Malsch
care & clinic design®

CLINIC DESIGN

INSTRUCTION MANUAL HOSPITAL BED

IMPULSE KL

Malsch
care & clinic design®

Dear Customers,

By purchasing a hospital bed from Malsch care & clinic design®, you have obtained a long-lasting medical device with functions that meet all the requirements of everyday hospital care while maintaining the highest standards of safety.

Thank you very much for the trust you have placed in us.

Our company guarantees carefully selected materials and continuous quality control while employing state-of-the-art production technologies.

Complying with the usage and operating instructions helps to prevent the risk of accidents and preserves the high value of your hospital bed.

Contents

PRODUCT RANGE

IMPULSE KL hospital bed
with undercarriage **Edition 200**

IMPULSE KL hospital bed
with undercarriage **Edition XL**

IMPULSE KL hospital bed
with undercarriage **Edition 300/400**

IMPULSE KL hospital bed
with undercarriage **Edition 300-P/400-P**

SPECIFIC FUNCTION

The hospital beds made by Malsch GmbH are used in the care of patients with physical limitations. The beds are designed exclusively for this purpose. The functions of these hospital beds assist the care staff in their daily work and offer convenient solutions for positioning the patient and compensating for certain symptoms experienced by patients in clinics and hospitals or comparable medical facilities. This complies with working environment 1, 2, 3 and 5 as stipulated by IEC 60601-2-52:2009/AMD1:2015.

Prior written consent from Malsch GmbH is required if the hospital beds are to be used for other applications.

The product is intended for use as a care aid or health device. As such, it is subject to the regulations of the relevant insurance associations. The hospital bed is a medical product with regard to applicable industry standards and regulations. Therefore, this product must only be used under medical supervision.

The hospital beds described in this instruction manual are intended for adult patients with a body weight of at least 40 kg and a height of at least 146 cm. In accordance with the standard IEC 60601-2-52:2009/AMD1:2015, the beds must not be used by patients whose body weight and height is below these limits or who have a BMI under 17, as the risk of injury is significantly increased for this group.

Caution! The use of incompatible side rails and mattresses can lead to injury, as body parts may become trapped.

ENVIRONMENTAL SUSTAINABILITY

Malsch GmbH hospital beds are manufactured in line with the relevant regulations using state-of-the-art processing technologies, and contain no hazardous materials. The materials used to finish surfaces are CFC- and solvent-free.

Hospital beds that are taken out of service due to their age or irreparable damage must be disposed of in line with local disposal regulations.

Caution! Please observe the relevant local regulations when disposing of metal, wood and electrical waste.

NOTES TO THE INSTRUCTION MANUAL

The following directions and statutory requirements in this instruction manual are intended for care staff or other persons and staff tasked with operating and using the hospital bed.

The instruction manual must be accessible to personnel at all times to avoid operating errors and to guarantee fault-free operation. The care staff must have a good understanding of the hospital beds and be trained in their operation before using them for the first time. The instruction manual must be used for this training.

This instruction manual has been written for the IMPULSE KL hospital bed. The images, graphics and texts it contains may differ from the equipment supplied.

The manufacturer offers technician training for maintenance and servicing work on their hospital beds. A certificate obtained as part of this training authorises the holder to carry out technical work independently on the beds.

PICTOGRAMS / SYMBOLS

For better orientation, this instruction manual uses the pictograms described below.

Important!
Instructions labelled in this way must be strictly observed in order to avoid injury or damage!

Information!
This pictogram identifies information relating to the current subject!

SAFETY INSTRUCTIONS

It is important that the following safety instructions are observed to prevent risks to patients as well as carers, and to avoid any damage to the hospital bed:

⚠ The instruction manual must be read and observed before using the hospital bed.

⚠ The information on the rating plate must be observed! The information on the rating plate is explained in detail on ☞ *p. 16* of this instruction manual.

⚠ In the event of any faults or defects that could endanger persons, the bed must not be used.

⚠ Electrically adjustable hospital beds must be operated by trained staff only.

⚠ Before the bed is used for the first time, the operator must ensure that it is safe to use and in good condition.

⚠ The castors must always be placed in the braked position to ensure the patient does not fall when getting into or out of the bed.

⚠ The bed can be moved into various positions. When doing so, take care to ensure no parts of the body or other objects are located in the adjustment area.

⚠ Only care staff may adjust the side rails. When adjusting the sleeping surface position, take care to ensure the patient does not come into contact with the side rails to avoid trapping any part of the body.

⚠ The functionality of the side rails must be checked every day. They must not bear any load of over 75 kg vertically or over 50 kg horizontally.

⚠ When using CPR (optional, mechanical emergency lowering of the back rest), always additionally relieve the load on the back rest by hand to prevent the back rest from dropping in an uncontrolled manner.

⚠ The IMPULSE KL hospital bed has a battery which makes it possible to adjust the height and the sleeping surface independently of the power supply, whereby emergency operation is guaranteed. In order to safeguard this function, annual checking of the batteries as part of the technical safety check is recommended. ☞ *p. 48 Battery replacement.*

⚠ The hand controller functions can be locked or released using the staff controller or the key switch on the rear side of the hand controller. Check that the locking function has taken effect on the hand controller.
☞ *p. 20 - p. 21 Hand controller symbols*

⚠ The drive system used must be operated using a VDE-approved power source, i.e. a 100 - 240 V, 50 / 60 Hz mains socket.

⚠ The mains connection cable is also protected by a mechanical strain relief device. Nevertheless, take care to ensure that the cable is not damaged by sharp edges, mechanical loads or pinch / shear points.

⚠ The mains connection cable must also be protected by a mechanical strain relief device. Nevertheless, take care

to ensure that the cable is not damaged by sharp edges, mechanical loads or pinch / shear points.

⚠ The hand controller can be placed flexibly. When placing the hand controller, take care to ensure that it cannot be triggered accidentally (e.g. by being trapped between two objects). The hand controller must be freely accessible.

⚠ The cable of the hand controller is usually on the right-hand side of the bed from the occupant's perspective, and attached to the underside of the sleeping surface with a strain relief. The use of the hand controller on a different side of the bed leads to over-stretching of the cable, which can result in damage such as breakage of the cable sheath or the wires inside the sheath. In a case such as this, the power supply of the bed must be disconnected from the mains and the hand controller replaced immediately. Otherwise there is a risk of electric shock.

In order to avoid potential damage and ensure that safe and efficient operation takes place, the following information regarding the positioning of the hand controller must be observed:

- The hand controller must always be installed at the side of the bed where the strain relief is located.
- It must be ensured that the cable is not over-stretched when the hand controller is fitted. Proper cable routing is required in order to avoid damage.
- The hand controller and the cable must be checked for signs of wear or damage at regular intervals. In the event of abnormalities, the bed must be disconnected from the mains immediately, and customer service must be contacted.

⚠ Observe safety distances to walls, window ledges and other furnishings when using the hospital bed in a patient's room. The safety distances depend on the design and model of the hospital bed and are based on the height adjustment and the tilting motions of the bed. The minimum distance is 30 mm.

⚠ Improper use of the bed may cause hazards. Examples of improper use include:

- Unauthorised activation of the electrical functions
- Use of the bed by persons with a body weight of less than 40 kg or a BMI of less than 17, or a height of less than 146 cm ☞ *p. 7 Specific function*
- Moving the bed by pulling on the mains cable or side rails
- More than one person adjusting the bed at the same time
- Activation of the functions by patients without prior instruction
- Pulling the mains cable to disconnect it from the power supply
- Moving the bed on sloping or unsurfaced ground

⚠ In accordance with IEC 60601-2-52:2009/AMD:2015, when choosing a mattress, it is important that there is a minimum

distance of 22 cm between the top of the sleeping surface and the top of the side rail in its fully extended position. The mattress used must meet the applicable safety standards.

⚠ The constant presence of liquid in the area of the motor must be avoided (e. g. incontinence).

⚠ For safety reasons, the handle on the trapeze bar must be replaced in its entirety every 5 years.

⚠ Servicing and repairs on electrical components must be carried out by specially trained staff, and only original replacement parts from the manufacturer may be used.

⚠ The hospital bed is not suitable for extended operation beyond a working cycle of two minutes. If the mains adapter is overloaded or if it overheats, it will shut off automatically. Further operation is possible only after a 30-minute cool-down phase. (Observe the drive manufacturer's notes on the rating plate!)

⚠ It is essential to avoid obstructing any part of the bed mechanism, as this can lead to damage or complete disabling of the drive system due to overheating.

⚠ Likewise, the safe working load must not be exceeded.

⚠ If an immobile patient remains in the same position for an extended period of time without the use of additional positioning aids, this can lead to pressure sores. The manufacturer of the hospital bed is not liable for this in any way.

⚠ Electrically operated hospital beds are active medical products and must be maintained according to Article 7 of the Medical Devices Operator Ordinance (MedProd-BetrV.) These maintenance measures must be carried out regularly (at least once per year). This must involve visual and operational inspections of functional and electrical safety in line with VDE0751. ☞ *p. 46 Maintenance*

⚠ Furthermore, electrically operated hospital beds are electrical appliances whose safety is the responsibility of the employer. The supervisory function of this obligation is the responsibility of the Employers' Liability Insurance Association for Health Service and Welfare Work (BGW) and the Trade Supervisory Board (Gewerbeaufsichtsamt). The regulations of the employers' liability insurance associations apply, particularly those of the German statutory accident insurance body (DGUV), rule 3 of which stipulates regular inspections of movable electrical equipment at a recommended interval of six months, but at least once a year. These inspections may only be carried out by a certified electrician or person with electrical training using specialist measurement and inspection equipment. The inspections according to DGUV rule 3 can be conducted by specialist staff trained by the manufacturer as part of the inspections and maintenance service for medical devices.

⚠ Electrically operated hospital beds are active medical products and must be listed in an inventory for each site in line with Article 13 of the German Medical Device Operator Ordinance (MedProd-BetrV). It is advisable to also document the correct implementation of the required checks

and servicing in this inventory and to specify the date of the next inspection. The required protocols concerning checks already performed must be appended to the inventory.

⚠ Proper execution and traceable documentation of the technical checks, maintenance and servicing work prescribed by the manufacturer, as well as the technical safety checks, are required in order to preserve the warranty rights of the purchaser. If the operator of a medical product does not meet their obligations, this could lead to the risk of damage and accidents for which the manufacturer is explicitly not liable.

