User manual and technical description

Eleganza 1

Hospital bed for standard care

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Hospital bed for standard care

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

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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** indicates potential damage to property.
- **Warning** warns against bodily injury.
- **Danger** warns against potential mortal 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.

Results, if necessary.

1.2.2 Lists

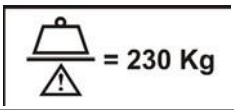
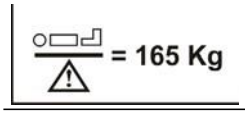
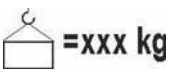
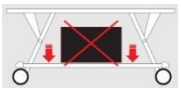
Structure of bulleted lists:

- 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

	Read user manual.
	Attention
	Thermal protection of transformer
	Only suitable for indoor use
	Protection against accidents due to electrical current - Type B instruments
	Safety isolating transformer, general
	CE mark
	TÜV mark
	Jack for attachment of conductor for potential equalisation
	Serial label
	Safe working load
	Warning against crushing or trapping
	Maximum weight of patient
	Use mattress recommended by manufacturer.
	Weight of bed
	Do not put any objects here.

2 Safety and Dangers

2.1 Safety Instructions

- Follow the instructions carefully.
  Any non-observance of this manual may lead to injuries or damage of property.
- Exclusively use the bed if it is in perfect working order.
  If necessary, check the bed functions daily or at each shift change.
- Use the bed exclusively in its original condition.
- Use the bed exclusively with the correct mains supply.
- Ensure that the bed is exclusively operated by qualified personnel.
- Ensure that the patient (health permitting) has been informed about the operation of the bed and all applicable safety instructions.
- Move the bed exclusively on even, hard-surfaced floors.
- Replace any damaged parts immediately with original spare parts.
- Ensure that maintenance and installation are performed exclusively by qualified personnel who have been trained by the manufacturer.
- Do not apply excess weight or loads to the bed according to SWL (Safe Working Load).
- During peak loads or unavoidable excess loads (CPR), place the mattress platform in the lowest position.
- Ensure that only one adult patient uses the bed at any time.
- Take care to avoid squeezing when operating moving parts.
- When using lifting poles or infusion stands, ensure that nothing will be damaged when you move or adjust the bed.
- Ensure that the castors are braked when the bed is occupied or not being moved.
- Ensure that the castors are braked when the bed is not being moved, regardless of whether it is occupied or empty.
- Keep the mattress platform in the lowest position at any time when the healthcare personnel are not treating the patient in order to prevent the patient from falling or injuries.
- Ensure that siderails are operated exclusively by healthcare personnel.
- Never use the bed in areas where there is a hazard of explosion.
- Enable or disable functions on the handset using the supervisor panel as appropriate for the patient's physical and mental state. Verify that the function is actually disabled.
- Never handle the mains plug with wet hands.
- Remove the mains cable exclusively by pulling on the plug.
- Position the mains cable so that there are no loops or bends 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 the bed.
- Ensure that the stipulated duty cycle (on-time) is not exceeded (see INT. on product label).
- Ensure that the moving parts of the bed are not blocked.
- To prevent failures, use exclusively the manufacturer's original accessories and mattresses.
- Ensure that the stipulated safe working load is not exceeded.
- If the patient's condition could lead to an entrapment, leave the mattress support platform in the flat position whilst unattended.
- Adjust bed height to approx. 20 cm below maximum height when transporting the bed in order to facilitate overcoming possible obstacles.
- Do not exceed maximum load of 150 kg for mattress platform extension.
- Ensure that the bed and its components are exclusively modified with the manufacturer´s approval.

- ❖ Ensure there is no danger of crushing or otherwise injuring the patient's limbs (e.g. between siderails and mattress platform, between movable parts etc.) before positioning the bed or collapsing the siderails.
- ❖ Close linen shelf before using the Reverse Trendelenburg position.
- ❖ Do not put any objects (e.g. accessories, infusions, cables) between or on siderails and movable parts.
- ❖ Use exclusively split plastic siderails for confused or disoriented patients.

2.2 Conditions of use

The bed may be used and stored in indoor environments where:

- the surrounding temperature is between + 10 °C and + 40 °C
- the relative humidity is between 30% and 75%
- the atmospheric pressure is between 700 hPa and 1060 hPa

The bed may not be used and stored in indoor environments:

- where there is a risk of explosion
- containing inflammable anaesthetics

The bed is designed for use in rooms for medical purposes. Electrical installations must therefore meet local standards laying down the necessary conditions for electrical installations.

- ❖ Disconnect the bed from the mains in exceptional cases (i.e. a storm).

3 Standards and Regulations Atitikimas punkto Nr.: 24

The bed complies with the following standards and directives:

- IEC 60601-1 ed. 3:2006
- IEC 60601-1-2 ed. 3:2007
- IEC 60601-1-6:2010
- IEC 60601-2-52:2010
- IEC 980:2008
- ISO 10993-5:2009
- ISO 10993-10:2010
- 93/42/EEC
- 2011/65/EU

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 Functioning

4.1 Correct Use

Eleganza 1 is a standard care hospital bed. It is designed for supporting the patient in several positions such as horizontal, Trendelenburg, Cardiac Chair etc.

The stable undercarriage with 4 castors makes it possible for the bed to be controlled by one person.

Eleganza 1 is suitable for:

- Patients
  - older than 15 years
  - whose weight (including mattress and accessories) does not exceed the SWL
- Personnel
  - qualified medical staff
  - any person familiar with the manual
  - patient (condition permitting)
- Use
  - standard care
  - uninterrupted operation
- Location
  - application environments 1, 2 and 3 according to EN 60601-2-52:2010

4.2 Incorrect Use

The bed is not suitable for:

- Patients
  - younger than 15 years
- Use
  - intensive care

NOTE *For information concerning uses other than those outlined in the "Correct Use" section above, please contact LINET®.*

LINET®'s efforts in research, design and manufacture ensure LINET® products are of the highest quality and fit for their intended purpose. However, LINET® can take no responsibility for any damage to the products or any harm to patients, staff or other individuals resulting from:

- Not following the instructions in the manual, including warning notices.
- Using the product for a purpose other than the intended purpose stated in the relevant documentation provided by LINET® (see Correct Use).

Danger

Risk of injury or death due to use of incorrect equipment!

❖ Always conduct the risk assessments required for the selection of suitable equipment.

❖ Do not use the bed in private homes without qualified supervision.

NOTE *For information concerning uses other than those outlined in the "Correct Use" section above, please contact LINET®.*

NOTE *The manufacturer shall not be liable for any damage, injury, etc. due to incorrect use.*

5 Scope of Delivery and Bed Variants

5.1 Scope of Delivery

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 make a note of them on the delivery note.

5.2 Bed variants and Features

Model 1GT Hospital Bed (model no. see product label)

- Mattress Platform
  - mattress platform consisting of removable plastic segments
- Bed Ends
  - design E3 - plastic bed ends
  - powder-coated bed ends with fixed coloured HPL panels, suitable for extension systems
- Siderails
  - without siderails
  - single collapsible siderails, powder-coated
  - split plastic siderails
- Castors Ratukai **Atitikimas punkto Nr.: 17**
  - Tente Motion 125 mm with individual braking system
  - Tente Motion 125 mm with central braking system
  - Tente Motion 150 mm with central braking system 150 mm su centrine stabdžių sistema
  - Tente Motion 150 mm with central braking system and 5th castor
- Control Elements
  - supervisor board
  - supervisor panel
  - handset
    with illuminated keyboard
    without illuminated keyboard
  - satellite control panel
  - control element integrated in siderail (only for split plastic siderails)
  - foot controls
- Other features
  - linen shelf
  - vertical safety bumpers
  - 1 pair of backrest angle indicators (only for split siderails)
  - 1 pair of urine bag holders
  - 1 pair of accessory rails
  - CPR emergency backrest release
  - brake alarm
  - Segufix holder
- Colour concept (Dažžžymas) **Atitikimas punkto Nr.: 1**
  - powder-coated metal parts, RAL 9002 (white) (Dengta miltelinių būdu- metalinės dalys (balta))
  - powder-coated metal parts, RAL 9006 (light gray) (Dengta miltelinių būdu- metalinės dalys (pilka))

Model 1GTD - Nursing Care Bed (model no. see product label)

- Bed Ends
  - design T - wooden bed ends
  - design Altura - wooden bed ends
- Siderails
  - without siderails
  - single collapsible siderails, powder-coated
- Castors
  - Tente Motion 125 mm with individual braking system
  - Tente Motion 125 mm with central braking system
  - Tente Motion 150 mm with central braking system with 5th castor
- Control Elements
  - supervisor panel
  - foot controls
  - handset
    with illuminated keyboard
    without illuminated keyboard
  - satellite control panel
- Other features
  - 4 head and foot end bushings for accessories
  - 2 head end bushings for accessories
  - brake alarm
  - Segufix holder
  - linen shelf
  - safety bumpers
    vertical
    horizontal
    without
  - 1 pair of urine bag holders
  - 1 pair of accessory rails
  - CPR
    CPR emergency lever
    CPR emergency backrest release
    without mechanical CPR system
- Colour concept
  - powder-coated metal parts, RAL 9002 (white)
  - powder-coated metal parts, RAL 9006 (light gray)

Caution

Damage to the bed due to incorrect use!

