

LINET

Instructions for Use and Technical Description



Virtuoso®

Air Mattress System

CE

D9U003VB3-0101

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1 Symbols and Definitions

1.1 Warning Notices

1.1.1 Types of Warning Notices

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

- **CAUTION** - risk of material damage.
- **WARNING** - risk of physical injury.
- **DANGER** - risk of fatal injury.

1.1.2 Structure of Warning Notices

 SIGNAL WORD!
Type and source of danger!
⇒ Measures to avoid the danger!

1.2 Instructions

Structure of instructions:


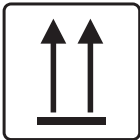



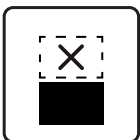
- ❖ Perform this step.
Result, if necessary.

1.3 Lists



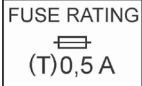








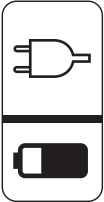



Structure of bulleted lists:














- List level 1
 - List level 2







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

 	<p>READ INSTRUCTIONS FOR USE</p>
	<p>2x T0.5A ANTI-SURGE FUSE (250 V, TYPE 5X20MM)</p>
	<p>ALTERNATING CURRENT (AC)</p>
	<p>ACTIVATION GO BUTTON DEVICE IS CONNECTED TO MAINS IF GREEN INDICATOR ON THE CONTROL PANEL IS LIT</p>
	<p>PROTECTION AGAINST ACCIDENTS DUE TO ELECTRICAL CURRENT – TYPE B APPLIED PARTS</p>
	<p>DOUBLE INSULATION (CLASS II EQUIPMENT)</p>
	<p>WARNING</p>
	<p>CE MARK OF CONFORMITY WITH EU REGULATION</p>
	<p>SCU MAINS SWITCH -: ON (CONNECTED TO THE MAINS SUPPLY) O: OFF (DISCONNECTED FROM MAINS SUPPLY) DEVICE IS CONNECTED TO MAINS WHEN GREEN PART OF THE SWITCH IS REVEALED.</p>
	<p>Accumulator POWER SWITCH -: ON (Accumulator ACTIVATED) O: OFF (Accumulator NOT ACTIVATED)</p>
	<p>SCU MAINS SWITCH Accumulator POWER SWITCH</p>
	<p>WEEE SYMBOL (RECYCLE AS ELECTRONIC WASTE, DO NOT PUT INTO THE HOUSEHOLD WASTE)</p>
	<p>ONLY SUITABLE FOR INDOOR USE</p>
	<p>DO NOT IRON!</p>

	<p>DO NOT USE PHENOL!</p>
	<p>DO NOT WRING!</p>
	<p>REGULARLY INSPECT THE INSIDE OF THE COVER FOR CONTAMINATION</p>
	<p>MACHINE WASH AT MAX. 71°C FOR 3 MINUTES</p>
	<p>TUMBLE DRY ON LOW HEAT SETTING (MAX. 60°C)</p>
<p>BS 7175</p>  <p>5 MEDIUM HAZARD</p>	<p>COVER MATERIALS ARE FIRE RESISTANT TO BS 7175, SOURCE 0, 1 AND 5</p>
	<p>HANDWASH WITH DETERGENT. INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50°C</p>
 <p>NaClO ≤1,000ppm</p>	<p>DISINFECT USING SOLUTION CONTAINING LESS THAN 1000 PPM OF CHLORINE (REFER TO INSTRUCTIONS FOR USE)</p>
 <p>(H₂O)</p>	<p>RINSE WITH WATER</p>
	<p>DRY</p>
	<p>MATTRESS FOOT PART</p>
 <p>254 kg MAX</p>	<p>MAXIMUM PATIENT WEIGHT</p>
	<p>MEDICAL DEVICE (COMPATIBLE WITH MEDICAL DEVICE REGULATION)</p>

	RECYCLING SYMBOL
	DO NOT POLLUTE THE ENVIRONMENT
	MANUFACTURER
	MANUFACTURING DATE
	REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON CONFIGURATION)
	SERIAL NUMBER

1.6 Serial Label

Serial label of the Virtuoso SCU is placed on the back side of SCU. The serial label contains information about Address of Manufacturer, Manufacturing Date (Year-Month-Day), Product Reference Number, Product Serial Number, Global Trade Item Number (GTIN), Unique Device Identification (UDI), symbols and electrical specifications.

Serial label of the Virtuoso mattress is placed at the mattress foot end. The serial label contains information about Address of Manufacturer, Manufacturing Date (Year-Month-Day), Product Reference Number, Product Serial Number, Global Trade Item Number (GTIN), Unique Device Identification (UDI) and symbols.

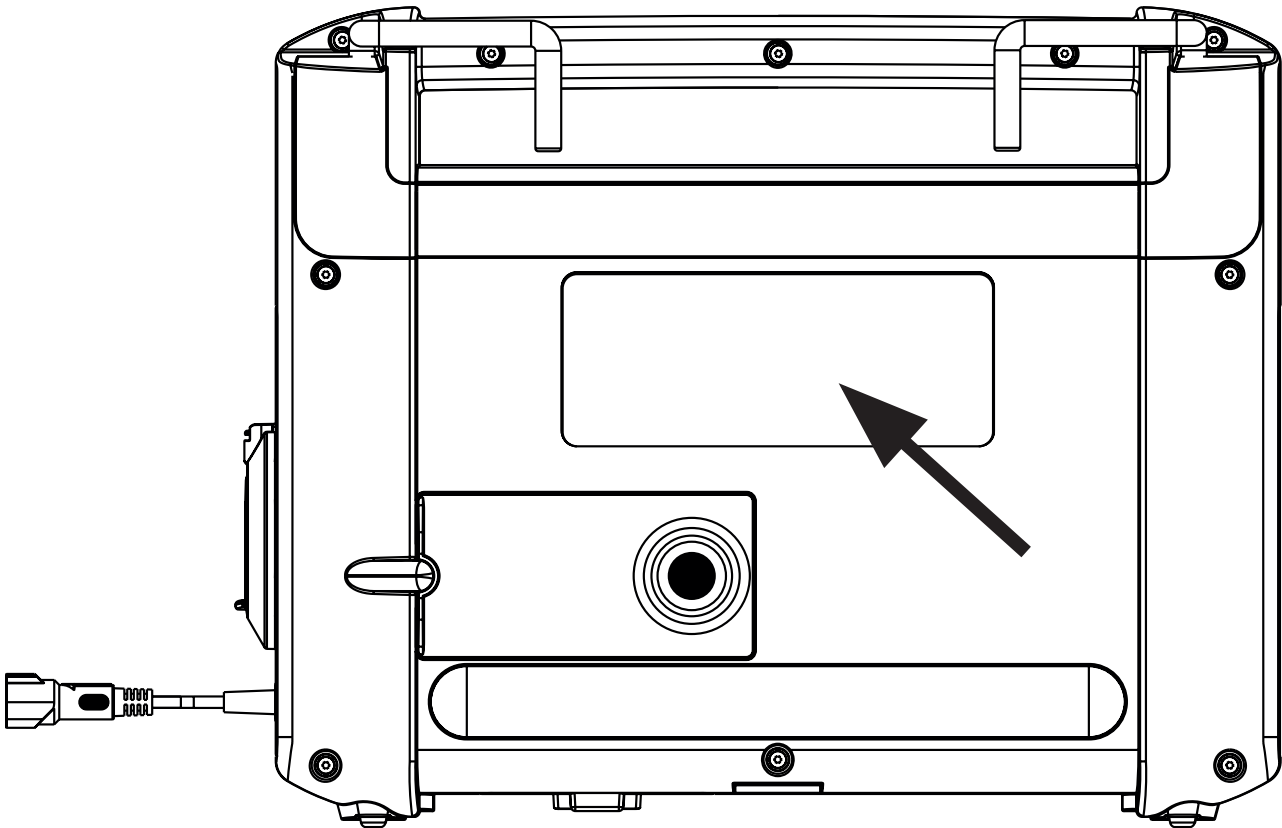
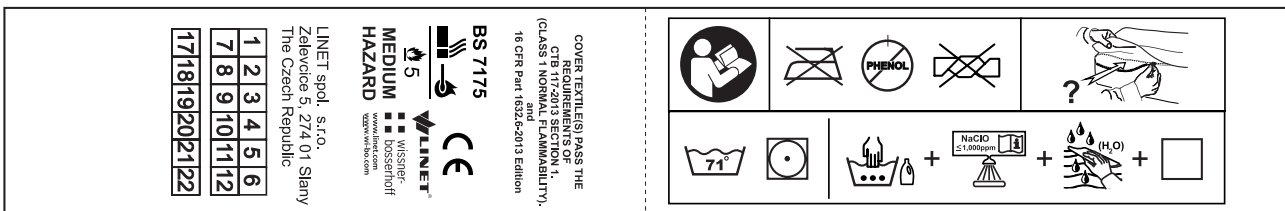


Fig. Position of the Virtuoso SCU Serial Label

1.7 Wash label (Virtuoso - mattress)



1.8 Acoustic signalisation

SOUND	MEANING
CONTINUOUS SOUND	mattress air connector is disconnected
	mattress air connector is not correctly connected
REPEATED 2 TONE SIGNAL: 1) during 1 minute: CONTINUOUS SOUND: 0,5s FIRST TONE BEEP / 0,5s SECOND TONE BEEP 2) during next minutes: FIRST TONE BEEP lasting 0,5s and SECOND TONE BEEP lasting 0,5s / 1min silence	disconnected from the mains
	mains voltage is not available when the mains switch is turned ON
	mains switch is turned OFF
	accumulator is discharged too much (only version with accumulator)
	accumulator switch is turned OFF (only version with accumulator)
BEEP after SCU activation if SCU is powered just by the accumulator: 10s sound + 5s silence	disconnected from the mains
	mains switch is turned OFF
	mains power is not available
REPEATED 2 TONE SIGNAL: FIRST TONE BEEP lasting 0,5s and SECOND TONE BEEP lasting 0,5s / 30s silence	accumulator discharge level less than 25% (only version with accumulator)
BEEP lasting 2s after accumulator switch has been turned ON	accumulator is correctly fitted in SCU (only version with accumulator)
REPEATED 2 TONE SIGNAL during 6 seconds: FIRST TONE BEEP lasting 0,5s and SECOND TONE BEEP lasting 0,5s	system error (number of the beeps (1-6) indicates the type of error)
REPEATED BEEP after 25 minutes of Max Mode: 0,25s sound / 30s silence	Max Mode will be ending (first activation of the Max Mode)
REPEATED 2 TONE SIGNAL after 25 minutes of Max Mode: FIRST TONE BEEP lasting 0,25s and SECOND TONE BEEP lasting 0,25s / 30s silence	Max Mode will be ending (second activation of the Max Mode)
BEEP lasting 0,25s	mode or pressure level is achieved

1.9 Abbreviations

AC (~)	Alternating Current
ACP	Attendant Control Panel
CE	European Conformity
CPR	Cardiopulmonary Resuscitation
dBA	Sound Intensity Unit
DC (---)	Direct Current
CUC	Configuration number
EMC	Electromagnetic Compatibility
FET	Field-effect transistor
HF	High Frequency
HPL	High Pressure Laminate
HW	Hardware
ICU	Intensive Care Unit
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 (active 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!

The patient should be under regular supervision of hospital staff during treatment of skin injuries!



WARNING!

No part of the Virtuoso mattress shall be serviced or maintained while in use with a patient!

Additional Instructions for Correct Use:

- ❖ Follow the instructions carefully.
- ❖ Ensure any user has read and understood the instructions for use completely before operating the product.
- ❖ Use the mattress system only as specified in the instructions for use and in perfect working order.
- ❖ Use the mattress system only with the correct mains supply (see Electrical Specifications).
- ❖ Use the mattress system only in its original state and do not modify it in any way.
- ❖ Have the mattress system used only by or under supervision of trained and qualified nursing personnel who have been trained according to the instructions for use.
- ❖ Replace any damaged parts immediately with original spare parts only.
- ❖ Have the mattress system serviced and installed only by qualified personnel trained and authorized by the manufacturer.
- ❖ Do not exceed the maximum patient weight limit (see Mechanical Specifications).
- ❖ Do not use the SCU near flammable gases. This does not apply to oxygen cylinders.
- ❖ Never use the mattress replacement system near radiators or other heat sources.
- ❖ Never cover the SCU while in use.
- ❖ Never cover filter of SCU while in use.
- ❖ Never manually deflate adjacent cells, unless by qualified medical direction for temporary procedures.
- ❖ Never handle the mains plug with wet hands.
- ❖ Disconnect the product from the mains only by pulling the mains plug. When pulling the mains plug, always hold the plug, not the cable.
- ❖ 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 replacement system.
- ❖ Zip up whole zipper to avoid risk of contamination.

3 Intended use of Virtuoso

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

3.1 Indications

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

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

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

3.2 User population of Virtuoso

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

3.3 Contraindications

Mattress system is contraindicated for patients:

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

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

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

3.4 Operator

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

4 Product Description

There are 6 configurations of Virtuoso mattress:

- Virtuoso Overlay
- Virtuoso 50 (Virtuoso Mattress Replacement (Air + Foam Base))
- Virtuoso 100 (Virtuoso Mattress Replacement (Air + Static Air Base))
- Virtuoso 200 (Virtuoso Mattress Replacement (Air + Alternating Air Base))
- Virtuoso 300 (Virtuoso With Head & Heel Zoner (Air + Alternating Air Base))
- Virtuoso Pro

VIRTUOSO	AIR DECKS			ALTERNATING LAYERS		FOWLERBOOST		ZONERS			Accumulator	MCM
	Overlay	Air + Foam	Air + Air	1	2	Single point	Linear	Head	Foot	Body		
Virtuoso Overlay	✓			✓		✓					optional	✓
Virtuoso 50		✓		✓		✓					optional	✓
Virtuoso 100			✓	✓		✓					optional	✓
Virtuoso 200			✓		✓	✓					optional	✓
Virtuoso 300			✓		✓		✓	✓	✓		optional	✓
Virtuoso Pro			✓		✓		✓	✓	✓	✓	optional	✓

4.1 Virtuoso Overlay

Virtuoso Overlay has one layer of air cells.

