tecfor care

INSTRUCTION MANUAL

ASSEMBLY AND OPERATION

BED-IN-BED SYSTEM

Eco-BiB

04441 - GA_Eco BiB_EN_10092024

CE

Last update: 10.09.2024

Dear customer,

The tecfor care team would like to thank you for the trust you have placed in our Eco-BiB bed-in-bed system.
The Eco-BiB is an insertion frame with lifting system that can be integrated into a standard bed frame and offers all the functions of a nursing bed. Thus, the homely ambience at home remains.
With the decision to purchase this healthcare bed from „trecfor care“ you receive a care product with high functionality at the highest safety level.
With the Eco-BiB we can guarantee you optimal lying comfort.
All beds are carefully checked by our staff before delivery.
The care bed delivered to you has left our house in perfect condition.
When you receive the Eco-BiB, the responsibility for its proper and intended operation also passes to you at the same time.
This instruction manual informs you as the operator and your users in their daily work about the functioning and safe handling of the Eco-BiB bed-in-bed system.
Please always keep the instruction manual at hand near the Eco-BiB .
We are convinced that our product will make a positive contribution to your care.

Best regards
Your tecfor care Team

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

Eco-BiB
Lying surface 90 cm x 200 cm
integrated / fixed in a bed frame

Eco-BiB as a freestanding bed „stand-alone-System“
Lying surface 90 cm x 200 cm
with additional feet

Before the first use:
Read the instructions for use conscientiously and completely!
Please pay attention to the various safety instructions.

The Eco-BiB bed-in-bed system should be cleaned and disinfected before using it for the first time and before each use. tecfor care healthcare beds carry the CE mark and meet the requirements for safety and functionality. For this purpose, the Eco-BiB has been tested according to the international standards which contain the safety requirements for medical devices.
However, these safety requirements can only be met if the user is convinced that the Eco-BiB (including accessories) is in proper condition before use.
Please observe the Medical Device Operator Ordinance (MPBetreibV, 2021).

1.1 Explanation of the symbols used

In these operating instructions, important information is indicated by the following symbols:

	Read information with this symbol carefully and observe it urgently. This information is relevant to safety.
	This symbol warns of dangerous voltage. There is a danger to life!
	This symbol warns of general dangers. There is danger to life and health.
	Mark of conformity according to Medical Devices Regulation (EU) 2017/745
	manufacturing date
	Manufacturer of the medical device
	medical device
	Serial number
	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 IEC 60601-1

The healthcare bed may only be used indoors

The product must be collected separately in the European Union. Disposal with normal household waste is not permitted.

Symbol for direct current

Symbol for alternating current

Symbol for safe working load

Symbol for maximum patient weight

Symbol for reading 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 industry and which is brought into a health facility by this member for use is the relevant member of the medical profession or the medical industry. 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, 2021]

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, 2021) are binding.
- The bed-in-bed system Eco-BiB is a medical device and may only be operated and used in accordance with its intended purpose and the regulations of the MPBetreibV, the relevant legal regulations 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.
- 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, 2021].

User requirements
- Use the Eco-BiB bed-in-bed system only as intended and in accordance with these operating instructions.
- 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 Eco-BiB, make sure that it is in good working order and condition.
- Observe the instructions for use and the other safety-related information enclosed.
- If suspected serious events occur in connection with the Elco-BiB care bed, they must be reported to tecfor care GmbH and the responsible federal authority. Serious incidents occurring in other contracting states of the Agreement on the European Economic Area must be reported to the competent authorities of this state.
- Suspected Serious events means an event that cannot be ruled out due to an undesirable side effect of a product, a malfunction, deterioration in the properties or performance of a product, including application errors due to ergonomic features or an inadequacy of the information provided by the manufacturer is based.
- Such a suspected serious event can have led directly or indirectly to death, to a temporary or permanent serious deterioration in the state of health of a patient, user or other person, as well as to a serious risk to public health (refer to the Ordinance on the Reporting of Suspected serious incidents with medical devices as well as for the exchange of information between the responsible authorities - MPAMIV.

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 healthcare bed.

requirements for the patient / resident
It is possible for the patient lying in bed to independently operate the electrical adjustment functions of the care bed via the hand switch if he has been instructed in the use of the care bed and is mentally and physically able to do so. Independent use of the care bed by the patient therefore requires that the patient can carry out the adjustment functions safely and specifically using the hand control and can also free himself from dangerous situations.

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.

2.1 Intended use (Application Environment)

The Eco-BiB bed-in-bed system is designed for the accommodation of adults with a height of 146 cm or more and a body weight of 40 kg to max. 185 kg. It is suitable for use in senior residences, nursing residences and in home care - i.e. in application environments 3 and 4 - and may only be operated under the operating conditions described in these operating instructions.
The Eco-BiB is intended to alleviate or compensate for disability or incapacity and to facilitate working conditions for the carer.
Any other use is considered improper and is excluded from possible liability.

The Eco-BiB bed-in-bed system is designed for use in standard beds or bed frames, provided that the circumferential safety distance between the insert frame and the bed frame is at least 2.5 cm in order to avoid pinching and clamping points.
The Eco-BiB can either be screwed directly to the bed frame or fixed on feet as a „stand alone system" (see chapters 5.4 and 5.5).
Attention: The Eco-BiB bed-in-bed systems are not designed for use in hospitals.
They are not EX-protected and must not be operated in hazardous areas.
The Eco-BiB bed-in-bed systems may only be used in dry interior rooms.

The Eco-BiB bed-in-bed systems has no connection option for equipotential bonding.
You must therefore take this into account when combining the care bed with other electrical medical devices or with other mains-operated products.
The operator, as a competent person, must check whether the corresponding combination of the care bed with other electrical devices is safe during the service life and no unacceptable risks can occur.
The operator of the medical devices is responsible for ensuring that the combination of the devices meets the requirements of IEC 60601-1.
Non-electrical medical devices must comply with the IEC or ISO safety standards applicable to these devices if they are to be used / combined with the care bed.
If cables from other devices are routed in the care bed, precautions must be taken to prevent these cables from being crushed between parts of the care bed.
Take into account the information and safety instructions in the instructions for use of the electrical devices that you want to combine with the Eco-BiB care beds (e.g. anti-decubitus alternating pressure systems, feeding systems, infusion pumps, lamps, etc.) as well as the requirements of the IEC 60601-1 standard (in the current Version).
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.

2.2 Unauthorized use

All uses deviating from the intended use, which can then also lead to hazards.
These include, for example:

- patient height <146cm
- patient weight <40kg
- BMI <17 (Body-Mass-Index = Patient weight (kg)/Patient height $(m)^2$
- Load on the Eco-BiB bed-in-bed system exceeds the permissible safe working load (see par. 12.1 and nameplate on bed frame)
- Operation of the Eco-BiB by the patient or resident who has not received any instruction
- Use of the Eco-BiB for children
- Use of the nursing bed on a non-horizontal surface (max. inclination 5°)

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

If the psychological or mental condition of the patient requires it, the hand control must be locked using the lock switch on the back of the hand control (nurse key). The locking function is described in detail in par. 6.3. 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 cables.

