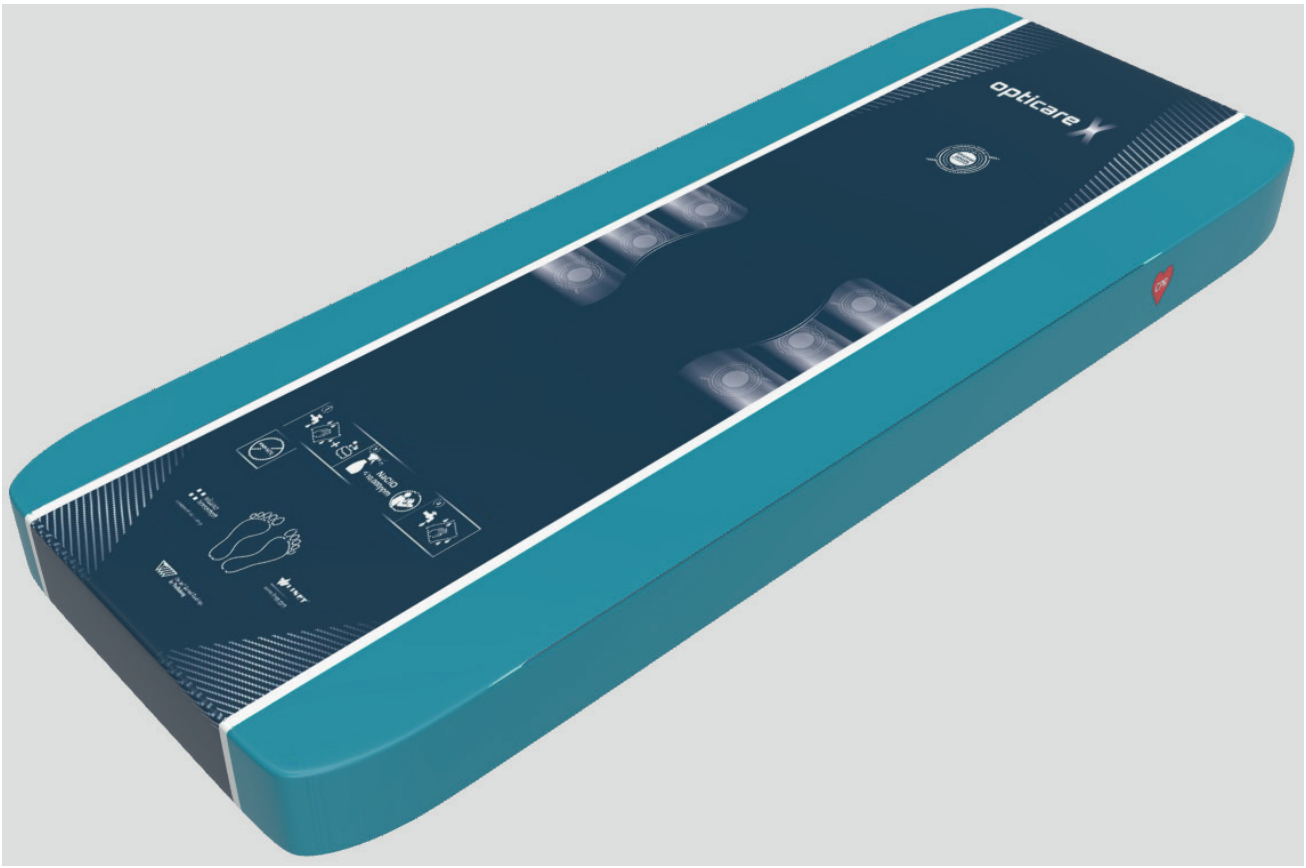
Instructions for Use and Technical Description



OptiCare X

Integrated Mattress System for Multicare X

CE

D9U003VSX-0110

Version: 02

Publication Date: 2021-03

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OptiCare X
Integrated mattress system for Multicare X

Author: LINET, s.r.o.
Related links: www.linet.com

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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:

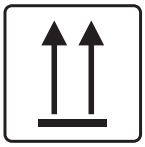
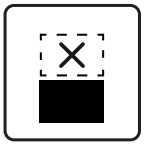
► Perform this step.
Results, if necessary.

1.3 Lists

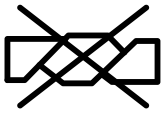
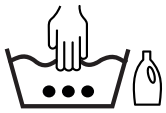
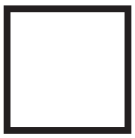
Structure of bulleted lists:

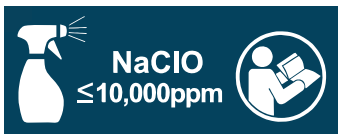
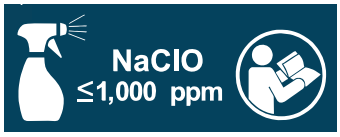
- List level 1
  - List level 2
    - List level 3

1.4 Symbols on the Package (OptiCare X)

	FRAGILE, HANDLE WITH CARE
	THIS WAY UP
	KEEP DRY (PROTECT FROM HUMIDITY)
	PAPER RECYCLING SYMBOL
	DO NOT STACK DURING STORAGE
	DO NOT USE HAND TRUCK HERE
	OVERSEAS PACKAGE: STACKING LIMIT BY NUMBER (3 PACKAGES FOR TRANSPORT)
	OVERSEAS PACKAGE: STACKING LIMIT BY NUMBER (5 PACKAGES FOR STORAGE)
	RECYCLING SYMBOL

1.5 Symbols and Labels on the Mattress (OptiCare X)

	DO NOT IRON!
	DO NOT USE PHENOL!
	DO NOT WRING!
	REGULARLY INSPECT THE INSIDE OF THE COVER FOR CONTAMINATION
	MACHINE WASH AT MAX. 71°C FOR 3 MINUTES
	TUMBLE DRY ON LOW HEAT SETTING (MAX. 60°C)
	HANDWASH WITH DETERGENT (INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50°C)
	DISINFECT USING SOLUTION CONTAINING LESS THAN 1000 ppm OF CHLORINE (REFER TO INSTRUCTIONS FOR USE)
	WIPE WITH WATER
	DRY

	DO NOT USE PHENOL!
	HANDWASH WITH DETERGENT (INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50°C)
	DISINFECT USING SOLUTION CONTAINING LESS THAN 10000 ppm OF CHLORINE (REFER TO INSTRUCTIONS FOR USE)
	DISINFECT USING SOLUTION CONTAINING LESS THAN 1000 ppm OF CHLORINE (REFER TO INSTRUCTIONS FOR USE)
	WIPE WITH WATER
	COVER MATERIALS ARE FIRE RESISTANT TO BS7175, SOURCE 0, 1 AND 5
	MATTRESS FOOT PART (OptiCare X)
	WEEE SYMBOL (RECYCLE AS ELECTRONIC WASTE, DO NOT PUT INTO THE HOUSEHOLD WASTE)
	MEDICAL DEVICE (compatible with Medical Device Regulation)
	MANUFACTURER

	MANUFACTURING DATE
	REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON CONFIGURATION)
	SERIAL NUMBER
	ONLY SUITABLE FOR INDOOR USE
	APPLIED PARTS TYPE B
	WARNING
	READ INSTRUCTIONS FOR USE
	T1AH ANTI-SURGE FUSE (SCU FUSE)
	ALTERNATING CURRENT
	THERMAL PROTECTION FOR TRANSFORMER

	SAFETY ISOLATING TRANSFORMER (GENERAL)
	EARTH GROUND

1.6 Serial Labels with UDI (OptiCare X)

Pictures of serial labels below serve just for explanation of the signs and fields on the serial labels.

1.6.1 Serial Label for OptiCare X (SCU)

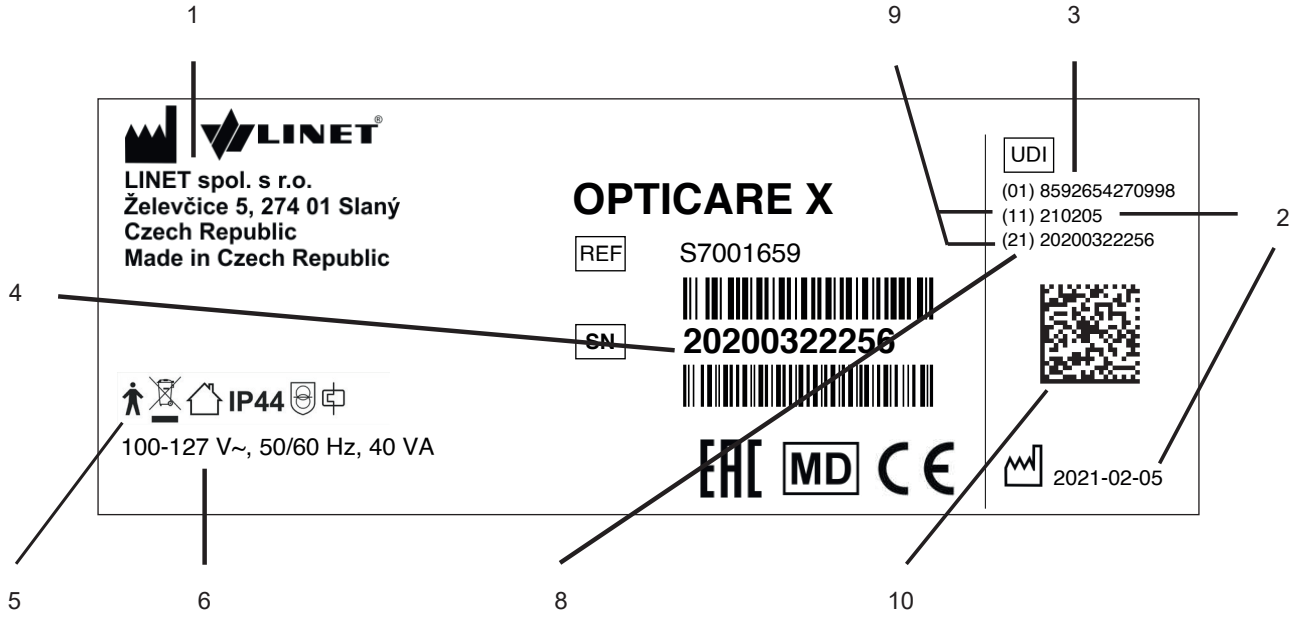


Fig. Serial Label with UDI for OptiCare X SCU (100-127 V)

1	Address of Manufacturer
2	Manufacturing Date (Year-Month-Day)
3	**DI** (Device Identifier) / GTIN (Global Trade Item Number)
4	1D Bar code GS1-128 (Serial Number)
5	Symbols
6	Electrical Specification
8	Serial Number
9	**PI** (Product Identifier)
10	2D Bar Code (GS1 DataMatrix) **DI+PI=UDI**

1.6.2 Serial Label for OptiCare X (mattress)

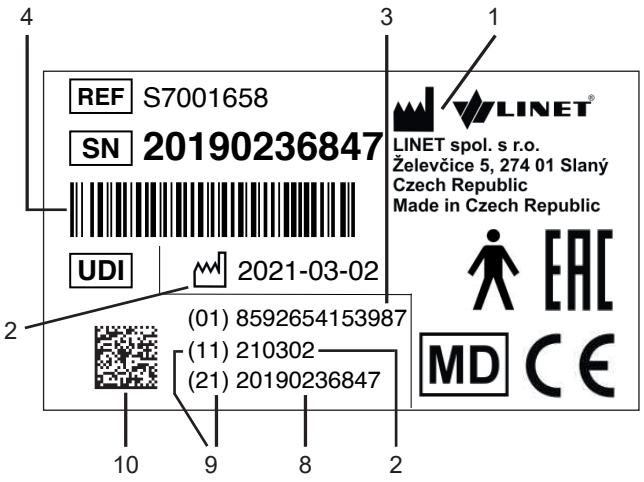
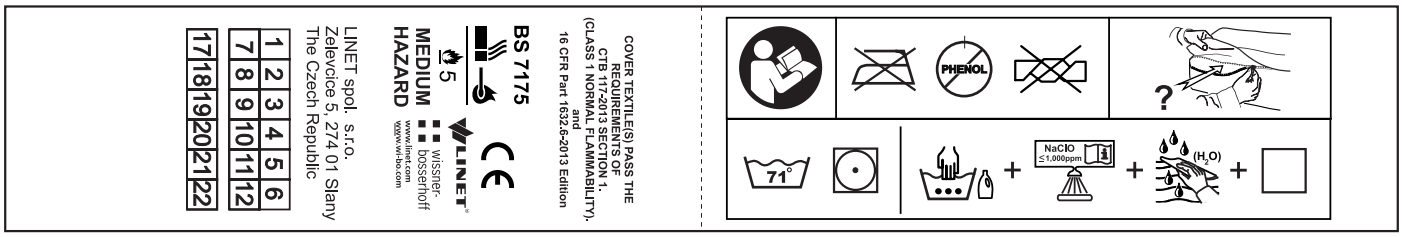


Fig. Serial Label with UDI for OptiCare X (mattress)

1.6.3 Wash Label (mattress)



THIS PRODUCT IS PROTECTED BY ONE OR MORE OF THE FOLLOWING PATENTS:

US7492111	US7647659	US8024101
US10010465	US8959680	US10130538
US9585490	US8959680	US10206835
US9271887	US8452508	US10335333
US9205011	US8112836	US8746710
US10376216	US10383780	

Fig. Label with applied patents

1.7 Acoustic signalisation (OptiCare X)

SOUND	MEANING
REPEATED BEEP: 0,2s sound / 1s silence (high priority)	mattress inflation fault (fault number 2)
	mattress overpressure (fault number 5)
	air valves fault (fault number 14)
	CPR mattress deflation fault (fault number 13)
	BOD valves fault (fault number 6)
	clogged air filter (fault number 8)
	automatic deflation is not available (Use manual CPR!)
REPEATED BEEP: 0,2s sound / 5s silence (medium priority)	pressure sensor fault (fault number 4)
	mattress disconnected
	air leak
REPEATED BEEP: 0,2s sound / 10s silence (low priority)	mattress deflation fault (fault number 3)
	MCM ventilator fault (fault number 7)

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
SWL	Safe Working Load
UDI	Unique Device Identification (for medical devices)
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment

1.9 Definitions

Maximum Patient Weight	The highest allowable load on the mattress.
Adult	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).

