORAGE AND CARE

**Control Unit (Air Pump):**

- Check the power cord and plug for abrasions or excessive wear.
- Plug in the unit and verify air flows from the units hose connection ports
- Place in plastic bag for storage.

**Mattress:**

- Disconnect the air feed tubes. After the air is released mattress can be folded. Place in plastic bag for storage.

It is recommended the following guidelines are used whenever this system is being stored or transported another location:

Temperature limitations: 41°F (5°C) ~ 140°F (60°C)

Relative Humidity 30% ~75%

## 9. EMC RELATED NOTIFICATION

**Warning:** Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories.

**Warning:** RF mobile communications equipment can effect medical electrical equipment.

**Recommended separation distances between portable and mobile RF communications equipment and the HealthCo Supreme**

The HealthCo Supreme is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HealthCo Supreme can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HealthCo Supreme as 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 m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1,2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1,2\sqrt{P}$ | 800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$ |
| 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 metres (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) according 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.

**Guidance and manufacturer's declaration – electromagnetic emissions**

The HealthCo Supreme is intended for use in the electromagnetic environment specified below. The customer or the user of the HealthCo Supreme should ensure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The HealthCo Supreme uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The HealthCo Supreme is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/ flicker emissions IEC 61000-3-3 | Compliance | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The HealthCo Supreme is intended for use in the electromagnetic environment specified below. The customer or the user of the HealthCo Supreme should ensure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment – Guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±8 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 | ±2 kV for power supply lines<br>±1 kV for input/ output lines | ±2 kV for power supply lines<br>±1 kV for input/ output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5 % UT<br>(>95 % dip in UT)<br>for 0,5 cycle<br><br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br><br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><br><5 % UT<br>(>95 % dip in UT)<br>for 5 sec | <5 % UT<br>(>95 % dip in UT)<br>for 0,5 cycle<br><br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br><br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><br><5 % UT<br>(>95 % dip in UT)<br>for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the HealthCo Supreme requires continued operation during power main interruptions, it is recommended that the HealthCo Supreme be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The HealthCo Supreme is intended for use in the electromagnetic environment specified below. The customer or the user of the HealthCo Supreme should ensure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2,5 GHz | Vrms<br><br>V/m | Portable and mobile RF communications equipment should be used no closer to any part of the HealthCo Supreme including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1,2\ \sqrt{P}$<br>$d = 1,2\ \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 1,2\ \sqrt{P}$ 800 MHz to 2,5 GHz<br>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 metres (m).<br><br>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]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 HealthCo Supreme is used exceeds the applicable RF compliance level above, the HealthCo Supreme should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HealthCo Supreme.

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

## 10. EXPECTED SERVICE LIFE

The HealthCo Supreme pump has an expected service life of two years. To maintain the condition of the pump have the pump serviced regularly according to the schedule recommended by HealthCo. Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the HealthCo Supreme system.

## 11. WARRANTY

- HealthCo warrants this equipment to be free from defects in material and workmanship for up to 12 months from the date of delivery.
- All warranty work will be performed at the service address below, shipping charges prepaid.
- At Manufacturers discretion we agree to service, repair or replace any equipment or part found to be defective at no charge.
- This warranty excludes equipment damaged through shipping, tampering, improper maintenance, carelessness, accident, negligence, misuse, or which has been altered, repaired or dismantled other than with the manufacture's written authorisation and by its approved procedures and by properly qualified technicians.
- In no event shall HealthCo be liable for any direct, indirect or consequential damage or loss resulting from the use of equipment.

## 12. DISCLAIMER

**WARNING:** The use of side rails and other restraints can result in injury or death - through potential entrapment and potential patient falls. Please see MHRA Device Bulletin DB 2006(06) for details.

**WARNING:** Risk of electrical shock, serious injury or death. Only authorised technicians should open the pump unit for servicing and maintenance procedures. Electrical equipment can be extremely dangerous if damage or misused.

**WARNING:** Before any cleaning or disinfection procedure, ensure that the pump system is switched off and unplugged from the mains power supply.

## LEGAL DISCLAIMER

A. Terms such as 'Medium Risk', 'High Risk' and 'Very High Risk' are a description of a person's risk levels, these persons may be at danger of developing a pressure sore at the higher risk status level. These risk levels are assessed by nurses and as there is a variability between nurse measurements/observations. Descriptive risk levels should only be used as guideline for the risk assessment methods being used.

B. HealthCo uses these factors and terms based on the existing market research and internal research to show the suitability and effectiveness of the pressure care systems provided. Internal and external research is and will always be ongoing. These risk factors should not be taken as prescriptive criteria.

C. HealthCo support surfaces should be seen as an aid to care and DO NOT replace the need for good nursing care and intervention. All HealthCo products must be used as part of an individualised care plan which include proper nursing practices i.e. turning/re-positioning, and regular patient skin assessments.

D. Pressure relieving equipment alone will not prevent pressure ulcers. Pressure ulcers are multi factorial and many external and internal factors cause them to develop. It is up to the professional judgement of the nurse to assess the risk and develop a care plan which prescribes suitable pressure reducing/relieving equipment and external care. Some pressure sores are inevitable due to falls and periods of immobility these sores can develop hours after the injury, in these instances a pressure ulcer can develop and HealthCo cannot guarantee the use of the equipment alone will prevent pressure ulcer formation.

E. The mattress usage guidance within this user guide in relation to clinical guidance, should always be operated in accordance with best clinical practice outlined by the care giver.