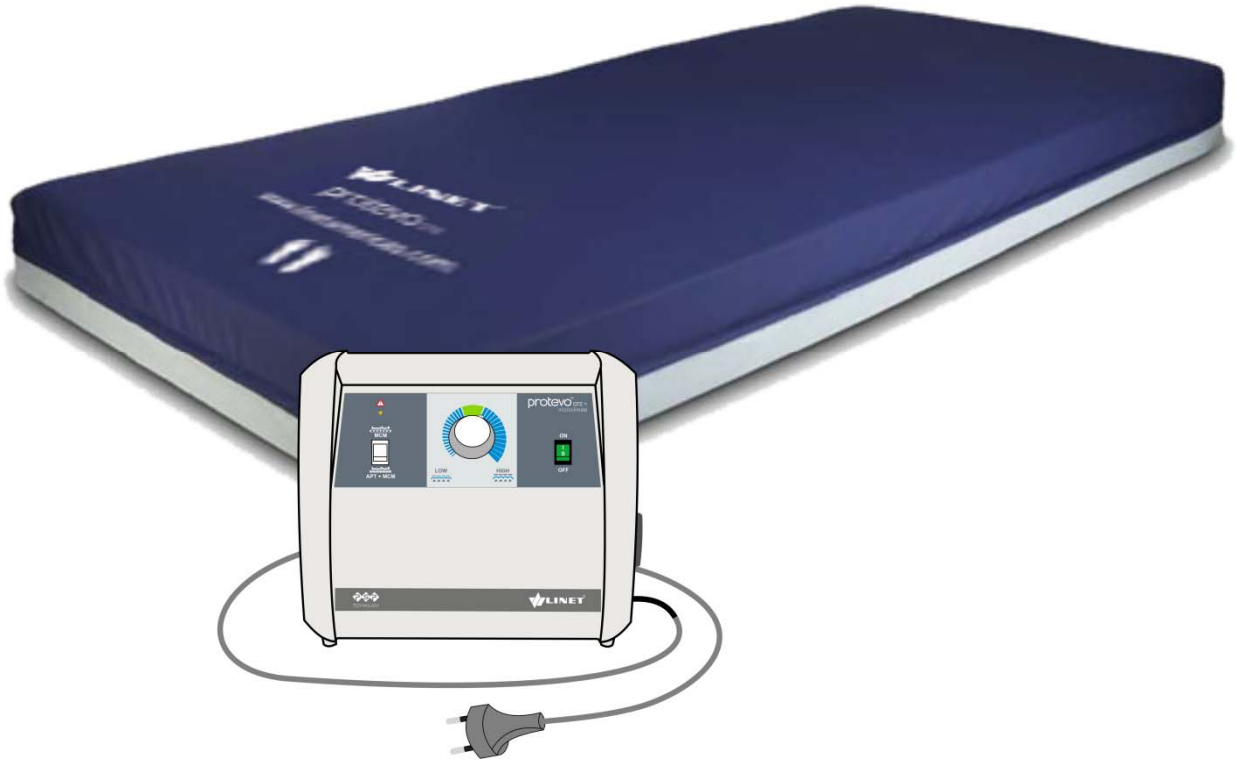
User manual and technical description



Protevo

Mattress Replacement System

9200-0671
Version: 03
Printdate: 03/2015

CAUTION!

➲ US Federal Law restricts this device to sale by or on the order of a licensed clinician.

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Protevo
Mattress Replacement System

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

Version: 03
Printdate: 03/2015

Content

1 Symbols

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 WORDS!

Type and source of danger!

➲ Measures to avoid the danger.

1.2 Other symbols

1.2.1 Instructions

Structure of instructions:

❖ Perform this step.

Result, if necessary.

1.2.2 Lists

Structure of bulleted lists:

- List level 1
  - List level 2

Structure of numbered lists:

a. List level 1

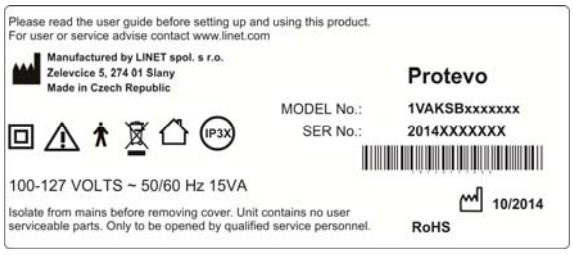
b. List level 1

1. List level 2
2. List level 2

1.3 Symbols and Labels on the Product

	Attention, see accompanying documents
	Only suitable for indoor use
	MET mark of conformity with US regulation
	2x 1A(T) anti-surge fuse
	Protection against accidents due to electrical current – Type B instruments
	Double insulation
	Power Switch **I :** On **O:** Off
	Alternating current
	Do not dispose of in a recyclable trash can

1.3.1 Serial label



The serial label is located on the back of the SCU (System Control Unit). The serial number and the model number can be found on the type plate. This information is required when contacting LINET.

