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OPERATING INSTRUCTIONS

Children's Therapeutic Bed
"LEON"

(door height 68 cm + door height 102 cm)

Read carefully before operating!

These operating instructions must be provided to all users!

CE

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1. ASSEMBLY INSTRUCTIONS

Assembly must be performed only by trained specialist personnel.
We recommend that assembly be performed by two people, following these steps:

Fig. 1

1.1 On the inside of the bed, there are stickers with arrows numbered from 1 to 4 (Fig. 1).
Arrange the side panels and the head and foot sections according to these numbers.

Screw the side panels to the head end and foot end according to the numbers (M8x45) (Fig. 2).

Fig. 2

1.2 There is a sticker that reads **"head end"** on the lifting scissors. Position the lifting scissors according to the **"head-end" sticker** in the bed frame (Fig. 3).

Move the lifting scissors to the uppermost position (Fig. 4).
Screw the lifting scissors adapter to the supporting strip using the enclosed screws (M6 x 15 mm) (Fig. 5).
Place the wooden bed base on the lifting scissors.

Fig. 3

Fig. 4

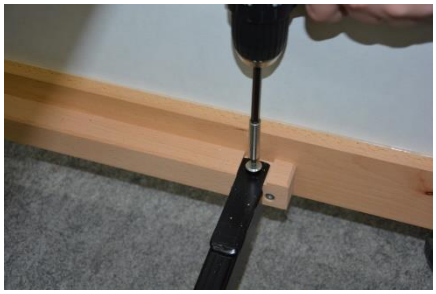


Fig. 5

Fig. 6

Move the bed base down to the level of the bed frame Align the bed base (Fig. 7)

Fig. 7

Move the lifting scissors to the uppermost position.
Screw the wooden bed base onto the lifting scissors adapter using the enclosed flat head screws (4 x 35 mm) (Fig. 8).

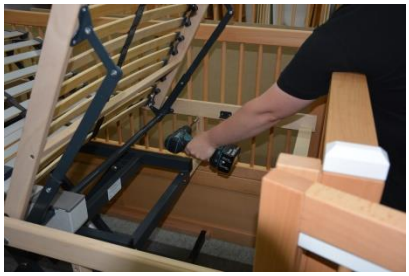


Fig. 8

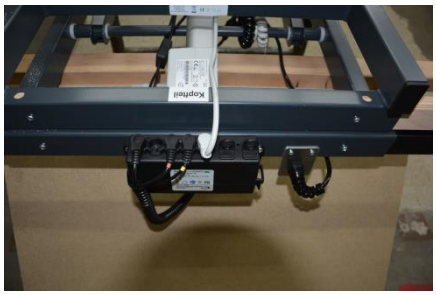
If present, connect the cable for the dual motor to the control unit (Fig. 9).

The control unit is located on the lifting scissors. Mount the protective cover on the control unit.

<u>When laying the cable, make sure that the cable cannot be crushed or damaged!!!</u>

Fig. 9

Fig. 10



Mount the protective guard (Fig. 11) using the enclosed flat head screws (M6 x 25).

Fig. 11

Fig. 12

1.3 The rear frame is colour coded.

RED: **left**
GREEN: **right**
(looking at the bed from the door side)

Position the rear frame between the foot end and the head end according to the colour coding and attach using the enclosed flat head screws (M8 x 45 mm) (Fig. 12).

DOOR HEIGHT 102 cm:

Insert the enclosed moulded wood springs into the recesses, then position the upper rear frame on the lower rear wall according to the colour coding and attach (M8 x 45 mm).

Fig. 13

1.4 The two door units are colour coded.

RED: **left**
GREEN: **right**
(looking at the bed from the door side)

Screw the first door unit to the head end/foot end of the bed frame according to the colour coding using the enclosed screws (M8 x 45mm). (Fig. 13).

Then attach the second door unit accordingly.