- use 125 mm castors exclusively on flat, even surfaces without any gaps.

6 Setup

6.1 Transport

To avoid damage during transport, please observe the following guidelines:

- Ensure that no cables are run over when moving the bed.
- Ensure that the mains cable is attached with a hook (at the head end of the bed).
- Ensure that the castors are unlocked before moving the bed during the loading/unloading process.
- Move the bed on exclusively suitable floor surfaces.

Suitable surfaces:

- Tile
- Hard linoleum
- Poured flooring

Unsuitable surfaces:

- Too soft, unsealed or defective flooring
- Soft wooden flooring
- Soft and porous stone floors
- Carpeted floors with underlay
- Soft linoleum
  - For longer distances, ensure that the castor steering function (main control) is activated.
  - Ensure that the brakes are released while moving the bed.

6.2 Setup

Set up the bed as follows:

- Unpack the bed.
- Check the delivery (see Scope of Delivery and Bed Variants).
- Remove isolating foil from mains control box (see Removing Isolating Foil).
- Install equipment and accessories (see Assembly).
- In case of delivery with dismantled ends:
  Mount the head and foot ends (see Bed Ends).
- Set up the bed exclusively on a suitable floor surface (see Transport).
- Ensure that the mains cable does not collide or get stretched when adjusting the bed.
- Check if the plug is inserted correctly.
- Do not leave any extension cables or power strips loose on the floor.
- Ensure that all of the required mechanical and electrical prevention mechanisms are available on site.
- There is no mains switch on the bed, i.e. the mains cable is the only means to isolate the bed from the mains.
  Ensure that the mains cable is always accessible.
- Have the separable plug of the mains cable changed and maintained exclusively by qualified and trained service technicians authorized by the manufacturer.

6.3 Removing Isolating Foil

Warning

Risk of injury when removing isolating foil!

- Wear gloves when removing isolating foil.

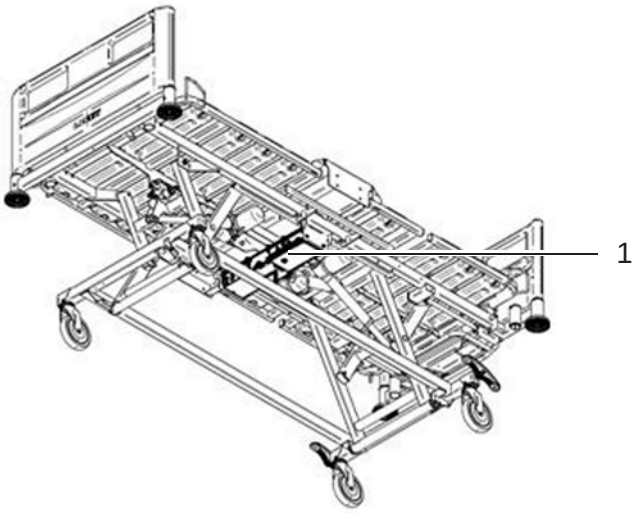


Fig. 1 *Removing Isolating Foil*

- Remove isolating foil from mains control box **1** by pulling strap **2**.
- Check if isolating foil is complete and undamaged as shown in Fig. 2.
- If isolating foil is damaged, contact the manufacturer's service department immediately.

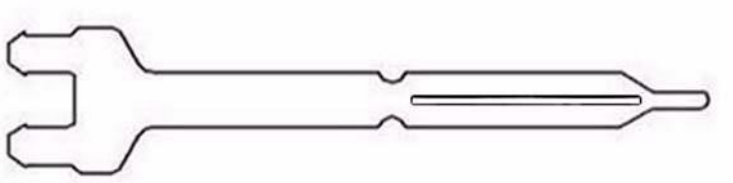


Fig. 2 *Isolating Foil*

7 Assembly

Warning

Risk of injury when working on the bed!

- Prior to assembly, disassembly and maintenance, ensure that bed is separated from mains.
- Prior to assembly, disassembly and maintenance, ensure that castors are locked.

Caution

Damage to property due to incorrect assembly!

- Ensure that the assembly is performed exclusively by customer service or trained hospital personnel.

7.1 Potential Equalisation

The bed is equipped with a standard protective connector. This connector shall be used for potential equalisation between the bed and any intravascular or intracardiac device connected to the patient to protect the patient from static electric shocks.

Fig. 3 *Potential Equalisation*

1. Potential equalisation connector - female
2. Potential equalisation connector - male

Use equalisation connector if:

- the patient is connected to any intravascular or intracardiac device.

Before connecting the patient to an intravascular/intracardiac device:

- Connect the ground wire of the device to the potential equalisation connector **2** on the bed on which the patient in question is lying.
- Use a standard hospital connector **1**.
- Ensure that the connectors match.
- Ensure that there is no possibility for inadvertent disconnection.

Before moving the bed:

- Disconnect the patient from the intravascular or intracardiac device.
- Disconnect the potential equalisation connector.

7.2 Mattress Platform

Fig. 4 *Mattress Platform*

The mattress platform consists of removable parts.

To remove/install parts of the mattress platform:

- Pull out mattress platform parts.
- Install mattress platform parts in directions indicated on label (see Fig. 5).
- Ensure that mattress platform parts are fitted correctly.

Fig. 5 *Label on Mattress Platform Parts*

7.3 Eleganza 1 (1GTA) - Single Collapsible Siderails

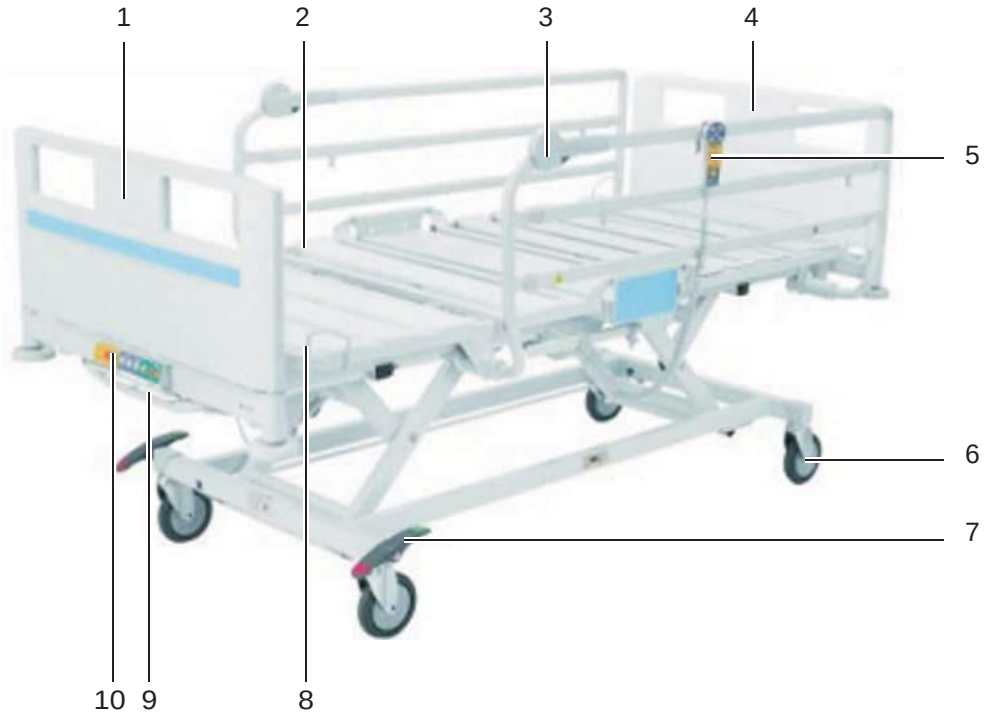


Fig. 6 *Overview Eleganza 1 - Single Collapsible Siderails*

1. Foot end
2. Single collapsible siderails
3. Siderail release mechanism
4. Head end
5. Handset (Rankinis pultelis) **Atitikimas punkto Nr.: 10**
6. Castors
7. Central castor system lever
8. Removable plastic parts
9. Linen shelf
10. Supervisor board

NOTE *For safe, easy handling, LINET® recommends having two technicians assemble the bed.*