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

If a possibly necessary side guard (side rail) is used, pay particular attention to the following instructions:

- Only use side rails approved by tecfor care GmbH as optional accessories. The permissible dimensions can be found in chapter 12.1.
- The use of incompatible side rails is not permitted and can lead to hazards, e.g. due to trapping.
- The distance between two side rails lying one above the other or between the lower edge of the lower side rail and the lying surface must not exceed 12 cm.
- Only instructed personnel may operate the side rails.
- Side rails may only be fully raised and locked or fully lowered.
- When lowering the side rails, take care not to drop them.
- No parts of the patient‘s body may protrude over the lying surface or touch the side rails while the adjustment function is being actuated.
- The side rails only offer protection against rolling out when the backrest and knee adjustment are in the horizontal position.
- Under no circumstances should side rails be used improperly (e.g. for climbing over or supporting).
- The distance between the top edge of the side rail and the top of the mattress in non-compressed condition must be at least 22 cm. If the distance is less than the specified minimum, use a side rail elevation.
- When in use, the side rails must not remain in a diagonal position.

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 stuck, as it is carried with the height adjustment of the care bed.

Otherwise the mains cable may 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 Eco-BiB must also not be pinched, squeezed or pulled by the functions of the care 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.

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

The Eco-BiB bed-in-bed system must not be used in potentially explosive atmospheres.

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

3.2 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 nursing bed. This also applies to persons who only operate the healthcare bed as representatives.

According to the Medical Devices Regulation (EU) 2017/745, care 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, function checks and visible damage must be carried out and documented at least once a year (see chapter 9.2).

3.3 Safety instructions for the user

Let the operator instruct you in the safe operation of the Eco-BiB.
Pay attention to the general safety instructions as described in section 3.1.
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 reduces the risk of injury to the patient when getting on and off the bed.

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.

3.4 Cleaning and disinfection

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, only wipe them 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.

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

3.5 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 (2021) §5.

Maintenance, inspection and repair work are not allowed to be carried out on the nursing bed when it is in use and the patient is in it.

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 9.2) after a longer period of inactivity and before each reuse.

If the tests reveal defects, damage or defects, the Eco-BiB may no longer be operated. Maintenance of the Eco-BiB must be carried out by qualified personnel in accordance with MPBetreibV (2021) §5.

Only original spare parts and accessories of the manufacturer may be used, otherwise all 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.

3.6 Accessories / Options

An lifting pole with triangle handle is available as an accessory (see chapter 5.7), the safe working load of which must not exceed 80 kg. The erector is not intended for lifting persons but facilitates the transition 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.

A fixed steel side rail is available as a further accessory. When using the optional side rails, observe the assembly instructions in Chapter 5.8 and the safety instructions in chapter 5.8.1.

Please only use mattresses that are compatible with the optional side rails supplied. The distance between the mattress surface in the non-compressed state and the upper edge of the upper side rail must be at least 22 cm. If the distance is less than this, a side guard must be used. As a rule, a mattress thickness of 12 cm is suitable.

Make sure that the dimensions of the mattress match the dimensions of the lying surface of your care bed. When using mattresses that are not compatible with this care bed, hazards can arise, e.g. through falling out, trapping, etc.

Further options are

- Reading light
- grab handle
- infusion stand

3.7 Storage

If the Eco-BiB bed-in-bed system is stored for a longer period, the 9V block battery should be removed as a precaution to avoid damage to the bed due to possible leaks.

3.8 Useful life and disposal

With correct operation and appropriate use, this care bed has an expected service life up to 10 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 tecfor care GmbH.

The electrical components (power supply units, control units, drives and hand controls) of these beds are to be treated like electronic waste in accordance with WEEE Directive 2012/19/EU (Waste Electrical and Electronic Equipment) and disposed of properly.

The components used conform to the directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
When disposing of it, please note that the bed or its accessories can be contaminated and contaminated with germs. Damage can also result in sharp edges, splintering, etc. These can lead to health risks.

The Eco-BiB bed-in-bed system is supplied either fully assembled or modularly mounted on a transport device. The Eco-BiB integrated on the transport device can be moved in the narrowest space by means of the rollers on the transport device.

As-delivered condition

Eco-BiB on the transport device

The Eco-BiB bed-in-bed system must be assembled and put into operation in accordance with the information in these instructions for use. Please refer to chapters 5.1 to 5.8.

5.1 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 (if present) (a) with a side cutter or scissors.

2. Lift the transport carton (b) from the entire bed unit including the transport device.

Please do not dispose of the cover! This can be used again as a dust cover when storing the nursing bed on the transport device later.

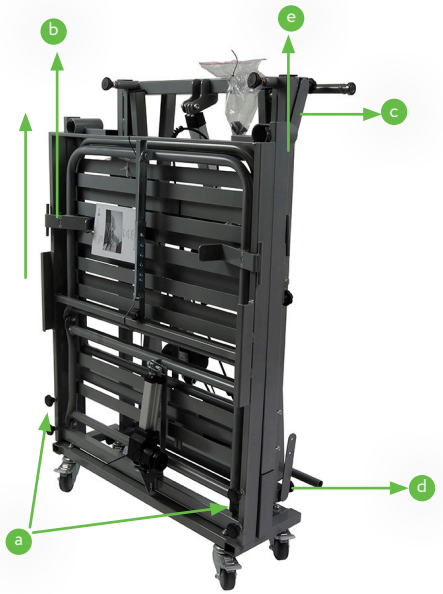
⚠ For removal from the transport device, the Eco-BiB must be stationary, i.e. the four individual brakes on the wheels must be stationary.

When removing the individual elements from the transport device, bear in mind that the centre of gravity of the transport device may shift and the Eco-BiB including the transport device may tilt sideways.

3. Loosen the four star grip screws (a) on the foot section lying surface half and pull the lying surface half out of the mounting brackets (b).

4. Then lift the underframe (c) out of the holder of the transport device.

5. Loosen the fastening screws (d) on the holders of the headrest lying surface half and lift them out (e).



5.2 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:

a. Head section with drive, control unit, hand switch and lying surface connector (1x)

b. Foot section with drive (1x)

c. Underframe with height adjustment drive (1x)

d. Mattress support bracket (4x)

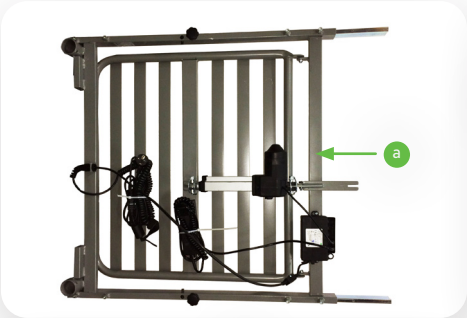
e. Hand switch with nurse key (1x)

f. SMPS-Power supply with mains plug (1x)

g. Plastic closing nozzle (2x)

h. Transport device (1x)

