

# sentida sc



Gebrauchsanweisung Instructions for Use



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## 2.1 About these instructions for use

This section contains information on the structure of the instructions for use and explanations of the signs and symbols used. These instructions for use contain instructions for operating the nursing home bed.

These instructions for use may contain inaccuracies or printing errors. The information provided here will be updated periodically and changes due to product maintenance will be included in later editions. Changes or improvements are possible at any time without prior notice. If you have any questions, please contact Customer Service.

The instructions for use must be read and used by every person who operates the low-set nursing home bed. In addition to the instructions for use and binding accident prevention regulations applicable in the country and place of use, the recognized rules for safe and professional work must also be observed.

## 2.2 Symbols used in this text

In these operating instructions, we use the following designations or symbols for particularly important information:



#### Danger!

Safety instructions that endanger persons are marked with this symbol. The symbol stands for imminent dangers that lead to death or severe injuries.



#### Caution!

This sign stands for possibly dangerous situations that lead to slight injuries.



#### Attention!

This sign is placed in front of warnings when there is a risk of damage to the device or other objects.



This sign is placed in front of additional helpful notices.

- A dash in front of the text means: This is part of an enumeration.
- A dot in front of the text means: This action is mandatory.
   Indented text describes the result of your action.

## 2.3 Purpose

The sentida nursing home bed is intended for use in retirement and nursing homes, in the outpatient care sector and comparable facilities or in the home environment in accordance with application environments 3 and 5 as per IEC 60601-2-52 (current version). It is a Class I medical device intended for human medical use only.

The sentida nursing home bed moves on castors, has infinitely variable motorized height adjustment and a bedding area that can be adjusted by multiple motors, for example, to set a sitting or exit position.

The sentida nursing home bed is designed for a safe working load of 250 kg, with a maximum resident weight of up to 215 kg and a mattress and accessories weight of 35 kg. If other heavier, loose or attached accessories are used, adjust the maximum resident weight accordingly (see the technical data).

We cannot accept liability for any product or personal damage caused by third-party accessories or in the event of mutual nullification of the intended purpose.

The specified possible use is the purpose. For the operator or user, it is derived completely from the labeling and the instructions for use.

#### Indication and target patient group

By means of motorized adjustment options, the sentida medical nursing home bed relieves caregivers of patients who are no longer spontaneously mobile and/or who are bedridden in the inpatient or outpatient environment for care carried out wholly or partly in bed.

The nursing home bed is intended for persons who have a height of at least 146 cm, a weight of at least 40 kg and a BMI  $\geq$  17.

Other applications must be agreed in writing with wissner-bosserhoff GmbH in advance. The product is to be used as work equipment for care applications and is subject to the regulations of the responsible professional associations.

#### **Application restrictions and contraindications**

Use only under medical supervision. The determining factor as to whether or not care is medically supervised is whether that care is provided under the direction of medical personnel.

Use of the bed is not recommended for fresh spinal injuries and extensive burns.

#### Intended users

The bed may only be used by persons who, based on their training or knowledge and practical experience, can guarantee proper handling.

In addition, the user of the nursing home bed must have been instructed in its correct use and must have familiarized himself with the product on the basis of these instructions for use. Common users include: Nursing staff, physicians, physical and occupational therapists, family members, house technicians, the person being cared for/resident and cleaning staff.



## 2.4 General safety instructions

The sentida nursing home bed has been built according to the state of the art and recognized technical safety rules. Nevertheless, improper use may result in a danger to life and limb of the user or third parties or impairment of the sentida nursing home bed and other material assets.

Only use the sentida nursing home bed when it is in perfect condition and for its intended purpose, in a safety-conscious and hazard-conscious manner, and in compliance with the instructions for use! In particular, have any faults that may affect safety rectified immediately!

Always keep these operating instructions within easy reach at the place of use of the nursing home bed! In addition to these instructions for use, observe generally applicable statutory and other binding regulations on accident prevention and environmental protection!

Do not make any modifications, additions or conversions to the nursing home bed without the manufacturer's approval. Spare parts must meet the requirements specified by the manufacturer. This is always guaranteed in the case of original spare parts. Comply with the required tests!

Ensure safe and environmentally friendly disposal of operating and auxiliary materials, as well as spare parts! Before using the bed, make sure that it is functioning properly and in good condition.

Always leave the castors in the braked position; this avoids the risk of the patient or resident falling when getting in and out of the bed. Adjust the height of the bedding area to the size of the patient to avoid risk of falling.

If incontinent residents are placed in bed, an incontinence guard must be used for the mattress.

## 2.5 Operating aids / PDF download

In addition to the operating instructions, operating videos are available for handling the handset and the SafeFree® divided siderail:

The instructions are available here in \*.pdf form:

Click here for the videos: (Scan QR code)



The instructions can be found here: (Scan QR code)

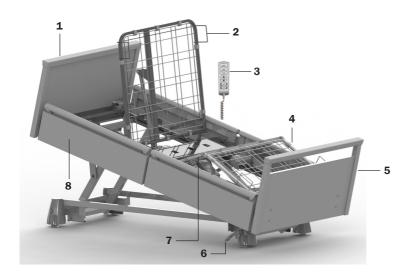




SWL Safe working load
Al Assembly instructions
Ul Instructions for use

## 3. Product overview

In the following, the sentida nursing home bed will be referred to as sentida or just as a bed.



Head part
 Backrest

4. Legrest section

3. Handset

5. Footrest6. Brake lever

7. Thighrest section

8. Siderail with side panel



## 4.1 Delivery

The nursing home bed is usually delivered fully assembled or assembled on site by qualified personnel.

- Upon delivery, check for completeness using the delivery papers.
- Note any defects or damage on the delivery note.
- Report any transport damage or defects immediately to your responsible service partner.
   The address and phone number can be found on the last page of these instructions.

## 4.2 Setting up the bed

- Ensure the suitability of the floor covering so that no damage occurs to the floor. Unsuitable floor coverings include, for example, too soft, unsealed or defective floors. In many cases, the following floor coverings are unsuitable: soft wooden floors, open-pored and soft stone floors, foam-backed carpets, soft linoleum or similar floor coverings. In case of doubt, please contact your flooring company and the technical customer service of wissner-bosserhoff GmbH.
- Make sure that the bed is free-standing in the room and that there is sufficient safety clearance around the bed in all adjustment positions (including the swivel function). For the extreme positions of the bed, an additional safety distance of 2.5 cm from objects, walls and installations as protection against trapping is required. The safety distance from the head part to objects, walls and installations is at least 20 cm.
- Make sure that mechanical and electrotechnical protective measures are in place on site,
   e.g. wall bump strips, bump angles, RCD switches, etc.
- Pay attention to sensible socket positions for the mains connection of the bed. Unsuitable
  positions are such that could lead to collisions or expansion when the bed is moved or where
  the power cable has to be routed across the floor or even under the bed for distances that
  are too long.
- Generally avoid using unsecured extension cords or socket strips on the floor of a room. A
  mains socket outlet 100 240 V, 50/60 Hz set up in accordance with VDE regulations must
  be used as the voltage source.
- Magnetic objects or magnetic fields must be kept away from the bed.
- The nursing home bed must be positioned in the room in such a way that a disconnection/connection to the supply mains can be easily established.
- → A nursing home bed is not normally equipped with an equipotential bonding connection. A combination with other electromedical devices is therefore not permitted without further safety measures.

## 4.3 Drives and connections



- 1 Reading light connection (switchable)
- 2 Battery
- 3 Height adjustment motor, foot end
- 4 Height adjustment motor, head end
- 5 Thighrest motor
- 6 Backrest motor
- 7 Handset / underbed lighting
- 8 Short-circuit plug / control unit ACP

## 5. SafeControl handset

### First-fault safety of the handset:

The handset of the nursing home beds has a first-fault safety feature. This means that adjusting the bed by accidentally pressing a button or playing with the handset is prevented. The functions of the handset are explained in detail in the following chapters.



#### Danger!

When moving the bed to the various positions, make sure that there are no persons, body parts or objects in the adjustment range or between the head part/footrest and the floor or underneath the bedding area.



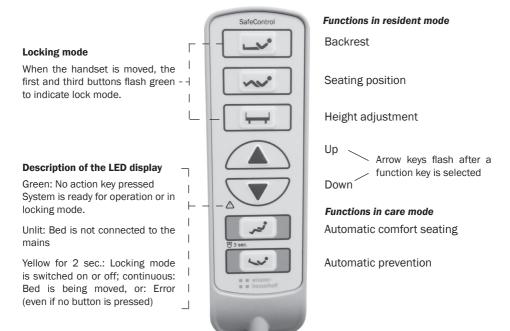
#### Attention!