7.4 Eleganza 1 (1GTA) - Split Plastic Siderails

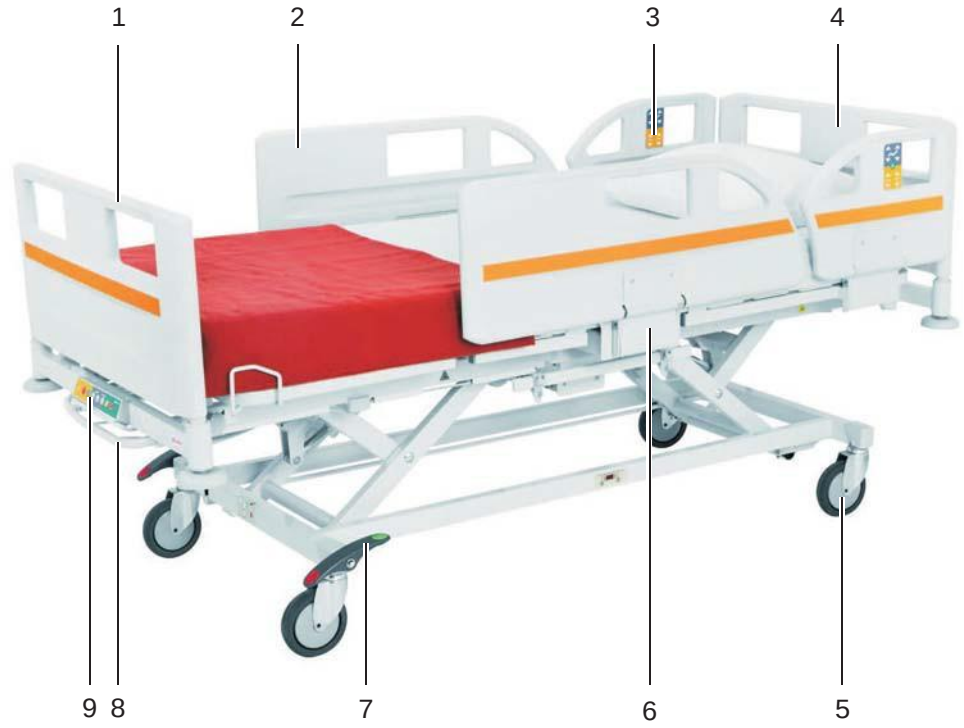


Fig. 7 *Overview Eleganza 1 - Split Plastic Siderails*

1. Foot end Kojūgalis
2. Split collapsible siderails Dvigubi nulenkiami lovos šonai **Atitikimas punkto Nr.: 16**
3. Control element, integrated in siderail
4. Head end Galvūgalis **Atitikimas punkto Nr.: 19**
5. Castors
6. Siderail release mechanism
7. Central castor system lever
8. Linen shelf
9. Supervisor board

NOTE *For safe, easy handling, LINET® recommends having two technicians assemble the bed.*

7.5 Eleganza 1 (1GTD) - Wooden Bed Ends

Fig. 8 *Overview Eleganza 1 - Wooden Bed Ends*

1. Foot end
2. Siderail release mechanism
3. Mattress base
4. Head end
5. Castors
6. Control element, integrated in siderail
7. Single collapsible siderail
8. Central castor system lever
9. Linen shelf

NOTE *For safe, easy handling, LINET® recommends having two technicians assemble the bed.*

7.6 Bed Ends

NOTE *Several variants of head and foot ends are available (see Bed variants and Features). The bed end variant does not affect the operation procedure.*

Warning

Risk of injury when inserting the bed ends!

- To insert bed ends into corner posts, hold them by the corner handles on top.
- Install bed ends before the first use.

Warning

Risk of injury due to incorrectly installed bed ends!

- Ensure that bed ends are correctly inserted, especially when moving the bed.
- Ensure that bushings on corner posts are locked, especially when moving the bed.

Warning

Risk of injury when removing the bed ends!

- Before removing bed ends, ensure that siderails are folded down and that there are no accessories attached to the bed ends.
- If a patient is lying in a bed with the head and/or foot board removed, supervise the bed at all times.

Warning

Damage to property due to excess load!

- Ensure that nobody sits on the bed ends.

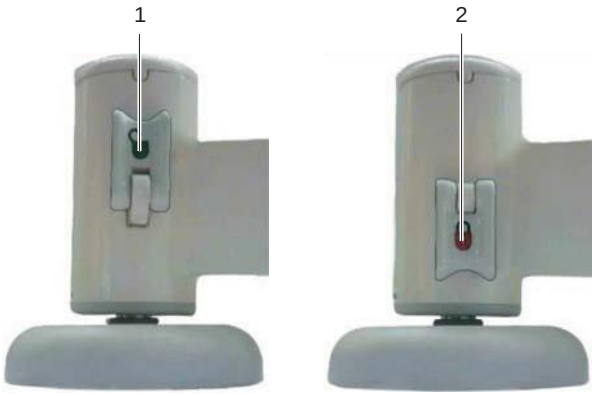


Fig. 9 *Locking the Bed Ends* **Atitikimas punkto Nr.: 19**

1. Unlocked Atrakinta
2. Locked Užrakinta

Install the bed ends as follows:

- Unlock safety levers on corner posts.
- Slide bed end into slots on corner posts with coloured panel on the outside.
- Lock safety levers on corner posts.

Remove the bed ends as follows:

- Unlock safety levers on corner posts.
- Pull bed end upward.

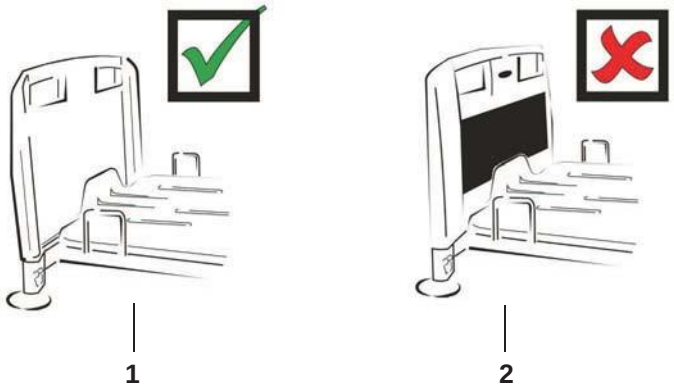


Fig. 10 *Installing the Bed Ends*

1. Right
2. Wrong

8 Operation

8.1 Initial Operation

Prepare the bed for service as follows:

- Connect the bed to the mains.
- Charge the battery.
- Raise and tilt the se platform to the highest position.
- Lower and tilt the mattress platform to the lowest position.
- Check that the castors as well as main brake work correctly.
- Check that the bed extension works correctly.
- Check that the head and foot boards can be removed.
- Check all of the functions on the control elements (Multiboard etc.).
- Check that the siderails function properly.
- Dispose of all packaging (see Disposal).

NOTE *If there is a substantial temperature difference between the bed (due to transport/storage) and the installation site, allow 24 hours for the difference to balance itself before connecting the bed to the mains.*

8.2 Battery Operation (Baterijos valdymas) **Atitikimas punkto Nr.: 6**

The battery supplied with the bed is delivered uncharged. The battery serves as a backup during power failures or while transporting the patient. (Pristatant lovą, baterija būna neįkrauta.)

NOTE *Batteries will remain in fully functional condition only for a certain period of time which is dictated by the laws of physics and chemistry used in this type of Dry Lead Acid battery technology and their frequency and method of use.*

- The user is obliged to monitor battery functionality and to change the batteries in accordance with the user & service manuals.
- Batteries must be checked according to the user manual at least once per month.

NOTE *Manufacturer provides 6 months warranty for full function of batteries.*

The manufacturer takes no responsibility for any damage to the bed or battery caused by:

- Not following manufacturers user manual instructions
- Fitting batteries which are not approved by LINET®
- Batteries fitted by an unqualified service organisation.

To charge the battery:

- Connect the bed to the mains.

NOTE *Some bed adjustments cannot be carried out without a battery, for example, height adjustment under a load of above 200 kg.*

The LED indicates the battery's charge status:

Yellow LED	Battery status
Not lit	Battery capacity is sufficient (charging completed)
Short flashing (shortly lit, longer not lit) (circa 1.8 sec.)	Battery is charging - continue charging until the LED is extinguished. In emergency cases, the battery can be used as a backup power source for a short period. If LED is still flashing after 12 hours of charging or stops flashing, but you can not position with bed, battery is defective or broken. Contact manufacturer.
Long flashing (longer lit, shortly not lit) (circa 0.2 sec.)	Low battery voltage - battery can not be used as a backup power supply even for a short period; battery is completely discharged or defective (if this type of signalisation persists, it is necessary to replace the battery - service action)
Lit continuously for several hours (circa 10 hours), when bed is connected to the mains.	Battery absence or failure condition (battery is connected incorrectly, line between the power supply and battery is broken or battery fuses are faulty); contact service department of the manufacturer in case of such signalisation.

Replacing the battery:

Caution

Damage to the bed due to incorrect battery replacement!

- Have the battery replaced exclusively by qualified personnel.
- Exclusively use batteries approved by the manufacturer.

Warning

Risk of damage or destruction of battery!

- If battery is faulty degassing can occur. In rare cases this can cause deformation of the battery pack housing and mains control box.
- If this occurs the bed must be immediately taken out of service and taken to an adequately ventilated room without sparks (electricity or fire)!
- Immediately inform service department of the manufacturer!

Warning

Danger of reducing battery durability due to wrong use!

- Use bed on battery exclusively in crisis situations (e.g.: power blackout, patient complications during transport, etc.)
- After reconnecting bed to the mains charge battery to full capacity (see chart Battery charge status)

- Battery must be replaced with new battery approved by the manufacturer.
- The manufacturer recommends to replace the battery by qualified service organization after 2 (two) years of use. After this period the supposed service life of battery ends and the manufacturer cannot guarantee the battery service life after this period.
- The battery must be replaced with the new battery approved by manufacturer after maximum 5 (five) years of use at the latest.
- Bed must exclusively be fitted with batteries approved by the manufacturer. To get more information on how to change battery, please refer to the Service manual (contact service department of the manufacturer).