i. Instruction manual (1x)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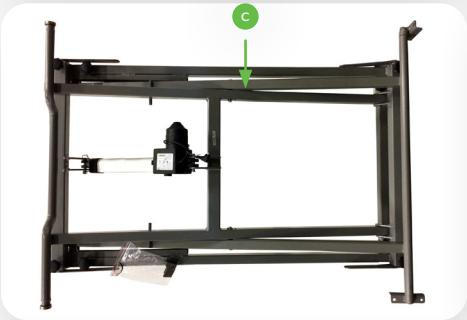
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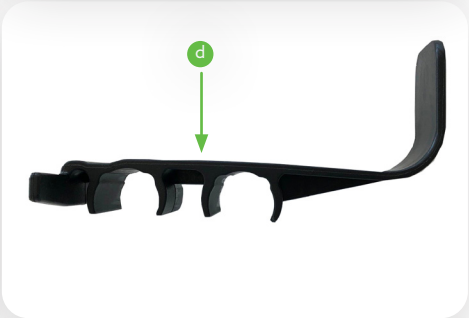
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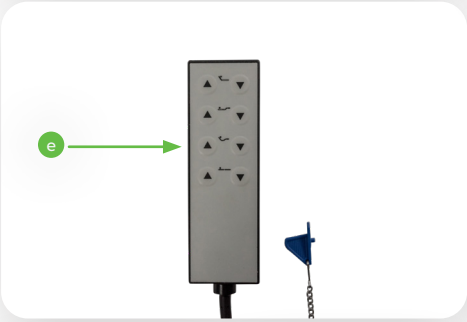
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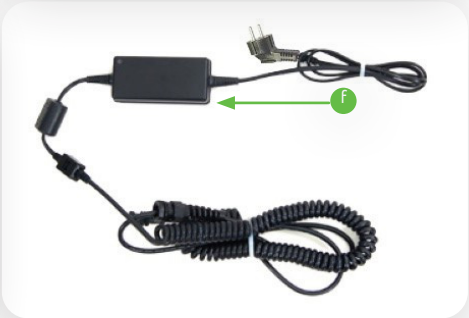
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i

5.3 Assembly of the Eco-BiB bed-in-bed system

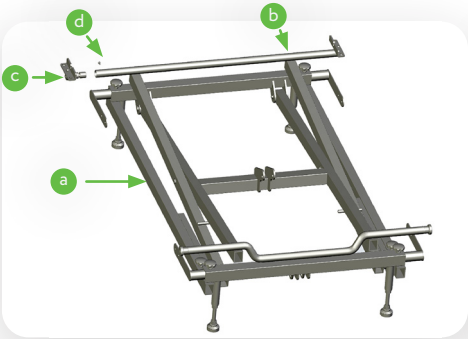
⚠ To assemble the Eco-BiB, proceed step-by-step as follows:
Depending on the extent to which the Eco-BiB is supplied pre-assembled, some steps may be omitted. For the purpose of completeness, we have listed the individual elements. This will help you with assembly and disassembly by one person.

1. Place the underframe with the feet on the floor(a).

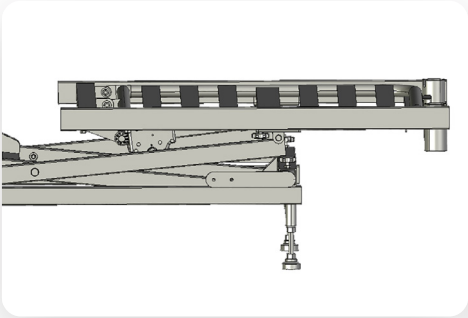
2. Press the two supplied plastic sealing nozzles into the front frame openings of the underframe, which were used for mounting on the transport device.(b).

3. Place the two holders on the base frame horizontally with the bulge and the side edges pointing upwards (c) and fasten them with one screw each (d).

4. Unscrew both star grip screws located centrally on the underside of the head section (e).



5. Place the head section on the underframe mounts (a) and connect both components with the star grip screws.(b). Tighten both star grip screws (1 star grip screw on each side).

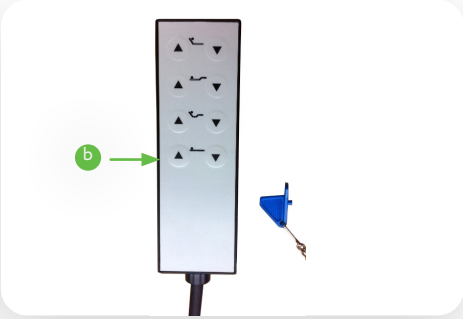


6. Disconnect the cable ties that attach the power supply unit and the hand control to the lying surface.

The electrical cables must not be damaged when the cable connectors are disconnected.

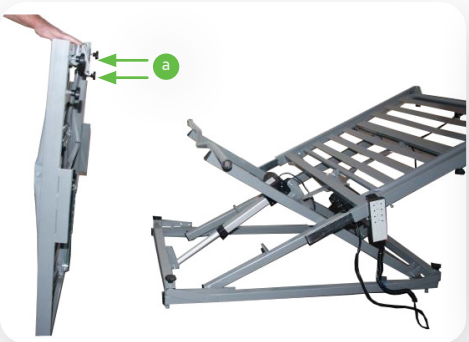
7. The plug for the handset (marked black) and the plug for the head unit (marked white) are already plugged into the control unit at the factory. Plug the Eco-BiB mains plug into the mains socket.

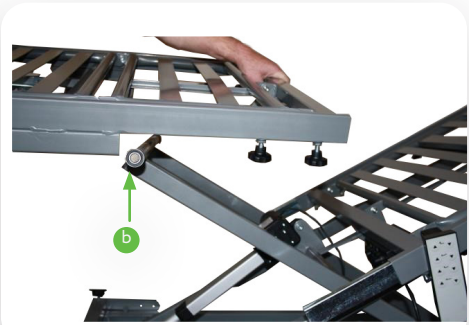
8. Raise the underframe including the headrest (a). To do this, press the button on the handset (b).



9. Prepare the footrest for mounting on the base frame, i.e. loosen the four star grip screws on the underside of the footrest.

10. Insert the castors of the base frame (b) into the guide rails of the foot section.





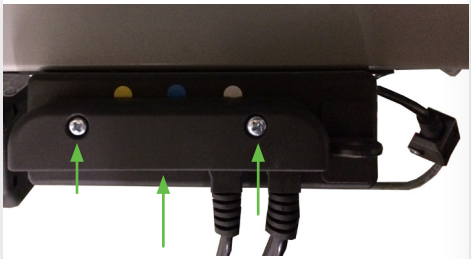
11. Connect both lying surface elements with each other. Slide the lying surface connectors (c) on the headboard into the frame openings on the footboard.

12. Tighten the 4 star grip screws (d) on the bottom of the footrest.

13. Remove the cover on the control unit by loosening both screws.

14. Insert the plug of the height adjustment drive (marked yellow) and the plug of the foot section drive (marked blue) into the corresponding sockets of the control unit.

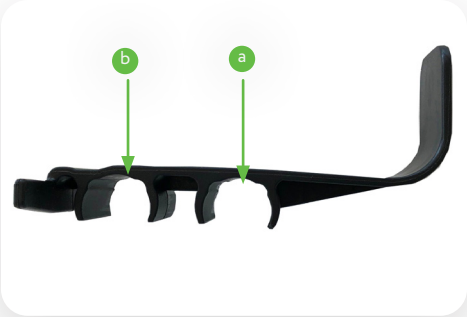
15. Replace the cover on the control unit with both crosshead screws.



(a) Height adjustment drive
(b) Thigh adjustment drive on foot section
(c) Backrest adjustment drive on headrest
(d) Hand control

16. Place the mattress support brackets on the side tubular frame of the lying surface. For this purpose, two mattress support brackets must be positioned opposite each other on the backrest lying surface and two mattress support brackets opposite each other on the lower leg lying surface.