2 Safety Instructions (only OptiCare X for Multicare X)



WARNING!
Multicare X bed with OptiCare X integrated mattress system should be left in its lowest position when the patient is unattended in order to reduce risk of injury due to falls!



WARNING!
Siderails of the Multicare X bed should be located in the „up“ position to reduce the risk of the patient accidentally slipping or rolling off the OptiCare X integrated mattress!



WARNING!
Inappropriate handling of the Multicare X power supply cord, e. g. by kinking, shearing or other mechanical damages is hazardous!



WARNING!
When routing cables from OptiCare X integrated mattress system in the Multicare X bed avoid squeezing those cables between parts of the Multicare X bed!



WARNING!
The OptiCare X integrated mattress system with Multicare X bed are intended for adults.
► Follow the chapter Intended use.



WARNING!
OptiCare X integrated mattress system is compatible only with Multicare X bed. The OptiCare X integrated mattress system can only be used when installed on a LINET Multicare X bed frame.



WARNING!
To avoid the risk of electric shock, the Multicare X bed must only be connected to a supply mains with protective earth.



WARNING!
No modification of OptiCare X integrated mattress system is allowed.



WARNING!
Do not modify OptiCare X integrated mattress system without authorization of the manufacturer.



WARNING!
If OptiCare X integrated mattress system is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.



WARNING!
An additional multiple socket-outlet or extension cord shall not be connected to the medical electrical system of the OptiCare X integrated mattress system with Multicare X bed.



WARNING!
OptiCare X integrated mattress system must be used exclusively by or under supervision of trained and qualified nursing personnel!



WARNING!
Staff expert assessment is needed to consider all individual cases of contraindications!
► Certain bed positions are not suitable for specific diagnosis/medical conditions. Fowler position is not suitable for spinal cord injuries! Trendelenburg position is not suitable for patients with higher intracranial pressure!



WARNING!
Length adjustment of the Multicare X bed must be proportional to the height of patient and to the placement of the OptiCare X integrated mattress system!
► Risk of trapping or squeezing because of patient´s body constitution disproportionate to the size of mattress support platform!



WARNING!
During specific investigations or treatments the significant risks of reciprocal interference posed by OptiCare X integrated mattress system with Multicare X bed may occur.



WARNING!
Any serious incident that has occurred in relation to the device (OptiCare X integrated mattress system) 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 of the OptiCare X integrated mattress system!



WARNING!
This medical device (OptiCare X integrated mattress system) is not intended for oxygen enriched environment!



WARNING!
This medical device (OptiCare X integrated mattress system) is not intended for use with flammable substances!



WARNING!
This medical device (OptiCare X integrated mattress system) is not portable medical electrical equipment!

Additional Instructions for correct use:

► Follow the instructions for use carefully.
► Ensure any user has read and understood the instructions for use completely before operating the product.
► Use OptiCare X integrated mattress system exclusively as specified in the instructions for use and in perfect working order.
► If necessary, check the OptiCare X functions daily or at each shift change.
► Use the Multicare X bed exclusively with the correct mains supply.
► Ensure that the OptiCare X integrated mattress system is operated exclusively by qualified personnel who have been trained according to the instructions for use.
► Ensure OptiCare X integrated mattress system is operated by qualified personnel trained in using the Multicare X bed in accordance with the instructions for use by manufacturer or by person approved by the manufacturer, eventually by authorized representative or by person approved by the authorized representative.
► Ensure that the patient (health permitting) has been informed about the operation of the OptiCare X integrated mattress system and all applicable safety instructions.
► Contact service department of the manufacturer immediately to let it replace any damaged parts by the original spare parts.
► Ensure that maintenance and installation are performed exclusively by qualified personnel who have been trained by the manufacturer.
► During unavoidable excess loads (e. g. CPR), adjust bed mattress support platform with OptiCare X integrated mattress system to the lowest position.
► Ensure that only one adult patient lies on the OptiCare X mattress at any time.
► To avoid injury or crushing, take extra caution when operating any moving parts of the Multicare X bed.
► When using lifting poles or infusion stands, ensure that OptiCare X integrated mattress system will not be damaged when you move or adjust Multicare X bed.
► Keep the Mattress support platform with OptiCare X integrated mattress system in the lowest position at any time when the healthcare personnel are not treating the patient in order to prevent the patient from falling or injuries.
► Ensure that siderails of Multicare X bed are operated exclusively by healthcare personnel.
► Never handle the mains plug of Multicare X bed with wet hands.
► Disconnect Multicare X bed from the mains exclusively by pulling the mains plug.
► Disconnect Outlet Power cable from the mains exclusively by pulling the mains plug.
► When pulling the mains plug, always hold the plug, not the cable.
► Improper handling of mains cable can cause an electric shock hazard, other serious injuries or damage to OptiCare X mattress system.
► Ensure that the stipulated duty cycle of Multicare X bed is not exceeded.
► To prevent failures, use exclusively the manufacturer’s original accessories.
► Ensure that the stipulated safe working load is not exceeded.
► If the patient‘s condition could lead to an entrapment, leave the mattress support platform with OptiCare X integrated mattress system in the flat position whilst unattended.
► Do not exceed the maximum patient weight limit of the Multicare X and of the OptiCare X integrated mattress system at the same time.
► Do not use the SCU near flammable gases. (This does not apply to oxygen cylinders.)
► Do not hang anything on any cable.
► Never use OptiCare X integrated mattress system near radiators or other heat sources.
► After each emergency situation always check if any of the Multicare X controllers (controllers in siderails, handset or Attendant Control Panel) is not involuntarily pressed by the bed accessories or by the OptiCare X integrated mattress.
► To avoid unintended activation of moving parts during any use of the bed always check that none of the control elements of the Multicare X bed is pressed by persons, by OptiCare X integrated mattress or by other objects.
► Never cover the SCU while in use.
► Never cover the filter of SCU while in use.

3 Intended use (OptiCare X)

The intended use is to prevent and support treatment of pressure injuries.
OptiCare X integrated mattress system is compatible only with Multicare X bed.

3.1 User population

- Caregivers (nurses, doctors)
- Technical Personnel
- Transport Personnel
- Cleaning Personnel
- Adult patients (weight >= 40 kg, height >= 146 cm, BMI >= 17) at moderate risk levels in the intensive care (Application Environment 1 and 2, as in IEC 60601-2-52)
- Patients with any stage/category of pressure ulcers

3.2 Contraindications

OptiCare X integrated mattress system is contraindicated for patients:

- With cervical traction
- Or unstable spinal fractures, spinal cord injury, fractures at risk of complication by a moving surface,
- Or trauma patients where spinal injuries have not been excluded or cleared

3.3 Operator

- Caregiver

4 Product Description (OptiCare X)

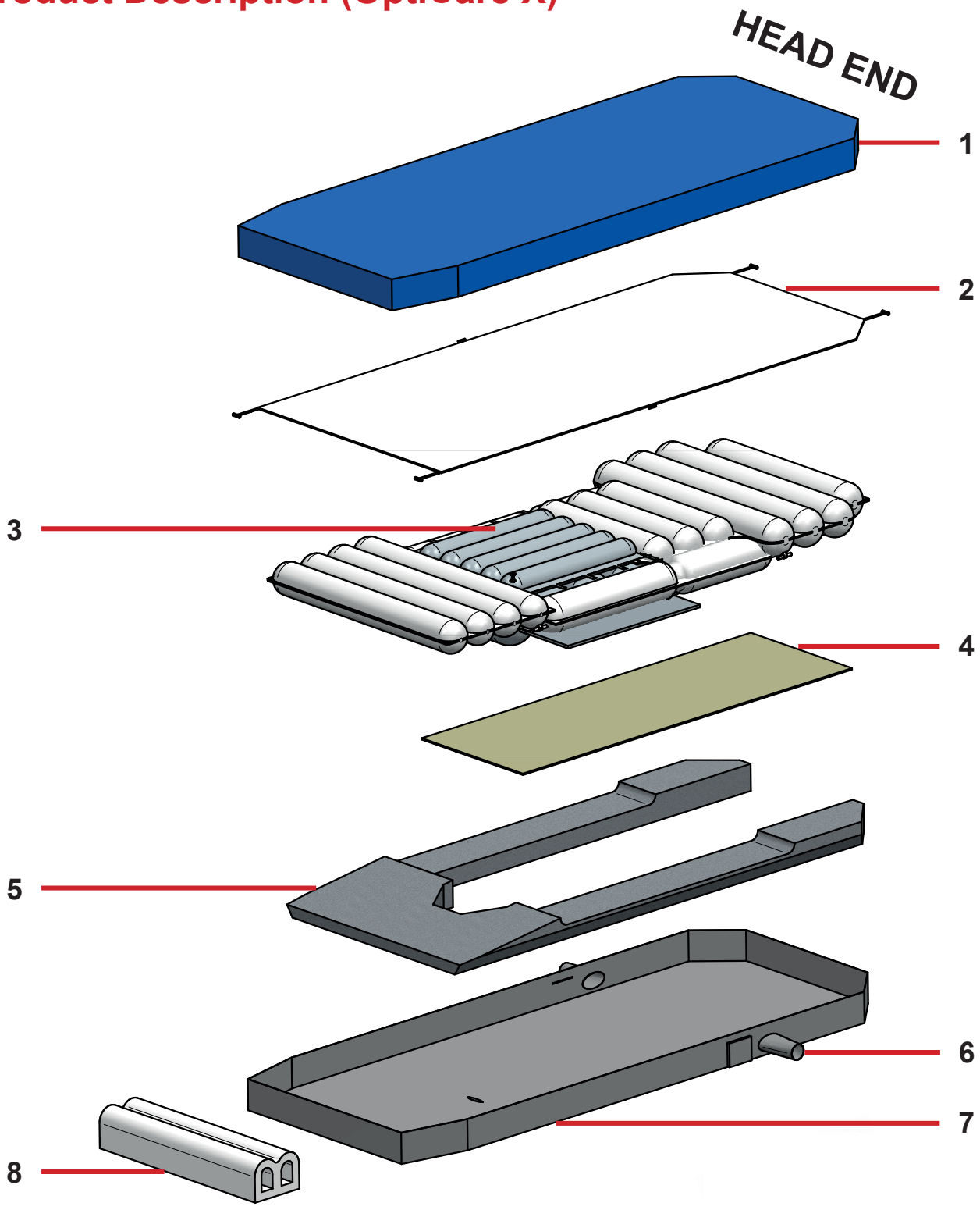


Fig. OptiCare X Mattress Description

1. Cover
2. Comfort Layer
3. Air Cell Sets
4. Plastazote Foam Base
5. Foam Base
6. CPR Valve
7. Base Cover
8. Heel Section