⚠ Maintenance work must be carried out and documented by trained staff.

⚠ The bed should be left in the lowest position if the patient is unattended in order to reduce the risk of injury caused by falling out of bed.

⚠ If the mains connection cable is damaged, the bed can no longer be used and must immediately be taken out of operation.

⚠ Improper use of the mains connection cable can result in hazards (e. g. electric shock). Examples of this are cable breaks due to kinking, shearing or other mechanical damage.

⚠ When using other ME devices in conjunction with the hospital bed, precautions must be taken to prevent damage to the device cable or other components of the ME device resulting from crushing between the movable parts of the medically used bed.

⚠ The hospital bed is not suitable for use in the vicinity of active facilities that use high-frequency surgical devices.

⚠ The hospital bed is not suitable for use in HF-shielded rooms used for magnetic resonance imaging in which high-intensity EM disturbance variables occur.

⚠ The use of this hospital bed directly next to or in conjunction with other electrical devices (e.g. stacked) must be avoided, as this can lead to faulty operation. If using the bed in the manner described above is absolutely necessary, the devices involved should be subjected to a function test for a longer period of time in order to rule out malfunction due to interference.

⚠ The use of accessories, transducers and cables other than those specified or provided by Malsch GmbH can cause increased emissions of electromagnetic interference or reduce the electromagnetic interference resistance of the device and thus lead to faulty operation.

⚠ Portable HF communication devices (radio devices) – including their accessories, such as antenna cables and external antennas – must not be used closer than 30 cm to the parts and cables of hospital beds as designated by Malsch GmbH. Non-observance can impair the performance of the hospital bed.

⚠ The emissions of this device are below the thresholds defined by IEC / CISPR 11:2009, Class A and thus permit the use of it in industrial environments and hospitals. This device may not provide adequate protection against wireless services if used in residential areas (for which Class B is

normally required according to CISPR 11). The user may have to implement remedial measures such as relocating or repositioning the device.

⚠ Servicing and maintenance tasks may not be performed while the ME device is in use.

⚠ The hospital bed must be positioned so that it does not obstruct anyone from disconnecting the mains plug.

TECHNICAL DATA

Model	Dimensions [cm]	Sleeping surface [cm]	Height adjustment [cm]	Weight	Safe working load	Reverse / Trendelenburg position	Thigh rest adjustment	Back rest adjustment
IMPULSE KL hospital bed with undercarriage **Edition 200**	**211 x 104**	**200 x 90**	**43 to 83***	**Approx. 100 kg**	**Total 200 kg** 135 kg patient 20 kg mattress 45 kg accessories	–	**43°**	**71°**
IMPULSE KL hospital bed with undercarriage **Edition 300** **Edition 300-P**	**216 x 106**	**200 x 90**	**36 to 86***	**Approx. 120 kg**	**Total 250 kg** 185 kg patient 20 kg mattress 45 kg accessories	**15° / 14°**	**43°**	**71°** / 12 cm mattress compensation
IMPULSE KL hospital bed with undercarriage **Edition 400** **Edition 400-P**	**216 x 106**	**200 x 90**	**27 bis 80***	**Approx. 120 kg**	**Total 250 kg** 185 kg patient 20 kg mattress 45 kg accessories	**15° / 14°**	**43°**	**71°** / 12 cm mattress compensation
IMPULSE KL hospital bed with undercarriage **Edition XL**	**216 x 116**	**200 x 100**	**36 to 86***	**approx. 160 kg**	**Total 300 kg** 235 kg patient 20 kg mattress 45 kg accessories	**15° / 14°**	**43°**	**71°** / 12 cm mattress compensation

*Measured from sleeping surface frame

ELECTRIC DRIVES

Model	Edition 200	Edition 300	Edition 400	Edition XL	Edition 300	Edition 400
Drive set	Dual drive	Standard	Standard	Standard	Basic	Basic
Electrical connection	100 - 240 V AC 50 / 60 Hz					
Output voltage	35 V DC 2 A	35 V DC 2,5 A				
Over-current off	7,5 A -11,5 A DC					
Over-voltage off	45 V DC					
Standby operation	max. 0.5 W					
Protection	IPX 4	IPX 6			IPX 4	
Protection class	II					

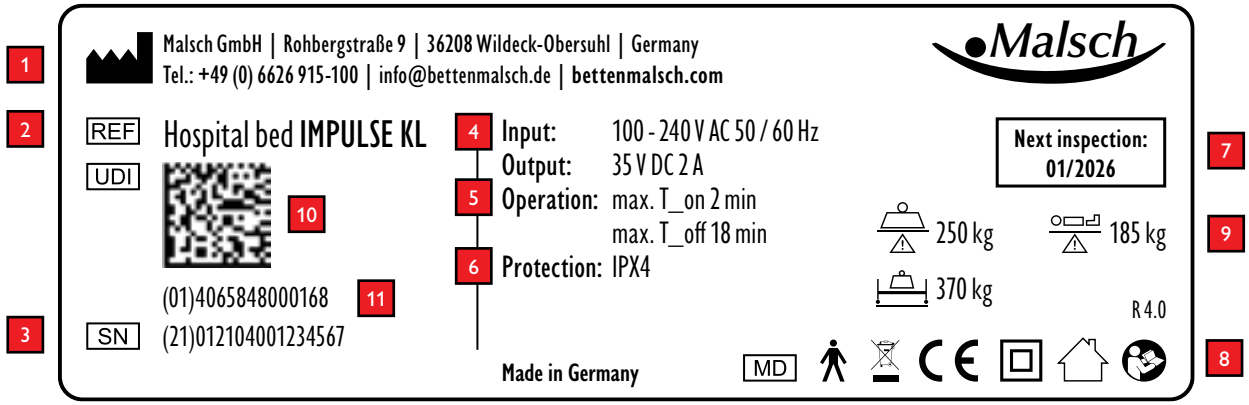
Lifting system force

Lifting system force	1 x 6,000 N	2 x 3,000 N	2 x 3,000 N	2 x 3,000 N
Force of sleeping surface adjustment	2 x 4,000 N	2 x 3,000 N	3 x 3,000 N	2 x 3,000 N
Motor running time	on 2 min. / off 18 min.			

Data on operation, transport and storage

Operating temperature range	+10° C to +40° C
Transport / storage temperature range	+5° C to +45° C
Relative humidity	30 - 75 %
Atmospheric pressure range	700 hPa to 1,060 hPa
Operating volume	54 dB (A)
Operating altitude	max. 3,000 m

RATING PLATE WITH UDI



Example of a rating plate with UDI of the IMPULSE KL hospital bed

The rating plate is located on the underside of the sleeping surface, at the head of the bed on the right. To inspect the rating plate, raise the head section to the upper position.

Notes:

1. Manufacturer's address
2. Model ID
3. Serial number
4. Electrical voltage; Frequency; Power consumption
5. Operating time of motorised adjustment: Please observe this information to protect against overheating! In the example, the drives of the bed are limited to a maximum of 2 minutes of continuous operation. If this limit is reached, a regeneration period of 18 minutes must be observed before the drives can be operated again.
6. Protection of electrical equipment from water spray "only use in dry areas"
7. Indicates the next technical check after delivery in line with VDE0751-1
8. Explanation of the safety symbols used on the rating plate:

MD	Labelling as a medical device
	Application part type B
	Directive 2012/19/EU relating to old electrical and electronic equipment
CE	Conformity marking in line with the Medical Device Directive (EU) 2017//745
	Protection class II
	"Only use in dry areas"
	"Observe the instruction manual"

9. Explanation of the weight icons used on the rating plate:

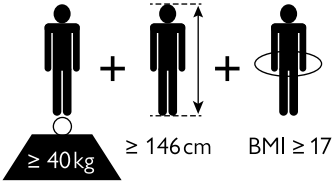
	Safe working load
	Maximum permissible weight of patients
	Maximum total weight of the medical device incl patient (bed weight plus maximum safe work load)

10. 2D barcode (GS1 data matrix) DI + PI = UDI
11. (DI) Device Identifier
    (01) UDI-DI/GTIN
    (PI) Production Identifier
    (21) Serial number

Labels

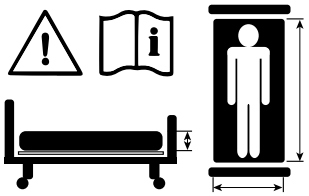
A separate sticker to the right of the rating plate refers to the labels described below:

Symbol: Label indicating beds for adults used for medical purposes in line with IEC 60601-2-52:2009 / AMD:2015



The hospital bed is approved for adult patients with a body weight of at least 40 kg and a height of at least 146 cm. In accordance with the standard IEC 60601-2-52:2009 / AMD1:2015, the hospital bed must not be used by patients whose body weight and height are below these limits or who have a BMI under 17, as the risk of injury is increased for this group.

Symbol: Label indicating replaceable mattresses in line with IEC 60601-2-52:2009 / AMD:2015 – please observe the information and instruction manual for the mattresses.