Fig. 1 *Serial label*

2 Safety and Dangers

2.1 Safety Instructions

2.1.1 Before use

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

2.1.2 Installation

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

2.1.3 Usage

- Ensure that the mattress system is only operated by suitably qualified personnel or after receiving instruction from them.
- Only use the mattress system if it is in perfect working order.
- Only use the system in clean environment.
- Always hold SCU with scoop handle when moving.
- Only use the mattress system with the correct power supply (see Electromagnetic Compatibility).
- Replace any damaged parts immediately with original spare parts only.
- Do not exceed the maximum patient weight (see Mechanical Specifications).
- Do not use the SCU in near flammable gases. This does not apply to oxygen cylinders.
- Do not cover SCU while in use.
- Do not place SCU near extreme heat sources such as radiators.
- Never handle the power plug with wet hands.
- Disconnect the product from the outlet only by pulling the power plug. While pulling the power plug, always hold the actual plug, not the cord.
- Mattress and SCU must be checked at least once a day. Check that:
  - the mattress is inflated to the required pressure
  - the Low Pressure indicator is not pernamently illuminated
    in case of error refer to the chapter “System Faults”

2.2 Use and Storage Conditions

DANGER!

Risk of injury due using Protevo™ system in incorrect environments!

➲ Never use or store Protevo™ system in environments which contains flammable gases (except oxygen cylinders).

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

Ambient temperature	32 °F – 104 °F
Relative humidity	30% - 75%
Atmospheric pressure	795 – 1060 hPa
Dust and water protection (SCU)	IP 3X
IP Code 3X	Protected against ingress of solid foreign objects with diameter of >0.1 in.
Flammability rating (mattress & mattress cover)	Meets requirements of 16CFR1632. Federal flammability open flame standard for mattress sets when used without a foundation.
Enviroment	ISO 14001 2011/65/EU (RoHS) 2002/96/EC (WEEE)
Electromagnetic compatibility	IEC 60601-1-2

2.3 Specification of Use

Medical purpose:

- The Protevo™ system is a dual-mode pressure area care system. The mode of use must be determined by a suitably qualified medical practitioner by means of a risk assessment.
  - Have Protevo™ used only by or under supervision of trained and qualified nursing personnel.

Patient:

- For patients without restrictions in terms of health, age or condition with low – moderate risk of creating pressure ulcers and for whom the mattress platform is suitable.

Personnel:

- Qualified medical staff (nurse, doctor) with medical school or university qualification.

Use:

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

Bed:

- Bed with mattress platform width from 33.9'' to 35.4'' and with length 84.0''

Suitable beds:

- Multicare
- Multicare LE
- Eleganza 3
- Beds which meets criterias above

Transport:

- In original packaging.

2.4 Contraindication

WARNING!

Risk of injury due to incorrect use!

- Before placing a patient on a Protevo™ mattress, always have a qualified person perform a risk assessment to ensure that the support provided is appropriate and fulfills the applicable local stipulations.
- Do not use APT mode for patients undergoing cervical traction. STATIC mode can be used only under supervision of qualified person.
- When using mattress replacement or overlay systems, make sure to use safe and appropriate siderail positions and bed height settings. Which positions and settings are safe and appropriate may vary with the type of bed frame and siderails.

The Protevo™ system is contraindicated for patients with cervical traction or unstable:

- spinal fractures
- spinal cord injury
- fractures at risk of complication by a moving support surface
- mentally unstable patients

3 Standards and Regulations

The mattress complies with the following standards and directives:

- 93/42/EEC
- 2011/65/EU
- IEC 60601-1:2012
- IEC 60601-1-2:2007
- IEC 60601-1-6:2010
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013
- UL 60601-1:2003
- CFR Parts 800-1299: Title 21

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

- ISO 9001:2008
- ISO 14001:2004
- EN ISO 13485:2003

4 System Description

4.1 Mattress

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

4.1.1 Protevo™ GTE

Protevo™ GTE is an advanced pressure redistribution mattress that provides flexible therapy to help you meet the wound care needs of patient. Used without the control unit, Protevo™ GTE provides reactive pressure redistribution through self adjusting air cells. Easily convert the surface with optional control units to provide alternating pressure therapy (APT) or micro-climate management (MCM).

Fig. 2 *Protevo™ GTE mattress*

Comfort layer (top):

- height: 2.5 inches

Air layer (middle):

- 10 self-adjusting air cells absorb and displace patient weight
- when used with SCU, air cells alternate in pressure, and micro climate management is optional
- height: 4.5 inches

Base:

- non-slip layer
- height: 1 inches

Cover:

- 4-way stretch & waterproof cover

4.2 SCU (System Control Unit)

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

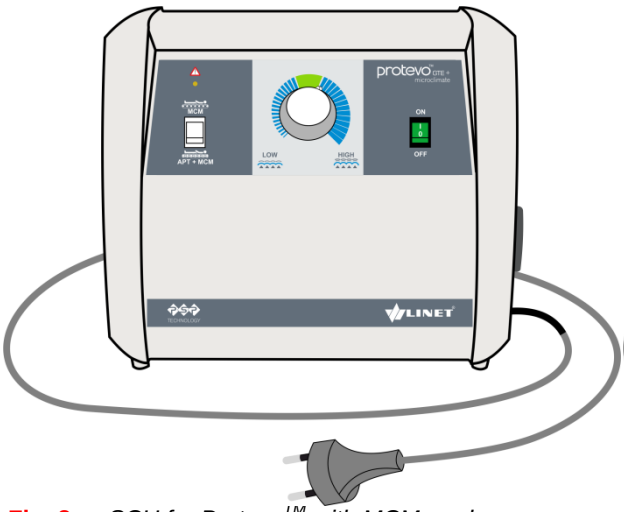


Fig. 3a *SCU for Protevo™ with MCM mode*

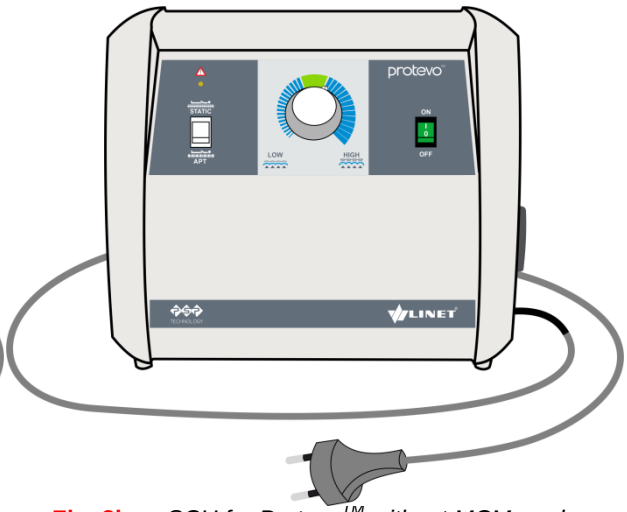


Fig. 3b *SCU for Protevo™ without MCM mode*

5 Scope of Delivery

5.1 Delivery

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

5.2 Contents

There are two versions of Protevo™. Check the table below to recognize your version.

Protevo™ with MCM mode:	**Protevo™ without MCM mode:**

■ Mattress with cover – Protevo™
  ■ 3 air connectors
■ SCU (System Control Unit) - Applied part type B
  ■ MCM and APT+MCM modes
■ User manual
	■ Mattress with cover – Protevo™
	  ■ 2 air connectors
	■ SCU (System Control Unit) - Applied part type B
	  ■ APT and STATIC modes
	■ User manual

6 Installation and Operation

6.1 Placing Protevo™ on the Bed

WARNING!

Material damage due to incorrect placement of the mattress!

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

WARNING!

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

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

CAUTION!

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

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

6.1.1 Installation – Protevo™ GTE Mattress

Before placing mattress on the bed:

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

To secure mattress on the bed:

- Place the Protevo™ mattress (in good condition and free of any damage or wear) on the mattress platform, with the air pipe at the patients left foot side (foot symbol on the mattress cover determines placement) and position so that the mattress is centred.
- Check if the mattress, air pipe or the SCU is not colliding with any part of the bed or if the mattress is not preventing side rails in its movement.
- Allow the mattress surface to recover from shipment 24 hours before use.
- After 24 hours, the mattress is ready to use. If the mattress does not appear to have recovered, do not use it and contact your distributor.

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

6.2 Installation of SCU (System Control Unit)

WARNING!

Risk of injury when installing SCU!

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

WARNING!

Risk of injuring the patient or damaging the accessories due to incorrect installation!

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

CAUTION!

Material damage due to incorrect installation of SCU!

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

If foot end of bed frame is suitable for hanging SCU:

- ❖ Hold SCU in one hand and unfold hooks on back with the other.
- ❖ Hang SCU on bed end of bed frame (see Fig. 4a).

If foot end of bed frame is not suitable for hanging SCU:

- ❖ Stand the SCU upright on the floor (see Fig. 4b).

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

Fig. 4a *Installation of SCU on the foot end*

Fig. 4b *Installation of SCU on the floor*

6.3 Connecting Mattress with SCU

Installation:

- Insert air connector **1** in the socket **2** at an angle of approx. 45° (see Fig. 5).
- Push air connector **1** down until it clicks into place and air connector latch **3** secures the air connector against dropping off.

Fig. 5 *Installation of SCU*

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

6.4 Connecting Air Pipes with Mattress

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

6.4.1 Mattress with MCM mode

Connect air pipes as follows:

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

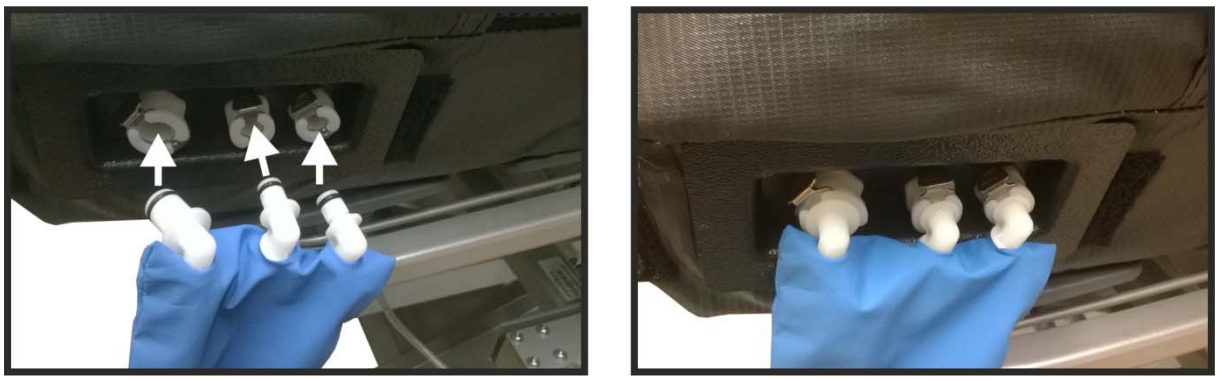


Fig. 6a *Connecting air pipes to the mattress with MCM mode*

6.4.2 Mattress without MCM mode

Connect air pipes as follows:

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

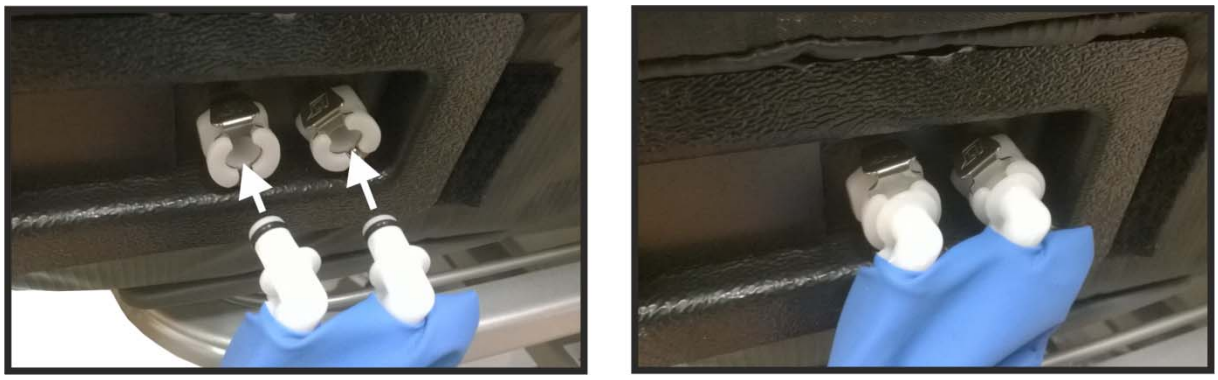


Fig. 6b *Connecting air pipes to the mattress without MCM mode*

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

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

6.5.1 Mattress with MCM mode

Disconnect air pipes as follows:

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

Air pipes are removed from the mattress.

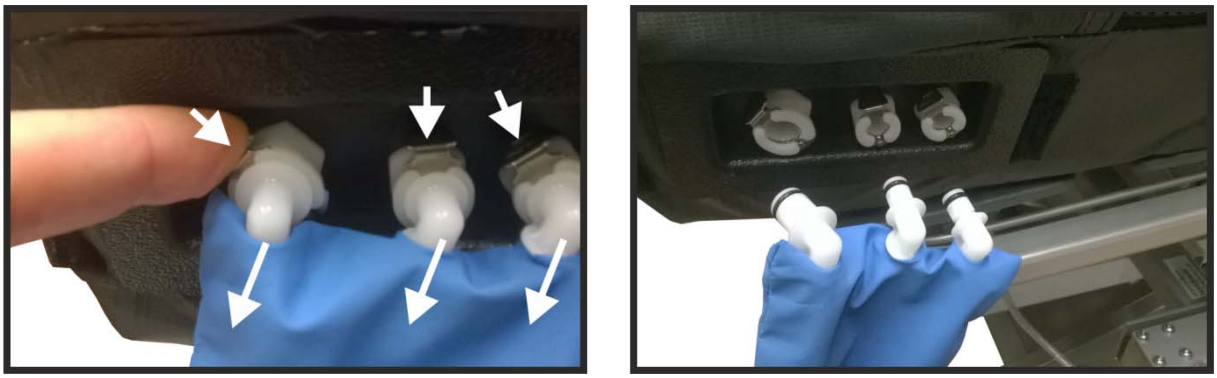


Fig. 7a *Disconnecting air pipes from the mattress with MCM mode*

6.5.2 Mattress without MCM mode

Disconnect air pipes as follows:

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

Air pipes are removed from the mattress.

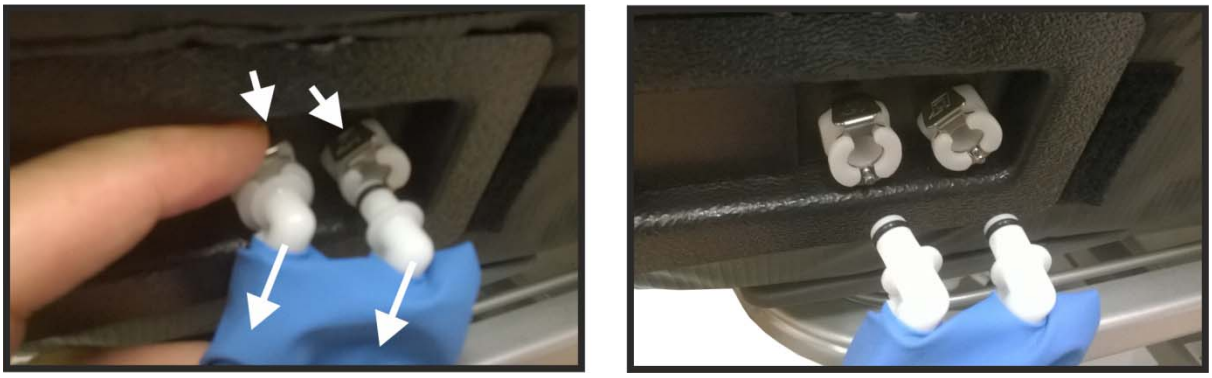


Fig. 7b *Disconnecting air pipes from the mattress without MCM mode*

7 Initial Operation

The SCU is operated via the SCU control panel (see Control Panel).