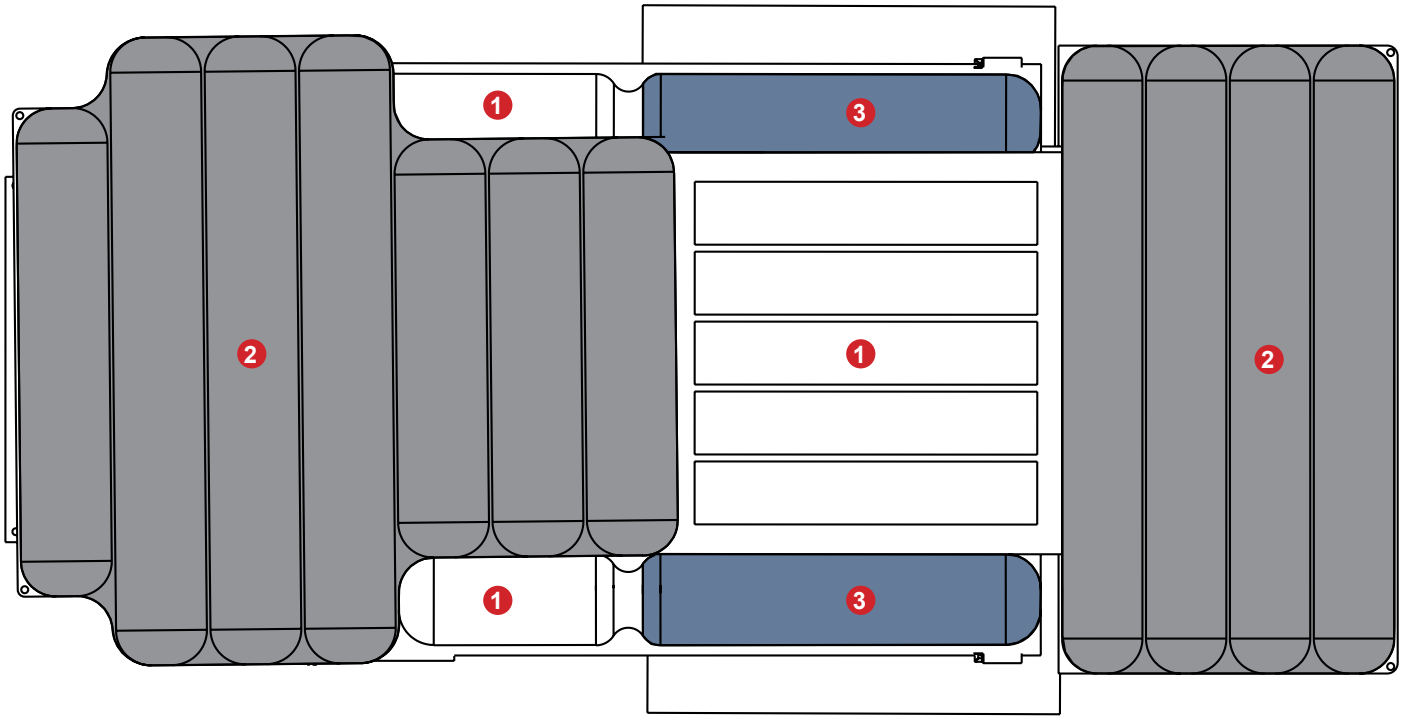


Fig. Structure of the Air Cell Sets (top view)

1. Area A (WHITE CELLS)
2. Area B (GREY CELLS)
3. Area S (BLUE CELLS)

4.1 Mattress Structure

The OptiCare X mattress consists of 4 sections that are held together by 6 quick release fixation toggles. The 3 sections include cover, comfort layer, air cell set and foam base which supports the leg section and side formers. Within the central cut-out of the foam base is a 10 mm high density foam sheet to protect the patient if the mattress is deflated. Air cell set is divided into Area A and Area B. A two-part cover (**1**) made of water resistent vapour permeable material encloses the mattress. Beneath the cover and on the top of the upper air layer is a removable polyester comfort layer (**2**). The 2 air layers consist of 10 separate air modules for easy and cost effective replacement in case of user damage. 7 of these air modules are connected together to form the Constant Low Pressure air mattress, while the other 2 act as air manifolds for the MICROCLIMATE Management (MCM) function. The mattress has a 7 degree heel slope to help further off-loading of pressure in the vulnerable heel area.

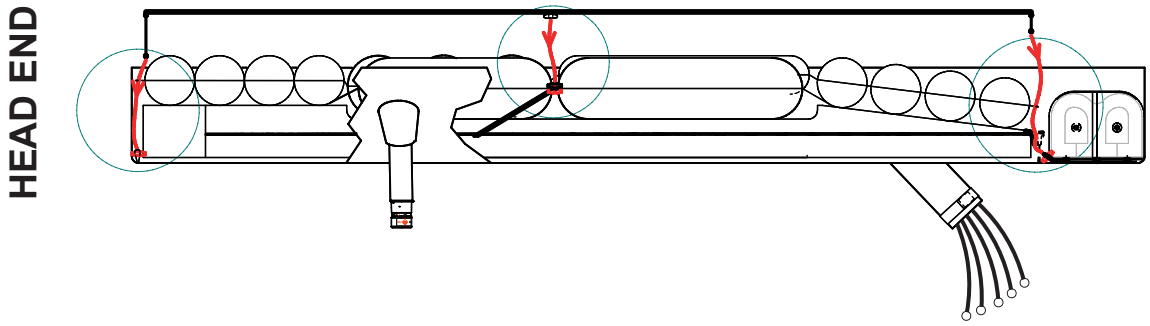


Fig. Fixation of Comfort Layer to the cells (Fixation toggles)

4.2 Cover

The top part of the cover consists of highly moisture- and vapour-permeable (MVP) two-way stretch material which forms an integral part of the MICROCLIMATE Management (MCM) function. The cover top is equipped with a full 360-degree zip to allow easy removal for cleaning or replacement. The zip is covered by a waterproof flap to protect the mattress against fluid ingress.
The cover base is made from water-impermeable high-strength non-stretch material that is suitable for any demanding environment. Additional quick-release straps prevent the mattress from shifting if the head board or foot board is removed. Optional ZONED Cover is characterized by the middle slippery zone on its surface.

4.3 Bottom Deck

The bottom air layer is enclosed by a foam base fully contained within a removable waterproof cover. This provides support for the patient when entering or exiting the bed. The angled sides of the foam base are designed to fit securely into the shaped sides of the Multicare X patient platform to prevent any movement of the mattress when the patient is getting into or out of the bed.

4.4 Heel Section

The heel section is made up of 2 foam in air cells each with a custom designed internal foam shape that allows the 2 cells to collapse back into a reduced shape when pressed in by the foot board of the bedframe. This reduces the length of the mattress by 190 mm when compressed. The heel cells will self inflate when the bed is lengthened.

4.5 Safety Straps

The sides of the foam base fit the sides of the Multicare X mattress support platform to prevent the mattress from shifting when the patient is getting into or out of bed.
The mattress is equipped with additional quick-release straps to prevent the mattress from shifting if the head or foot board is removed. These straps are located on head end and foot end of the bed.

To fix the strap:
► Loop black strap around metal bed frame and feed it back through the plastic clip.

To release the strap:
► Pull loose end of strap upward to release clip.

4.6 Transport Handles

WARNING!
Material damage and risk of injury due to incorrect use!
► Transport the mattress using transport handles without patient on it!

Transport handles are intended for transport of the mattress only.

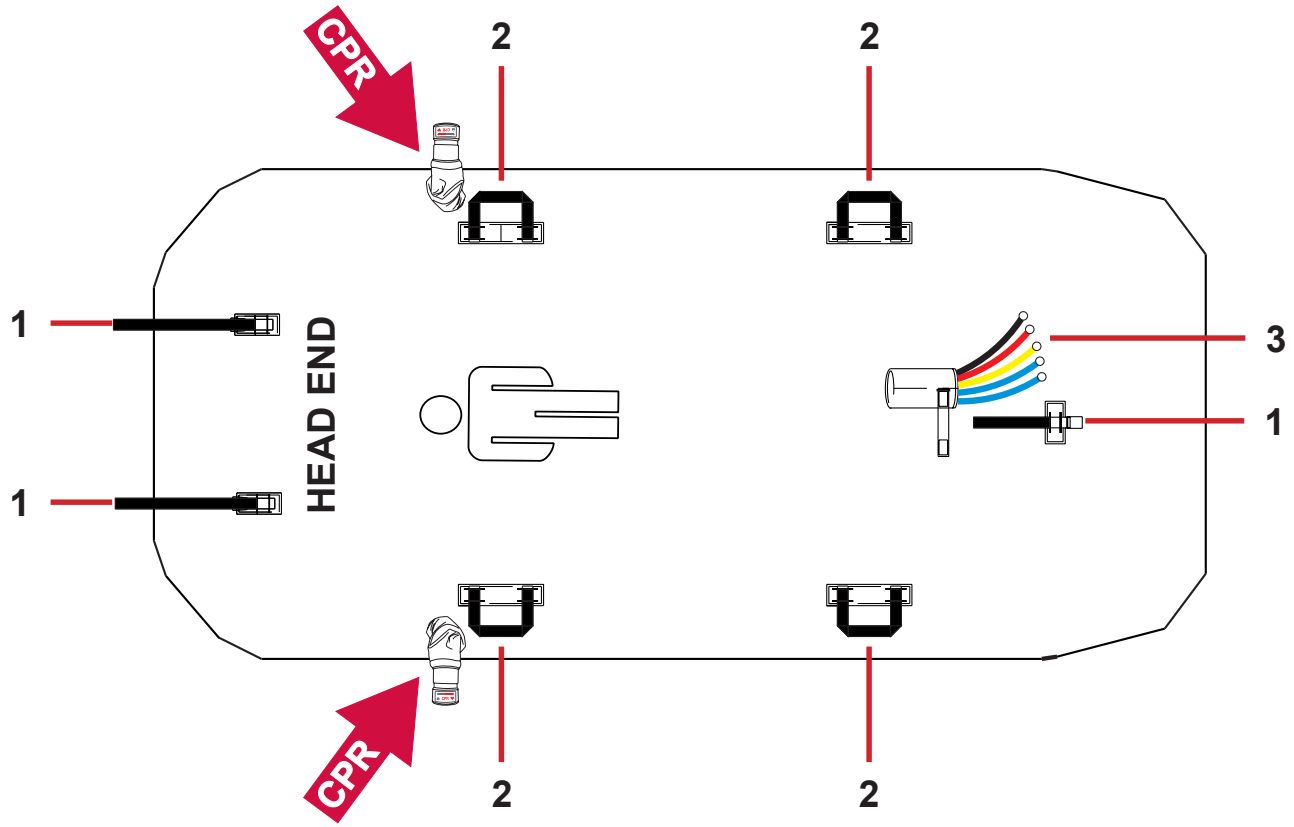


Fig. Base Cover Description

1. Safety Straps
(to fix mattress on the Matress Platform)
2. Transport Handles
3. Aip Pipes

4.7 SCU (System Control Unit)

The SCU (System Control Unit) is installed under the leg section of the bed frame. It is possible to have the Multicare X bed delivered with the SCU factory-fitted, or to have it retrofitted by approved service personnel. OptiCare X ready Multicare X bed is equipped with a dedicated power outlet for the SCU at the auxiliary power distribution point. The SCU is operated via the Integrated Mattress Screen on the Multiboard X LCD touchscreen. There is no ON/OFF switch on SCU. The SCU is equipped with a comprehensive alarm system which detects any problems with the system performance.

The alarm system
► Gives audible and visual alarms via the Multiboard X if a problem requires immediate action.
► Stores information for the service personnel to review later.

4.7.1 FIRMWARE

The system control unit includes firmware that can be updated only by an authorised service technician.
This firmware is protected against unauthorised access by mechanical housing (tool is needed to access) and by exclusive compatibility with an authorised software tool and specific cable.

5 Technical Specification (OptiCare X)

All technical data are rated data and are subject to construction and manufacturing tolerances.

WARNING!
If Multicare X bed is used with OptiCare X integrated mattress system, respect values of mechanical and electrical specifications which can harm none of them!

5.1 Mechanical Specifications

Parameter	Value
External dimensions of Inflated Mattress (length x width x height)	214 cm x 87 cm x 23 cm
Length of the Integrated Mattress Extension	19 cm
Dimensions of the X-ray Pocket (length x width)	90 cm x 92 cm
External dimensions of SCU	36 cm x 22 cm x 10 cm
Weight of Inflated Mattress	14 kg (31 lbs)
Weight of SCU	6 kg (13.1 lbs)
Inflation time after storage	max. 10 min
CPR deflation time (depending on patient weight, chosen mode - optimization or maximum internal pressure - and on type of CPR - electric or manual)	max. 30 s
Remain Inflated in Transport Mode	12 hours (whem starting from Maximum Inflate Mode)
Sound Pressure Level	max. 46 dBA (normal operation without any sounding alert signal)
Maximum Patient Weight	250 kg (551 lbs)
Minimum Mattress Load	40 kg
Maximum Washing Temperature of the mattress cover ELITE (MIC200)	71°C
Maximum Washing Temperature of the mattress cover ENDURANCE (SIOEN RP9774-2)	71°C
Maximum Washing Temperature of the mattress cover ZONED (DARTEX)	55°C
Maximum Drying Temperature of the mattress cover ELITE (MIC200)	55°C
Maximum Drying Temperature of the mattress cover ENDURANCE (SIOEN RP9774-2)	55°C
Maximum Drying Temperature of the mattress cover ZONED (DARTEX)	55°C
Fire Resistance of the Cover	according to BS7175 - ignition source 5
Fire Resistance of the Top Cover	according to 16 CFR 1632
Fire Resistance of the whole mattress	according to BS7177 - ignition source 5, 16 CFR 1632

5.2 Electrical Specifications

Parameter	Value
Input Voltage, Frequency: EU version USA version Brazilian version	 220-240 V AC, 50/60 Hz 100-127 V AC, 50/60 Hz 220 V AC, 60 Hz
Maximum Power Input	max. 40 VA (when operating from mains supply)
Ingress Protection (EN 60529)	IPX4
Protection Class	Class I with Applied Parts Type B
Electrical Safety	in conformity with EN 60601-1
SCU Fuse 220-240 V AC version 100-127 V AC version	 2 x T0,5AH Anti-surge Fuse 2 x T1AH Anti-surge Fuse

5.3 Environment Conditions

Use Conditions	
Ambient Temperature	10°C - 40°C
Relative Humidity	30% - 75 %
Atmospheric Pressure	795 - 1060 hPa
Storage and Transport Conditions	
Ambient Temperature	-40°C - 70°C
Relative Humidity	10% - 100 % (non-condensing)
Atmospheric Pressure	795 - 1060 hPa

5.4 Electromagnetic Compatibility

OptiCare X integrated 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.

