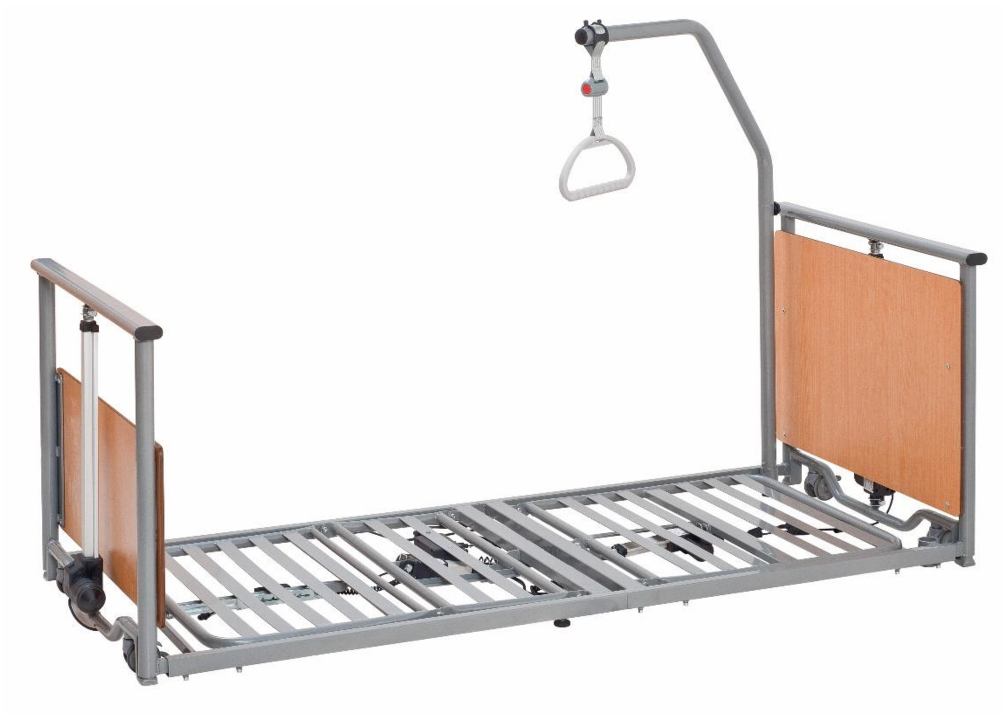
Instruction manual

(original instruction manual)

Assembly and operation

ULB FONDO

(Ultra-Low Bed)



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Please read and observe these operating instructions before each use!
If you change ownership, please include this instruction manual!

Foreword

Dear customer,

The TekVor Care team would like to thank you for the trust you have placed in our ULB Fondo care bed.

With the decision to purchase a care bed from "TekVor Care" you receive a care product with high functionality at the highest safety level.

With the purchased care bed, we can guarantee you optimal lying comfort.

All beds are carefully checked by our staff before delivery.

The healthcare bed delivered to you has left our premises in perfect condition.

When you receive the healthcare bed, the responsibility for its proper and intended operation also passes to you at the same time.

These instructions for use inform you as the operator and your users about the function and safe handling of the ULB Fondo healthcare bed in their daily work.

Please always keep the instructions for use at hand near the healthcare bed.

We are convinced that our product will make a positive contribution to your care.

Yours sincerely

Your TekVor Care Team

1 General information

Before the first use:

Read the instruction manual conscientiously and completely!

Please pay attention to the various safety instructions. The ULB Fondo nursing bed should be cleaned and disinfected before using it for the first time and before each use.
TekVor Care healthcare beds carry the CE mark and meet the requirements for safety and functionality. The ULB Fondo healthcare bed has been tested according to international standards, which include the safety requirements for medical products.

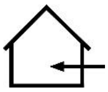
However, these safety requirements can only be met if the user is satisfied that the patient bed (including accessories) is in proper condition before use.

Please note the Medical Device Operator Ordinance (MPBetreibV, July 2017).

1.1 Explanation of the symbols used

In these instruction manual, important information is indicated by the following symbols:

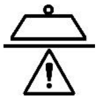
	Read information with this symbol carefully and observe it urgently. This information is relevant to safety.
Lebensgefahr	This symbol warns of dangerous voltage. There is a danger to life!
Gefahr	This symbol warns of general dangers. There is danger to life and health
CE	Mark of conformity according to Medical Devices Directive (93/42/EEC)
IPX4	Protection of electrical equipment against splashing water
	Symbol for device of protection class II, double protective insulation
	Symbol for type B application part according to DIN EN 60601-1

 The nursing bed may only be used indoors

 The product must be sent to a separate waste collection system in the European Union. Disposal with normal household waste is not permitted.

 Symbol for direct current (DC)

~ Symbol for alternating current (AC)

 Symbol for safe working load

 Symbol for maximum patient weight

 Symbol for reading the instruction manual

1.2 Explanation of the designated groups of persons

Operator

The operator of a medical device is any natural or legal person who is responsible for the operation of the health facility in which the medical device is operated or used by its employees. Contrary to sentence 1, the operator of a medical device which is owned by a member of the medical profession or the medical profession and which is brought into a health facility for use by this member shall be the relevant member of the medical profession or the medical profession. A person is also considered to be an operator if he keeps medical devices ready for use outside of health facilities in his company or facility or in public space.

[§2, paragraph 2, MPBetreibV, 2017]

Requirements to be met by the operator

- Please note that for you as the operator of this medical device, the requirements of the Medical Device Operator Ordinance (MPBetreibV, 2017) are binding.
- The ULB Fondo nursing bed is a medical device and may only be operated and used in accordance with its intended purpose and the regulations of the MPBetreibV as well as the generally recognised rules of technology.
- Only instruct persons to use this medical device who have the necessary training or knowledge and experience and who have been instructed in the medical device to be used.
- Instruct the user in the proper handling of this medical device and document the instruction in an appropriate form.
- A combination with other medical devices (including accessories) or with other objects may only be operated and used if they are suitable for use in this combination, considering the intended purpose and the safety of patients, users, employees or third parties.

User
The user is anyone who uses a medical device on a patient within the scope of the Medical Device Operator Ordinance (MPBetreibV). [§2, Para. 3, MPBetreibV, 2017]

User requirements

- Use the ULB Fondo nursing bed only as intended and in accordance with these instructions for use.
- Only use this product if you have been properly instructed in its use and have the necessary training or knowledge and experience.

  (e.g. nursing staff).
- Before using the ULB Fondo nursing bed, make sure that it is in good working order and condition.
- Observe the instructions for use and the other safety-related information enclosed.

Patient / Resident
In these instructions for use, a patient is defined as a person who needs nursing care due to his or her illness, disability or age and is lying in a nursing bed.

Qualified personnel
The operator's employees who are authorised to deliver, assemble, dismantle and transport the healthcare bed based on their training or instruction are referred to as qualified personnel. In addition, these persons are instructed in the instructions for cleaning and disinfecting the healthcare bed.