- 21 transverse air cells
- 2 longitudinal air filled side formers
- 3 Static head cells
- 11 alternating torso and leg cells
- 7 Foot section cell

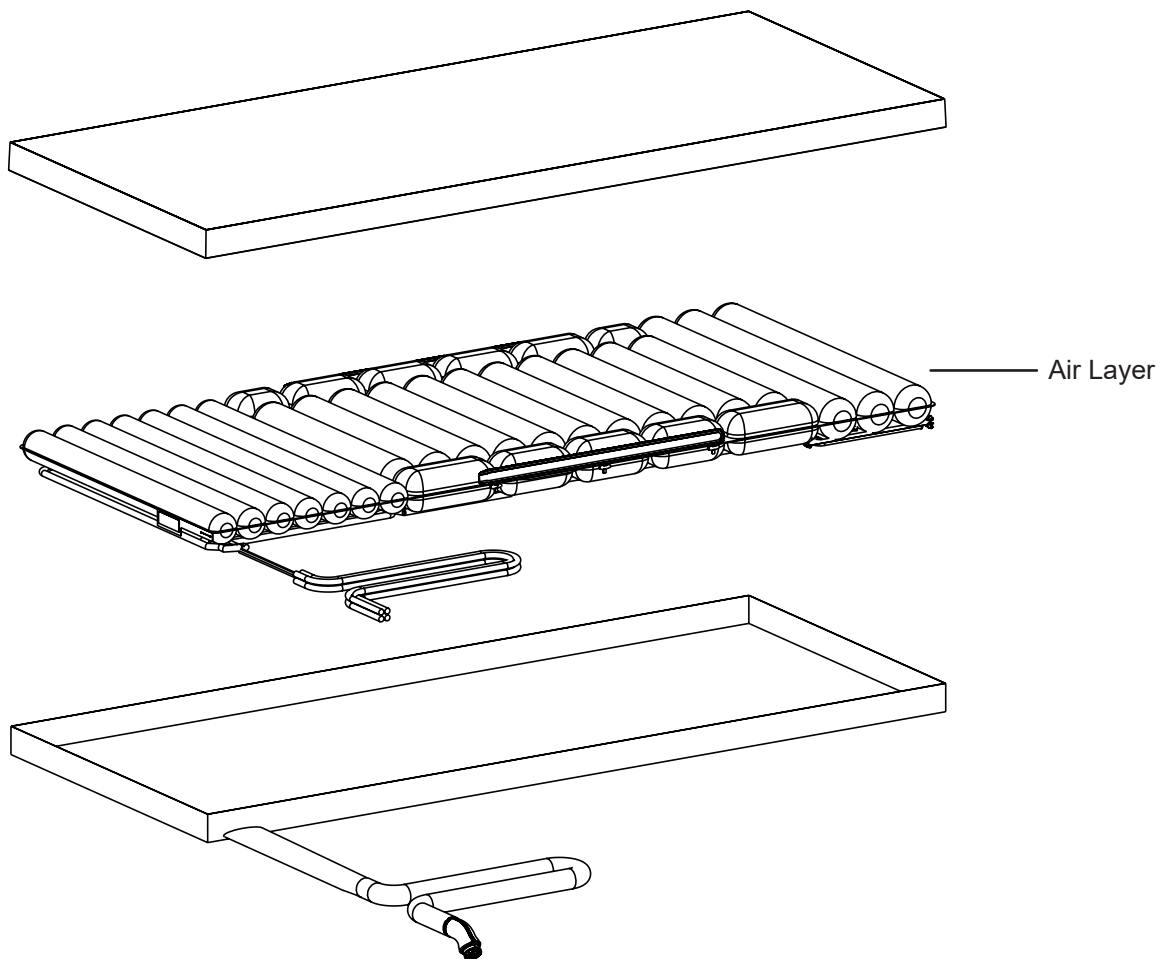


Fig. Mattress structure (Virtuoso Overlay)

4.2 Virtuoso 50

Virtuoso Mattress Replacement (Air + Foam Base) has one layer of alternating air cells and one foam layer.

4.2.1 Top Deck

- 21 transverse air cells
- 2 longitudinal air filled side formers
- 3 static head cells
- 11 alternating torso cells
- 7 alternating foot section cells

4.2.2 Bottom Deck

- passive foam base of CMHR foam
- waterproof removable cover

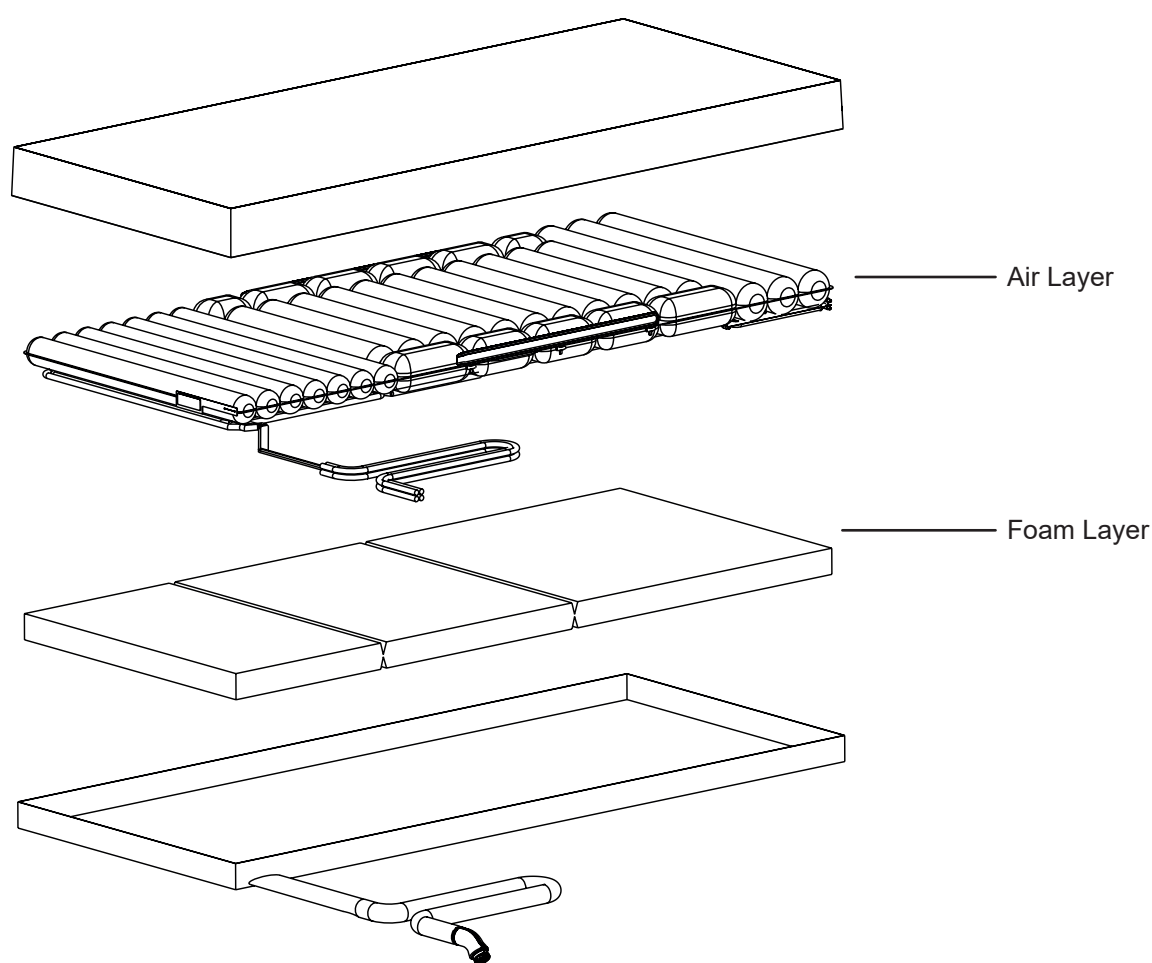


Fig. Mattress structure (Virtuoso Mattress Replacement (Air + Foam Base))

4.3 Virtuoso 100

Virtuoso Mattress Replacement (Air + Static Air Base) has two air layers.

4.3.1 Top Deck

- 21 transverse air cells
- 2 longitudinal air filled side formers
- 3 Static head cells
- 11 alternating torso cells
- 7 alternating foot section cells

4.3.2 Bottom Deck

- 3 ribbed static air sections

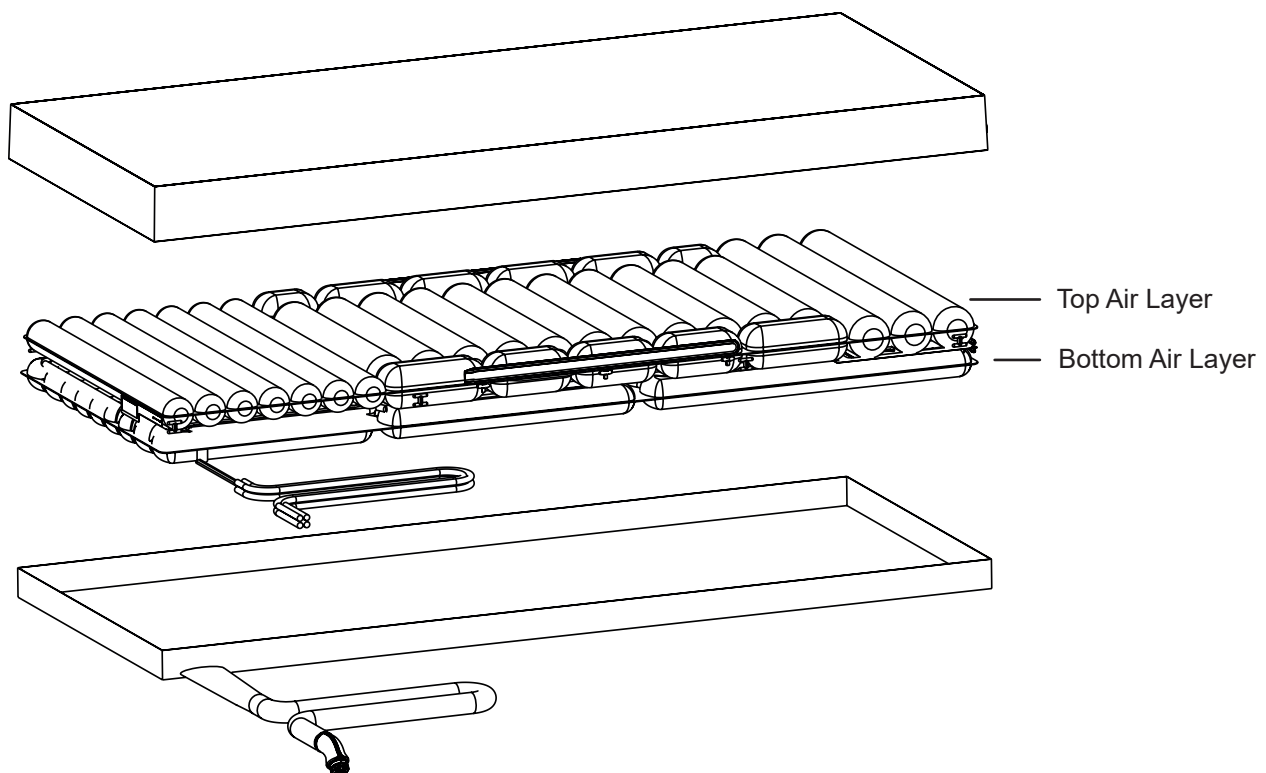


Fig. Mattress structure (Virtuoso Mattress Replacement (Air + Static Air Base))

4.4 Virtuoso 200

Virtuoso Mattress Replacement (Air + Alternating Air Base) has the same two air layers.

4.4.1 Top Deck

- 21 transverse air cells
- 2 longitudinal air filled side formers
- 3 static head cells
- 11 alternating torso cells
- 7 alternating foot section cells

4.4.2 Bottom Deck

- 21 transverse air cells
- 2 longitudinal air filled side formers
- 3 Static head cells
- 11 alternating torso and leg cells
- 7 Static foot section cells

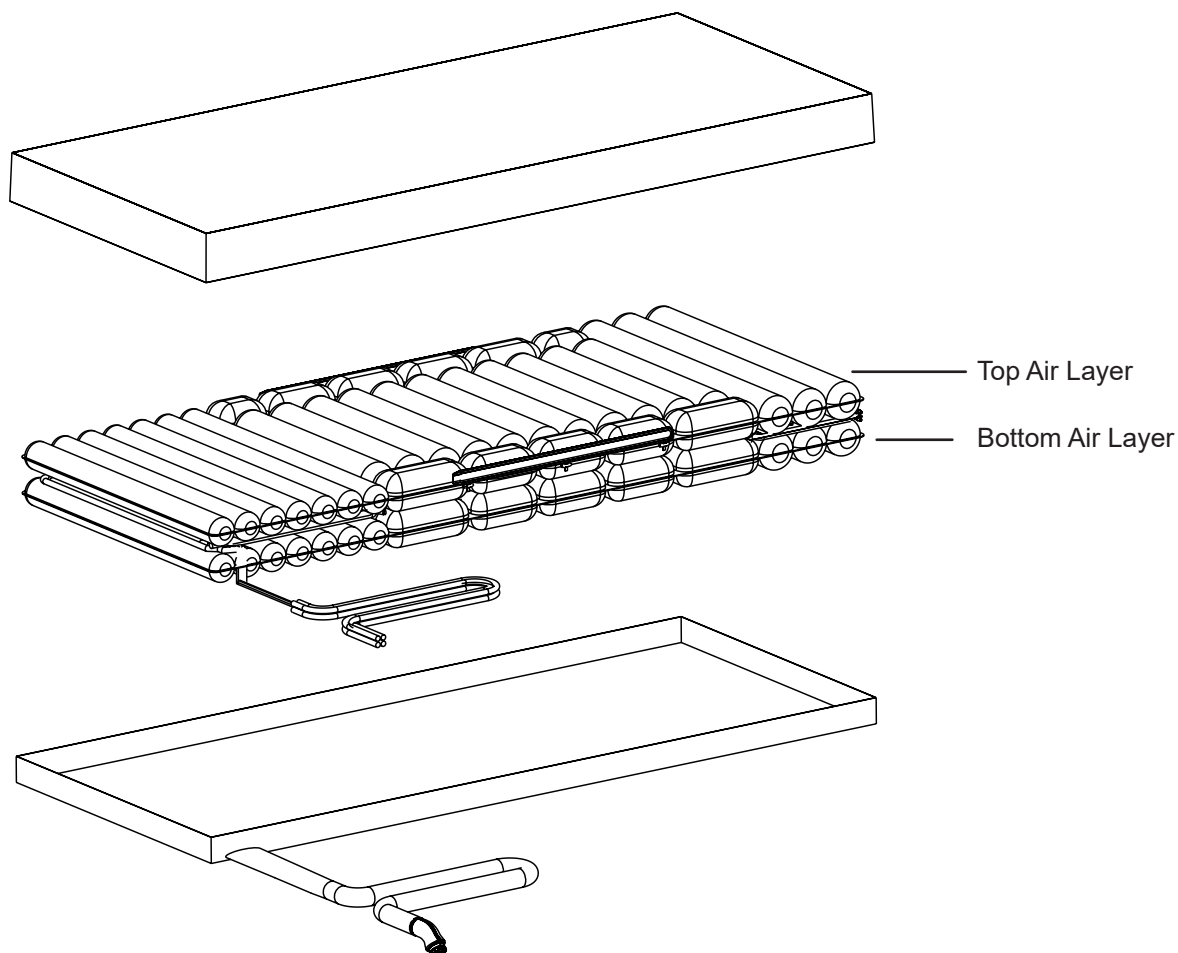


Fig. Mattress structure (Virtuoso Mattress Replacement (Air + Alternating Air Base))

4.5 Virtuoso 300

Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) has two air layers.