OptiCare X integrated 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:

► **Mains cable**, maximum length 6 m



WARNING!
Use of the accessories, converters and other cables, than specified and provided by manufacturer of this OptiCare X integrated mattress system could lead to increase of electromagnetic emission or lower the electromagnetic immunity of this OptiCare X integrated 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 OptiCare X integrated mattress system, including cables specified by manufacturer. Otherwise this could lead to deterioration of functionality of this OptiCare X integrated mattress system.



WARNING!
Do not overload the OptiCare X integrated mattress system (SWL), respect the duty cycle (INT.) and consider chapter 12 Maintenance in order to maintain the basic safety with regard to electromagnetic disturbances for the expected service life.

5.4.1 Manufacturer Instructions - Electromagnetic Emissions

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

5.4.2 Manufacturer Instructions - Electromagnetic Susceptibility

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

Table 1 - IMMUNITY to RF wireless communications equipment

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



DANGER!
Danger to life due to electric shock!
To ensure the bed's class I protection against electric shocks:
► Ground the mains.
► Use exclusively Hospital Grade or Hospital Only receptacles for grounding.

Multicare X with OptiCare X integrated mattress system is designed for use in rooms for medical purposes. Electrical installations must therefore meet local norms laying down the necessary conditions for electrical installations.
► Disconnect the bed from the mains in exceptional cases (i.e. lightnings, earthquake).

OptiCare X integrated mattress system is not suitable for indoor environments containing flammable gases (except oxygen cylinders).

6.1 Storage

When SCU is not in use:

► Log off the mattress.
► Unplug mains cable.

When mattress is not in use:

► Unclip all 5 air pipes.
► Undo webbing strap next to air pipes.
► Make sure mattress has been cleaned and is completely dry inside and out (see Cleaning/Disinfection).
► Deflate mattress and leave air connector open (CPR position).
► Roll mattress up carefully to get air out completely.
Store in a dry and safe place and keep away from sharp objects.

7 Scope of Delivery and Product Variants (OptiCare X)

7.1 Delivery

► Upon receipt, check that the shipment is complete as specified on the delivery note.
► Notify the carrier and supplier of any deficiencies or damages immediately as well as in writing or make a note on the delivery note.

7.2 Scope of Delivery

- OptiCare X integrated mattress
- Mattress Cover
  - ELITE
  - ENDURANCE
  - ZONED
    - with X-ray Pocket
    - without X-ray Pocket
- SCU (System Control Unit)
- Instructions for use

8 Putting into Service (only OptiCare X for Multicare X)

WARNING!
Risk of injury when working on the OptiCare X integrated mattress system!
► Ensure that the Multicare X bed is disconnected from the mains connection prior to putting OptiCare X integrated mattress system into service, putting it out of service and maintenance.
► Ensure that the castors are locked prior to putting OptiCare X integrated mattress system into service, putting out of service and maintenance.

CAUTION!
Material damage due to incorrect putting into service!
► Ensure that putting into service is performed exclusively by manufacturer´s customer service or trained hospital personnel.

The OptiCare X mattress system replaces any mattress on the Multicare X bed frame.

► Remove any existing mattress.
► Put mattress on the Mattress support platform with air pipes at foot end of the bed.
► Connect Air Pipes to SCU observing colour code.
► Make sure that the CPR valves on both sides of the head end of the mattress are not left open but connected and accessible to manipulation.

NOTE During first installation of the mattress CPR valve is open!

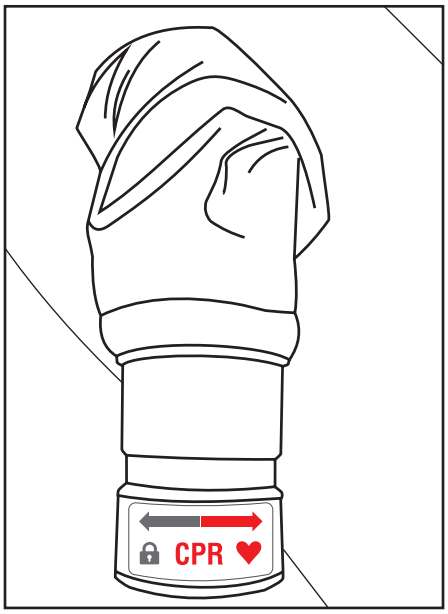


Fig. Closed CPR valve

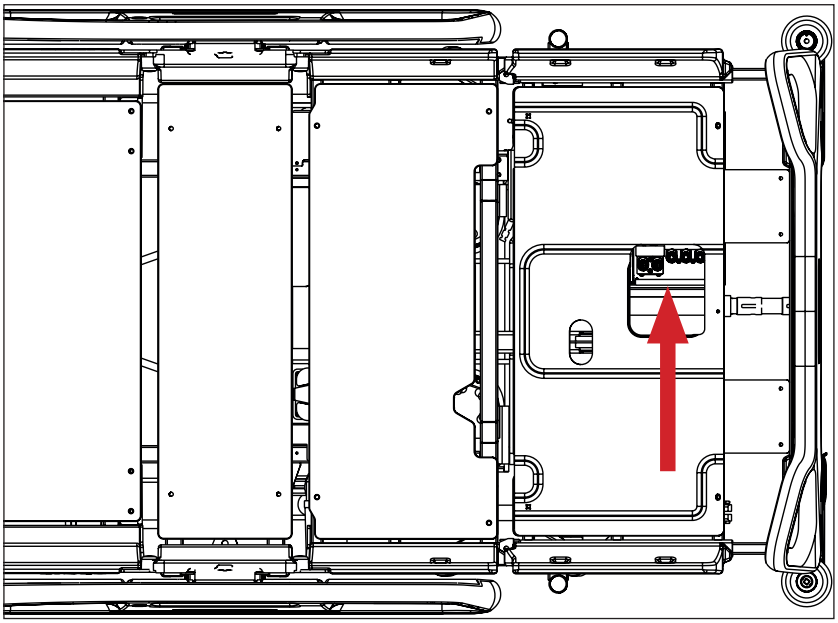


Fig. SCU with Air Pipe Connectors (foot end of the Multicare X bed)

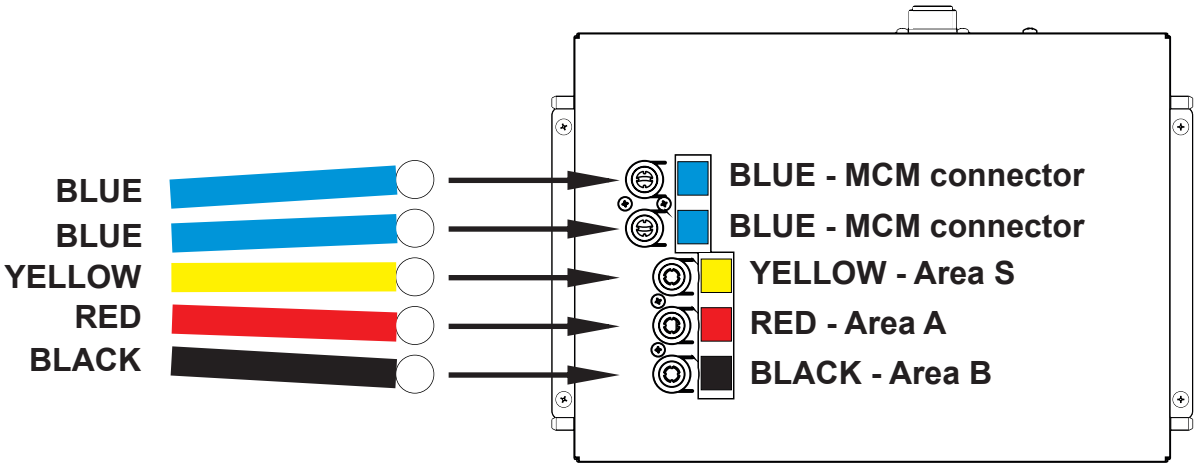


Fig. Air Pipes and SCU with Air Pipe Connectors

Mattress Detection System (MDS)

Sensors in the System Control Unit (SCU) Area A, B and ODV mattress air connectors detect that a valid air connector has been connected. When all three correct air connectors are detected, the SCU will enter Standby Mode. In Standby Mode mattress areas A and B are inflated to a static pressure ready for a patient to be placed onto the mattress and Optimization to start.

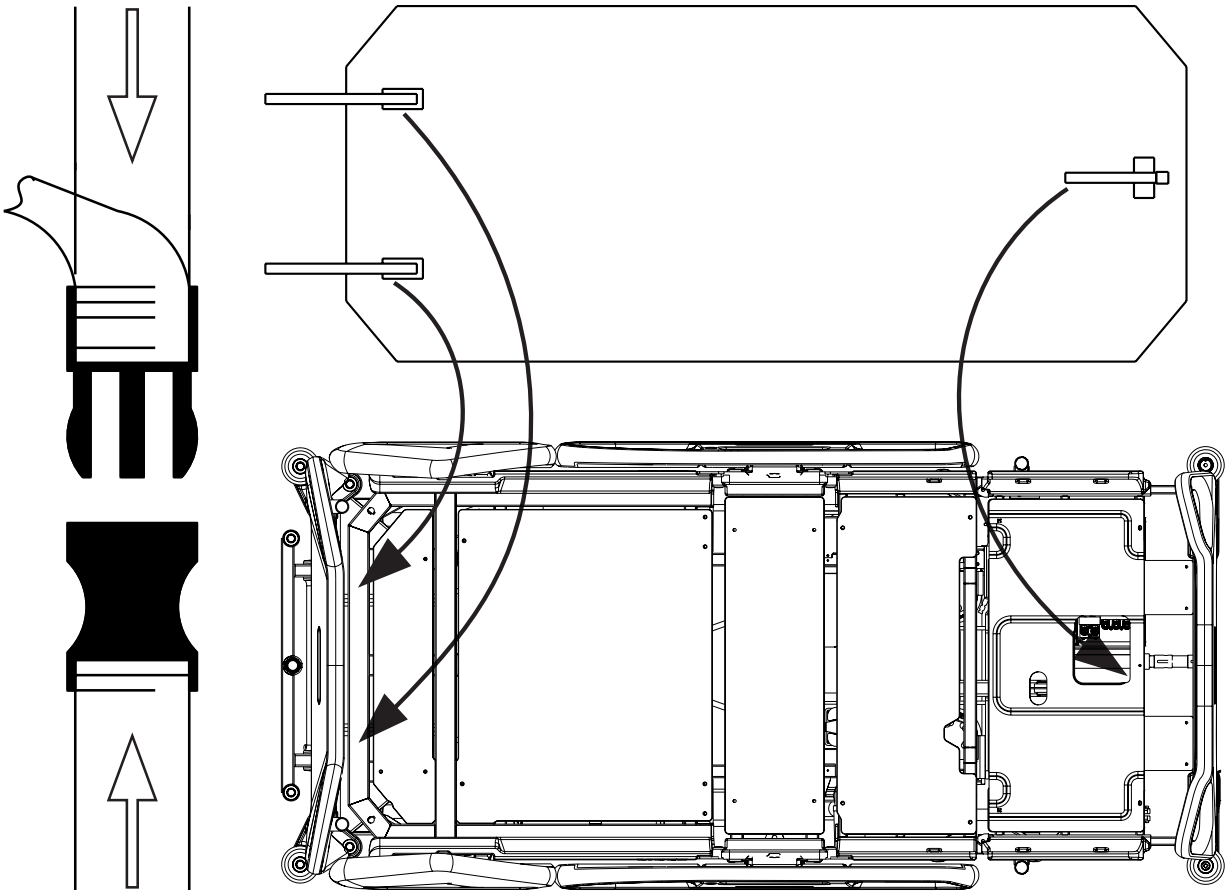


Fig. Fixation of the mattress with straps on the mattress support platform of Multicare X bed

8.1 SCU (System Control Unit)

WARNING!
OptiCare X mattress is compatible with System Control Unit delivered by manufacturer only!
► Do not use any other System Control Unit with OptiCare X mattress!

CAUTION!
Material damage due to incorrect installation of SCU!
► If the SCU does not come factory-fitted, have it installed by a service engineer authorised by LINET ®.

8.2 Replacing the Mattress

When replacing the OptiCare X mattress with a compatible integrated mattress or compatible mattress replacement system from the LINET portfolio, the system will automatically detect that type of mattress that has been connected and switch to the correct Multiboard X control screen. If replacing the OptiCare X mattress with one that is not from the LINET integrated systems range, then you will need to cancel the Mattress Not Connected alarm and log out the OptiCare X mattress.

To log out OptiCare X mattress:
► press MATTRESS LOG OUT Icon for 5s.