7.1 Inflation

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

7.1.1 Switching SCU ON/OFF

To switch ON SCU:

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

SCU has been switched on.

To switch OFF SCU:

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

SCU has been switched off.

Fig. 8 Switching on SCU

7.1.2 Inflation

Inflation:

- Select required mode (see chapter “Control panel – Protevo™”).
- After switching ON the mattress will start to inflate, the indicator ⚠ is illuminated during inflation. Set the pressure control dial into middle – green position (see Controls and Indicators).
- Inflation may take up to 18 minutes. When inflation is complete, the indicator ⚠ is no longer illuminated.

When the inflation process is finished:

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

If indicator ⚠ is illuminated longer than 25 minutes:

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

8 Use

8.1 Preparing the Bed for the Patient

DANGER!

Risk of injury when putting patient into bed!

Before putting patient on the bed:

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

WARNING!

Danger of suffocation due to vapor permeable mattress cover!

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

CAUTION!

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

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

8.1.1 Preparation

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

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

NOTE: *It is possible to inflate mattress with patient on the mattress. Manufacturer recommends to inflate mattress without load first and then place patient on it.*

8.1.2 Putting Patient into Bed

- ❖ Lay patient on mattress.

For an ideal lying position:

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

9 Controls and Indicators

9.1 Control panel – Protevo™ with Micro-climate management

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

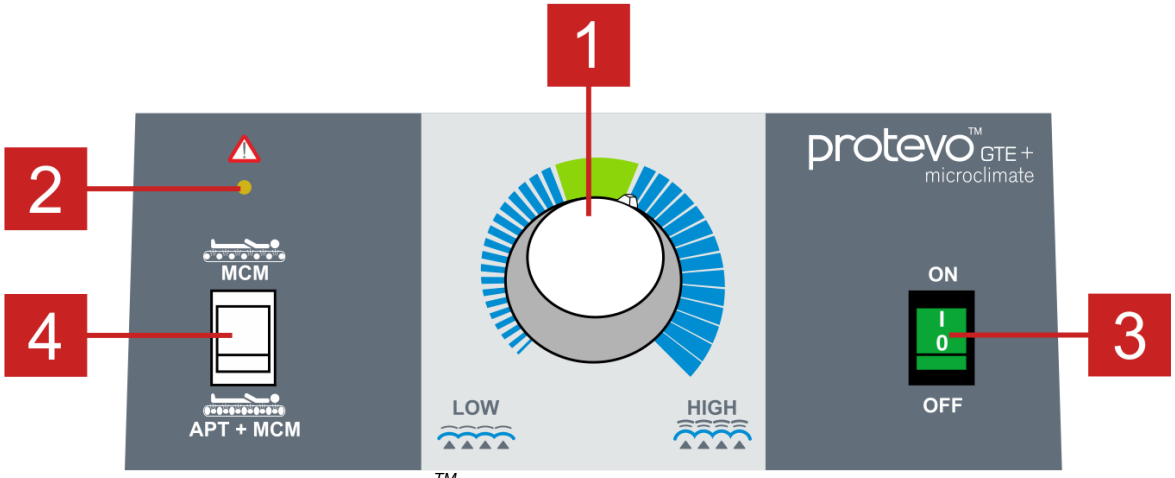


Fig. 9 *SCU Control Panel – Protevo™ with MCM mode*

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

9.1.1 MCM – Micro-climate management

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

When MCM mode is selected:
SCU will inflate the 8 air cells under the patients torso to the same pressure.

9.1.2 APT+MCM – Alternating pressure therapy + Micro-climate management

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

When APT mode is selected:

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

9.2 Control panel – Protevo™ without Micro-climate management

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

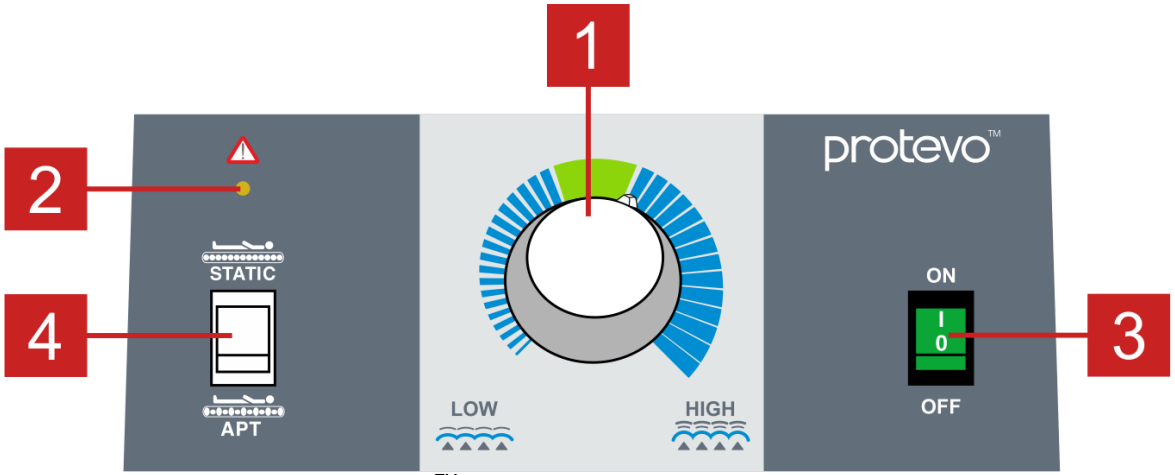


Fig. 10 *SCU Control Panel – Protevo™ without MCM mode*

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

9.2.1 APT – Alternating pressure therapy

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

When APT mode is selected:

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

9.2.2 STATIC – Static inflated mode

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

When STATIC mode is selected:

- SCU will inflate all cells to the same pressure.

