

# Instructions for Use and Technical Description



## CliniCare 100 HF

## Hybrid Mattress Replacement System



D9U003VC0-0101

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# 1 Symbols and Definitions

## 1.1 Warning Notices

### 1.1.1 Types of Warning Notices

Warning notices are differentiated by the type of danger using the following key words:

- ▶ **CAUTION** warns about the risk of material damage.
- ▶ **WARNING** warns about the risk of physical injury.
- ▶ **DANGER** warns about the risk of fatal injury.

### 1.1.2 Structure of Warning Notices



**SIGNAL WORDS!**

Type and source of danger!

- ▶ Measures to avoid the danger.

## 1.2 Instructions

Structure of instructions:

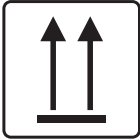
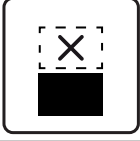
- ▶ Perform this step.
- Results, if necessary.

## 1.3 Lists

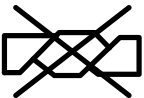
Structure of bulleted lists:

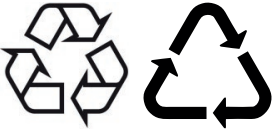
- List level 1
  - List level 2
    - List level 3

1.4 Symbols on the Package

|                                                                                     |                                  |
|-------------------------------------------------------------------------------------|----------------------------------|
|    | FRAGILE, HANDLE WITH CARE        |
|    | THIS WAY UP                      |
|    | KEEP DRY (PROTECT FROM HUMIDITY) |
|    | PAPER RECYCLING SYMBOL           |
|   | DO NOT USE HAND TRUCK HERE       |
|  | DO NOT STACK DURING STORAGE      |

## 1.5 Symbols and Labels on the Product

|                                                                                                                       |                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
|                                      | READ INSTRUCTIONS FOR USE                                                                      |
| BS 7175<br><br>5<br>MEDIUM<br>HAZARD | COVER MATERIALS ARE FIRE RETARDENT TO BS7175, SOURCES 0, 1 AND 5                               |
|                                      | DO NOT IRON                                                                                    |
|                                      | DO NOT USE A CLEANER CONTAINING PHENOL                                                         |
|                                      | DO NOT WRING                                                                                   |
|                                     | REGULARLY INSPECT THE INSIDE OF THE COVER FOR CONTAMINATION                                    |
|                                    | MACHINE WASH AT 71 DEG. CENTIGRADE FOR 3 MINUTES                                               |
|                                    | TUMBLE DRY ON LOW HEAT SETTING                                                                 |
|                                    | HANDWASH WITH DETERGENT. INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50 DEG. CENTIGRADE |
|                                    | DISINFECT USING SOLUTION CONTAINING <1000 PPM OF CHLORINE (SEE CLEANING/ DISINFECTION)         |
|                                    | RINSE WITH WATER                                                                               |
|                                    | DRY                                                                                            |
|                                    | WARNING                                                                                        |

|                                                                                     |                                                                                   |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
|    | ONLY SUITABLE FOR INDOOR USE                                                      |
|    | CE MARK OF CONFORMITY WITH EU REGULATION                                          |
|    | 2X 1A(T) ANTI-SURGE FUSE                                                          |
|    | PROTECTION AGAINST ACCIDENTS DUE TO ELECTRICAL CURRENT – TYPE B APPLIED PARTS     |
|    | DOUBLE INSULATION                                                                 |
|    | POWER SWITCH<br>I : ON<br>O: OFF                                                  |
|   | ALTERNATING CURRENT                                                               |
|  | WEEE SYMBOL (RECYCLE AS ELECTRONIC WASTE,<br>DO NOT PUT INTO THE HOUSEHOLD WASTE) |
|  | MEDICAL DEVICE (COMPATIBLE WITH MEDICAL DEVICE REGULATION)                        |
|  | RECYCLING SYMBOL                                                                  |
|  | DO NOT POLLUTE THE ENVIRONMENT                                                    |
|  | REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON CONFIGURATION)                        |
|  | SERIAL NUMBER                                                                     |

|                                                                                     |                                                    |
|-------------------------------------------------------------------------------------|----------------------------------------------------|
|    | THERMAL PROTECTION FOR TRANSFORMER                 |
|    | SAFETY ISOLATING TRANSFORMER (GENERAL)             |
|    | MANUFACTURER                                       |
|    | MANUFACTURING DATE                                 |
|   | MATTRESS FOOT PART                                 |
|  | MAXIMUM LOAD SYMBOL (FOR 86 CM WIDE MATTRESS)      |
|  | MAXIMUM LOAD SYMBOL (FOR 86 CM WIDE MATTRESS)      |
|  | UNIQUE DEVICE IDENTIFICATION (FOR MEDICAL DEVICES) |



## 1.8 Abbreviations

|            |                                                            |
|------------|------------------------------------------------------------|
| AC ( ~ )   | Alternating Current                                        |
| CE         | European Conformity                                        |
| CPR        | Cardiopulmonary Resuscitation                              |
| dB         | Sound Intensity Unit                                       |
| DC ( --- ) | Direct Current                                             |
| CUC        | Configuration number                                       |
| EMC        | Electromagnetic Compatibility                              |
| FET        | Field-effect transistor                                    |
| HF         | High Frequency                                             |
| HPL        | High Pressure Laminate                                     |
| ICU        | Intensive Care Unit                                        |
| INT.       | Duty Cycle                                                 |
| IP         | Ingress Protection                                         |
| IV         | Intravenous                                                |
| LED        | Light Emitting Diodes                                      |
| ME         | Medical Electrical (Equipment)                             |
| ON         | Activation                                                 |
| OFF        | Deactivation                                               |
| ppm        | parts per million, millionth (1000 ppm = 0,1%)             |
| REF        | Reference Number (product type depending on configuration) |
| SCU        | System Control Unit (integrated mattress)                  |
| SN         | Serial Number                                              |
| SW         | Software                                                   |
| UDI        | Unique Device Identification (for medical devices)         |
| USB        | Universal Serial Bus                                       |
| WEEE       | Waste Electrical and Electronic Equipment                  |

## 1.9 Definitions

|                     |                                                                                                                                                                                     |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Duty Cycle</b>   | Cycle of operation of the motor: time of activity/time of rest.                                                                                                                     |
| <b>Maximum Load</b> | The highest allowable load on the mattress (patient weight + accessories).                                                                                                          |
| <b>Adult</b>        | Patient having a physical size equal to or more than 146 cm, a mass equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17 (according to IEC 60601-2-52). |

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## 2 Safety Instructions



**WARNING!**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!



**WARNING!**

Only authorised and trained person using the tool is allowed to change fuses and power supplies!



**WARNING!**

This medical device is not intended for oxygen enriched environment!



**WARNING!**

This medical device is not intended for use with flammable substances!



**WARNING!**

This medical device is not portable medical electrical equipment!



**WARNING!**

Patient is allowed to use selected control elements only if hospital personnel had assessed that the patient's physical and psychological state is in accordance with use of them and only if the hospital personnel had trained the patient in accordance with the instructions for use!



**WARNING!**

Risk of injury due to incorrect use!

- ▶ Before placing a patient on a CliniCare 100 HF mattress, always have a qualified person perform a risk assessment to ensure that the support provided is appropriate and fulfills the applicable local stipulations.
- ▶ Do not use APT mode for patients undergoing cervical traction. STATIC mode can be used only under supervision of qualified person.
- ▶ When using mattress replacement or overlay systems, make sure to use safe and appropriate siderail positions and bed height settings. Which positions and settings are safe and appropriate may vary with the type of bed frame and siderails.
- ▶ CliniCare 100 HF mattress without System Control Unit is not intended for immobile patients.

---

## 2.1 Before use

- It is necessary to read the instructions for use before operating the mattress system.
- Follow the instructions carefully.
- Use the mattress system only as specified in this manual.
- LINET shall not assume any responsibility for any damage or injury resulting from incorrect use.
- Position the power cord so that there are no loops or kinks in the cable; protect the cable from mechanical wear and tear. Improper handling of power cord can cause an electric shock hazard, other serious injuries or damage to the mattress system.
- Position the power cord so there is no risk of injuring the patient (e.g. choking hazard).
- Regular inspection of the mattress interior to be carried out on a regular basis.
- In case of any problem please contact manufacturer for help at installation, service or if an unexpected event occurs.

## 2.2 Installation

- Ensure that installation is performed in accordance with the instructions in this manual.
- Ensure that maintenance is performed only by qualified personnel who have been trained by the manufacturer.