Fig. MATTRESS LOG OUT Icon (Multiboard X LCD touchscreen)

9 Manipulation (OptiCare X for Multicare X)

Preparing OptiCare X for Patient

DANGER!
Risk of suffocation due to air-impermeable mattress cover!
► Use mattress cover correctly.
► The nursing staff are responsible for the safety of the patient on the mattress cover.

WARNING!
Risk of injury when positioning patient on the bed!
Before positioning the patient on the bed:
► Ensure that mattress is completely and correctly inflated.
► Ensure that mattress is correctly secured with safety straps.
► Use of the mattress without the safety straps could impair the mattresses ability to function correctly!

CAUTION!
Material damage due to dampness or contamination!
► Make sure mattress cover has been cleaned and is completely dry (see Cleaning/Disinfection).

Preparation
► Ensure that mattress is correctly secured with safety straps.
► Inflate mattress.
► Put a sheet loosely on the mattress if not prescribed otherwise by qualified personnel.

Position of a Patient on the Bed
► Put the patient on the mattress. Head of a lying patient points towards head end of the bed. Position of pelvic area is indicated by symbols on the inner sides of the Multicare X foot siderails.

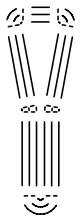


Fig. Symbol indicating position of a patient´s pelvic area

Create the ideal patient 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 injuries (e.g. due to creases, seams etc.).
► Do not place any additional sheets, blankets etc. between mattress and patient.

9.1 Manual CPR (during Transport or Power Loss)

OptiCare X is equipped with CPR valve on both sides next to the Manual Backrest Release.

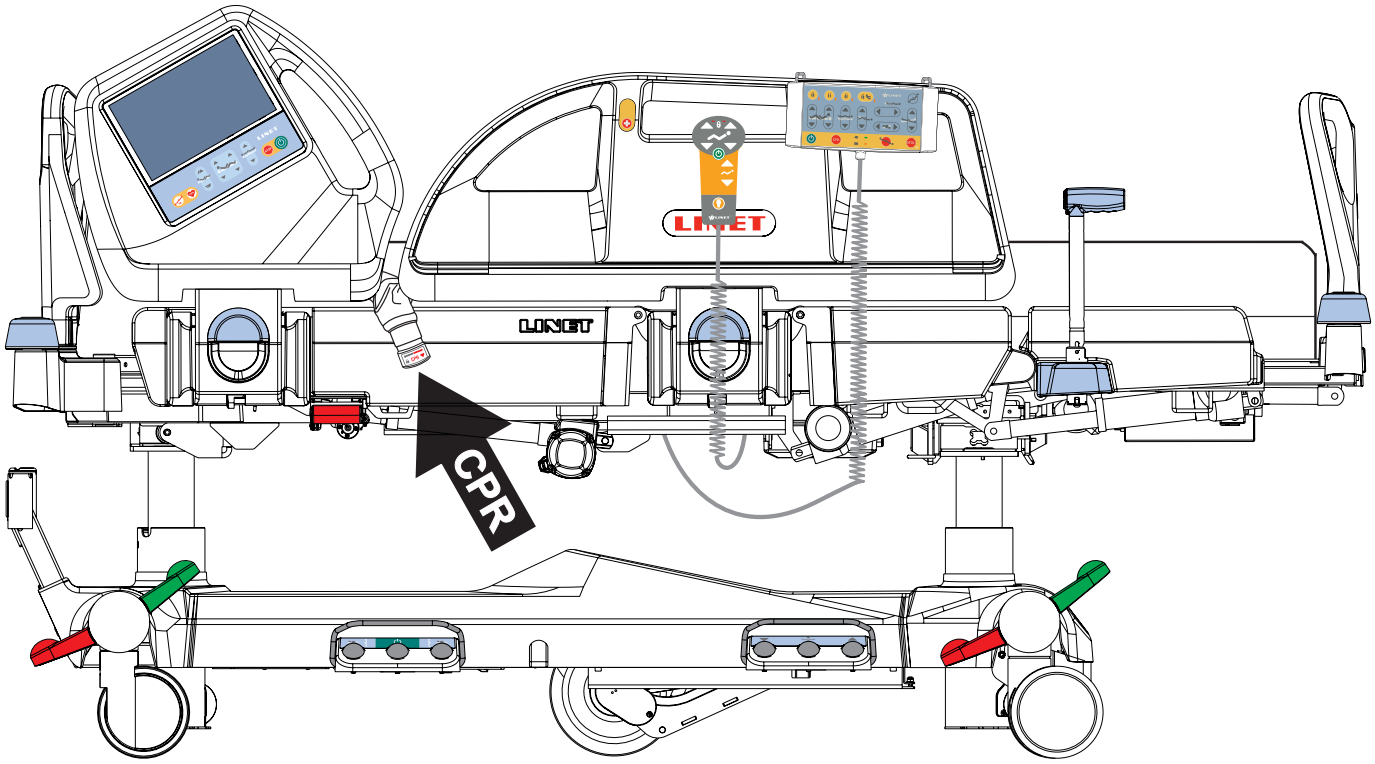


Fig. Position of the CPR valve on the OptiCare X integrated mattress placed on the Multicare X bed

To activate manual CPR:

► Open CPR valve on patient's left- or right-hand side by turning the end of CPR valve clockwise in accordance with the red arrow.

► The mattress will deflate.

To activate automatic CPR on the bed:

► Press CPR Position Button on the Multiboard X until intended position is reached. The Mattress support platform will enter the CPR position.



Fig. CPR Button (Multiboard X)



Fig. CPR valve label

9.2 Automatic CPR (Multicare X with OptiCare X)

Cardiopulmonary Resuscitation Mode (CPR Mode) causes the mattress to deflate completely to facilitate resuscitation of patient. Typical deflation time for OptiCare X mattress is 15 seconds (max. 30 s). Stopwatch indicator counts down 1 hour during CPR Mode.

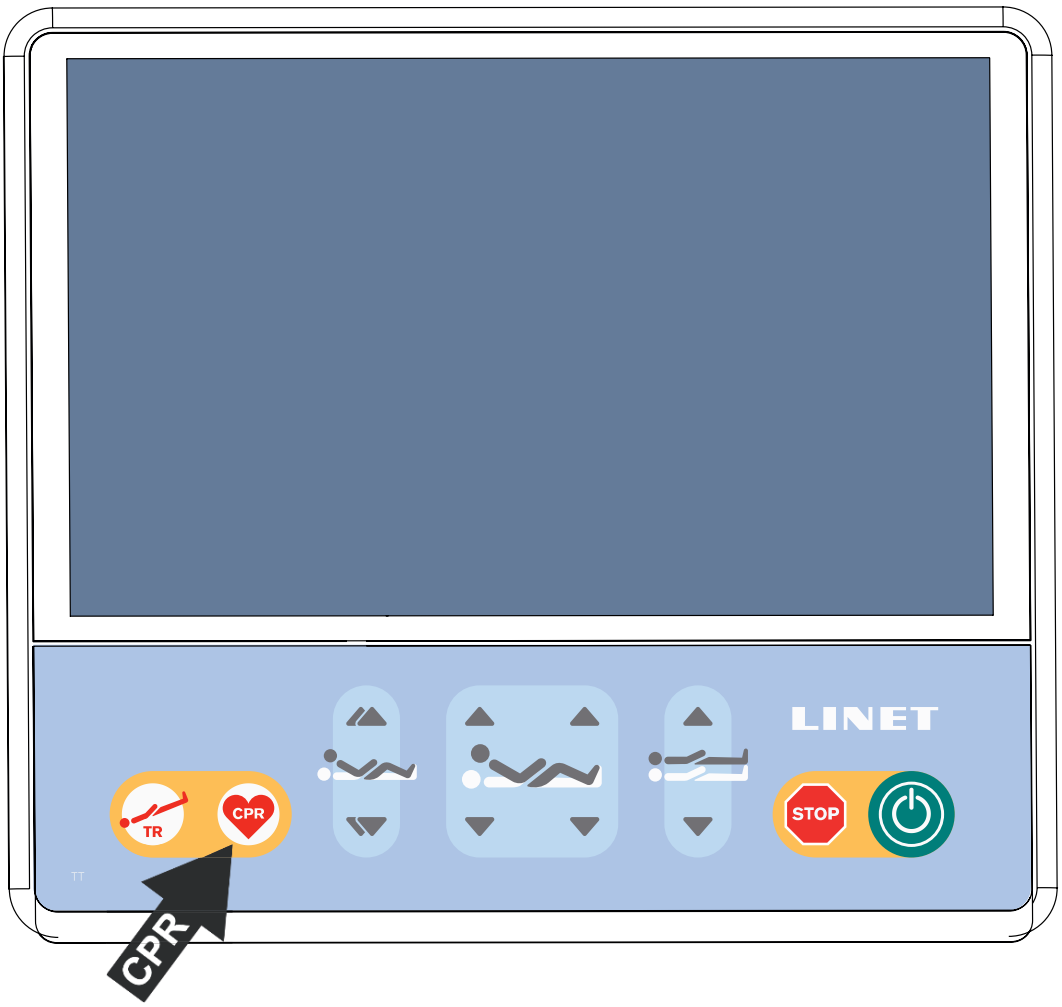


Fig. CPR button

To activate the CPR Mode:

► Press and hold CPR button on Multiboard X for at least 3 s.

The mattress deflates completely and mattress support platform will enter the CPR position.
The mattress platform will straighten up.

NOTE: It is possible to use Attendant Control Panel also to activate CPR Mode.

9.3 Integrated Mattress Screen (Multicare X with OptiCare X)

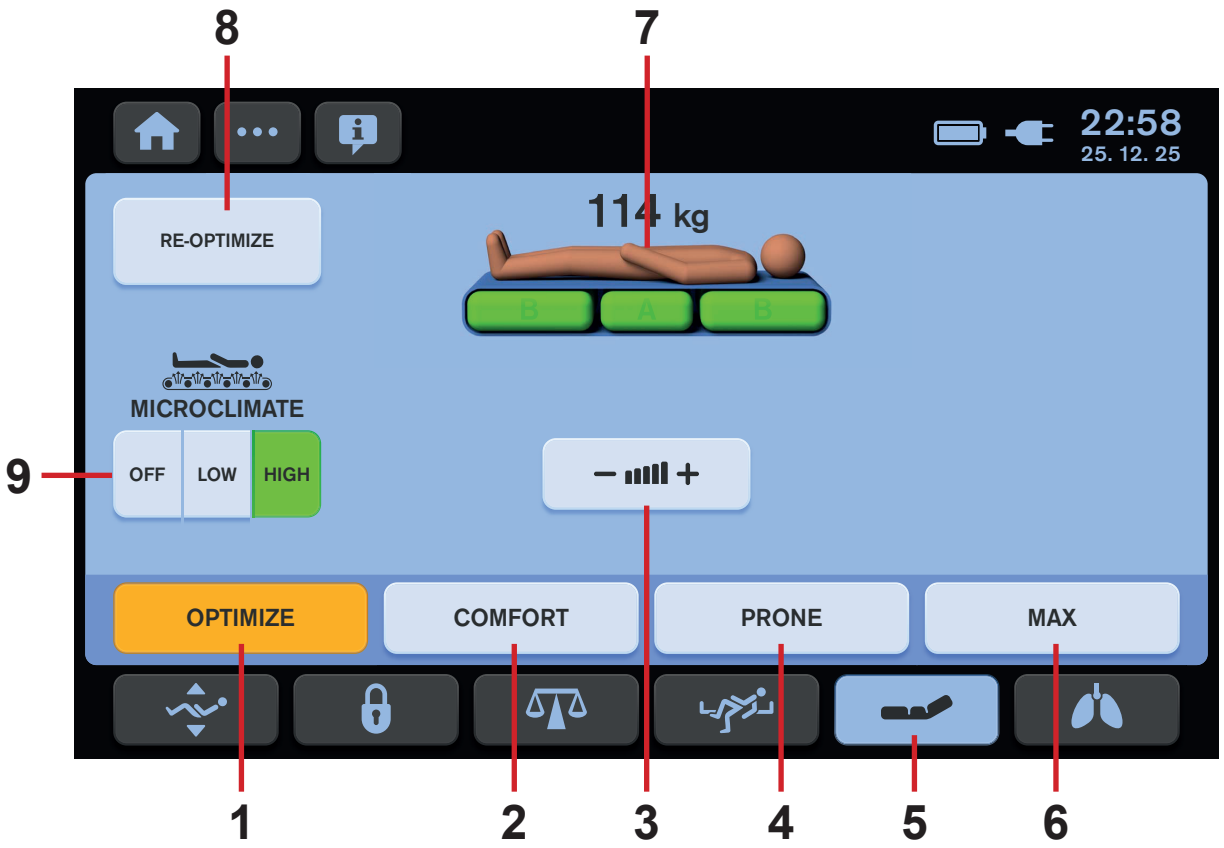


Fig. Integrated Mattress Screen - LCD touchscreen

1. OPTIMIZE Mode Icon (press to enter OPTIMIZE Mode)
2. COMFORT Mode Icon (press to enter COMFORT Mode)
3. Manual Pressure Settings Icon (press to enter Manual Pressure Settings)
4. PRONE Mode Icon (press to enter PRONE Mode)
5. Integrated Mattress Screen Icon (press to enter Integrated Mattress Screen)
6. MAX Mode Icon (press to enter MAX Mode)
7. Mattress Status Indicator (signalising mattress condition in relation to patient)
8. RE-OPTIMIZE Icon (press to start pressure optimisation process manually)
9. MICROCLIMATE Management Icons (OFF/LOW/HIGH)

Yellow colour on the Integrated Mattress Screen indicates activated function.