⚠ The mattress temples are equipped with two holders in order to widen the lying surface to 100cm. When using a 100 cm wide mattress, the left holders of the mattress support brackets must be used.



(a) Slot for 90cm wide lying surface
(b) Slot for 100cm wide lying surface

⚠ The Eco-BiB is now functional.
The patient may only be positioned on the Eco-BiB after the additional feet have been fitted (see Chapter 5.4) or after they have been fitted in a bed frame (see Chapter 5.5).

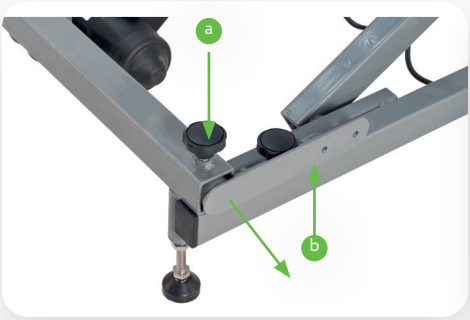
5.4 Use of the Eco-BiB as a free-standing bed „stand-alone system“

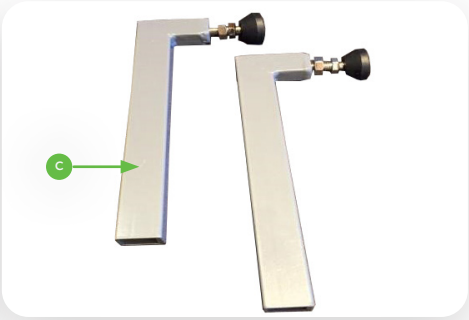
⚠ If the bed-in-bed system is not to be or cannot be fixed to the bed frame and is to be used as a so-called stand-alone system, i.e. a free-standing bed, the additional feet (optionally available) must be used to increase the tilt stability. Proceed as follows to install the additional feet:

1. Loosen the star grip screws **(a)** on the angle pull-outs **(b)** on the base frame and pull the 4 angle pull-outs out of the frame.

2. Slide the auxiliary feet **(c)** at each corner into the mountings of the underframe and tighten the star grip screws. In order to achieve good tilt stability, the additional feet should be at least 1/3 of their length pushed into the frame.

3. If necessary, adjust the height of the feet on the additional feet to ensure that the Eco-BiB stands securely. The instruction steps for adjusting the height of the feet are described in chapter 5.6.



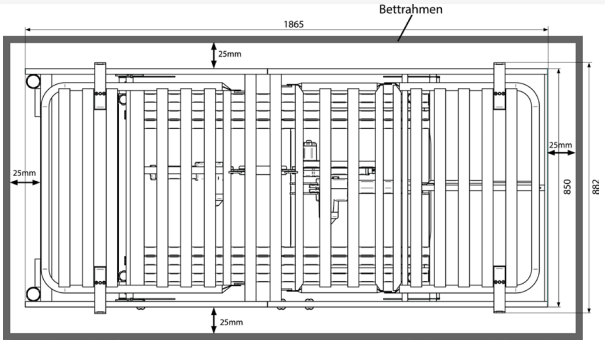


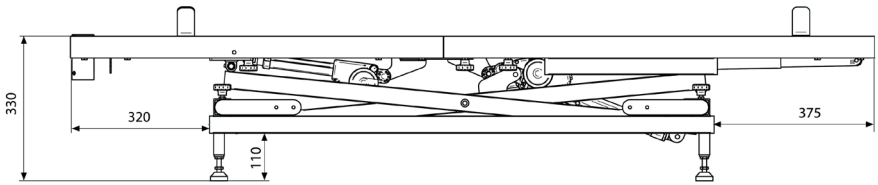
Slide the additional feet into the holders of the underframe and tighten the star grip screws.

5.5 Mounting in a bed frame

Before installation, check whether your Eco-BiB bed-in-bed system fits into your bed frame using the following dimensional sketches.

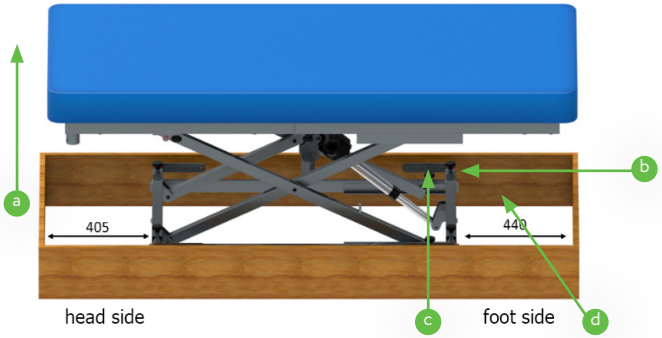
⚠ Please note that a safety distance of at least 25mm must be maintained between the outer frame of the Eco-BiB and the inner dimension of the bed frame in order to avoid pinching and clamping points.





When mounting the Eco-BiB in a bed frame, proceed as follows:

1. Note that the pull-outs for fixing the Eco-BiB or the additional feet (when used as a stand-alone system) are already mounted and fully inserted before the Eco-BiB is positioned in the bed frame.

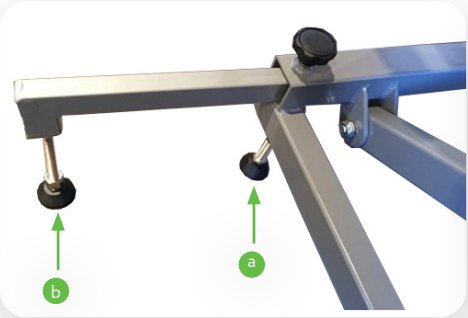


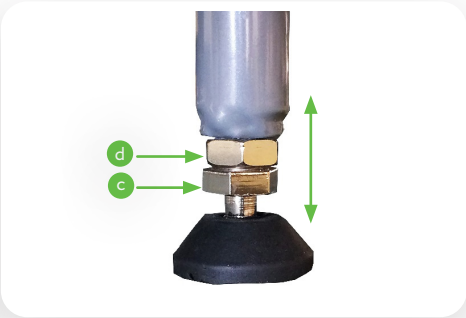
2. Place the Eco-BiB in the existing bed frame as shown in Figure
3. If the floor is uneven, align the bed-in-bed system horizontally with the height-adjustable feet (see section 5.6).
4. Move the Eco-BiB down as far as it will go to determine the distance between the bed frame and the lying surface frame.
5. Place the Eco-BiB in such a way that there is a constant amount of free space all around, but at least 25mm is available.
6. Move the Eco-BiB to the top position. (a)
7. Loosen the 4 star grip screws (b) on the angle pull-outs and pull out the 4 pull-outs sideways until they touch the inside of the bed frame.
8. Fix the pull-outs to the inside of the bed frame (c) with two wood screws each. Check beforehand the suitability of the wood screws (length, thickness) for your bed frame.
9. Tighten the 4 star grip screws (b) on the pull-outs. (c) Do not use any tools to tighten them.
10. The Eco-BiB is now connected to your bed frame.