## 2.3 Usage

- Ensure that the mattress system is only operated by suitably qualified personnel or after receiving instruction from them.
- Only use the mattress system if it is in perfect working order.
- Only use the system in clean environment.
- Always hold SCU with scoop handle when moving.
- Only use the mattress system with the correct power supply (see Electromagnetic Compatibility).
- Replace any damaged parts immediately with original spare parts only.
- Do not exceed the maximum patient weight (see Mechanical Specifications).
- Do not use the SCU in near flammable gases. This does not apply to oxygen cylinders.
- Do not cover SCU while in use.
- Do not place SCU near extreme heat sources such as radiators.
- Never handle the power plug with wet hands.
- Disconnect the product from the outlet only by pulling the power plug. While pulling the power plug, always hold the actual plug, not the cord.
- Mattress and SCU must be checked at least once a day. Check that:
  - the mattress is inflated to the required pressure
  - the Low Pressure indicator is not permanently illuminated
- in case of error refer to the chapter "System Faults"
- The handles located on the both sides of the mattress cover are designed only for manipulation with the mattress without load (without patient).

---

## 3 Intended use of CliniCare 100 HF

The intended purpose of this pressure air mattress with foam cells is to provide a support surface for patients by pressure redistribution designed for management of tissue loads and microclimate management. This mattress is intended to be used as mattress replacement.

### 3.1 Indications

The mattress is recommended for use with patients who have been identified as having from low to very high-risk rating of pressure injuries development, (very high risk includes patients with pressure injuries in the past or currently having a pressure injury of any category) according to EPUAP/NPIAP standards for pressure injury prevention in line with local policy and guidelines.

The use of the mattress does not remove the need for regular repositioning of patients in line with best clinical practice.

**NOTE:** A full risk assessment of the patient's risk of a pressure injury development must be carried out by an appropriately trained clinician and clinical judgement must be made to identify the suitability of the product for use with the patient.

### 3.2 User population of CliniCare 100 HF

- ▶ Adult patients (weight  $\geq 40$  kg, height  $\geq 146$  cm, BMI  $\geq 17$ )
- ▶ Application Environment 1 (ICU), 2 (Acute care), 3 (Long-term care) and 5 (Ambulatory care), as in IEC 60601-2-52

### 3.3 Contraindications

**Mattress system is contraindicated for patients:**

1. with cervical or skeletal traction
2. with unstable skeletal fractures
3. with unstable spinal fractures
4. exceeding maximum patient weight of the mattress

Other contraindications may be identified on an individual patient basis depending on clinical risk assessment.

**NOTE:** For patients in prone position - before placing the patient into prone position a detailed clinical risk assessment should be carried out by an appropriately trained clinician.

### 3.4 Operator

- ▶ Caregivers (nurses/doctors) that are fully trained in use of the mattress. Operators must familiarize themselves with all warnings and cautions contained in the instructions for use before use of the mattress. Clinical risk assessment should be carried out by appropriately trained staff and clinical judgement should be made to ascertain that the product is suitable for meeting the care needs of the individual patient.
- ▶ Technical, transport and cleaning personnel should be fully trained in the maintenance and service of the product and must familiarize themselves with all warnings and cautions contained in the instructions for use.

## 4 Product Description

### 4.1 Mattress

The CliniCare 100 HF system is designed for use in all healthcare facilities, hospitals, nursing homes and community care as an aid to the prevention and treatment of skin injuries related to pressure damage.

#### 4.1.1 CliniCare 100 HF

CliniCare 100 HF is a hybrid foam including cell system. Cells are connected into two groups for pressure distribution. Air tubes inside the mattress are separate for these two groups. Cells also includes pressure valve to gain pressure from atmosphere when needed. The system can be connected to compressor thanks to outer valves. The system works as a separate mattress or in connection with compressor. Separate mattress redistributes the pressure according to patient's position and movement. When the compressor is connected the mattress provides alternating therapy. In case of MCM version compressor also delivers air for MCM feature in mattress. Inside the mattress there is foam with different densities. On the top of mattress there is visco foam. Inside the cells there is PU foam. The pressure delivered by compressor can be adjusted by controller.

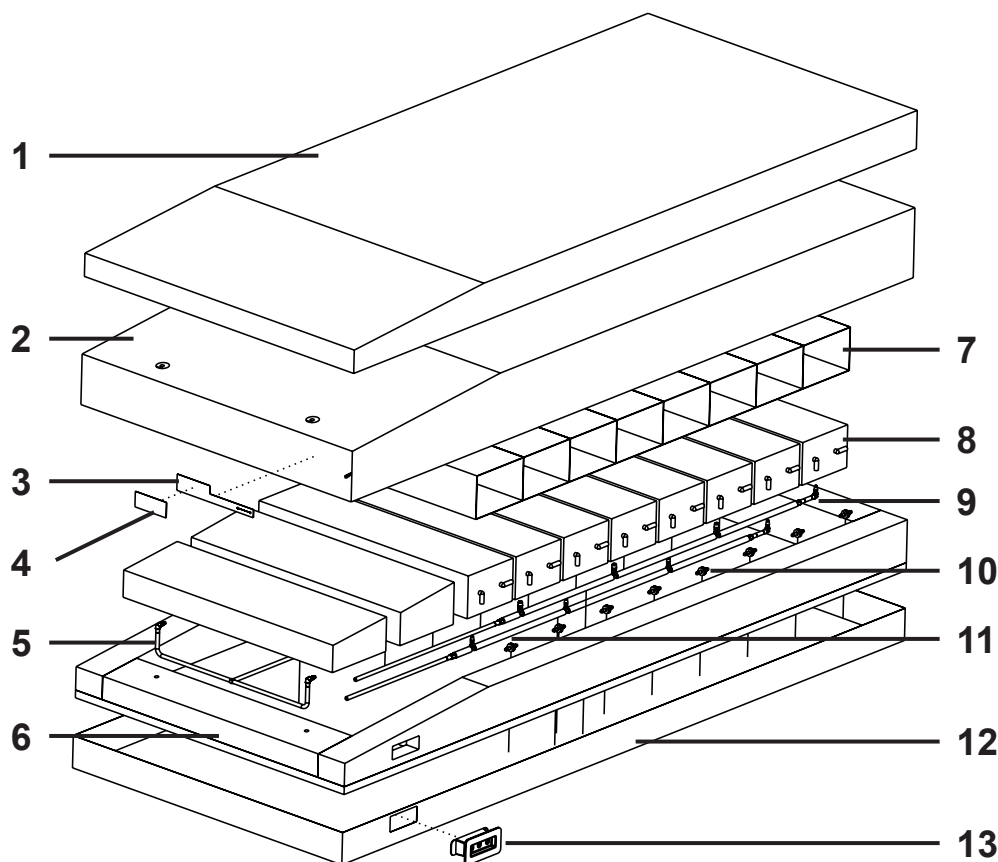


Fig. CliniCare 100 HF mattress

- |    |                                            |
|----|--------------------------------------------|
| 1  | Top cover                                  |
| 2  | Comfort layer                              |
| 3  | Mattress Serial Label Holder               |
| 4  | Mattress Serial Label Lamination           |
| 5  | Tubing Harness MCM (only version with MCM) |
| 6  | Foam layer                                 |
| 7  | Cell Sleeve                                |
| 8  | Reactive Cell                              |
| 9  | Tubing Harness A                           |
| 10 | Check Valve                                |
| 11 | Tubing Harness B                           |
| 12 | Base Cover                                 |
| 13 | Air Connection                             |

---

**Top foam:**

- height: 5 cm
- material: visco foam

**Middle section:**

- 10 self-adjusting air cells absorb and displace patient weight
- when used with SCU, air cells alternate in pressure, and micro climate management is optional
- material:PU

**Cover:**

- **Top**
  - 4 way stretch with 360 degree zip
  - waterproof / high Moisture Vapour Permeability
- **Base**
  - high durability / non stretch / waterproof
  - 2 strong mattress Transport Handles on each side of the base

## 4.2 SCU (System Control Unit)

The SCU inflates and deflates the air mattress. It is connected to the air mattress with a custom-designed air connector. The analogue electro-mechanical controlled SCU maintains the set pressure regardless of the patient's weight distribution or position. The SCU is equipped with visual indicators for power failure or mattress low air pressure that may be caused by air pipe disconnection or other faults (see chapter "System Faults").