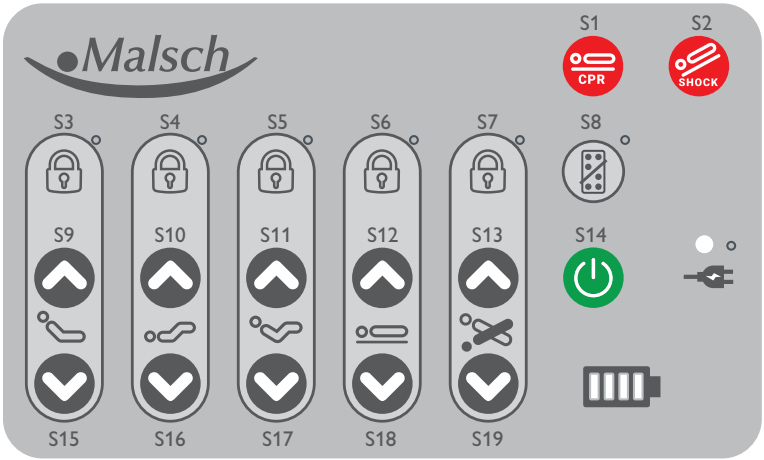


The following table contains information concerning mattress sizes depending on the sleeping surface dimensions:

Mattress size [cm]	Sleeping surface dimensions [cm]	Volumetric weight [kg / m^3]
78 × 200 × 12 / 14	80 × 200*	35 - 50
88 × 200 × 12 / 14	90 × 200	35 - 50
98 × 200 × 12 / 14	100 × 200*	35 - 50
108 × 200 × 12 / 14	110 × 200*	35 - 50
118 × 200 × 12 / 14	120 × 200*	35 - 50

* Optional special sizes

SYMBOLS OF STAFF CONTROLLER



ADJUSTMENTS	
S1	CPR (electric)
S2	Shock position
S9	Back rest up
S10	Thigh rest up
S11	Auto contour up
S12	Height adjustment up
S13	Reverse Trendelenburg position
S15	Back rest down
S16	Thigh rest down
S17	Auto contour down
S18	Height adjustment down
S19	Trendelenburg position

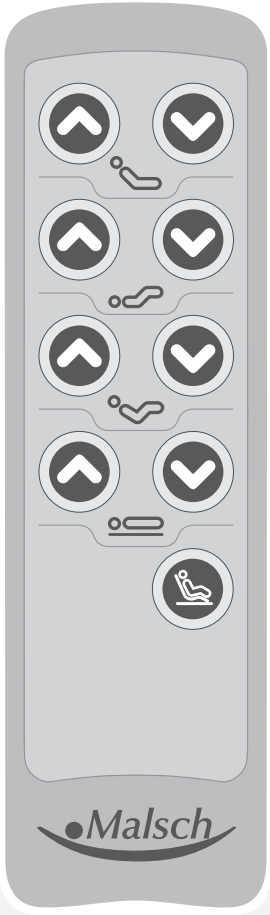
LOCKING OF FUNCTIONS		
S3	Lock back rest adjustment	LED red = locked
S4	Lock thigh rest support	
S5	Lock auto contour	
S6	Lock height adjustment	
S7	Lock Reverse Trendelenburg position	
S8	Lock hand controller (LED red = locked)	
S14	Switch on operating panel (LED green = ON)	

LED green = 220 V AC

Yellow LED indicates battery charging status

HC-146 HAND CONTROLLER SYMBOLS

IMPULSE KL hospital bed with undercarriage **Editions 300(-P)/400(-P)/XL**
Drive type "Standard" with staff controller



S1
Back rest up

S2
Back rest down

S3
Thigh rest up

S4
Thigh rest down

S5
Auto contour up

S6
Auto contour down

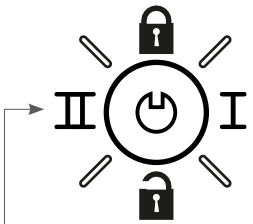
S7
Height adjustment up

S8
Height adjustment down

S10
Automatic chair position

Locking functions

positioned on the back of the hand controller to restrict operation by patient. ☞ *p. 29 Hand controller locking function*



R1
LOCKED
No functions operational

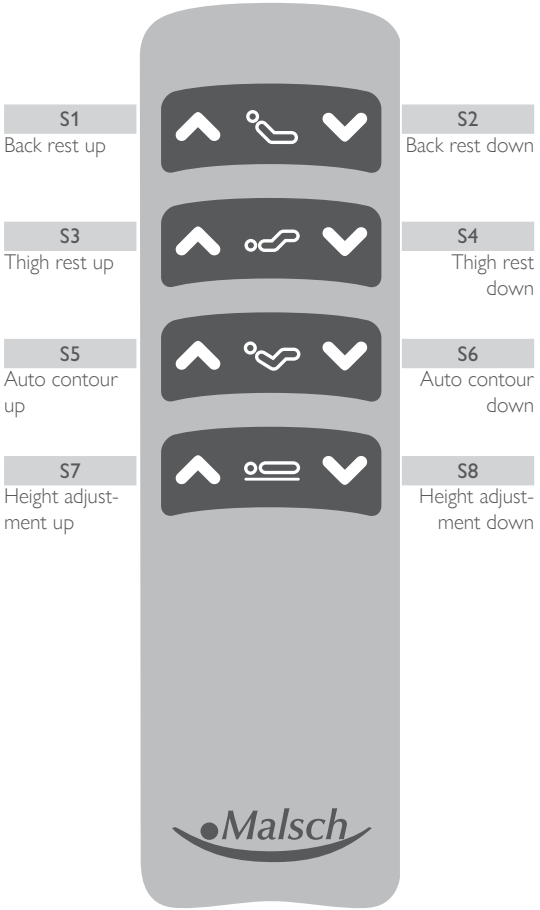
R2
UNLOCKED
All functions available

R3
UNLOCKED
All functions available

R4
UNLOCKED
All functions available

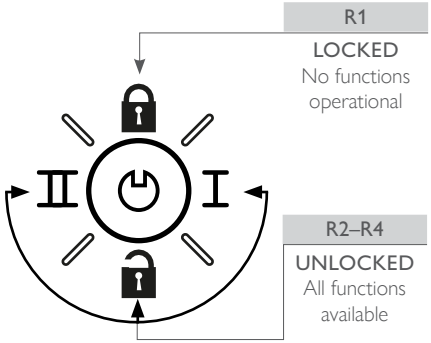
HC-147 HAND CONTROLLER SYMBOLS

IMPULSE KL hospital bed with undercarriage **Edition 200**
Drive set without staff controller



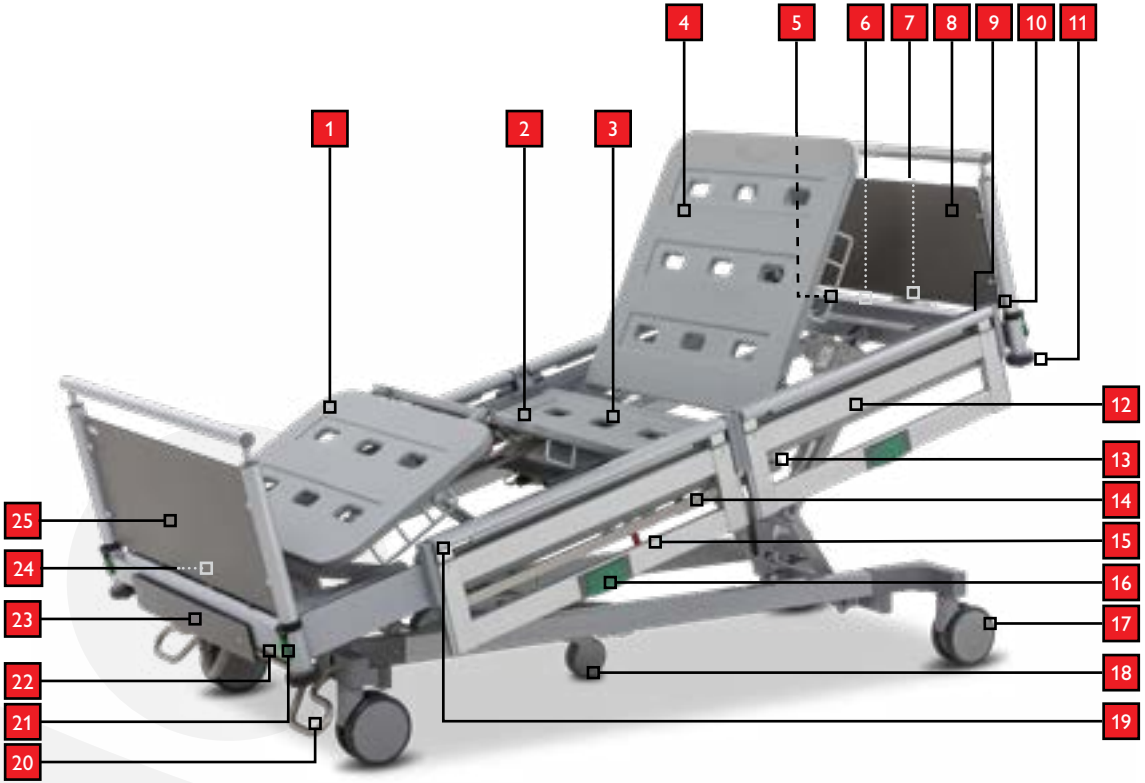
Locking functions

positioned on the back of the hand controller to restrict operation by patient. ☞ *p. 29 Hand controller locking function*



FUNCTION ILLUSTRATION

IMPULSE KL hospital bed with undercarriage **Editions 300/400/XL***



* The IMPULSE KL hospital bed with undercarriage Edition XL is only available with reinforced metal mesh sleeping surface (Fig. p. 23).

IMPULSE KL hospital bed with undercarriage **Editions 300/400/XL**

1. Adjustable lower leg rest
2. Adjustable thigh rest
3. Static seat section
4. Adjustable back rest
5. Restraint bar*
6. Potential equalisation (external)
7. Trapeze bar mount (external)
8. Head board
9. Receiving sleeve for IV drip holder and accessories (4× surrounding the bed)
10. CPR lever for emergency unlocking mechanism of back rest in design with vertical side rail (E)VGS (1)(2)*
11. Wall bumper (4× surrounding the bed)
12. Vertical side rail with one-handed operation (EVGS) (1)(2)*
13. ISO standard rail on bed frame
14. ISO standard rail integrated into the side rail for (E)VGS (1)(2)*
15. CPR lever for emergency unlocking mechanism of the back rest in design with swivelling side rail/no side rail
16. One-hand release handle for EVGS (1)(2)*
17. 150 mm double castors
18. 5. Castor*
19. Telescopic side rail extension *
20. Foot pedal for central brake (▼), freewheeling (–) and fixed direction (▲) of the double castors
21. Release lever for removable head/foot boards
22. Quick release of integrated bed extension (1)
23. Bed linen holder with bracket for staff controller
24. 2 release bolts (internal) for releasing the integrated bed extension (2)
25. Foot board