2 Intended purpose

2.1 Intended use (application environment)

The ULB Fondo nursing bed is designed for the accommodation of adults with a height from 150 cm and a body weight from 40 kg to max. 170 kg. It is suitable for use in retirement homes, nursing homes and in home care - i.e. in 3 and 4 - and may only be operated under the operating conditions described in these operating instructions.

The ULB Fondo nursing bed is designed to alleviate or compensate for a disability or incapacity and to facilitate working conditions for the caregiver.

The ULB Fondo is a low bed, i.e. the bed frame can be lowered close to the floor. It can therefore be used specifically to prevent falls.

Any other use is considered improper and is excluded from possible liability.

Attention:

The ULB Fondo nursing bed is **not** designed for use in **hospitals** and is **not** suitable for applications with **medical electrical equipment**.

It is not EX-protected and must not be operated in hazardous areas.

The nursing bed should only be used in dry indoor areas. It is only suitable **for transporting patients within the patient's room** and with the lying surface adjusted to the **lowest horizontal position**.

The ULB Fondo can under certain circumstances be combined with other electrical medical devices such as anti-decubitus systems, nutrition systems etc. for therapeutic purposes. In this case, all **bed functions** must be **deactivated** for safety reasons for the duration of use via the **integrated locking device** on the hand control.

The operator of the medical devices is responsible for ensuring that the combination of devices meets the requirements of DIN EN 60601-1.

If lines from other equipment are routed in the care bed, precautions must be taken to prevent these lines from being crushed between parts of the care bed.

2.2 Unauthorized use

All uses deviating from the intended use, which can then also lead to hazards.

These include, for example:

- Load on the nursing bed exceeds the permissible safe working load (see par. 13.5 and nameplate on bed frame)
- Operation of the nursing bed by the patient or resident who has not received any instruction
- Use of the nursing bed for children and adults with atypical anatomy
- Try to move the nursing bed in the braked position
- Use of the nursing bed on a non-horizontal surface (max. inclination 5°)

3 General provisions for the user

The nursing bed may only be used for its intended purpose.

During installation, operation and application, the regulations of the Medical Devices Act (MPG) and the legal regulations issued for this purpose, the generally recognised rules of technology as well as the occupational health and safety and accident prevention regulations must be observed.

If the care bed is in a faulty condition in which the patient / occupant, nursing staff or third parties could be endangered, operation must not be started.

3.1 User qualification

The healthcare bed may only be operated by persons who have the appropriate training or experience for proper handling.

4 Safety instructions

4.1 General safety instructions

Possible potential dangers which may occur despite proper operation must be pointed out separately during the instruction. Before initial operation, the user/care personnel must read the operating instructions carefully and in detail.

No objects or body parts of persons may be in the movement area of the bed while the adjustment functions are being actuated. Risk of crushing!

Ensure that the nursing bed cannot be operated by children playing and that there are no pets under the bed when the bed is adjusted.

If the psychological or mental condition of the patient requires it, the hand control must be locked via the lock switch on the back of the hand control (nurse key). The locking function is described in detail in par. 7.3. For this patient group it may also be necessary to place the hand control outside the patient's access area in order to avoid the risk of strangulation by the cable.

Bed adjustments may only be carried out by instructed persons or in the presence of an instructed person.

The mains plug should always be accessible so that in an emergency the device can be disconnected from the mains supply by pulling it out of the socket.

The mains cable must be exposed and must not be jammed, as it is carried along when the bed is adjusted in height. Otherwise the mains cable can be torn out of its strain relief and damaged. In addition, the mains plug can be torn out of the socket and expose electrical cores.

Cables from other devices used in the ULB Fondo healthcare bed must not be pinched, squeezed or pulled by the functions of the healthcare bed. Take appropriate precautions.

If the mains supply cable or the mains plug is damaged, the complete supply cable with plug must be replaced. The work may only be carried out by the manufacturer or authorized specialists.

Do not use multiple sockets to connect the mains plug, as liquids can penetrate here. (Fire hazard and electrical shock)

Before cleaning and disinfecting the care bed, the mains plug must be disconnected from the mains and securely hung up. The plugs for the handset and the motors which are plugged into the control unit on the lying surface drive must be plugged in. This is necessary so that no water can penetrate the control unit.

Gefahr

The maximum duty cycle and safe working load must not be exceeded, otherwise safe operation is no longer guaranteed (see technical data).

The ULB Fondo care bed must not be used in potentially explosive areas.

The care bed may only be dismantled if there is no patient or occupant in it.

4.2 Safety instructions for the operator

Use these operating instructions to instruct each user on safe operation before initial use.

Inform the user of any hazards that may exist if the device is not handled properly.
Only instructed persons may operate the care bed. This also applies to persons who only operate the healthcare bed as representatives.

According to the Medical Device Act (MPG), healthcare beds are Class I active medical devices. ,

This results in obligations for you in accordance with the Medical Device Operator Ordinance (MPBetreibV) in order to ensure the permanently safe operation of this medical device without endangering patients, users and third parties. For long-term use of the systems, checks must be carried out and documented at least once a year for function and visible damage (see section 10.2).

4.3 Safety instructions for the user

Let the operator instruct you in the safe operation of the care bed.

Observe the general safety instructions as described in para. 4.1.

Bed adjustments may only be carried out by instructed persons or in the presence of an instructed person.

Move the lying surface to the lowest position if you leave the nursing bed unattended with the patient. This will reduce the patient's risk of injury from falling.

If a malfunction or damage is suspected, immediately unplug the power plug from the socket. Mark the healthcare bed as a "defect" and take it out of operation. After that, please inform the responsible operator immediately.

4.4 Cleaning and disinfection

Lebensgefahr

Before cleaning and disinfection, the mains plug must be disconnected from the mains and securely hung up. The plug for the handset and the motors, which are plugged into the control at the lying surface drive, must be plugged in. This is necessary so that no water can penetrate the control unit.

Do not immerse the electrical components in water, but only wipe them off with a damp cloth.

The electrical components must not be sprayed with a high-pressure cleaner or water jet. Only wipe disinfection is permitted.

To avoid skin irritation, always wear liquid-impermeable gloves during cleaning and disinfection work.

Gefahr

Attention: When spray disinfecting with alcohol-containing agents, there is a risk of explosion and fire when used over large areas.

4.5 Maintenance and repair

Maintenance measures (inspection and maintenance) and maintenance (repair) may only be carried out by persons who have at least read the safety regulations, followed these operating instructions and are qualified in accordance with MPBetreibV (2017) §5.

In order to detect possible defects in time and to ensure safe use, a technical check (visual and functional check) must be carried out by qualified personnel at least once a year according to the maintenance schedule (see chapter 10.2) after a longer period of inactivity and before each reuse.