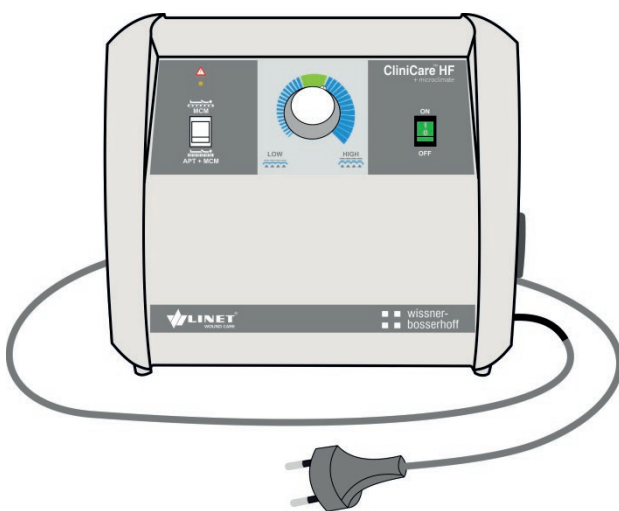


Fig. SCU for CliniCare 100 HF with MCM mode

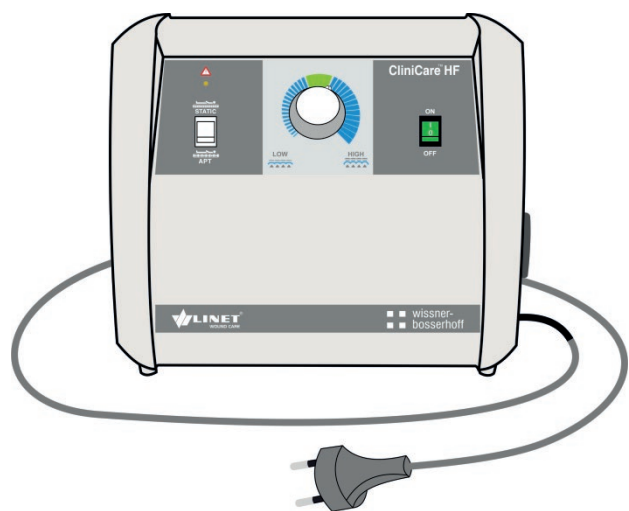


Fig. SCU for CliniCare 100 HF without MCM mode

## 5 Technical Specification

### 5.1 Mechanical Specification

#### 86 CM WIDE VERSION

**CAUTION!**

Height value of the edge of not loaded inflated mattress is 20 cm and height value in the middle of the mattress is 24,5 cm. This fact does not increase the risk of patient's falling down over the siderails. Decisive value for choice of the safe mattress in relation to the siderails is 20 cm.

| Parameter                                                                                                                             | Value                                         |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| External mattress dimensions (length x width)<br>Version 1<br>Version 2<br>Version 3                                                  | 200 x 86<br>208 x 86<br>213 x 86              |
| Mattress height (inflated)                                                                                                            | 24,5 cm                                       |
| Mattress height (deflated)                                                                                                            | 20 cm                                         |
| External dimensions of SCU (length x width x height)                                                                                  | 30 x 12 x 22 cm                               |
| Weight<br>■ CliniCare 100 HF mattress<br>■ CliniCare 100 HF System Control Unit (SCU)                                                 | 16 kg<br>2,5 kg                               |
| Cycle<br>■ Mattress (inflated)                                                                                                        | 2 cells technology, 12 minutes                |
| Environmental conditions (Use conditions)<br>■ Ambient Temperature<br>■ Relative Humidity<br>■ Atmospheric Pressure                   | 10 °C – 40 °C<br>30% – 75%<br>795 – 1060 hPa  |
| Environmental conditions (Storage and Transport Conditions)<br>■ Ambient Temperature<br>■ Relative Humidity<br>■ Atmospheric Pressure | -20 °C – 50 °C<br>20% – 90%<br>795 – 1060 hPa |
| Maximal load                                                                                                                          | 230 kg                                        |
| Sound Pressure Level                                                                                                                  | 35 dBA                                        |

## 100 CM WIDE VERSION



### CAUTION!

Height value of the edge of not loaded inflated mattress is 18 cm and height value in the middle of the mattress is 22,5 cm. This fact does not increase the risk of patient's falling down over the siderails. Decisive value for choice of the safe mattress in relation to the siderails is 18 cm.

| Parameter                                                                                                                                                                                    | Value                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| External mattress dimensions (length x width)                                                                                                                                                | 200 x 100                                     |
| Mattress height (inflated)                                                                                                                                                                   | 22 cm                                         |
| Mattress height (deflated)                                                                                                                                                                   | 18 cm                                         |
| External dimensions of SCU (length x width x height)                                                                                                                                         | 30 x 12 x 22 cm                               |
| Weight <ul style="list-style-type: none"><li>■ CliniCare 100 HF mattress</li><li>■ CliniCare 100 HF System Control Unit (SCU)</li></ul>                                                      | 17 kg<br>2,5 kg                               |
| Cycle <ul style="list-style-type: none"><li>■ Mattress (inflated)</li></ul>                                                                                                                  | 2 cells technology, 12 minutes                |
| Environmental conditions (Use conditions) <ul style="list-style-type: none"><li>■ Ambient Temperature</li><li>■ Relative Humidity</li><li>■ Atmospheric Pressure</li></ul>                   | 10 °C – 40 °C<br>30% – 75%<br>795 – 1060 hPa  |
| Environmental conditions (Storage and Transport Conditions) <ul style="list-style-type: none"><li>■ Ambient Temperature</li><li>■ Relative Humidity</li><li>■ Atmospheric Pressure</li></ul> | -20 °C – 50 °C<br>20% – 90%<br>795 – 1060 hPa |
| Maximal load                                                                                                                                                                                 | 180 kg                                        |
| Sound Pressure Level                                                                                                                                                                         | 35 dBA                                        |

## 5.2 Electrical Specifications

| Parameter                        | Value                                               |
|----------------------------------|-----------------------------------------------------|
| Supply nominal voltage           | 220-240 VAC, 50/60 Hz                               |
| Maximum input power              | 15VA                                                |
| Ingress Protection (SCU)         | IP3X                                                |
| Power plug                       | NEMA Type 1-15P polarized                           |
| Fuses (SCU)                      | 2x (T 1A L) anti-surge fuse<br>(250 V, type 5x20mm) |
| Electrical safety class          | Class II with applied parts type B                  |
| Electrical safety                | In conformity with IEC 60601-1                      |
| Electromagnetic compatibility    | IEC 60601-1-2                                       |
| Fire Resistance (mattress cover) | BS 7175 ignition sources 0, 1 and 5                 |

## 5.3 Electromagnetic compatibility

Air mattress system is intended for hospitals except for near active HF surgical equipment and the RF shielded room of a medical system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Air mattress system has defined no essential performance.



**WARNING!**

It is recommended to avoid the use of this device next to or in block with other device, because it could lead to improper operation. If such use is needed, this device and the other equipment should be under surveillance to verify proper operation. (Does not apply for compatible medical bed from LINET)

**List of used cables:**

1. Mains cable, maximum length 6 m



**WARNING!**

Use of the accessories, converters and other cables, than specified and provided by manufacturer of this air mattress system could lead to increase of electromagnetic emission or lower the electromagnetic immunity of this air mattress system and lead to improper operation.



**WARNING!**

Mobile RF communication device (including end use devices like antenna cables and external antenna) should not be used closer than 30 cm (12 inches) from any part of this air mattress system CliniCare 100 HF, including cables specified by manufacturer. Otherwise this could lead to deterioration of functionality of this air mattress system.



**WARNING!**

Do not overload the air mattress system (Maximum Load), respect the duty cycle (INT.) and consider chapter 11 Maintenance in order to maintain the basic safety with regard to electromagnetic disturbances for the expected service life.

### 5.3.1 Manufacturer instructions - electromagnetic emissions

| Emission Test                                             | Compliance |
|-----------------------------------------------------------|------------|
| RF emissions<br>CISPR 11                                  | Group 1    |
| RF emissions<br>CISPR 11                                  | Class B    |
| Harmonic emissions<br>IEC 61000-3-2                       | Class A    |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | Complies   |

### 5.3.2 Manufacturer instructions - electromagnetic susceptibility

| Immunity Tests                                                                                                  | Compliance level                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                                  | ± 8 kV for contact discharge<br>± 15 kV for contact discharge                                                                                                   |
| Radiated RF<br>IEC 61000-4-3<br><br>Proximity fields from RF wireless communications equipment<br>IEC 61000-4-3 | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz<br><br>See Table 1                                                                                                |
| Fast electrical transients / burst<br>IEC 61000-4-4                                                             | ±2 kV for power line<br>repetition frequency 100 kHz                                                                                                            |
| Surge<br>IEC 61000-4-5                                                                                          | ± 1 kV Line-to-line<br>± 2 kV Line-to-ground                                                                                                                    |
| Conducted RF<br>IEC 61000-4-6                                                                                   | 3 V (0,15 MHz – 80 MHz)<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz                                                                     |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8                                                      | 30 A/m                                                                                                                                                          |
| Voltage dips, short interruptions on power supply input lines<br>IEC 61000-4-11                                 | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° a 315°<br>0 % UT; 1 cycle and 70 % UT; 25/30 cycle<br>Single phase: at 0°<br>0 % UT; 250/300 cycle |

**Table 1 - IMMUNITY to RF wireless communications equipment**

| Test frequency (MHz)    | Band (MHz)    | Service                                                                  | Modulation                         | Immunity Test Level<br>V/m |
|-------------------------|---------------|--------------------------------------------------------------------------|------------------------------------|----------------------------|
| 385                     | 380 - 390     | TETRA 400                                                                | Pulse modulation 18 Hz             | 27                         |
| 450                     | 430 - 470     | GMRS 460, FRS 460                                                        | FM ± 5 kHz deviation 1<br>kHz sine | 28                         |
| 710<br>745<br>780       | 704 - 787     | LTE band 13, 17                                                          | Pulse modulation 217<br>Hz         | 9                          |
| 810<br>870<br>930       | 800 - 960     | GSM 800/900, TETRA<br>800, iDEN 820, CDMA<br>850,<br>LTE band 5          | Pulse modulation 18 Hz             | 28                         |
| 1 720<br>1 845<br>1 970 | 1 700 - 1 990 | GSM 1800; CDMA<br>1900; GSM 1900;<br>DECT; LTE band 1, 3,<br>4, 25; UMTS | Pulse modulation 217<br>Hz         | 28                         |
| 2 450                   | 2 400 - 2 570 | Bluetooth, WLAN,<br>802.11 b/g/n, RFID<br>2450,<br>LTE band 7            | Pulse modulation 217<br>Hz         | 28                         |
| 5 240<br>5 500<br>5 785 | 5 100 - 5 800 | WLAN 802.11 a/n                                                          | Pulse modulation 217<br>Hz         | 9                          |

**NOTE** There are applied no deviations to requirements of IEC 60601-1-2 ed. 4

**NOTE** There are no known other measures for keeping the basic safety based on EMC phenomena.

## 6 Use and Storage Conditions



### **DANGER!**

**Risk of injury due using CliniCare 100 HF system in incorrect environments!**

- ▶ Never use or store CliniCare 100 HF system in environments which contains flammable gases (except oxygen cylinders).

