

Instructions for Use and Technical Description



Air2Care Model 10 & 20

Mattress Replacement and Overlay Systems



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**Air2Care 10 & 20**

Mattress Replacement and Overlay Systems

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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:


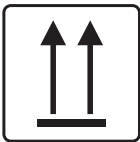



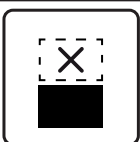
- ▶ Perform this step.
- Results, if necessary.

1.3 Lists




Structure of bulleted lists:










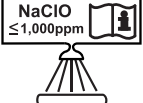



- List level 1
 - List level 2
 - List level 3










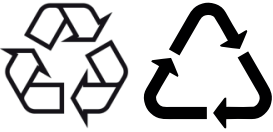



1.4 Symbols on the Package

	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

	MEDICAL DEVICE (COMPATIBLE WITH MEDICAL DEVICE REGULATION)
	MANUFACTURER
	MANUFACTURING DATE

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

	<p>ONLY SUITABLE FOR INDOOR USE</p>
	<p>CE MARK OF CONFORMITY WITH EU REGULATION</p>
	<p>2X 1A(T) ANTI-SURGE FUSE (AIR2CARE 10)</p>
	<p>2X 250MA (T) ANTI-SURGE FUSE (AIR2CARE 20)</p>
	<p>PROTECTION AGAINST ACCIDENTS DUE TO ELECTRICAL CURRENT – TYPE B APPLIED PARTS</p>
	<p>DOUBLE INSULATION</p>
	<p>POWER SWITCH I : ON O : OFF</p>
	<p>ALTERNATING CURRENT</p>
	<p>WEEE SYMBOL (RECYCLE AS ELECTRONIC WASTE, DO NOT PUT INTO THE HOUSEHOLD WASTE)</p>
	<p>RECYCLING SYMBOL</p>
	<p>DO NOT POLLUTE THE ENVIRONMENT</p>
	<p>REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON CONFIGURATION)</p>
	<p>SERIAL NUMBER</p>

1.5.1 Serial labels with UDI

The serial label is located on the back of the SCU (System Control Unit). The serial number and the model number can be found on the serial label. This information is required when contacting LINET®. Pictures of serial labels below serve just for explanation of the signs and fields on the serial labels.

Serial Label for Air2Care 10 (SCU)

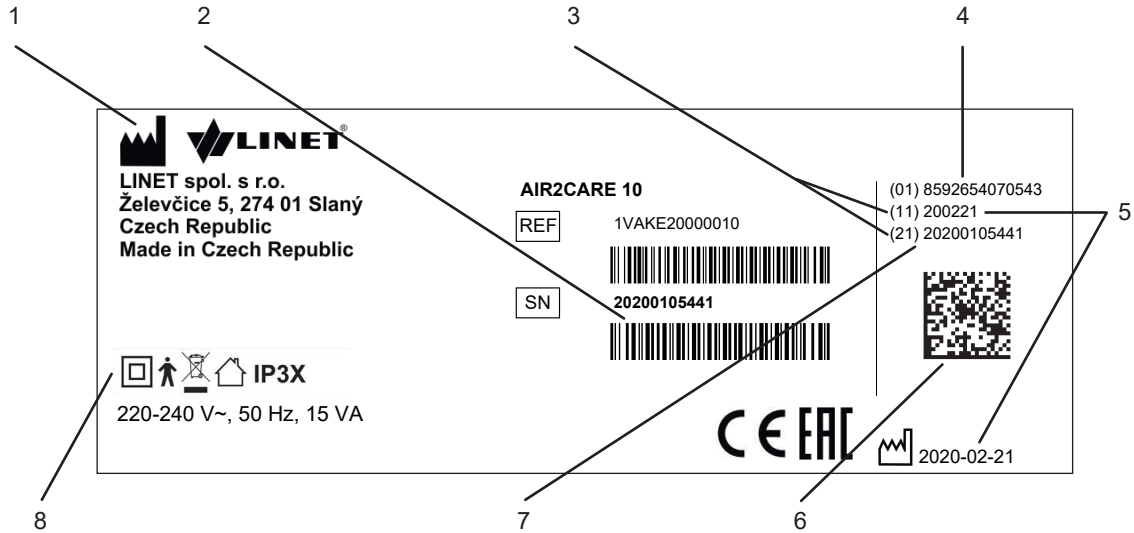


Fig. Serial label for Air2Care 10 (220-240 V)

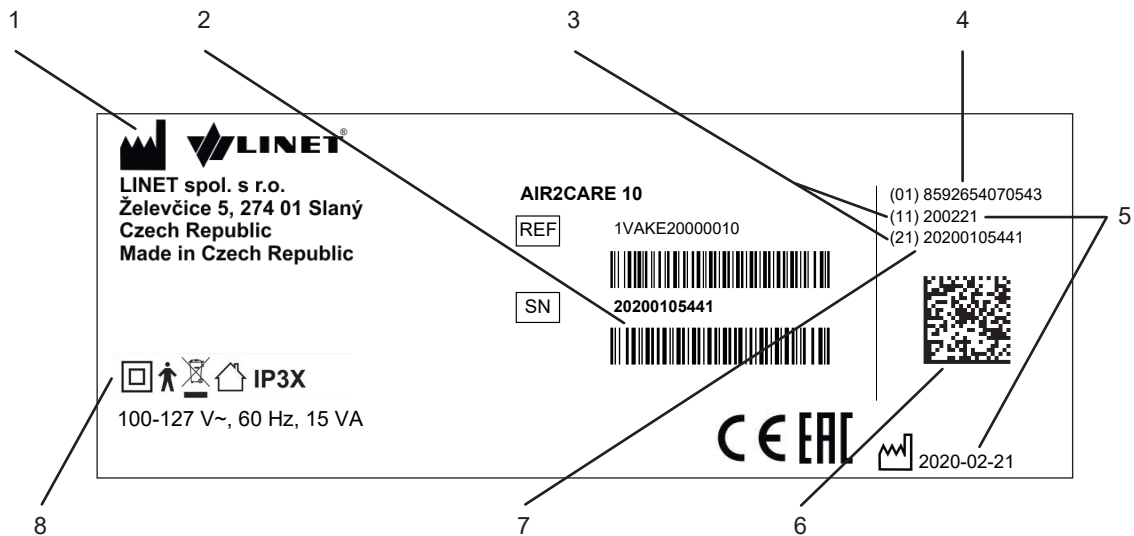


Fig. Serial label for Air2Care 10 (100-127 V)

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

Serial Label for Air2Care 20 (SCU)