4.5.1 Top Deck

- 11 alternating transverse cells
- 3 static transverse head cells
- 6 alternating foot zone cells

4.5.2 Bottom Deck

- Head section - static longitudinal cells
- Torso section - 9 transverse alternating cells
- Leg section - 5 static longitudinal cells
- 2 static side formers

4.5.3 Valves

- Head zone : 4 cells with individual 3 position (Alt/Static/Deflate) control valves
- Heel zone: 4 cells with individual 2 position (Alt/Deflate) control valves

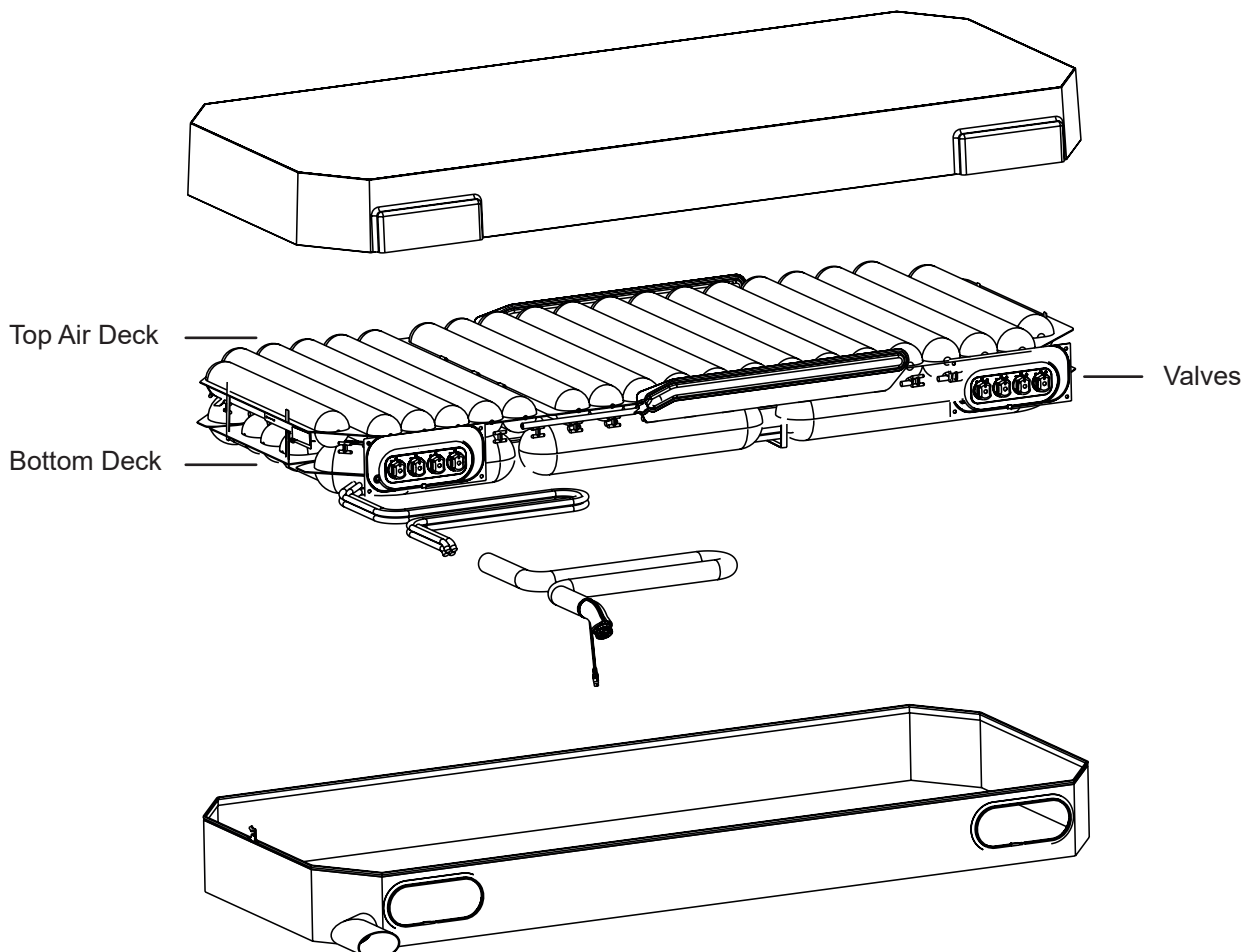


Fig. Mattress structure (Virtuoso With Head & Heel Zoner (Air + Alternating Air Base))

4.6 Virtuoso Pro

The Virtuoso Pro mattress consists of two decks that are connected with stainless steel press studs, fixation toggles and polyurethane loops.

A two-part cover made of polyurethane-coated nylon covers both mattress decks. The top part of the cover consists of four-way stretch material and has High Moisture Vapour Permeability. The Bottom cover is air and water impermeable.

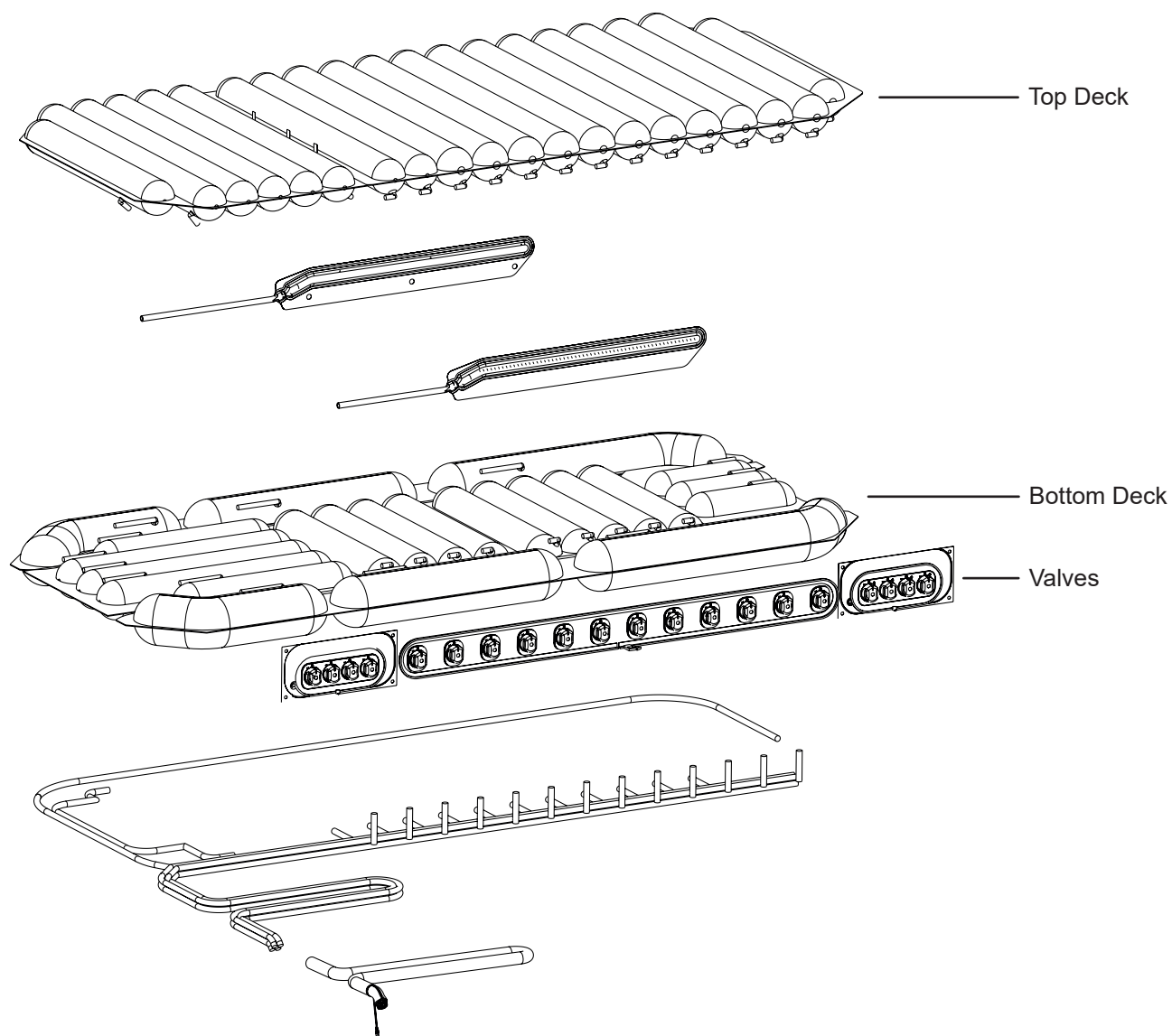


Fig. Mattress structure (Virtuoso Pro)

4.6.1 Top Deck

The top part consists of two modules:

a. Body module consisting of two sections:

Head section:

- 4 head cells
- alternating / static / deflated (depending on Head Zone Valves)
- transverse cells

Body section:

- 12 torso/upper leg cells
- alternating / deflated (depending on Body Zone valves)
- transverse cells

b. Foot module consisting of one section:

Heel section:

- 4 lower leg/foot cells
- alternating / deflated (depending on Heel Zone Valves)
- transverse cells

4.6.2 Bottom Deck

The bottom part consists of 5 modules.

Head section:

- 3 longitudinal cells
- remains inflated (static)

Heel section:

- 5 cells
- remains inflated (static)
- longitudinal cells

2 side formers:

- 3 cells per former
- remain inflated (static)
- longitudinal cells

Body section:

- 9 cells
- alternates in 3-cell cycle
- transverse cells

4.6.3 Valves

Top Air Cell Layer

Head zone:

- 4 cells - each with 3 positions (APT / Static / Deflate) on control valves

Heel zone:

- 4 cells - each with 2 positions (APT / Deflate) on control valves

Body zone:

- 12 cells - each with 2 positions (APT / Deflate) on control valves

4.7 Cover (all configurations)

Top

- 4 way stretch with 360 degree zip
- waterproof / high Moisture Vapour Permeability / Dartex

Base

- high durability / non stretch / waterproof / PU coated nylon material
- 2 strong mattress Transport Handles on each side of the base
- 6 strong Mattress Fixing Straps with „mini Trident style“ quick release clips
- mattress rolling strap for ease of transport/storage

4.8 Base Cover (all configurations)

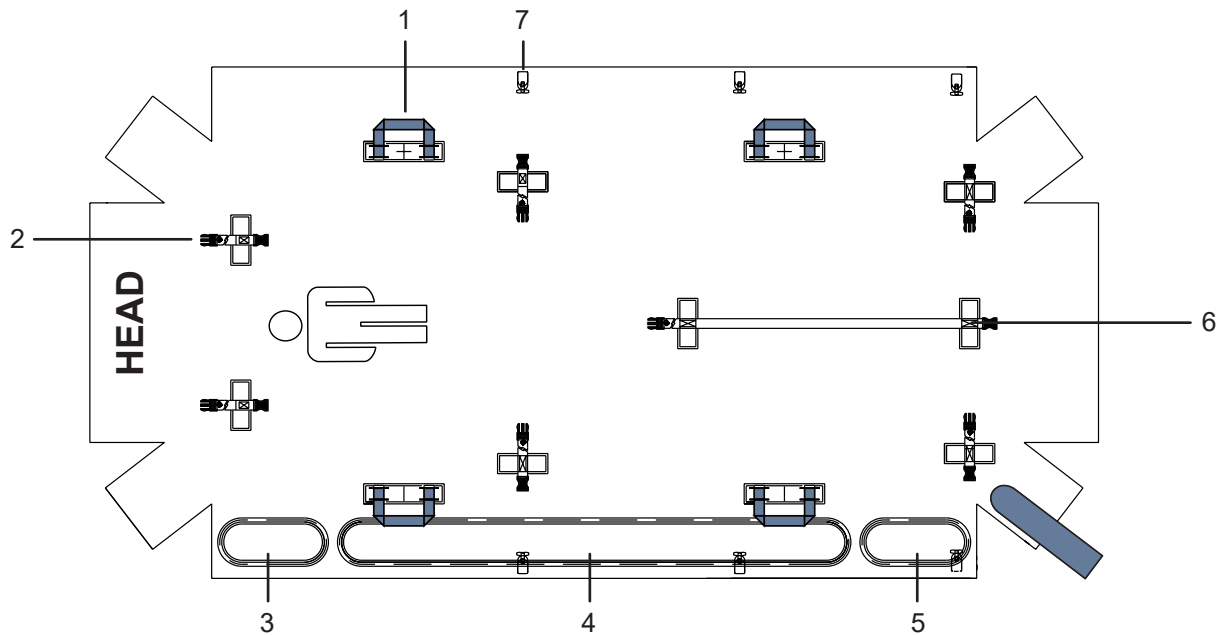


Fig. Base cover description

1. Transport Handle
2. Mattress Fixing Strap (to fix mattress on the mattress platform)
3. Head Zone Selector (Virtuoso With Head & Heel Zoner and Virtuoso Pro)
4. Body Zone Selector (Virtuoso Pro only)
5. Heel Zone Selector (Virtuoso With Head & Heel Zoner and Virtuoso Pro)
6. Strap for mattress transport
7. Cable routing clip

4.8.1 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.

4.9 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 that is permanently attached to the mattress. The microprocessor-controlled SCU maintains the set pressure regardless of the patient's position by continuously monitoring and adjusting the air pressure in the mattress.

The SCU is equipped with an audio/visual alert system for detecting power failures, air pipe disconnections or other faults. The SCU is equipped with self-retracting bed hanging arms and with mounting feet on base of SCU for floor mounting.

5 Control Panel Description

The control panel of the SCU serves to control the mattress replacement system and shows errors and maintenance requirements with indicators and alert sounds.

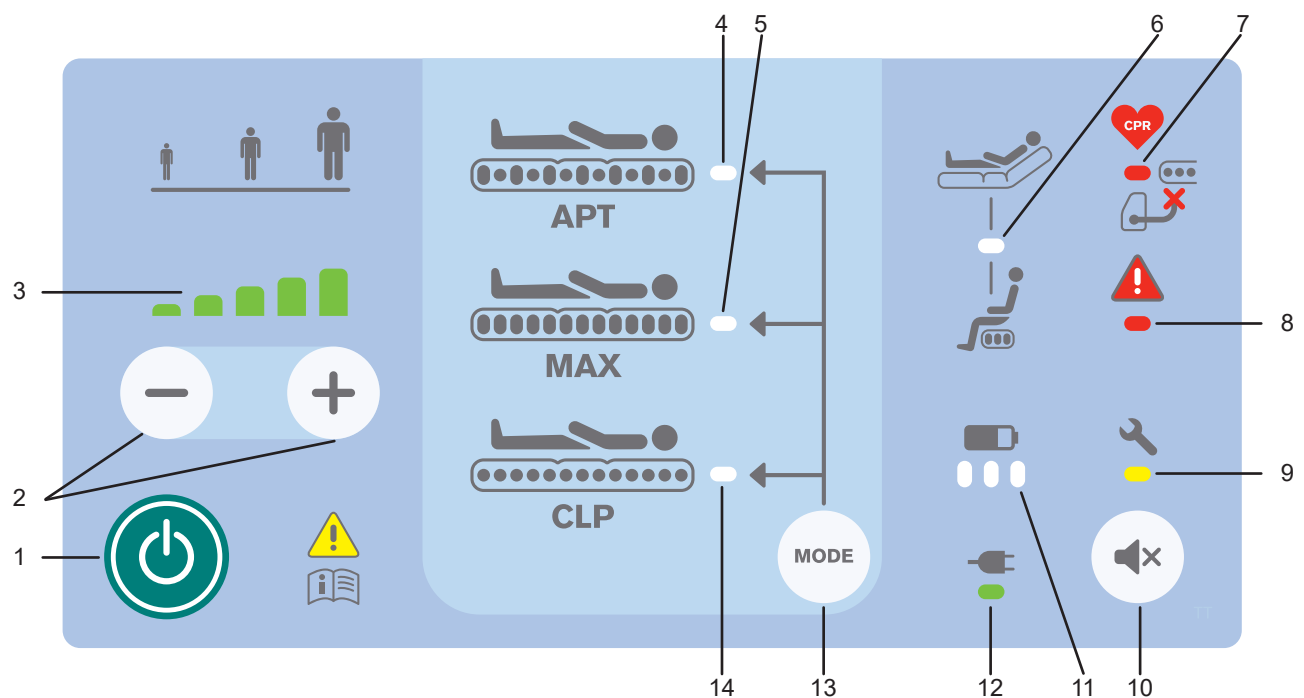


Fig. SCU Control Panel

1. GO Button (Control Panel activation)
2. Pressure Control Buttons (- / +)
3. Pressure Level Indicators
4. APT Mode Indicator
5. Max Mode Indicator
6. Fowler Boost Indicator or Seat Cushion Indicator
7. CPR/ Air Connector Open Indicator
8. System Error Indicator
9. Service Due Indicator
10. Mute Button
11. Accumulator Charge Status Indicator
12. Mains Power Indicator
13. MODE Button
14. CLP Mode Indicator

6 Technical Specification

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

6.1 Mechanical Specifications (Virtuoso Overlay)

Dimensions ■ Mattress (inflated) - length x width x height	200 cm x 86 cm x 11 cm (78,7' x 33,9' x 4,3')
Weight ■ Mattress (deflated)	6,5 kg (14,3 lbs)
Cycle ■ Mattress (inflated)	3 cells, 7.5 min
Maximum Patient Weight (Safe Working Load) ■ Mattress	180 kg (397 lbs)
Inflation time ■ Mattress	max. 15 min
Deflation time (CPR)	30 s
Remain Inflated time in Transport mode	12 hours
Sound Pressure Level (mattress)	max. 29 dB(A)
Cover Fire Resistance	according to BS7175 - ignition source 5
Mattress Core Fire Resistance according to BS7175 - ignition source 5	NO
Top Cover Fire Resistance	according to 16 CFR 1632
Mattress Fire Resistance	according to 16 CFR 1632
Top Cover Biocompatibility	according to ISO 10993-5 (cytotoxicity), according to ISO 10993-10 (skin sensation and irritation)