### 6.1 Storage



### **CAUTION!**

**Incorrect storage can damage the mattress!**

- ▶ Do not store mattress in compressed state (e.g. underneath other mattresses) or rolled state for long periods of time as this may affect the performance of the air/foam cells.

#### **When SCU is not in use:**

- ▶ Switch off SCU using power switch on the control panel of SCU.
- ▶ Unplug power cord.
- ▶ Wrap power cord around SCU.
- ▶ Pack in suitable cover.
- ▶ Store in a place suitable for electronic medical devices.

#### **When mattress is not in use:**

- ▶ Store flat, unfolded and in dust proof bag.
- ▶ Store in a place suitable for medical devices.
- ▶ The most convenient storage: vertical

## 7 Scope of Delivery and Bed Variants

### 7.1 Delivery

- Upon receipt, check that the shipment is complete as specified on the delivery note.
- Notify the carrier and supplier about any deficiencies or damages immediately as well as in writing or enter them on the delivery note.

### 7.2 Contents

There are two versions of CliniCare 100 HF. Check the table below to recognize your version.

|                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>CliniCare 100 HF with MCM mode:</b> <ul style="list-style-type: none"><li>■ Mattress with cover with MCM layer – CliniCare 100 HF</li><li>□ 3 air connectors</li><li>■ SCU (System Control Unit) with hose – Applied part type B</li><li>□ STATIC and APT+MCM modes</li><li>■ Instructions for use</li></ul> | <b>CliniCare 100 HF without MCM mode:</b> <ul style="list-style-type: none"><li>■ Mattress with cover – CliniCare 100 HF</li><li>□ 2 air connectors</li><li>■ SCU (System Control Unit) with hose – Applied part type B</li><li>□ STATIC and APT modes</li><li>■ Instructions for use</li></ul> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

---

## 8 Putting into Service

### 8.1 Placing CliniCare 100 HF on the Bed



**WARNING!**

**Material damage due to incorrect placement of the mattress!**

- ▶ When using mattress replacement or overlay systems, make sure to use safe and appropriate siderail positions and bed height settings. Which positions and settings are safe and appropriate may vary with the type of bed frame and siderails. Before placing a patient on CliniCare 100 HF mattress, always have a qualified person perform a risk assessment to ensure that the support provided is appropriate and fulfills the applicable local stipulations.



**WARNING!**

**Malfunction of the system due to incorrect placement of the sheet!**

- ▶ Ensure the sheet is not preventing the functions of the mattress and system (e.g. due to overtightening the sheet over the mattress).



**CAUTION!**

**Risk of damaging the mattress due to use of inappropriate bed!**

- ▶ Ensure that the mattress dimensions and shape are correct for the bed frame and that the patient surface is flat and level once the mattress is in place.

#### 8.1.1 Putting into Service – CliniCare 100 HF Mattress

**Before placing mattress on the bed:**

- ▶ Unpack the mattress in area with clear, sufficient space for unfolding and expansion.
- ▶ Inspect the mattress for shipping damage. In case of damage do not use the mattress and contact your distributor.

**To secure mattress on the bed:**

- ▶ Place the CliniCare 100 HF mattress (in good condition and free of any damage or wear) on the mattress platform, with the air pipe at the patients left foot side (foot symbol on the mattress cover determines placement) and position so that the mattress is centred.
- ▶ Check if the mattress, air pipe or the SCU is not colliding with any part of the bed or if the mattress is not preventing side rails in its movement.
- ▶ If the mattress is compressed (e.g. after storage) wait until it returns back to the original state.
- ▶ If the mattress does not appear to have recovered, do not use it and contact your distributor.

The CliniCare 100 HF mattress can now be connected to the SCU and inflated.

#### 8.1.2 Putting into Service – SCU (System Control Unit)



**WARNING!**

**Risk of injury when putting SCU into service!**

- ▶ Make sure that your hands are not trapped between hook and foot board when using spring-loaded SCU hanging hooks.
- ▶ Make sure that the SCU is installed securely so that it cannot slide or be accidentally knocked off.



**WARNING!**

**Risk of injuring the patient or damaging the accessories due to incorrect putting into service!**

- ▶ Ensure the SCU does not collide with any accessories placed on the bed.



**CAUTION!**

**Material damage due to incorrect putting SCU into service!**

- ▶ Do not install SCU on linen rack on bed frame.
- ▶ Make sure that the SCU is installed securely so that it cannot slide or be accidentally knocked off.

---

**If foot board of the bed is suitable for hanging SCU:**

- ▶ Hold SCU in one hand and unfold hooks on back with the other.
- ▶ Hang SCU on the foot board of the bed.

**If foot board of the bed is not suitable for hanging SCU:**

- ▶ Stand the SCU upright on the floor.

**NOTE:** Take extra caution when manipulating the bed or moving around the bed when the SCU is standing on the floor.



*Fig. Installation of SCU on the foot board*

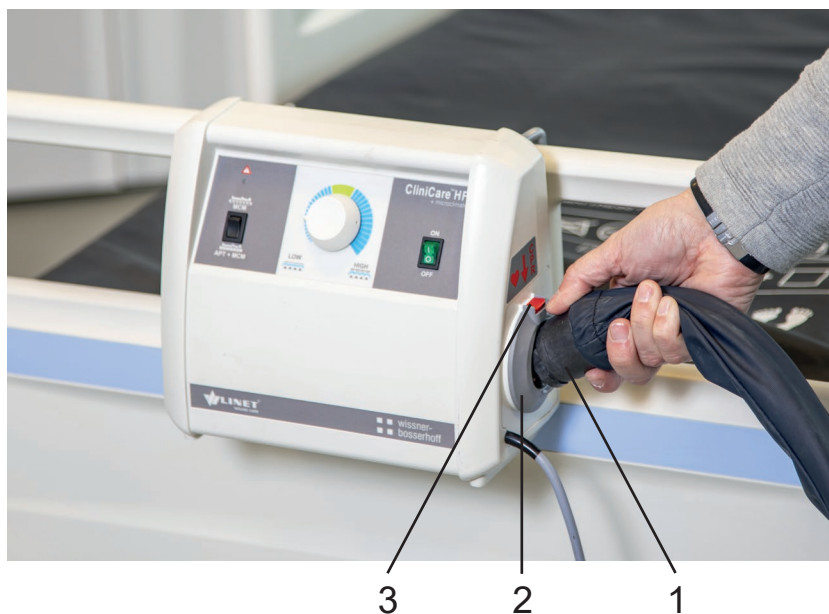


*Fig. Installation of SCU on the floor*

## 8.2 Connecting Mattress with SCU

**Installation:**

- ▶ Insert air connector **1** in the socket **2** at an angle of approx. 45°.
- ▶ Push air connector **1** down until it clicks into place and air connector latch **3** secures the air connector against dropping off.



- 1. Air connector
- 2. SCU air connector socket
- 3. Air connector latch

*Fig. Installation of SCU*

---

## 8.3 Connecting Air Pipes with Mattress

In order to switch mattress from reactive to active it is necessary to connect air pipes from the SCU to the mattress.

### 8.3.1 Mattress with MCM mode

Connect air pipes as follows:

- ▶ Connect all 3 air pipes with 3 air connectors on the mattress in the direction of arrow until it clicks into place.
- ▶ Ensure that all 3 air pipes are connected properly by pulling them back.



*Fig. Connecting air pipes to the mattress with MCM mode*



*Fig. Connected air pipes to the mattress with MCM mode*

---

### 8.3.2 Mattress without MCM mode

Connect air pipes as follows:

- ▶ Connect both air pipes with 2 air connectors on the mattress in the direction of arrow until it clicks into place.
- ▶ Ensure that both air pipes are connected properly by pulling them back.