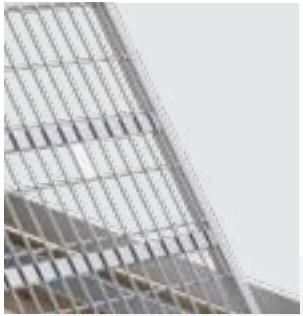
* Optional special equipment

(1) Only with IMPULSE KL hospital bed with undercarriage **Edition 300**

(2) Only with IMPULSE KL hospital bed with undercarriage **Edition 400**

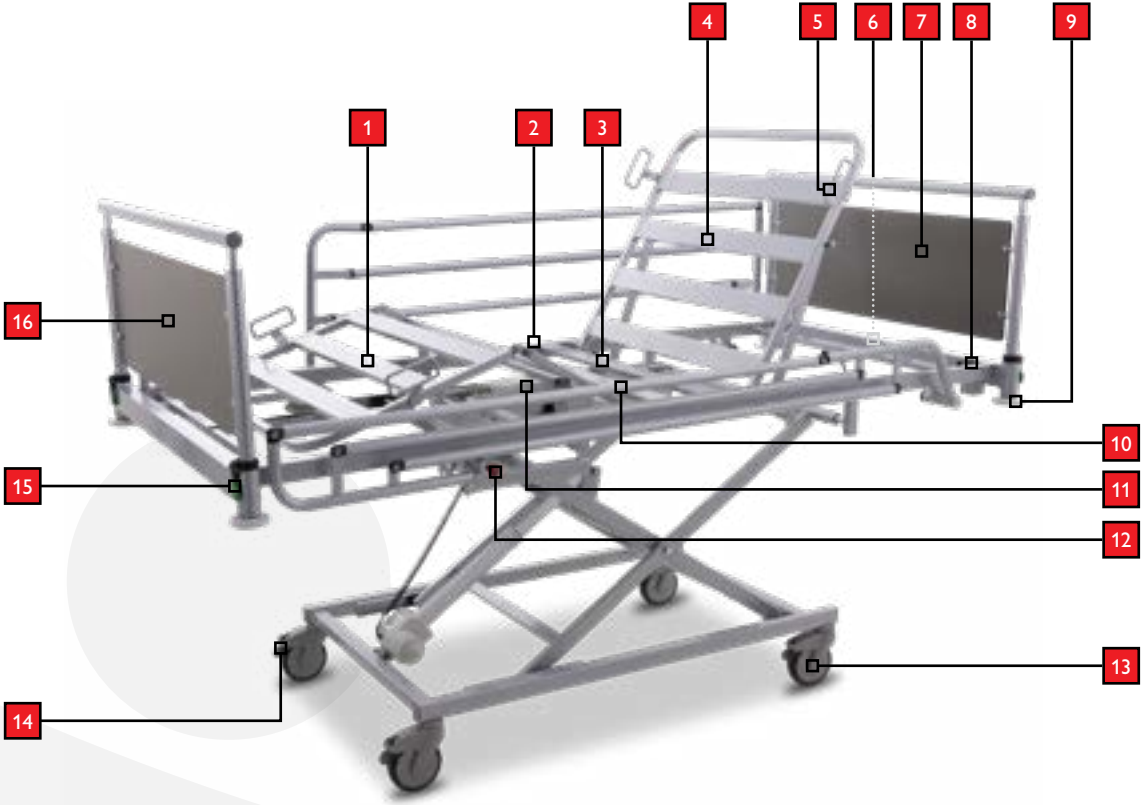
(3) Only with IMPULSE KL hospital bed with undercarriage **Edition XL**

Reinforced metal mesh sleeping surface in IMPULSE KL hospital bed with undercarriage Edition XL



FUNCTION ILLUSTRATION

IMPULSE KL hospital bed with undercarriage **Edition 200**



IMPULSE KL hospital bed with undercarriage **Edition 200**

1. Adjustable lower leg rest (notched bracket)
2. Adjustable thigh rest
3. Static seat section
4. Adjustable back rest
5. Mattress holder
6. Potential equalisation (external)
7. Head board
8. Receiving sleeve for IV drip holder and accessories (4× surrounding the bed)
9. Wall bumper (4× surrounding the bed)
10. One-part side rail (ESG)
11. Dual drive
12. Release button for side rails
13. 150 mm single castor
14. Single castor brake
15. Release lever for removable head/foot boards
16. Foot board

Depending on the design and type of hospital bed, it can be moved into various positions by adjusting the back rest, the thigh rest, lower leg rest and the lift adjustment:

Back rest

Use the corresponding buttons on the hand controller to adjust the back rest.

(Back rest operating buttons)

When raised, the back rest can be adjusted by 120 mm over its usual length to the head board.

This function (mattress compensation) allows the patient to sit in a comfortable position while avoiding compression of the buttocks area, the stomach and the upper body.

Caution! The back rest is designed for the mechanical load that is applied when a reclining person with a maximum resident weight according to the specification on the rating plate is being raised. Sitting on the back rest is not the intended use and may result in damage and injury.

Mechanical back rest release / CPR

Design with VGS
Handle at head end on a level with the siderails.

When operating the mechanical release, hold the back rest in the current position and, if possible, relieve some of the load. Pull the release to disengage the back rest and lower it manually into the end position.

Design with GS / design without side rails
Handle in the middle of the bed below the side panel

When operating the mechanical release, hold the back rest in the current position and, if possible, relieve some of the load. Pull the release lever towards the back rest to disengage the back rest and lower it manually into the end position.

Press the S1 button on the hand controller again to reactivate electrical back rest adjustment.

Caution! Before pressing the lever, ensure that there are no objects or parts of the body below the back rest. Manually relieve the weight on the back rest during adjustment to prevent it dropping in an uncontrolled manner.

Adjustable thigh / lower leg rest

Use the corresponding buttons on the hand controller to adjust the thigh rest.

(Thigh rest operating buttons)

Care staff can move the lower leg rest into the extended leg elevation position using the adjustable notched bracket.

For safety reasons, this position must only be adjusted by medical personnel.

Auto contour

Use the corresponding buttons on the hand controller to adjust the auto contour.

(Auto contour operating buttons)

Using the button function adjusts both the back rest and thigh rest.

This function should only be used with mobile patients without any physical problems.

Caution! Please consider resident safety when adjusting the height! Ensure that that no objects or parts of the body are located in the area of the lifting mechanism.

Height adjustment

Use the corresponding buttons on the hand controller to adjust the height.

(Height adjustment operating buttons)

Caution! Please consider resident safety when adjusting the height! Ensure that that no objects or parts of the body are located in the area of the lifting mechanism.

Low position / fall prevention

(only with IMPULSE KL hospital bed with undercarriage Edition 400)

The low bed IMPULSE KL with undercarriage Edition 400 can be moved to the low position in one continuous movement using the height adjustment buttons *(☞ p. 27)*.

Caution! Before pressing the button ensure that the telescopic side rail extension on the folded split side rail (GS) is pushed in (*☞ p. 32, Fig. 1*). Ensure that that no objects or parts of the body are located under the bed!

Trendelenburg / Reverse Trendelenburg position

(only with IMPULSE KL hospital bed with undercarriage Editions 300(-P) / 400(-P))

The button function shown on the staff control unit is used to set the head or foot low position.

(Trendelenburg / Reverse Trendelenburg operating buttons)

Caution! Please consider patient safety when swivelling the bed! Ensure that no objects are located in the area of the lifting mechanism. The functions must only be activated by specialist staff and must be locked on the back of the hand controller. Incorrect settings may result in permanent injury to the patient.

Automatic chair position

(only with IMPULSE KL hospital bed with undercarriage Editions 300(-P) / 400(-P))

Use the corresponding buttons on the hand controller to adjust the Automatic chair position.

(Automatic chair position operating buttons)

Pressing the button moves the bed quickly into a comfortable chair position by simultaneously adjusting the sleeping surface and the lifting mechanism.

This function should only be used with mobile patients without any physical problems.

Caution! Please consider resident safety when adjusting the bed to the automatic chair position. Ensure that that no objects or parts of the body are located in the area of the lifting mechanism. The functions must only be activated by specialist staff and must be locked on the back of the hand controller. Incorrect settings may result in permanent injury to the patient.

Caution! When activating the reverse Trendelenburg position or automatic chair position in conjunction with a pull-out bed extension, ensure that there are no objects or parts of the body below the foot end of the bed.

Hand controller locking function

The electrical unit combines state-of-the-art technology and single-fault safety.

The locking function is a further safety precaution. The locking function is located on the back of the hand controller and can be operated by staff with a key switch.

Operation:

The hand controller functions can be restricted by turning the key switch to the different switch positions. ☞ *p. 20-p. 21 Hand controller symbols*

Further locking functions are located on the staff controller ☞ *scheme p. 19*

Braking and transport

IMPULSE KL hospital bed with undercarriage Editions 300/400/XL

The IMPULSE KL hospital bed with undercarriage Editions 300/400/XL has one central castor brake, which is operated mechanically using a central foot pedal. The brake pedal is located in the central foot area of the undercarriage.

The IMPULSE KL hospital bed with undercarriage Editions 300/400/XL offers three different adjustment options:

1. Central braking of the castors (brake pedal in bottom position)
2. All four castors enabled for 360° movement (brake pedal in middle position)
3. Directional locking of one castor (brake pedal in upper position)

Caution! The IMPULSE KL hospital bed with undercarriage Editions 300/400/XL can be moved with the sleeping surface at any height. However, this should only be done in exceptional cases and under the supervision of care staff. The castor brakes should subsequently be checked in order to ensure that the bed is in a braked position after transport. The patient's safety is the top priority!

5th castor (optional)

The 5th castor installed in the middle of the bed allows for easy rotation of the bed when transporting patients. It is locked by means of a brake pedal and allows the bed to be easily rotated on its own axis, making it simpler to manoeuvre.

Caution! Ensure that the foot pedal of the central brake is in the middle position (castors enabled for 360° movement). With a locked brake or directional locking, unrestricted movement is not possible.

Caution! When rotating and manoeuvring the bed, be sure to avoid collisions with furnishings or other objects.

Caution! After completing the rotation, always release the castor brake!

Supplementary information about 5th castor

The 5th castor is exclusively responsible for providing the user with better manoeuvrability, whereby attention must be paid to the following:

Rotating movement
It must be noted that the 5th castor for the rotating movement and the axis of the 5th castor must be locked. This locking takes place in the uppermost switch setting of the brake pedal.

Normal procedure
The middle switch setting must be used when moving the bed, since all rollers are released in this position and travel comfort is therefore guaranteed.

Thresholds
When travelling over thresholds which are higher than 2cm, it may temporarily occur that not all castors are in contact with the floor.

Caution! If the 5th castor is not used correctly, the manufacturer will not accept liability for any damage.