9.3 Pressure Control

WARNING!

Risk of injury due to incorrect pressure setting!

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

9.3.1 Pressure Settings - Mattress

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

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

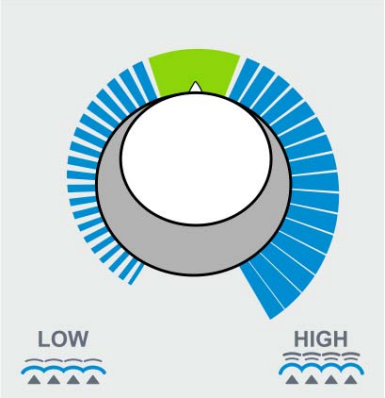


Fig. 11 *Pressure levels control*

To adjust pressure:

- ❖ Turn the rotating dial to the left to decrease pressure.

-OR-

- ❖ Turn the rotating dial to the right to increase pressure.

Pressure levels:

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

Select pressure as follows:

With the mattress fully inflated using MCM or STATIC mode.

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

9.3.2 Pressure Settings – Changes in Patient's Position

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

Select pressure as follows:

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

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

10 Additional Functions

10.1 CPR – Cardipulmonary resuscitation

Fig. 12 *CPR Function*

Before starting CPR with SCU connected:

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

10.2 Power failure

WARNING!

Risk of injury due to power failure!

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

In case of power failure the mattress will remain inflated for at least 12 hours. No active modes are available without power power.

10.3 System faults

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

NOTE: *During initial inflation the low pressure indication will come on until the mattress has achieved its minimum pressure. This does not mean there is a fault unless the indicator has been on for more than 30 minutes after a power cycle.*

Protevo™ SCU	
Meaning	**Indicator**
Low pressure	Low pressure indicator is illuminated
Power failure	Power switch is not illuminated

Table 1 *Error indications Protevo™ SCU*

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

Table 2 *Troubleshooting*

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

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

11 Cleaning/Disinfection

CAUTION!

Incorrect cleaning/disinfection can damage the system!

- Do not use pressure or steam cleaners.
- Follow the instructions and observe the dosages recommended by the manufacturer.
- Ensure that disinfectants are selected and applied by qualified hygiene experts only.
- Continued use of high concentration, chlorine-based disinfectants may significantly reduce the performance and the working life of a coated material.
- Refer to CDC guidelines (see http://www.cdc.gov).

11.1 General Guidance

For safe and gentle cleaning:

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

Mattress parts to be cleaned	Recommended Cleaning Agents (General cleaning)
Top Cover	Standard hospital detergents, Alcohol or Quaternary Ammonium based disinfectants, Chlorine based disinfectants containing up to 1000 ppm (0.1%) Chlorine, (1:50 dilution of household chlorine bleach), followed by rinsing with water and drying thoroughly before use.
	Decontamination: Blood spills/C-diff. etc
	Chlorine based disinfectants containing up to 5,500 ppm (0.55%) Chlorine, (1:10 dilution of household chlorine bleach), followed by rinsing with water and drying thoroughly before use.
Base Cover	As procedures above.

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

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

Type of Cleaning	Parts to be cleaned
Routine Cleaning and Disinfection	■ exposed mattress parts ■ exposed SCU parts
Full Cleaning and Disinfection	■ exposed mattress parts ■ exposed SCU parts

11.2 Routine Cleaning and Disinfection

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

Cleaning the mattress:

- Check mattress cover top for any signs of damage or for liquid ingress. Any fluid contamination inside the mattress means the entire mattress must be replaced.
  Replace or repair and completely disinfect mattress cover top if damaged.
- Leave mattress cover on mattress.
- Clean with 122 °F warm water and cleaning detergent.
- Rinse mattress with cold water.
- Let mattress air dry or wipe dry.
- Wipe mattress with disinfectant.
- Rinse mattress with cold water.
- Let mattress air dry or wipe dry.

Cleaning the SCU:

- Wipe SCU with disinfectant.
- Let SCU air dry or wipe dry.

11.3 Full Cleaning and Disinfection

CAUTION!

Incorrect cleaning/disinfection can damage the system!

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

Cleaning Top/Base Cover and Internal Air Cells:
Read section “General Guidance” for more details of the recommended cleaning and disinfection processes. Use standard hospital detergents, Alcohol-based cleaners or Quaternary Ammonium based disinfectants. Suitable Chlorine based cleaners can be used at a concentration of 1000ppm. Stronger concentrations of chlorine can be used if required, of up to 10,000ppm (1%) Chlorine, (1:5 dilution of household chlorine bleach), with a maximum dwell time of two minutes at 10,000ppm, followed by rinsing with water and drying thoroughly before use.