6.2 Mechanical Specifications (Virtuoso 50)

Dimensions ■ Mattress (inflated) - length x width x height	200 cm x 86 cm x 17 cm (78,7' x 33,9' x 6,7')
Weight ■ Mattress (deflated)	12,5 kg (27,6 lbs)
Cycle ■ Mattress (inflated)	3 cells, 7.5 min
Maximum Patient Weight (Safe Working Load) ■ Mattress	200 kg (441 lbs)
Inflation time ■ Mattress	max. 15 min
Deflation time (CPR)	30 s
Remain Inflated time in Transport mode	12 hours
Sound Pressure Level (mattress)	max. 29 dB(A)
Cover Fire Resistance	according to BS7175 - ignition source 5
Mattress Core Fire Resistance according to BS7175 - ignition source 5	NO
Top Cover Fire Resistance	according to 16 CFR 1632
Mattress Fire Resistance	according to 16 CFR 1632
Top Cover Biocompatibility	according to ISO 10993-5 (cytotoxicity), according to ISO 10993-10 (skin sensation and irritation)

6.3 Mechanical Specifications (Virtuoso 100)

Dimensions ■ Mattress (inflated) - length x width x height	200 cm x 86 cm x 17 cm (78,7' x 33,9' x 6,7')
Weight ■ Mattress (inflated)	8,5 kg (18,7 lbs)
Cycle ■ Mattress (inflated)	3 cells, 7.5 min
Maximum Patient Weight (Safe Working Load) ■ Mattress	210 kg (463 lbs)
Inflation time ■ Mattress	max. 15 min
Deflation time (CPR)	30 s
Remain Inflated time in Transport mode	12 hours
Sound Pressure Level (mattress)	max. 28 dB(A)
Cover Fire Resistance	according to BS7175 - ignition source 5
Mattress Core Fire Resistance according to BS7175 - ignition source 5	NO
Top Cover Fire Resistance	according to 16 CFR 1632
Mattress Fire Resistance	according to 16 CFR 1632
Top Cover Biocompatibility	according to ISO 10993-5 (cytotoxicity), according to ISO 10993-10 (skin sensation and irritation)

6.4 Mechanical Specifications (Virtuoso 200)

Dimensions ■ Mattress (inflated) - length x width x height	200 cm x 86 cm x 19 cm (78,7' x 33,9' x 7,5')
Weight ■ Mattress (inflated)	10 kg (22 lbs)
Cycle ■ Mattress (inflated)	3 cells, 7.5 min
Maximum Patient Weight (Safe Working Load) ■ Mattress	210 kg (463 lbs)
Inflation time ■ Mattress	max. 15 min
Deflation time (CPR)	30 s
Remain Inflated time in Transport mode	12 hours
Sound Pressure Level (mattress)	max. 46 dB(A)
Cover Fire Resistance	according to BS7175 - ignition source 5
Mattress Core Fire Resistance according to BS7175 - ignition source 5	NO
Top Cover Fire Resistance	according to 16 CFR 1632
Mattress Fire Resistance	according to 16 CFR 1632
Top Cover Biocompatibility	according to ISO 10993-5 (cytotoxicity), according to ISO 10993-10 (skin sensation and irritation)

6.5 Mechanical Specifications (Virtuoso 300)

Dimensions ■ Mattress (inflated) - length x width x height	204 cm x 90 cm x 23 cm (80,3' x 35,4' x 9,1')
Weight ■ Mattress (inflated)	12 kg (26,5 lbs)
Cycle ■ Mattress (inflated)	3 cells, 7.5 min
Maximum Patient Weight (Safe Working Load) ■ Mattress	254 kg (560 lbs)
Inflation time ■ Mattress	max. 20 min
Deflation time (CPR)	30 s
Remain Inflated time in Transport mode	12 hours
Sound Pressure Level (mattress)	max. 30 dB(A)
Cover Fire Resistance	according to BS7175 - ignition source 5
Mattress Core Fire Resistance according to BS7175 - ignition source 5	NO
Top Cover Fire Resistance	according to 16 CFR 1632
Mattress Fire Resistance	according to 16 CFR 1632
Top Cover Biocompatibility	according to ISO 10993-5 (cytotoxicity), according to ISO 10993-10 (skin sensation and irritation)

6.6 Mechanical Specifications (Virtuoso Pro)

Dimensions ■ Mattress (inflated) - length x width x height	204 cm x 90 cm x 23 cm (80,3' x 35,4' x 9,1')
Weight ■ Mattress (inflated)	13 kg (28,7 lbs)
Cycle ■ Mattress (inflated)	3 cells, 7.5 min
Maximum Patient Weight (Safe Working Load) ■ Mattress	254 kg (560 lbs)
Inflation time ■ Mattress	max. 20 min
Deflation time (CPR)	30 s
Remain Inflated time in Transport mode	6 hours
Sound Pressure Level (mattress)	max. 29 dB(A)
Cover Fire Resistance	according to BS7175 - ignition source 5
Mattress Core Fire Resistance according to BS7175 - ignition source 5	NO
Top Cover Fire Resistance	according to 16 CFR 1632
Mattress Fire Resistance	according to 16 CFR 1632
Top Cover Biocompatibility	according to ISO 10993-5 (cytotoxicity), according to ISO 10993-10 (skin sensation and irritation)

6.7 Mechanical Specifications (Seat cushion)

Dimensions	
■ Seat cushion (inflated)	450 mm x 500 mm x 125 mm (17' x 19' x 4')
Weight	
■ Seat cushion (inflated)	2,5 kg (5,5 lbs)
Cycle	
■ Seat cushion (inflated)	2 cells, 12 min
Maximum Patient Weight (Safe Working Load)	
■ Seat cushion	127 kg (279 lbs)

6.8 Mechanical Specifications (SCU and Accumulator)

Dimensions	
■ SCU without accumulator pack (length x width x height)	13,2 cm x 36,3 cm x 29 cm (5,2' x 14,3' x 11,4')
■ Accumulator pack (length x width x height)	13,5 cm x 36 cm x 30 cm (5,3' x 14,2' x 11,8')
Weight	
■ SCU without accumulator	4,9 kg (10,8 lbs)
■ SCU with accumulator	5,6 kg (12,3 lbs)
■ Accumulator pack	0,7 kg (1,5 lbs)
Sound Pressure Level (SCU)	max. 46 dB(A)
Accumulator operation	8,5 hours

6.9 Electrical Specifications

Supply voltage	
■ Model 230 V with Accumulator back-up	220 — 240 V ~ , 50/60Hz
Nominal power	
■ Model 230 V with Accumulator back-up	40 VA
■ Accumulator in accumulator pack	6 VA
Fuse	
■ Model 230 V with Accumulator back-up	2x T0.5A 250V
■ Accumulator pack	2x T3.8A 15V DC
Accumulator in accumulator pack	NiMH 12V 3800mAh
Electrical safety class	Class II
Electrical safety (IEC 60601-1)	in conformity with IEC 60601-1

SCU is compatible with different types of Power Supply Cords. If a compatible Power Supply Cord belongs to the Electrical Safety Class I (a cord with type E/F (CEE 7/7) plug), the whole Virtuoso system still belongs to the Electrical Safety Class II.

6.10 Environment Conditions

Use conditions	
■ Ambient Temperature	10 °C — 40 °C
■ Air Humidity	30 — 75 %
■ Atmospheric pressure	700 — 1060 hPa
Storage and Transport Conditions	
■ Ambient Temperature	-40 °C — 70 °C
■ Air Humidity	20% — 90%
■ Atmospheric pressure	795 — 1060 hPa
Ingress Protection (SCU)	IP2X
Electromagnetic compatibility	IEC 60601-1-2

6.11 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:

- ❖ 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 Virtuoso, including cables specified by manufacturer. Otherwise this could lead to deterioration of functionality of this air mattress system.

⚠ WARNING!

Do not overload the mattress (SWL) and consider chapter 24 Maintenance in order to maintain the basic safety with regard to electromagnetic disturbances for the expected service life.

6.11.1 Manufacturer instructions - electromagnetic emissions

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

6.11.2 Manufacturer instructions - electromagnetic susceptibility

Immunity Tests	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV for contact discharge ± 15 kV for air 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 NOTE: Following phenomenon may occur in range 200 – 250 MHz - Indication of charging and charging of battery backup while the battery is in fully charged status. 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° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycle Single phase: at 0° 0 % UT; 250/300 cycle
Proximity magnetic fields IEC 61000-4-39	See Table 2.

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

Table 2 - IMMUNITY to proximity magnetic fields

Test frequency	Modulation	Immunity Test Level A/m
30 kHz	CW	8
134,2 kHz	Pulse modulation 2,1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7,5

NOTE There are applied no deviations to requirements of IEC 60601-1-2 ed. 4.1.

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

7 Use and Storage Conditions

Virtuoso is suitable for use or storage in indoor environments.

Virtuoso is not suitable for indoor environments:

- containing flammable gases (except oxygen cylinders).

7.1 Storage

When SCU is not in use:

- ❖ Switch off SCU using Mains and Battery power switch on side 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:

- ❖ Deflate mattress and leave air connector open (CPR position).
- ❖ Roll mattress up to get air out completely.
- ❖ Rotate end of umbilical air connector and main body in opposite directions.
- ❖ Pack in suitable cover.
- ❖ Store in a place suitable for electronic medical devices.

8 Scope of Delivery and Product Variants

8.1 Scope of Delivery

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.

8.2 List of Parts

- Mattress - Applied part type B
- SCU (System Control Unit)
- Accumulator pack - 12 V DC (optional)
- Mains Cable
- Instructions for use

9 Putting into Service

Virtuoso Overlay needs to be placed on top of an existing passive mattress. Virtuoso Mattress Replacement (Air + Static Air Base), Virtuoso Mattress Replacement (Air + Foam Base), Virtuoso Mattress Replacement (Air + Alternating Air Base), Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) and Virtuoso Pro mattress replaces any mattress on the bed frame.

9.1 Mattress

! WARNING!

Risk of injury due to incorrect use!

- When using mattress replacement system, 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 Virtuoso mattress, always have a qualified person perform a risk assessment to ensure that the support provided is appropriate and fulfils the applicable local stipulations.
- Ensure all Head, Body, and Foot Zone valves are set to Alternate or Static Mode for initial inflation.

! CAUTION!

Material damage due to incorrect fastening of safety straps!

Mattress replacement system

- Fix safety straps exclusively 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.

- ❖ Remove any existing mattress.
- ❖ Ensure that there are no protruding parts or sharp objects on the bed frame to avoid damage to the mattress.
- ❖ Put mattress on mattress platform of bed frame so that air pipe is located as shown below.
- ❖ Prevent air pipe from getting trapped by moving parts of the bed frame or getting looped or bent in such a way as to block or restrict the air flow.
- ❖ Loosely fasten Mattress Fixing Straps to suitable parts of the bed frame.



Fig. Installation of Mattress

9.2 SCU (System Control Unit)

⚠ CAUTION!

Risk of incompatibility when installing SCU!

- ➔ Do not replace SCU with SCU from different series of Virtuoso Air Mattress System.

⚠ WARNING!

Risk of injury when installing SCU!

- ➔ Ensure that no body parts are trapped between hook and foot board when using spring-loaded SCU hanging hooks.
- ➔ Do not insert power cable to SCU when the cable is connected to the mains!
- ➔ Fix SCU securely to prevent it from sliding or accidentally being knocked off.

⚠ CAUTION!

Material damage due to incorrect installation of SCU!

- ➔ Do not install SCU in linen shelf on bed frame.
- ➔ Avoid possible collisions with accessories!
- ➔ Do not overload foot board when installing SCU on it!

If foot board is suitable for hanging SCU:

- ❖ Hold SCU in one hand and unfold hook on back with the other.
- ❖ Hang SCU on foot end of bed frame.

If foot board is not suitable for hanging SCU:

- ❖ Put SCU on floor with integrated mounting feet.



Fig. SCU on the Foot Board

9.2.1 Mains Cable Installation

⚠ WARNING!

Risk of injury when installing Mains Cable to the SCU!

- Do not insert Mains Cable to SCU when the Mains Cable is connected to the mains!
- Only use the original Mains Cable from manufacturer!

Fit the Mains Cable to the SCU as follows:

- ❖ Remove the Mains Connector Cover on the rear of the SCU by unscrewing the small black wheel.
- ❖ Fit the Mains Cable Connector to the SCU Mains Connector.
- ❖ Replace the Mains Connector Cover while ensuring that the Mains Cable is fed through the slots provided in the Mains Connector Cover and the back side of the SCU.
- ❖ Tighten the black wheel.

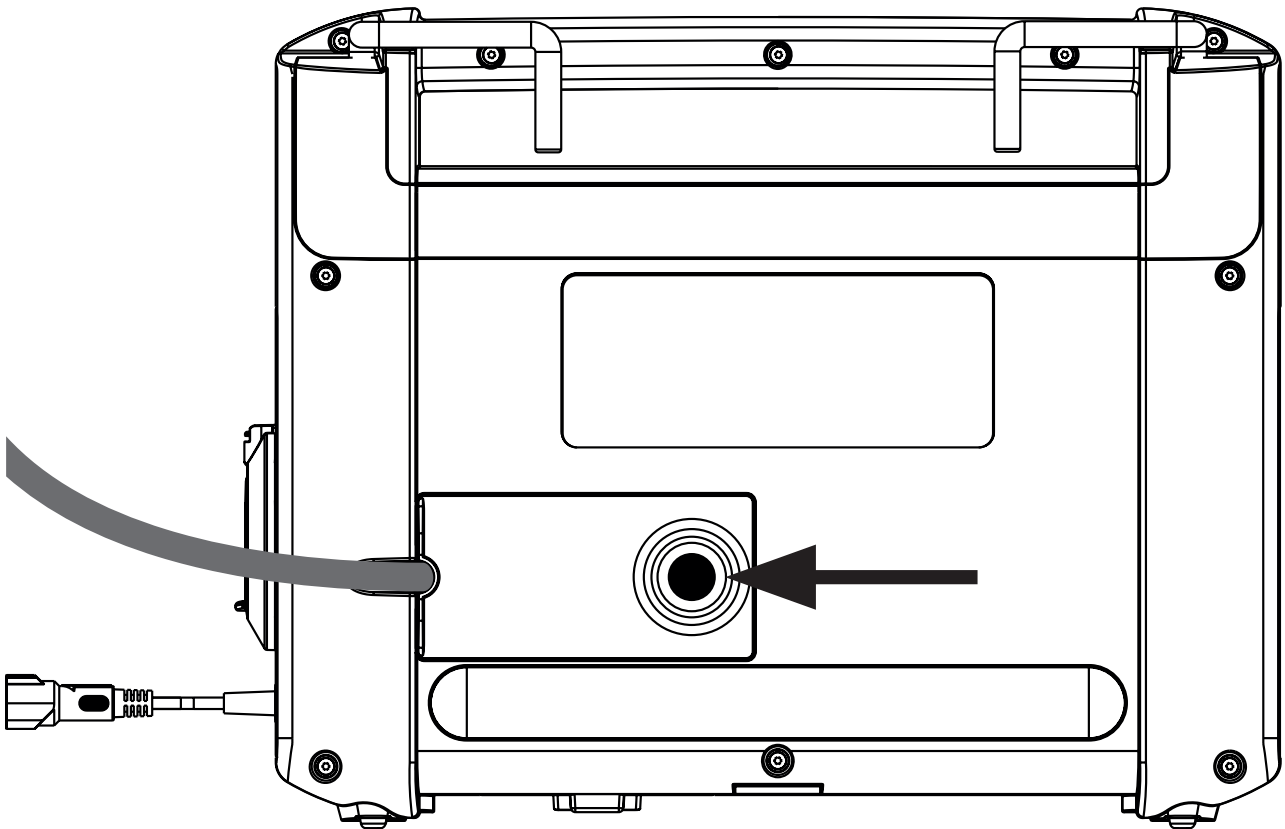


Fig. Position of the black wheel securing the Mains Cable installed to the SCU

9.3 Connecting Mattress and SCU

- ❖ Ensure that air connector is in open mode.
- ❖ Insert air connector **1** in the socket **2** at an angle of approximately 45°.
- ❖ Push air connector **1** down until it clicks into place.
- ❖ Insert Fowler Boost male connector **3** to Fowler Boost female connector in SCU.