*Fig. Connecting air pipes to the mattress without MCM mode*



*Fig. Connected air pipes to the mattress without MCM mode*

---

## 8.4 Disconnecting Air Pipes from Mattress (aka Switching to reactive mattress)

It is possible to disconnect air pipes and switch the mattress from active to reactive. This means the mattress can be used without SCU. The mattress then provides reactive pressure redistribution through self adjusting air cells.

### 8.4.1 Mattress with MCM mode

Disconnect air pipes as follows:

- ▶ Press and hold the metal plate on the air connector.
- ▶ Pull the air pipe out of the air connector.
- ▶ Repeat on the remaining air pipes.

Air pipes are removed from the mattress.



*Fig. Disconnecting air pipes from the mattress with MCM mode*



*Fig. Disconnected air pipes from the mattress with MCM mode*

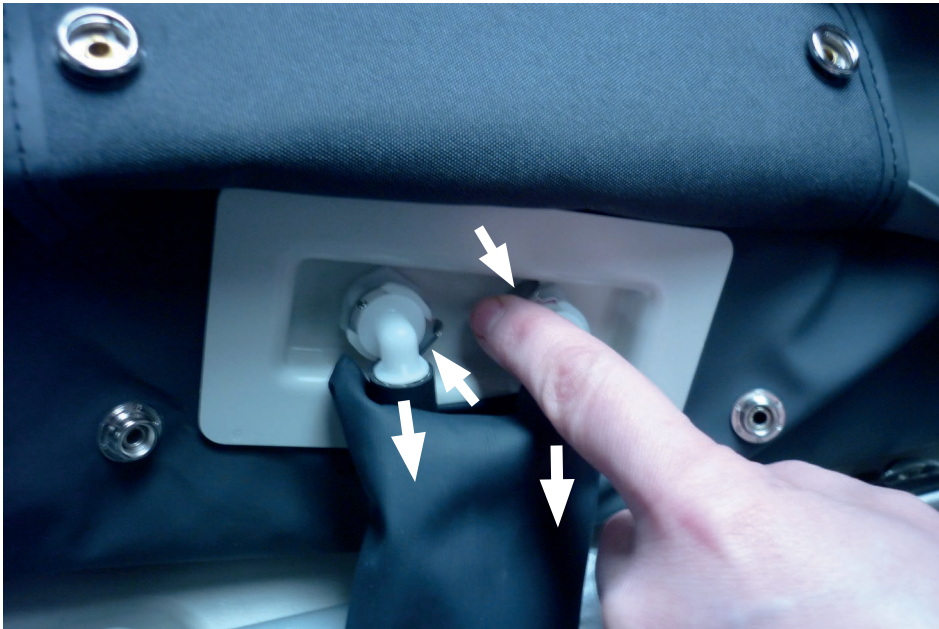
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## 8.4.2 Mattress without MCM mode

Disconnect air pipes as follows:

- ▶ Press and hold the metal plate on the air connector.
- ▶ Pull the air pipe out of the air connector.
- ▶ Repeat on the remaining air pipe.

Air pipes are removed from the mattress.



*Fig. Disconnecting air pipes from the mattress without MCM mode*



*Fig. Disconnected air pipes from the mattress without MCM mode*

---

## 8.5 Inflation

- ▶ Connect mattress to the SCU using air connectors.
- ▶ Ensure that SCU is not covered and air flow around SCU is not obstructed in order to avoid overheating.
- ▶ Position the power cord so there is no risk of injuring the patient (e.g. choking hazard) or blocking the bed positioning functions.
- ▶ Plug SCU power cord into suitable power socket.

### 8.5.1 Switching SCU ON/OFF

**To switch ON SCU:**

- ▶ Switch on SCU using green illuminated power switch on front of SCU (see Fig. Switching on SCU).  
SCU has been switched on.

**To switch OFF SCU:**

- ▶ Switch off SCU using green illuminated power switch on front of SCU (see Fig. Switching on SCU).
- ▶ Disconnect power cable from the power source.  
SCU has been switched off.



*Fig. Switching on SCU*

### 8.5.2 Inflation

**Inflation:**

- ▶ Select required mode (see chapter “Control panel – CliniCare 100 HF”).
- ▶ After switching ON the mattress will start to inflate, the indicator  is illuminated during inflation.  
Set the pressure control dial into middle – green position (see Controls and Indicators).
- ▶ Inflation may take up to 10 minutes. When inflation is complete, the indicator  is no longer illuminated.

**When the inflation process is finished:**

- ▶ Check the mattress is still securely positioned on the bed frame.

**If indicator  is illuminated longer than 20 minutes:**

- ▶ Check if air pipe is connected correctly.
- ▶ Check the meaning of the system error (see System errors).

---

## 9 Manipulation

### 9.1 Use

#### 9.1.1 Preparing the Bed for the Patient

**DANGER!****Risk of injury when putting patient into bed!**

Before putting patient on the bed:

- ▶ Ensure the mattress is fully inflated and placed correctly.
- ▶ Alignment of the bed frame, side rails and the mattress should leave no gap wide enough to entrap a patient's head or body, or to allow egress to occur in a hazardous manner where entanglement with the power cable or air connector may result. Care should be exercised to prevent occurrence of gaps by compression or movement of the mattress. Death or serious injury may occur.

**WARNING!****Danger of suffocation due to vapor permeable mattress cover!**

- ▶ Use the mattress cover correctly.
- ▶ The nursing staffs are responsible for the safe nursing of the patient on the mattress cover.

**CAUTION!****Risk of infection due to lacking of cleaning or cover damage!**

- ▶ Ensure that no moisture gets into the mattress.
- ▶ Ensure that no body fluids get into the mattress cover.
- ▶ Mattress must be cleaned thoroughly between patients and decontaminated after patients with known or suspected infections.
- ▶ If moisture gets into the system, notify LINET Service.

**Preparation**

- ▶ Inflate mattress (see Initial Operation).
- ▶ Put a sheet loosely on the mattress if not prescribed otherwise by qualified personnel.

**NOTE:** The air connector on the SCU must be kept uncovered for visibility and access.

**NOTE:** It is possible to inflate mattress with patient on the mattress.

**Putting Patient into Bed**

- ▶ Lay patient on mattress.

**For an ideal lying position:**

- ▶ If additional blankets or sheets are used, make sure that ease of movement is sufficient.
- ▶ Ensure that blankets, sheets, clothing etc. do not cause pressure sores (e.g. due to creases, seams etc.).
- ▶ Do not place any additional sheets, blankets, pads etc. between mattress and patient.

## 9.2 Control panel – CliniCare 100 HF with Micro-Climate Management

The control panel of the SCU serves to control the mattress replacement system and shows errors. Alarms are signaled by illumination of the indicator 2.

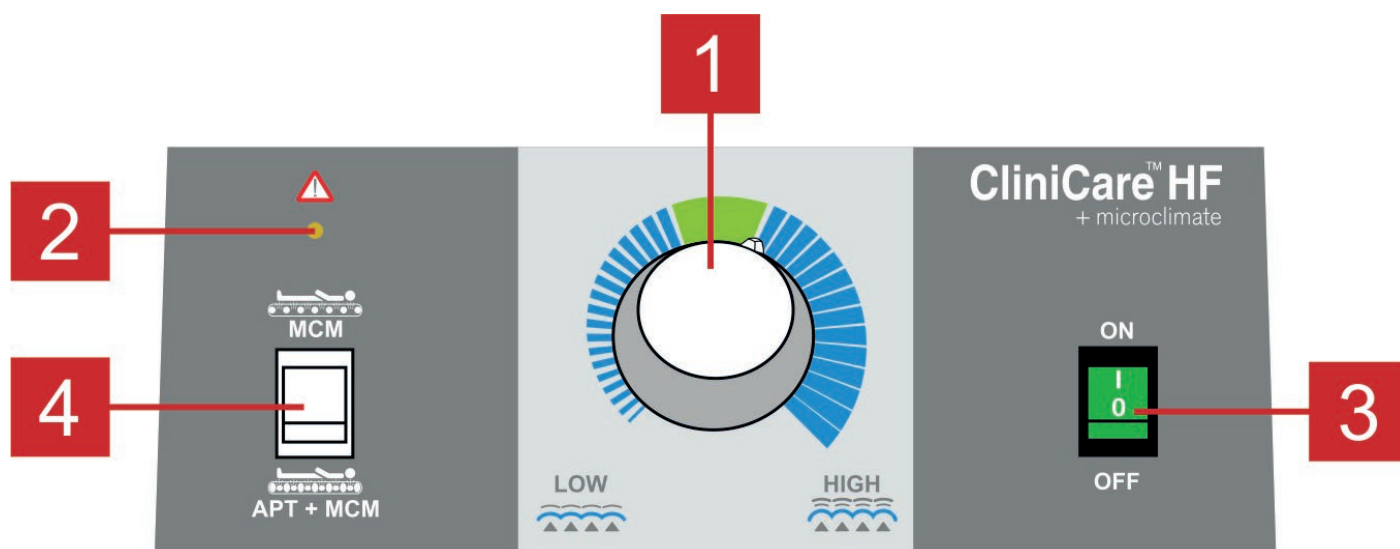


Fig. SCU Control Panel – CliniCare 100 HF with MCM mode

| Position | Control / Indicator    | Function                                                                                                                                                                       |
|----------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1        | Pressure control dial  | Adjusting the mattress pressure for more comfort or support of the patient<br><b>HIGH:</b> High pressure<br><b>LOW:</b> Low pressure                                           |
| 2        | Low pressure indicator | Indicates low pressure in the mattress (see System errors).                                                                                                                    |
| 3        | Power switch           | <b>I</b> : ON<br><b>O</b> : OFF                                                                                                                                                |
| 4        | Mode selection switch  | <b>MCM:</b> Fully inflated mattress. Static mode with micro-climate management.<br><b>APT + MCM:</b> Alternating pressure therapy. Dynamic mode with micro-climate management. |

### 9.2.1 MCM – Micro-Climate Management

MCM mode provides a stable non-alternating surface for the patient when getting into or out of bed or if required when performing nursing procedures, whilst also maintaining a circulating micro climate beneath the patient. Air cell pressure can be varied using the manual pressure control.