GS side rail adjustment

Split side rails

In standby position, the side rails are located next to the sleeping surface and thus prevent the mattress from slipping. (Fig. 1)

1. The side rails are raised by tilting them upwards. In this middle position, they prevent the patient falling out of bed. When raised at the head end, they also provide stable standing and mobility assistance for the patient. (Fig. 2)
2. The upright side rail is released by means of two spring catches in the side rail bars below the height adjustment handrail and positioned at its maximum height. Perform telescopic adjustments upwards and downwards using both hands simultaneously to prevent jamming. (Fig. 3) **Do not force the movement!**
3. To lower the telescoping side rail height extension, proceed the same way as to raise it.
4. To swivel the side rails back to the standby position, press the indicated latches on the lower side rail bar inwards simultaneously and initiate the tilting motion. (Fig. 4)

Caution! When raising the side rails and side rail height extensions, ensure and check that the latches engage securely. Always use both hands to move this element!

Caution! Activate the low position for the low IMPULSE KL hospital bed with undercarriage Edition 400 only once the telescopic side rail extension on the folded split side rail (GS) has been pushed in (Fig. 1).

Fig. 1

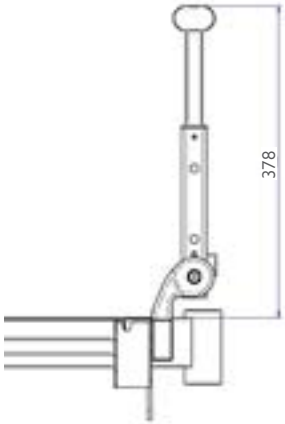
Fig. 2

Fig. 3

Fig. 4

GS side rail dimensions

When using the ABS/metal grid sleeping surface



Adjustment of side rails VGS

Vertically lowering split side rails

In standby position, the side rails are located next to the sleeping surface and thus prevent the mattress from slipping.

1. To raise the side rails, pull them upwards with both hands until they engage with an audible click. In this middle position, they prevent the patient falling out of bed. When raised at the head end, they also provide stable standing and mobility assistance for the patient. (Fig. B, 1. – Pos. 3)

2. For telescopic movement, the side rail extension can be released using the two spring catches below the handrail and adjusted to the position of extended fall prevention or their maximum height. Pull the rail upwards using both hands simultaneously (Fig. A, 1./2). Take care not to tilt and jam the element. Follow these actions in reverse to lower the rail. **Do not force the movement!**

3. To lower the side rails, push the two release slides inwards with both hands (Fig. B, 2.) and lower the side rails carefully into the standby position.

Caution! When raising the side rails and side rail height extensions, check that the latches engage securely. Always use both hands to move this element!

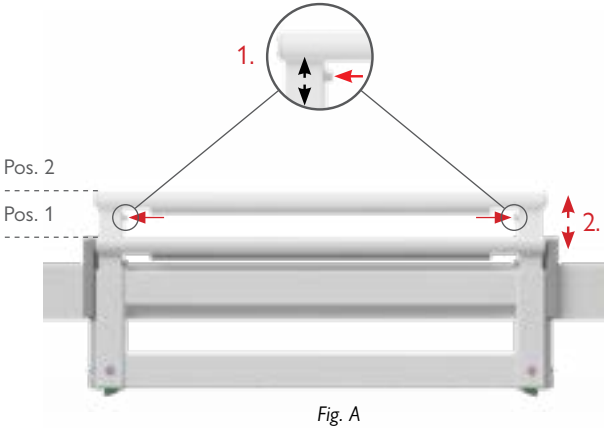


Fig. A

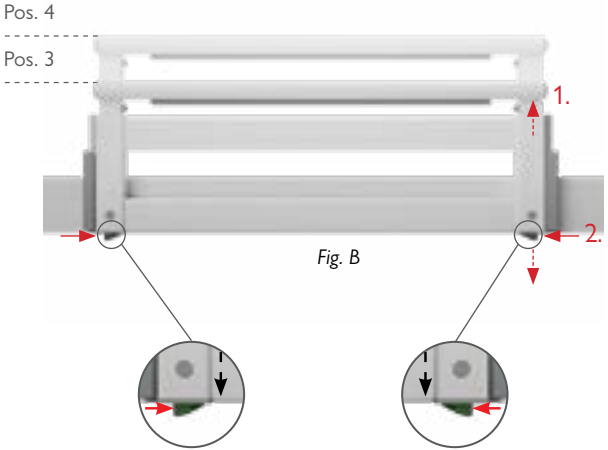


Fig. B

Adjustment of side rails EVGS

Vertically lowering split side rails with one-handed operation

In standby position, the side rails are located next to the sleeping surface. In this position, they prevent the mattress from slipping.

1. To raise the side rails, pull them upwards with both hands until they engage with an audible click. In this middle position, they prevent the patient falling out of bed. When raised at the head end, they also provide stable standing and mobility assistance for the patient. (Fig. A, 1.)

2. The side rail extension can be released using the two spring catches below the handrail for telescopic movement and adjusted to maximum height. Pull the rail upwards using both hands simultaneously (Fig. B, 1./2). Take care not to tilt and jam the element. Follow these actions in reverse to lower the rail. **Do not force the movement!**

3. To lower the side rails, pull the release handle forward with one hand (Fig. A, 2.) and carefully lower the side rails into the standby position.

Caution! When raising the side rails and side rail height extensions, ensure and check that the latches engage securely.

Abb. A

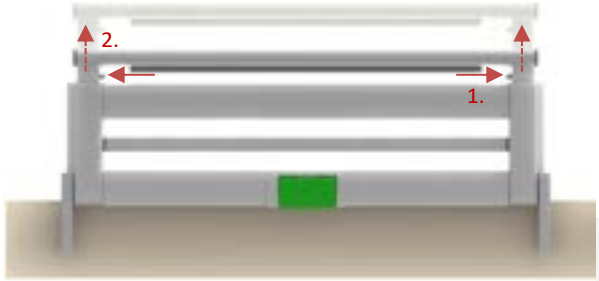
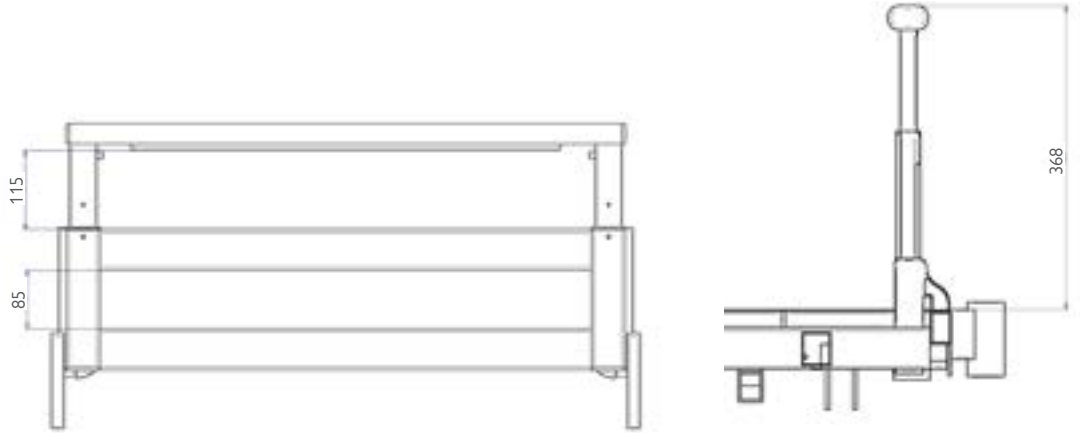


Abb. B

VGS side rail dimensions

When using the ABS/metal grid sleeping surface



ESG side rail adjustment

One-part side rail

(IMPULSE KL hospital bed with undercarriage **Edition 200)**

The side rails are in the standby position (Fig. 1) and allow the patient to get into and out of bed easily.

1. In order to raise the side rail, grab it by the upper bar and swivel it upwards along the sleeping surface until it audibly clicks into place (Fig. 1/2).
2. To lower the side rail, proceed in reverse. Pulling the locking button at the foot end of the side rail (Fig. 3) releases the locking mechanism. At the same time, initiate the downward swivelling motion and carefully lower the side rail (Fig. 4).

Caution! When raising the side rails and side rail height extensions, ensure and check that the latches engage securely. Always use both hands to move this element!

Caution! When lowering and raising the side rails, please be extremely careful not to trap fingers, hands or any other parts of the body between the side rails and the sleeping surface frame.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Integrated sleeping surface extension with quick release

(IMPULSE KL hospital bed with undercarriage **Edition 300**)

The IMPULSE KL hospital bed with undercarriage Edition 300 is equipped at the factory with an integrated sleeping surface extension. The sleeping surface can thus be extended by 10 or 20 cm by means of a quick release mechanism.

This function is activated in three stages and without tools using two levers at the lower foot end of the sleeping surface:

1. Use both levers simultaneously and pull the sleeping surface extension all the way out.
2. Put the mattress insert in place.
3. Now, push the sleeping surface extension back in without using the levers until it snaps into place with an audible click.

If extended only 10 cm, an intermediate position is possible which requires no insert. Centre the mattress accordingly. In this position as well, be sure that the sleeping surface extension snaps into place audibly.

Caution! If the sleeping surface is extended by 20 cm, a mattress extension must be mounted.

Caution! The sleeping surface extension must only be activated by authorised specialist staff.

Integrated sleeping surface extension

(IMPULSE KL hospital bed with undercarriage **Edition 400**)

The IMPULSE KL hospital bed with undercarriage Edition 400 is equipped at the factory with an integrated sleeping surface extension. The sleeping surface can be extended by 10 or 20 cm using two locking bolts at the lower foot end.

The extension is activated without tools in three stages:

1. Pull both locking bolts upwards and then to the right until they engage. The sleeping surface extension has been released.

2. Reach below the foot board and carefully pull out the sleeping surface extension by approx. 10 cm or 20 cm.

3. Finally, turn the locking bolts back to their original positions. Push the bed extension back carefully until the mechanism engages.

Caution! A mattress insert (accessory) must be used with 20 cm extensions. To use a mattress insert, first pull the bed extension out as far as it will go. Once the insert has been positioned, continue as described in point 3.

Caution! The sleeping surface extension must only be activated by authorised specialist staff.

IMPULSE KL hospital bed with undercarriage **Edition 400**

Caution! When activating the reverse Trendelenburg position or automatic chair position in conjunction with a pull-out bed extension, ensure that there are no objects or parts of the body below the foot end of the bed.