Fig. 14

Insert or remove **spacers** as required between the door unit and head end/foot end to achieve the **correct clearance** between the two door units (**7 mm**).

1.5 The outer doors are secured/opened during a lock in the edge of the door (Fig. 14).

The middle doors are locked using a simple patent lock. Move the hand lever of the patent lock along the groove to close or open the door (Fig. 15). There are two patent locks at the bottom and one at the top (Fig. 16).
The doors can also be secured using a sliding rail (Fig. 16 + Fig. 17).

Fig. 15

Fig. 16

Fig. 17

1.6 Transport casters

Caster, 75 x 30 mm.
To secure the lock, press the foot lever down. To release the lock, pull the foot lever up (Fig. 18).

After moving the bed, <u>all</u> wheels must be correctly locked!

Fig. 18

1.7 Securing the inner doors

The inner doors are held in place by a magnet to prevent them opening

Fig. 19

1.8 Adjusting the doors

It is possible to correct stiff or hanging doors using a size-3 Allen key by unscrewing the support foot in the outer door hinges.
Together with a second person, pull the head end or foot end outwards by hand and unscrew the support foot in a clockwise direction until the desired dimension is achieved (Fig. 20).

Fig. 20

1.8 OPTIONAL: Accessories

The doors can be additionally stabilised in the upper area with a U-shaped wooden strip (Fig. 21). After placing the wooden strip on the doors according to the recesses in the upper cross-pieces of the two middle doors, turn the locking pins approx. 90° (they will lock due to the tension of the spring). To release the locking pins, pull and turn them 90° into the resting position.

Fig. 21

Fig. 21

2. OPERATING INSTRUCTIONS

2.1 Intended use

The **"LEON"** children's therapeutic bed is designed for use in a home-care environment. Application environment 3 + 4 in accordance with DIN EN 60601-2-52. The medical treatment to be provided is the diagnosis, treatment and monitoring of illnesses under medical supervision. It is permitted for use for **one person only**

- (**height**: min. 75 cm, max. bed base minus 15 cm / **weight**: max. 135 kg) and the safe working load (see type plate) must not be exceeded. The bed must only be used in enclosed rooms and must be protected against excessive moisture.

Use of the various adjustment functions can be carried out by the user by means of an **IPX4 manual control unit with closure**.

- Bed height and bed base adjustment

Make sure that the patient is always lying with their head at the "head end" of the bed.
All components of the bed must be used in accordance with the appropriate intended use. Overloading causes damage and is not permitted.

2.1.1 Indications

For children with restricted movement who no longer have spontaneous mobility, or young people and adults with cognitive developmental disorders, for example it

- An ergonomic sitting position is necessary in bed due to trunk instability
- Secure contact between the feet and the floor is necessary when getting into/out of bed
- The height of the bed must be adjustable so as to enable the patient to be transferred to a wheelchair, for example
- The height of the bed base must be adjustable for treatment purposes

2.1.2 Contraindications

- None known

Always consult a doctor or therapist before using the bed.

2.2 Important information on operational safety

I. Setup and initial operation are performed by the sales agent. Prior to handing over the bed and before each re-use, a functional check and a safety check must be performed.

It must be ensured that all functions are running smoothly, the power cable is routed correctly, and the bed base is securely mounted in the bed frame. This also applies to any further operation of the children's therapeutic bed.
Incorrect routing of the power cable (e.g. kinks, shearing) may pose a serious risk to people (electric shock).

II. The patient can weigh up to a maximum of 135 kg. Persons of any age with reduced perception are only permitted to use the system under supervision.

III. The lowest setting of the bed base is the safest and this is the only one that should be used, unless another setting is required for therapy and treatment purposes. Following therapy or treatment, always move the lifting unit down to the lowest position.

IV. When adjusting the lifting unit, do not place any parts of the body inside or underneath moving parts. There is a **RISK OF CRUSHING**.