If defects, damages or defects are found during the tests, the healthcare bed may no longer be operated. Maintenance of the healthcare bed must be carried out by qualified personnel in accordance with MPBetreibV (2017) §5.

Only original spare parts and accessories of the manufacturer may be used, otherwise any warranty and product liability are excluded.

The 9V block battery is the energy storage device for electrical emergency lowering in the event of a power failure. The energy storage is enough for max. one emergency lowering and must then be replaced. If the expiry date of the battery has expired, it must also be replaced immediately. As batteries are self-discharging, it is recommended to replace the battery every two years when not in use. Make sure that the battery is an alkaline manganese battery of type 6LR61 and that only this type may be used. Empty batteries must be disposed of in an environmentally friendly manner.

4.6 Accessories / Options

An erector with triangle handle is available as an accessory (see chapter 6.4), the safe working load of which must not exceed 80 kg. The erector is not intended for lifting persons but facilitates the change from lying to sitting position or for changing the position. The trapeze bar must not be swivelled outside the bed and must only be used within its permissible adjustment range, which is defined by the tube holder on the bed. Otherwise the bed may tip over completely and lead to serious injuries.

Further options are:

- Trendelenburg / Antitrendelenburg function (see chapter 7.6)
- Mattress extension 200mm
- Reading lamp
- Floor lighting

4.7 Electromagnetic compatibility

The electric drives comply with the requirements of EN 60601-1-2:2007 regarding their interference emission and immunity (see point 13.6). However, electrical devices may interfere with each other. In this case, switch off the care bed briefly or remove the source of interference. We refer to the letter of the BfArM reference no. 9/0508.

4.8 Storage

If the nursing bed is to be stored for a longer period, the 9V block battery should be removed as a precaution to prevent damage to the bed from any leaking liquid.

4.9 Useful life and disposal

The service life for beds in domestic areas is assumed to be approx. 5 years. The nursing bed must not be disposed of with normal household waste at the end of its service life. For environmentally friendly disposal, please contact your local authority or TekVor Care.

5 Storage and transport

Due to the modular design of the care bed, transport can be carried out effortlessly. This is made possible by a transport device. The care bed integrated in the transport frame can be manoeuvred in the narrowest space by means of the bed rollers.

As-received condition

Care bed in the transport device

6 Assembly and commissioning

6.1 Removal from the transport device

On receipt of the delivery and before assembly, check whether the packaging is damaged. Complain any visible damage immediately to the delivering company.

1. Cut the packaging tapes with a side cutter or scissors.
2. Lift the transport carton from the entire bed unit including the transport device.

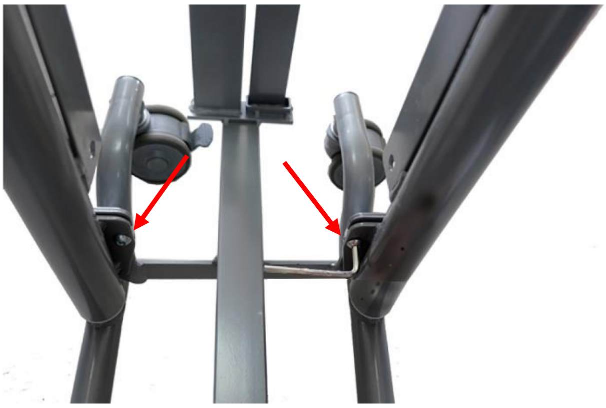
Please do not dispose of the cover! This can be reused as dust protection when the care bed is later stored in the transport frame.

3. First lift the lying surface half for the foot end **(a)** and then the lying surface half for the head end **(b)** out of the transport device.

(a) Lying surface half for the foot end

(b) Lying surface half for the head end

4. Remove both bedsteads from the transport device. Loosen the 4 Allen screws on the connecting straps and unhook them.
5. The Allen screws are needed again for the assembly of the lying surface with the bed control parts!



6.2 Control of the delivery and the scope of delivery

After unpacking and removal from the transport device, please check that the delivery is complete. The following parts are included in the scope of delivery:

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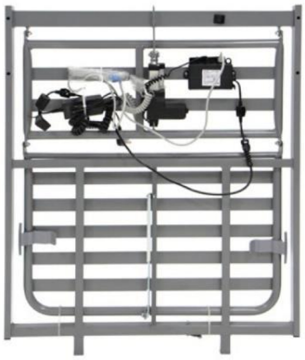
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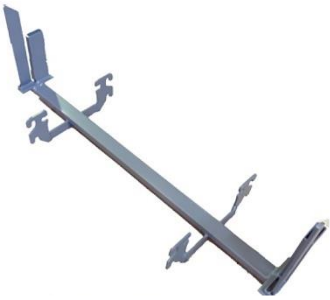
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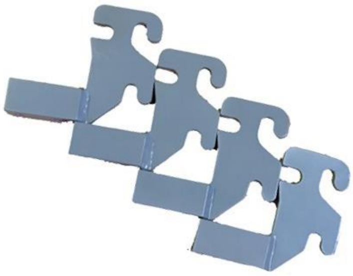

9

10


1	Bed control unit head side 1x	**6**	Power supply unit with mains plug 1x
2	Bed control unit foot side 1x	**7**	Transport device 1x
3	Hand control with nurse key 1x	**8**	Connecting pieces 4x
4	Lying surface half head side 1x	**9**	Allen screw 12x and nuts 4x
5	Lying surface half foot side 1x	**10**	Mattress holder 4x
11	Instruction manual 1x (without illustration)		