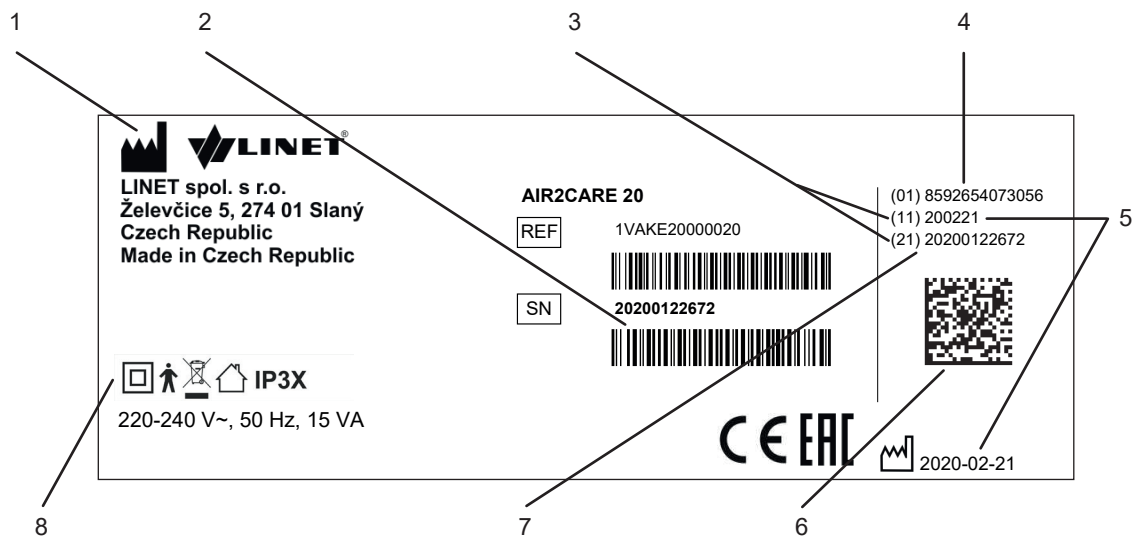


Fig. Serial label for Air2Care 20 (220-240 V)

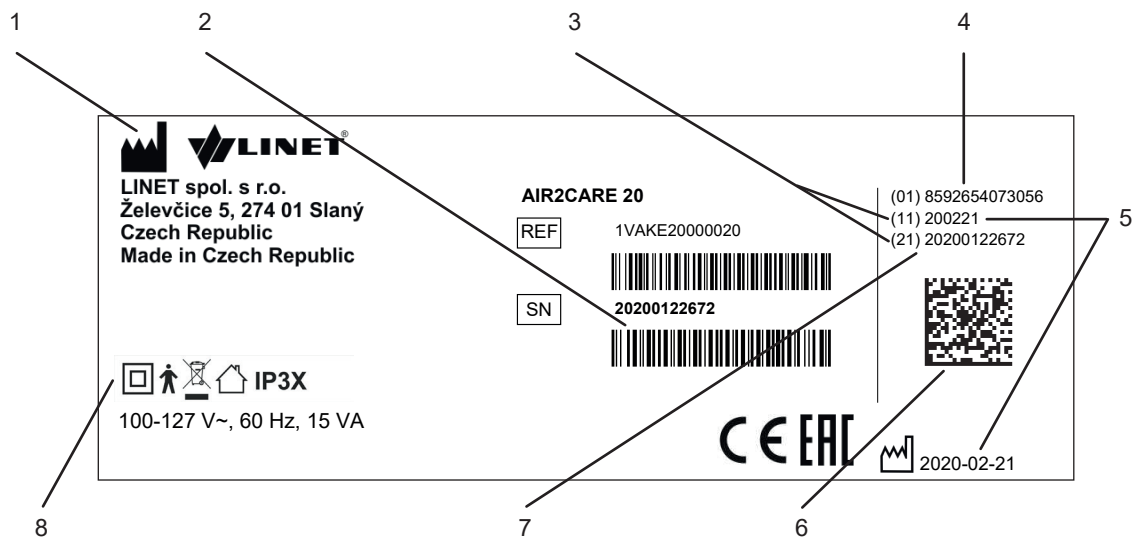


Fig. Serial label for Air2Care 20 (100-127 V)

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

Serial Label for Air2Care 10 and Air2Care 20 (mattress)

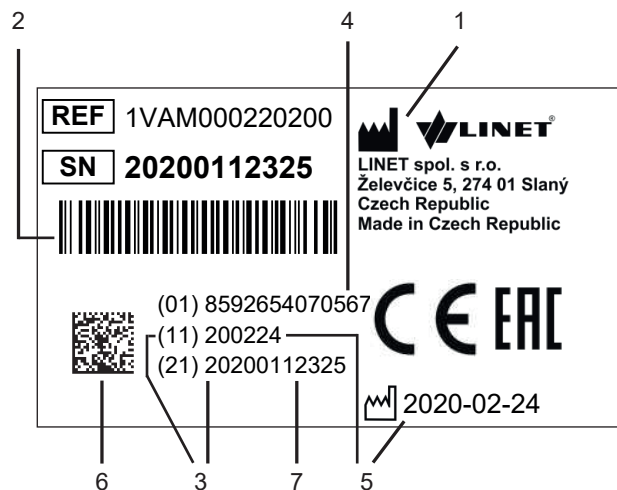
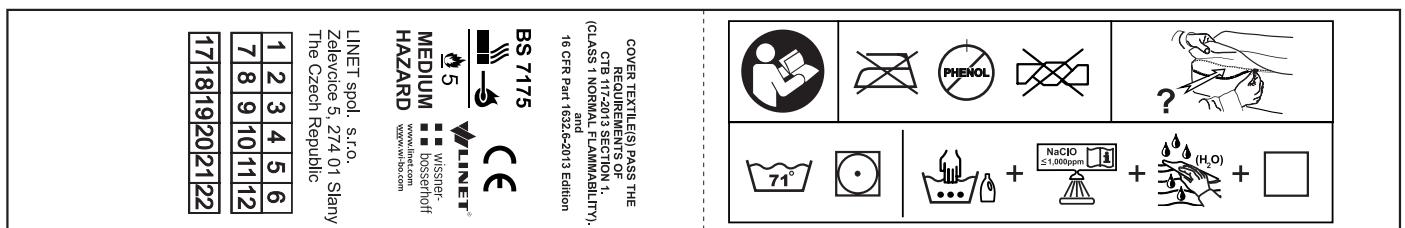


Fig. Serial Label with UDI (Air2Care 10 and Air2Care 20 - mattress)

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

1.5.2 Wash Label (mattress)



1.6 Acoustic signalisation (Air2Care 10)

There are no acoustic signals in the case of Air2Care 10.