Status “Faulty battery”

The battery is regarded as faulty if at least one of the following conditions applies:

- Battery charging constantly
- Low voltage on battery
- Low charging current of battery

- This status is indicated by the battery status indicator being constantly lit.
- These statuses are summarised to Linis and written to Blackbox.

To cancel this status:

- ❖ Press STOP button.

Status “Discharged battery”

The battery is regarded as discharged if the following condition is met:

- Defined decrease of voltage depending on discharging current

- This status is indicated by the battery status indicator flashing quickly.
- The electric CPR position is the only possible position.
- This status will be cancelled automatically when the bed switches to sleep mode.

To cancel this status:

- ❖ Press STOP button.

8.3 Switching Off

To switch off the bed:

- ❖ Disconnect the bed from the mains.

8.4 Removing the Bed from Service

Remove the bed from service as follows:

- ❖ Disconnect the bed from the mains.
- ❖ Disconnect the ground wire.
- ❖ Deactivate the battery (see Deactivating the Battery).
- ❖ Remove accessories.

To prevent damage during storage:

- ❖ Pack or cover the bed and accessories.
- ❖ Ensure that storage conditions are the same as the operating conditions.

8.4.1 Deactivating the Battery

To avoid damaging the bed and the environment during storage:

- Deactivate the battery on the supervisor panel.

To deactivate the battery on the supervisor:

- Disconnect the bed from the mains.
- Disconnect the ground wire.
- Activate the keypad by pressing the GO button on the supervisor.
- Press the Thigh Rest Up + Thigh Rest Down + Trendelenburg Position buttons at the same time and hold them for three seconds.

The battery is deactivated.

- Try some functions to ensure the battery is deactivated.

NOTE *Deactivating the battery using the Supervisor board is not possible.*

9 Manipulation

Warning

Risk of injury when adjusting the bed!

- Ensure that there are no body parts between mattress platform elements and mattress platform frame when adjusting the bed.
- Ensure that there are no body parts below the mattress platform frame before adjusting the bed.
- Secure or remove any items on the bed.

The bed is operated by different control elements.

Control elements depending on the model:

- Supervisor board
- Supervisor panel
- Handset without illuminated keyboard
- Handset with illuminated keyboard
- Handset with adapter for easy connection (Plug and Play)
- Controls integrated in siderails

Disabling individual functions on the supervisor board/panel affects all control elements.

If the bed does not react to individual position settings:

- Check whether the function is disabled on the supervisor panel.

9.1 Supervisor Board

The supervisor board is an optional control element. The supervisor board is located at the foot end of the bed.

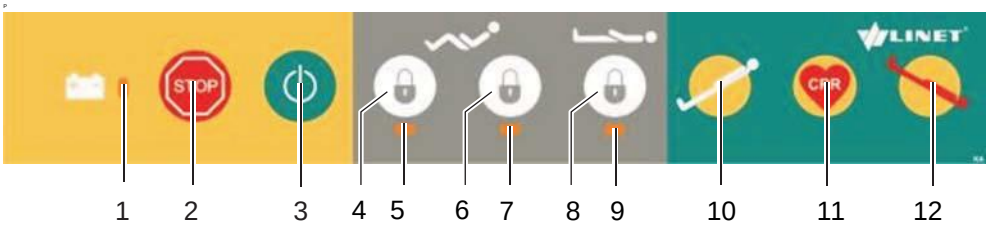


Fig. 11 *Supervisor Board*

1. Battery Charge Status LED
2. Central STOP Button
3. Activating GO Button
4. Thighrest Lock Button
5. Thighrest Lock LED
6. Backrest Lock Button
7. Backrest Lock LED
8. Height Lock Button
9. Height Lock LED
10. Reverse Trendelenburg Button
11. CPR Button
12. Trendelenburg Button (optional)

To set positions:

- Press button **3** to activate keypad.
- Press and hold corresponding button until required position is reached.

9.2 Supervisor Panel (Personalo pultas) Atitikimas punkto Nr.: 11

The supervisor panel is an optional control element. The supervisor panel can be suspended from the foot board if required. It is also possible to hold the supervisor in the hand while using it.

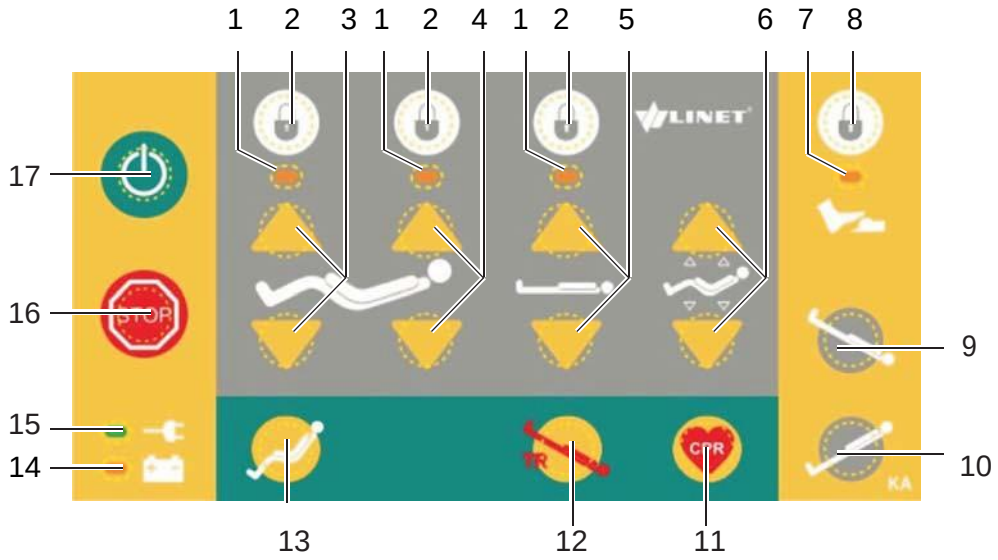


Fig. 12 *Supervisor Panel* Atitikimas punkto Nr.: 11.1 ir 11.2 ir 11.3

1. Lock LEDs
2. Lock Buttons Užrakinimo mygtukai.
3. Thighrest Positioning Buttons Šlaunų sekcijos valdymas
4. Backrest Positioning Buttons Nugaros sekcijos valdymas
5. Height Adjustment Buttons Aukščio valdymas
6. Auto-Contour Buttons (simultaneous setting of back- and thighrest) Auto-kontūro mygtukas (vienu metu kelia nugaros ir šlaunų sekcijas.
7. Foot Control Lock LED
8. Foot Control Lock Button
9. Trendelenburg Button (mattress platform tilt only) Trendelenburgo mygtukas (tik čiužinio platformos pavertimas)
10. Reverse Trendelenburg Button (mattress platform tilt only) Trendelenburgo mygtukas (tik čiužinio platformos pavertimas)
11. CPR (Resuscitation) Position Button CPR (gaivinimo) pozicijos mygtukas
12. Trendelenburg Button (optional) Trendelenburgo mygtukas (pasirinktinai)
13. Cardiac Chair Position Button Kardiologinės kėdės pozicijos mygtukas
14. Battery Charge Status LED (only for beds with backup battery)
15. Mains Power LED
16. Central STOP Button
17. Activating GO Button

To set positions:

- Press button **17** to activate keypad.
- Press and hold corresponding button until required position is reached.

9.2.1 Central STOP Button

The central STOP button **16** immediately interrupts all bed movements.

Pressing central STOP button **16** for at least 0.3 seconds immediately stops all electronic bed movements.

9.2.2 Activating GO Button

The GO button **17** activates the keypads on all control elements.

A GO button is included on a number of different control elements. The function of the GO button is identical on all control elements.

After pressing GO button **17**, the keypad will remain active for 3 minutes.

During this time the following is possible:

- Adjust individual mattress platform elements by pressing the corresponding function buttons.
- Disable individual functions with the lock button.

Each time you press a function button, the keypad will remain active for another 3 minutes.

9.2.3 Function Buttons

Function buttons **3**, **4**, **5**, **6**, **9** and **10** allow setting different positions, for example the height and tilt of the mattress platform, adjust individual mattress platform elements, etc.

NOTE *Pressing two function buttons at the same time will be recognised as an error by the controller. The controller will interrupt immediately all bed movements immediately.*

Set the position as follows:

- Activate the keypad by pressing the GO button.
- Press and hold corresponding button until required position is reached.

9.2.4 Lock Buttons

Lock buttons **2** allow disabling individual functions on the supervisor panel.

To disable functions:

- Press button **17** to activate keypad.

The respective LED indicates the lock by blinking.

NOTE *The individual functions are locked in the central control panel, the satellite control, the handset, and the siderail control.*

To enable disabled functions:

- Activate the keypad by pressing the GO button **2.**
- Press the respective lock button.

The respective LED goes out.

The function is enabled.