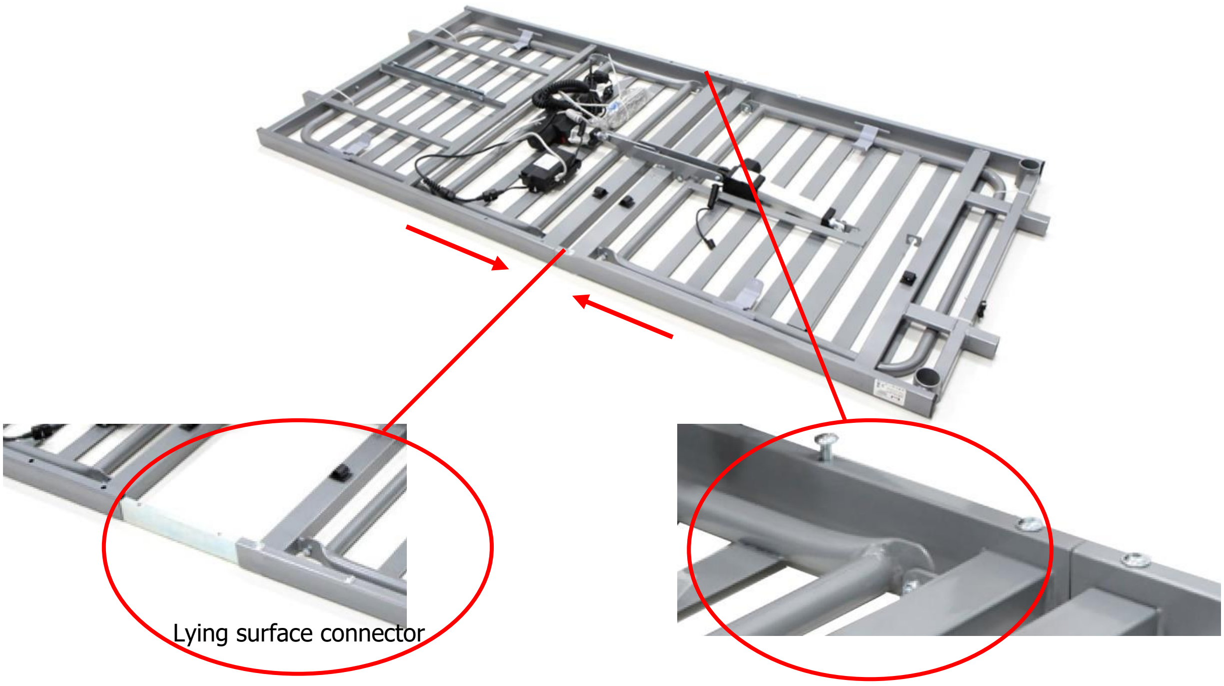
6.3 Assembling the ULB Fondo

Proceed as follows to assemble the ULB Fondo:

1. Place the two halves of the lying surface (head and foot side) on the floor with the upper side facing downwards.
2. Push the two lying surface connectors already mounted on the lying surface half of the head side into the frame openings of the lying surface half of the foot side.

3. When both lying surface halves are completely pushed into each other, screw the Allen screws into the 4 holes on the frame of the lying surface half of the foot side.

   Check that the 4 Allen screws are tight on the lying surface half of the head side.



4. Disconnect the cable ties that attach the power supply unit and the hand control to the lying surface.

The electrical cables must not be damaged when the cable ties are cut.

5. Remove the cover from the control unit by loosening both screws.

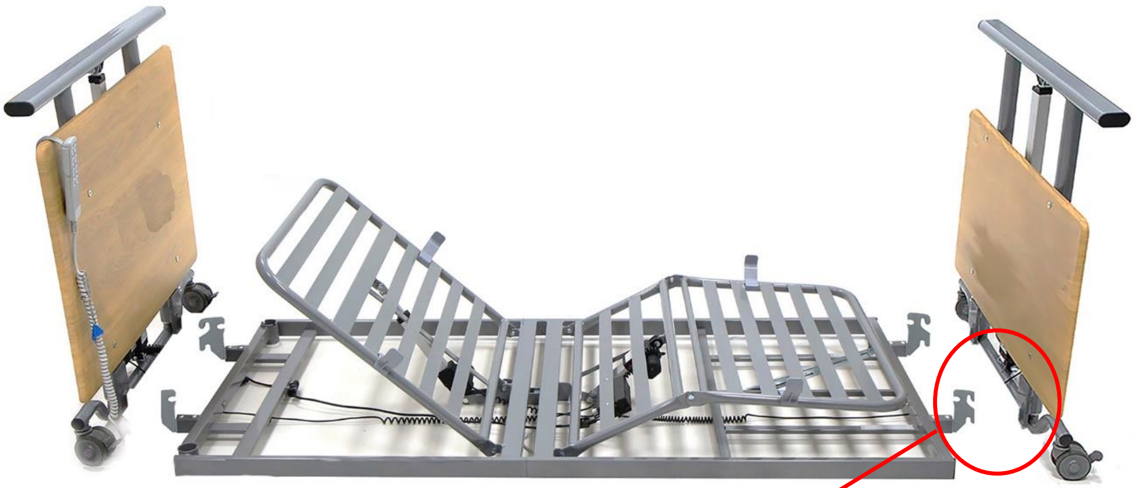
6. Connect the two plugs of the height adjustment drives of the bed control parts (marked yellow) and the plug of the backrest adjustment drive (marked white) to the control unit.
7. The plug for the thigh adjustment drive (marked blue) and the plug for the hand switch are already plugged into the control unit at the factory.

1 Height adjustment drive
2 Height adjustment drive
3 Thigh adjustment drive
4 Backrest adjustment drive
5 Hand control

8. Replace the cover plate on the control unit by screwing in both screws.
9. Fix the cable of the hand control and the mains cable to the underside of the lying surface using the tabs provided.
10. Fasten the strain relief of the mains cable in the holder at the head end.


11. Carefully turn the lying surface over so that the drives point downwards to the floor. Do not damage the control unit or the drives.
12. Use a side cutter or knife to remove the cable ties that fix the lying surface to the frame.
13. Insert the connecting straps into the front frame openings and fasten each with two Allen screws.


14. Connect the lying surface to the bed control parts. To do this, hook the previously assembled connecting straps into the locating pins on the bed control elements. Then fasten the connections with one Allen screw and one nut each.



Be sure to mount the bed control for the head side to the lying surface end of the backrest and the bed control for the foot side to the lying surface end of the thigh rest.

15. At the front side of the lying surface frame there is a cable guide at the head and foot side to hold and protect the cables of the height adjustment drives.
16. To be able to guide the cables through the cable guide, you must loosen the reel on the cable guide with two ring spanners (7mm), insert the cable of the height adjustment drive and fasten the reel again.

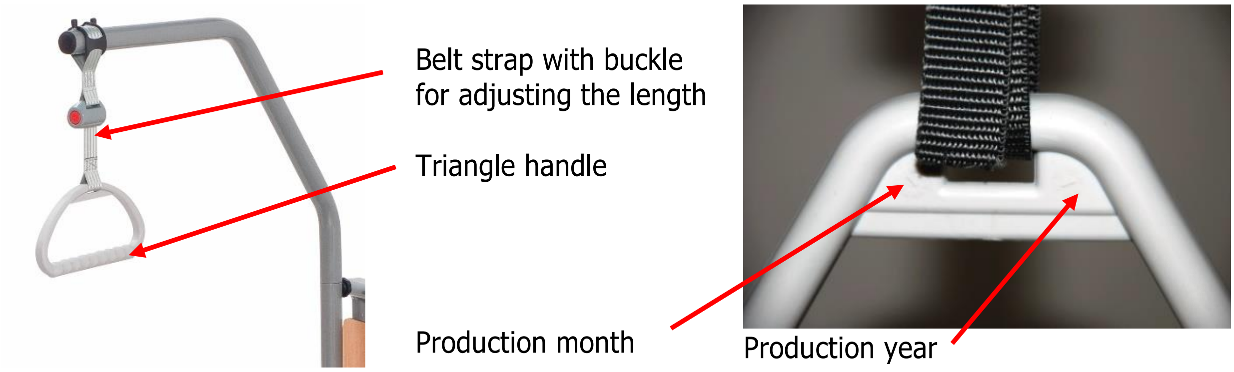
17. Position the ULB Fondo care bed in the desired position in the room and plug the mains plug into the socket.