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

Cleaning the mattress:

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

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

Machine washing of Protevo GTE removable top mattress cover:

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

NOTE: *Maximum washing temperature 167 °F.*

Cleaning the air pipe:

- Wipe air pipe with cleaning agent or disinfectant.

-or-

- Remove the air pipe cover and clean it as stated above if full disinfection is required.
- Let air pipe dry.

Cleaning the SCU:

- Remove filter.
- Wash the filter or replace it with the new one.
- Wipe SCU with disinfectant.
- Let SCU and filter dry.
- Reinsert filter.

11.4 Removing the Mattress Cover

- Carefully open zip under side skirt of mattress cover on foot end of mattress.
- Remove top part of mattress cover. Inspect cover and clean if necessary.

After cleaning the mattress cover:

- Reinstall mattress cover by reversing the process described above.

12 Maintenance

Check at least every 12 months:

- Check mattress and SCU externally and internally for mechanical damage or signs of severe wear and tear.
- Check if mattress and air connector are fully operational.
- Check if the mattress, air pipe or the SCU is not colliding with any part of the bed or if the mattress is not preventing side rails in its movement.
- Perform electrical safety checks as defined by your local safety regulations.
- Replace the filter.

Check every month:

- Check filter in top left of SCU for dust and dirt.
- If dust or dirt is visible: Pull out, clean and reinsert filter.
- Replace any damaged parts immediately with original spare parts only.
- Ensure that maintenance and installation are performed only by qualified personnel who have been trained by the manufacturer.
- LINET provides service documentation for qualified personnel.

12.1 LINET Service

Our responsible LINET Service partners will ensure your LINET products are up and running when you need them. For more information on available service support and contract offerings, please contact us at **877-815-8895** and ask for technical support. LINET's nationwide network of highly skilled service providers that are equipped to service and maintain your LINET equipment at the highest level.

13 Storage

CAUTION!

Incorrect storage can damage the mattress!

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

When SCU is not in use:

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

When mattress is not in use:

- Store flat, unfolded and in dust proof bag.
- Store in a place suitable for medical devices.

14 Disposal

14.1 Environmental Protection

LINET is aware of the important role that the protection of our environment plays for future generations.

The materials of this product are environmentally compatible. It does not contain hazardous substances on the basis of cadmium, mercury, asbestos, PCB or CFC. Noise emissions and vibrations meet the directives for healthcare facilities. LINET has taken care to ensure all wood used in the production of its bed systems is responsibly source (Mahagony, Jacaranda, Ebony, Teak or wood from Amazonian rainforests are not used).

Packaging materials are produced according to the respective directives. Please ensure packaging materials are disposed of according to the symbols displayed and taken to an authorised disposal location.

The product consists of recyclable steel, plastic and electronic components.



14.2 Disposal

To dispose of the appliance (SCU):

- When you dispose of your appliance do not put it into household waste.
- Appliances should be taken to an authorised electrical appliance recycling location.

Materials of the appliance may be reused. When recycling or reusing old appliances you are making an important contribution in the protection of the environment.

- Ask the responsible environmental protection authorities for the appropriate disposal point.
- Observe local and country-specific specifications for disposal.

15 Warranty

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

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

- Do not continue to use the product.

16 Technical Specifications

16.1 Mechanical specification

Dimensions	
■ **Protevo™ GTE and GTE+MCM for Multicare bed**	85.50 x 35.00 x 8.0”
■ **Protevo™ GTE and GTE+MCM for flat deck**	84.00 x 35.00 x 8.0”
■ **Protevo™ ST and APC for flat deck**	84.00 x 35.00 x 7.0”
■ **SCU**	10.25 x 4.75 x 8.5“
Weight	
■ **Protevo™ GTE**	26.5 lbs.
■ **Protevo™ System Control Unit**	5.5 lbs.
Cycle	
■ **Mattress (inflated)**	2 cells technology, 12 minutes
Environmental conditions	
■ **Temperature**	32 °F – 104 °F
■ **Humidity**	30% - 75%
■ **Atmospheric pressure**	795 – 1060 hPa
Maximal load (SWL)	
■ **Protevo™ GTE**	550 lb.
Inflation time	
■ **Mattress**	up to 18 min
Deflation time (CPR)	Max. 30 s
Noise level	35 dBA

16.2 Electrical specification

Supply nominal voltage	
■ **Model 127V**	100-127 VAC, 60 Hz
Maximal power Protevo™	
■ **Model 127V**	15VA
Power plug	NEMA Type 1-15P polarized
Fuse	
Protevo™	2x (T 1A L) anti-surge fuse (250 V, type 5x20mm)
Electrical safety class	Class II with applied parts type B
Electrical safety	In conformity with UL 60601-1

16.3 Electromagnetic compatibility

Protevo™ requires special preliminary measures pertaining to EMC that necessitates installation and commissioning in conformity with the EMC information given in this Manual.

WARNING!

Increased electromagnetic radiation or reduced electromagnetic resistance due to unsuitable accessories, converters or cables!

➲ Consult LINET or local dealer before using other parts than those provided by LINET.

WARNING!

Material damage due to electromagnetic radiation!

➲ Do not use electrical equipment near Protevo™ system.