9.2.5 Positioning Buttons

Warning

Risk of injury due to moving parts!

- Ensure that no body parts are trapped between moving parts of bed and mattress platform.
- Ensure that no persons or body parts are close to bed or accessories (e.g. infusion stand, lifting pole) when mattress platform is moving.

Caution

Damage to property due to moving parts!

- Ensure that no objects (e.g. cables) are trapped between moving parts of bed and mattress platform.
- Ensure that no objects are close to bed or accessories (e.g. infusion stand, lifting pole) when mattress platform is moving.

The therapeutic and safety-related positions are pre-programmed. When a position is set, several parts of bed and mattress platform will move simultaneously.

The following buttons set programmed positions:

- Cardiac Chair Position (pre-programmed) **13**
- Trendelenburg Position **12**
- CPR (Resuscitation) Position (pre-programmed) **11**

Set the position as follows:

- Press button **17** to activate keypad.
- Press and hold corresponding button until required position is reached.

Cardiac Chair Position

The cardiac chair position is suitable for patients with cardiac arrhythmia and breathing difficulties.

Settings after pressing positioning button 13:

- Foot of mattress platform is tilted to lowest position.
- Backrest and thighrest are moved to upright position.

It is possible to disable this function. If individual functions (e.g. thighrest adjustment) are disabled, they will not be performed.

Trendelenburg Position

The Trendelenburg position serves as an anti-shock position.

Settings after pressing positioning button 12:

- All parts of the mattress platform are flattened.
- Mattress platform is tilted head down.

CPR (Resuscitation) Position

The CPR position is for resuscitating the patient in an emergency.

Settings after pressing positioning button 11:

- Mattress platform is moved to horizontal position.

NOTE *All mattress platform elements must be retracted to their lowest position by function buttons.*

NOTE *For quick mechanical positioning, see CPR Backrest Release.*

9.3 Handset (rankinis pultelis) Atitikimas punkto Nr.: 10

A handset is included as a standard feature.

The handset is available with and without button illumination. The button illumination of the illuminated handset is active when the bed is connected to the mains. The functions of both handsets are identical.

Where the handset is to be kept depends on the patient's condition.

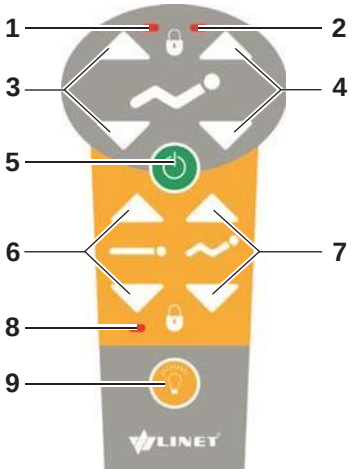


Fig. 13 *Handset*

1. Lock LED Thighrest
2. Lock LED Backrest
3. Thighrest Positioning Buttons
4. Backrest Positioning Buttons
5. Activating GO Button
6. Height Adjustment Buttons
7. Auto-Contour Buttons
8. Height Lock LED
9. Flashlight Button (Žibintuvėlio mygtukas)

To switch on flashlight:

- Press flashlight button **9**.

To set positions:

- Press button **5** to activate keypad.
- Press and hold corresponding button until required position is reached.

NOTE *The nursing staff decide whether the patient can adjust the bed.*

If the patient's condition requires it, prevent the patient from adjusting the bed by:

- Disabling functions.
- Unplugging the handset (if the bed is equipped with Plug and Play).

NOTE *An adapter for the handset is optionally available. The adapter enables quick installation and removal (e.g. replacing a defective handset, using the handset for another bed)*

9.4 Satellite Control Panel

The satellite panel is optional.

The satellite panel is attached to the backrest with a flexible arm.

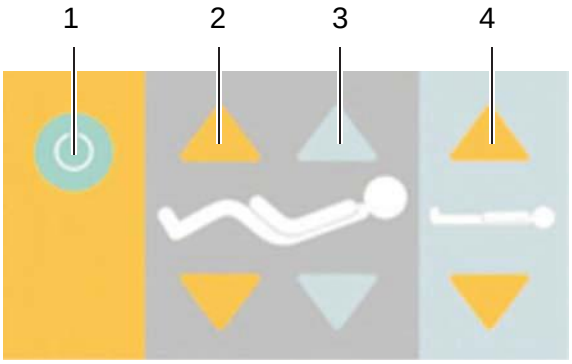


Fig. 14 *Satellite Control Panel*

1. Activating GO Button
2. Thighrest Adjustment Buttons
3. Backrest Adjustment Buttons
4. Height Adjustment Buttons

- Have a qualified person fix the satellite control panel on the bed.

NOTE *The satellite control panel can be fixed on the right or left side of the bed.*

To set positions:

- Press button **1** to activate keypad.
- Press and hold corresponding button until required position is reached.

NOTE *The nursing staff decide whether the patient can adjust the bed.*

If the patient's condition requires it, you can prevent the patient from adjusting the bed by:

- Moving the satellite panel out of the patient's reach.

Or

- Disabling functions.

9.5 Control Element Integrated in Siderail

The integrated control element is optional.

The integrated control element is attached to the split siderail.

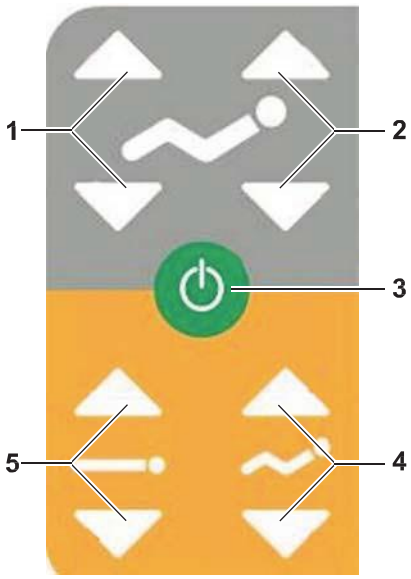


Fig. 15 *Control Element Integrated in Siderail*

1. Thighrest Adjustment Buttons
2. Backrest Adjustment Buttons
3. Activating GO Button
4. Auto-Contour Buttons
5. Height Adjustment Buttons

NOTE *The nursing staff decide whether the patient can adjust the bed.*

If the patient's condition requires it, you can prevent the patient from adjusting the bed by:

- Disabling functions.

9.6 CPR Backrest Release

Warning

Danger of injury due to lowering the backrest too quickly!

- Ensure that single collapsible siderails are in their lowest position.

Or

- Ensure that split plastic siderails are in their highest position.

- Ensure that there are no body parts between siderails and backrest.
- Press the backrest down exclusively by the mattress guard handle or the split plastic siderail.

The bed permits quick mechanical lowering of the backrest for emergency resuscitation (CPR) procedures.

Fig. 16 *Releasing the CPR Handle*

NOTE *In some cases (e.g. with bed in Trendelenburg position without power supply) it is possible to use the CPR lever to raise the backrest.*

9.7 Siderails

Split plastic siderails or single collapsible siderails are components of the bed.

The nursing personnel are responsible for folding the siderails up and down if required by the patient's condition, while a patient is in the bed.

9.7.1 Single Collapsible Siderails

Folding the siderails

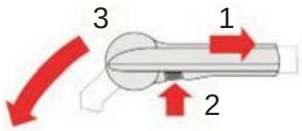


Fig. 17 *Release Mechanism for Single Collapsible Siderails*

- Take hold of release mechanism and push siderail towards head end to unlock locking system.
- Press button **2** to unlock.
- Fold siderail up or down as required.
- Push siderail towards head end.

Siderail will click into place and lock automatically.

9.7.2 Split Plastic Siderails Dvigubi pastikiniai šonai **Atitikimas punkto Nr.: 16.1 ir 16.2**

Folding the siderails Šonų nulenkimas

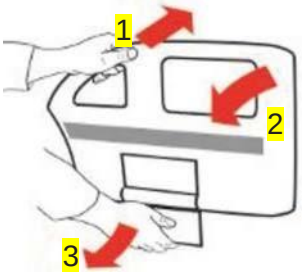


Fig. 18 *Release Mechanism for Split Plastic Siderails*

- Take hold of the siderail's top bar and push towards mattress platform **1**. Laikydami šoną paspauskite pirmyn
- Pull out locking mechanism **3** to unlock. Patraukite užrakto mechanizmą 3 atrakinimui
- Fold siderail up or down **2** as required. Atlenkite šoną 2 kaip parodyta

When folding the siderail up, it will click into place and lock automatically.

When folding the siderail down, it will not lock.

NOTE *In certain cases (e.g. when there is no weight on the siderails), it is possible to unlock the split plastic siderail only be pulling out the locking mechanism **3**. This does not mean that the mechanism is faulty. The manufacturer recommends always using the procedure described above.*

9.8 Castor Control and Bed Transport

Caution

Damage to property due to incorrect transport or involuntary movement!

- Prior to transport, ensure that bed is disconnected from mains.
- Prior to assembly, disassembly and maintenance, ensure that castors are locked.
- Ensure that castors are locked while the bed is occupied and/or not being transported.
- Put mains cable on hook provided for transport.
- Have bed transported exclusively by nursing personnel.