9.4 OptiCare X Mattress Controls (Multicare X with OptiCare X)

Control and information on status of the OptiCare X mattress is by the display and keyboard on the Multiboard X.
Yellow colour on the LCD touchscreen indicates activated function.

9.4.1 MATTRESS DISCONNECTED

When OptiCare X compressor is installed on the bed but OptiCare X mattress is not connected to the compressor „MATTRESS DISCONNECTED“ screen appears. If the OptiCare X mattress has been deliberately removed from the mattress support platform in order to use an alternative mattress then you must log out the OptiCare X.

To connect OptiCare X mattress to the compressor:
► connect each air pipe to the compressor.

To log out OptiCare X mattress:
► press MATTRESS LOG OUT Icon for 5s.



Fig. Mattress Disconnected Screen

9.4.2 MATTRESS IDENTIFICATION

When OptiCare X mattress is connected to the compressor and its identification starts „MATTRESS IDENTIFICATION“ screen appears.

To achieve identification of connected mattress:

► wait until „MATTRESS IDENTIFICATION“ disappears.



Fig. Mattress Identification Screen

9.4.3 MATTRESS INFLATION

When OptiCare X mattress is identified it is not prepared for a patient because mattress is not inflated enough.

To achieve minimum inflation of the mattress:

► wait until „MATTRESS INFLATION“ disappears.



Fig. Mattress Inflation Screen

9.4.4 OPTIMIZE MODE

When OptiCare X has finished inflating, it will switch to Optimize Mode. This is the default mode. As long as the patient remains on the mattress automatic optimization of the mattress internal pressure continues. Optimization will occur if the patient´s position changes sufficiently to trigger Optimization Detection, or if initiated by the Optimization automatic timer. The integrated MICROCLIMATE Management system will start working automatically when the patient gets into bed, and stops if the patient gets out (MICROCLIMATE OFF).

OptiCare X system in OPTIMIZE Mode detects when a patient has entered or left the bed. This automatically starts the optimization process on patient ingress and puts the mattress into Standby mode on patient egress. During Standby mode mattress areas A and B are inflated to a static pressure. There is a short stable pressure detection delay before reacting to change of status to prevent unnecessary mode changes because patient has changed position. If at any time nursing staff feel it necessary to re-optimize the patient then this can be initiated manually by touching the RE-OPTIMIZE Icon.

Optimization will stop working and the mattress air pressure will be set at a fixed level if:

- ► The mattress support platform is tilted by 10 and more degrees (Anti-Trendelenburg Tilt).
- ► The mattress support platform is tilted by 10 and more degrees (Lateral Tilt).
- ► The mattress support platform is tilted by 5 and more degrees (Trendelenburg Tilt).
- ► Tilt reduction of the mattress support platform has value of 7 or less degrees (Anti-Trendelenburg Tilt).
- ► Tilt reduction of the mattress support platform has value of 7 or less degrees (Lateral Tilt).
- ► Tilt reduction of the mattress support platform has value of 3 or less degrees (Trendelenburg Tilt).
- ► Automatic Lateral Therapy (ALT) is activated.

Manual re-optimization:

► press RE-OPTIMIZE Icon.

To set intensity of MICROCLIMATE Management:

- ► press MICROCLIMATE OFF Icon to turn off the MICROCLIMATE Management.
- ► press MICROCLIMATE LOW Icon to lower intensity of the MICROCLIMATE Management.
- ► press MICROCLIMATE HIGH Icon to intensify the MICROCLIMATE Management.

NOTE: MICROCLIMATE Management will be automatically OFF if there is no patient on the mattress.

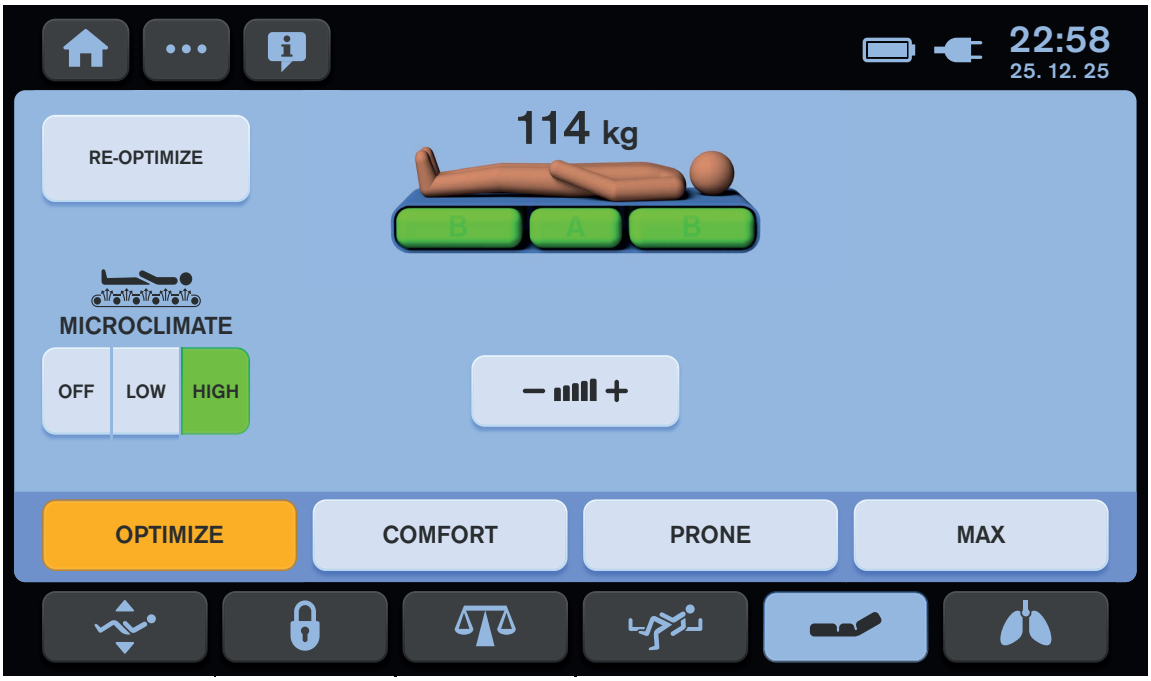


Fig. OPTIMIZE MODE

MANUAL PRESSURE SETTINGS (IN OPTIMIZE MODE)

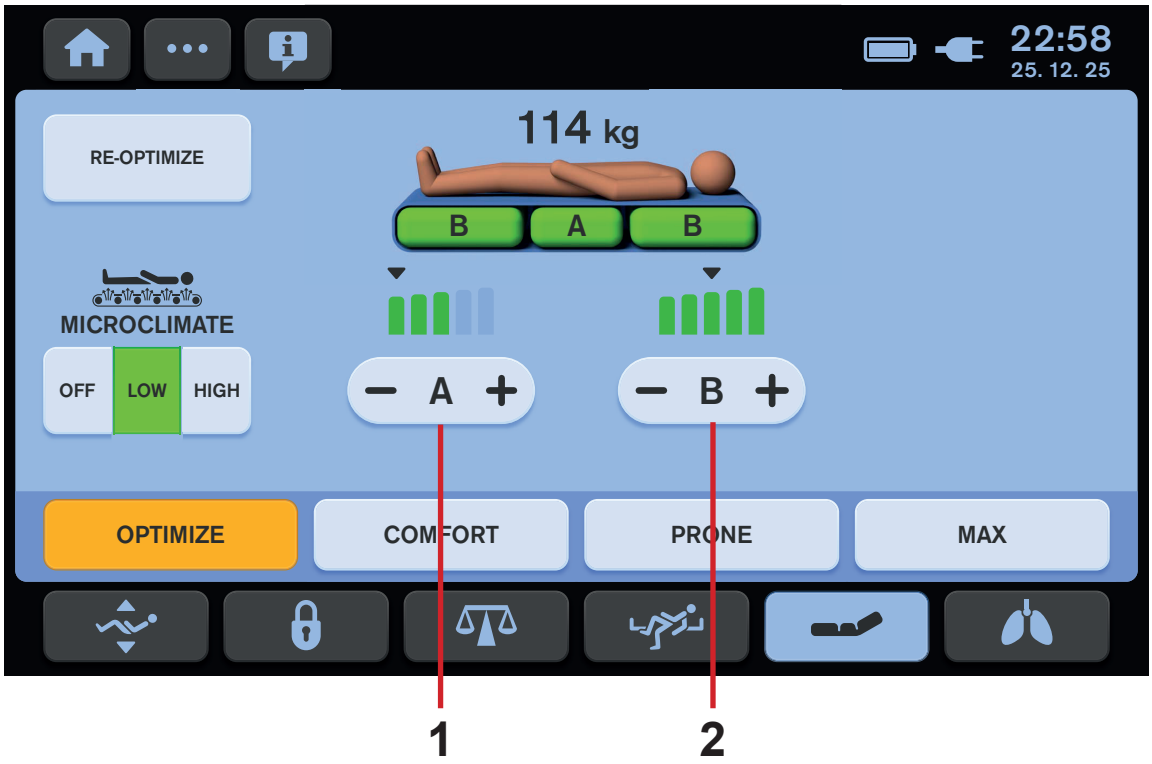


Fig. Manual Pressure Settings in OPTIMIZE Mode

To adjust air pressure in the mattress manually for seat section A:
► Press MINUS (**-**) on the **A** Section Icon (**1**) to decrease pressure level.
► Press PLUS (**+**) on the **A** Section Icon (**1**) to increase pressure level.

To adjust air pressure in the mattress manually for head and foot section B:
► Press MINUS (**-**) on the **B** Section Icon (**2**) to decrease pressure level.
► Press PLUS (**+**) on the **B** Section Icon (**2**) to increase pressure level.

9.4.5 MICROCLIMATE MANAGEMENT

WARNING!
Risk of incompatibility due to incorrect bed sheet!
► Use air-permeable bed sheet exclusively!

The MICROCLIMATE Management function starts to operate automatically when the SCU is turned on, mattress is connected and apatient is detected on the mattress. MCM function stops when patient leaves the bed and mattress.
The integrated MCM function is achieved by providing air through two dedicated mattress parts running down each side of the torso section of the mattress. These manifolds direct the MCM air flow between the top surface of the mattress air cells and the inside surface of the top cover to encourage moisture vapour transmission.
It is possible to set intensity of MICROCLIMATE Management during each mattress mode.

9.4.6 COMFORT MODE

Comfort Mode is intended for providing a less immersive surface to improve comfort and facilitate such independent movement of the more mobile patients. The mattress internal pressure can be adjusted based on the patient´s needs. It is possible to select one of the 5 pressure levels. Each pressure level is suitable for different patient´s weight.

Recommended pressure levels:
- ► 1: 40–54 kg
- ► 2: 54–90 kg
- ► 3: 90–135 kg
- ► 4: 135–180 kg
- ► 5: 180–254 kg

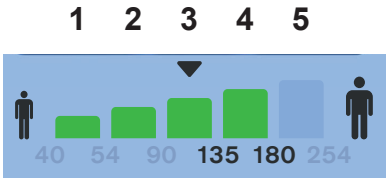


Fig. Five pressure levels

To adjust mattress internal pressure after pressure optimization:
- ► Press MINUS (-) Icon under the five pressure levels to decrease internal cell pressure.
- ► Press PLUS (+) Icon under the five pressure levels to increase internal cell pressure.

To adjust validity period of manual pressure setting:
- ► Press PLUS (+) Icon next to the hourglass icon to add 1 hour to the Comfort Mode operation.
- ► Press MINUS (-) Icon next to the hourglass icon to remove 1 hour of the Comfort Mode operation.

To set unlimited validity period of manual pressure setting:
- ► Press MINUS (-) Icon next to the hourglass icon when the last hour of validity period is passing.

TIMER OFF is displayed above the hourglass icon when unlimited validity period of manual pressure setting is adjusted.