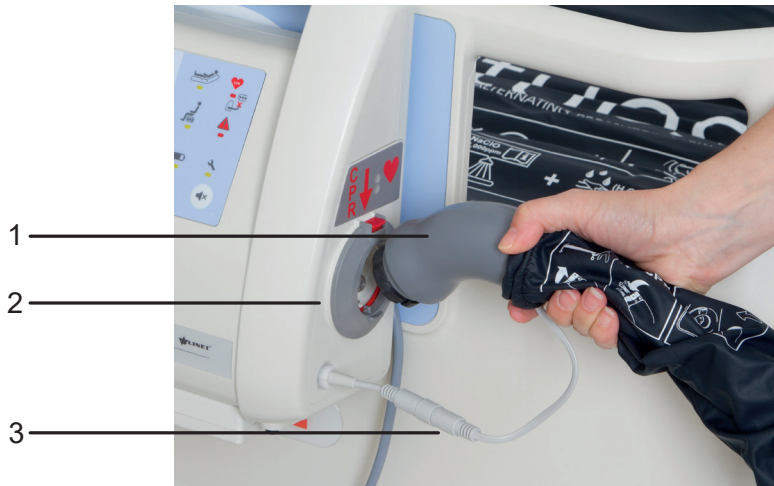


Fig. Air Connector and Fowler Boost Connector

1. Air connector
2. Air connector socket
3. Fowler Boost Connector

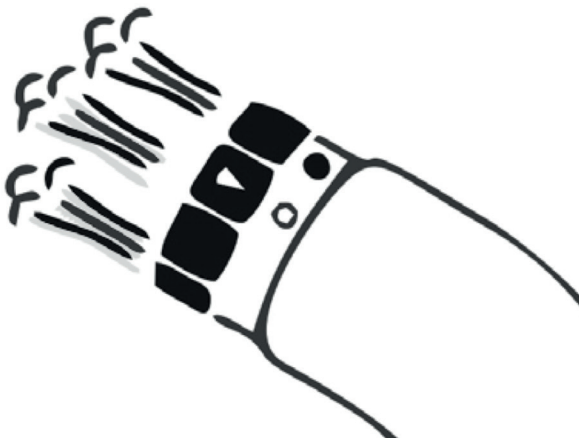


Fig. Open Mode

9.3.1 Air Connector Detection

When the mattress is first connected and the SCU switched on, the display will turn on 2 LEDs from the left for Virtuoso Overlay and Virtuoso Mattress Replacement (Air + Alternating Air Base) or 3 LEDs from the left for Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) or 4 LEDs from the left for Virtuoso Pro (see position 3 on Control Panel picture). These LEDs will remain on until the SCU starts to run. Then they will return to displaying the air pressure setting. In case of Seat Cushion the display will not turn on any LED because it has its own indicator on the Control panel.

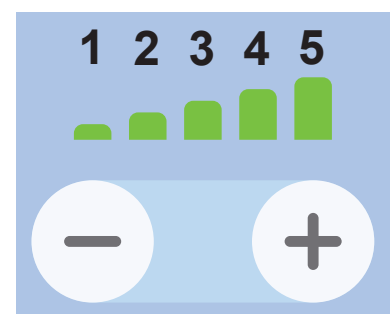


Fig. Five LEDs.

9.3.2 Fowler Boost Connection

White visual indicator on SCU control panel indicates activated Fowler Boost. Pressure increases in seat and back sections (Fowler Boost) automatically at a single point when Backrest is adjusted to 30 degrees (Virtuoso Overlay, Virtuoso Mattress Replacement (Air + Foam Base), Virtuoso Mattress Replacement (Air + Static Air Base), Virtuoso Mattress Replacement (Air + Alternating Air Base)). Pressure increases in seat and back sections automatically and linearly when backrest is adjusted between 11 and 46 degrees (Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) and Virtuoso Pro).

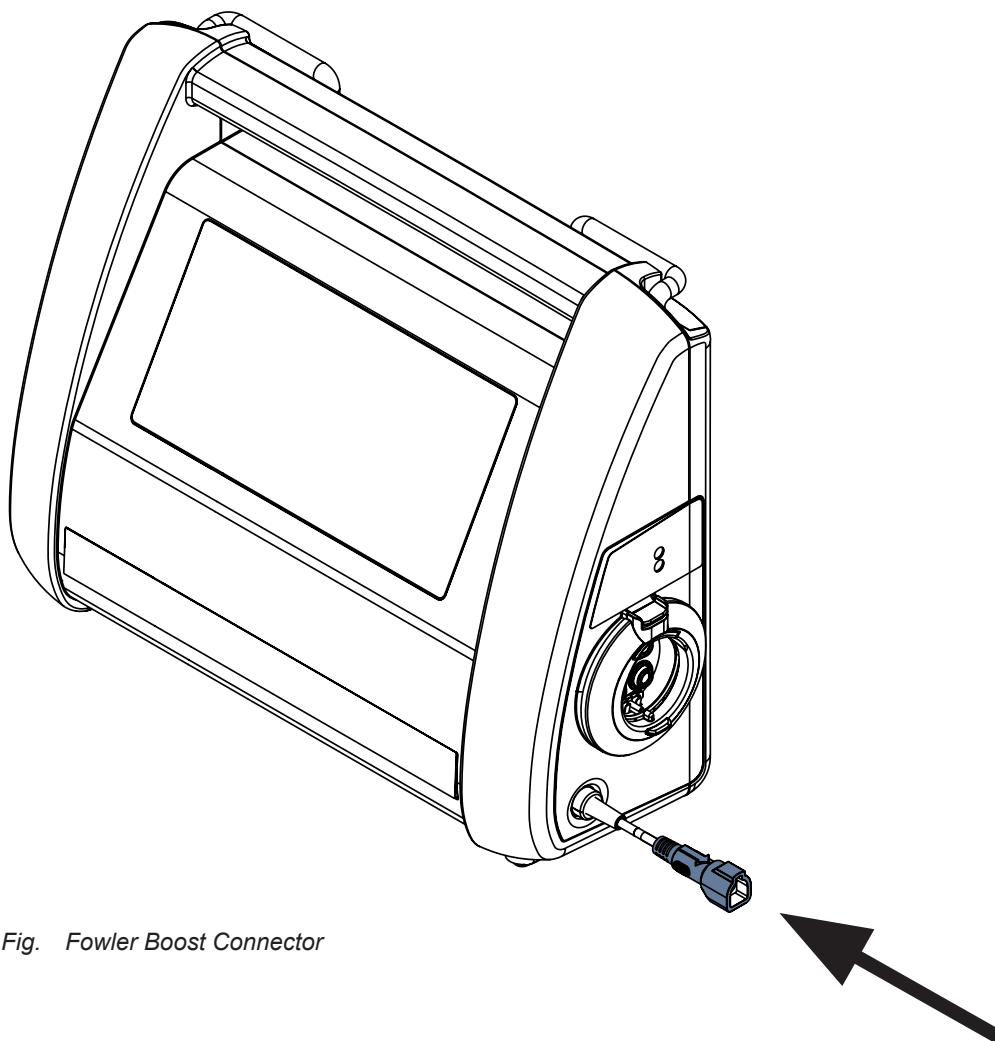


Fig. Fowler Boost Connector

9.4 Cable Management System

⚠ WARNING!

Risk of injury due to exposed cable!

- Ensure that cable is not twisted, crushed or strained.
- Use cable routing clips in order to avoid tripping hazards.
- Ensure that it is not possible for the cable to get trapped between any moving parts of the bed frame.

⚠ WARNING!

Risk of incompatibility due to incorrect cable!

➤ Use original cable exclusively.
 Virtuoso is equipped with 3 cable routing clips on both sides of the mattress cover. The cable routing clips prevent the cable from getting twisted, crushed or strained or becoming a tripping hazard.

Safe cable routing:

- ❖ Route cable through cable routing clips.
- ❖ Ensure that cable is not hanging over head end to prevent it from getting stretched or trapped when raising or lowering the back rest.



Fig. Cable routing clips

9.5 Before Use

The SCU is operated via the SCU control panel (see chapter 5 **Control Panel Description**).

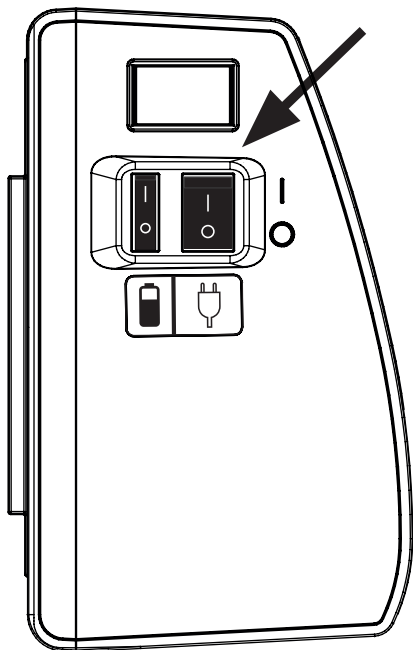
9.5.1 Inflation

- ❖ 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 suitable mains socket.

For Mains Operation (For Accumulator Operation see chapter 10):

- ❖ Switch on SCU using bigger power switch on side of SCU.
- ❖ The SCU will take 30 s for the initialisation. After that the mattress will start to inflate.

After activation of SCU the mode set before turning off starts again if this previous mode was used for 15 minutes or more. This settings is saved in SCU unless backup memory is completely erased. After that default mode is set back to APT mode with pressure level 3.



To switch off SCU:

- ❖ Switch off SCU using Mains and Accumulator power switch on side of SCU.
- ❖ Disconnect mains cable from mains.

NOTE When switched on, the SCU will return to the last mode (APT) or CLP) and pressure setting. The mode and pressure settings are only valid when the SCU has been running with these settings for more than 15 minutes.

During the inflation process:

- Indicator 14 or 4 flashes white, depending on the last mode setting. The inflation process takes 15 minutes at most.

Inflation Mode APT:

- When APT is set, indicator 4 and indicator 3 will keep flashing during the initial inflation.
- Then APT indicator 4 will light solid and indicator 3 will flash while pressure is adjusted to the set pressure level.
- When the set pressure level is reached, indicator 4 and indicator 3 will

Inflation Mode CLP:

- When CLP is set, indicator 14 and indicator 3 will keep flashing during the initial inflation.

- When APT is set, indicator 14 will light solid and indicator 3 will flash while pressure is adjusted to the set pressure level.
- When the set pressure level is reached, indicator 14 and indicator 3 will remain solid on.

When the inflation process is finished:

- ❖ Check if safety straps of mattress cover are too tight and correct if necessary.

If indicator 7 (see Control Panel picture) flashes during inflation process and audio alert signal sounds:

- ❖ Check if air pipe is connected correctly.

9.6 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.

10 Accumulator

⚠ WARNING!

Risk of injury due to insufficient power supply!

In case of power fail signal:

- ➔ Select Transport mode if the patient is to remain on the mattress.

⚠ CAUTION!

Risk of reduction of the accumulator service life!

- ➔ If a accumulator fully discharged audio/visual alert occurs and mains power cannot be immediately supplied to the SCU, then the SCU and accumulator mains switches must be turned off. Failure to do so may reduce the long term life of the accumulator back-up pack.

⚠ CAUTION!

Damage to accumulator due to complete discharge!

- ➔ If accumulator is discharged, switch off SCU or connect it to power supply to prevent complete discharging.

To switch on accumulator:

- ❖ Switch on accumulator using smaller power switch on side of SCU.

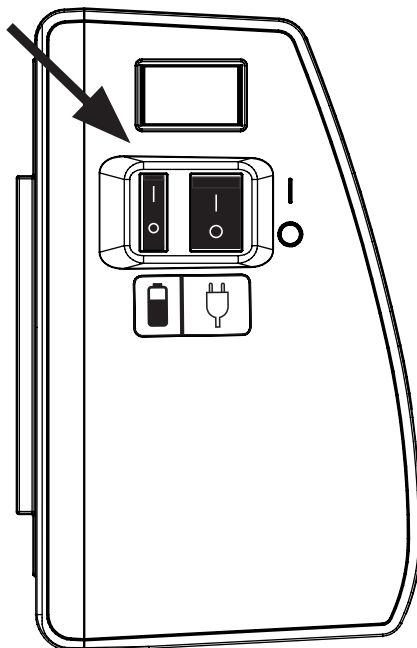


Fig. Switching on accumulator

10.1 Accumulator Charge Status Indicator

With the accumulator fully charged, the mattress replacement system will be operable in Alternating mode for 8,5 hours. Charging the accumulator completely takes up to 6 hours, but one hour of charging will be sufficient for running the SCU for an hour.

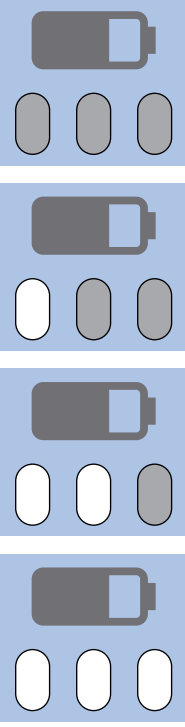
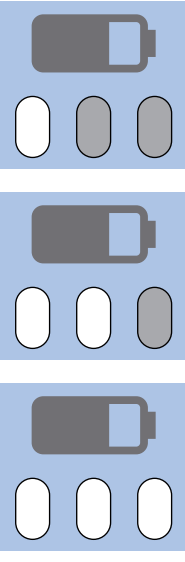
- ❖ Charge the accumulator before use.
- ❖ Use only batteries approved by the manufacturer.
- ❖ The manufacturer provides a 6-month warranty for the full function of batteries.
- ❖ Check the accumulator functionality at least once a month in accordance with the user and service manuals and have the accumulator changed if necessary.

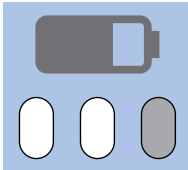
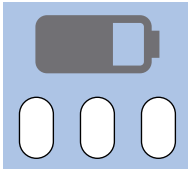
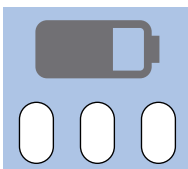
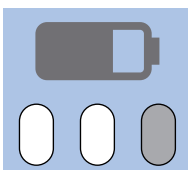
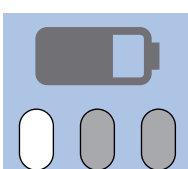
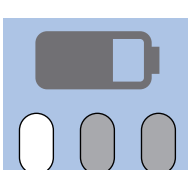
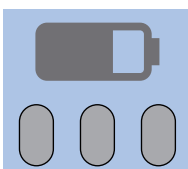
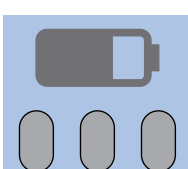
- ❖ The manufacturer recommends to replace the accumulator by qualified service organization after 2 (two) years of use. After this period the supposed service life of accumulator ends and the manufacturer cannot guarantee the accumulator performance after this period.
- ❖ The accumulator must be replaced with the new accumulator approved by manufacturer after maximum 5 (five) years of use at the latest.