Removable head/foot boards

The standard IMPULSE KL hospital bed has head/foot boards that can be removed without the use of tools. These boards can be released and removed by pulling them upwards after releasing the snap lock mounted on the bed frame (green lever).

Caution! Ensure that the head/foot boards are locked before you start operating the bed.

Caution! Secure the patient before removing the head/foot boards.

Caution! When inserting the head/foot boards, take care to ensure no parts of the body or other objects are located in the hazard area.

Potential equalisation

The IMPULSE KL hospital bed with undercarriage Editions 300/400/XL is equipped with a standard protective conductor. This conductor serves to equalise the potential between the bed and devices to which the patient is connected, in order to protect the patient from electrostatic shock.

If the patient is connected to an intravascular or intracardial device, the potential equalisation must be used.

First, connect the ground wire of the device to which the patient will be connected to the potential equalisation. Be sure to use the standard connection for hospitals and check that the connectors are compatible.

Caution! Make sure that the two connectors are compatible and that they cannot be inadvertently disconnected.

Caution! Be sure that the potential equalisation is disconnected from the bed before the bed is moved.

Caution! Potential equalisation is a protective measure which ensures that all conductive parts of an electrical system have the same electrical potential. This prevents potentially hazardous voltage differences between different components. Having a safe electrical environment for patients and medical personnel is extremely important. Guaranteeing correct potential equalisation minimises the risk of electric shocks, which is very important when patients are in direct contact with electrical devices.

Caution! In order to ensure that the potential equalisation is effective at all times, we urgently recommend inspection of the potential equalisation connection (Fig. A, page 40) and the associated connecting cable and also the connecting cable to the potential equalisation between the backrest and the sleeping surface frame (Fig. B) at regular intervals. The components can become worn or damaged due to frequent use and the environmental conditions, which could impair the effectiveness of the potential equalisation.

The following points must be checked at least once per annum:

- Condition of the potential equalisation and the connecting cable to the potential equalisation for visible damage, wear and secure connection
- Condition of the connecting cable to the potential equalisation between the back rest and the sleeping surface frame (Fig. B) for visible damage, wear and a secure connection
- Electrical conductivity and correct functioning of the components for potential equalisation by a qualified electrician

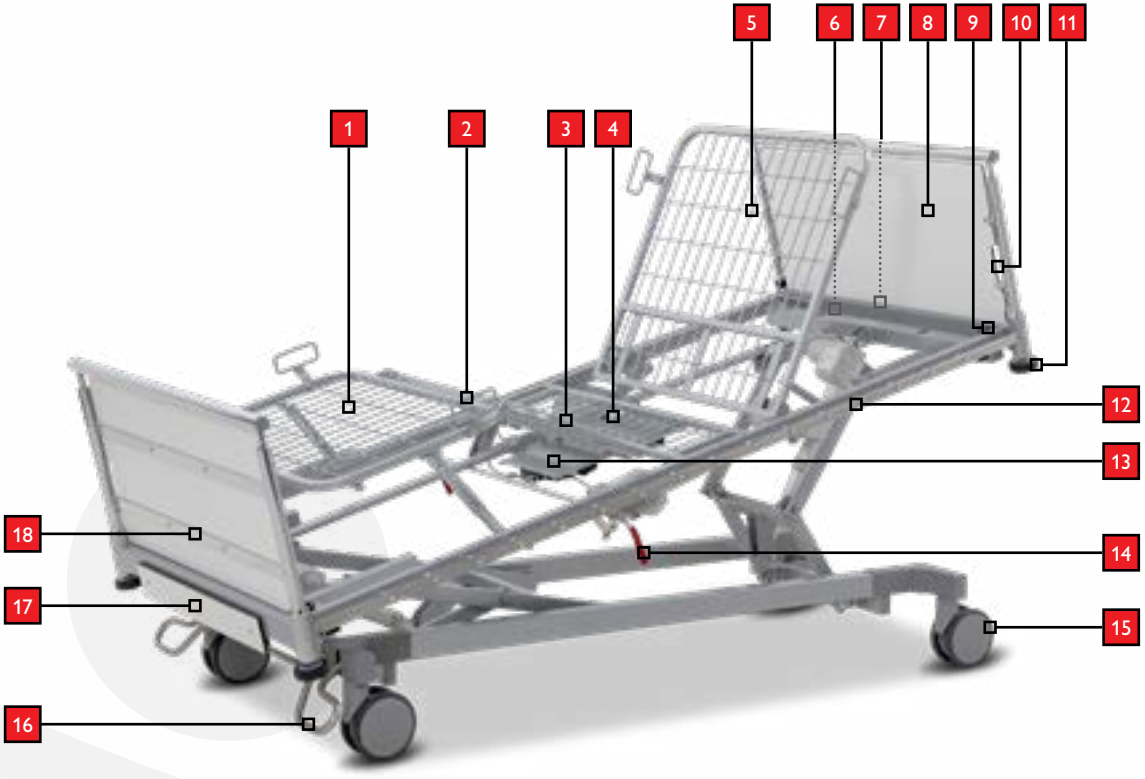
If there are any signs of problems or irregularities, a qualified electrician must be called immediately to carry out a repair, or our customer service must be contacted.

Regular inspection and servicing of these components will help to guarantee the safety and efficiency of the electrical system of the hospital bed.

Fig. B

FUNCTION ILLUSTRATION

IMPULSE KL hospital bed with undercarriage **Editions 300-P / 400-P**



IMPULSE KL hospital bed with undercarriage **Editions 300-P / 400-P**

1. Adjustable lower leg rest (notched bracket)
2. Mattress holder
3. Adjustable thigh rest
4. Static seat section
5. Adjustable back rest
6. Potential equalisation (external)
7. Trapeze bar mount (external)
8. Head board
9. Receiving sleeve for IV drip holder and accessories (4× surrounding the bed)
10. Recess for retrofitting a side rail
11. Wall bumper (4× surrounding the bed)
12. ISO standard rail with restraint grid
13. Mounting panel for controller
14. CPR lever for emergency release of the back rest
15. 150 mm double castors
16. Foot pedal for central brake (▼), freewheeling (–) and fixed direction (▲) of the double castors
17. Bed linen holder with bracket for staff controller
18. Reinforcement of the HPL panels against kicking through

* Optional special equipment

The following differences from the standard equipment are a result of the special adaptations of the bed to the requirements of psychiatric treatment:

- Sleeping surface elements not removable (welded)
- Bolted-in, non-removable head / foot boards with sturdily attached HPL filler boards without gaps between them and the frame of the head / foot board. (To remove the head / foot boards, the wall bumpers must be loosened and removed by means of two screws M8×70. After that, the head / foot board can be pulled up and out.)
- Head / foot boards reinforced with steel rails against kicking through *
- Recesses on the head / foot board for retrofitting a full-length side rail
- No side rails
- Full-length side rail system with snap lock for retrofitting *
- Removable patient hand controller *
- Bed linen holder with bracket for controller
- Four firmly bolted wall bumpers
- CPR lever for mechanical back rest release *
- Stainless steel DIN standard rail, full-length on both sides for holding accessories and for attaching approved restraint systems
- Two sockets for accessories at the head and foot end
- Trapeze bar mount (external) at the head end
- Powder-coated metal parts in RAL 9006

ADDITIONAL SAFETY INSTRUCTIONS FOR BEDS USED IN PSYCHIATRIC WARDS

⚠ Removable accessories such as trapeze bars, IV drip stands and accessories of the DIN standard rail etc. are not recommended. The responsible staff must decide on the use of these types of accessories after assessing the health and psychological state of the patient .

⚠ Furthermore, the staff must consider whether or not to leave the bed connected to the power grid while the patient is unattended. For psychologically unstable patients, we recommend removing the staff controller/hand controller and securing the disconnected mains cable under the bed.

⚠ Using a bed extension is not recommended for psychologically instable patients.

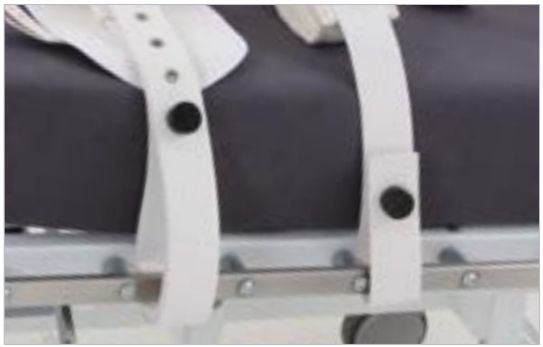
⚠ For beds used on psychiatric wards, regular inspection for damage is urgently recommended. In case of damage, the damaged parts should be replaced immediately.

⚠ The bed is equipped with a conductive castor. Always check the grounding of the bed by making sure that the castor marked with a yellow dot is in contact with the ground.

⚠ Be aware that if a patient is restrained, the hand controller must be actively locked via the staff controller. The bed is equipped with a battery, which allows for adjusting the sleeping surface even when not connected to the power grid.

ISO standard rail with restraint grid

The IMPULSE KL hospital bed with undercarriage for psychiatric wards Editions 300-P / 400-P comes with full length ISO standard rails with restraint grids on both sides of the bed. The grids are designed for straps up to 89 mm wide.



Caution! Always heed the restraint regulations of your workplace, your facility's internal restraint protocol and the current legal regulations of your state! The instruction manuals provided by the manufacturers of the restraint systems used must be adhered to at all times.

Caution! Restraint systems may only be used and applied by persons who are trained or knowledgeable on the practice, and only in connection with approved restraint systems and according to the instruction manual of the system used. Legal regulations and medical instructions must be strictly observed! The attending physician must ensure that the patient's health allows for the use of a restraint system.

Caution! Faulty use of restraint systems can lead to serious injury, even death.

Caution! To avoid accidents while restraining a patient, the side rails must be raised (exception: 5-point restraint). With split side rails, a protector must be used to keep the patient from slipping through.

MAINTENANCE

The manufacturer is only liable for the safety and reliability of the product if it is serviced regularly and used in line with the safety instructions. If any significant faults are found during maintenance work which mean the safe operation of the product cannot be guaranteed, the product must be taken out of use. Maintenance work must be carried out at least once a year.

Any faults that impair the function and safety of the hospital bed must be resolved before the bed is used again and must be reported to the responsible person.