The mains plug must always be accessible so that in an emergency the system can be disconnected from the mains supply by pulling it out of the socket.

Make sure that the power cord is positioned so that it cannot be crushed or damaged by driving over it.

6.4 Erector with triangle handle (accessory)

With the help of the erector, the patient can stand up and move more easily into another position. A triangle handle is attached to the erector.



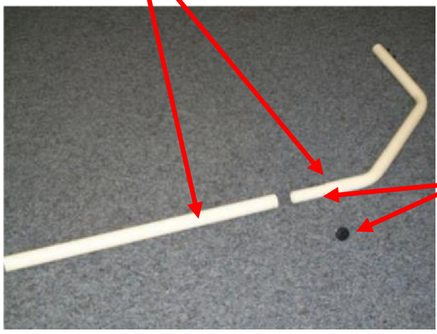
Mount the erecting bracket and insert it into the erecting fixture in the lying surface. Make sure that the locking cylinder pin engages in the recess of the erecting fixture.

Attention: The erecting bracket must not be used outside the latching mechanism.

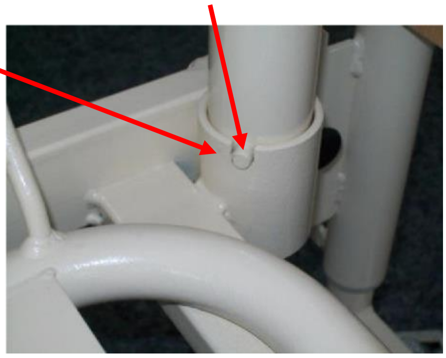
Plug together

Engage the snap-in cylinder pin in the recess

Erector admission



Screw the star grip screw into the threaded hole and tighten.



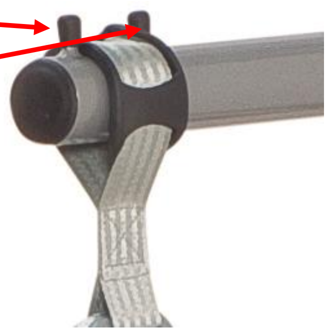
The length of the strap of the triangle handle can be adjusted by the buckle. Select an adjustment that allows the user to easily reach the handle when lying down (usually between 55-70 cm measured from the upper edge of the mattress).

Make sure that the belt is securely fastened again.

The triangle handle has a shelf life of at least 5 years under normal use (see embossing of production date). It is then recommended to replace the triangle handle.

Slide the fixed loop of the triangle belt over the first bolt of the erector and check its secure hold by pulling the triangle handle firmly downwards.

Attention: Fix the loop of the triangle belt only between these two bolts!



6.5 Commissioning

The ULB Fondo care bed is ready for operation after it has been successfully carried out and all steps from chapter 6, paras. 6.3 and 6.4 have been observed. Once the ULB Fondo has been installed, carry out a check in accordance with Chapter 10, Section 10.2.

Clean and disinfect the bed before using it for the first time and before each use according to chapter 8.

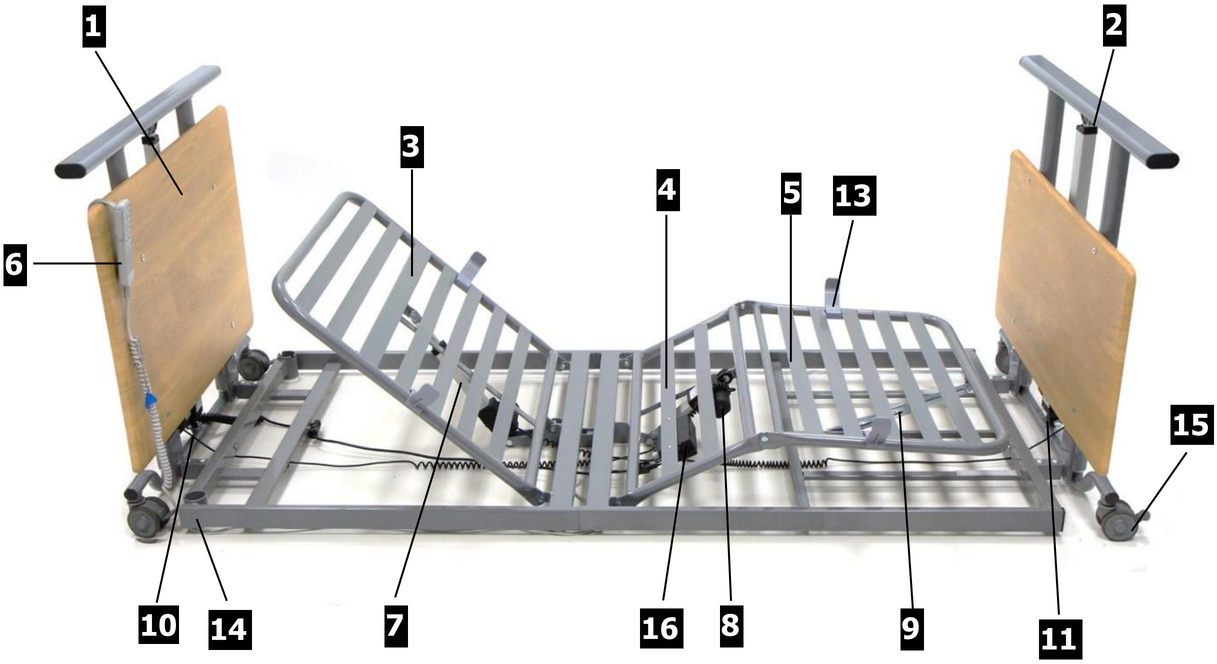
6.6 Disassembling the ULB Fondo care bed

Always disconnect the mains plug from the socket before dismantling!

Disassembly of the care bed is carried out in reverse order to the assembly.