All electrical functions can be faulty. Unless you lock them and release them for the duration of the function (cf. section 5.3).



#### Attention!

Other devices emitting electromagnetic radiation (e.g., DECT cordless telephones) may affect electrical bed functions. Therefore, bed functions that are not required must be locked for safety. The use of such devices in the environment should be avoided if possible.



### 5.1 Basic functions of the handset



To carry out adjustment functions with the handset, a function key must always be activated first before the adjustment can be carried out using the action keys up/down (first-fault safety).

#### **Backrest**











Adjustment of the backrest (individual).

### **Seating position**











Synchronous adjustment of the backrest and legrest.

### **Height adjustment**











Height adjustment of the entire bed. This function has no influence on the position of the bedding area.

Please observe the warning notes on height adjustment in chapter 6!

### **Automatic comfort seating**











The bed moves to the preset sitting position.



#### Caution!

Particularly in connection with a bed extension, a risk of getting caught between the bed and the floor may arise or the head or foot end may touch down on the floor! Before adjusting the bed, always move the bedding area to an appropriate height! The same applies in combination with a linen holder!



### Attention!

If the nursing home bed is operated in facilities with medical supervision, this position may be enabled only by medical personnel or only "under medical supervision" for safety reasons! Enabling is done by pressing the corresponding button for a minimum of 3 seconds (cf. chapter "Switching modes"). Due to the intended purpose, a Trendelenburg position is not required!

### **Automatic prevention**











First press the Automatic Prevention button and then the Up and Down button at the same time.



#### Attention!

If the nursing home bed is operated in facilities with medical supervision, this position may be enabled only by medical personnel or only "under medical supervision" for safety reasons! Enabling is done by pressing the corresponding button for a minimum of 3 seconds (cf. Chapter "Switching modes". Due to the intended purpose, a Trendelenburg position is not required!



#### Caution!

The leg elevation function is not used for acute care in emergency/shock positioning for nursing home beds. Primarily, this function only serves to effortlessly set the leg elevation for therapeutic reasons! To avoid the risk of an unintentional Trendelenburg position, we strongly recommended that the backrest be raised approximately one hand width at the same time as the legs are raised. It is important that the resident's head is higher than the orthostatic point of the body.

## 5.2 Additional functions of the handset

Switching the underbed lighting (option) on and off











First press the button for the backrest and then simultaneously the Up and Down button for at least 3 seconds.













Hold down the seating position button and press the Up or Down button at the same time.

#### **Nursing position**







Press the height adjustment button and the Up button at the same time.

### Reading light (accessory)









First press the seating position button and then the Up and Down button at the same time.

### Individual entry/exit position



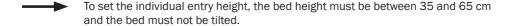


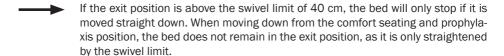




First, move the bed to the desired height. Then press the comfort seating position button and the Up and Down button for 3 seconds at the same time:

- 1x beep: Desired height was saved
- 2x beep: Position could not be saved; the factory setting of the exit height is saved (40 cm).







### **Changing modes**

### **Activating care mode**







Press and hold the comfort position or prevention automatic button for at least 3 seconds.

### Locking the handset







Press and hold the backrest and height adjustment button simultaneously for at least 5 seconds until the LED briefly lights up yellow and then permanently lights up green.

### **Activation times**



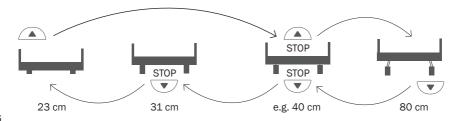
The activation time is the time in which an adjustment can be made after the handset or a specific function has been activated.

When moving the handset approx. 20 sec.
 Selection of a function approx. 16 sec.

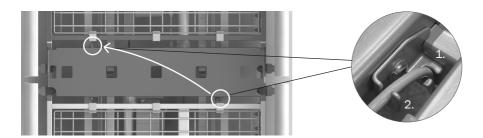
- Activation of care mode approx. 2 min.

### Comfort exit / 4-stop

When the height is adjusted, upwards, the bed stops in a preset exit position. To continue the movement, the corresponding adjustment button on the handset must be released and then pressed again. When the height is adjusted downward, an additional intermediate stop is programmed in to protect against pinching for the lowest position. Moving down again can lead to a jamming hazard (see chapter "Safety notes for height adjustment").



## 5.4 Relocating the handset to the other side of the bed



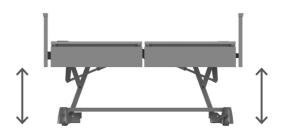
To move the handset from one side of the bed to the other, proceed as follows:

- Release the handset on one side of the bed from the holders on the seat section (between the seat section and the thighrest).
- Guide the handset under the bedding area diagonally to the other side of the bed.
- Thread the cable of the handset on the other side first through the horizontal holder (1.) and then through the vertical holder (2.).



For a better understanding, note the exemplary illustration above.

## 6. Safety instructions for height adjustment





### Danger!

Before each height adjustment of the bed, make sure that there are no persons, animals or objects in the danger zone! Always leave the handset in the locked position so that no unauthorized persons can manipulate the height adjustment of the bed!



#### Caution!

Avoid getting your feet in the trapping risk area (bed ends or free space under the bed) during height lowering or the tilting of the seating position.



#### Caution!

Comfort position/leg elevation: Particularly in connection with a bed extension, a risk of getting caught between the bed and the floor may arise or the head or foot end may touch down on the floor! Before adjusting the bed, always move the bedding area to an appropriate height! The same applies in combination with a linen holder!



#### Caution!

The design as a low-set nursing home bed requires the clear height to be less than 150 mm. Before each height adjustment of the bed, make sure that there are no persons, objects or anything else in the trapping zone under the bed. Always leave the handset in locked mode so that no unauthorized person can adjust the height.



The design as a low-set nursing home bed requires the safety distance to be less than 150 mm. Before using mobile lifting equipment, make sure that the free space under the low-set nursing home bed is sufficient for the mobile lifting equipment. In the other case, adjust the height before using mobile lifting devices.

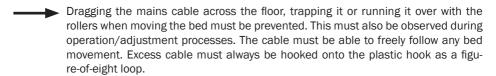
## 7. Plug-and-play for the handset (option)

The plug-and-play option makes it possible to quickly and conveniently move the handset from one side of the bed to the other:

- Disconnect the power plug of the bed from the power socket
- If the handset is to be moved from the left to the right side, pull the multi-pin plug out of the left connection and close the bushing with the attached plug.
- Connect the plug to the right connector after removing the plug from the bushing.
- The keys of the handset light up when the bed is reconnected to the power supply.

## 8. Proper handling of the mains cable

The sentida nursing home bed is equipped with a spiral connection cable. A plastic hook is attached to it.



Do not pull the mains cable out of the socket with wet hands and pull it out only by the plug.



- If you want to move the sentida nursing home bed, hang the hook of the mains connection cable on the upper edge of the head part. In this way, you prevent it from being run over by accident.
- Check the mains connection cable, the mains plug bushing, the mains plug housing and the housing inlets on the bed regularly for damage in order to exclude hazards.



The bed is movable. The easy positioning within the room simplifies the cleaning of the floor space and the low-set nursing home bed. However, the low-set nursing home bed is not suitable for transporting residents. The low-set nursing home bed may only be moved in the lowest position and only without the resident; moving the low-set nursing home bed to other rooms together with the resident is not part of the intended use.



#### Caution!

If feet or other body parts get under the running castors or undercarriage panel during the procedure, injuries will result. During the procedure, be careful not to put your foot under the running castors or undercarriage panel.



#### Caution!

Unbraked beds can pose a fall hazard. Always leave the bed in a braked position. Should the resident be unattended, the bed should be left in the lowest position.



#### Attention!

Power supply lines can be damaged if the bed rolls over them. Never move it over mains cables or other lines.



#### Attention!

The anchors of the sidewalls can tear out if strong forces are applied to them. To move the bed, grasp and hold it only by the head part or footrest.

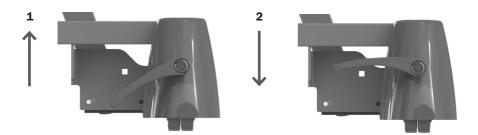


### Attention!

Moving the bed is possible only when the brakes are properly released. If rollers that are still fixed are moved across the floor contrary to the operating specifications, damage to the floor covering and braking system may result.