⚠ When using the stand-alone system, i.e. without fixing it to the bed frame, follow steps 1 to 6. The additional feet should be pulled out until they touch the inside of the bed frame.
Finally, check the safe and secure position of your Eco-BiB.
Check the unobstructed clearance of all adjustment functions and compliance with the safety distances in order to avoid pinching or clamping points.
The lying surface of the Eco-BiB must not be completely submerged during lowering. The distance between the lower edge of the lying surface and the upper edge of the bed frame must be at least 25 mm.
Make sure that the power cord and the handset cord are not pinched or squeezed.
If you have any questions regarding the bed frame, please contact tecfor care GmbH, as they depend on the bed frame in question.

5.6 Adjusting the height-adjustable feet

In order to compensate for slight unevenness of the floor and to ensure a stable position of the bed-in-bed system, it is possible to adjust the height of all 4 feet (a) and the additional feet (b) (optionally available) of the Eco-BiB.





1. Turn the lower nut (c) anticlockwise using a wrench (SW 19). The stand is extended, i.e. the bed-in-bed system is moved upwards. The upper lock nut runs with it.

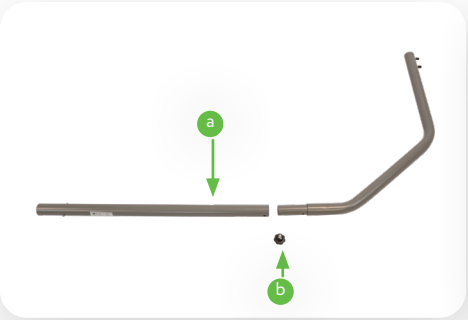
2. Once the stand has reached the desired position, turn the upper locking nut (d) back to the stop.

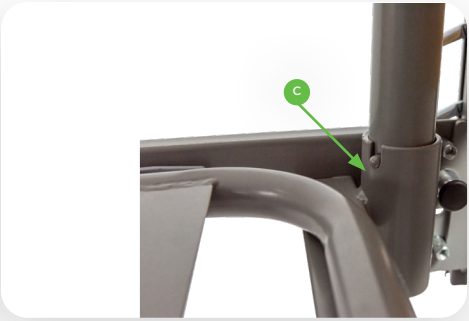
5.7 Lifting pole with triangle handle (accessory)

With the help of the lifting pole, the patient can stand up and move more easily into another position. A triangle handle is attached to the lifting pole.
Mount the erecting yoke by putting the two parts together (a) and screwing the star grip screw into the threaded hole(b) and tightening it! Insert it into the erecting fixture in the lying surface.

⚠ Make sure that the locking cylinder pin (c) engages in the recess of the lifting pole fixture.

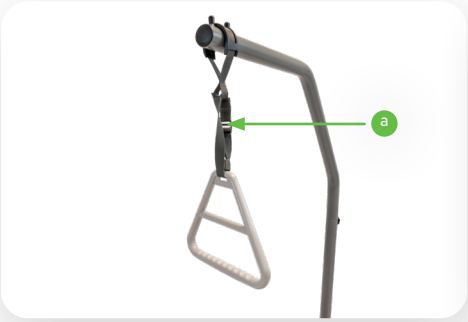
⚠ Attention: The pole fixture bracket must not be used outside the latching mechanism.

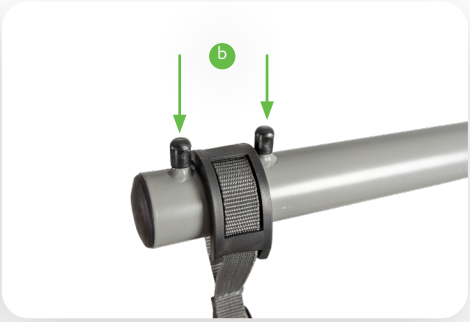


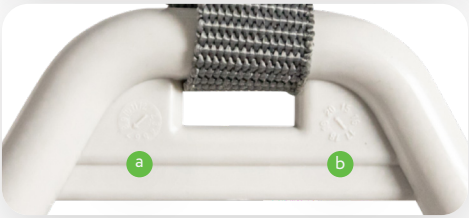


The length of the strap of the triangle handle can be adjusted by the buckle (a). Select an adjustment that allows the user to easily reach the handle when lying down (usually between 55-70 cm measured from the upper edge of the mattress). Make sure that the belt is securely fastened again.
The triangle 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 that it is securely held by pulling the triangle handle downwards. Fix the loop of the triangle belt only between these two bolts (b)!







a. Production month

b. Production year

5.8 Steel side rails (accessories- item no. BC 1.47.0220340 or 01775)

Tecfor care GmbH steel side rails are available as accessories for the Eco-BiB bed-in-bed system.
The intended use of the steel side rails is the installation exclusively on the Bed-in-bed system Eco-BiB. The use of the steel side rails reduces the risk of the patient falling out of the Eco-BiB unintentionally.
The side rails are not designed to prevent the patient from leaving the bed intentionally.

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

5.8.1 Safety instructions when using the steel side railser

If a possibly necessary side railing is used, special attention must be paid to the following instructions:

- Only use side rails approved by tecfor care GmbH as optional accessories (item number BC 1.47.0220340 or 01775).
- The use of incompatible side rails is not permitted and can lead to hazards, e.g. due to trapping.
- The distance between two side rails lying one above the other or between the lower edge of the lower side rail and

the lying surface must not exceed 12 cm.

- Only instructed personnel may assemble/disassemble the side rails.
- When using the side rails, their suitability must be assessed by the attending physician or a nurse, considering the individual needs and abilities of the patient.
- During operation of the adjustment functions of the nursing bed, no parts of the patient's body may protrude over the lying surface or touch the side rails.
- The side rails only offer protection against rolling out when the backrest and knee adjustment are in the horizontal position.
- Under no circumstances should side rails be used improperly (e.g. for climbing over or supporting).
- The distance between the top edge of the side rail and the top of the mattress in non-compressed condition must be at least 22 cm.
- When using side rails, there is an increased risk of crushing and clamping.

5.8.2 Control of the delivery and the scope of delivery

After unpacking, please check that the delivery is complete. The following parts are required for assembly:

Steel side guard (2x), item number BC 1.47.0220340/ 01775

Side rail holder incl. 8 screws for 90x200cm (4x)

item number BC 1.47.0050340 /01493 or

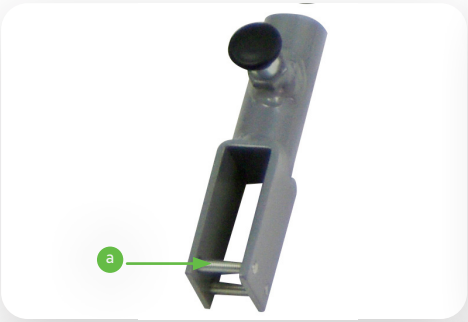
Side rail holder incl. 8 screws for 100x200cm (4x)

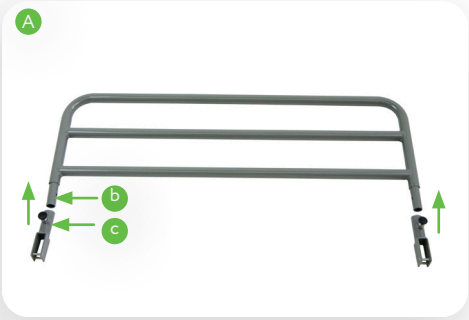
item number BC 1.47.0040340 / 01492

5.8.3 Assembly of the steel-side rails

Proceed as follows to install the steel side rails:

1. Fully unscrew the screws (a) on the side rail brackets.
2. Push the side rail holders onto the ends of the side rails (b).
3. Pull out the locking bolt (c) on the side rail holder and let it engage in the hole in the side rail.