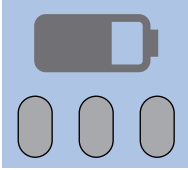
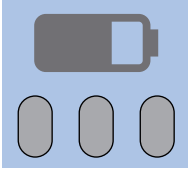
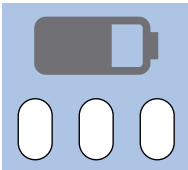
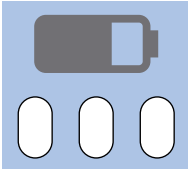
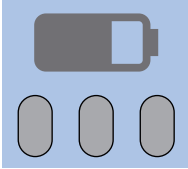
To charge the accumulator:

- ❖ Connect the SCU with a mattress to the mains.
- ❖ Turn on SCU Mains switch.
- ❖ Turn on the Accumulator switch.

While the accumulator is being charged, the status indicator will indicate the accumulator charge status (see table below).

Accumulator Status Indicator	Meaning	Visual Signal and Audio Alert Signal
	<p>CHARGING 0% - 25% (SCU is connected to the mains)</p>	<p>4 statuses of Accumulator Status Indicator in repetitive sequence</p> <p>no audio alert</p>
	<p>CHARGING 25% - 50% (SCU is connected to the mains)</p>	<p>3 statuses of Accumulator Status Indicator in repetitive sequence</p> <p>no audio alert</p>

Accumulator Status Indicator	Meaning	Visual Signal and Audio Alert Signal
 	<p>CHARGING 50% - 99% (SCU is connected to the mains)</p>	<p>2 statuses of Accumulator Status Indicator in repetitive sequence</p> <p>no audio alert</p>
	<p>CHARGED 100%</p>	<p>1 status of Accumulator Status Indicator</p> <p>no audio alert</p>
	<p>DISCHARGING 99% - 50% (accumulator is turned on, SCU is disconnected from the mains)</p>	<p>1 status of Accumulator Status Indicator</p> <p>no audio alert</p>
	<p>DISCHARGING 50% - 25% (accumulator is turned on, SCU is disconnected from the mains)</p>	<p>1 status of Accumulator Status Indicator</p> <p>no audio alert</p>
 	<p>DISCHARGING less than 25% (accumulator is turned on, SCU is disconnected from the mains)</p>	<p>2 statuses of Accumulator Status Indicator in repetitive sequence</p> <p>single beep every 30 seconds</p>
	<p>Accumulator DISCONNECTED or Accumulator INCORRECTLY FITTED (accumulator turned off, SCU is connected to the mains, SCU is turned on)</p>	<p>1 status of Accumulator Status Indicator</p> <p>no audio alert</p>

Accumulator Status Indicator	Meaning	Visual Signal and Audio Alert Signal
	POWER FAIL MODE or Accumulator TOO LOW TO USE	1 status of Accumulator Status Indicator Power Fail Alert (2-tone alert, sounds until backup memory is erased): <ul style="list-style-type: none"> ❖ when the backup accumulator is not fitted or is switched off (loss of mains power) ❖ when SCU is running from accumulator if the accumulator is too low to use
 	CHARGE FAULT or Accumulator FAULT (SCU is connected to the mains)	2 statuses of Accumulator Status Indicator in repetitive sequence (for 5 seconds not lit LEDs and after there are 3 flashes of the LEDs) no audio alert
 	Accumulator CORRECTLY FITTED (SCU is connected to the mains)	2 statuses of Accumulator Status Indicator in sequence (LEDs are lit for 2 seconds) 2 seconds long beep

To mute the audio alert signal:

- ❖ Mute audio alert signal (see „Mute“ - chapter 11.2.2).

10.2 Accumulator Back-up Pack

SCUs with the back-up accumulator feature can be equipped with an optional accumulator back-up pack. The identification label of the accumulator back-up pack is placed on the front of the accumulator back-up pack.



Fig. Identification label of the accumulator back-up pack

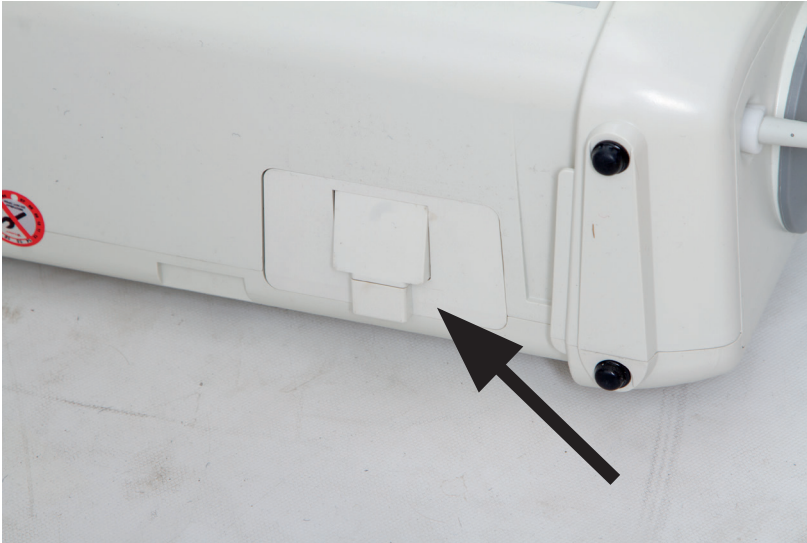


Fig. Accumulator Release Button on the bottom of SCU

To fit the accumulator back-up pack:



Fig. Fitting the accumulator pack

- ❖ Disconnect SCU from mains.
- ❖ Mute audio alert signal (see „Mute“ - chapter 11.2.2).
- ❖ Make sure the bottom side of the accumulator with label is oriented correctly.
- ❖ Push accumulator pack into mounting slots 1 until it clicks into place.
- ❖ Switch SCU back on.

To remove the accumulator back-up pack:



Fig. Removing the accumulator pack

- ❖ Switch off SCU.
- ❖ Pull down the accumulator pack's release tab 2.
- ❖ Pull out accumulator pack while holding down release tab.

NOTE There is no need to remove the accumulator pack except when replacing it.

10.2.1 Detection of the correctly inserted accumulator (with Mains power switch turned on)

Accumulator is correctly inserted to SCU when the Accumulator Charge Status Indicator is lit for 2 seconds and the acoustic signal sounds for 2 seconds after the Accumulator power switch is turned on. The Accumulator Charge Indicator flashes 3 times during disconnection after the Accumulator power switch is turned off. After the disconnection of the accumulator by Accumulator power switch, it is necessary to wait at least 10 seconds for correct function of the accumulator detection before the Accumulator power switch is turned on again.

11 Manipulation

11.1 Use

11.1.1 Preparing the Bed for the Patient

⚠ WARNING!

Risk of injury when putting patient into bed!

Before putting the patient into bed:

- Ensure that mattress is completely and correctly inflated.
- Ensure all Head, Body and Heel valves, on the side of the mattress, are in an inflate position.
- Ensure that mattress is correctly secured with safety straps.

⚠ WARNING!

Danger 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.

⚠ CAUTION!

Material damage due to dampness or contamination!

- Ensure that no moisture gets into the mattress.
- Ensure that no food or drink gets into the mattress.
- If moisture, food or drink get into the mattress, notify LINET® Service.

⚠ CAUTION!

Risk of incompatibility of the mattress with siderails!

- Avoid collision of valves on the side of the mattress with siderails!
- Besides observing dimensions of the mattress in the Mechanical Specifications table a space for manipulation with valves is needed!

Preparation

- ❖ Inflate mattress (see „Putting into Service“ - chapter 9).
- ❖ Put a sheet loosely on the mattress if not prescribed otherwise by qualified personnel.

Putting the Patient into the 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 etc. between mattress and patient.

11.1.2 Supine Nursing

WARNING!

Ensure adequate patient support is maintained during normal mattress operation. Remember that APT mode alternately deflates cells in a 3-cell cycle, hence it is recommended not to manually deflate more than one cell per body zone, nor two adjacent cells, unless necessary for a nursing procedure.

If the patient is being nursed in the Supine position (Face Up) then the Head and Heel Zoner valves can be used to deflate appropriate cells of the mattress to relieve pressure on patient body parts. Seek instruction from medically qualified personnel for which cells to deflate. See chapter 19 for valve operation instructions.

11.1.3 Prone Nursing












WARNING!

Ensure adequate patient support is maintained during normal mattress operation. Remember that APT mode alternately deflates cells in a 3-cell cycle, hence it is recommended not to manually deflate more than one cell per body zone, nor two adjacent cells, unless necessary for a nursing procedure. The exception to this advice, for Prone nursing only, is the Head Zone where up to 4 cells can be deflated, under medical supervision, to accommodate the patients face should it be considered necessary.


If the patient is being nursed in the Prone position (Face Down) then the Head, Body, and Heel Zone valves can be used to deflate appropriate cells of the mattress to relieve pressure on patient body parts. Seek instruction from medically qualified personnel for which cells to deflate. See chapter 19 for valve operation instructions.


11.2 Controls and Indicators (Control Panel)

For picture of the Control Panel see chapter 5 Control Panel Description.


Button/Indicator	Function
Pressure Control Buttons 	Changing air pressure in mattress.
MODE Button 	Selects desired mode: APT = Alternating Pressure Therapy Mode MAX = Maximum Inflate Mode CLP = Constant Low Pressure Mode
Seat Cushion Indicator 	Indicates that seat cushion is connected.
Fowler Boost Indicator 	Indicates if backrest is raised.
CPR/ Air Connector Open Indicator 	Indicates that air pipe is not connected correctly or not at all.
System Error Indicator 	Indicates system error. ❖ Call service department authorized by manufacturer.
Mute Button 	Muting audio alert signals.
Service Due Indicator 	Indicates that service is due.
GO Button 	Activates the control panel.
Accumulator Charge Status Indicator (accumulator back-up model only) 	Indicates charge status of accumulator.
Pressure Level Indicators 	Indicate the air pressure set in mattress. Pressure Level Indicators are active only in APT Mode or CLP Mode. Pressure Level Indicators are disabled in MAX Mode or when Seat Cushion is connected to SCU.

11.2.1 Button GO


The GO button  activates the SCU control panel.

After pressing the button , the SCU control panel will remain active for 3 minutes.

To activate control panel:


- ❖ Press the button .

If no button has been pressed for 3 min:

- ❖ Activate control panel again by pressing button  .

11.2.2 Mute

To mute audio alert signal:

- ❖ Press the button  .

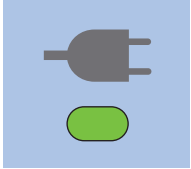
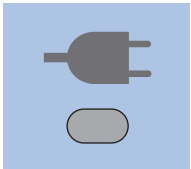
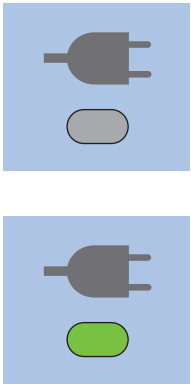
If cause of error signal is not remedied:

- Audio alert signal will switch back on after 30 min.

If cause of CPR alert is air connector removed for CPR or for other reasons:

- Audio alert signal will switch back on after 60 min.

11.2.3 Mains Power Indicator

Mains Power Indicator	Meaning	Visual Signal and Audio Alert Signal
	SCU IS POWERED BY MAINS POWER (mains cord is connected and Mains Power Switch is ON)	Mains Power Indicator is illuminated no audio alert
	SCU IS POWERED BY Accumulator (mains cord is disconnected or Mains Power Switch is OFF)	Mains Power Indicator is not illuminated no audio alert
	SCU IS POWERED BY Accumulator AND MAINS CORD IS DISCONNECTED OR MAINS POWER SWITCH IS OFF (WHEN SCU IS INITIALLY TURNED ON)	2 statuses of Mains Power Indicator in sequence (not illuminated Mains Power Indicator for 5 seconds and after there is 20 seconds long blink of the Mains Power Indicator) alert: after 5 seconds long silence there is 10 seconds long beep (Alert is cancelled by connecting mains voltage to SCU.)

11.2.4 Pressure Control

When switched on, the SCU will inflate the mattress to the recommended pressure. Once this pressure is reached, indicator **3** will stop flashing and remain solid on, and an audio signal will sound.

In order to guarantee optimum protection, the operator must adjust the pressure to the patient's weight and position in APT mode.

Manual Pressure Adjustment

⚠ WARNING!

Risk of injury due to incorrect pressure setting!

- ➡ Consult qualified hospital staff prior to adjusting pressure.

⚠ WARNING!

Risk of injury due to incorrect pressure level!

The recommended pressure levels may not be the optimum for all situations but should be used in conjunction with clinical judgment based on the individual patient; e.g. weight, weight distribution, position and comfort needs.

- ➡ Do not reduce pressure level setting by more than 1 step for the patient's comfort.
- ➡ Regardless of the pressure level, make sure the patient is not lying directly on the bed frame.

NOTE *Pressure adjustment is exclusively possible in APT mode and CLP mode.*

The pressure control allows the nursing staff to adjust the pressure within a pre-set range.

To adjust pressure:

- ❖ Press button - to decrease pressure.
- ❖ Press button + to increase pressure.

Recommended pressure levels:

- 1: 0–50 kg (0 - 110 lbs)
- 2: 50–80 kg (110 - 176 lbs)
- 3: 80–120 kg (176 - 264 lbs)
- 4: 120–180 kg (264 - 396 lbs)
- 5: 180–210 kg (396 lbs - 462 lbs)

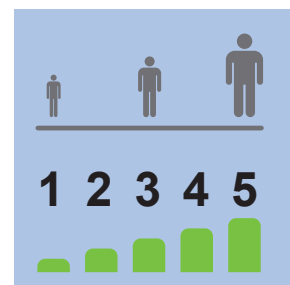


Fig. Five pressure levels

NOTE *The larger size of the figure above the pressure level indicator signifies the heavier weight of the intended patient.*

During pressure adjustment:

- The section of the pressure control indicator corresponding to the desired pressure flashes green.

When desired pressure is reached:

- The section of the pressure control indicator corresponding to the desired pressure lights green.

Pressure levels:

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

11.2.5 APT Mode

Once the mattress is fully inflated, a confirming signal sounds and the mattress switches into APT Mode (Alternating Pressure Therapy). APT Mode with pressure level 3 becomes automatically default mode if SCU is turned off for a long time. APT Mode is intended to be used as an aid to patient care in prevention and treatment of skin breakdown related to pressure damage.

To select APT mode:

- ❖ Press button **13** once or repeatedly until indicator **4** comes on.

When APT mode is switched on:

- 3-cell mattress units will inflate and deflate in cycles of 7.5 minutes.
- Indicator **4** lights white.
- Pressure indicator **3** flashes.
- Once the pre-set pressure is reached, indicator **3** will remain solid on.

NOTE *After 3 cycles of APT Mode with deflated individual cell an alert indicating fail to inflate is triggered.*

11.2.6 Max Mode

Max Mode (maximum inflation mode) provides a solid and stable surface for patient care.

Max Mode will run for 30 min at most. If no other mode is selected within last 5 minutes, a confirmation signal will sound, and the mattress replacement system will switch back to APT or CLP mode automatically. Selected Max Mode interrupts the return to the previous mode.

To select Max Mode:

- ❖ Press button **13** once or repeatedly until indicator **5** flashes yellow.

If Max Mode is required for less than 30 minutes:

- ❖ Set new mode by pressing button **13**.

If Max Mode is required for more than 30 minutes:

- ❖ Press MODE Button once or repeatedly until Max Mode is set again after 25 minutes of Max Mode.

When Max Mode is selected:

- SCU inflates all mattress cells to the same pre-set pressure.
- Indicator **5** flashes white until preset pressure is reached.
- Once the set pressure is reached, indicator **5** will remain solid on.
- During the last 5 min, an alert signal will sound every minute.

When Max Mode is selected for the second time:

- ❖ During the last 5 min, an audible reminder will sound every minute to remind the personnel that Max Mode will soon end automatically.