1.7 Acoustic signalisation (Air2Care 20)

SOUND	MEANING
3 SOUND MODES: 1) during 2 minutes: REPEATED BEEP: lasting 0,25s / 3s (± 1s) silence 2) during next 6 minutes: REPEATED BEEP: lasting 0,25s / 9s (± 1s) silence 3) during next minutes: REPEATED BEEP: lasting 0,25s / 2 min (± 5s) silence	disconnected from the mains
	mains voltage is not available when the mains switch is turned ON
	mains switch is turned OFF
REPEATED BEEP: 0,25s sound / 4s silence	mattress inflation failure
	valve rotation failure
	pressure fault

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

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!

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 the instructions for use.
- ▶ Only use mattress with original SCU. Using mattress with non-original SCU is not allowed.
- ▶ Never use safety straps designed for fixing the mattress to the bed for emergency evacuation of the patient.
- ▶ LINET® shall not assume any responsibility for any damage or injury resulting from incorrect use.
- ▶ Position the mains cable so that there are no loops or kinks in the cable; protect the cable from mechanical wear and tear. Improper handling of mains cable can cause an electric shock hazard, other serious injuries or damage to the mattress system.
- ▶ Position the mains cable 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 the instructions for use.
- ▶ 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 mains 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 mains plug with wet hands.
- ▶ Disconnect the product from the mains only by pulling the mains plug. To pull the mains plug, always hold the actual plug, not the cable.
- ▶ Mattress and SCU must be checked at least once a day. Check that:
 - the mattress is inflated to the required pressure
 - the error code indicator is not illuminatedin case of error refer to the chapter System Faults

3 Intended use

The intended use is to prevent and support treatment of pressure injuries.

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

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

4.1 Mattress

The Air2Care mattress system is designed for use in all health care 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 The Overlay

This system is designed to be used with current mattress. The overlay is an air-filled mattress consisting of a central set of 21 transverse air cells and two separate full length side formers.

Mattress system cover is water proof and vapour permeable cover made of polyurethane-coated nylon which has a two 180° zip. It has straps to prevent the mattress ends from moving when fitted on top of a standard hospital foam or a domestic mattress.

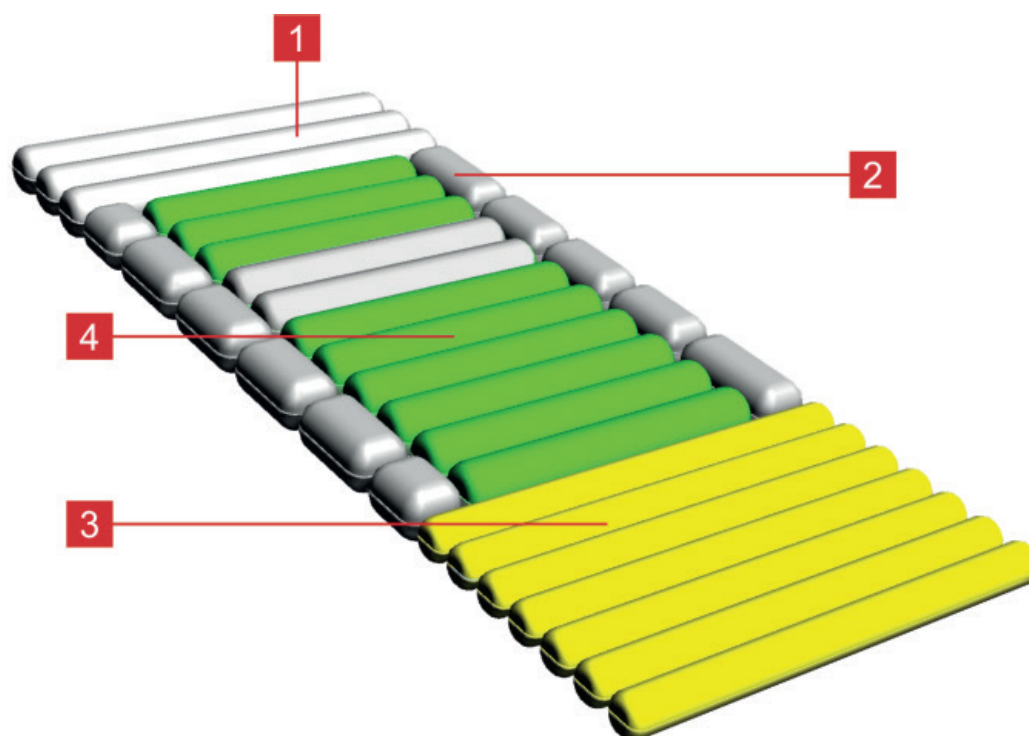


Fig. Overlay

1. Head section
 - 3 head cells which remains inflated (static)
2. Side formers
 - 10 small full-length side formers which remain inflated (static)
3. Foot section
 - 7 lower leg/foot cells (25% smaller) which alternate in 2-cell cycle
4. Torso section
 - 11 torso/upper leg cells (9 alternating, 2 static for support of patient's back and patient's comfort) which alternate in 2-cell cycle

4.1.2 Mattress replacement system (air + foam)

The mattress replacement system is designed to replace a standard hospital, nursing home or domestic foam mattress. It consists of the overlay system and an additional lower 3-section foam base. The replacement system cover is water proof and vapour permeable with a two 180° zips to allow easy access for cleaning. Cover has straps to secure the mattress to the bed.

Overlay (top air layer):

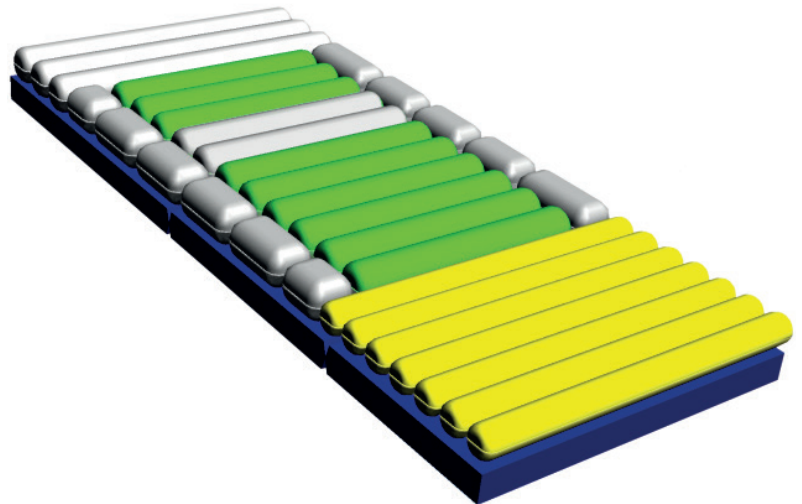
- air-filled overlay (see Overlay)

Base (bottom foam layer):

- consists of hospital-grade fire-retardant foam

Cover:

- bottom part: non-flexible, resistant material
- top part: flexible, water proof material



Mattress replacement system (air + foam)

4.1.3 Mattress replacement system (air + air)

The mattress replacement system is designed to replace a standard hospital, nursing home or domestic foam mattress. It consists of two air layer. Upper layer is dynamic and the bottom layer is static. The replacement system cover is water proof and vapour permeable with a two 180° zips to allow easy access for cleaning. Cover has straps to secure the mattress to the bed.