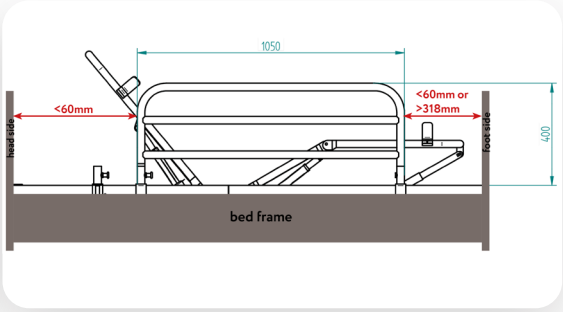
A side rail holder for 90cm wide lying surface

B side rail holder for 100cm wide lying surface

4. Place the side rail holders with the side rails centrally on the lying surface frame.

⚠ If the Eco-BiB bed-in-bed system is mounted in a bed frame, the distance between the headboard of the bed frame and the side rail must be <60mm.

⚠ The distance between the foot part of the bed frame and the side rail must be <60mm or >318mm.



5. Screw the fastening screws (2 per side rail holder) back into the side rail holders and tighten them.

⚠ After installing the side rails, check that they are firmly mounted to the lying surface frame and that the locking mechanism between the side rail holder and side rail is fully engaged.

⚠ Check whether the Eco-BiB can be adjusted in height without touching the bed frame.

5.9 Commissioning

The Eco-BiB bed-in-bed system is ready for operation after it has been successfully carried out and all steps from Chapter 6, Paragraphs 5.3 to 5.8 have been observed. After the Eco-BiB has been installed, carry out a check in accordance with Chapter 9, Paragraph 9.2.
Clean and disinfect the bed before using it for the first time and before each use according to Chapter 7.
Place your mattress on the lying surface of your Eco-BiB. The mattress dimensions must correspond to the dimensions of the lying surface.
Connect the mains plug into the mains 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 not crushed or driven over.

The Eco-BiB bed-in-bed system can now be used.

5.10 Disassembly of the Eco-BiB bed-in-bed system

Always disconnect the mains plug from the socket before dismantling!
Disassembly of the Eco-BiB is carried out in reverse order to assembly.

6.1 Technical overview of the Eco-BiB

a. Electrically adjustable backrest

b. Electrically adjustable thigh support

c. Mechanically adjustable lower leg support

d. Hand control with nurse key

e. Electric drive for backrest

f. Electric drive for thigh support

g. Electric height adjustment drive

h. Mechanical snap-in fitting for adjusting the lower leg support

i. Mattress support bracket

j. Tube holder for erecting bracket (on both sides)

k. Erector with triangle handle (option)

l. Height-adjustable feet

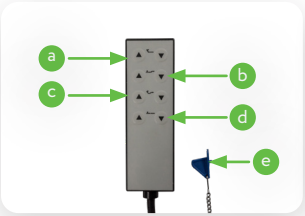
m. Angle pull-outs for fastening to the bed frame

n. Power supply unit with SMPS, mains cable and mains plug

o. Underframe

6.2 Handset with locking function

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



a. Backrest adjustment up/down electric infinitely variable 0°-70°

b. Thigh adjustment up/down electric infinitely variable 0°-30°

c. Backrest and lower leg section simultaneously up/down

d. Lying surface up/down

e. Nurse key

f. Hand switch hook

g. Lock for activating/deactivating the handset functions

⚠ To avoid damage, the hand control should always be suspended from the hand control hook when not in use (e.g. lying surface frame or side rails).

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

6.3 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 **(a)**.

The switching positions I and II are test positions which serve to check the safety during the regular safety check or after repair work (see chapter 9.3).

6.4 Emergency lowering

6.4.1 Emergency lowering via integrated 9V battery (electric)

The control unit attached to 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 block battery, as the capacity of the 9V block battery is very limited.

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

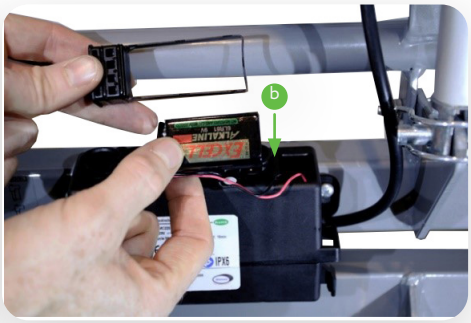
However, the 9V block battery should be replaced every 2 years even if not in use.

6.4.2 Battery change

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

Replace the battery as follows:

- Disconnect the mains plug!
- Remove the plug lock by unscrewing the two cross-head screws.
- Pull the battery compartment together with the 9V battery out of the control unit (a)
- Disconnect the batteries from the battery clip
- Replace the batteries with new equivalent batteries of the type „Alkali- Manganese battery type 6LR61(b)
- Slide the cover with the new 9V block battery back into the opening of the control unit. Make sure that the seal is not damaged.
- Finally fasten the cover to the control unit with both screws. Make sure that the screws are not overtightened during tightening.



6.4.3 Emergency lowering of the backrest (manual)

If the backrest must be lowered in less than 30 seconds in the event of a power failure or the Eco-BiB's electric drive system has failed, you can lower the backrest manually.

⚠ Observe these safety and implementation instructions, as non-compliance can lead to uncontrolled falls from the backrest and thus to serious injuries for the user and the patient!

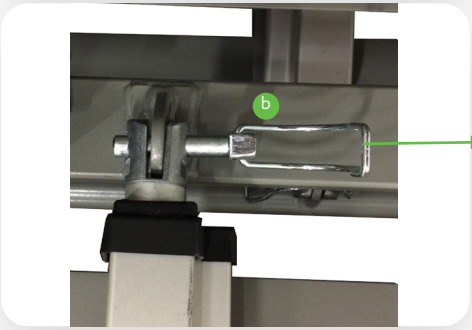
⚠ Always carry out the emergency lowering of the backrest by hand with two users!

⚠ Manual emergency lowering may only be carried out by instructed users and should be practised several times under normal conditions in order to be able to lower the backrest safely in an emergency.

Execution of mechanical emergency lowering:

- The first user relieves the backrest before the emergency lowering by lifting the frame and holding it in this position. If necessary, the second user supports this process. (a).
- The second user folds the bent safety clip of the pin at the end of the backrest lift motor (b).
- Then he pulls the socket pin out of the lifting rod. The lift motor is now separated from the backrest and swivels
- downwards.
- Both users lower the backrest slowly and in a controlled manner.

Loosen this socket pin on the backrest drive for manual emergency lowering.



Open the safety clip on the socket pin and pull out the socket pin.

Restoration of the original condition:

- Swivel the lifting rod of the drive up again in the direction of the backrest.
- Insert the socket pin into the mounting of the lifting rod and the bed frame.
- Make sure to reinsert the socket pin from the operator side so that it is always accessible .
- Close the safety clip on the socket pin.