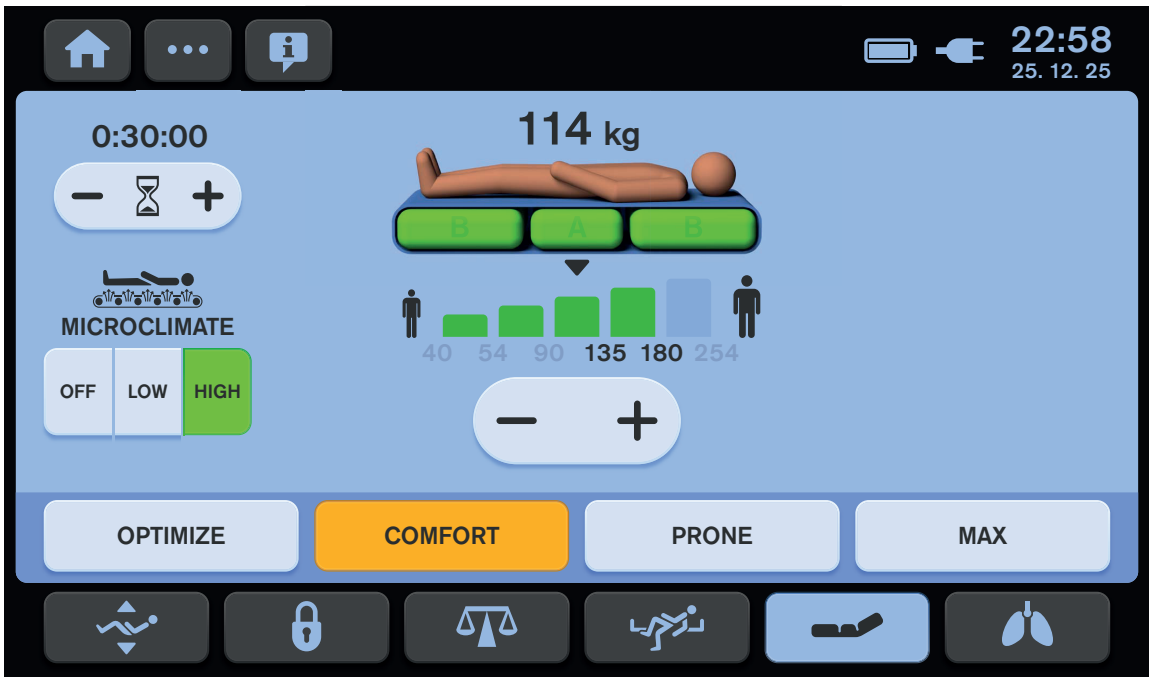


Fig. COMFORT MODE

9.4.7 PRONE MODE

CAUTION!
Turn the patient on their back before leaving the Prone Mode!

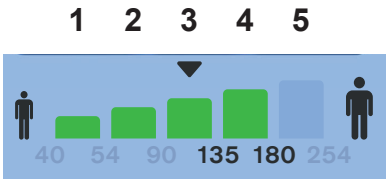


Fig. Five pressure levels

Prone Mode is intended for patients who need to lie prone. This mode does not provide optimization in order to prevent extubation of a patient and to prevent the breathing hoses from kinking. Prone Mode provides setting of the mattress intrernal pressure when patient lies prone. Stopwatch indicator shows how long patient lies prone (HOUR : MINUTE : SECOND).

To adjust mattress internal pressure after pressure optimization:

► Press MINUS (-) Icon under the five pressure levels to decrease internal cell pressure.
► Press PLUS (+) Icon under the five pressure levels to increase internal cell pressure.

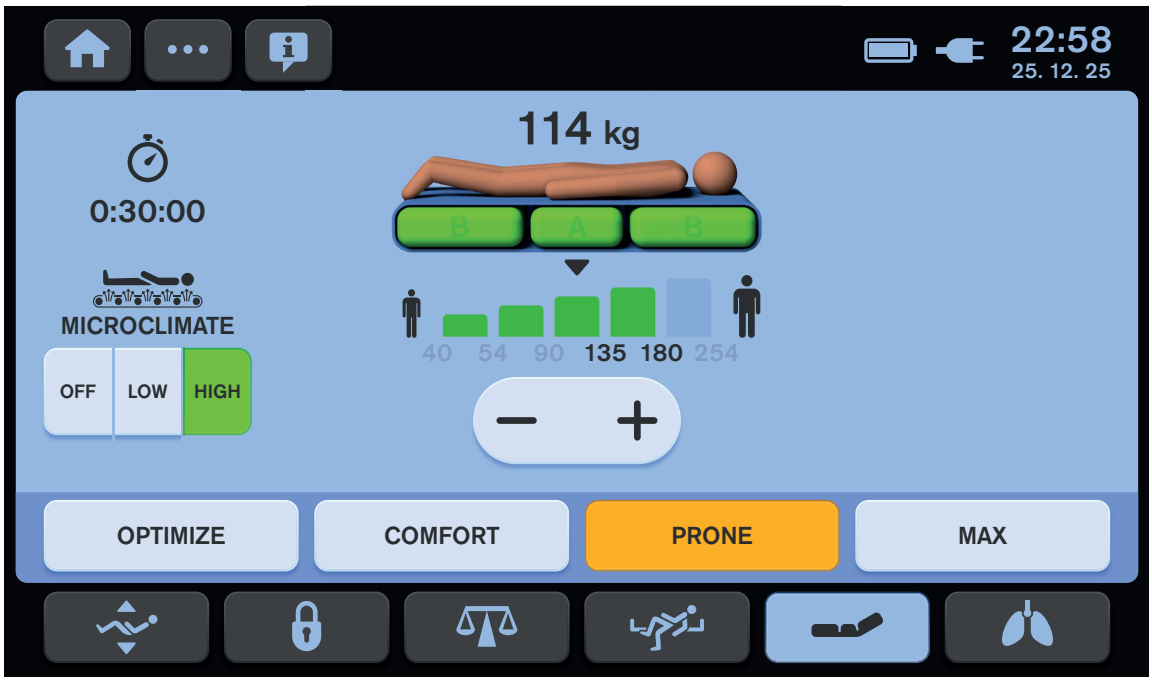


Fig. PRONE MODE

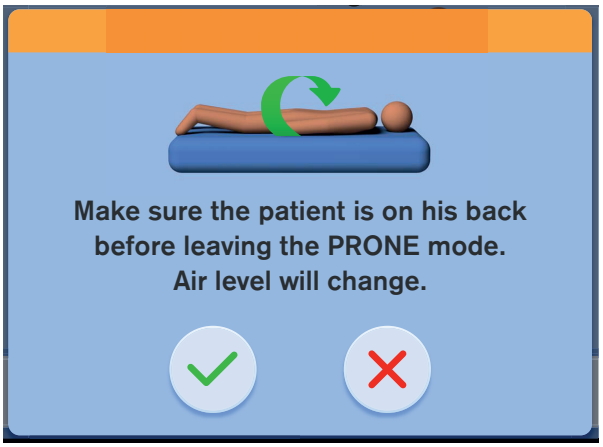


Fig. Check patient position after Prone Mode (warning pop--up window)

Before leaving the PRONE Mode, a pop-up window will appear to remind you to check the patient´s position on the mattress:

► Press TICK Icon to confirm that patient is lying on his/her back.
► Press CROSS Icon to return to the PRONE Mode.

9.4.8 MAX MODE

MAX Mode is intended for sliding transfers, turning patients and certain medical procedures (e.g. physiotherapy).
MAX Mode causes maximum mattress internal pressure for 30 minutes.
Countdown is displayed on the MAX Mode Screen above hourglass icon in the upper left corner of the screen.
OptiCare X system returns to previous mode after end of the MAX Mode.

To set Maximum Mattress Internal Pressure for 30 minutes:
► press MAX Mode Icon.

To set Maximum Mattress Internal Pressure for 30 minutes again:
► press PLUS (**+**) Icon next to the hourglass icon.

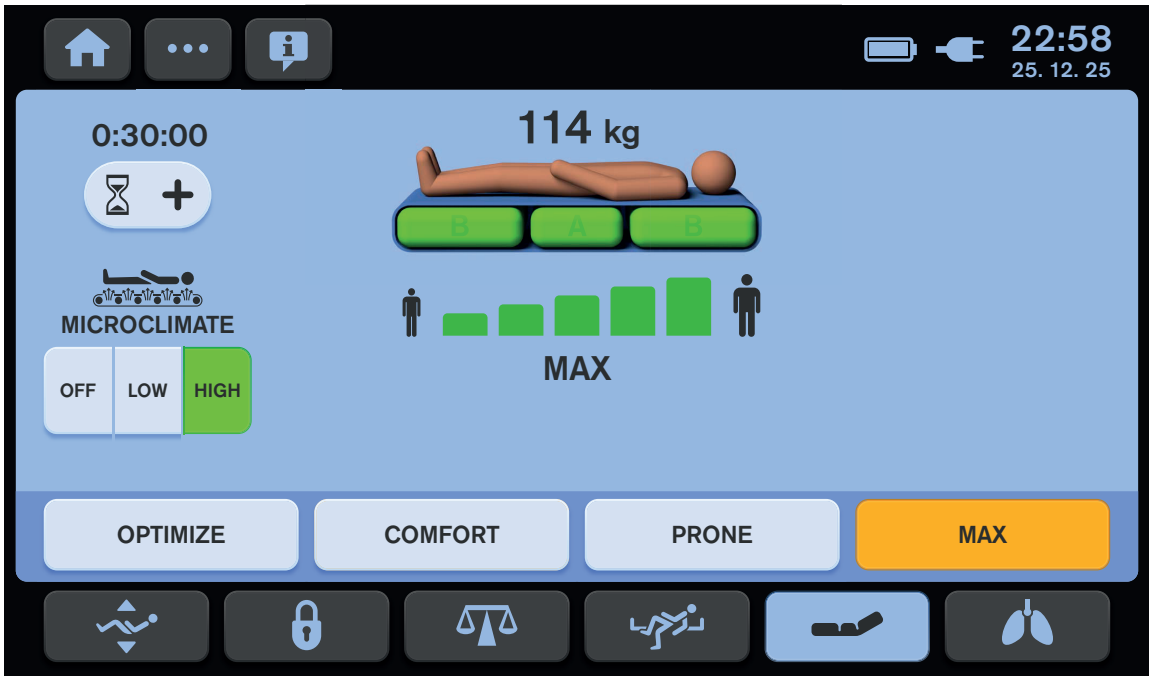


Fig. MAX MODE

9.4.9 CPR MODE (CPR ACTIVATED)

When CPR is activated, the mattress will deflate and chest compression can start immediately.
CPR Mode period is limited to 1 hour and this period is counted down on the CPR Mode Screen.
OptiCare X inflates automatically when this time is up.

To deactivate CPR Mode:
► press CPR CANCEL Icon.
The mattress will inflate again and return to the mode it was in before CPR started.

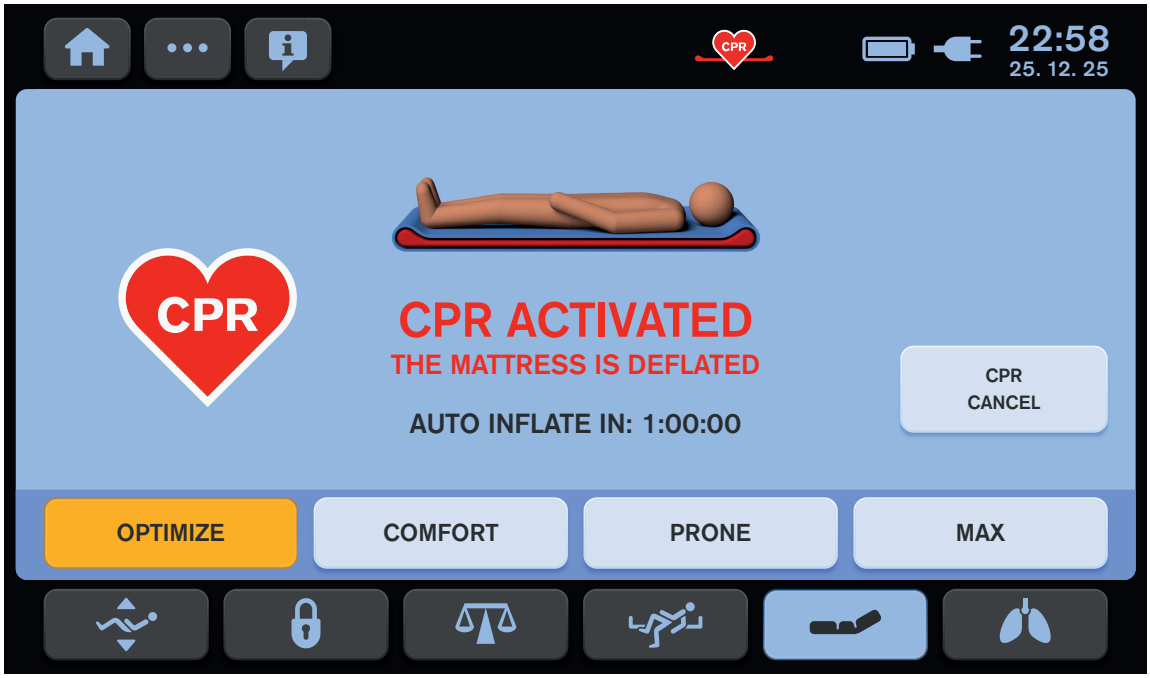


Fig. CPR MODE

9.4.10 PUMP DISCONNECTED

When SCU is removed from the bed or communication between the bed and the SCU is lost this alert appears with „PUMP DISCONNECTED“ text.

To remove this alert:

- ► Install compressor on the bed!
- ► Log out the SCU.
- ► If problem remains, contact the service department of the manufacturer!