V. The **"LEON"** children's therapeutic bed is intended for use only in dry rooms and must only be operated and stored in these conditions. The system must only be connected to a conventional 230-volt socket. The cable and plug must be dry and must not be crushed or abraded at any location. Make sure that all cables are routed and connected correctly at the points provided.

VI. To prevent overloading and faults in the electric motors, a maximum switch-on time of two minutes must not be exceeded.
The electric-powered adjustment of the head end and foot end must only be used to lift and lower the upper body or legs (observe the position of the patient in the bed).

Overloading causes damage and is not permitted!

Overloading the mechanical components causes damage and is therefore not permitted. (see operating instructions, item 2.3 + 2.4 and type plate)

VII. In the event of misuse, improper use, incorrect operation or incorrect assembly/repair, no liability will be accepted. In such cases, all warranties are also excluded.

VIII. The drives must not be operated in the presence of flammable gases or vapours.

IX. The **"LEON"** children's therapeutic bed must only be operated with original accessories and maintained using original parts. The use of mattresses that are incompatible with this bed can be **hazardous**. Please observe the technical data (item 3/page 11.0 et seq. of these operating instructions).

X. If any malfunctions occur, inform your sales agent immediately. In particular, disconnect the power and do not operate the device in the event of damage to electrical or mechanical parts.

XI. Avoid the improper routing of electrical cables for other devices in the bed for medical use. **Risk of crushing** between moving parts of the bed.

2.3 Warning notices

I. If the patient is not supervised, the lifting unit must be moved to its lowest, horizontal position. The revolving doors must be locked.

II. Do not leave anything in the bed that could be used to climb on or that may result in a risk of suffocation or strangulation.

III. Only trained persons or the nursing staff are permitted to adjust the lifting unit. The patient themselves must not adjust the bed.

If the patient is alone, all functions must be locked (see item 2.6 Manual control unit).

IV. The patient's clinical condition may cause them to become trapped.

V. Take care when opening and closing the revolving doors. RISK OF CRUSHING. The open, middle revolving doors are secured by the magnet at the top end. Only open and close the complete door units in supervised situations.

VI. The "LEON" children's therapeutic bed must only be used on a flat, horizontal and solid surface.

VII. Only use in dry rooms.

VIII. Do not position the bed in the vicinity of open flames or other strong sources of heat (e.g. electric radiant heaters, gas ovens etc.).

IX. The maximum user load is 135 kg.
The safe working load is 170 kg, including accessories.
<u>The electrical adjustment of the head end or the head end/foot end</u> (accessories) must only be used to lift and lower the upper body and legs (observe the position of the patient in the bed).

2.4 Lifting unit

The lifting unit is used for the electrical lifting and lowering of the bed base.

The maximum user load is 135 kg.
The safe working load is 170 kg, including accessories.
Overloading causes damage and is not permitted.

2.5 Bed base

The four-part wooden bed base allows for infinite adjustment of the head end and foot end.

It is not advisable to move the back section and the foot end to the uppermost position at e same time as this will be too restricted and uncomfortable for the patient.

a power cut or a fault in the bed base motor causes the backrest to remain in an upright position, there is the option to move the back section to the lowest position using batteries (Fig. 21).

Fig. 21

The batteries must be replaced after a single use.

2.6 Manual control unit

The manual control unit is used to control all electrical functions. The height adjustment and the bed base adjustment are marked by appropriate symbols. Press lightly on the appropriate button to move the system to the desired position.

Make sure that the manual control unit cable does not become crushed during the adjustment. To prevent malfunctions, hang the manual control unit on the edge of the bed when not in use, with the keypad facing outwards.

The lock for enabling and disabling the function keys is located on the back of the manual control unit (Fig. 22). Turn the key to enable and disable the manual control unit. The arrow indicates the relevant position.

The key is a safety element that prevents unauthorised use of the manual control unit and must therefore always be kept in a separate place.