Overlay (top air layer):

- air-filled overlay (see Overlay)

Base (bottom air layer):

- static air-filled base

Cover:

- bottom part: non-flexible, resistant material
- top part: flexible, water proof material

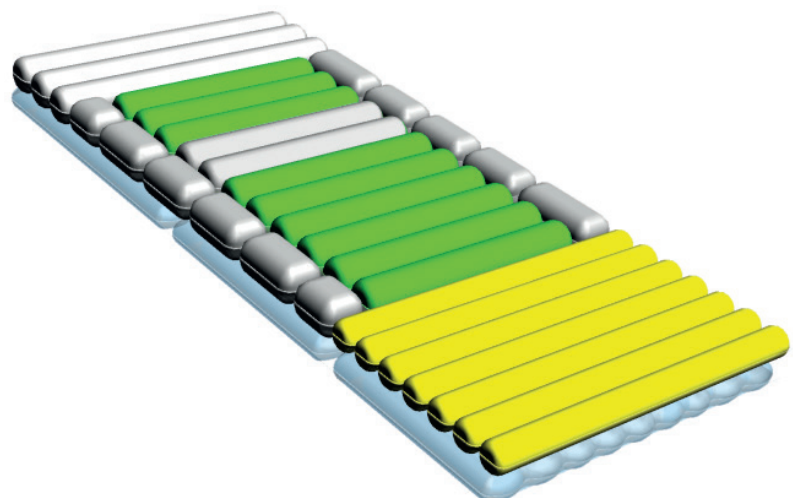


Fig. Mattress replacement system (air + air)

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 (Air2Care 10) or microprocessor-controlled SCU (Air2Care 20) maintains the set pressure regardless of the patient's weight distribution or position. The SCU is equipped with an audio and/or visual alarm system to detect power failures, air pipe disconnections or other faults.

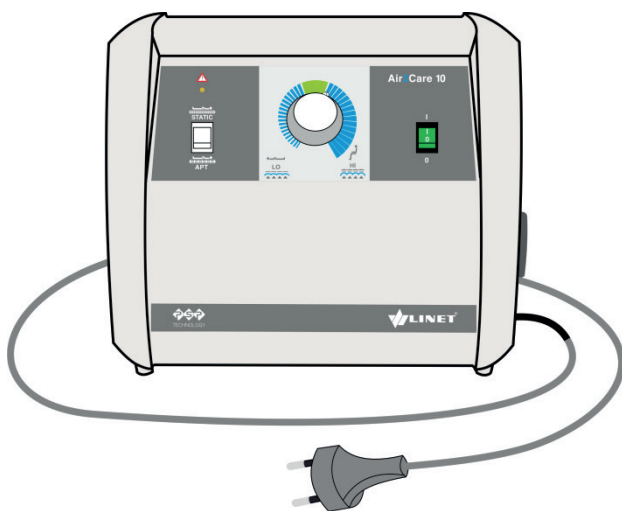


Fig. SCU for Air2Care 10

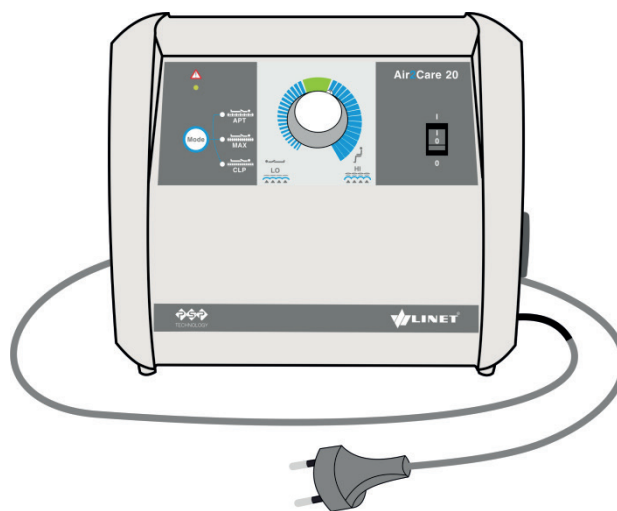


Fig. SCU for Air2Care 20

4.2.1 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

5.1 Mechanical Specification

Parameter	Parameter
Dimensions <ul style="list-style-type: none"> ■ Mattress replacement (inflated) ■ Overlay (inflated) ■ Seat cushion (inflated) ■ SCU 	2 000 x 860 x 170 mm 2 000 x 860 x 93 mm 450 x 500 x 125 mm 260 x 120 x 215 mm
Weight <ul style="list-style-type: none"> ■ Mattress replacement (inflated) ■ Overlay (inflated) ■ Seat cushion (inflated) ■ With optional seat plate ■ SCU Cycle <ul style="list-style-type: none"> ■ Mattress (inflated) ■ Seat cushion (inflated) 	7,5 kg 6 kg 2,1 kg 3,5 kg 2,5 kg 2 cells, 12 minutes 2 cells, 12 minutes
Environmental conditions <ul style="list-style-type: none"> ■ Temperature ■ Humidity ■ Atmospheric pressure 	10 °C – 40 °C 30% - 75% 795 – 1060 hPa
Maximal load (SWL) <ul style="list-style-type: none"> ■ Mattress replacement (air + air) ■ Mattress replacement (air + foam) ■ Overlay ■ Seat cushion 	210 kg 200 kg 180 kg 127 kg
Inflation time <ul style="list-style-type: none"> ■ Mattress ■ Seat cushion 	up to 30 min 6 min
Deflation time (CPR)	Max. 30 s
Sound Pressure Level	35 dBA

5.2 Operating pressure settings

Parameter	Parameter
Air2Care 10 <ul style="list-style-type: none"> ■ APT ■ STATIC 	20 – 45 mmHg 20 – 45 mmHg
Air2Care 20 <ul style="list-style-type: none"> ■ APT ■ CPT ■ MAX 	15 – 50 mmHg 12 – 45 mmHg 45 mmHg
Pressure settings tolerance	± 5 mmHg

5.3 Electrical Specifications

Parameter	Parameter
Supply nominal voltage ■ Model 127V ■ Model 230V	100-127 VAC, 60 Hz 220-240 VAC, 50 Hz
Maximal power Air2Care 10 ■ Model 127V ■ Model 230V Maximal power Air2Care 20 ■ Model 127V ■ Model 230V	15VA 15VA 25VA 35VA
Fuse Air2Care 10 Air2Care 20	2x (T 1A L) anti-surge fuse (250 V, type 5x20mm) 2x (T 500mA L) anti-surge fuse (250 V, type 5x20mm)
Electrical safety class	Class II with applied parts type B
Electrical safety	In conformity with EN 60601-1

5.4 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 Air2Care, 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 (SWL), respect the bed 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.