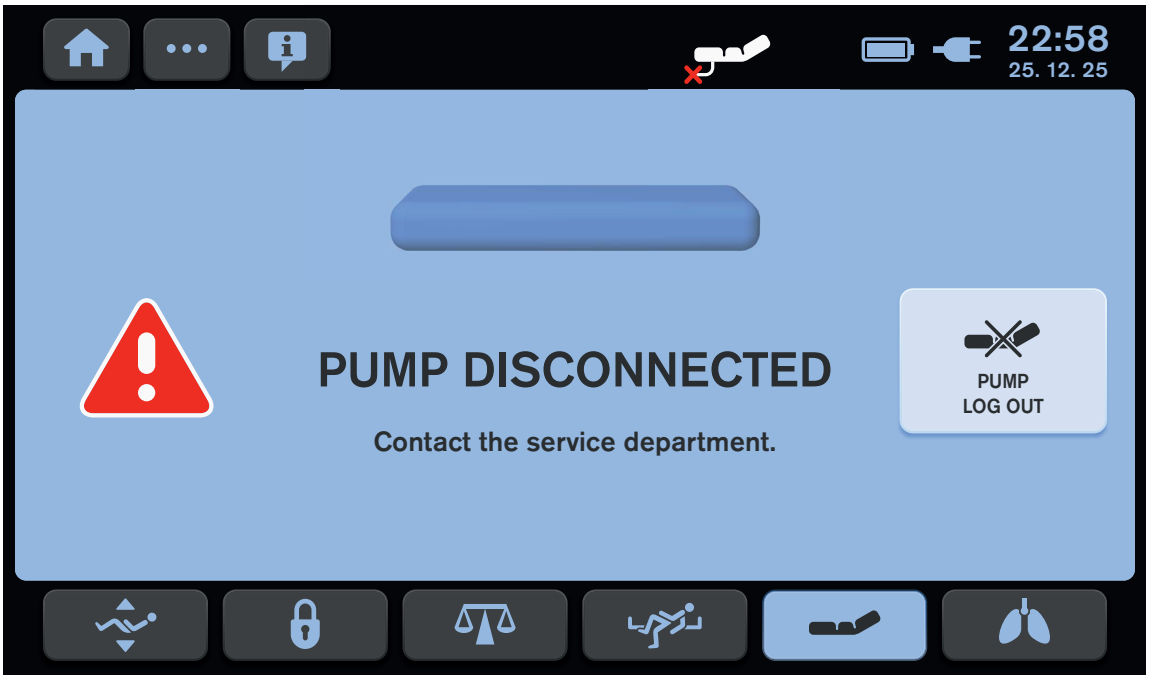


Fig. PUMP DISCONNECTED

10 Equipment

Product equipment depends on product configuration.

10.1 X-ray Pocket

CAUTION!
It is forbidden to wash the X-ray Pocket in the washing machine!

Mattress Cover ZONED could be equipped with X-ray Pocket.
The X-ray Pocket is accesible from the left side and from the right side of the OptiCare X integrated mattress.
The X-ray Pocket is connected to the mattress cover by zip so it can be removed from the mattress cover when it is completely unzipped.

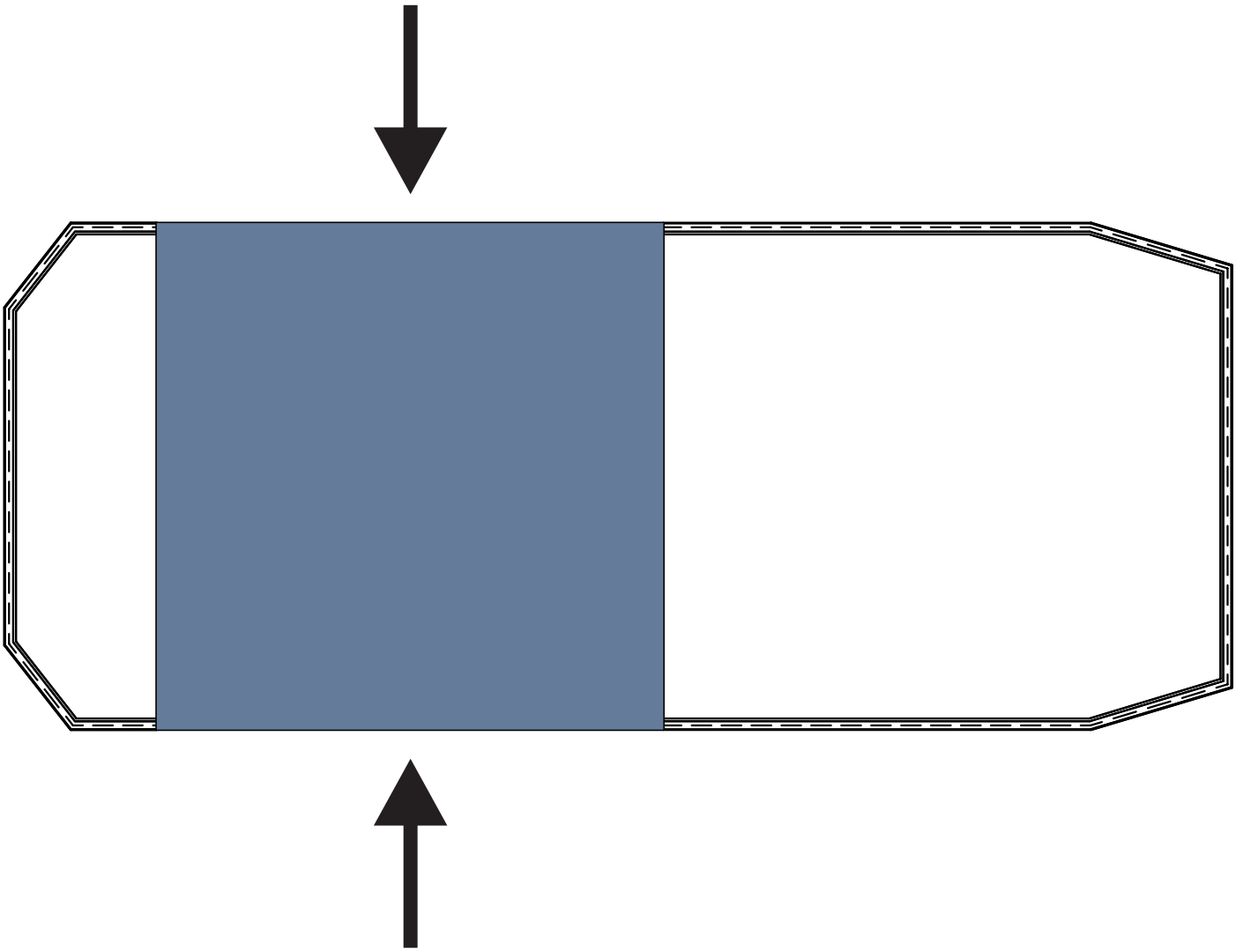


Fig. Access to the X-ray Pocket (mattress cover ZONED)

11 Cleaning/Disinfection (OptiCare X)

CAUTION!
Material damage due to incorrect cleaning/disinfection!
► Do not use pressure or steam cleaners.
► Follow the instructions and observe the dosages recommended by the manufacturer. Never exceed recommended concentrations stated in this document. Always rinse and dry before putting the mattress back into service, even if the chemical manufacturer states their cleaning agent need not to be rinsed.
► Ensure that disinfectants are selected and applied exclusively by qualified hygiene experts.

General Guidance – Standard Cover:

► Do not use any strong acids or alkalines, (optimum pH range 6 – 8. Do not exceed pH of 9). Some hard surface cleaners have pH values outside this range, these are not suitable for use on coated textiles.
► Only use detergents that are suitable for cleaning medical equipment and for use on coated 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, phenol, etc.).
► Use only hospital-approved cleaners and observe local directives concerning infection control.
► Always rinse with water after cleaning and dry thoroughly before use.

Mattress parts to be cleaned	**Recommended Cleaning Agents (General cleaning)**
Top Cover **High MVP (Moisture Vapor Permeable) Material**	Standard hospital detergents, Alcohol or Quaternary Ammonium based disinfectants, Chlorine based disinfectants containing up to 1000ppm Chlorine, followed by rinsing with water and drying thoroughly before use.
	Decontamination: Blood spills/Clostridium difficile etc
	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. PU coated fabrics may feel dry to the touch, but still retain moisture. Wait until the surface is no longer cold to the touch before putting PU coated fabrics back into service.
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 and durability. The High MVP Coating may swell and change appearance during cleaning. This will recover after being thoroughly dried.

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

Type of Cleaning	**Parts to be cleaned**
Routine Cleaning and Disinfection	■ Exposed mattress parts ■ Exposed SCU parts
Full Cleaning and Disinfection	■ Exposed mattress parts ■ Exposed SCU parts ■ Internal parts of mattress ■ Internal parts of cover

11.1 Routine Cleaning and Disinfection

Cleaning the mattress:

► Check mattress cover top for any signs of damage.
Replace or repair and completely disinfect mattress cover top if damaged.
► Check inside of mattress cover top for signs of liquid ingress.
Replace or clean and completely disinfect mattress cover top if damp inside.
► Leave mattress cover on mattress.
► Clean with 60°C warm water and cleaning detergent.
► Rinse mattress with cold water.
► Let mattress dry or wipe dry.
► Wipe mattress with disinfectant.
► Rinse mattress with cold water.
► Let mattress dry or wipe dry.

Cleaning the SCU:

► Wipe SCU with disinfectant.
► Let SCU dry or wipe dry.

11.2 Full Cleaning and Disinfection

Cleaning the mattress:

► Deflate mattress and remove cover (see Removing the Mattress Cover).
► Check mattress cover top and base for any signs of damage.
Replace or repair and completely disinfect mattress cover top and base if damaged.
► Check mattress cover top and base for signs of liquid ingress.
Replace or clean and completely disinfect mattress cover top and base if damp inside.
► Clean all mattress cells and pipes with 60°C warm water and cleaning detergent.
► Rinse mattress with cold water.
► Let mattress dry air dry or wipe dry.
► Wipe mattress with disinfectant.
► Rinse mattress with cold water.
► Let mattress dry air dry or wipe dry.

Cleaning the mattress cover:

► Remove cover (see Removing the Mattress Cover).
► If machine washing mattress top/base covers, the temperature should be raised during the wash cycle, to 65°C/149°F, for 10 -15 minutes, or 71°C/160° F, for 3 - 10 minutes, using hospital approved detergents and rinsing agents.

NOTE Maximum wash temperature is 75°C/167°F.

► Dry cover in tumble dryer at low temperature.

Cleaning the air pipe:

► Wipe air pipe with cleaning agent or disinfectant.
► Let air pipe dry.

Cleaning the SCU:

► Remove filter.
► Wipe SCU and filter with disinfectant.
► Let SCU and filter dry.
► Reinsert filter.

11.3 Removing the Mattress Cover

► Carefully open zipper under side skirt of mattress cover on foot end of mattress.
► Remove top part of mattress cover.
► Undo corner toggles holding comforter cover and remove comforter cover.
Inspect comforter cover and clean if necessary.
► Undo toggles holding top deck to foam base.
► Undo plastic clip next to air pipe inlet on base cover holding foam base to cover.
► Remove bottom part of mattress cover.

After cleaning the mattress cover:

► Reinstall mattress cover by reversing the process described above.
► Make sure all toggles are put back in their respective holes.

12 Troubleshooting (OptiCare X)

DANGER!
Risk of mortal injury due to electric shock!
► If a fault occurs, have the electric motor, power box or other electrical parts repaired by qualified personnel exclusively.
► Do not open the protective covers of the electric motor or the power box.

WARNING!
Risk of injury due to lack of support!
If the OptiCare X integrated mattress is empty so that the patient is lying directly on the foam base, and it is not possible to solve the problem by following the troubleshooting instructions:
► Move patient onto a suitable support surface as quickly as possible.

13 Maintenance (OptiCare X)

WARNING!
Risk of injury when working on the mattress system!
► Ensure that the mattress system is disconnected from the mains power prior to installation, putting into service, maintenance and deinstallation.

WARNING!
Risk of injury due to defective mattress system!
► Have a defective mattress system repaired immediately.
► If the defect cannot be repaired, do not use the mattress 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 system.

13.1 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.

13.2 Spare Parts

The serialt 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

13.3 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 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.

14 Disposal (OptiCare X)

14.1 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.linet.cz**).

14.2 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 battery or accumulator are designed so that the used batteries or accumulators can be safely removed by LINET® qualified service technicians. There is an information about its type on the built-in battery or accumulator.

14.2.1 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/**).
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.

14.2.2 Outside Europe

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

15 Warranty (OptiCare X)

LINET ® will only be held responsible for the safety and reliability of products that are regularly serviced, maintained and used in accordance with the safety guidelines.

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

► Do not continue to use the bed.

This product is covered by a 24-month warranty from the date of purchase. The warranty covers all material and manufacturing-related failures and errors. Failures and errors caused by incorrect use and external effects are not covered. Justified complaints will be fixed free of charge during the warranty period. Proof of purchase, with the date of purchase, is required for all warranty service.

16 Standards and Regulations (OptiCare X)

16.1 OptiCare X

The OptiCare X integrated mattress system complies with the following standards:

- **IEC 60601-1**
- **CAN/CSA C22.2 NO. 60601-1**
- **ANSI/AAMI ES60601-1**
- **IEC 60601-1-2**
- **IEC 60601-1-6**
- **ISO 10993-5**
- **ISO 10993-10**

16.2 Manufacturer

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)**