#### When MCM mode is selected:

SCU will inflate the 8 air cells under the patients torso to the same pressure.

### 9.2.2 APT+MCM – Alternating pressure therapy + Micro-Climate Management

In APT + MCM mode CliniCare 100 HF operates by alternating pressure in a two cell system in a 12 minute interval cycle. This imitates the natural movement of the patient. During this cycle reduced pressure acts on the patient which helps to prevent and treat pressure sores. Whilst also maintaining a circulating microclimate beneath the patient.

#### When APT mode is selected:

- 2-cell mattress will inflate and deflate in cycles of 12 minutes.

## 9.3 Control panel – CliniCare 100 HF without Micro-Climate Management

The control panel of the SCU serves to control the mattress replacement system and shows errors. Alarms are signaled by illumination of the indicator 2.

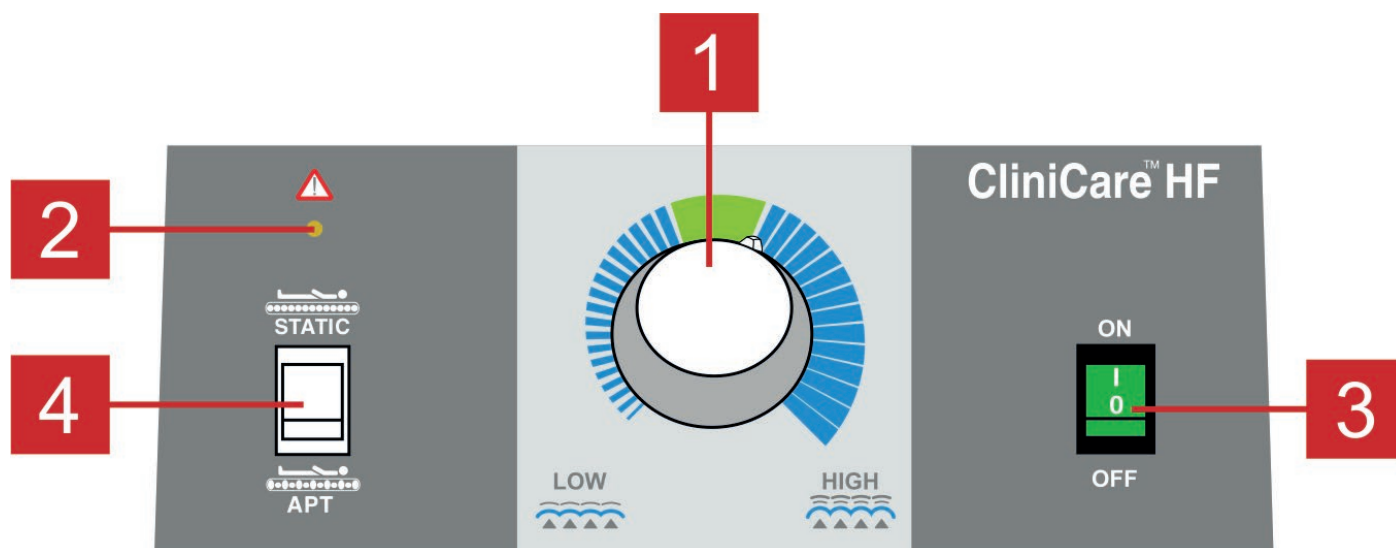


Fig. SCU Control Panel – CliniCare 100 HF without MCM mode

| Position | Control / Indicator    | Function                                                                                                                               |
|----------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 1        | Pressure control dial  | Adjusting the mattress pressure for more comfort or support of the patient<br><b>HIGH</b> : High pressure<br><b>LOW</b> : Low pressure |
| 2        | Low pressure indicator | Indicates low pressure in the mattress (see System errors).                                                                            |
| 3        | Power switch           | <b>I</b> : On<br><b>O</b> : Off                                                                                                        |
| 4        | Mode selection switch  | <b>STATIC</b> : Fully inflated mattress. Static mode.<br><b>APT</b> : Alternating pressure therapy. Dynamic mode.                      |

### 9.3.1 APT – Alternating pressure therapy

CliniCare 100 HF operates by alternating pressure in a two cell system in a 12 minute interval cycle. This imitates the natural movement of the patient. During this cycle reduced pressure acts on the patient which helps to prevent and treat pressure sores.

#### When APT mode is selected:

- 2-cell mattress will inflate and deflate in cycles of 12 minutes.

### 9.3.2 STATIC – Static inflated mode

Static mode provides a stable surface for the patient when getting into or out of bed or if required when performing nursing procedures. Air cell pressure can be varied using the manual pressure control.

#### When STATIC mode is selected:

- SCU will inflate all cells to the same pressure.

## 9.4 Pressure Control



### **WARNING!**

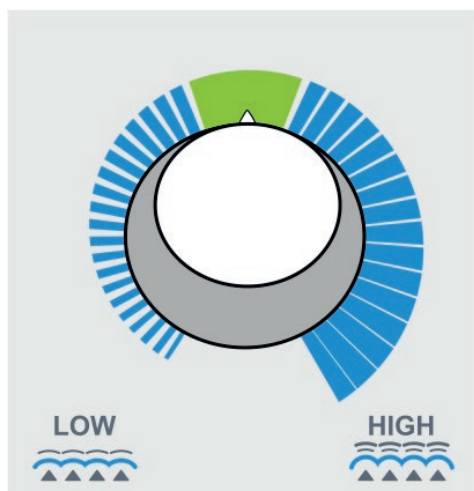
#### **Risk of injury due to incorrect pressure setting!**

- ▶ Consult qualified hospital staff prior to adjusting pressure.
- ▶ The recommended pressure levels may not be the optimum for all situations but should be used in conjunction with clinical judgement based on the individual patient; e.g. weight, weight distribution, position and comfort needs.
- ▶ Always make sure the patient is not lying directly on the foam base or bed frame.

### 9.4.1 Pressure Settings - Mattress

The pressure control dial allows the nursing staff to adjust the pressure within a preset range. It is important to follow the correct pressure setting procedure to ensure the patient receives good support, pressure redistribution and comfort.

The green section (top non-striped section) of the dial should be suitable for laying patients in the weight range 100-220 lbs (50-90 kg). This should serve as an approximate guide only as patients BMI and position will affect their required level of support pressure.



#### **To adjust pressure:**

- ▶ Turn the rotating dial to the left to decrease pressure.
- OR-
- ▶ Turn the rotating dial to the right to increase pressure.

#### **Pressure levels:**

- ▶ below green section
- ▶ for small or light patients
- ▶ above green section
- ▶ for big or heavy patients
- ▶ for patients sitting up in bed
- ▶ for patient positions or body shapes that concentrate the patient's weight on small areas of the mattress

*Fig. Pressure levels control*

#### **Select pressure as follows:**

With the mattress fully inflated using MCM or STATIC mode.

- ▶ Select the required operating mode.
- ▶ Set the pressure control dial vertical, pointing into the center of the green section (top non-striped section) of the dial.
- ▶ Lay the patient on the mattress.
- ▶ Wait at least 6 minutes while the pump adjusts the pressures.
- ▶ A clinical professional needs to confirm that the patient is properly supported.
- ▶ If the support level is ok but the patient needs greater comfort then the pressure level can be reduced by turning the pressure control dial to the left, then repeating the patient's sacral check.

### 9.4.2 Pressure Settings – Changes in Patient's Position

When a patient is lying down, their body weight is supported over the full length of the mattress. While sitting up the weight is concentrated on a smaller area and they may need more support.

#### **Select pressure as follows:**

- ▶ If the patient is in seated position it is recommended, in order to maximize the benefit of the mattress, to repeat select pressure instructions from chapter "Pressure Settings – Mattress".

**NOTE:** Take note of the pressure setting that was being used when patient was lying so that it can be reset to the same level when patient lies down.