Clean and disinfect the Eco-BiB before using it for the first time and before using it again. For cleaning, the bed-in-bed system should be wiped by hand with a damp cloth. We recommend suitable cleaning and care products 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:
Note: In order to achieve effective disinfection, the Eco-BiB must first be cleaned.
Disinfection is possible by spray or wipe disinfection with standard 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 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.

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

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

Disruption	Possible cause	Remedy
No function	Mains plug not plugged in	Plug in the mains plug.
	Lock function on handset activated	Unlock the handset.
	Handset not plugged in	Insert the handset into the control unit.
	Drive not plugged in	Plug the drive into the control unit.
Reversed adjustment functions	Connection cable on the sockets reversed	Check plugs and sockets and reconnect.
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	Plug in the mains plug and replace the 9V block battery preventively.

9.1 Bases

In accordance with MPBetreibV §7 (as of 2021), 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 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, 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 according to the maintenance schedule and the test regulations according to IEC 62353 in its current version.
The following tests according to IEC 62353 apply to our care beds:

1. Visual inspection
2. Leakage current measurement
3. Insulation resistance measurement
4. Functional test
5. Overall assessment and documentation

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

Maintenance, inspection and repair work are not allowed to be carried out on the nursing bed when it is in use and the patient is in it.

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

The electrical tests described here in accordance with IEC 62353 may only be carried out by a qualified electrician or, if suitable measuring and testing equipment with an automated measuring sequence is used, by an electrically trained person.

The safety assessment and documentation of the test results must be carried out by a qualified electrician who has the appropriate knowledge for testing care beds.

9.2 Maintenance schedule

Care bed Type	O	Eco-BiB		Class II , Type of application part B		
Accessories	O	with steel side rails	O			
Serial No.:	.....		Responsible:		.....	
Location:	.....		Inspector:		.....	
	O	Test before commissioning	O	periodic inspection	O	Inspection after repair
Test devices used (type/inventory number):						

Pos.	Test instruction	OK	n.OK	Comment
1.	Is the general condition okay?			
1.1	Type plate from nursing bed and electrical components legible?			
1.2	Instructions for use available and accessible to personnel?			
1.3	Appropriate and safe use?			
1.4	Will the steel side rails be used appropriately?			
1.5	Werden die Stahl-Seitengitter (Zubehör) zweckentsprechend eingesetzt?			
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 fixed?			
2.4	Lying surface floor without damage?			
2.5	Firm fit and no damage to the head and foot end pieces?			
2.6	All four feet available and fixed with star grip screws?			
2.7	Eco BiB stands securely on the ground with all 4 feet?			
2.8	Angled pull-outs completely attached to the bed frame?			
2.9	Was the circumferential safety distance of at least 25mm between the outer edge of the lying surface and the bed frame maintained?			
2.10	Erector with grab handle and erector holder undamaged and no wear?			
2.11	Mains cable, connecting cables and plugs without damage?			
2.12	Transport protection for mains plug available?			
2.13	Strain relief for mains cable and handset securely fastened?			
2.14	Are all plug connections firmly plugged in? (sealing rings without damage)			
2.15	Correct and safe cable laying? (no damage)			
2.16	Motor, SMPS power supply and mains plug housings without damage?			
2.17	Manual operation without damage?			
2.18	Thrust tubes of the height adjustment drives are undamaged?			
2.19	Socket pin with safety bracket on backrest drive is freely accessible for mechanical emergency lowering?			
2.20	9V block battery OK / expiration date enough until next test?			
2.21	Is the safe working load maintained?			
2.22	No surface damage, corrosion or deformities on the steel side rails?			

3.	Electrical test according to IEC 62353			
3.1	Insulation resistance >7MΩ? / measured value: **Note:** The measurement of the insulation resistance must be carried out in addition to the device leakage current measurement if there is any doubt regarding the insulation (IEC 62353). Examples: • if the RCD circuit breaker (residual current circuit breaker) has tripped several times, • if liquid has been spilt over the appliance and creepage distances are therefore doubtful, or • if certain parts/components or devices are present where the insulation properties can change depending on the temperature, for example heating elements.			
3.2	Device leakage current <0.1mA? / measured value: **Notes:** • Possible measurement methods Direct measurement or differential current measurement (IEC 62355) • Observe the test device manufacturer's specifications for the leakage current test • The measurement of the device leakage current does not have to be carried out in the normal life expectancy of the care bed (within the first 10 years) if the visual and functional test has been passed if these care beds are equipped with a drive set from the manufacturer limoss and a power supply unit (SMPS) from the manufacturer limoss. With these care beds, the incoming mains voltage is converted into a protective low voltage of 35V in the power supply unit (SMPS).			
4.	Functional test			
4.1	All adjustment possibilities of the nursing 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	When using the steel side rails			
	Side rails height above the mattress at least 22cm?			
4.8	All screws on the side rail holders (2 per side rail holder) are present and tightened?			
4.9	Locking bolt on all 4 side rail holders without damage and functional?			
4.10	All locking pins are fully engaged in the side rails?			
4.11	Was the distance between the side rails and the bed frame maintained?			

Overall rating

Test passed

O No safety or functional defects were found

O No direct risk, the defects detected can be rectified at short notice

Test not passed

O Device must be taken out of service until the defects have been rectified!

O Device does not meet the requirements - Modification/ replacement of components/ decommissioning is recommended!

Remarks: .....

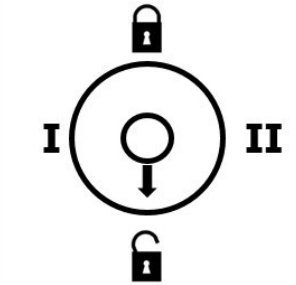
Place / Date: ..... Inspector: .....

Next test: ..... Signature: .....

9.3 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.

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.

The service life naturally depends on the way in which the bed is used. With correct operation and appropriate use, this care bed has an expected service life up to 10 years.
The care beds ULB Fondo are suitable for re-use in accordance with the measures in chapters 7 and 9. 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 care 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 tecfor care GmbH.

The electrical components (power supply units, control units, drives and hand controls) of these beds are to be treated like electronic waste in accordance with WEEE Directive 2012/19/EU (Waste Electrical and Electronic Equipment) and disposed of properly.
The components used conform to the directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

12.1 Technical data (mechanical)

Safe working load (max. permissible load)		220kg
Individual loads of the safe working load	max. Patientengewicht	185kg
	mattress 200x90x12cm	20kg
	Accesories	15kg
	Total	220kg
Safe working load of lifting pole	80kg	
Max. Patient weight	185kg	
Max. Mattress height	12 cm -20cm	
Max. Mattress height when the side rails are used	18cm	
Overall length	1865mm (with 2000mm long lying surface)	
Overall width	873mm (with 900mm wide lying surface) 973mm (with 1000mm wide lying surface)	
Height adjustment of lying surface	electric stepless from 360-800mm	
Backrest adjustment	electric stepless up to approx. 70°	
Thigh back adjustment	electric stepless up to approx. 30°	
Foot elevation	mechanical, -20°to 0° in 3 steps	
Lying surface floor	Steel spring slats	
Empty weight	74kg (without side rails)	
Weigtht of side rails	5kg (per side rail incl. 2 side rail holders)	
Materials	Frame, lying surface, side rails etc.: Steel (powder-coated) Electronic components: plastic and aluminum	