7 Functional description

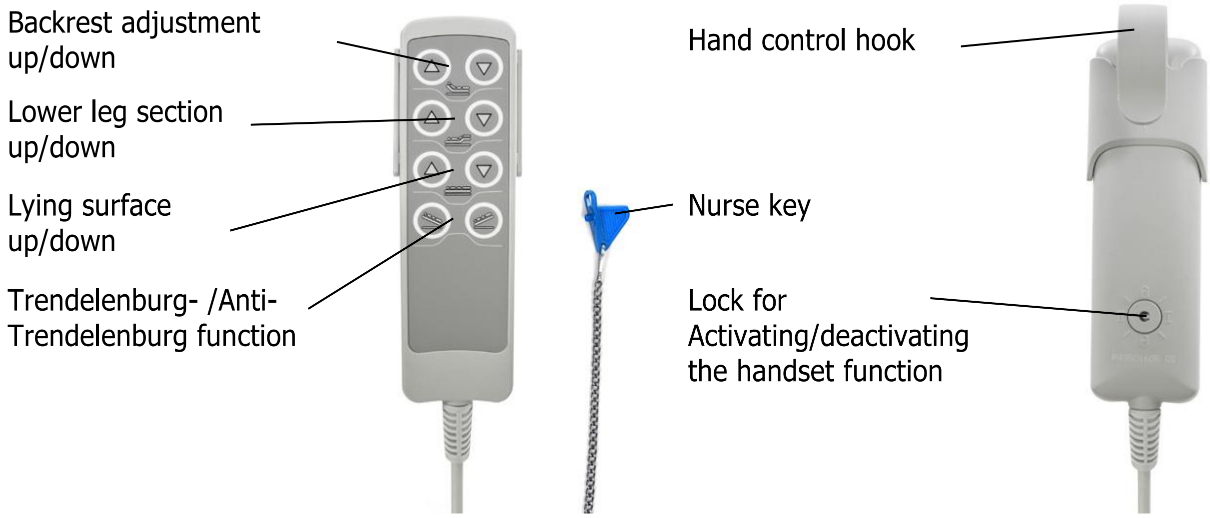
7.1 Technical overview of the ULB Fondo



1 Bed control unit on the head side with integrated height adjustment drive
2 Bed control unit on the foot side with integrated height adjustment drive
3 Electrically adjustable backrest
4 Electrically adjustable thigh support
5 Mechanically adjustable lower leg support
6 Hand control with nurse key
7 Electric drive for backrest
8 Electric drive for thigh support
9 Mechanical latching mechanism for adjusting the lower leg support
10 Electric height adjustment drive for the head side
11 Electric height adjustment drive on foot side
12 Power supply unit with SMPS, mains cable and mains plug
13 Mattress holder
14 Tube holder for erecting bracket (on both sides)
15 Mechanically lockable track roller
16 Control unit

7.2 Hand control with locking function

The electric bed functions can be operated via the handset. All functions can be locked with the nurse key.

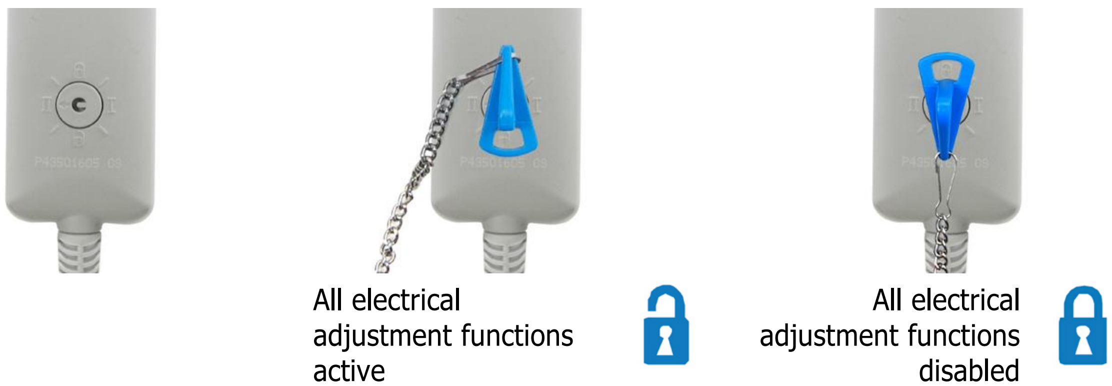


In order to avoid damage, the hand control should always be suspended from the hand control hook when not in use. (e.g. bed control unit)

Do not press multiple keys at the same time as this may overload and damage the system.

7.3 Locking function for handset

There is a lock on the back of the hand control. All electrical adjustment functions can be locked simultaneously by turning the enclosed nurse key in the lock.

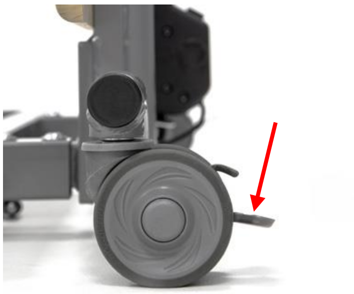


Switching positions I and II are test positions used to check safety during regular safety checks or after repair work.

7.4 Operation of the lockable track rollers

All rollers of the bed can be locked individually and must always be locked during normal operation. This is total locking, i.e. directional locking and simultaneous braking of the roller.

Released brake



Lock the brake with your foot.

Attention: The brakes may only be released to move the bed!

See also safety instructions!

7.5 Emergency lowering

7.5.1 Emergency lowering via integrated 9V battery (electric)

The control unit mounted on the lying surface is equipped with a 9V block battery, which enables the individual electrical adjustment functions to be lowered in the event of a mains power failure. If the mains power should fail, you have the option of returning the electric drives to their lowest position. Please note that this is only possible once per 9V battery, as the capacity of the 9V battery is very limited.

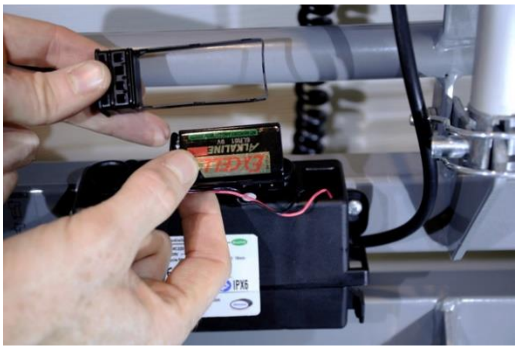
After using the emergency lowering once, the 9V battery must be replaced with a new equivalent one (alkaline manganese battery type 6LR61).

However, the 9V battery should be replaced every 2 years even if not in use.

7.5.2 Battery change

To replace, check or remove the 9V battery for longer storage, the battery compartment of the control unit must be opened.

1. Disconnect the mains plug!
2. Remove the cover on the control unit by unscrewing the two crosshead screws.
3. Pull out the cover together with the 9V battery.
4. Disconnect the battery from the battery clip and replace it with a new equivalent battery of the type "alkaline manganese battery type 6LR61".



5. Slide the cover with the new 9V battery back into the opening of the control unit. Make sure that the seal is not damaged.
6. Finally fasten the cover to the control unit with both screws. Make sure that the screws are not overtightened during tightening.

7.6 Trendelenburg / Antitrendelenburg function (option)

As an option, the ULB Fondo nursing bed can be equipped with Trendelenburg or anti-Trendelenburg bearings.

With Trendelenburg bedding, the lying surface of the nursing bed is inclined in the headroom bedding.

With anti-Trendelenburg positioning, the lying surface is inclined to the low foot position.

Trendelenburg positioning may only be used at the instigation of a doctor, as it can influence the clinical condition of the patient.

Do not leave the patient unattended during Trendelenburg or anti-Trendelenburg positioning.