5.4.1 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
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

NOTE: Compressor self-reset can occur in the case of Air2Care 20, no effect to product functionality. After the reset previous mode continues functional.

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

Air2Care is suitable for use and storage in indoor environments meeting the following requirements:

Ambient temperature	10 °C – 40 °C
Relative humidity	30% - 75%
Atmospheric pressure	795 – 1060 hPa
Dust and water protection (SCU)	IP 3X (Protected against ingress of solid foreign objects with diameter of >2,5 mm.)
Flammability rating (mattress and cushion covers)	BS7175, ignition source 0, 1 & 5
Environment	ISO 14001 2011/65/EU (RoHS) 2002/96/EC (WEEE)
Electromagnetic compatibility	EN 60601-1-2

Air2Care is not suitable for use in environments:

- Containing flammable gases (except oxygen cylinders).

6.1 Storage

When SCU is not in use:

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

When mattress is not in use:

- ▶ Clean and disinfectate mattress.
- ▶ Let the mattress dry completely.
- ▶ Deflate.
- ▶ Roll mattress up to get air out completely.
- ▶ Pack in suitable cover.
- ▶ Store in a place suitable for medical devices.

NOTE: Never store more than 4 mattresses on each other. This may result by damaging the mattress or system malfunction.

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

- Mattress with cover
- SCU (System Control Unit) - Applied part type B
- Instructions for use
- Air2Care seating cushion (optional)
 - Seat plate (optional)

8 Putting into Service

8.1 Securing Strap System



WARNING!

Material damage due to incorrect fastening of safety straps!

- ▶ 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 a Air2Care 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 secure the straps to fixed parts of the bed frame.

Mattress overlay system

- ▶ Firmly fix head and foot straps only around existing mattress.

Mattress replacement system

- ▶ Fix safety straps only to movable parts of bed frame.
- ▶ Use all safety straps to prevent the mattress from moving when the patient is getting into or out of bed.



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 air connector).

The Air2Care Mattress Base Cover has a strapping system for securing it to either the existing mattress in an overlay situation, or the bedframe in a mattress replacement situation.

There are 6 straps sewn onto the Base cover underside. These are positioned at the Head, Thigh, and Foot areas of the mattress on both left and right sides. Two separate straps are supplied also. Each strap has a trident buckle arrangement, with a fixed female part (1), and a male part (2) that can be moved along the webbing (3) to adjust the effective length of the strap.

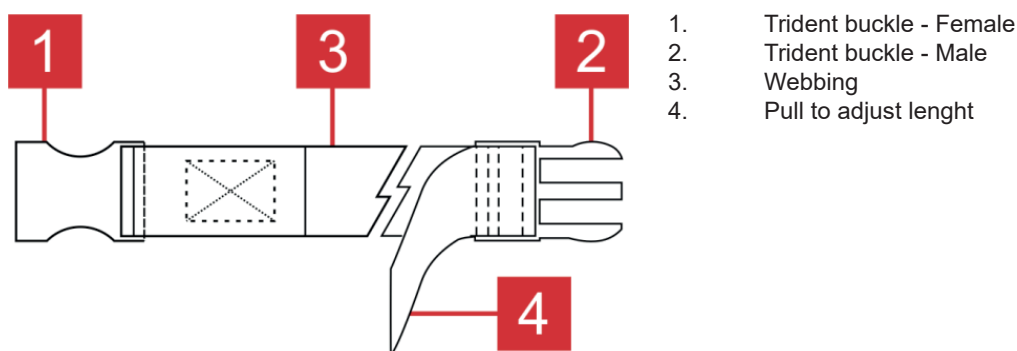


Fig. Safety strap

8.1.1 Installation – Overlay Mattress

To secure mattress on the bed:

- ▶ Place the deflated Air2Care Overlay mattress (is in good condition and free of any damage or wear) on top of the existing mattress, with the air pipe at the patients left and position so that the overlay is centred. The foot symbol on the mattress cover is located at the foot end of the bed.
- ▶ Using one of the separate straps, fasten the female part (1) of the trident buckle to the male part (2) of the buckle on the base cover strap nearest to the air pipe. Pass the strap underneath the existing mattress, and clip the male buckle part (2) into the female part (1) of the strap buckle on the opposite side of the base cover.
- ▶ Pull the webbing (3) through the male buckle (2) to adjust the length of the strap until the Overlay mattress is securely held on the existing mattress. Ensure the Overlay mattress remains centrally positioned.
- ▶ Repeat the above process at the head end of the Overlay mattress, using the remaining separate strap, and the base cover straps.
- ▶ The straps sewn to the base cover in the thigh area are not used in this situation. The Overlay mattress can now be connected to the SCU and inflated.

8.1.2 Installation – Mattress Replacement

To secure mattress on the bed:

- ▶ The two separate straps are not used in this situation, and should be removed and stored safely.
- ▶ Ensure that there are no protruding parts or sharp objects on the bed frame to avoid damage to the mattress.
- ▶ Place the deflated Air2Care Replacement Mattress onto the mattress platform, with the air pipe at the left side foot end, and position so that the mattress is centred. The foot symbol on the mattress cover is located at the foot end of the bed.
- ▶ For each of the 6 base cover straps, pass the webbing (3) around the mattress platform and clip the male part (2) of the trident buckle into the female part (1). Pull the webbing (3) through the male part (2) to adjust the length of the strap, so that the mattress is held securely to the frame.

The Replacement mattress can now be connected to the SCU and inflated.



Fig. Fixing of the mattress

8.2 Installation of 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 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

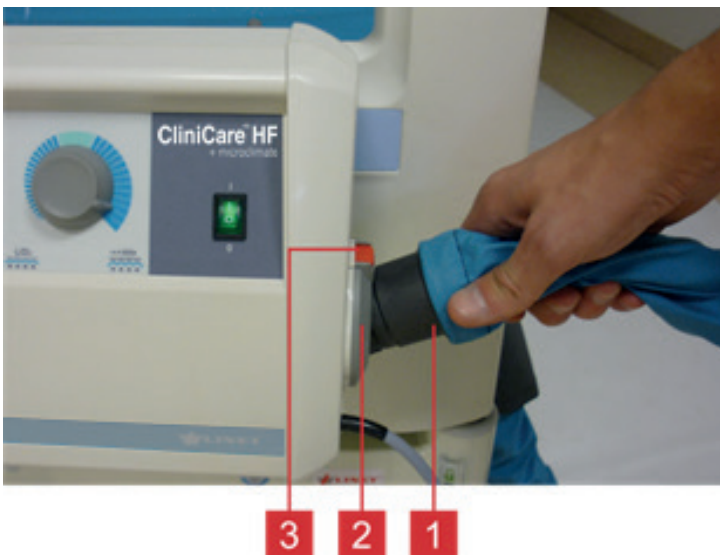


Fig. Installation of SCU on the floor

8.3 Connecting Mattress with SCU

Installation:

- ▶ Make sure the air connector is not in transport mode (see Transport mode).
- ▶ 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

8.4 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.
- ▶ Plug SCU power cord into suitable power socket.