9.8.1 Beds with Castor Control Levers

The castor control levers are located on both sides of the foot end.

Fig. 19 *Castor Control*

Castor control: Ratukų valdymas Atitikimas punkto Nr.: 18

1. Forward Movement Judėjimas pirmyn
   Beds without 5th castor: Front left castor is locked so that it is exclusively possible to move the bed straight ahead.
   Bed with 5th castor: 5th castor is activated.
2. Unrestricted Movement Laisvas judėjimas
   All of the castors are unlocked.
3. Braked Stabymas
   All of the castors are locked.

To move the bed:

- Adjust bed height to at least 20 cm below maximum height.
- Push bed by handles on head or foot end.

9.8.2 Beds without Castor Control Levers

Fig. 20 *Braking Castors*

- Always block/unblock all castors.

To block a castor:

- Push brake down by foot **1**.

Castor is blocked.

To unblock a castor:

- Push brake up by foot **2**.

Castor is unblocked.

9.9 Foot Control

Warning

Risk of injury due to unlocked foot control!

- Ensure that the foot control is locked if it is not in use.

It is possible to equip the bed with a foot control. The foot controllers enable the adjustment of the bed height or pre-programmed examination positions.

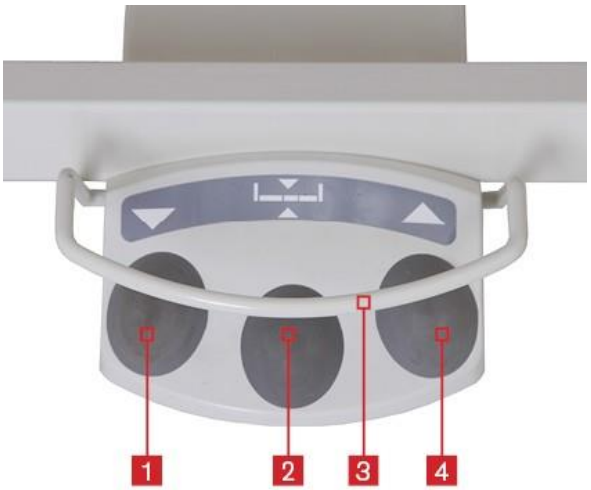


Fig. 21 *Foot Control*

1. Lower Mattress Platform
2. Examination Position
3. Protection frame against unwanted activation
4. Raise Mattress Platform

Button **2** straightens backrest and thigh rest while moving the mattress platform up.

Set the position as follows:

- Press foot switch for activation (mini GO function).
- Press and hold the foot switch until the desired position is reached.

9.10 Accessories

Danger of injuries due to incompatible accessories!

- ❖ Use exclusively the manufacturer's original accessories.

Caution

NOTE *The manufacturer does not assume any responsibility if accessories not approved by the manufacturer are used.*

NOTE *All accessories conform to IEC 60601-2-52:2009.*

9.10.1 Mattresses

The following mattresses are suitable for Eleganza 1:

- 4ZZEE1F40SZP - Ergomatt (Foam F 40S)
- 4ZZEE1DU50MP - Ergomatt (Foam DUMENRGO 50)

9.10.2 Lifting Pole

The lifting pole is an optional accessory. It is necessary to specify this feature in the order.

Fig. 21 *Bushing for lifting pole and infusion stand*

Lifting pole variants:

- Lifting pole for beds without fixed bed end

To ensure safe use of the lifting pole:

- ❖ Never exceed the maximum load of 75 kg.
- ❖ Never use the lifting pole for rehabilitation exercises.
- ❖ To prevent the bed from tipping over, ensure that the lifting pole does not project out from the bed.
- ❖ Replace plastic handle every 4 years.

Lifting pole positions:

- Over the backrest (working position).
- Parallel to the head board (when not in use).

To install the lifting pole:

Fig. 22 *Safety pin, locked in place*

- Insert lifting pole into corresponding bushings at the head end of the bed (corners).
- Ensure that the safety pin locks into place.

A plastic grab handle with an adjustable strap shall be attached to the lifting pole.

NOTE *The date of manufacture is marked on the grab handle. LINET® recommends replacing the plastic grab handle every four years.*

9.10.1 Infusion Stands

It is possible to insert infusion stands into the bushings at the head and foot ends of the bed.

- Use exclusively infusion stands with 4 hooks for hanging IV bags or baskets for intravenous solutions.
- Ensure that the infusion stand's weight-bearing capacity is not exceeded.
- Ensure that the weight-bearing capacity of the 4 hooks is not exceeded.
  Capacity per hook: 5 kg

Warning

Risk of injury due to use of unsuitable accessories!

- Use infusion stands exclusively for accessories listed in the instructions for use.
- Do not use infusion stands for hanging infusion pumps, dosing devices etc. as this equipment might collide with movable parts of the bed.

9.10.2 Accessory Rails

Fig. 23 *Accessory Rail*

The bed is optionally equipped with two accessory rails with plastic hooks. The hinge mechanism allows the rail to adjust to meet the patient's needs.

Load capacity:

- Maximum load of 5 kg without leverage
- Maximum load of hook pair 10 kg

Accessories for hanging on the accessory rail:

- Cannula holder
- DIN steel bar
- Urine bag holder

- Urine bottle basket

9.10.3 Urine Bottle Holder

9.10.3.1

Material damage due to collision!

Make sure that urine bottle in holder always faces bed ends.

Caution

Fig. 24 *Correct position of urine bottle holder*

9.11 Eleganza Protector Papildomos apsaugos Atitikimas punkto Nr.: 16

Eleganza Protector® is not a component of the bed. Eleganza Protector® is optionally available.

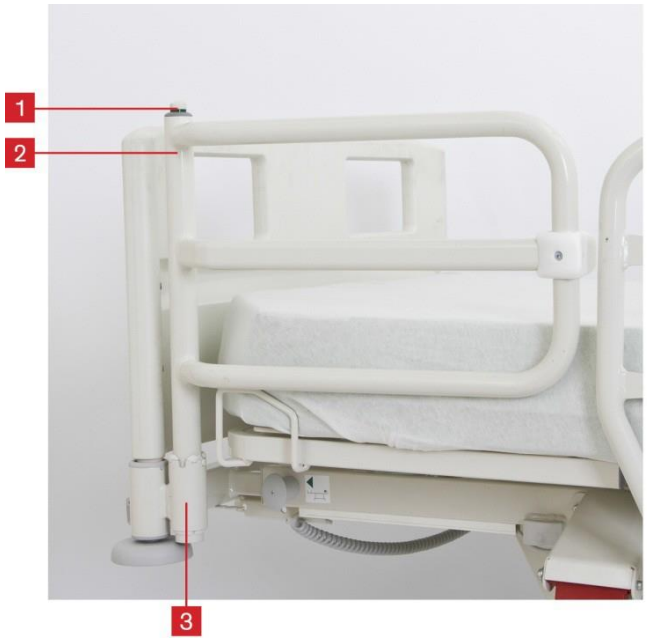


Fig. 25a *Closed Eleganza Protector®*

Fig. 25b *Opened Eleganza Protector®*

Warning

Risk of injury due to patient falling out of bed!

- Ensure that Eleganza Protector® is securely anchored to the bushing.
- To check stability, push the protector up without touching the release button.
- Always check that the siderail is properly locked.

Warning

Risk of damage to the bed or patient injury!

- Do not mount bed end to accessory bushing (**3**).
- Do not mount lifting pole to accessory bushing (**3**).
- Do not use protector with bed extension.

Mount Eleganza Protector® to closed position as follows:

- Put the tube of protector (**2**) into bushing near foot end of the bed (**3**) so the protector is facing the siderail.
- Safety pin must be locked in place.

Mount Eleganza Protector® to open position as follows:

- Put the tube of protector (**2**) into bushing near foot end of the bed (**3**), so the protector is facing out from bed.
- Safety pin must be locked in place.

Dismount Eleganza Protector® as follows:

- Press and hold the releasing button (**1**).
- Push the protector up.

10 Cleaning/Disinfection

Warning

Risk of injury when working on the bed!

- Always disable function buttons when cleaning between undercarriage and mattress platform.
- Prior to cleaning, ensure that bed is disconnected from mains.
- Prior to assembly, disassembly, cleaning and maintenance, ensure that the adjustment function on the Supervisor panel is locked.

Caution

Damage to property due to incorrect cleaning/disinfection!

- Do not use washing machines.
- Do not use pressure- or steam-cleaners.
- Use exclusively the recommended cleaning agents.
- Follow the instructions and observe the dosages recommended by the manufacturer.
- Ensure that disinfectants are selected and applied exclusively by qualified hygiene experts.

For safe and gentle cleaning:

- Disconnect the bed from the mains.
- Do not use any strong acids or bases (optimum pH range 6 - 8).
- Use exclusively detergents suitable for cleaning medical equipment.
- Do not use abrasive powders, steel wool, or other material and cleaning agents that might damage the finish.
- 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 the bed with a well-wrung, damp cloth.
- Clean electrical components carefully and allow them to dry completely.