Under the head part and footrest, there is a covered axle with lockable castors. On the inside of these undercarriage panel are brake levers on the left and right sides of the bed (in the case of the central braking system, only on the foot end). Use these brake levers to release or lock the castors axle by axle.



- 1. To release the brakes, pull up the brake lever.
- 2. To lock the bed, press down the brake lever.

## 9.2 Mobile variant with central braking system

To operate the brake bar, move the bed to the comfort exit position or higher. The brake bracket can now be operated with the foot in three positions.

Position 01: Brake

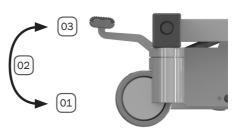
Position 02: Freely movable

Position 03: Direction detection

(Blocks the swivel movement of the left

head-end castor, making it easier to maneuver

the bed.)

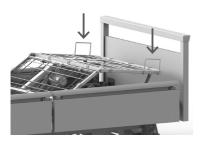


To move the bed, please follow the steps below:

- Release the brake.
- Grasp the bed by the head part or footrest and then move the bed to the desired position.
- Then tighten the castors again by pressing the brake bracket.



The legrest section is height-adjustable via ratchets.



• If you want to lift the legrest section by hand, grasp it by the mattress limit brackets (see arrows) and lift it up.

It snaps into the desired position.

• If you want to lower the legrest section by hand, grasp it by the mattress limit brackets, lift it to the stop and then lower it.

Make sure that both sides of the calfrest are tightened to the stop!

## 10. Siderails

Special care and caution are required when using siderails. Siderails are used primarily as patient protection. Under no circumstances may the siderails be used as a means of patient immobilization.



Court orders are required for the use of siderails as soon as the resident's mobility becomes restricted. Only split siderails or individually lowerable siderails, in which only the head section is erected and which can be used as an entry and ascent aid, constitute a permissible exception here for mobile residents.



When using siderails, the suitability must be checked taking into account the physical and mental characteristics of the respective resident. In particular, the distances between the bars and stays must be observed in relation to the physique of the resident so that becoming trapped or slipping through can be ruled out. If necessary, additional side protection pads should be used to reduce the gap dimension or close the gaps. This decision is the sole responsibility of the appropriate medical supervisor.



### Caution!

Incorrectly fixed siderails can sink again, causing the resident to fall. In each new position, shake to make sure that the siderail is properly engaged. Correct engagement can also be checked visually for divided siderails: The yellow detent buttons must be visible in the detent recess of the telescopic mechanism on both sides.



#### Caution!

If necessary, also use an attachment for siderails as an elevation when using raised mattress systems and the available siderail pads (accessories) as an important additional safety and protection feature.



#### Caution!

When lowering or raising siderails, fingers, hands or other parts of the resident's body can be crushed. Raise or lower the siderails with utmost attention. And only grip at the positions intended for this purpose according to the instructions for use.



#### Caution!

Restless and disoriented persons can get caught in the free spaces of the siderails. Protect them by using siderail pads.



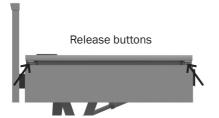
#### Attention!

The siderails can be overloaded and damaged by large loads, bracing or pulling. Avoid such loads.



The SafeFree® siderails are divided into two parts on each side of the bed. There is a release button on the bottom of each of the outer ends of the handrail, which can be used to release the lock. It can be extended in 4 steps up to the height of 400 mm.

Guide the siderail with both hands to ensure even lowering/lifting in both guides.



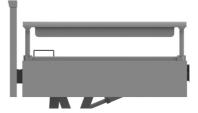
### 1. Stage: Accessibility

The sideboard is in the lowered position.



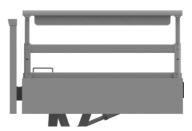
### 3. Stage: Security

Full protection at a height of 349 mm.



### 2. Stage: Mobilization

3/4 protection at a height of 247 mm.



### 4. Stage: Increased safety

Increased protection at a height of 407 mm with higher mattress thickness.

If you want to raise the lowered SafeFree® siderail:

- Grasp the SafeFree® siderail by the handrail, and lift it until the SafeFree® siderail clicks into the next higher position.
- To raise the SafeFree® siderail further, **simultaneously** press in both release buttons and then pull the siderail upwards by the handrail until the SafeFree® siderail locks into the next higher position with a clear click.

To lower the SafeFree® siderail, reverse the procedure:

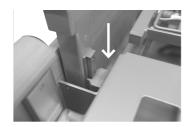
• Simultaneously press in both release buttons and lower the SafeFree® siderails on the handrail to the desired position.

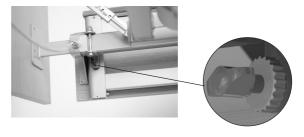
## 10.2 SafeFree® Flex

SafeFree® Flex is an addition to the SafeFree® concept with flexible and individually retrofittable siderails or mobilization elements.

To attach/remove elements (identical for all variants):

- Insert the element with the rails into the corresponding guides on the longitudinal member of the upper frame.
- Tighten element with thumbscrew and knurled nut on mounting bracket.
- To remove an element, first loosen the wing screw and knurled nut and pull the element out upwards.







#### Caution!

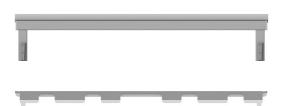
In order to prevent the wing screws from loosening imperceptibly or becoming loose, they must be checked regularly for tightness!

## 10.2.1 Continuous side panel

#### **Variants**



High-quality SafeFree® siderail. For operation, see section 10.1.



Dummy with handrail for attachment between bedding area and side panel, including the handrail.

Dummy for attachment between bedding area and side panel.



# 10.2.2 Divided side panel

### **Variants**



Full SafeFree® siderail, including divided side panel. For operation, see section 10.1.



Dummy as a cover without siderail.

## 10.3 Continuous siderails (type 09)

The continuous siderails are available with two tie bars (type 09, 2-fold) or with 3 tie bars (type 09, 3-fold). Lifting and lowering are identical for both versions.



Type 09 siderail, 2-fold

If you want to raise the lowered type 09 siderail:

• Grasp the siderail at the lower edge and lift it upwards until the release button audibly engages.

If you want to lower the type 09 siderail:

- Lift the siderail by the release button and push and hold it in the direction of the arrow.
- Slowly lower the siderail.



#### Caution!

In some model variants, it is possible to lock the siderail in the "center position." This position does not serve as sufficient protection against falling out.



#### Caution!

Inclining the siderails is not a suitable, sufficient side protection against falling out of bed.

# 11. Compatible accessories



### Danger!

The use of accessories not approved for the product and unapproved combination products can cause serious hazards. Therefore, only accessories approved by wissner-bosserhoff GmbH and products approved for combination are to be used.

### 11.1 Mattresses

The bed must always be used with a suitable, compatible mattress.



#### Attention!

Do not use waterbed mattresses. In this case, exceeding the safe working load can cause the drives or other components to fail and cause accidents. Always observe the safe working load.



### Attention!

Replace wissner-bosserhoff mattresses only with equivalent mattresses of identical dimensions. Also pay attention to the presence of movement incisions on the underside of the mattress, otherwise the adjustment functions may be impaired or the drives may overload. Do not use spring mattresses.

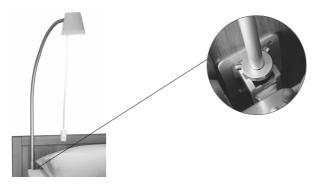
We recommend using mattresses that have a minimum density of 40 kg/m³ (RG 40). This is always guaranteed with wissner-bosserhoff standard mattresses. Please refer to the following list for suitable mattress dimensions for the corresponding bedding areas:

Model	Dimensions of the mattress	
Beds with standard bed-	Aero/Easyclean bedding area 12-18 cm x 87/90 cm x 200 cm	
ding area	Comfort bedding area 12-15 cm x 87/90 cm x 200 cm	

## 11.2 Lights / lighting

## 11.2.1 Reading lights

Like the lifting pole or IV holder, the soluna LED and lymera LED reading lights are inserted into the accessory holders at the head of the bed.



Item	Designation	Art. no.	Reference
1	Design light soluna LED without transformer	50-0550	AI 01-011120
2	Comfort reading light "lymera LED"	50-0677	UI 01-011671 AI 01-011120
3	External plug-in power supply unit for LED comfort reading light lymera	01-010790	AI 01-011120



The underbed lighting is plugged into the slot of the handset on the motor. The handset is then in turn plugged into the free slot on the floor lamp.