8.4.1 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 (A2C10) or black (A2C20) power switch on front of SCU (see Fig. Switching on SCU).
- ▶ Disconnect mains cable from mains.




Fig. Switching on SCU

8.4.2 Inflation

Inflation:

- ▶ 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 check all safety straps.
- ▶ Ensure that the mattress is inflated completely and correctly before putting the patient onto it.
- ▶ Alignment of the bed frame, siderails 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 mains 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 lack of cleaning!

- ▶ Ensure that no moisture gets into the mattress.
- ▶ Ensure that no body fluids get into the mattress cover.
- ▶ Regularly inspect the inside of the cover for contamination.
- ▶ 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.
- ▶ Put a sheet loosely on the mattress if not prescribed otherwise by qualified personnel.

NOTE: The air connector must be kept uncovered for visibility and access.

NOTE: It is possible to inflate mattress with patient on the mattress. This applies only for the options overlay or mattress replacement system – air + foam. Manufacturer recommends to inflate mattress without load first and then place patient on it.

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 Controls and Indicators

9.2.1 Control panel - Air2Care 10

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.

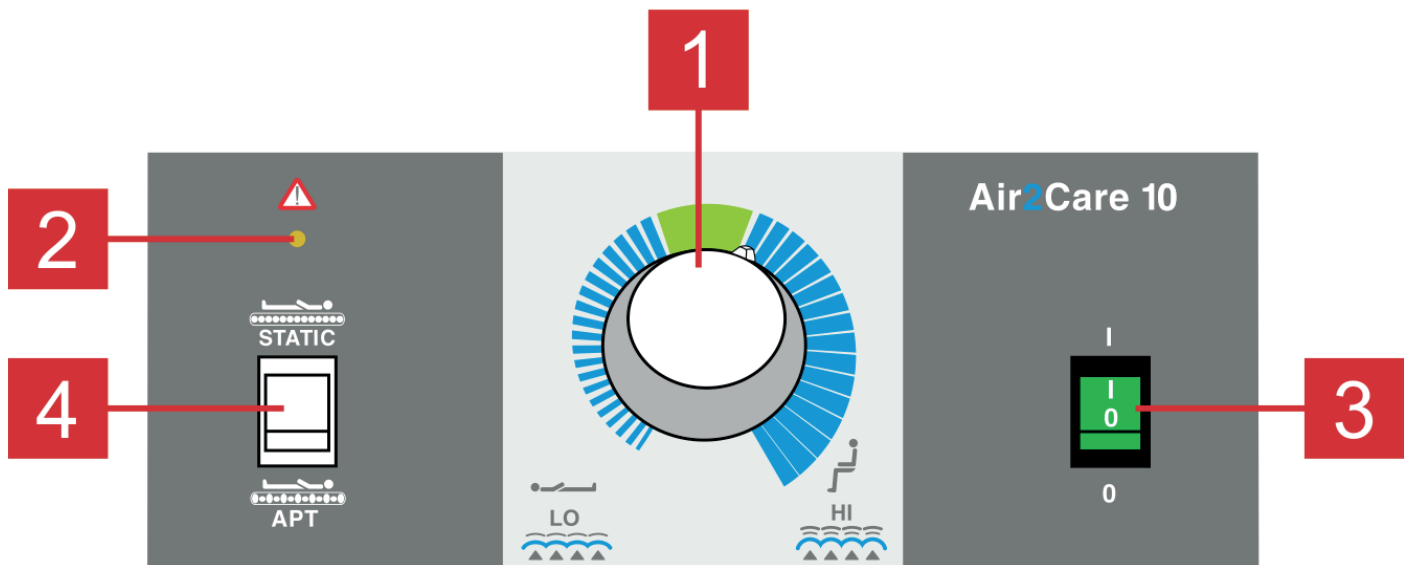


Fig. SCU Control Panel – Air2Care 10

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

APT – Alternating pressure therapy

Air2Care 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.

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.

9.2.2 Control panel - Air2Care 20

The control panel of the SCU serves to control the mattress replacement system, for mode selection and shows errors. Alarms are signaled by blinking of the indicator 2 or by acoustic signal.

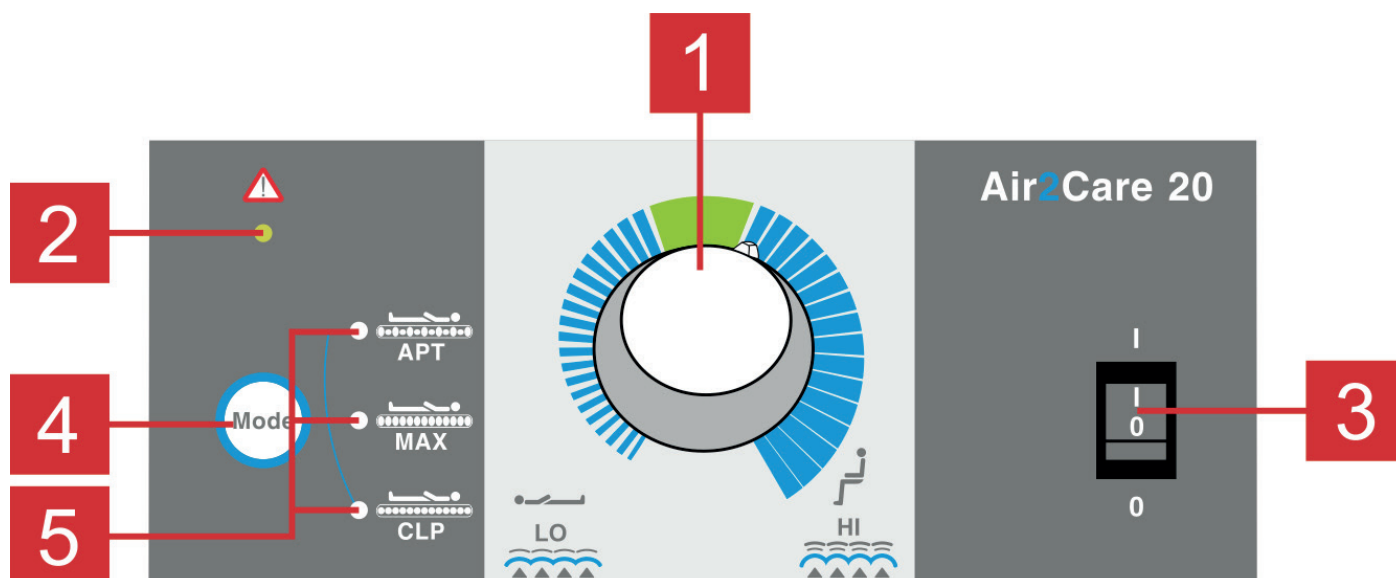


Fig. SCU Control Panel – Air2Care 20

Position	Control / Indicator	Function
1	Pressure control dial	Adjusting the mattress pressure for more comfort or support of the patient HI : High pressure LO : Low pressure
2	Indicator – error codes	Indicates system error (see System errors).
3	Mains switch	I : On O : Off
4	Mode selection button	APT : Alternating pressure therapy. Dynamic mode. MAX : Maximum inflation mode CLP : Constant low pressure mode
5	Mode indicator	Indicates the chosen mode of mattress

APT – Alternating pressure therapy

Air2Care 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.