## 9.5 CPR – Cardipulmonary resuscitation



Fig. CPR Function

### Before starting CPR with SCU connected:

- ▶ Press red CPR button.
- ▶ Remove air connector plug from SCU.
- ▶ Mattress starts to deflate and resuscitation procedure can commence.

## 9.6 Power failure



### WARNING!

#### Risk of injury due to power failure!

- ▶ Seek clinical advice immediately as alternating pressure therapy is not possible during power failures.

In case of power failure the mattress will return to reactive only operation. If the air connectors and SCU are left attached the mattress will remain inflated for at least 12 hours. No active modes are available without power.

## 9.7 System faults

System faults are indicated by the amber light on the SCU.

**NOTE:** During initial inflation the low pressure indication will come on until the mattress has achieved its minimum pressure. This does not mean there is a fault unless the indicator has been on for more than 20 minutes after a power cycle.

| CliniCare 100 HF SCU |                                       |
|----------------------|---------------------------------------|
| Meaning              | Indicator                             |
| Low pressure         | Low pressure indicator is illuminated |
| Power failure        | Power switch is not illuminated       |

| Problem                              | Symptom CliniCare 100 HF SCU                                                                                                                                                                              | Action                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Power failure (SCU will not turn on) | Power switch not illuminated                                                                                                                                                                              | <p>Check that the Power switch on the SCU is in the on ( I ) position.</p> <p>Check the SCU is connected to an electrical wall socket and the outlet switch is in the correct position.(If necessary check the outlet by connecting a different appliance). Then <b>1</b>.</p> <p><b>NOTE:</b> If the power switch is not illuminated but the SCU is running then the internal indicator has failed and will need to be replaced by a service engineer.</p> |
| Power failure during use             | Power switch not illuminated                                                                                                                                                                              | As above. Then <b>1</b> .                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Fail to inflate or soft mattress     | <p>Low pressure indicator on</p> <p><b>NOTE:</b> This may happen during normal use while the mattress is adjusting and no action is required unless the indicator remains on for an extended period.)</p> | <p>Check air if connection to mattress is ok.</p> <p>Check that the mattress has been rolled out flat and air pipes are not twisted or trapped in any part of the bedframe.</p> <p>Open the mattress cover and check that no air pipes are damaged or disconnected</p> <p><b>NOTE:</b> Slightly increase the pressure setting and see if problem stops.</p> <p>Then <b>1</b>.</p>                                                                           |
| Not alternating                      | Air cells not alternating in APT+MCM mode                                                                                                                                                                 | Check all air connections same as for 'Fail to inflate' and <b>1</b> .                                                                                                                                                                                                                                                                                                                                                                                      |
| Hard mattress                        | Air cells very hard in APT+MCM or MCM modes                                                                                                                                                               | <p>Check all air connections same as for 'Fail to inflate'</p> <p>Reduce pressure setting to lowest level then <b>1</b>.</p>                                                                                                                                                                                                                                                                                                                                |

**1** Restart unit by turning power off and then back on. If fault re-occurs turn off SCU and immediately call your local approved service provider.

**NOTE:** If ATP and/or MCM modes are not available due to system fault then immediately consult a suitable clinician to confirm if the patient must be transferred onto a working system while waiting for the service engineer to arrive.

## 10 Cleaning/Disinfection



### CAUTION!

**Incorrect cleaning/disinfection can damage the mattress and SCU!**

- ▶ Do not use pressure or steam cleaners.
- ▶ Follow the instructions and observe the dosages recommended by the manufacturer.
- ▶ Ensure that disinfectants are selected and applied by qualified hygiene experts only.
- ▶ Continued use of high concentration, chlorine-based disinfectants may significantly reduce the performance and the working life of a coated material.
- ▶ The SCU is not sealed against fluid ingress so care must be taken to ensure that no fluid enters the SCU during cleaning.

### 10.1 General Guidance

#### For safe and gentle cleaning:

- ▶ Disconnect SCU from mains.
- ▶ Do not use any strong acids or alkalines, (optimum pH range 6 – 8. Do not exceed pH of 9).
- ▶ Only use detergents that are suitable for cleaning medical equipment non-hard surfaces and textiles.
- ▶ Do not use abrasive powders, steel wool, or other material and cleaning agents that might damage the mattress. Do not scrub mattress surface.
- ▶ Never use any corrosive or caustic detergents.
- ▶ Never use detergents that deposit calcium carbonate.
- ▶ Never use detergents with solvents that might affect the structure and consistency of the plastics (benzene, toluene, acetone, alcohol etc.).
- ▶ Use only hospital-approved cleaners and observe local directives concerning infection control.
- ▶ Always rinse with water (except SCU) after cleaning and dry thoroughly before use.
- ▶ Clean electrical components carefully and allow them to dry fully. It is recommended to use the cleaning wipes.
- ▶ Neither immerse SCU in water nor heat or steam-clean it.
- ▶ Observe local directives concerning infection control.

| Mattress parts to be cleaned                               | Recommended Cleaning Agents (General cleaning)                                                                                                                                                                                            |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Top Cover<br>High MVP (Moisture Vapor Permeable) Material. | Standard hospital detergents, Alcohol or Quaternary Ammonium based disinfectants, Chlorine based disinfectants containing up to 1000 ppm Chlorine, followed by rinsing with water and drying thoroughly before use.                       |
|                                                            | <b>Decontamination: Blood spills/C-diff. etc</b><br>Chlorine based disinfectants containing up to 10,000 ppm Chlorine. Dwell time on surface at 10,000 ppm of 2 minutes, followed by rinsing with water and drying thoroughly before use. |
| Base Cover, Air Cells, Foam Base                           | As procedures above.                                                                                                                                                                                                                      |

Due to the variety of laundry equipment, chemicals and conditions in use, customers should satisfy themselves through pre-testing. It is essential that articles be thoroughly rinsed and dried after all cleaning procedures and before storage or reuse. Wet or damp PU surfaces are more prone to mechanical damage than when dry.

As stated above, after application of a suitable cleaner, the surface must be rinsed with water and dried before use. (Even if the cleaner instructions say that this is not required). This prevents a build up of chemicals on the mattress surface which could be reactivated during use and affect biocompatibility.

| Type of Cleaning                  | Parts to be cleaned                                                                                   |
|-----------------------------------|-------------------------------------------------------------------------------------------------------|
| Routine Cleaning and Disinfection | <ul style="list-style-type: none"><li>■ exposed mattress parts</li><li>■ exposed SCU parts</li></ul>  |
| Full Cleaning and Disinfection    | <ul style="list-style-type: none"><li>■ vexposed mattress parts</li><li>■ exposed SCU parts</li></ul> |

---

## 10.2 Routine Cleaning and Disinfection

Read section “General Guidance” for more details of the recommended cleaning and disinfection processes.

### Cleaning the mattress:

- ▶ Check mattress cover top for any signs of damage or for liquid ingress. Any fluid contamination inside the mattress means the entire mattress must be replaced.
- Replace or repair and completely disinfect mattress cover top if damaged.
- ▶ Leave mattress cover on mattress.
- ▶ Clean with 50 °C warm water and cleaning detergent.
- ▶ Rinse mattress with cold water.
- ▶ Let mattress air dry or wipe dry.
- ▶ Wipe mattress with disinfectant.
- ▶ Wipe mattress with cold water.
- ▶ Let mattress air dry or wipe dry.

### Cleaning the SCU:

- ▶ Before cleaning of SCU, cover the air connector in order to prevent anything from penetrating into the air
- ▶ **connector during cleaning.**
- ▶ Wipe SCU with disinfectant. Wipe SCU with cold water. It is recommended to use the cleaning wipes.
- ▶ Let SCU air dry or wipe dry.

## 10.3 Full Cleaning and Disinfection



### CAUTION!

**Incorrect cleaning/disinfection can damage the system!**

- ▶ Continued use of high concentration, chlorine-based disinfectants may significantly reduce the performance and the working life of a coated material.

### 10.3.1 Cleaning Top Cover and/or Base Cover

Read section “General Guidance” for more details of the recommended cleaning and disinfection processes.

Use standard hospital detergents, Alcohol-based cleaners or Quaternary Ammonium based disinfectants. Suitable Chlorine based cleaners can be used at a concentration of 1000ppm. Stronger concentrations of chlorine can be used if required, of up to 10,000ppm (1%) Chlorine, (1:5 dilution of household chlorine bleach), with a maximum dwell time of two minutes at 10,000ppm, followed by rinsing with water and drying thoroughly before use.

After application of a suitable cleaner, the surface should be rinsed with water and dried before use. (Even if the cleaner instructions say that this is not required). This prevents a build up of chemicals on the mattress surface that could reactivate during use and affect biocompatibility.