Item	Designation	Art. no.	Reference
1	Underbed lighting	01-007458	-

### 11.3 Mobilization

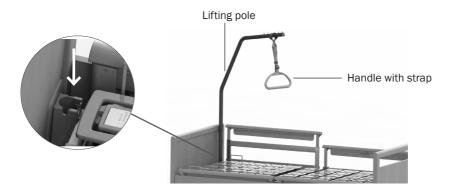
## 11.3.1 Lifting pole

The holder for the lifting pole is located on the head part of the bedding area frame.



#### Caution!

The handle and belt are made of high-quality plastic. However, all plastics have limited resistance to aging, which means that the handle or strap may break or crack after long use, This may possibly cause injuries. Replace the handle and belt after 4-5 years at the latest. The year of manufacture is stamped on the product.



If you want to attach a patient lifting pole:

- Place the patient lifting pole in its holder from above.
   It is held in its height position by a bolt.
- Rotate the patient erector so that the bolt is located in one of the notches of the holder.
   Longitudinal or transverse direction is possible.



#### Caution!

The handle and belt can break or tear under high loads, causing injury. Only use a patient lifting pole if it is loaded with a maximum of 75 kg.

• Hang the handle with the belt onto the patient lifting pole.

Deformed lifting poles must be replaced immediately and blocked for further use!



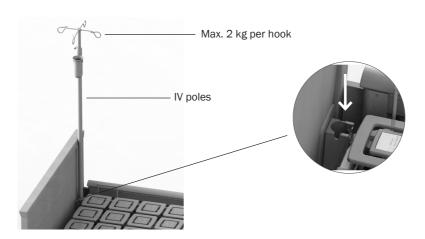
Item	Designation	Art. no.
1	Lifting pole with 4 retaining pins, white aluminum (RAL 9006)	04-0674-0000
2	Trapezoidal handle for lifting pole, light gray	01-009160
3	Oval trapezoidal handle II with retractable strap, light gray	10-0502

## **11.4 Supply**

## **11.4.1** IV pole

The IV pole is intended exclusively for hanging infusions. Infusion pumps may not be attached here.

The IV pole may be loaded with a maximum of 8 kg in total, whereby each hook may be loaded with max. 2 kg.



The holder for the IV pole is located on the head part of the bedding area frame. If you want to attach an IV pole:

- Place the IV pole in its holder from above.
- Turn the IV pole so that the pin of the adapter sleeve lies in one of the notches of the lifting pole holder.



Item	Designation	Art. no.	Reference
1	IV pole, straight	50-0694	AI 01-010949
2	IV pole, 45° angled	50-0693	AI 01-010949
3	IV clip for lifting pole, powder-coated	50-0003	-

## **11.4.2 Telescopic wall spacers**

The wall spacers are available as telescopic versions for both chassis variants (homely and extramobile).

### Head-end



#### Side-mounted



The wall spacers are placed on the undercarriage of the bed and screwed in place.

• To adjust the length, turn the knob and pull it upwards at the same time, extend the telescopic arm to the desired length and then lower the knob again and tighten it.

Item	Designation	Art. no.	Reference
1	Telescopic side-mounted wall spacer (8x20mm)	10-0936	follows
2	Telescopic WAH head left (8x20 mm)	10-0935	follows
3	Telescopic WAH head right (8x20 mm)	10-0934	follows



## 11.5.1 Extensions of the bedding area

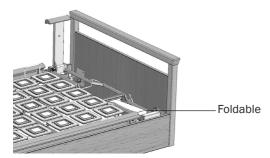
The sentida nursing home bed offers two methods of extending the bedding area. A permanent (fixed) extension of the bedding area by the manufacturer's factory or an optional temporary extension.



### Danger!

If the gap on the foot side created by the bedding area extension is not closed with a protector and an extension pad, there is a risk of jamming! This applies to both temporary and fixed bedding area extensions. Alternatively, a longer mattress can be used with the extension pad.

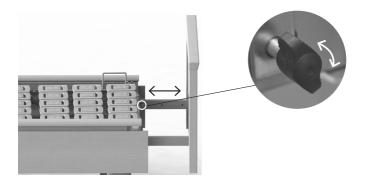
#### Permanent (fixed) extension of the bedding area



The sentida nursing home bed can be supplied with a 10 cm or 20 cm extended bedding area. This extension of the bedding area can also be carried out subsequently in the factory or also by authorized specialists. An appropriate protector must be used to close the resulting gap on the foot side. If you would like to have the bedding area of your sentida nursing home bed extended, contact your service partner. You will find the address at the end of these instructions.



If the bed is equipped accordingly, the bedding area of the bed can also be lengthened by 10 cm or 20 cm at the footrest and shortened again without tools. For this purpose, the footrest of the bed is extendable and lockable in two stages. The footrest can be unlocked by means of two wing screws located on the left and right locks of the footrest. Here, too, it is necessary to close off the resulting foot-side gap with a protector.



If you want to extend the bedding area of your sentida nursing home bed:

- Loosen and remove the wing screws on both sides.
  - The footrest is now unlocked.
- Now pull the footrest out to the desired position and fix it in place by inserting and tightening the wing screws. The holes must be congruent for this purpose.

To shorten the bedding area of the sentida nursing home bed again, proceed in reverse order.

### **Variants**

Item	Designation	Art. no.
1	For type 10 siderails, without padding, without protector	10-0595
2	For type 10 siderails, without padding, without protector	10-0595



#### Caution!

The siderails at the footrest must be left down when the bedding area is extended, as otherwise there is a risk of the resident becoming trapped in the resulting gap between the siderails and the footrest without the protector.

# **11.5.2** Extension elements and protectors



Item	Designation	Art. no.	Reference
1	Extension element to extend the lower legrest (20 cm)	follows	follows
2	Protector to close the gap at the foot end of beds in 220cm, RAL 9006 (firmly screwed bedding area pull-out)	follows	follows



## 11.6.1 SafeSense®

In the area of nursing and care, SafeSense® informs the nursing staff when the patient leaves the bed. For night-time orientation, it offers the resident automatic under-bed lighting. Other applications must be agreed in writing with wissner-bosserhoff GmbH in advance. For details on operation and installation, see UI 01-010136.



The operation and assembly of the SafeSense® is described in the provided instructions for use.

Item	Designation	Art. no.
1	Bed-exit system SafeSense® 1 (cabled)	10-0871
2	Bed-exit system SafeSense® 2 (radio-controlled)	10-0872
3	Call receiver (for connection to the nurse call system)	50-0681-000 (EU), 50-0772-0000 (Australia), 50-0772-0001 (Canada)
4	Adapter cable with or without ON / OFF switch for connection to nurse call system (always necessary), customer-specific configuration	04-1508 / 04-1608
5	With retaining plate for single drives	01-012401
6	Radio receiver RCL07	50-0681



## 11.6.2 SafeSense® 3

SafeSense® 3 is an assistance system for continuous resident monitoring in real time, using non-contact data collection and visualization via sensor pads and software. Differentiated call management let nursing staff prioritize calls more quickly and indicates whether the resident is in the bed. For details on operation and installation, see UI 01-012189.

#### **Standalone**



Article no. 50-0880 For use on multiple care beds

Item	Designation	Art. no.
1	SafeSense® 3 Standalone	50-0880
2	SafeSense® 3 Box including holder	10-0833
3	SafeSense® 3 Box holder	follows
4	Sensor pad, complete	10-0831
5	Signal line, cut to size	10-0834



An attachment is available as an accessory for the SafeFree® siderail to increase side protection by approx. 60 mm. For details on assembly, see Al 01-009185.



#### Caution!

An unsuitable attachment that is not designed for SafeFree® siderails can come loose, causing the patient or resident to fall. Make sure that the attachment is suitable for the SafeFree® siderail. Convince yourself of the safe fixation of the attachment on the SafeFree® siderail.



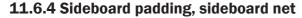
If you want to attach an attachment for the SafeFree® siderail:

- Pull the SafeFree® siderails all the way up.
- Place the attachment centrally on the handrail of the siderail. Pay attention to the geometry of the handrail so that the attachment is placed the right way around.
- Press the fastening clips onto the handrail until they grip over the handrail there and fix the attachment.

If you want to detach an attachment for the SafeFree® siderail:

- Position the SafeFree® siderails of one side at different heights.
- Press the release button of the SafeFree® siderail and slide the attachment sideways beyond the handrail.