To select APT mode:

- ▶ Press Mode (4) button until indicator next to APT mode symbol is illuminated.

When APT mode is selected:

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

MAX – Maximum inflation mode

MAX mode provides a solid and stable surface for patient treatment. MAX mode will run for 30 minutes at most. If no other mode is switched on within these 30 minutes, then the SCU will turn back into previously selected mode APT or CLP.

To select MAX mode:

- ▶ Press Mode (4) button until indicator next to MAX mode symbol is illuminated.

When MAX mode is selected:

- SCU will inflate all cells to the maximum pressure.
- MAX mode indicator will flash until maximum pressure is reached, then will remain on.
- 30 minutes after selecting the MAX mode the system will switch back into previously selected mode (APT or CLP).

CLP – Constant low pressure

CLP mode keeps the mattress pressure at the selected level. The pressure is checked automatically and adjusted if necessary.

To select CLP mode:

- ▶ Press Mode (4) button until indicator next to CLP mode symbol is illuminated.

When CLP mode is selected:

- SCU will inflate all cells to the same selected pressure.
- CLP mode indicator will flash until preset pressure is reached, then will remain on.
- The system automatically checks pressure in the mattress according to the selected pressure level and automatically adjusts pressure if required.

9.2.3 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. health status of the patient, weight, weight distribution, position and comfort needs.
- ▶ Always make sure the patient is not lying directly on the foam base, existing mattress or bed frame.

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 of the dial should be suitable for laying patients in the weight range 50-90Kg This should serve as an approximate guide only as patients BMI and position will affect their required level of support pressure.

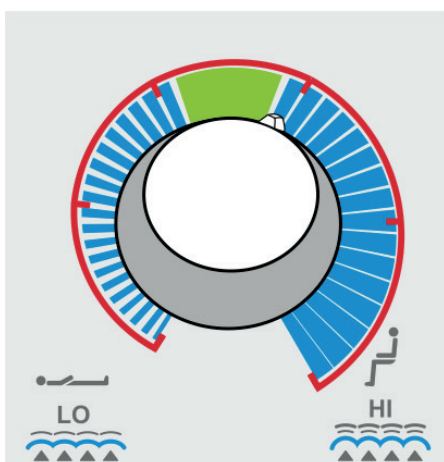


Fig. Pressure levels control

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

Select pressure as follows:

With the mattress fully inflated using STATIC (A2C 10) / MAX (A2C 20) mode.

- ▶ Select the required operating mode STATIC (A2C10 only), APT or CLP (A2C 20 only).
- ▶ Set the pressure control dial vertical, pointing into the centre of the Green 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. To do this and ensure that the patient is not 'bottoming out'.
- ▶ Unfasten the cover and slide a hand beneath the patient's sacral area and check that;
- ▶ For APT mode there is at least 2.5cm clearance between the sacrum and base foam layer (Overlay and Air +Foam) or air filled base (Air+Air) when the relevant air cell is deflated.
- ▶ For CLP mode the patient is still supported by some air (press down onto the air cell using 2 fingers until you touch the base layer)
- ▶ If the caregiver feels less than 2.5cm of support material, the patient has bottomed out and the support pressures should be raised by turning the pressure control dial to the right until a suitable level has been found.
- ▶ 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.

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: It is not necessary to start STATIC/MAX mode as the mattress is already inflated and working in the chosen mode of operation.

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.

Pressure Settings – Air2Care Seating Cushion

When using the Air2Care seating cushion it is recommended that the pressure control dial be turned full clockwise to its 'Hi' setting in the APT mode.

If this is uncomfortable for the patient then the pressure can be reduced after repeating select pressure instructions from chapter "Pressure Settings – Mattress".

NOTE: When doing this with a cushion it is not necessary to put your hand inside the cushion but can be done on the outside between the top cover and the patient

9.3 CPR – Cardipulmonary resuscitation



Fig. CPR Function

Before starting resuscitation with SCU connected:

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

The air in the mattress will deflate immediately after pressing patient's chest.

9.4 Transport mode

If the SCU becomes disconnected from mains power supply, the system will automatically enter Transport mode and the mattress will remain inflated but all active pressure adjustment will stop. It is not possible to use any mode in transport mode. The mattress will stay inflated for up to 12 hours, depending on the patient's weight and set pressure level when switching into transport mode.

To activate transport mode:

Option 1:

- ▶ For A2C 10 select STATIC mode and move the pressure control dial to its 'Hi' position and wait until the mattress is fully inflated.
- ▶ For A2C 20 select MAX mode and wait until the indicator (next to MAX mode) stops flashing.
- ▶ Switch off SCU via mains switch (O).
- ▶ Disconnect SCU from mains.
Mattress is now in Transport mode.

Option 2:

- ▶ Disconnect air connector from the SCU and twist the end to seal so symbols ● and ▼ are heading each other.
Mattress is now in Transport mode.

To deactivate transport mode:

Option 1 and 2:

- ▶ Repeat the process above backwards.



9.5 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 remain inflated for up to 12 hours. No active modes are available without mains power.

9.6 System faults

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

NOTE: During initial inflation the Air2Care 10 low pressure indication will come on until the mattress has achieved its minimum pressure. This does not mean there is a fault unless it remains on for more than 30 minutes.

Air2Care 10		
Meaning	Audible sound	Indicator
Low pressure	-	Low pressure indicator is illuminated
Power failure	-	Mains switch is not illuminated

Air2Care 20		
Meaning	Audible sound	Indicator
Power failure	1st minute – Beep every 2 sec. 2nd-4th minute – Beep every 8 sec. 5th and more – Beep every 2 min.	
Fail to inflate	Beep	Flashes twice
Valve rotation fail	Beep	Flashes three times
Pressure fault	Beep	Flashes four times

Problem	Symptom Air2Care10	Symptom Air2Care20	Action
Power failure (SCU will not turn on)	Mains switch not illuminated	No indicators on front panel illuminated	<p>Check that the Mains 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 1.</p> <p>NOTE: For Air2Care10 only: If the mains 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 but the mattress can still be used.</p>
Power failure during use	Mains switch not illuminated	No indicators on front panel illuminated and audio alarm sounds	As above. For Air2Care 20 only Audio alarm will cancel if power restored or mains switch turned off (O) Then 1.