Button assignment on the manual control unit (Fig. 22):

1. Keypad (from top).
   Head end up/down (left/right) for electric-powered bed base
2. Keypad (from top).
   Foot end up/down (left/right) for electric-powered bed base
3. Keypad (from top).
   Head end and foot end up/down at the same time (left/right) for electric-powered bed base
4. Keypad (bottom)
   Lifting motor (bed base) up/down (left/right)

Fig. 22

2.7 Revolving doors

The **outer** doors are secured/opened using a lock in the edge of the door (Fig. 23). The **middle** doors are locked using a simple patent lock. Move the hand lever of the patent lock along the groove to close or open the door (Fig. 24). There are two patent locks at the bottom and one at the top.

The doors can also be secured using a sliding rail. As an option **(accessories),** the doors can be secured at the top with a U-shaped wooden strip (Fig. 25). In this case, the doors are locked by turning the locking pins.

Fig. 23

Fig. 24

Fig. 25

2.8 Transport casters

Caster, 75 x 30 mm.

To secure the lock, press the foot lever down. To release the lock, pull the foot lever up (Fig. 26).

After moving the bed, all wheels must be correctly locked!

Fig. 26

2.9 Securing the inner doors

The inner doors are held in place by a magnet to prevent them

opening unintentionally (Fig. 27).

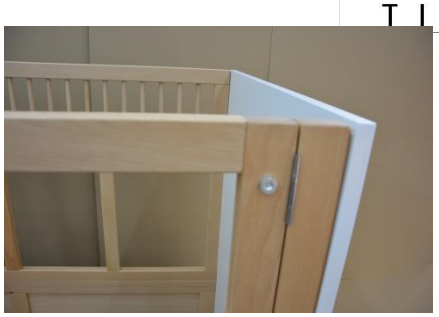


Fig. 27

2.10 Patient lifting unit

When using the children's therapeutic bed "LEON", only the patient lifting units "ARNOLD" and "JAMES" from REBOTEC, D-49610 Quakenbrück must be used. The required free space under the bed is a maximum of 110 mm / 90 mm

2.11 Cleaning, maintenance and reuse

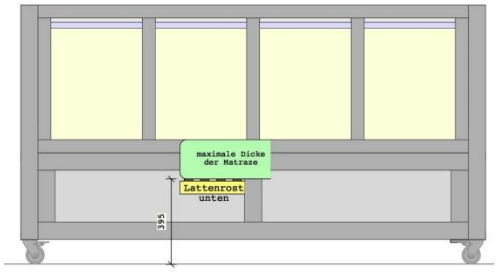
The surfaces are smooth so that they are easier to clean and disinfect. Neither the electrical system nor the bed frame are suitable for high-pressure cleaners. To clean, use a damp cloth with a small amount of neutral soap then wipe until dry.

It is possible to disinfect the bed with conventional disinfectant.
Once the bed has been cleaned, disinfected and maintained, it can be used again.

Maintenance must only be performed by authorised persons. For information on maintenance, safety checks and inspection intervals, see item 4 of the "ANNEX" to the operating instructions.

Spare parts lists can be obtained from the manufacturer!

2.12 Accessories



Mattress, not readily flammable in accordance with DIN 597-1/2

- For length x width, see the technical data
- For max. thickness of the mattress, see diagram
  (must not project beyond the lower cross-member of the rear wall).

Retouching pen for metal lifting system
Surface set for wooden parts

2.13 Symbols

Protection class II

For use in dry rooms only

Risk of crushing

Important information in the operating instructions

Type B applied part

Manufacturer: **FreiStil Tischlerei**, Ruppenkampstraße 16, D - 49084 Osnabrück
Phone +49 (0)541-800 3969 0, Fax +49 (0)541-800 3969 99, info@freistil.com