Only original replacement parts from Malsch GmbH are permitted to be used.

Service and maintenance tasks must not be conducted when the bed is occupied. The patient or the care staff must not conduct maintenance tasks.

Procedure

1. Visual inspection

Check the welded structures for cracked weld seams and for plastic deformation and wear. The welded structures include the undercarriage and the sleeping surface with the moving interior components. Also check that all screw joints are firmly connected.

2. Level of protection and functionality check of the side rails

During the functionality check, determine whether the side rails can be easily locked in place and ensure that no impermissible wear or deformation is visible.

The spacing requirements stated in IEC 60601-2-52:2009/AMD:2015 are used for protection. This is shown by the following diagram and table.

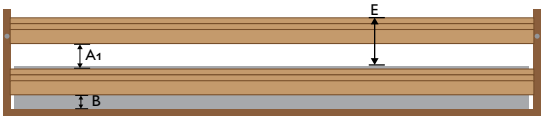


Fig. 1 (dimensions of a single-piece side rail)

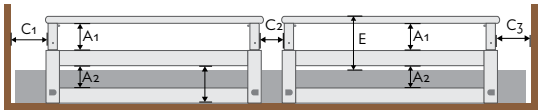
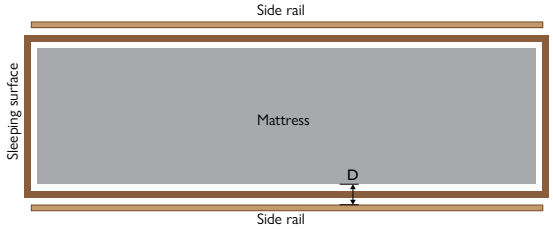


Fig. 2 (dimensions of a split side rail)

Check whether the required spacings are also complied with under load. Check dimensions A and C with a tool in line with IEC 60601-2-52:2009/AMD:2015. The test force for dimension A is 250 N.

Dimensions		Requirement
A1	Fully enclosed opening within the side rail	< 120 mm
A2	Fully enclosed opening resulting from the arrangement of the side rail, its supports and the sleeping surface in relation to each other	< 120 mm
B	Distance between sleeping surface and the lowest point of the side rail on the outside of the rail support	< 60 mm
C1	Distance between head section and neighbouring side rail	< 60 mm
C2	Opening between segmented or split side rails	< 60 mm or > 318 mm
C3	Opening between side rail and foot section	< 60 mm or > 318 mm
D	Area between side rail and mattress.	according to check conditions Standard
E	Height of the upper edge of the side rail to the upper edge of the mattress, resulting in the thickness of the mattress used (without compression, as specified by the manufacturer). with VGS side rail version with GS side rail version with DS side rail version	≥ 220 mm 12 - 16 cm* 12 - 15 cm* 12 - 15 cm*



3. Functionality check of brakes

Depending on the variant, the functionality of the brakes must be checked in every position. With electrical brake systems, check whether the brakes fully retract and extend.

4. Functionality check of lifting motors

Move all lifting motors to their end position and back again. When doing so, please observe the following points:

- Any unusual noises generated
- Synchronism of the lifting motors
- Smooth operation of the lifting motors
- Correct path of the lifting motors
- Automatic switch-off in the end position

The travel path of the lifting motors may vary depending on the model variant. If in doubt, please contact our customer service.

5. Visual inspection of mains connection cable

Check the following points on the mains connection cable:

- Visually inspect and check the function of the strain relief and kink protection
- Visual inspection of the insulation parts
- Visual inspection of the connection cables (damage, crushing)
- Visual inspection of the mains connection plug
- Visual inspection of the cable hooks

6. Visual inspection of wiring

Check the following points:

- Damage to the cables
- Correct cable routing
- Proper seating of plug connections and pull-out protection

7. Visual inspection of housing

The housings must be checked for external damage and intact seals.

8. Measurements in line with DIN EN 62353

Check the electrical components of the hospital bed as specified in DIN EN 62353. Measure the leakage current with the help of the equivalent leakage current test. The limit is ≤ 500 µA.

9. Visual inspection of grab handle for lifting pole

Check that the plastic components and straps show no signs of damage. The grip handles must be replaced every five years.

MAINTENANCE INTERVALS

Every two years and after every emergency lowering

- Testing of the accumulators

Annually

- Inspection and maintenance

As required

- Lubrication of mechanical components
- Replacement of worn components if a defect occurs.

DELIVERY AND ASSEMBLY

Malsch GmbH hospital beds are generally delivered fully assembled, or are assembled on site by company technicians or authorised staff.

Check the delivered bed against documentation for completeness and conformity.

Any defects or damage must be pointed out to the freight company immediately and noted on the delivery document.

Signing of the delivery documents by both parties is obligatory before commissioning.

If necessary, e.g. for maintenance, simple assembly procedures can also be performed by professional authorised persons.

Assembly of head / foot board / sleeping surface

- The head / foot boards can be removed without the use of tools, as they have plug connections.
- Exchange the side rails and sleeping surface cladding with the aid of suitable assembly aids and carry out a function test!

Replacement of the drive system

- Disconnect the power supply and pull out the plugs.
- Once the motor has been replaced, plug in the individual systems again.

After maintenance and servicing work has been completed, check the functionality of electrical systems.

The manufacturer offers technician training for maintenance and servicing work on their hospital beds. A certificate obtained as part of this training authorises the holder to carry out technical work independently on the beds.

DISPOSAL INSTRUCTIONS

The service life of the hospital bed is specified as ten years if used appropriately.

Disposal instructions

- The operator must ensure that none of the components being disposed of are infectious / contaminated.
- If the bed is scrapped, the wood, plastic and metal parts used in its construction must be separated and disposed of properly.
- If you have any questions, contact your local authority, waste-disposal company or our customer service.

Electrical component disposal

- This bed is electrically adjustable and classified as a commercially used electrical device according to WEEE Directive 2012/19/EU (implemented in Germany in the electrical equipment act).
- The electrical components used are free from banned harmful substances in line with the RoHS-II Directive 2010/65/EU.
- Replaced electrical components (drives, control units, hand controllers etc.) of these beds must be treated as electronic waste in line with the WEEE Directive and disposed of properly.

Battery disposal

- Any individual removed batteries that can no longer be used must be disposed of properly as defined by Directive 2006/66/EC (implemented in Germany in the battery legislation) and must not be discarded with domestic waste.
- For information on this matter, contact your local waste-disposal company or our Service department.

In other countries outside Germany / the EU, the relevant, applicable national requirements must be observed.

TROUBLESHOOTING

Malfunction	Possible cause	Possible solution
Drives cannot be operated using the hand controller	Mains cable not plugged in	Plug in the mains cable
	Socket not live	Check socket
	Cable plug connection not firmly connected	Check plug connections on the motor and hand controller
	Hand controller or drive faulty	Inform the operator, specialised dealer or our customer service
	Functions locked on the hand controller	Release the functions on the hand controller *(☞ p. 20)*
Motorised adjustment system is not functioning properly	Obstruction in the adjustment area	Check moving parts and remove any obstructions
	Safe working load exceeded	Reduce the load
Drives cut out after a long period of operation	The adjustment time or safe working load has been exceeded and the control unit has reacted to overheating	Allow the drive system to cool down sufficiently
Opposite function activates when operating the hand controller button	Motor plugs mixed up	Check that the cables are connected correctly or inform your operator, specialist retailer or our customer service
Side rails can no longer be properly adjusted	Mechanism blocked or bent	Check all moving parts and remove any obstructions or contact our customer service
Castors do not brake or cannot be rolled	Foreign objects have become trapped in the castors	Remove foreign objects
	The castor system is faulty	Contact our customer service

PRODUCT SAFETY

This product bears the CE seal and therefore meets the requirements of the applicable German and European safety standards.

Laws and standards	Title
Regulation (EU) 2017/745	European Medical Device Regulation
MPDG	Medical devices implementation act
DIN EN ISO 13485	Quality management for medical devices – Requirements for regulatory purposes
DIN EN ISO 9001	Quality management systems
DIN EN ISO 14001	Environmental management systems
IEC 60601-2-52	Medical electrical equipment – Particularly requirements for safety
DIN EN 60601-1	Medical electrical equipment – General requirements for safety
DIN EN 60601-1-2	Medical electrical equipment – Electromagnetic (EM) disturbances
IEC 60601-1-6	Medical electrical equipment – Usability
DIN EN ISO 14971	Risk management for medical devices
IEC 62366	Medical devices – Application of usability engineering to medical devices
DIN EN ISO 20417	Medical devices – Requirements for the information to be supplied by the manufacturer
DIN EN ISO 15223-1	Symbols to be used with medical device labels
DIN EN 12182	Technical aids for disabled persons
DIN EN 12530/DIN EN 12531	Medical castors/hospital bed castors
DIN 33402-1	Ergonomics – Body dimensions of people
DIN 68861-1	Furniture surfaces – Resistance to chemical attack

CLEANING AND DISINFECTION

Disinfection

The hospital bed must be disinfected regularly, at least before every change of patient. All detergents in line with DIN EN 12720 are suitable for wipe-down disinfection of the bed. The hospital bed must not be disinfected in inline washing systems or using water spray. Only those disinfectants recommended by the RKI are permitted to be used for wipe and surface disinfection at the specified concentration. Complaints resulting from improper use e.g. hand disinfectant used for surface disinfectant, are excluded.

The detergents used for disinfection must only be used in line with the manufacturer's instructions.

Caution! Under no circumstances use abrasives, cleaning pads or stainless-steel cleaners for cleaning. Before using any disinfectants, please consider the dosage and any potential hazards that may be caused by combining them with other substances. Remove the plug from the mains socket when disinfecting the hospital bed and protect the drive system from moisture.

Prior to prolonged storage, the batteries of the electric emergency lowering function should be removed to prevent damage caused by leaked battery acid.

Safe decommissioning / storage

Proceed as follows to safely decommission the bed or prepare the bed for storage:

- Disconnect the bed from the power by pulling out the mains plug.
- Activate the brake system.

Storage

- Charge the (optional) battery regularly to prevent deep discharge.
- Remove any accessories such as bed lights, trapeze bars etc.
- Cover the hospital beds so that the wooden parts and the frame cannot be damaged.
- Mark the storage date clearly on the bed (so that maintenance intervals can be observed).
- Lock the hand controller.
- Prior to prolonged storage, the batteries of the electric emergency lowering function should be removed to prevent damage caused by leaked battery acid.