NOTE *It is not possible to select Max Mode a third time. Selecting Max Mode again is only possible when APT Mode or CLP Mode has been running for at least 30 min.*

11.2.7 CLP Mode (Constant Low Pressure Mode)

CLP Mode (constant low pressure mode) keeps the mattress pressure at the selected level. The pressure is checked every 30 seconds, and adjusted if necessary. CLP Mode is intended to be used as an aid to patient care in prevention of skin breakdown related to pressure damage.


To select CLP Mode:

- Press button **13** once or repeatedly until indicator **14** flashes white.

When CLP Mode is switched on:

- CLP indicator **14** will light solid and indicator **3** will flash while pressure is adjusted to the set pressure level.
- Once the pre-set pressure is reached, indicator **14** and indicator **3** will remain solid on.

11.2.8 Fowler Boost

 WARNING!
<p>Risk of injury due to incorrect pressure setting!</p> <ul style="list-style-type: none"> ➞ Consult qualified hospital staff prior to adjusting pressure.

Fowler Boost provides increased support for the patient when sitting up in bed in APT or CLP mode. SCU activates Fowler Boost automatically when backrest is raised and Fowler Boost cable is connected to SCU.

Activating Fowler Boost

- ❖ Raise backrest.

When backrest is raised:

- When the backrest is raised the SCU automatically increases the mattress pressure (single point pressure increase at 30 degrees for Virtuoso Overlay and Virtuoso Mattress Replacement (Air + Alternating Air Base), linear pressure increase within 11 - 46 degrees for Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) and Virtuoso Pro).
- The Fowler Boost Indicator **6** will illuminate and the pressure range indicator will start to flash until the required pressure is achieved.
- Once the pressure is achieved, the pressure range indicator **3** will be permanently on.


Deactivating Fowler Boost

- ❖ Lower backrest.

When backrest is lowered:

- When the Backrest is lowered the SCU automatically reduces the mattress pressure.
- The Fowler Boost Indicator **6** will extinguish and the pressure range indicator **3** will start to flash until required pressure is achieved.
- Once the pressure is achieved the pressure range indicator **3** will be permanently on.

11.2.9 Micro-Climate Management (MCM)

 CAUTION!
<p>Risk of incompatibility due to incorrect bed sheet!</p> <ul style="list-style-type: none"> ➞ Use air-permeable bed sheet exclusively!

The Microclimate Management (MCM) function starts to operate automatically when the SCU is turned on and a mattress is connected. The integrated MCM function is achieved by providing air through two dedicated manifolds 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.

11.3 CPR/Air Disconnected Mode

SCU activates CPR/Air Disconnected mode automatically if air pipe is not connected correctly or removed while in use.

When CPR/Air Disconnected mode is activated:

- Indicator 7 lights red.
- Uninterrupted audio alert signal sounds.
- Mattress deflates.

To stop audio alert signal:

- ❖ Connect air pipe correctly.

-or-

- ❖ Switch off SCU using Mains and Accumulator power switch on side of SCU.
- ❖ Press MUTE button to stop audio alert. The acoustic alert will return once after 60 minutes. Press MUTE button again to cancel the audio alert.

11.4 System error

⚠ WARNING!

Risk of injury due to incorrect positioning of patient!

↻ If a system error occurs, do not continue to use mattress replacement system and notify LINET® Service immediately.

If a system error occurs:

- Indicator 8 flashes red.
- Audio alert signal (synchronized with flash sequence) sounds.

NOTE *The number of times that the alert sounds and indicator 8 flashes indicates the type of error. The number of flashes will be required when contacting a service engineer.*

To mute audio alert signal:

- ❖ Mute audio alert signal (see Mute - chapter 11.2.2).

To stop audio alert signal:

- ❖ Reset system by switching SCU off and back on.

NOTE *The error signal will repeat every time the device is switched on until the cause of the error is remedied.*

11.5 Service

LINET® recommends maintenance after 10,000 operating hours of the SCU. Indicator 9 lights yellow after 10,000 operating hours.

When indicator 9 lights yellow:

- ❖ Notify LINET® Service.

11.6 CPR (umbilical connected)

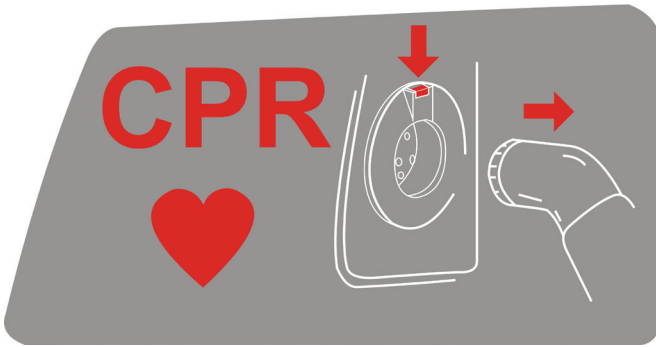


Fig. CPR (SCU connected)

To allow resuscitation with SCU connected:

- ❖ Press red CPR button above the air connector on the side of SCU.
 - ❖ Remove air connector plug from air connector.
- Mattress deflates.
- ❖ CPR chest compression can start immediately.

NOTE During this process, it is possible that the backrest detector plug is pulled out. This does not affect the CPR function.

11.7 CPR (umbilical disconnected)

To allow resuscitation in Transport mode:

- ❖ Rotate end of air connector and main body in opposite directions until the red symbols ▲ and O are aligned and air starts to escape.

Mattress deflates.

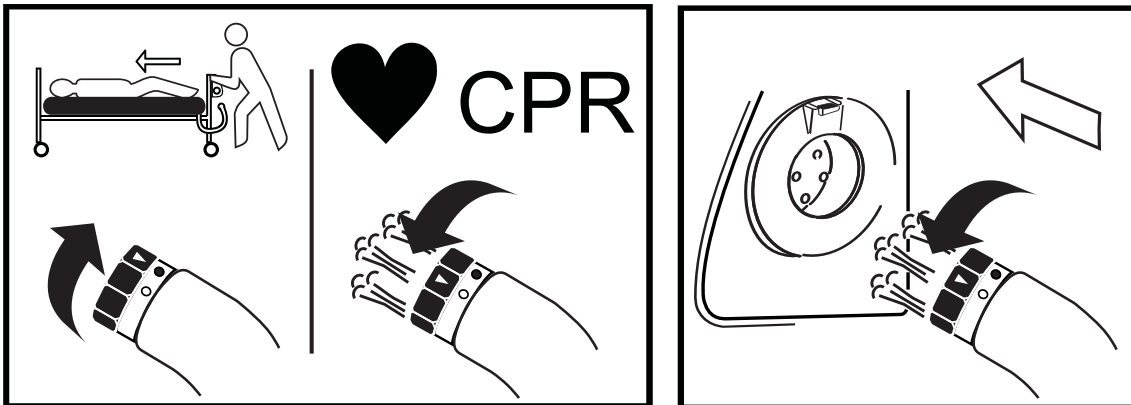


Fig. CPR (SCU disconnected)

11.8 Transport Mode (Static and Active)

! WARNING!

Risk of injury due to incorrect positioning of patient!

- ➡ Prior to more than 30 minutes of Static Transport Mode, consult qualified hospital staff.

Static Transport Mode allows disconnecting the mattress from the SCU for transporting the bed.

NOTE *In Static Transport Mode, alternating pressure therapy is not possible.*

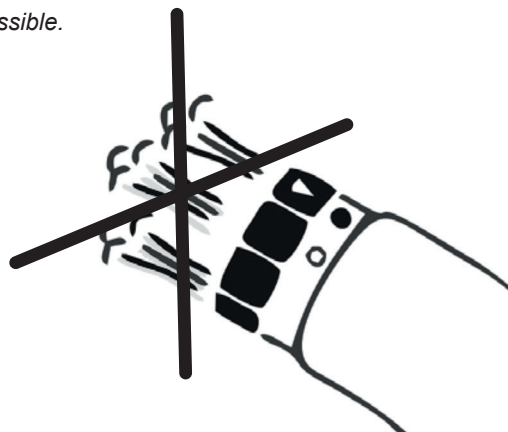


Fig. Transport Mode

To activate Static Transport Mode:

- ❖ Select Max Mode in order to completely inflate all mattress cells (see Max Mode - chapter 11. 2. 6).
- ❖ Disconnect air connector socket and rotate its end and body in opposite directions until red symbol ▲ and black symbol ● are aligned and no air is escaping.

11.8.1 Active Transport Mode

Active Transport Mode allows the patient being transported in bed to continue to receive ALT or CLP therapy. See Accumulator - chapter 12 (only available on Accumulator Back-up ready SCU).

To activate Active Transport Mode:

- ❖ Turn on the Accumulator power switch.
- ❖ Disconnect mains plug from wall outlet.

11.9 Power Failure

! WARNING!

Risk of injury due to power failure!

Alternating pressure therapy is not possible during power failures.

- ➡ In case of power failure, seek medical advice immediately.

In case of a power failure, the mattress will remain inflated for the time mentioned in the Technical Specification chapter. However, alternating pressure therapy is not possible.

If no power supply will be available for a longer time:

- ❖ Switch to Active Transport Mode (see Active Transport Mode - chapter 11.8.1).

After activation of SCU the mode set before turning off starts again if this previous mode was used for 15 minutes or more. This settings is saved in SCU unless backup memory is completely erased. After that default mode is set back to APT mode with pressure level 3.

11.10 Manual Deflating - Body Zoner (only Virtuoso Pro)

⚠ WARNING!
Risk of injury due to incorrect deflating!
 ➔ Never open more than 2 valves next to each other!

To deflate individual cell:

- ❖ Turn selector to the position



To inflate individual cell and set APT Mode:

- ❖ Turn selector to the position



NOTE Green colour in the circle indicates default mode of corresponding cell.

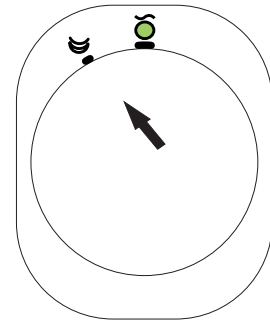


Fig. Indication of deflated individual cell

11.11 Head Zoner / Heel Zoner

If a Head/Heel Zoner is fitted (Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) or Virtuoso Pro), it is possible to configure the head and heel section of the mattress for nursing procedures (e.g. prone positioning, intubation). It permits setting each cell of the head or heel section separately to one of three (Head Zoner) or one of two (Heel Zoner) modes.

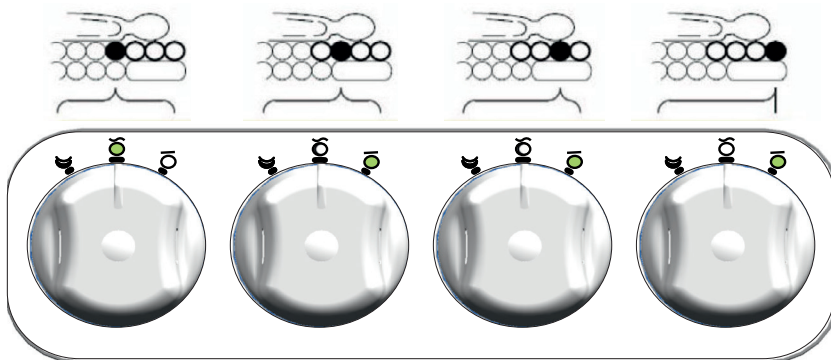


Fig. Head Zoner

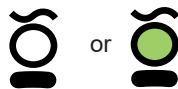
To deflate individual cell:

- ❖ Turn selector to the position



To inflate individual cell and set APT Mode:

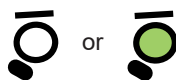
- ❖ Turn selector to the position



NOTE Green colour in the circle indicates default mode of corresponding cell.

To inflate to a static pressure in the individual cell:

- ❖ Turn selector to the position



NOTE Green colour in the circle indicates default mode of corresponding cell.

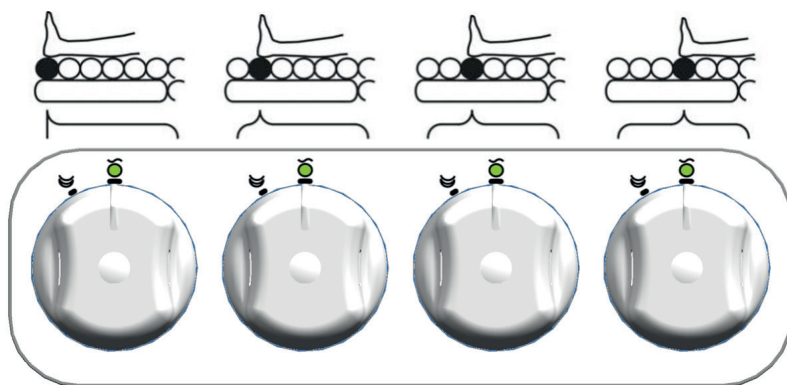


Fig. Heel Zoner

To deflate individual cell:

- ❖ Turn selector to the position



To inflate individual cell in APT Mode or CLP Mode:

- ❖ Turn selector to the position



NOTE Green colour in the circle indicates default mode of corresponding cell.

11.12 Seating System

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 LINET® dynamic 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 LINET Dynamic seat cushion is available in two versions replacement or overlay. In addition the overlay is available in two widths to fit smaller chairs if required.

The function of all cushion versions is the same but the fitting instructions vary.



Fig. Replacement Seat Cushion

11.12.1 Functioning

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

- ❖ Have seating system used only by or under supervision of trained and qualified nursing personnel.

Seat cushion:

- six cells (two sets of three)
- cells are inflated and deflated in 12 minute cycles

11.12.2 Installation of Seat Cushion

⚠ WARNING!
<p>Risk of injury due to unsuitable chair!</p> <ul style="list-style-type: none"> ➤ Suitable chair is in accordance with dimensions of the seat cushion (50 cm x 45 cm). ➤ There are no protruding parts or sharp objects on the surface of the seat base. ➤ Conduct risk evaluation if necessary.

⚠ WARNING!
<p>Risk of injury due to exposed cable!</p> <ul style="list-style-type: none"> ➤ Ensure that neither the air umbilical or SCU cable are twisted, crushed or strained. ➤ Ensure that neither the air umbilical or SCU cable present tripping hazard.

11.12.3 Replacement Seat Cushion

- ❖ If using the replacement seat cushion then remove existing seat cushion. If this is not possible, then a correctly sized overlay cushion is required.
- ❖ Ensure that chair supports weight of seat cushion.
- ❖ Place the 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 and lay the air pipes out through the side of the chair. If this is not possible then lay them along the side of the cushion or over the chair arm.
- ❖ Connect air pipe (see Connecting Mattress and SCU - chapter 9. 3).
- ❖ Put SCU on floor next to chair.