3.14	Bed frame: LEON 68 – 100 x 200 cm	
	External dimensions:	1,072 x 2,050 mm
	Bed base:	1,000 x 2,000 mm
	Mattress size:	1,000 x 2,000 mm
	Adjustment range of the lifting scissors:	390 – 830 mm
	Bed height (wheel diameter 75 mm):	1,184 mm
	Door height:	680 mm
3.12	Bed frame: LEON 68 – 80 x 170 cm	
	External dimensions:	872 x 1,750 mm
	Bed base:	800 x 1,700 mm
	Mattress size:	800 x 1,700 mm
	Adjustment range of the lifting scissors:	390 – 830 mm
	Bed height (wheel diameter 75 mm):	1,184 mm
	Door height:	680 mm
3.13	Bed frame: LEON 102 – 100 x 200 cm	
	External dimensions:	1,072 x 2,050 mm
	Bed base:	1,000 x 2,000 mm
	Mattress size:	1,000 x 2,000 mm
	Adjustment range of the lifting scissors:	390 – 830 mm
	Bed height (wheel diameter 75 mm):	1,528 mm
	Door height:	1,020 mm
3.14	Bed frame: LEON 102 – 80 x 170 cm	
	External dimensions:	872 x 1,750 mm
	Bed base:	800 x 1,700 mm
	Mattress size:	800 x 1,700 mm
	Adjustment range of the lifting scissors:	390 – 830 mm
	Bed height (wheel diameter 75 mm):	1,528 mm
	Door height:	1,020 mm

Weight of bed frame + lifting unit	approx. 171/5 / 199.5 kg
Weight	LEON 68 / LEON 102
Head end and foot end	22 / 28 kg
Bed sides	28 kg
Protective guard	3 kg
Rear frame	13/21 kg
Revolving doors	18/28 kg
Total weight of bed frame:	approx. 84/108 kg
Mattress Standard:	RG40, 14 cm thick, approx. 10 kg
Upholstery (OPTIONAL)	33 kg

3. TECHNICAL DATA

3.2 Lifting unit: (Kirchner)

Dimensions	105 x 54 x 16 cm (L x W x H)
Weight	approx. 43.5 kg
Travel	440 mm
Lifting force	230 kg

3.3 Bed base: (RINOVA-Flex)

Bed base	95 x 196 cm
Division	4-part
Angle **A** (backrest/horizontal)	> 70°
Angle **Y** (backrest + rotary points of back section/seating section + upper/lower leg section)	94°
Weight	approx. 20 kg
User load	135 kg
Safe working load	170 kg

3.4 Motors: Limoss

Mains voltage/frequency	230 volts / 50 Hz
Motor voltage	24 volts
Protection class	II
Noise emissions	< 65 dB (A)
Nominal rating	max. 2 min./18 min. pause

Subject to technical modifications

4. ANNEX

4.1 General instructions

- Maintenance/safety checks must only be carried out by persons with the appropriate qualifications.
- All other laws and DGUV regulation 3 remain unaffected.
- Repair of all electrical components must be carried out **exclusively** by **persons authorised by the motor manufacturer**.
- **Inspection intervals**:

  When the bed is first put into use and every time it is re-used.

  Maintenance/safety check **once a year or every 12 months**.
  Visual and function check of all mechanical + electrical parts.
  Electrical inspection in accordance with DIN EN ISO 62353.
- Inspections performed as part of the scheduled maintenance work can be performed on the installed system (at site of installation). All other repairs must be performed at a suitable place of work.
- Only the installation of original parts is permitted. The use of self-made parts will cancel all liability and warranty obligations on the part of the manufacturer. Spare parts lists can be obtained from the manufacturer.
- System modifications and additions require the manufacturer's written approval.
- Complete functional checks must be performed after all maintenance and repairs. Make sure that there are no collisions between moving parts so that there are no hazards for patients or third parties and no damage to materials.
- Instructions and a check list form are provided below so that you can document your work.

4.2 Maintenance instructions

The bed must undergo maintenance at least once a year or every 12 months. Only trained technical personnel from the operating company or manufacturer are authorised to perform this work. If there are any deviations from the requirements specified below, the bed must be taken out of service and repaired if the limitations are safety-related. Complete the check list (Annex) for every maintenance inspection.