Caution! The same conditions apply to the storage location of hospital beds as to the working environment (temperature, humidity, heat, etc.).

The manufacturer's transport aid must be used to transport the beds.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The bed is intended for operation in the electromagnetic environments listed below. The customer or user of the bed must ensure that it is used in a suitable environment.

Guidelines and manufacturers' declarations – electromagnetic emissions

Emission measurement	Compliance	Electromagnetic environment directive
RF emissions, CISPR 11	Group 1	The bed uses HF energy exclusively for its internal functions. Therefore, it produces very low HF emissions, and it is unlikely that nearby electronic devices will be adversely affected.
RF emissions, CISPR 11	Class A	The bed is suitable for use in all inpatient / professional care.
HF emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	Compliant	

Guidelines and manufacturers' declarations – electromagnetic resistance

Phenomena	EMC basic standard or test procedure	Environments in domestic health care areas	Compliance level	Electromagnetic environment – directives
Static electricity discharge	IEC 61000-4-2	± 8 kV contact	±8 kV contact	The flooring material must consist of wood or concrete. If synthetic materials are used, the relative humidity must be at least 30 %.
		± 2 kV; ± 4 kV; ± 8 kV; ± 15 kV air discharge	± 2 kV; ± 4 kV; ± 8 kV; ± 15 kV air discharge	
High-frequency electromagnetic fields	IEC 61000-4-3	3 V/m	3 V/m	Portable and mobile radio devices must not be used closer to the hospital bed and its cables than the recommended distance calculated using the equation applicable to the frequency of the transmitter.
		80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	
			80 % AM at 1 kHz	

Magnetic fields with energetic rated frequencies	IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power-frequency magnetic fields must correspond to the typical value found in the business and hospital environments.
Electrical fast transient disturbanc-es/bursts	IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV	The power supply quality must correspond to that of a typical business or hospital environment.
Surge voltage Cable to cable	IEC 61000-4-5	±0.5, ±1kV	±0.5, ±1kV	The power supply quality must correspond to that of a typical business or hospital environment.
Surge voltage Cable to ground	IEC 61000-4-5	±0.5, ±1kV, ±2kV	±0.5, ±1kV, ±2	The power supply quality must correspond to that of a typical business or hospital environment.
Conducted disturbances induced by high-frequency fields	IEC 61000-4-6	3V 6V in ISM and amateur radio frequency bands	3V 6V in ISM and amateur radio frequency bands	
Voltage dips	IEC 61000-4-11	0% UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT; 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees	0% UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT; 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees	The power supply quality must correspond to that of a typical business or hospital environment. If the user of the bed requires continued func-tionality even in the event of power supply disruptions, it is advisable to supply the bed with power from an uninterruptible power supply or from a battery.
Power failures	IEC 61000-4-11	0% UT; 250/300 cycles	0% UT; 250/300 cycles	

Interference resistance of enclosure ports to high-frequency wireless communication equipment

Test frequency [MHz]	Band [MHz]	Service	Modulation	Maximum power [W]	Distance [m]	Immunity test level [V/m]
385	380 to 390	TETRA 400	Pulse modulation 16 HZ	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	Frequency modulation ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation 217 HZ	0.2	0.3	9
145						
780						
810	800 to 960	GSM 800 / 900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 HZ	2	0.3	28
870						
930						
1,720	1,700 to 1,990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3,4,5 UMTS	Pulse modulation 217 HZ	2	0.3	28
1,845						
1,970						
2,450	2,400 to 2,570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	Pulse modulation 217 HZ	2	0.3	28
5,240	5,100 to 5,800	WLAN 802.11 a/n	Pulse modulation 217 HZ	0.2	0.3	9
5,500						
5,785						

WARRANTY AND SERVICE

By purchasing a hospital bed from Malsch GmbH, you have chosen a premium, high-quality product.

Malsch hospital beds are covered by a 24-month warranty calculated from the date of purchase.

In the event of material or manufacturing faults occurring within the warranty period, the bed will be replaced or repaired free of charge.

This excludes faults and errors caused by inappropriate handling or external influences.

Our normal terms of business and delivery apply.

If you have any questions, please contact us on the following numbers:

Customer service

Tel: +49 (0) 6626 915-100
Fax: +49 (0) 6626 915-127

info@bettenmalsch.de
bettenmalsch.com

DECLARATION OF CONFORMITY

reddot award 2016 winner

GERMAN DESIGN AWARD WINNER 2018

Malsch care & clinic design

DE

EU-Konformitätserklärung

nach der Verordnung (EU) 2017/745 des europäischen Parlaments und des Rates vom 5. April 2017 über Medizinprodukte, Anhang IV.

Der Hersteller
Malsch GmbH
Rohbergstraße 9, 36208 Wildeck
Tel.: +49 (0) 6626 915-100
SRN DE-MF-000005173

erklärt in alleiniger Verantwortung, dass die nachfolgend benannten Produkte den grundlegenden Anforderungen und Bestimmungen der Verordnung (EU) 2017/745 für Medizinprodukte entsprechen und gemäß der Anhänge II, III und VIII, Regel (1,13) der Risikoklasse I zugeordnet werden:

Klinikbett IMPULSE KL

Basis UDI-DI: 4065848MALSCH-PKL00002V

Die bezeichneten Produkte wurden unter Anwendung der folgenden Richtlinien und harmonisierten Normen produziert:
Elektrische Sicherheit:
IEC 60601-1 A2:2020

Mechanische Sicherheit:
IEC 60601-2-52:2009+A1:2015

Elektromagnetische Verträglichkeit (EMV):
IEC 60601-1-2:2014

Gebrauchstauglichkeit:
IEC 60601-1-6:2010+A1:2013
IEC 62366-1:2015+COR1:2016

Risikomanagement:
DIN EN ISO 14971:2022-04

Richtlinie zur Beschränkung gefährlicher Stoffe RoHS:
Richtlinie 2011/65/EU

REACH-Verordnung, Verordnung (EG) Nr. 1907/2006

Durch die Einhaltung der Bestimmungen der Verordnung (EU) 2017/745 werden die Anforderungen zur Anbringung einer CE-Kennzeichnung erfüllt. Aufgrund der Spezifikation als Medizinprodukt Klasse I werden Produkt und Verpackung spätestens ab Mai 2025 zusätzlich mit einer UDI-Kennzeichnung versehen. Eine Konformität der Produkt- und Entwicklungsdokumentation sowie des QM-Systems wird durch die Zertifizierung nach DIN EN ISO 13485:2021 bestätigt.

Bei einer mit uns nicht abgestimmten Änderung des oben genannten Produktes verliert diese Erklärung ihre Gültigkeit.

Wildeck, den 18.06.2025

Rayk Malsch
Geschäftsführer / CEO / Gérant

EN

EC Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices, Ann. IV.

The manufacturer
Malsch GmbH
Rohbergstraße 9, 36208 Wildeck, Germany
Phone +49 (0) 6626 915-100
SRN DE-MF-000005173

declares under its sole responsibility that the devices named below comply with the essential requirements and provisions of Regulation (EU) 2017/745 for medical devices and are assigned to risk class I in accordance with Annexes II, III and VIII (Rule 1,13):

Hospital bed IMPULSE KL

Basic UDI-DI: 4065848MALSCH-PKL00002V

The designated products have been produced in application of the following directives and harmonised standards:
Electrical safety:
IEC 60601-1 A2:2020

Mechanical safety:
IEC 60601-2-52:2009+A1:2015

Electromagnetic Compatibility (EMC):
IEC 60601-1-2:2014

Usability:
IEC 60601-1-6:2010+A1:2013
IEC 62366-1:2015+COR1:2016

Risk Management:
DIN EN ISO 14971:2022-04

Directive on the Restriction of Hazardous Substances RoHS:
Directive 2011/65/EU

REACH-Regulation, Regulation (EC) Nr. 1907/2006

By complying with the provisions of Regulation (EU) 2017/745, the requirements for affixing a CE marking are fulfilled. Due to the specification as a medical device class I, the product and packaging will additionally be provided with a UDI marking from May 2025 at the latest. Conformity of the product and development documentation as well as the QM system is confirmed by certification according to DIN EN ISO 13485:2021.

In the event of a modification of the above-mentioned product not agreed with us, this declaration loses its validity.

CERTIFICATES

CERTIFICATE

for a management system as per

EN ISO 13485:2016/AC:2018,
EN ISO 13485:2016/A11:2021

Evidence of conformity has been furnished.

Malsch GmbH
Rohbergstraße 9
36208 Wildeck - Obersuhl / Germany

Scope - for the European Economic Area:
Development, manufacturing, distribution and servicing of clinic- and care bed systems, along with related consulting services, particularly in the areas of project planning and outfitting within the medical field.

Certificate registration No.:
73 105 1297

Certificate valid from:
2023-11-17 to: 2025-07-10

Dr. M. Povick
Head of Certification body
Release: Darmstadt 2023-07-06
Certification Body of TÜV Hessen

CERTIFICATE

for a management system as per

DIN EN ISO 9001:2015

Evidence of conformity has been furnished.

Malsch GmbH
Rohbergstraße 9
36208 Wildeck - Obersuhl / Germany

Scope:
Development, manufacture and distribution of medical beds and accessories

Certificate registration No.:
73 100 1297

Certificate valid from:
2024-11-26 to: 2025-09-30

Start of certification cycle:
2022-10-01

Andreas Fuchs
Head of Certification body
Release: Darmstadt 2024-11-26
Certification Body of TÜV Hessen

CERTIFICATE

for a management system as per

DIN EN ISO 14001:2015

Evidence of conformity has been furnished.

Malsch GmbH
Rohbergstraße 9
36208 Wildeck - Obersuhl / Germany

Scope:
Development, manufacture and distribution of medical beds and accessories

Certificate registration No.:
73 104 1297

Certificate valid from:
2024-11-26 to: 2025-09-30

Start of certification cycle:
2022-10-01

Andreas Fuchs
Head of Certification body
Release: Darmstadt 2024-11-26
Certification Body of TÜV Hessen

Item no. 91300 102103.2.1
EN, Stand 06/2025, Rev. 3.2.1

Colours may vary

Subject to technical changes

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bettenmalsch.com | info@bettenmalsch.de

CE