Protective padding or nets are available for the SafeFree® siderails. They can provide additional protection to the resident by reducing or closing gaps or gaps.





- To fit the padding, slip it onto the siderail and close the press studs at the bottom of the padding.
- To attach the net, slip the net onto the siderail and pass the hook-and-loop fasteners around the siderail and fasten.

### **Variants**

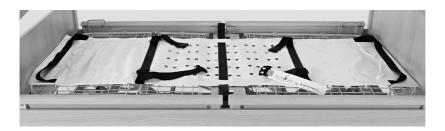
Item	Designation	Art. no.
1	Siderail net type 10	50-0207
2	Siderail type 10 with push buttons	50-0155
3	Siderail type 10 closed version	50-0174
4	Siderail type 11 closed version	50-0357
5	Siderail type 11 with push buttons	50-0354



The side section guard is attached to the fully retracted siderail from the inside and locked with a wrench. For details on assembly, see Al 01-010841.



# 11.6.6 Further protective elements



# **Variants**

Item	Designation	Art. no.
1	Falls prevention mat with anti-slip protection, gray	50-0771
2	Evacuation sheet with belt and fixation straps, white	50-0544



# **11.7.1 SafeControl handset (10-0790)**



#### Caution!

Since the handset holder is flexible, it must not be used as a stand-up aid or grab

### For SafeFree® divided siderails-:

The handset holder is used to position the handset within the resident's reach. It is attached to the handrail of the side rest, as shown in the adjacent figure.



### **Additional accessories**

Item	Designation	Art. no.	Reference
1	Bed transport trolley, type A (for assembled beds)	10-0511	AI 01-010910
2	Name tag holder	50-0108	-
3	Serving tray with bookholding rails	10-0586	-

# 12. Cleaning and disinfection

The nursing home bed must be cleaned and disinfected at regular intervals (e.g. according to the specifications of the present hygiene plan), in case of special need (acute contamination), but at least before each change of resident according to the present hygiene plan.



### Danger!

When liquids come into contact with electrical components, there is a greatly increased risk of electric shock or fire. Therefore, disconnect the bed from the mains before cleaning/disinfection.



#### Caution!

Damaged surfaces should be repaired/replaced immediately since they cannot be properly cleaned/disinfected and allow liquids to penetrate. There is therefore a risk of infection and damage to the bed.



#### Attention!

The nursing home bed must not be machine cleaned/disinfected in washing lines or with spray water. Only cleaning/disinfection by wiping is permissible.



#### Attention!

In case of uncertainty, first check the suitability of the cleaning/disinfecting agent for the respective surface on a non-visible area.



#### Attention!

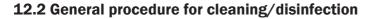
After cleaning/disinfection, make sure that proper neutralization has been performed and that no moisture or cleaning agent residues remain on the surfaces.

## 12.1 Cleaning

The furniture surfaces of wissner-bosserhoff products comply with the requirements of EN 12720 for furniture surfaces exposed to chemical stress and therefore have excellent resistance to common, normal stresses.

However, no cleaners or detergents may be used that contain corrosive or mechanically abrading (abrasive) components and act as scouring agents.

Only all-purpose cleaners that are weakly alkaline (soap suds) and contain surfactants or phosphates as cleaning-active components should be used. Dose the all-purpose cleaner according to the specifications of the cleaning agent manufacturer.



### **Preparation**

- Move the bed to its highest position and adjust the backrest slightly.
- Disconnect the bed from the power supply.
- Lock the brakes and pull up the siderails.
- Make sure that the product is free of coarse impurities and dirt particles that could damage the surface during cleaning/disinfection.
- Dose cleaning agents or disinfectants exactly according to the manufacturer's instructions.
- Use a soft cloth lightly moistened with all-purpose cleaner/disinfectant solution.

### Sequence of components for cleaning/disinfection

- Handrails of the head part and footrest
- Inside and outside of the head part and footrest (if upholstery is present, see chapter "Cleaning upholstery")
- Handrails and release buttons of the siderails
- Front and rear siderails and telescopic mechanism
- Handset including handset hook and holder, if applicable
- · All accessories attached to the bed
- Side panels inside and outside
- Top and bottom of the mattress
- Bedding area elements, top frame
- Undercarriage, brake bracket

#### Post-preparation

- Then wipe the product thoroughly with a soft, slightly damp cloth (water only) to neutralize it.
- Make sure that the product is free of cleaning and disinfectant residues.
- Dry the product with an absorbent, non-linting cloth.
- Make sure that no moisture/wetness has remained on the surfaces or penetrated into gaps.
- Reconnect the bed to the power supply.



A prerequisite for effective disinfection is previous cleaning of the bed.

Only suitable disinfectants may be used which correspond to the disinfectants described in Annex 1 of EN 12720 Part 1 or to the agents on the DGHM or RKI list. The application (e.g. concentration) of the disinfectants should be carried out exactly according to the instructions of the respective disinfectant manufacturer.

If there is any doubt about the suitability of a particular disinfectant, please contact us or the detergent manufacturer.

### 12.4 Special feature: genuine wooden components

We have used materials of the highest quality to create a product with high utility and a homely, genuine wood character. Slight differences in brightness, contrast and color between veneer surfaces, solid wood parts or decorative surfaces (melamine, HPL) as well as growth-related inclusions in the genuine wooden materials do not constitute a defect.

Lacquered genuine wooden components (studs of the head parts and footrests) must be cleaned/disinfected with special care since they are particularly sensitive to moisture. No moisture of any kind should be allowed to remain on these surfaces as otherwise damage to the paint and wood may occur.

## 12.5 Recommended cleaning/disinfection intervals

### **Daily cleaning**

We recommend that you clean all parts of the bed that are frequently touched by the resident or staff (e.g. siderails, bed ends, handsets, lifting pole, etc.).

### Cleaning at resident change

We recommend that you completely clean and disinfect all parts of the bed that are frequently touched by the resident or staff (see daily cleaning), bedding area, columns, undercarriage shelters and mattress.

#### Complete cleaning/cleaning before first use

We recommend that you clean the bed completely before it first use and then at least once every 4 to 8 weeks.

#### Removing spilled liquids

Spills should be cleaned up as soon as possible. Always disconnect the bed from the mains before cleaning up spills. Some liquids used in healthcare can cause permanent stains.





#### Attention!

Soiling on padding should always be removed immediately.



When cleaning with a brush or cloth, always treat the stain from the outside inwards so as not to enlarge it!

#### **Imitation leather**

- Remove coarse soiling (food or liquid residues) with a cloth.
- Remove stains with lukewarm water and a damp cloth (cotton or microfiber).
- For heavier soiling, use a warm, mild soapy water solution and a soft hand brush.
- Then wipe off the remains of the cleaning agent with a damp cloth and lukewarm water and dry the padding carefully.



#### Attention!

Do not use any cleaning agents containing oil and grease. Furthermore, dry cleaning and the use of solvents, chlorides, polishing agents, washing polishes and aerosol sprays are not suitable.



If necessary, the imitation leather padding can be disinfected. You can view a list of agents approved for purchase here:

http://www.wi-bo.com/de/Kontakt/BDA

#### **Fabrics**

- Remove coarse soiling (food or liquid residues) with a cloth.
- Apply warm water and some dishwashing liquid to the stain and leave it for a short time.
- Gently rub the fabric with a soft brush or cloth and repeat this process 2-3 times as needed.
- Wipe with warm water and dry with a cotton cloth.
- Allow velour fabrics to dry first and then brush them on in the direction of the line.

# 13. Maintenance and servicing

According to

- Medical Devices Operator Ordinance (MPBetreibV) / § 7 Maintenance of medical devices
- German Social Accident Insurance (DGUV) Regulation 3 / Safety testing of portable electrical devices and equipment in commercial use

bed operators are obligated to maintain the safe condition of medical devices throughout their entire period of use. This also includes regular, professional maintenance and safety checks.

The nursing home beds of wissner-bosserhoff GmbH are designed for a service life of up to 15 years. Here, the beds are extremely low-maintenance. This is because attention was already paid to ensuring the lowest possible maintenance requirements with low operating costs during the development of the products.

In daily operation, however, experience has shown that careless handling of products and rough operation also lead to faster aging and wear of certain components, without the manufacturer having any direct influence on this.

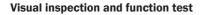
The manufacturer is only liable for the safety and reliability of the product if it is regularly maintained and used in accordance with the operating, usage and safety instructions in these instructions for use.