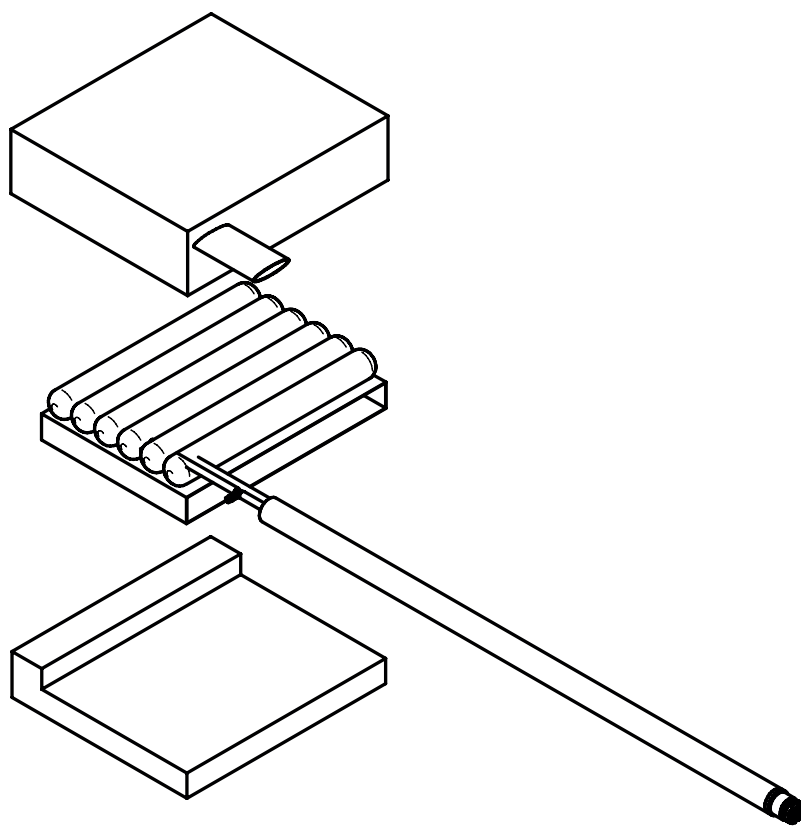


Fig. Replacement Seat Cushion (structure)

11.12.4 Overlay Cushion

- ❖ Remove any existing loose additional cushions that do not form part of the chairs original seating area.
- ❖ Ensure the chair supports the weight of the seat cushion and any arm rests are at a suitable height for the patient.
- ❖ Ensure that there are no protruding parts or sharp objects on the chair to avoid damage to the seat cushion.
- ❖ **Choose which position on the chair is best for the air pipes to be connected to the cushion.**
- ❖ **Then place the cushion on the chair with the picture that shows the chosen position at the front. The selected picture is hidden behind the patient's knees when a patient sits on the cushion. Cells inside the cushion cover are parallel to the width of the cushion from the front view.**
- ❖ If the standard air pipe that is provided to connect the cushion to the SCU is not long enough then additional extension air pipes can be used to achieve the most convenient positioning of the SCU. (See figure showing parts supplied with the standard overlay cushion).

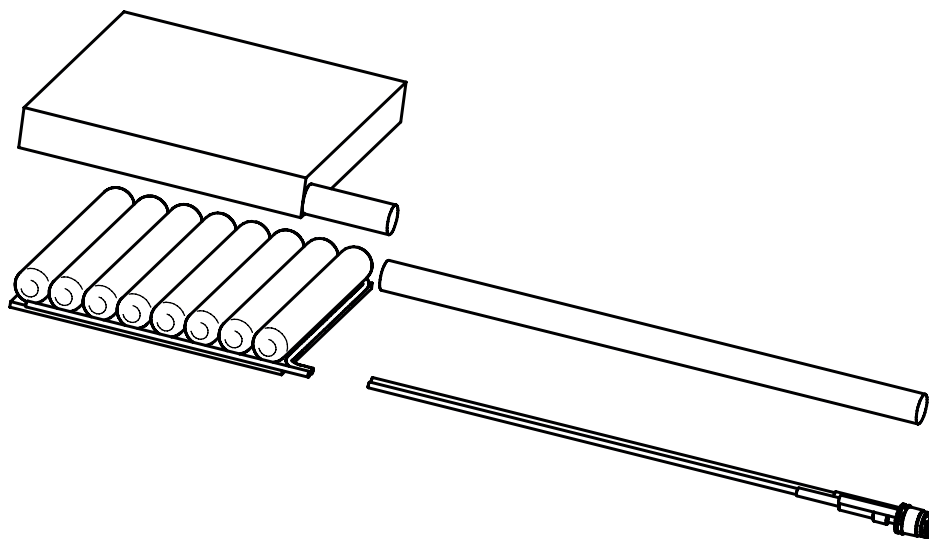


Fig. Overlay Cushion (structure)



Fig. Overlay Cushion (front right hand side exit)



Fig. Overlay Cushion (rear left hand side exit)

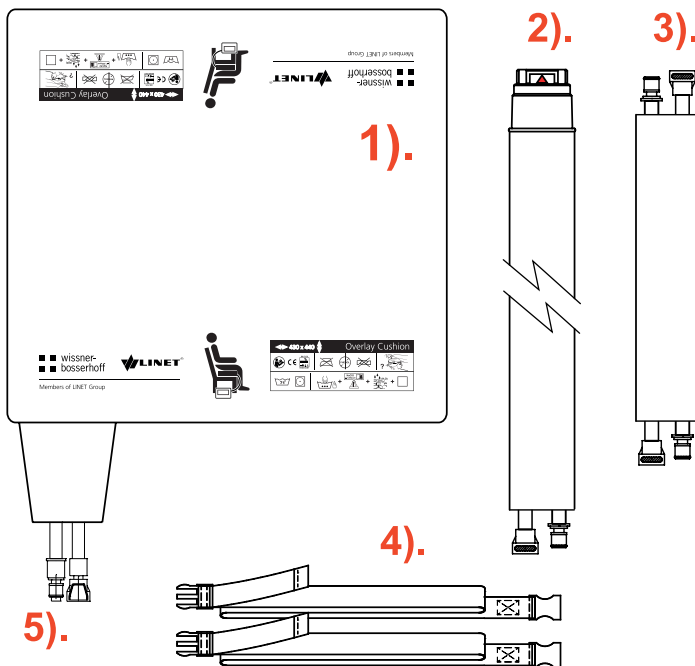


Fig. Components of the Overlay Cushion

1. The Overlay Cushion, with Internal cells and External Cover.
2. Air Umbilical with Air Connector.
3. Extension Umbilical, (Optional).
4. Two fixing straps, to secure the cushion to a chair if required.
5. Valved Cushion Connectors. (For Transport Mode).

The underside of the Cushion Cover has an Anti-Slip patch to reduce sliding of the cushion on the chair and has D-rings to which the fixing straps can be fastened, if required.

To deflate the overlay cushion after use disconnect the air connector from the SCU.

Transport Mode

Disconnecting the Cushion using the Valved Cushion Connectors, will retain the air present in the cells at the time of disconnection. Ensure there is air in both Cushion cell sets prior to disconnection. The Cushion Connectors can be joined together to equalise the pressure in both cell sets. Reconnect the cushion to the SCU as soon as possible if alternating pressure mode is required.

Straps

The base of the cushion has an anti-slip panel to help prevent the overlay cushion moving around when in use. If there are any concerns that the patient's own movements may put them at risk of falling due the cushion sliding off the chair then the optional fixing straps must be used. See instructions and pictures below.



Fig. Feed a loop of the strap through a D-ring. (Non-adjustable end).



Fig. Pass the strap end through the loop.



Fig. Pull the strap tight around the D-ring.



Fig. Run the strap to another D-ring and repeat for the Adjustable end of the strap. (The straps, if required can be fitted to the cushion from side to side, or from front to back and adjusted as necessary.)

11.12.5 Initial Operation

- ❖ 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 power switch on side of SCU.
- ❖ Indicator **6** flashes.
- ❖ Confirming signal sounds.
- ❖ Seat cushion is being inflated.

During the inflation process:

- Indicator **6** flashes white.

When the inflation process is finished:

- Indicator **6** lights solid.
- Cushion is ready for placement of patient.

NOTE *Pressure adjustment is not available in this mode.*

If indicator **6** flashes during inflation process and audio alert signal sounds:

- ❖ Check if air connector is connected correctly.

11.12.6 Use

WARNING!

Risk of injury when seating the patient!

- ➡ Ensure that seat cushion is completely inflated!

Preparation

- ❖ Inflate seat cushion (see Putting into Service).

Seating of 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.

12 Cleaning / Disinfection

⚠ CAUTION!
<p>Incorrect cleaning/disinfection can damage the mattress and SCU!</p> <ul style="list-style-type: none"> ➤ Do not use pressure or steam cleaners. ➤ Use the recommended cleaning agents only. ➤ 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.

For safe and gentle cleaning:

- ❖ Disconnect SCU from mains.
- ❖ Do not use any strong acids or bases (optimum pH range 6 - 8).
- ❖ 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 replacement system.
- ❖ 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.).
- ❖ 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.

LINET® recommends the following cleaning agents:

Cleaning agents	Manufacturer
Presept	Johnson&Johnson
Terralin, Mikrozyd, Thermosept	Schülke&Mayr
Bacillol Plus, Bacillocid Rasant, Microbac Forte, Dismozon Pur	BODE Chemie

12.1 Cleaning

Type of Cleaning	Parts to Clean
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

12.1.1 Routine Cleaning and Disinfection

Cleaning the mattress:

- ❖ Select Static mode in order to completely inflate all mattress cells (see Max Mode).
- ❖ Remove air connector and select Transport mode (see Transport Mode).
- ❖ 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.
- ❖ Allow mattress to dry or wipe it dry.
- ❖ Wipe mattress with disinfectant.
- ❖ Wipe mattress with cold water.
- ❖ Allow mattress to dry or wipe it 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.
- ❖ Allow SCU to dry or wipe it dry.

12.1.2 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.
- ❖ Allow mattress to dry or wipe it dry.
- ❖ Wipe mattress with disinfectant.
- ❖ Wipe mattress with cold water.
- ❖ Allow mattress to dry or wipe it dry.

Cleaning the mattress and cushion cover:

- ❖ Remove cover (see Removing the Mattress Cover).
- ❖ Wash cover in washing machine for 3 min at 71 °C.
- ❖ Tumble dry cover at low temperature.

Cleaning the air pipe:

- ❖ Wipe air pipe with cleaning agent or disinfectant.
- ❖ Rinse air pipe with cold water.
- ❖ Allow air pipe to 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.
- ❖ Allow SCU and filter to dry.
- ❖ Reinsert filter.

12.1.3 Removing the Mattress Cover

- ❖ Carefully open zipper under side skirt of mattress cover on foot end of mattress.
- ❖ Remove top part of mattress cover.
- ❖ Open clips in bottom part of mattress cover to remove mattress cells.
- ❖ Remove umbilical cover.
- ❖ Remove bottom part of mattress cover.

13 Troubleshooting

Problem	Symptom	Action (Equipment)	Action (Patient) 4
Mattress not working	Mattress does not inflate, feels too soft, and goes flat or not alternating. SCU lights are on.	Check umbilical air pipes are not severely bent, twisted or trapped in bed frame. 1	<p>If fault persists & there is sufficient air in the mattress put mattress into Transport mode before calling manufacturer's service department.</p> <p>If there is very little air in the mattress then transfer patient onto another mattress before calling manufacturer's service department.</p>
		If possible un-zip mattress cover and check mattress is not badly folded up under the patient and there is no obvious sound of escaping air. 1	
	Red CPR Indicator is on and audio alert is sounding.	Check air connector is properly in place. (see 9.3 Connecting Mattress and SCU on page 35) 1	
		Check correct mattress type is being used (not Virtuoso series 1,2 or Precioso). 2	
Mattress not working	No indicator lights on SCU	Check Mains power switch in side of SCU is in on position (I) and green Mains power indicator on control panel is on.	
		Check mains power chord is plugged into rear of SCU and protective cover is in place.	
		Check SCU is plugged into mains outlet that has been switched on.	
		If available connect Accumulator back-up pack. (see 10.2 Accumulator Back-up Pack on page 42)	
Mattress not working	Red System Error Indicator is flashing & audio alert is sounding. 3	Mute audio alert. (see 11.2.2 Mute on page 48)	
		Count number of times alert light flashes (1x - 6x). If fault persists turn SCU power off & back on. If fault persists turn SCU off & call manufacturer's service department.	
Mattress is working correctly	Yellow Service Due Indicator is on.	Arrange routine annual service safety check.	No action required.
Controls not working	SCU lights on but press any button & nothing happens.	Press & hold green GO button for 3 seconds then try controls again. If fault persists turn SCU power off & back on.	<p>If fault persists & there is sufficient air in the mattress put mattress into Transport mode before calling manufacturer's service department.</p> <p>If there is very little air in the mattress then transfer patient onto another mattress before calling manufacturer's service department.</p>
	Cannot select new mode after pressing green GO button.	SCU maybe in self-calibration mode which runs for up to 30 seconds when the power is turned on. Wait until green level indicators start flashing then try to select new mode again.	

Problem	Symptom	Action (Equipment)	Action (Patient) 4
	Cannot select MAX inflate mode	MAX mode has already been used for its maximum length of time and mattress must run in APT or CLP modes for at least 30 minutes before MAX mode can be used again.	If fault persists & there is sufficient air in the mattress put mattress into Transport mode before calling manufacturer's service department. If there is very little air in the mattress then transfer patient onto another mattress before calling manufacturer's service department.
Mattress will not run with Accumulator back-up pack connected.	No accumulator indicators on	Check Accumulator power switch on side of SCU is in on position (I).	
		Check Accumulator back-up pack is correctly fitted. (see 10.2 Accumulator Back-up Pack on page 42)	
		Accumulator may not have sufficient charge to run the SCU and will need to be connected to an SCU with the mains power connected and turned on for at least 1 hour before use. Find a charged accumulator.	
Fowler Boost Indicator does not come on		Check Backrest is raised to an angle of at least 30 degrees (Virtuoso Overlay, Virtuoso Mattress Replacement (Air + Foam Base), Virtuoso Mattress Replacement (Air + Static Air Base), Virtuoso Mattress Replacement (Air + Alternating Air Base)) or at least 11 degrees (Virtuoso With Head & Heel Zoner (Air + Alternating Air Base) and Virtuoso Pro).	If fault persists a patient can stay on the mattress. Use manual controls to increase pressure level by 1 when Backrest is raised to 30 ° or higher.
		Check Fowler Boost Cable is connected properly to the SCU. (see 9.3.2 Fowler Boost Connection on page 36)	
Fowler Boost Indicator stays on with Backrest down		Check Fowler Boost Cable is connected properly to the SCU & visually check the cable for damage.	
		If fault persists disconnect Fowler Boost Cable and call manufacturer's service department.	If fault persists a patient can stay on the mattress. Use manual controls to decrease pressure level as required for patient comfort and support.
		If seating system is connected instead of mattress no action required because this is a valid indication for connected seating system.	
Cushion connected and not working	Yellow Seat Cushion Indicator is not on	Check air connector is properly in place. (see 9.3 Connecting Mattress and SCU on page 35)	

Problem	Symptom	Action (Equipment)	Action (Patient) 4
Mattress or Cushion Air connector will not fit properly		Check air connector is not in Transport mode or has been damaged. (see 11.8 Transport Mode (Static and Active) on page 54)	If fault persists & there is sufficient air in the mattress put mattress into Transport mode before calling manufacturer's service department. If there is very little air in the mattress then transfer patient onto another mattress before calling manufacturer's service department.
Air connector will not release properly	Air connector will not come away from side of SCU. Red CPR Indicator does not come on & audio alert does not sound.	Press red CPR release button next to air connector and remove air connector with gentle lifting action. (see 11.6 CPR (umbilical connected) on page 53)	If fault persists & patient is at risk of needing CPR transfer the patient onto another mattress before calling manufacturer's service department.
Mattress moving around on bed frame		Check mattress securing straps have been attached to bed frame correctly. (see 4.8 Base Cover (all configurations) on page 22)	

1 Restart unit by turning power off then back on (see 9.5.1 Inflation on page 38). If Fault re-occurs turn off SCU and immediately call manufacturer's service department.

2 To Identify that the product type is being used check picture of series 3 SCU control panel and mattress. Also see quick identification table below.

Product type/model	Virtuoso Series 3	Virtuoso series 1 & 2	Precioso
SCU control panel colours	Light blue and light grey	Dark grey and yellow	Dark grey and medium blue turquoise
Mattress cover colours	Top surface dark blue	Top surface medium grey with yellow printing	Top surface medium grey with medium blue turquoise printing

3 If the System Error Indicator on the SCU is flashing red then please count the number of flashes (1x-6x) and tell the service engineer when reporting the fault.

4 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 11.8 Transport Mode (Static and Active) on page 54) to ensure that the patient is supported while waiting for a service engineer to arrive.

14 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.
- ▶ No part of the Virtuoso mattress shall be serviced or maintained while in use with a patient!



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.

14.1 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.

14.2 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

14.3 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.

15 Disposal

15.1 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).

15.2 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.

15.2.1 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.

15.2.2 Outside Europe

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

16 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)