Problem	Symptom Air2Care10	Symptom Air2Care20	Action
Fail to inflate or soft mattress	Low pressure indicator on NOTE: 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.	Indicator error code flashing twice.	Check air connection to mattress is ok. Check that the mattress has been rolled out flat and air pipes are not twisted or trapped in any part of the bedframe. Open the mattress cover and check that no air pipes are damaged or disconnected. NOTE: For Air2Care 10 only: Slightly increase the pressure setting and see if problem stops. Then 1.
Not alternating	Air cells not alternating in APT mode	Indicator error code flashing three times.	Check all air connections same as for 'Fail to inflate' and 1.
Hard mattress	Air cells very hard in APT or Static modes	Indicator error code flashing four times.	Check all air connections same as for 'Fail to inflate'. Reduce pressure setting to lowest level then 1.

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 any of the above problems occur and cannot be solved by the user it is recommended to put the mattress into Transport mode (see chapter „Transport mode“) to ensure that the patient is supported while waiting for a service engineer to arrive.

9.7 Seating System



Fig. SCU and cushion

For patients who are not bed-ridden, it is possible to connect a seat cushion operating in a 2-cell cycle to the SCU instead of the mattress. The Air2Care seat cushion fits on most standard chairs and chairs for specialist geriatric care. The seat cushion consists of two sets of alternating cells on a foam base with a front support. The cover consists of vapour-permeable, water-impermeable two-way stretch material. The cushion is only designed for LINET® SCUs.

9.7.1 Function

The seating system provides alternating pressure therapy for patients that are not bed-ridden.

Have the seating system used only:

- under supervision of trained and qualified nursing personnel
- by trained and qualified nursing personnel

Seating system:

- 6 cells
- cells are inflated and deflated in 12 minutes cycles

9.7.2 Installation and Startup



WARNING

Risk of injury due to unsuitable chair!

- ▶ Ensure that chair is suitable for seating system.
- ▶ Conduct risk evaluation if necessary.



WARNING

Risk of injury due to exposed cable!

- ▶ Ensure that cable is not twisted, crushed or strained.
- ▶ Ensure that cable does not present a tripping hazard.

Install seating system as follows:

- ▶ Remove existing seat cushion if possible. If it is not possible to remove the existing seat cushion then the height of the patient when seated relative to the chair side arms must be checked by a competent clinical professional for patient safety.
- ▶ Ensure that chair supports weight of seat cushion.
- ▶ Ensure that the chair seat base or existing cushion fully supports the dynamic cushion and it does not overlap at the front.



NOTE: If there is an unsupported overlap or the existing chair base is not solid enough then the optional cushion seat plate should be used. This will provide a solid base for the dynamic cushion allowing it to operate effectively and preventing the patient damaging the cushion when sitting in the chair, sitting down or standing up.

- ▶ Place the Air2Care seat cushion directly on the seat base.
- ▶ Ensure that there are no protruding parts or sharp objects on the chair to avoid damage to the seat cushion.
- ▶ Put seat cushion on seat of chair so that umbilical points to the back.
- ▶ Push seat cushion back as far as it will go.
- ▶ Put SCU on the floor next to the chair.
- ▶ Connect air pipe (see Connecting Mattress and SCU).

Fig. Unsupported overlap

To install optional seat plate:

- ▶ Unzip the cover of the seat cushion.
- ▶ Insert optional seat plate under the foam base of the cushion so the plate copies position of the foam base.
- ▶ Zip the cover.

To startup SCU:

- ▶ Ensure that SCU is not covered and air flow around SCU is not obstructed in order to avoid overheating.
- ▶ Connect mains cable of SCU to mains.

To switch on SCU:

- ▶ Switch on SCU using mains switch button I/O on the control panel of SCU.
- ▶ Set APT mode and set the pressure to the maximum value. Cushion is being inflated.

When the inflation process is finished:

- ▶ Cushion is ready for placement of the patient.



9.7.3 Seating of the Patient



WARNING

Risk of injury when seating the patient!

- ▶ Ensure that seat cushion is completely inflated!

Preparation:

- ▶ Inflate seat cushion (see Installation and Startup).

Seating of the patient:

- ▶ Sit patient on seat cushion.

For an ideal sitting position:

- ▶ Ensure that chair is suitable for patient's size in order to guarantee correct seating position.

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.
- ▶ 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 the bed and SCU from the 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.
- ▶ 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 etc.).
- ▶ Use only hospital-approved cleaners and observe local directives concerning infection control.
- ▶ Always rinse with water 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 , Seating System	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.
	Decontamination: Blood spills/C-diff. 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.
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.

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	<ul style="list-style-type: none"> ■ exposed mattress parts ■ exposed SCU parts
Full Cleaning and Disinfection	<ul style="list-style-type: none"> ■ exposed mattress parts ■ exposed SCU parts ■ internal parts of mattress ■ internal parts of cover

10.2 Routine Cleaning and Disinfection

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 Complete Cleaning and Disinfection

Cleaning Top/Base Cover and Internal Air Cells:

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, (up to 10,000ppm), with a maximum dwell time of two minutes 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:

- ▶ 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.
- ▶ Clean all mattress cells and pipes with 50 °C warm water and cleaning detergent.
- ▶ Rinse mattress with cold water.
- ▶ Let mattress dry air dry or wipe dry.
- ▶ Wipe mattress with disinfectant.
- ▶ Wipe mattress with cold water.
- ▶ Let mattress dry air dry or wipe dry.

Machine washing of the top/base mattress covers:

- ▶ 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.
- ▶ Dry cover in tumble dryer at low temperature.

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

Cleaning the air pipe:

- ▶ Wipe air pipe with cleaning agent or disinfectant.
- or-
- ▶ Remove the air pipe cover and clean it as stated above if full disinfection is required.
 - ▶ Let air pipe dry.

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.
- ▶ Wipe SCU and filter 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 both zippers under the flap covering the zippers of mattress cover on foot end of mattress.
- ▶ Remove top part of mattress cover. Inspect cover and clean if necessary.
- ▶ Undo corner toggles:
 - Overlay: 4 toggles, 1 on each corner
 - Mattress replacement (Air + Foam): 4 toggles, 1 on each corner holding top deck, foam is loose
 - Mattress replacement (Air + Air): 4 toggles, 1 on each corner holding both air decks
- ▶ Undo next to air pipe inlet on umbilical cover held by toggle to base 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.

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.

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).

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 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.

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/). 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!

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.

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

- ▶ Do not continue to use the product.

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. Our standard terms and conditions apply.

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)