Cleaning agents

LINET® recommends the following cleaning agents:

Cleaning Agents	Manufacturer
Mikrozid, Terralin Protect, Thermosept	Schülke & Mayr
Bacillol AF, Bacillol Rasant, Dismozon Pur, Microbac Forte, Neodisher Dekonta	BODE Chemie
Lysoformin 3000, Lysoform Spezial	LYSOFORM
Incidin plus, Incidin rapid	Ecolab
Perform, TPH protect,	Schülke

10.1 Preparing for Cleaning

Prepare for cleaning as follows:

- Set mattress platform to highest position.
- Adjust back- and thighrests so that the reverse sides are accessible.
- Disable function buttons on control elements using the supervisor panel.
- Disconnect bed from mains.
- Move bed to location where it will be cleaned.
- Lock brakes.

10.2 Cleaning

10.2.1 Daily Cleaning

Clean the following bed parts:

- All of the control elements for adjusting the bed
- All handles
  - Back- and thighrest handles
  - CPR release handle
- Head and foot boards
- Siderails (in highest position)
- Freely accessible mattress surface
- Accessory rails

10.2.2 Cleaning before Changing Patients

Clean the following bed parts:

- All of the control elements for adjusting the bed
- All handles
  - Back- and thighrest handles
  - CPR release handle
- Head and foot boards
- Siderails (in highest position)
- Freely accessible mattress surface
- Accessory rails
- All plastic mattress platform covers
- Undercarriage frame with castor covers
- Linear motors
- Mattress on all sides
- Freely accessible metal parts on the mattress platform
- Cable ducts
- Lifting pole bushing
- Infusion stand bushing
- Wall deflection bumpers
- Castors
- Brakes

10.2.3 Complete Cleaning and Disinfection

Clean the following bed parts:

- All of the control elements for adjusting the bed
- All handles
  - Back and calf rest handles
    - CPR release handle
- Head and foot boards
- Siderails (in highest position)
- Freely accessible mattress surface
- Accessory rails
- All plastic covers
- Linear motors
- Mattress on all sides
- Freely accessible metal parts on the mattress platform
- Cable ducts
- Lifting pole bushing
- Infusion stand bushing
- Wall deflection bumpers Sienų apsaugos bamperiai **Atitikimas punkto Nr.: 21**
- Castors
- Brakes

11 Troubleshooting

Error/Fault	Cause	Solution
The bed cannot be adjusted with the position buttons	GO button was not pressed	Press GO button.
	Function disabled on supervisor panel	Enable disabled function.
	Drive motors have no power, Defective drive motors, Defective battery	Check mains connection. Notify service department.
	Plug inserted incorrectly	Insert mains plug correctly.
	Faulty power box.	Notify service department.
	Faulty control element	Notify service department.
Faulty mattress platform height/tilt adjustment	There is an object on the undercarriage cover	Remove object.
	Function disabled on supervisor panel	Enable disabled function.
	Drive motors have no power, Defective drive motors, Defective battery	Check mains connection. Notify service department.
	Plug inserted incorrectly	Insert mains plug correctly.
	Faulty power box	Notify service department.
	Faulty control element	Notify service department.
Backrest cannot be lowered from the upright position	There is an object under the backrest or in the drive mechanism	Remove object.
	Locking handle is defective	Notify service department.
The siderails cannot be adjusted	The siderail lock is dirty	Clean locking mechanism.
	Locking handle is defective	Notify service department.
Faulty brakes	The brakes are blocked by dirt	Clean brake system.
	The brake mechanism is defective	Notify service department.
The head and foot boards cannot be inserted	The head or foot board is in the wrong position	Check locking mechanism. Position head or foot board correctly.
	Defective mechanism	Notify service department.

Danger

Risk of mortal injury due to electric shock!

- If a fault occurs, have electric motor, power box or other electrical parts repaired by qualified personnel exclusively.
- Do not open protective covers of electric motor or power box.

12 Maintenance

Warning

Risk of injury when working on the bed!

- Prior to assembly, disassembly and maintenance, ensure that bed is separated from mains.
- Prior to assembly, disassembly and maintenance, ensure that castors are locked.
- Prior to assembly, disassembly, cleaning and maintenance, ensure that the adjustment function on the Supervisor panel is locked.

Warning

Danger of injury due to defective bed!

- Have a defective bed repaired immediately.
- If the defect cannot be repaired, do not use the bed.

Caution

Damage to property due to incorrect maintenance!

- Ensure that any maintenance is performed exclusively by customer service or trained hospital technicians.

12.1 Maintenance Work

- Have the connector replaced exclusively by service personnel trained by LINET®
  For service-relevant instructions refer to the service documentation.
- Ensure that the following maintenance work is performed every 12 months by the manufacturer or by a qualified service organisation trained and certified by the manufacturer.
- Do not use the bed if any malfunction or defect occurs.
  Contact manufacturer or service department immediately.

NOTE *The manufacturer will give a certificate to service organisations in which the manufacturer declares that the service organisation is qualified to perform maintenance on LINET® products.*

NOTE *On request, the LINET® will provide service documentation and circuit diagrams for qualified service technicians trained by LINET®.*

12.1.1 Spare Parts

The product label is located on the longitudinal rail of the mattress platform frame. The product plate contains information for claims and ordering replacement parts.

Information about spare parts is available from:

- Customer service
- Sales
- Our technical support department

12.1.2 Completeness

- Perform a visual check (with delivery note if necessary).
- Have any missing parts replaced.

12.1.3 Wear

- Check all bolts and tighten if necessary.
- Check all locking mechanisms.
- Check the bed for wear, scratches or rub marks.
- Eliminate the cause if necessary.
- Have any defective parts replaced.

12.2 Functioning

- Check that all bed adjustments reach the maximum position.
- If necessary, clean, lubricate or replace any worn spots and parts.

12.2.1 Electric Control

Plug Connections

- Replace O-rings on connectors.
- Check plug connections for dirt and defects.
- Clean or replace if necessary.
- Check if plug connectors are correctly inserted.

Motors

- Check motor movement (adjust bed positions).
  Check for incorrect and interrupted movements.
- Have defective motors replaced if necessary.
- Check cables for signs of wear and entanglement.
- Install a new cable or have it replaced if necessary.

Battery

- Check if battery is working correctly (disconnect bed from mains).
- Have battery replaced if necessary.

12.2.2 Castors

- Clean castors completely.
- Grease castors if necessary.
  Use Caro EP 2 by DEA or an equivalent grease
- Check if the castors are working correctly.
  - Forward movement
  - Unrestricted movement
  - Braked
- Have brakes adjusted if necessary.
- Have any defective castors replaced.

12.2.3 Accessories

- Check if all accessories (e.g. lifting pole, siderails, infusion stand, etc.) are working correctly.
- Replace if necessary.

12.2.4 Safety Checks

Warning

Danger of injury due to incorrect safety checks!

- Ensure that safety checks are exclusively performed by customer service or authorised personnel (certified by the manufacturer).
- Ensure that the safety checks are recorded in the service and maintenance log.

Warning

Danger of injury due to defective bed!

- Have a defective bed repaired immediately.
- If the defect cannot be repaired, do not use the bed.

In accordance with §6 of the Medical Devices Operator Ordinance, the operator is required to perform a technical safety check on the hospital bed every 12 months.

The procedure for performing the safety check is stipulated in IEC 60601-1-2005.

13 Disposal

13.1 Environment 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. The noise emission and the vibrations meet the directives for premises. None of the wooden parts are made of tropical woods (for example, mahogany, jacaranda, ebony, teak, etc.) or of woods from the Amazonian region or similar rainforests.

The packaging materials are produced according to the respective directives. Dispose of the packaging material according to the symbols and by delivering it to an authorised person.

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



13.2 Disposal

13.2.1 Within Europe

To dispose of the appliance:

- When you dispose of your appliance do not put it into the household waste.
- Send the appliance to the recycling of electrical appliances.

The materials of the appliance are reusable. By reusing, material recycling or other forms of use of old appliances you give an important contribution to the protection of our environment.

Ask the responsible environmental protection authorities for the appropriate disposal point.

13.2.2 Outside Europe

- Dispose of the bed or its components in accordance with local laws and regulations:
  - After using the bed
  - Following maintenance and installation work
- Hire an approved waste disposal company for disposal.

14 Warranty

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

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

- Do not continue to use the bed.

This product is covered by a 24-month warranty from the date of product shipment from LINET® to the customer. The warranty covers all material and manufacture-related failures and errors. The warranty does not cover any failures or errors caused by incorrect use and external influences. Justified complaints will be fixed free of charge during the warranty period. Proof of purchase, with the date of purchase, is required for any warranty service. Our standard terms and conditions apply.