Perform a visual inspection of all the parts on the bed base (slatted frame).
If you discover any damage, these parts must be repaired or replaced immediately.
Check that the moving parts are moving freely, and lightly apply grease if necessary.

-

Check all pinned fittings, screw joints, rivets and welding seams. There must be no cracks or deformation and no individual parts of the joint must be missing (e.g. circlip, nut etc.).

- Perform a visual inspection of all parts of the bed:
  head end and foot end/bed sides/rear wall/doors/adjustable side rails.

- Check that the locking mechanisms for the doors/adjustable side rails are working correctly and moving freely.

- Check that the brake wheels of the bed are working correctly. The moving and braking functions must be working correctly.

- For electrically adjustable beds, perform a visual and functional check of the drives. These are subject to wear. If any of the following are observed, the affected drive is damaged and must be replaced immediately: significant heat generation, significant noise, grinding or squeaking noises, metal or plastic chips on or under the motor, restricted adjustment range, unresponsive limit switches or drives that are slower than usual.

- For electrically adjustable beds, check the power cable and all cable routing for damage, kinks and shear points, and check that cables are routed securely.
  Caution: If the power cable or power plug are damaged, they must be replaced immediately. If any damage is discovered, the bed must be taken out of use immediately.

- For electrically adjustable beds, check that the manual control unit is working correctly and has no external damage.

Check the bed on a regular basis every time it is used to ensure it is working correctly. Please correct any loose connections immediately using the appropriate tool.
If a product has any faults whatsoever, it must be taken out of use immediately.

Manufacturer: **FreiStil Tischlerei**, Ruppenkampstraße 16, 49084 Osnabrück, Germany
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Maintenance/safety check in accordance with § 6 of the German Medical Device Operator Ordinance (MPBetreibV)

This form is available to download from our website.
www.freistil.com/service

Check list

Maintenance/safety check in accordance with § 6 of the German Medical Device Operator Ordinance (MPBetreibV)

Medical equipment supplier	Inspector	Bed location
Name	Name	Name .....
Street	Street	Street .....
Postal code/city	Postal code/city	Postal code/city .....

Bed	Reason for inspection	Maintenance confirmation
Type	Before initial operation □	
Serial no.	Regular maintenance □	.....
.....	Following repair □	Date/signature (customer)

Inspection	Component	OK / NOK	Comments		Elec. testing	Component	OK / NOK	Comments
Visual	Type plates	□ □	.....		Visual	Mains	□ □	.....
Visual	Operating	□ □	.....		Visual	connection	□ □	.....
Visual	instructions	□ □	.....		Visual	Mains plug	□ □	.....
Visual	Head end and	□ □	.....		Visual	Mains cable	□ □	.....
Visual	foot end	□ □	.....		Visual	Strain relief	□ □	.....
Visual	Side parts	□ □	.....			Drives		
Visual	Lifting system	□ □	.....		Function	Manual control	□ □	.....
Visual	Bed base	□ □	.....			unit	□ □	.....
	Wheels					Limit switch	□ □	.....
	Screw joints					Battery		
Function	Freely rolling	□ □	.....				Actual	Target
Wheels	Locking	□ □	.....		Measurement	Resistance	□ □	..... > 2 MOhm
	Braking	□ □	.....			Leakage current	□ □	..... < 0.1 mA
Functions	Ease of	□ □	.....		Measuring device used:			
Side parts	movement	□ □	.....					
	Locking	□ □	.....					
	Hinges							
Function	Lifting motors	□ □	.....		Comments:			
Motors	Head end motor	□ □	.....					
	Foot end motor	□ □	.....					
	Trendelenburg	□ □	.....					
Function	.....	□ □	.....		.....			
Accessories	.....	□ □	.....					
	.....	□ □	.....					Date/signature (inspector)
Overall mechanical inspection		□ □	.....					