If a visual or functional check, inspection, measurement or maintenance reveals serious defects that cannot be rectified, the product must be blocked for further use! In addition to the regular, comprehensive checks performed by qualified technical personnel, the user (nursing staff, family caregivers, etc.) must also perform brief visual and functional checks at shorter, regular intervals. This applies in particular before each new occupancy.

RECOMMENDATION: The safety inspection (STÜ and DGUV Regulation 3) should take place at 12-month intervals together with the mechanical maintenance, with proven compliance with the 2% error rate (see DGUV Regulation 3: § 5, table 1B). If a defect rate of less than 2% is achieved, the rhythm can be extended to a maximum of 2 years (taking into account the manufacturer's specifications) under the customer's own responsibility.

The following sequence of inspections is to be observed according to IEC 62353-VDE 0751-1:

- 1. Visual inspection
- 2. Electrical measurement
- 3. Function test



 According to MPBetreibV § 7 (German Medical Device Operating Company Ordinance) and IEC 62353-VDE 0751-1, these tests may only be carried out by competent persons who have the necessary training and resources and are not bound by instructions.

#### **Electrical measurement**

- Electrical measurements in accordance with IEC 62353-VDE 0751-1 may also be carried out by instructed persons (e.g. in-house technicians) as defined by DGUV Regulation 3 with additional medical and bed-specific knowledge if suitable measuring equipment is available.
- However, only a qualified electrician with additional medical and bed-specific knowledge may evaluate and document the test results.

### DGUV Regulation 3 / IEC 62353-VDE 0751-1- short checklist

#### Visual inspection

- Mechanisms: (undercarriage, siderails, wooden edging, bedding area frame, lifting pole holder)
- Electrical system: Mains and handset cable, handset
- Leakage current test (difference Δ I without load) Inspection report, defect report, inventory list,

#### Function test:

- Mechanisms: Rollers, siderails, legrest, motor bolts, screws
- Electrical system: Handset

#### Documentation:

Inspection report, defect report, inventory list, instructions for use

## 13.1 Spare parts



#### Danger!

When using non-compatible electrical components, there is a greatly increased risk of electric shock or fire. Replace electrical components only with original spare parts.

Only original spare parts from wissner-bosserhoff GmbH may be used. Customer Service, Sales or Technical Consulting Center will provide information regarding spare parts supplies. Have the type plate data, order number and delivery note ready.

Our qualified, technical customer service is at your disposal:

Phone +49 2377 784-456 Fax +49 2377 784-150



Fault	Possible cause	Remedy
Electromotive adjustments are not performed properly	Mechanism system is blocked	Check moving parts and remove foreign objects
Electromotive adjustments are not performed	Handset is defective or not plugged in correctly	- Pull out the mains plug, wait 3 minutes and plug in again - Perform a handset reset - Contact WiBo Customer Service
	The plug is not connected to the power supply or the battery (if present) is empty	Connect the mains plug to the mains supply
	The system has been over- loaded and the thermal fuse has switched off; the fuse has tripped	Wait for the cooling phase (up to 18 minutes). If the system still does not work after this, contact our customer service.
Error tone during height adjust- ment. Height, comfort seat and automatic prevention can no longer be adjusted	Faulty switching on the motor	Contact Technical Customer Service
The SafeFree® siderails can no longer be set properly	The mechanism is blocked	Check moving parts and remove foreign objects
	The mechanism is bent	Contact our Customer Service
The castors do not brake or cannot be rolled	Foreign bodies have twisted into the rollers over time	Remove foreign objects
	The castor system is defective	Contact our Customer Service
The handset does not work	Handset blocked, not plugged in correctly, or defective	- Pull out the mains plug, wait 3 minutes and plug in again - Perform a handset reset - Unlock the handset, check the plug connection; otherwise contact Wibo Customer Service



## 13.3 Storage

When stored, the sentida nursing home bed may be exposed to environmental conditions that are within the following limits:

Ambient temperature	+10 °C - +40 °C
Relative humidity	30% - 75%
Air pressure	800 hPa - 1060 hPa



#### Attention!

If the nursing home bed sentida was stored or transported at low temperatures, it needs a certain time and temperature to acclimatize. If the adjustment time is too short or the temperature is unsuitable, the sentida nursing home bed may be damaged and fail. Acclimatize the nursing home bed sentida for at least 12 hours after severe temperature fluctuations.

For storage, you need to prepare the nursing home bed as follows:

Disconnect the power plug.

- Remove all accessories, such as trapeze bar, serving tray, etc.
- Remove the battery.
- Cover the nursing home bed so that it is protected from damage.
- Note in writing the date of storage; this will help you meet maintenance deadlines.



This device falls within the scope of EC Directive 2002/96/EC (WEEE). It is not registered for use in private households; disposal via the municipal collection points for waste electrical equipment is not permitted. wissner-bosserhoff GmbH is responsible for the legally compliant disposal of this device. For further information, please contact your responsible sales partner or, within Germany, contact us directly.

If the device is passed on to a commercial third party, you are contractually obligated to inform the third party that the device must be disposed of properly after it is no longer used. If you fail to do so, you will be responsible for the proper disposal of the device after the third party ceases to use it.

The nursing home bed contains lead-gel batteries, electrical parts and metal parts; it may also contain plastic parts made of ABS, PA, PU, PE.

The metal and plastic parts resulting from maintenance and repair must be disposed of properly and correctly in accordance with the laws and regulations. The electric motors and the electric control system in particular may only be disposed of by specialist companies and disposal centers approved for this purpose.

# 15. Warranty

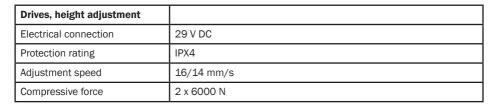
The statutory warranty regulations of 24 months apply.

This warranty covers all faults and errors caused by material and manufacture. Malfunctions and faults caused by improper handling and external influences are excluded. Should there be cause for justified complaints within the warranty period, they will be rectified free of charge. With the proof of purchase, which bears the date of purchase, this warranty can be claimed. Our terms and conditions of business and delivery apply.



Outer dimensions	208 × 106 cm	
Nominal dimensions of bedding area	87 × 200 cm	
Height adjustment	23 - 80 cm (depending on the type of roller)	
Backrest adjustment	70°±5°, including electrical sliding backrest retraction RLR by about 11.5 cm	
Thighrest adjustment	30°-5°, including electrical sliding thighrest retraction by about 4.8 cm	
Tilting	Head approx. 17° / Foot approx. 17°	
Safe working load*	250 kg (215 kg resident weight, 35 kg mattress + accessories)	
Bed weight	Approx. 115 kg depending on the model	
Protection rating	IPX4	
Protection class	II	
Lifter underride capability	15 cm	
Duty cycle	INT 2 min./18 min. The device is not designed for continuous operation. After 2 minutes of full load operation, an 18-minute break is recommended.	
Maximum noise level	Approx. 65 dB/A	
Application environment	3 and 5	
Humidity	30% - 75%	
Atmospheric pressure	800 hPa - 1060 hPa	
Ambient temperature	+10°C - +40°C	
Manufacturer	wissner-bosserhoff GmbH Hauptstraße 4 – 6 58739 Wickede (Ruhr) GERMANY Phone +49 2377 784-0	

<sup>\*</sup> Manufacturer's recommendation: The maximum resident weight can be increased depending on the weight of the mattress and accessories used. E.g.: Safe working load 250 kg – mattress 10 kg – accessories 10 kg = max. resident weight 230 kg. When using heavier mattresses/accessories, the resident weight changes accordingly!



Drives, bedding area	
Electrical connection	29 V
Protection rating	IPX4
Adjustment speed	12 mm/s 9 mm/s backrest, 9 mm/s 6 mm/s thighrest
Compressive force	3000 N backrest, 4000 N thighrest, without emergency lowering

SafeControl data	
Electrical connection	24 V DC
Supply	14 - 38 V DC
Standby current	9 mA
Application environment	3 and 5
Humidity	30%-75%
Ambient temperature	10°C - 40°C
Protection rating	IPX7



According to Annex VIII, #13 of the Medical Device Directive (MDD) 2017/745, the sentida nursing home bed is a Class I medical device.