12.2 Technical data (electrical)

Control + power supply SMPS	MC220 + PS1103 (Limoss company)
Nominal voltage	230V
Nominal frequency	50/60Hz
Current type	AC~
Output SMPS	35V, 1,7A
Max. power consumption	2,4A
Rated recording in idle state	0,5 Watt
Rated operation/nominal rest time	2Min/18Min (max. 5 switching cycles/min)
Emergency lowering battery	9V block battery (alkaline manganese type 6LR61)
Protection class	II
Protection class of the drives	IPX4 (protec. against splashing water all sides)
Operating noise	<53 db(A) at a distance of 1m
Reclining surface drive (back)	MD121 (Limoss company)
Reclining surface drive (knee)	MD120 (Limoss company)
Height adjustment drive	1xMD120 (Limoss company)

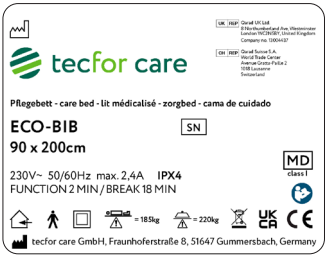
12.3 Technical data environment

Temperature range operation	+10°C to +40°C
Temperature range storage/transport	-20°C to +60°C
Air humidity	30% to 75% rel
Air pressure	between 795 and 1060 hPa

12.4 Classification

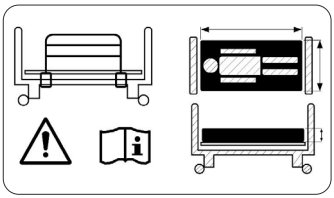
Medical device	Class 1
Degree of protection according to IEC 60601-1	Application part of type B (Protection against electric shock)
Housing protection class according to IEC 60529	IPX4 (protection against splashing water on all sides, but not suitable for tunnel washers)
Max. Duty cycle	10%, On 2Min/Off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

12.5 Identification plates



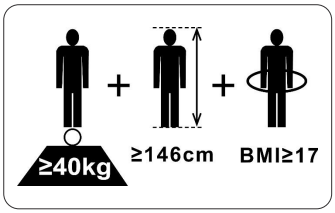
Identification plate

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



Note:
1)Exchangeable mattresses
2)Removable side rails

Position:
Frame upper side of the bed lifting frame at the foot side



Note:
Use of the care bed for adults

Position:
Frame upper side of the bed lifting frame at the foot side

Identification plate lifting pole (option)

Position:
lifting pole

12.6 Information on electromagnetic compatibility

⚠ The care bed Eco-BiB meets the normative requirements with regard to its electromagnetic interference emissions and its immunity to interference. Therefore, if the care bed is used as intended, no functional restrictions are to be expected due to possible electromagnetic interference from adjacent electrical devices.

Attention:
⚠ Nevertheless, the use of the care bed in the immediate vicinity of other electrical devices should be avoided in order to prevent the care bed from malfunctioning due to electromagnetic interference. If it is necessary to use the care bed in addition to other electrical devices, the proper functioning of the care bed and these devices should be observed.

⚠ Only spare parts (mains cable, handset, motors, etc.) and accessories that have been approved by the manufacturer tecfor care GmbH may be used in order to be able to guarantee trouble-free operation of the care bed.

⚠ The use of other accessories, other converters and other cables than those provided by tecfor care for this care bed Eco-BiB can result in increased electromagnetic interference emissions or reduced electromagnetic interference immunity of the care bed and lead to faulty operation.

⚠ Portable HF communication devices (mobile phones, two-way radios, etc.) including their accessories (e.g. antenna cables and external antennas) should not be used within a distance of less than 30 cm from the electrical components and cables of the Eco-BiB care bed. Non-observance can lead to a reduction in the performance characteristics of the care bed.

⚠ The Eco-BiB care bed is intended for use in the following specified electromagnetic environment during its entire service life in order to maintain basic safety and functional characteristics.
The operator or user of the care bed should ensure that it is used in such an environment.
The Eco-BiB care bed meets the requirements of the following EMC standards for interference emission and interference immunity:

Ambient limit values of the interference emissions	
Phenomenon	operation site in the field of medical care in a home environment
Conducted and radiated interference emissions	CISPR 11, Group 1, Class B
Harmonic distortions	see IEC 61000-3-2
Voltage fluctuations and flicker	see IEC 61000-3-3

Sheathing		
Phenomenon	EMC basic standard or test method	Immunity test level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
High-frequency electromagnetic fields	IEC 61000-4-3	10 V/m ;(80 MHz up to 2,7 GHz; 80% AM at 1 kHz)
High-frequency electromagnetic fields in the immediate vicinity of wireless communication devices	IEC 61000-4-3	see table Test specifications for the immunity of sheathings to high-frequency wireless communication equipment (at the end of this chapter)
Magnetic fields with energetically rated frequencies	IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz
Magnetic fields at close range	IEC 61000-4-39	no magnetically sensitive components, therefore no immunity rating required

AC port for supply input		
Phenomenon	EMC basic standard or test method	Immunity test level
Short, transient electrical disturbances / bursts	IEC 61000-4-4	± 2 kV, 100 kHz repetition frequency
Surges: conductor to conductor	IEC 61000-4-5	± 0,5 kV, ± 1kV
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0,15 MHz up to 80 MHz 6 V in ISM and amateur radio frequency bands between 0,15 MHz and 80MHz 80 % AM at 1kHz
voltage dips	IEC 61000-4-11	0% U_T ; ½ period at 0, 45, 90, 135, 180, 225, 270 and 315 degree
		0% U_T ; 1 period and 70% U_T; 25/30 periods single-phase at 0 degree
voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 periods

DC port for supply input		
Phenomenon	EMC basic standard or test method	Immunity test level
Short, transient electrical disturbances / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges: conductor to conductor	IEC 61000-4-5	± 0,5 kV, ± 1kV
Surges: conductor to earth	IEC 61000-4-5	± 0,5 kV, ± 1kV, ± 2kV
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0,15 MHz up to 80 MHz 6 V in ISM and amateur radio frequency bands between 0,15 MHz and 80MHz 80 % AM at 1kHz

Patients' connection ports		
Phenomenon	EMC basic standard or test method	Immunity test level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0,15 MHz up to 80 MHz 6 V in ISM and amateur radio frequency bands between 0,15 MHz and 80MHz 80 % AM at 1kHz

SIP/SOP-Tor (Signal Input/Output Part		
Phenomenon	EMC basic standard or test method	Immunity test level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Short, transient electrical disturbances / bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0,15 MHz up to 80 MHz 6 V in ISM and amateur radio frequency bands between 0,15 MHz and 80MHz 80 % AM at 1kHz

Test specifications for the immunity of sheathings to high-frequency wireless communication equipment				
Test Frequency (MHz)	Frequency band (MHz)	Radioservice	Modulation	Immunity test level (v/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5% lift, 1kHz sine	28
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800 iDEN820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1;3; 4; 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

⚠ The minimum distances for higher immunity test levels shall be calculated using the following equation.

$$E = \frac{6}{d}\sqrt{P}$$

P = maximum power in watts (W)
d = Minimum distance in meters (m)
E = Immunity test level in volts per meter (V/m)

If a test with these increased test levels is passed, the stated minimum distance of 30cm can be replaced by the new minimum distance calculated for the increased immunity test levels.

notes:

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