Push-button for Antitrendelenburg function (inclination of the lying surface to the low foot position)

Push-button for Trendelenburg function (inclination of the lying surface to the head low position)

8 Care, cleaning and disinfection

Clean and disinfect the ULB Fondo care bed before using it for the first time and before using it again. For cleaning, wipe the bed by hand with a damp cloth. We recommend suitable cleaning and care products as cleaning agents for wooden and plastic furniture.

Household cleaners without ammonia and scouring agents are also permitted but should be dermatologically tested.

Solvents and scouring agents are not permitted as they attack and damage the various surfaces of the care bed.

For disinfection:

Indication:
In order to achieve effective disinfection, the nursing bed must be cleaned beforehand.

Disinfection is possible by spray or wipe disinfection with commercially available disinfectants. Do not use disinfectants containing chlorine as they can have a corrosive effect on metals, plastics etc. and are not environmentally friendly.

For wipe disinfection (surface disinfection) we recommend approved disinfectants and disinfection procedures from the list of disinfectants and disinfection procedures tested and approved by the Robert Koch Institute (https://www.rki.de) or from the VAH disinfectant list (Verbund für Angewandte Hygiene e.V. / https://vah-online.de).

Before cleaning and disinfection, the mains plug must be disconnected from the mains and securely suspended. The plug for the handset and the motors, which are plugged into the control at the lying surface drive, must be plugged in. This is necessary so that no water can penetrate the control unit.

The electrical components must not be sprayed with a high-pressure cleaner or water jet. Only wipe disinfection is permitted.

9 Cause and remedy of malfunctions

Not every malfunction is directly attributable to a defect in the nursing bed. Before contacting your dealer or TekVor Care, please check the malfunction using the table below.

Malfunction	Possible cause	Remedy
No function of the drives	Mains plug not connected	Connect mains plug
	Lock function on hand control activated	Unlock the hand control.
	Hand control not plugged in	Insert the hand control into the control unit.
	Drive not plugged in	Plug the drive into the control unit.
Reversed adjustment functions	Connection cable on the connectors reversed	Check plugs and connectors and reinsert.
No function after power failure	9V block battery is empty	Replace 9V block battery
Bed moves very slowly	Bed can only be adjusted via battery. Mains plug not plugged in	Plug in the mains plug and replace the 9V block battery preventively.

10 Maintenance

10.1 Fundamentals

In accordance with MPBetreibV §7 (as of 2017), operators of care beds are obliged to ensure the safe and proper operation of the medical device on an ongoing basis by means of maintenance measures (inspection and maintenance).

The service life of the care bed depends essentially on the handling and maintenance. To ensure safe operation, we recommend that a visual and functional check, including an electrical check, be carried out at least once a year and before each reuse as a guide value. This should be carried out under your own responsibility and with verifiable compliance with the 2% error rate (see also DGUV regulation 3 §5, table 1B). If an error rate of <2% is demonstrably achieved during the electrical test, the test cycle can be extended to a maximum of two years.

Carry out maintenance at least once a year and before each reuse in accordance with the maintenance schedule and the test regulations in accordance with DIN EN 62353 in its current version.

The following tests according to DIN EN 62353 apply to our care beds:

- Visual inspection
- Leakage current measurement
- Insulation resistance measurement
- Functional test
- Overall assessment and documentation

If you have any doubts about the safety or function of any part of the bed during the work described below, the bed must never be put back into operation. Then contact the supplier or manufacturer.

Electrical components must not be opened and must be replaced. Defective electrical components must be replaced by qualified personnel.

The electrical tests described here in accordance with DIN EN 62353 may only be carried out by a qualified electrician or, if suitable measuring and testing equipment is used, by a person trained in electrical engineering.

10.2 Maintenance plan

Care bed type	ULB FONDO		
Serial No.:	………………………………	Responsible:	………………………………
Location:	………………………………	Inspector:	………………………………

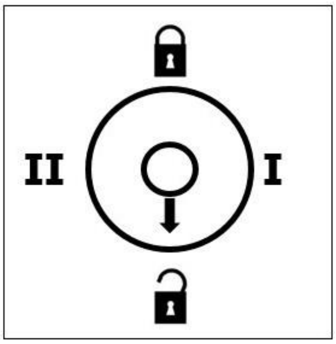
Pos.	Test instruction		OK	n. OK	Comment
1.	Examination of the basic prerequisite				
1.1	Is the general condition okay?				
1.2	Type plate of the nursing bed and the electrical components legible?				
1.3	Instruction manual available and accessible to personnel?				
1.4	Appropriate and safe use?				
2.	Visual inspection				
2.1	No surface damage or corrosion?				
2.2	Mechanical components and welds without defects?				
2.3	All mechanical connecting elements are tight?				
2.4	Lying surface floor without damage?				
2.5	Firm fit and no damage to the head and foot end pieces?				
2.6	All 4 rollers undamaged and tight?				
2.7	Parking brakes are undamaged and tight?				
2.8	Erector with grab handle and erector holder undamaged and no wear?				
2.9	Mains cable, connecting cables and plugs without damage?				
2.10	Transport protection for mains plug available?				
2.11	Strain relief for mains cable and handset securely fastened?				
2.12	Are all plug connections firmly plugged in? (sealing rings without damage)				
2.13	Correct and safe cable laying? (no damage)				
2.14	Motor, SMPS power supply and mains plug housings without damage?				
2.15	Hand control without damage?				
2.16	Thrust tubes of the height adjustment drives are undamaged?				
2.17	Socket pin with safety bracket on backrest drive is freely accessible for mechanical emergency lowering?				
2.18	9V block battery OK / expiration date enough until next test?				
2.19	Is the safe working load maintained?				
3	Electrical test according to DIN EN 62353				
3.1	Insulation resistance >7MΩ?	Measured value:			
3.2	Device leakage current <0.5mA?	Measured value:			

4	Functional test			
4.1	All adjustment possibilities of the care bed without obstacles on site?			
4.2	Does the locking mechanism for lower leg adjustment work?			
4.3	Stress test successfully carried out according to regulations?			
4.4	Function test of the handset: correct operation of the keys?			
4.5	Function test of the handset locking device: On/Off OK?			
4.6	Check of the first-error safety by means of an integrated locking box in the handset without complaint?			
4.7	Track rollers, easily rotatable by 360°?			
4.8	Wheels, individual parking brakes are functional (enough braking effect available)?			

10.3 Check of first-error safety by means of locking function in manual switch

Proceed as follows to check the safety device:

The switching positions I and II are test settings which are used for the safety checks as part of the annual inspection or after repair or before each re-use of the care bed.



Check the switch positions on the back of the handset using the following four points:

- Switch position adjustment : Move all bed adjustments to a slightly raised position.
- Setting the switch position : Electrical adjustments must not be possible when the adjustment keys are pressed.
- Set the switch on the back of the hand control to test position **I**: Electrical adjustments must not be possible when the adjustment keys are pressed.
- Move the switch on the back of the handset to test position **II**: Electrical adjustments must not be possible when the adjustment keys are pressed.