Naming	Comment	
MDD 2017/745	EU regulation for medical devices	
Medical Device Law Implementation Act	MPDG (national implementation)	
DIN EN ISO 14971	Application of risk management to medical devices	
DIN EN 60601-1 (pertinent sections)	Medical electrical equipment	
DIN EN 60601-2-52 (pertinent sections)	Medical beds	
BfArM recommendations	Recommendations of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)	
DIN 33402-2	Körpermaße des Menschen (Human Body Measurements)	
DIN 68861-12011-01 DIN EN 12720	Furniture. Assessment of surface resistance to cold liquids	
DIN EN 60529 VDE 0470-1	Schutzarten durch Gehäuse (Hous- ing-Based Protection Rating) IP code (protection against moisture)	
DIN EN 12530 (pertinent sections)	Castors and wheels. Castors and wheels for manually propelled institutional applications	
EN 50419 Directive 2002/96/EC (WEEE)	Labeling of electrical and electronic equipment	

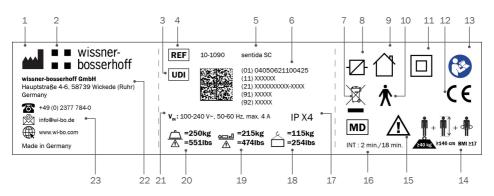


# **18. Product labeling**

# **18.1 Symbols used**

	General warning!	Black exclamation mark in a yellow triangle
GE .	Follow the operating instructions!	White person on a blue background
<b>†</b>	Type B application part	
	This device falls within the scope of EC Directive 2002/96/EC (WEEE). It was placed on the market after 8-13-2005.	
+ + + + + + + + + + + + + + + + + + +	Adult identification (minimum weight, minimum height, minimum BMI)	
	QR code to open operating videos	
UDI	UDI (Unique Device Identification) symbol	
MD	MD (Medical Device) symbol	

# 18.2 Bed type plate



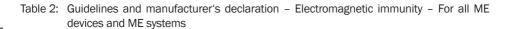
1	Manufacturer symbol
2	Company logo
3	UDI symbol
4	Item number
5	Model name
6	Data matrix code, including plain text: GTIN, date of manufacture, serial number, internal data
7	Attention; electrical scrap – observe legal disposal of old equipment
8	Switching power supply unit
9	For indoor use only
10	Type B application part (classification according to the degree of protection against electric shock).
11	Device of protection class II (classification according to the type protection against electric shock)
12	CE marking
13	Commandment sign "Follow instructions for use"
14	Adult identification (minimum weight, minimum height, minimum BMI)
15	General warning sign
16	Duty cycle (2 minutes of operation, 18-minute break)
17	Code letters for protection classes according to DIN EN IEC 60529 (VDE 0470-1):
18	Total weight of bed
19	Max. occupant weight
20	Safe working load
21	Input voltage/frequency/apparent power
22	Company name, company address/contact
23	Contact data of manufacturer



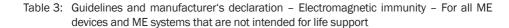
Table 1: Guidelines and manufacturer's declaration – Electromagnetic emissions – For all ME devices and ME systems

The sentida nursing home bed is intended for operation in an ELECTROMAGNETIC ENVIRONMENT as specified below. The customer or user of the sentida nursing home bed should ensure that it is operated in such an environment.

in such an environment.				
Interference emission measurements	Compliance	Electromagnetic environment - Guideline		
High-frequency emissions according to CISPR 11	Group 1	The sentida nursing home bed uses high-frequency energy exclusively for its internal function. Therefore, its high-frequency emissions are very low and unlikely to interfere with neighboring electronic devices.		
High-frequency emissions according to CISPR 11	Class [B]	The sentida nursing home bed is suitable for use in all facilities,		
Harmonic emissions IEC 61000-3-2	[compliant]	including those in residential areas and those directly connected to the PUBLIC SUPPLY		
Emission of voltage fluctuations/flicker IEC 61000-3-3	[compliant]	NETWORK, which also supplies buildings used for residential purposes.		



The sentida nursing home bed is intended for operation in an ELECTROMAGNETIC ENVIRONMENT as specified below.							
INTERFERENCE IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDELINES				
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact discharge ± 15 kV air dis- charge	± 8 kV contact discharge ± 15 kV air dis- charge	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.				
Fast transient electrical distur- bances/bursts (IEC 61000-4-4)	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should be that of a typical business or hospital environment.				
Surges (IEC 61000-4-5)	± 1 kV outer conductor-outer conductor voltage ± 2 kV outer conductor-ground voltage	± 1 kV outer conductor-outer conductor voltage ± 2 kV outer conductor-ground voltage	The quality of the supply voltage should be that of a typical business or hospital environment.				
Voltage dips, short- term interruptions and fluctuations in the supply voltage (IEC 61000-4-11)	< 5% U <sub>T</sub> (>95% dip of $U_T$ ) for $\frac{1}{2}$ period 40% U <sub>T</sub> (60% dip of $U_T$ ) for 5 periods 70% U <sub>T</sub> (30% dip of $U_T$ ) for 25 periods < 5% U <sub>T</sub> (>95% dip of $U_T$ ) for 5 sec.	< 5 % $U_{\tau}$ (>95% dip of $U_{\tau}$ ) for $\frac{1}{2}$ period 40% $U_{\tau}$ (60% dip of $U_{\tau}$ ) for 5 periods 70% $U_{\tau}$ (30% dip of $U_{\tau}$ ) for 25 periods < 5% $U_{\tau}$ (>95% dip of $U_{\tau}$ ) for 5 sec.	The quality of the supply voltage should be that of a typical business or hospital environment.  If the user of the sentida nursing home bed requires continuous operation even in case of power supply interruptions, it is recommended that the sentida nursing home bed is powered by an uninterruptible power supply or battery.				
Magnetic field at the supply fre- quency (50/60 Hz) (IEC 61000-4-8)	30 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to typical values found in business and hospital environments.				
NOTE: $U_{\tau}$ is the mains AC voltage before applying the test levels							



The sentida nursing home bed is intended for operation in an ELECTROMAGNETIC ENVIRONMENT as specified below. The customer or user of the sentida nursing home bed should ensure that it is operated in such an environment.

III Such an envilor	in such an environment.						
INTERFERENCE IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDELINES				
Conducted high-frequency disturbances (IEC 61000-4-6)	3 Vrms 150kHz to 80MHz 6 Vrms 150kHz to 80MHz	3 Vrms 6 Vrms	Portable and mobile radios should not be used at a short distance from the sentida nursing home bed, including the lines, less than the recommended safety distance calculated according to the equation applicable to the transmission frequency.				
			Recommended safety distance				
Radiated high- frequency distur- bances (IEC 61000-4-3)	3 V/m 80 MHz to 2.7 GHz 10 V/m 80 MHz to 2.7 GHz		d=0,35*√P				
			d=0,35*√P 80 MHz bis 800 MHz				
			d=0,35*√P 800 MHz bis 2,7 GHz				
		3 V/m 10 V/m	Where <i>P</i> is the rated power of the transmitter in watt (W) as specified by the transmitter manufacturer and <i>d</i> is the recommended safety distance in meters (m).				
			The field strength of stationary radio transmitters should be less than the compliance level <sup>b</sup> at all frequencies according to a study conducted on site <sup>a</sup> .				
			Interference is possible in the vicinity of devices bearing the following symbol.				
			(((•)))				
NOTE 1:	NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.						
NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorption and reflections of the buildings, objects and people.							

- The field strength of stationary transmitters, such as base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot theoretically be accurately predicted. To determine the electromagnetic environment with respect to stationary transmitters, a study of the electromagnetic phenomena of the site should be considered. If the measured field strength at the location where the sentida nursing home bed is used exceeds the above compliance levels, the sentida nursing home bed should be observed to prove that it is functioning as intended. If unusual performance characteristics are observed, additional measures may be required, such as changing the orientation or location of the sentida nursing home bed.
- Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Table 4: Recommended safety distances between portable and mobile high-frequency telecommunication devices and the ME device or ME system - for ME devices or ME systems that do not provide life support

Recommended safety distances between portable and mobile high-frequency telecommunication devices and the sentida nursing home bed

The sentida nursing home bed is intended for operation in an ELECTROMAGNETIC ENVIRONMENT in which high-frequency disturbances are monitored. The customer or the user of the sentida nursing home bed can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile high-frequency telecommunication devices (transmitters) and the sentida nursing home bed - depending on the output power of the communication device, as indicated below.