➲ Do not use Protevo™ in close proximity to:

- ➲ sources of radio frequency
- ➲ other equipment not approved according to IEC 60601-1-2
- ➲ equipment whose performance affects this product
- ➲ equipment that is affected by electromagnetic fields radiating from this product

If it is necessary to use the mattress near electrical equipment:

- Observe whether the mattress functions normally.
- If any abnormal properties are observed, move or relocate the mattress.

NOTE: *Continuing in its selected mode of operation or permanent deflation of the mattress is considered the essential performance of Protevo™.*

Protevo™ is intended for the application in electromagnetic environment as specified below. The customer or user of the bed is responsible for these requirements are met.

16.3.1 Manufacturer's Manual and Declaration - Electromagnetic Radiation

Radiation Test	Conformity	Electromagnetic Environment
High-frequency radiation CISPR 11	Group 1	Protevo™ utilizes high-frequency energy for its internal function only. The high-frequency radiations are very low and unlikely to cause any interference to nearby electronic devices.
High-frequency radiation CISPR 11	Class B	Protevo™ is suitable for all institutions, including households and objects directly connected to the public low-voltage power supplying residential buildings.
Harmonic radiations IEC 61000-3-2	Class A	
Fluctuating voltage/Flashing radiation EC 61000-3-3	Satisfactory	

16.3.2 Manufacturer's Manual and Declaration - Electromagnetic Resistance

Resistance Test	Test Level as per IEC 60601	Level of Compliance	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV for contact ± 8 kV for air	± 6 kV for contact ± 8 kV for air	❖ Ensure that the following requirements are met: Floors: wood, concrete or ceramic tiles Relative humidity: >30%
Electrical fast transient response/ group of impulses IEC 61000-4-4	± 2 kV in feeder line ± 1 kV in input/output line	± 2 kV in feeder line ± 1 kV in input/output line	❖ Ensure the power quality is suitable for a commercial or hospital environment.
Shock pulse IEC 61000-4-5	± 1 kV between lines ± 2 kV between line (lines) and earth	± 1 kV in differential mode ± 2 kV in co-phasal mode	❖ Ensure the power quality is suitable for commercial or hospital environment.
Short-time voltage drop, short-duration interruptions and slow voltage changes on the feeder input line IEC 61000-4-11	<5 % UT (>95 % short-duration drop of UT) within 0.5 cycles 40 % UT (60 % short-duration drop of UT) within 5 cycles 70 % UT (30 % short-duration drop of UT) within 25 cycles <5 % UT (>95 % short-duration drop of UT) within 5 s	<5 % UT (>95 % short-duration drop of UT) within 0.5 cycles 40 % UT (60 % short-duration drop of UT) within 5 cycles 70 % UT (30 % short-duration drop of UT) within 25 cycles <5 % UT (>95 % short-duration drop of UT) within 5 s	❖ Ensure that power quality is suitable for a commercial or hospital environments. ❖ For permanent operation during a power failure, connect the bed to a power generator as the back-up battery's capacity is limited.
Magnetic field of network frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	❖ Ensure the magnetic fields of the network frequency conform to the normal levels of commercial or hospital environments.

NOTE *UT refers to the AC power voltage before the test level is applied.*

Resistance Test	Test Level as per IEC 60601	Level of Compliance	Electromagnetic Environment
Conducted high frequency phenomena IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	❖ Do not use portable and mobile HF communication equipment near the bed. ❖ Observe the distances indicated below. Recommended distances: d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz P is the rated maximum output power of the transmitter in Watts (W) defined by the transmitter's manufacturer. d is the recommended separating distance in metres (m). ❖ Ensure the field intensities of permanent HF transmitters determined by the summary of electromagnetic characteristics for the given place do not exceed the satisfactory level b in each frequency range. Interferences are possible in the vicinity of the instrument marked with the following symbol: 
Radiated high-frequency phenomena IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

a It is not possible to accurately indicate field intensities from permanent transmitters (e.g. radio base stations of the radio, phones and ground mobile and amateur radio stations, AM and FM radio and television broadcasting). To assess the electromagnetic environment for permanent HF transmitters, take into account the on-site electromagnetic characteristics.
If the measured field intensity is higher than the pertinent satisfactory HF level stated above, observe whether the bed is functioning normally.
If any abnormal properties are observed, move or relocate the bed.
b The field intensity in the entire frequency range from 150 kHz to 80 MHz should be lower than 3 V/m.

NOTE *With 80 MHz and 800 MHz, the higher frequency range is applicable.*

NOTE *The absorption and reflection of buildings, objects and people will influence electromagnetic propagation*

Recommended separation distances between portable and mobile RF communications equipment and the Protevo™

Protevo™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Protevo™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Protevo™ as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.12	0.40	0.40
0,1	0.37	1.26	1.26
1	1.17	4.00	4.00
10	3.69	12.65	12.65
100	11.67	40.00	40.00

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

17 Log

17.1 Delivery Log

Order number:	
Customer:	
Model number:	
Serial number:	
Delivery date:	
Delivered by:	

I hereby confirm personnel have been trained to correctly operate the bed.

Date:

Customer‘s Signature and Seal:

Supplier’s Signature and Seal:

17.2 Service and Maintenance Log

Description of Service	Date	Performed By