15 EC Declaration of Conformity

EC CONFORMITY DECLARATION

Date and place of issue: 22. 07. 2014, Želevčice

Conformity declaration issued by:	
Commercial name	**Linet spol. s r. o.**
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
Reg. No.	00507814
Telephone	+420 312 576 111
Fax	+420 312 522 668

As the producer of the product - name (brand):	**Eleganza 1**
Variants of the product:	**1GT** (Variants are specified in the technical documentation of the product).
Description and function designation:	Electrically operated hospital bed, intended for use in standard, acute and long term care. This EC conformity declaration also covers all applicable accessories.
Classification of the product as the medical device:	**Class I** nonsterile, without measuring function, according to annex IX MDD 93/42/EEC – rule 1

A) Declaration

I declare that the said product is safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

B) Fulfilled technical requirements of related regulations

This product's characteristics comply with the technical parameters related to it and stated in MDD 93/42/EEC which stipulates the technical parameters for healthcare products, with applicable specific requirements in directive 2006/42/EC which stipulates the technical parameters for machinery devices and with requirements in directive 2011/65/EU which stipulates the restriction of the use of certain hazardous substances in electrical and electronic equipment.

C) Means of assessing conformity

Conformity was assessed by the procedure stated MDD 93/42/EEC, Annex VII.

D) Used standards for product conformity assessment

The said product fulfills the requirements of these harmonized technical standards which were used for assessing of conformity: EN 60601-1:2006/A1:2013, EN 60601-1-2:2007, EN 60601-1-6:2010, EN60601-2-52:2010 and EN ISO 14971:2012.

Ing. Tomáš Kolář
managing director

CE

16 Technical Specifications

16.1 Mechanical Specifications

Dimensions **Atitikimas punkto Nr.: 2** with split plastic siderails (su dvigubais šonais) with single collapsible siderail	Išmatavimai, 217.9 cm x 99.2 cm 217.9 cm x 99.3 cm
Siderail dimensions split plastic siderail ▪ centre ▪ head single collapsible siderail	 96 cm x 37.9 cm 52 cm x 37.9 cm 146.3 cm x 38.7 cm
Mattress platform dimensions (mattress) standard Čiužinio platformos (čiužinio) išmatavimai.	**Atitikimas punkto Nr.: 3** 90 cm x 200 cm x 14 cm
Space underneath bed split plastic siderails down split plastic siderails up	 12.5 cm 18.5 cm
Siderail height over mattress platform (without mattress) with split plastic siderails with single collapsible siderails	 37.9 cm 38.7 cm
Mattress platform extension Čiužinio agrindo pailgėjimas	15 cm **Atitikimas punkto Nr.: 23**
Mattress platform height adjustment 125 mm castors 150 mm castors (ratukai)	Čiužinio platformos aukščio keitimas 37 cm — 73.5 cm 39.5 cm — 76 cm **Atitikimas punkto Nr.: 7.1**
Maximum backrest angle Maksimalus nugaros kampas	70° **Atitikimas punkto Nr.: 12**
Maximum thighrest adjustment (electric)	34° **Atitikimas punkto Nr.: 13**
Ergoframe®	10 + 6 cm **Atitikimas punkto Nr.: 9**
Trendelenburg/Reverse Trendelenburg position	+15°/-15° **Atitikimas punkto Nr.: 14**
Weight (depending on equipment)	135 kg
Application environments	1, 2, 3
Max. lifting pole load	75 kg
Environmental conditions ▪ Temperature ▪ Humidity ▪ Atmospheric pressure	 +15 °C — +40 °C 30 — 75% 795 — 1060 hPa
Safe Workload (including mattress and accessories) 125 mm castors without central brake system 125 mm castors with central brake system ▪ with battery ▪ without battery ▪ 150 mm castors (Su 150mm ratukais) ▪ with battery (Su baterija) ▪ without battery	**Atitikimas punkto Nr.: 4** 185 kg (for application environment 3 only) 250 kg (for application environment 3 only) 200 kg (for application environment 3 only) 250 kg 200 kg
Max. mattress height split plastic siderails single collapsible siderails siderails equipped with an extender	 15.9 cm 16.7 cm 16.7 cm + 10 cm

Maximum patient weight and safe working load (SWL) SWL is the sum of:	
Patient	
125 mm castors without central brake system	150 kg
125 mm castors with central brake system	
▪ with battery	215 kg
▪ without battery	165 kg
150 mm castors	
▪ with battery	185 kg
▪ without battery	135 kg
Mattress	20 kg
Accessories (if supported by bed's support system) + load supported by accessories patient excluded)	
125 mm castors without central brake system	15 kg
125 mm castors with central brake system	
▪ with battery	15 kg
▪ without battery	15 kg
150 mm castors	
▪ with battery	45 kg
▪ without battery	45 kg

16.2 Electrical Specifications

Atitikimas punkto Nr.: 5

Input voltage (Srovė)	230 VAC, 50 — 60 Hz
Maximum power input	max. 1.6 A, 370 VA
DIN EN 60529 safety protection	IP X4
Safety class	Class I (with type B applied parts)
Electrical motor operating time	10%, max. 2 min. out of 20
Battery	2 sealed lead batteries 12 V (15 A fuse) capacity 1.2 Ah.
Fuse Version 230 V Version 100 V - 127 V	 T1.6A L 250 V T3.15A L 250 V

NOTE *Upon request, LINET® can deliver hospital beds with electrical specifications that comply with regional standards (custom voltage, different mains plugs).*

Danger

Danger to life due to electric shock!

- Ensure that maintenance and service of electrical parts are performed exclusively by qualified personnel if the bed is connected.

Identification of applied parts (Type B)

- Supervisor panel
- handset
- siderails
- bed ends
- mattress platform

16.3 PB 4X Electronic System of Eleganza 1

Eleganza 1 requires special preliminary measures pertaining to EMC that necessitates installation and commissioning in conformity with the EMC information given in this manual.

Warning

RF communication equipment can affect bed functions!

- Do not use portable and mobile RF communication equipment near the bed.

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

Damage to property due to electromagnetic radiation!

- Do not use electrical equipment near the bed.

Eleganza 1 is intended for the application in electromagnetic environment as specified below. The customer or user of the bed is responsible for the fact that these requirements are met.

16.3.1 Manufacturer's Manual and Declaration - Electromagnetic Radiation

Radiation Test	Conformity	Electromagnetic Environment
Radiation	Conformity	Electromagnetic environment
High-frequency radiation CISPR 11	Group 1	Eleganza 1 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	Eleganza 1 is suitable for all institutions, including households and objects directly connected to the public low-voltage mains 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 that mains quality is suitable for 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 that mains 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 U_T) within 0.5 cycles 40% U_T (60% short-duration drop of U_T) within 5 cycles 70% U_T (30% short-duration drop of U_T) within 25 cycles <5% U_T (>95% short-duration drop of U_T) within 5 s	<5% U_T (>95% short-duration drop of U_T) within 0.5 cycles 40% U_T (60% short-duration drop of U_T) within 5 cycles 70% U_T (30% short-duration drop of U_T) within 25 cycles <5% U_T (>95% short-duration drop of U_T) within 5 s	❖ Ensure that mains quality is suitable for commercial or hospital environments. ❖ For permanent operation during a power failure, connect the bed to a power generator since 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 that the magnetic fields of the network frequency conform to the normal levels of commercial or hospital environments.

NOTE *U_T refers to the AC mains voltage before the test level is applied.*

16.3.3 Portable and Mobile RF Communication Equipment

Eleganza 1 is suitable for electromagnetic environments with controlled RF disturbances. To prevent electromagnetic interference, it is necessary to observe certain minimum distances between the bed and portable or mobile RF communication equipment. These minimum distances depend on the maximum output power of the communication equipment.

Resistance Test	Test Level as per IEC 60601	Level of Compliance	Electromagnetic Environment
Conducted high-frequency phenomena IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	❖ Do not use portable and mobile HF communication equipment near the bed. ❖ Observe the distances indicated below. ❖ Ensure that the field intensities of permanent HF transmitters determined by the summary of electromagnetic characteristics for the given place [a] are 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.

The following distances between bed and RF communication equipment must be observed:

Rated Maximum Output of Transmitter	Distance According to Frequency of Transmitter		
	150 kHz - 80 MHz $d = \frac{3,5}{V_1} P$	80 MHz - 800 MHz $d = \frac{3,5}{E_1} P$	800 MHz - 2.5 GHz $d = \frac{7}{E_1} P$
0.01 W	0.12 m	0.40 m	0.40 m
0.1 W	0.37 m	1.26 m	1.26 m
1 W	1.17 m	4.00 m	4.00 m
10 W	3.69 m	12.65 m	12.65 m
100 W	11.67 m	40.00 m	40.00 m
For transmitters with a rated maximum output power not listed in the table above, it is possible to estimate the recommended distance d using the equation applicable to the transmitter's frequency. P = maximum power output rating in Watts (W) according to the transmitter manufacturer d = recommended separating distance in metres (m).			

NOTE *With 80 MHz and 800 MHz, the higher frequency range is applicable. The absorption and reflection of buildings, objects and people will influence electromagnetic propagation.*

17 Log

17.1 Delivery Log

Order Number:	
Customer:	
Model Number:	
Serial Number:	
Delivery Date:	
Delivered By:	

I hereby confirm that the personnel has been familiarised with the correct operation of 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

Contact:
Linet spol. s r. o.
Želevčice 5, 274 01 Slaný
Czech Republic

Tel.: +420 312 576 111
Fax: +420 312 522 668
E-mail: info@linet.cz
http://www.linet.com