### Cleaning the mattress (exterior):

- ▶ Disconnect mattress from SCU.
  - ▶ Check mattress cover top and base for any signs of damage.
- Replace or repair and completely disinfect mattress cover top and base if damaged. If there are any signs of fluid ingress through a damaged cover then all foam mattress parts must be disposed of as clinical waste and replaced with new original supplier spare parts.
- ▶ Rinse mattress with cold water.
  - ▶ Let mattress air dry or wipe dry.
  - ▶ Wipe mattress with disinfectant.
  - ▶ Wipe mattress with cold water.
  - ▶ Let mattress air dry or wipe dry.

**DO NOT ATTEMPT TO DISMANTLE OR CLEAN THE INTERIOR COMPONENTS OF THE MATTRESS!**

**NOTE:** Mattress should not be used for 30 minutes after drying to allow fabric coating to recover before use.

### 10.3.2 Machine washing of CliniCare 100HF removable top mattress cover

- ▶ Remove top cover (chapter Removing the Mattress Cover).
- ▶ **DO NOT ATTEMPT TO DISMANTLE OR CLEAN THE INTERIOR COMPONENTS OF THE MATTRESS**
- ▶ (MCM Cover only – Fully open the zipper in the white fabric to open the air space envelope.)
- ▶ If machine washing mattress top/base covers, the temperature should be raised during the wash cycle, to 65 °C, for 10 -15 minutes, or 71 °C, for 3 - 10 minutes, using hospital approved detergents and rinsing agents.
- ▶ Dry cover in tumble dryer at low temperature. Do not overload the dryer, otherwise covers will not dry.
- ▶ (MCM cover only – IMPORTANT - Fully close the zipper in the white fabric)

**NOTE:** Maximum washing temperature 75 °C.

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### 10.3.3 Cleaning the air pipe

- ▶ Wipe air pipe cover and exposed pipes with cleaning agent or disinfectant.
- ▶ Let air pipe dry.
- or-
- ▶ Remove the air pipe cover (see chapter Removing the Mattress Cover) and clean it as stated above (for the top mattress cover see chapter Machine washing of CliniCare 100HF removable top mattress cover), if full disinfection is required.
- ▶ Clean the pipes in general accordance with chapter Cleaning Top and/or Base Cover.
- ▶ Let air pipe dry.

### 10.3.4 Cleaning the SCU

- ▶ Remove filter.
- ▶ Before cleaning of SCU, cover the air connector in order to prevent anything from penetrating into the air connector during cleaning.
- ▶ Wash the filter or replace it with the new one.
- ▶ Wipe SCU with disinfectant. Wipe SCU with cold water. It is recommended to use the cleaning wipes.
- ▶ Let SCU and filter dry.
- ▶ Reinsert filter.

## 10.4 Removing the Mattress Cover

- ▶ Carefully open zip under side skirt of mattress cover on foot end of mattress.
- ▶ (MCM model only. Carefully disconnect the 2 MCM air pipes at the foot end of the mattress!)
- ▶ Remove top part of mattress cover. Inspect cover and clean if necessary.

#### After cleaning the mattress cover:

- ▶ Reinstall mattress cover by reversing the process described above.

## 10.5 Removing the Air Pipe Cover

- ▶ Carefully pull the cover from the (elasticated) SCU end connector block, and draw along the pipes lengths.
- ▶ Carefully pass the 3 connector elbows through the holes to separate from the cover.
- ▶ Machine wash the cover as per chapter Machine washing of CliniCare 100HF removable top mattress cover.

#### After cleaning the air pipe parts:

- ▶ Reinstall air pipe cover by reversing the process described above.

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## 11 Maintenance



### **WARNING!**

#### **Risk of injury when working on the mattress replacement system!**

- ▶ Ensure that the mattress replacement system is disconnected from the mains power prior to installation, putting into service, maintenance and deinstallation.



### **WARNING!**

#### **Risk of injury due to defective mattress replacement system!**

- ▶ Have a defective mattress replacement system repaired immediately.
- ▶ If the defect cannot be repaired, do not use the mattress replacement system.



### **CAUTION!**

#### **Material damage due to incorrect maintenance!**

- ▶ Ensure that maintenance is performed exclusively by manufacturer's customer service or by authorised service personnel certified by the manufacturer.
- ▶ If the defect cannot be repaired, do not use the mattress replacement system.

### 11.1 Regular maintenance

- ▶ Perform regularly visual check of the product (with delivery note if necessary).
- ▶ Ask service department of the manufacturer for addition of the original spare parts if some product parts are missing.
- ▶ Ask service department of the manufacturer for replacement of any damaged product parts by the original spare parts.
- ▶ Check inside and outside of mattress and outside of SCU for mechanical damage and signs of severe wear and tear.
- ▶ Check if mattress and SCU are working properly.
- ▶ Check external air filter in side of SCU for dust and dirt. If dust or dirt is visible, replace filter.

### 11.2 Spare Parts

The serial label is located on the SCU and on the mattress. The serial labels contain information for claims and ordering replacement parts.

#### **Information about spare parts is available from:**

- Manufacturer's customer service
- Sales department

### 11.3 Safety Technical Checks



### **WARNING!**

#### **Risk of injury due to incorrect safety technical checks!**

- ▶ Ensure that safety technical checks are performed exclusively by manufacturer's customer service or by authorised service personnel certified by the manufacturer.
- ▶ Ensure that the safety technical checks are recorded in the service and maintenance log.

**Safety technical check of the mattress replacement system must be performed at least once every 12 months.**

The procedure for performing the safety technical check is stipulated in EN 62353:2014.

**NOTE** On request, the manufacturer will provide service documentation (e.g. circuit diagrams, component part lists, descriptions, calibration instructions etc.) for service personnel for the repair of ME equipment designated by the manufacturer as repairable by service personnel.

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## 12 Disposal

### 12.1 Environment Protection

The company LINET® is aware of the importance of environmental protection for future generations. Within this company the environmental management system is applied in accordance with the internationally agreed standard ISO 14001. The compliance with this standard is annually tested by the external audit executed by an authorised company. Based on the Directive No. 2002/96/EC (Directive **WEEE** - Waste, Electric and Electronic Equipments) the company LINET, s. r. o. is registered in the List of Electric and Electronic Equipment Producers (**Seznam výrobců elektrozařízení**) on the Ministry of the Environment of the Czech Republic (Ministerstvo životního prostředí).

Materials used in this product are not environmentally hazardous. LINET® products meet valid requirements of national and European legislation in the areas of **RoHS** and **REACH**, so they do not contain any prohibited substances in excess quantities. None of the wooden parts is made of tropical wood (such as mahogany, rosewood, ebony, teak etc.) or made of timber from the Amazon region or from similar rainforests. Product noise (sound pressure level) meets requirements of the regulations for the protection of public health against undesirable effects of noise and vibration in protected interior spaces of buildings (according to standard IEC 60601-2-52). Used packaging materials are in accordance with requirements of the Packaging Act (**Zákon o obalech**). For disposal of packaging materials after installation of products contact your sales representative or manufacturer's customer service about the possibility of a free take-back of packaging through an authorized company (more details on [www.linnet.cz](http://www.linnet.cz)).

### 12.2 Disposal

The main objective of the obligations arising from the European Directive No. 2012/19/EU on Waste, Electric and Electronic Equipments (nationally regulated in Act No. 185/2001 Coll. as amended. On Waste and in Decree of the Ministry of the Environment No. 352/2005 Coll. as amended), is to increase the re-use, material recovery and recovery of electric and electronic equipment at the required level, thereby avoiding the production of waste and thereby avoiding the possible harmful effects of hazardous substances contained in electric and electronic equipment on human health and the environment. LINET® electric and electronic equipments that have a built-in accumulator or accumulator are designed so that the used accumulators or accumulators can be safely removed by LINET® qualified service technicians. There is an information about its type on the built-in accumulator or accumulator.

#### 12.2.1 Within Europe

**To dispose of the electric and electronic equipment:**

- ▶ The electric and electronic equipment must not be disposed of as household waste.
- ▶ Dispose of this equipment at designated collection points or take-back points.

**To dispose of the other equipment:**

- ▶ The equipment must not be disposed of as household waste.
- ▶ Dispose of this equipment at designated collection points or take-back points.

LINET® participates in a collective system with take-back company REMA System (see [www.remasystem.cz/sberna-mista/](http://www.remasystem.cz/sberna-mista/)). By bringing electric and electronic equipment to a take-back point, you participate in recycling and you save primary raw material resources while protecting your environment from effects of unprofessional disposal.

#### 12.2.2 Outside Europe

- ▶ Dispose of the product or its components in accordance with local laws and regulations!
- ▶ Hire an approved waste disposal company for disposal!

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## 13 Warranty

LINET will only be held responsible for the safety and reliability of products that are regularly serviced and used in accordance with the safety guidelines. Consult the warranty provided for your country.

**Should a serious defect arise that cannot be repaired during maintenance:**

► Do not continue to use the product.

Standards and Regulations

## 14 Standards and Regulations

Applied norms are stated on Declaration of Conformity.

The manufacturer adheres to a certified quality management system in compliance with the following standards:

- ISO 9001
- ISO 14001
- ISO 13485
- MDSAP (Medical Device Single Audit Program)