11 Warranty

Within the scope of our terms of delivery and payment, we guarantee the perfect condition of our care beds.

In the event of unauthorised modifications to the product, improperly carried out maintenance work and use contrary to the instructions for use, warranty and product liability claims shall lapse.

12 Useful life and disposal

The service life for beds in domestic areas is assumed to be approx. 5 years. The service life naturally depends on the way in which the bed is used. The ULB Fondo nursing bed is suitable for re-use in accordance with the measures in chapters 8 and 10. Frequent transport, installation and adjustment reduce the service life just as much as improper handling, irregular maintenance and exceeding the safe working load or permissible load cycles of the electric drives. The healthcare bed must not be disposed of with normal household waste at the end of its service life. For environmentally friendly disposal, please contact your local authority or TekVor Care.

13 Technical specifications

13.1 Technical data (mechanical)

Safe working load (max. permissible load)	180kg
Individual loads of the safe working load	Max. patient weight 170kg Mattress 200x90x12cm 10kg Total 180kg
Safe erecting load (optional)	80kg
Max. patient weight	170kg
Total length	2170mm (with 2000mm long lying surface)
Total width	900mm (with 900mm wide lying surface)
Height of upper edge of head/foot section	846 – 1419mm
Height adjustment of lying surface	electric stepless from 67-640mm
Backrest adjustment	electric stepless up to approx. 70°
Thigh rest adjustment	electric stepless up to approx. 30°
Foot elevation	mechanical, -20°to 0° in 4 steps
Lying surface floor	Steel spring connectors
Individual weights / empty weight	Half of the lying surface head side: 24kg Half of the lying surface foot side: 23,5kg Bed control parts: 13kg each Empty weight: 73kg
Track rollers	Ø 75mm double plastic rollers
Materials	Frame, lying surface, etc.: Steel (powder-coated) Header and foot section: wood
Operating noise	<53 dB(A) at 1m

13.2 Technical data (electrical)

Control + power supply SMPS	MC220 + MC125 (Limoss Company)
Nominal voltage	230V / 240V ~
Nominal frequency	50-60Hz
Current type	AC~
Nominal admission during operation	70 Watt
Rated recording in idle state	0,5 Watt
Rated operation/nominal rest time	2Min/18Min (max. 5 switching cycles/min)
Primary fuse	2,0 A
Emergency lowering battery	9V block battery (alkaline manganese type 6LR61)
Reclining surface drive (back/knee)	2xMD125 (Limoss Company)
Height adjustment drive	2xMD121 (Limoss Company)
Protection class of the drives	IPX4 (protection against splashing water on all sides)

13.3 Technical data environment

Temperature range operation	+10°C to +40°C
Temperature range storage/transport	-10°C to +60°C
Air humidity	30% to 75% rel.
Air pressure	between 795 and 1060 hPa

13.4 Classification

Medical device	Class 1
Degree of protection according to DIN EN 60601-1	Application part of type B (Protection against electric shock)
Housing protection class according to DIN EN 60529	IPX4 (protection against splashing water on all sides, but not suitable for tunnel washers)
Max. Duty cycle	10%, On 2Min/Off 18Min
Max. Switch-on cycles / min	5
Safety inspections	1x yearly

13.5 Identification plates

Identification plate
Position:
Glued to the right inside of the lying surface frame

Identification plate erector (option)

Position:
Erector

Identification plate bed extension (option)

Position:
Top side bed extension

13.6 Information for electromagnetic compatibility

Guidelines and manufacturer's declaration - Electromagnetic emissions		
The care bed is intended for operation in an environment as specified below. The customer or user of the healthcare bed should ensure that it is operated in such an environment.		
Interference emission measurements	Concordance	Electromagnetic environment - Guide
HF emissions according to CISPR 11 (partial)	Group 1	The care bed uses HF energy exclusively for its internal function. Therefore, its RF emission is very low, and it is unlikely that adjacent electronic equipment will be disturbed.
HF emissions according to CISPR 11 (partial)	Class B	The care bed is suitable for use in all facilities and those directly connected to a public supply network that also supplies buildings used for residential purposes.
Transmittance of harmonics according to IEC 61000-3-2	Class A	
Transmissions of voltage fluctuations / flicker to IEC 61000-3-3	Matches	

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The healthcare bed is intended for use in the electromagnetic environment specified below. The customer or user of the healthcare bed should ensure that it is used in such an environment.			
Immunity examinations	IEC 60601 - Test level	Concordance level	Electromagnetic environment - Guidelines
Conducted HF disturbances according to IEC 61000-4-6 Radiated HF disturbances according to IEC 61000-4-3	3 V 3 V/m	3 V 3 V/m	Portable and mobile radios should not be used at a shorter distance from the nursing bed, including the cables, than the recommended protective distance calculated according to the equation applicable to the transmission frequency. Recommended protective distance: $d = [\frac{3,5}{V_1}]\sqrt{P}$ for 80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ for 800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ With P as the rated power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and [b] d as the recommended protective distance in meters (m). The [a]field strength of stationary radio transmitters should be less than the compliance level at all frequencies according to a field study. Interference may occur in the vicinity of equipment with the following symbol. 
NOTE 1 The higher frequency range applies at 80 MHz and 800 MHz			
NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities [a] is influenced by absorptions and reflections from buildings, objects and people. The field strength of stationary transmitters, such as base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot theoretically be predicted exactly. In order to determine the electromagnetic environment with respect to the stationary transmitters, an investigation of the location should be considered. If the measured field strength at the site where the healthcare bed is used exceeds the above compliance levels, the healthcare bed should be monitored to demonstrate proper functioning. If unusual performance characteristics are observed, additional measures may be required, such as a change in orientation or a different location of the healthcare beds.			

Recommended protective distances between portable and mobile HF telecommunications equipment and the care bed

The nursing bed is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or user of the healthcare bed can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the healthcare bed, depending on the rated power of the communication device as specified below.

Transmitter rated power W	Protective distance dependent on transmission frequency 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	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters whose maximum rated power is not specified in the table above, the recommended protective distance d in metres (m) can be determined using the equation corresponding to the frequency of the transmitter, where P is the maximum rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the protective distance applies to the higher frequency range.

NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections from buildings, objects and people.

14 Declaration of conformity

DECLARATION OF CONFORMITY

We, the company

TekVor Care GmbH
Fraunhoferstraße 8
D-51647 Gummersbach

declare under our sole responsibility that the medical device:

Handicapped accessible bed / care bed type:
ULB-Fondo

complies with all applicable requirements of Directive 93/42/EEC, Annex I.

Conformity assessment procedure: Annex VII

This declaration of conformity loses its validity if the product is modified without consultation with the manufacturer.

Gummersbach,01.06.2019
Place, Date

Jakob Löwen, Executive Manager