	Safety distance, depending on the transmission frequency [m]				
Rate power of the transmitter [W]	150 kHz to 80 MHz d=0,35*√P	80 MHz to 800 MHz d=0,35*√P	800 MHz to 2.7 GHz d=0,35*√P		
0.01	0.12	0.12	0.23		
0.1	0.37	0.37	0.74		
1	1.17	1.17	2.33		
10	3.69	3.69	7.38		
100	11.67	11.67	23.33		

For transmitters whose maximum power rating is not specified in the table above, the recommended safety distance d in meters (m) can be determined using the equation associated with the respective column, where P is the maximum power rating of the transmitter in watt (W) as specified by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not be applicable in all cases. The propagation of elec-

tromagnetic quantities is influenced by absorption and reflections of the build-

ings, objects and people.



- 1) The specifications on the type plate must be observed.
- 2) The bed may not be operated if it has defects that could endanger persons.
- Before using the bed, the user must verify the functional safety and proper condition of the bed.
- 4) If pertinent, the bed may need to be functionally tested daily or at each shift change to ensure that the bed can be used as intended without risk to the patient and user.
- 5) Adjustments of the siderails must be carried out by the personnel. When adjusting the bedding area positions, the nursing staff must ensure that the resident does not come into contact with the siderails to prevent crushing of the hand, leg or other body parts.
- 6) Extreme lateral leaning of the upper body should be avoided.
- 7) Do not load the siderails more than 75 kg in the vertical direction and 50 kg in the horizontal direction.
- 8) Depending on the patient's physical and mental condition, the functions must be locked or unlocked at the handset. The effectiveness of the locking functions must be checked on the handset.
- 9) Since the system can be powered by battery, it is not sufficient to disconnect the power plug in case of malfunction of the motors. If a malfunction occurs, please contact customer service.
- 10) Lay the power supply cable and the supply cable to the handset in such a way that they cannot be crushed and do not place any objects on the connection and supply cables.
- 11) Care should be taken not to leave the handset in the care mode. Otherwise, risky positions can be reached for the resident, such as a misapplied Trendelenburg position.



### 12) Improper use of the bed may result in hazards due to:

- Unauthorized operation of the electrical functions during uncontrolled positioning of the bed.
- Operation of the functions of the bed by the patient without prior instruction,
- Simultaneous operation of the electrical functions by several persons.
- Connection of non-provided electrical devices to the bed.
- Movement of the bed by pulling the power cord or the side panels,
- Pull the power cord to disconnect the power plug from the power supply,
- Lack of protection of the connection and supply cables against sharp edges or other mechanical stress (e.g. running over the power cable),
- Movement of the bed on uneven ground,
- Use of the bed on sloping ground with an angle of inclination of 10° and more,
- Devices that generate strong electromagnetic fields and may influence the control of the bed are not allowed in the immediate vicinity of the bed (e.g. cell phones),
- Before cleaning or servicing the bed, always disconnect the power plug from the power supply,
- Constantly dripping liquid in the motor area (e.g., in case of incontinence)
- Improper repair work on the electrical equipment

#### 13) Safety instructions – Measures for safe operation of hospital and nursing home beds:

- Electrical components on hospital and nursing home beds may only be repaired and maintained by the manufacturer or by specialist personnel who have been specially trained by the manufacturer. Otherwise, there is a risk that special procedures will not be carried out properly due to ignorance of the product functionalities, resulting in an increased risk of electric shock or fire.
- A safe place for handsets on the bed must be specified so that playing with handsets can be prevented.
- Permanent positioning of immobile patients/residents without further positioning aids (e.g. pressure injury mattresses) and without special nursing measures for pressure injury prevention can lead to pressure ulcers. In no case is the manufacturer of the bed responsible for this.
- The product is expressly not suitable for continuous operation. If the specified duty cycle is exceeded, the actuator may heat up and be switched off automatically. The drive must then first cool down for at least two hours and can only be put back into operation after this time has elapsed.
- Blocking of the bed or parts of the bed mechanism must be avoided at all costs, as this
  may result in damage and total failure of the drive due to overheating.
- It is essential to avoid exceeding the safe working load, as this may result in damage and total failure of the drive.



#### INTENDED USE AND PURPOSE OF NURSING HOME BEDS

A nursing home bed may only be commissioned, operated and used in accordance with its intended purpose, the regulations of the German Medical Devices Act (MPG), the associated ordinances, the generally recognized rules of technology and the occupational safety and accident prevention regulations. A nursing home bed must not be operated in a faulty condition in which the bed could endanger patients, nursing staff or third parties.

The specifications of the respective product instructions for use apply.

### The following points must be observed:

- In general, the professional judgment of the responsible caregiver (medical supervisor) is necessary to ensure safe use of the nursing home beds. The physical, psychological, and medical needs and conditions of the patient must be considered. Accordingly, the bed functions must be enabled or disabled individually for each resident. This applies in particular to products with special swivel options for the bedding area and when using siderails.
- The nursing home beds are not explosion-proof and must not be used in application rooms where flammable anesthetics, flammable cleaning agents or solvents or possibly flammable substance-air mixtures are encountered. The regulations of the employers' liability insurance associations must be observed in this regard.
- Any use that deviates from this intended purpose constitutes improper use and is excluded from any liability claims.

# 22. Basic functions and benefits of nursing home beds

Modern nursing home beds have numerous positioning functions, which are described in detail in the respective product instructions for use. The full benefit of a nursing home bed can only be achieved through careful training of users and residents of a care facility. Please repeat these training sessions as regularly as possible, paying particular attention to the necessary safety rules that must be observed.

- In general, there is also always a risk of unintentional or incorrect adjustment of the bed. Thus, accidental switch actuations or unintended function releases can endanger certain patients/residents! In order to ensure a high level of protection for patients/residents, it is essential to use locking devices and/or release buttons in a targeted manner.

- The use of the locking devices and, if necessary, the deliberate disconnection of the bed from the mains as an absolute locking measure for maximum protection of a possibly endangered patient/resident is exclusively at the discretion and under the responsibility of the responsible medical supervisor and nursing staff. Appropriate actions should be noted in the shift report to ensure proper shift handover.
- The use of the special positioning options, e.g. stepwise bed positioning or relative headdown position as a shock position, is expressly permitted only by medical supervisory personnel. For residents, these functions must be blocked, otherwise hazards may occur.

The safety instructions in the special product operating instructions must be observed, otherwise hazards will arise.

- Only use siderails on the beds that are also approved for the respective bed type; otherwise there is an increased risk of accidents.
- Before each use, the siderails must be checked for any damage, for secure attachment to the bed and for proper functioning of the safety interlock! Information on the correct handling of the siderail can be found in the respective product operating instructions.
- The use of the handset by the resident himself is solely at the discretion and responsibility of the responsible medical supervisor and nursing staff. Appropriate actions should be noted in the shift report or nursing documentation to ensure proper shift handover and tracking of usage rights.
- If the handset is not to be used by the resident himself, it must be securely hooked onto the footrest of the bed, for example, to prevent the resident from accessing it and getting trapped.
- Handsets may not fall to the floor, be overloaded by weight or be flooded with liquids. Cleaning should be performed using cleaning cloths for PC keyboards. In the event of mechanical or moisture damage, the remote controls must be replaced immediately. The supply lines must also be checked regularly for damage at shorter intervals.





# EU-Konformitätserklärung | EU Declaration of Conformity Déclaration CE de Confomité | Dichiarazione CE di Conformità



Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante: Wissner-Bosserhoff GmbH Hauptstraße 4-6 58739 Wickede (Ruhr) Deutschland SRN: DE-MF-00006538

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

die Pflegebetten der Modellreihen: / the nursing home beds of the model series: les lits de soins de la série modèle : i letti di cura della serie di modelli:

mit der Zweckbestimmung: / with the intended use: / avec la utilisation conforme: / con la destinazione d'uso: sentida, movita, carisma



Basis UDI-DI: 4050621CAREBEDSYSTEMHH

Medizinisches Pflegebett zum Ruhen und Schlafen / Medical nursing bed for rest and sleep / Lit de sions médicalisé pour se reposer et dormir / Letto di lungodegenti medica per riposare e dormire

inklusive der dem Bett zugehörigen Zubehöre / including the accessories associated with the bed / y compris les accessoires appartenant au lit / compresi gli accessori del letto

der Klasse: / of class: / de la classe: / di classe:



Klasse | / class | / classe |

nach Klasse I, Verordnung 2017/745 Anhang VIII, #13 / according to class I, regulation 2017/745 annex VIII, #13 selon Classe I, Règlement 2017/745 Annexe VIII, #13 / secondo Classe I, Regolamento 2017/745 Allegato VIII, #13

den einschlägigen Bestimmungen der Medizinprodukteverordnung (MDR) 2017/745 und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen "Endprüfprotokoll"./

meets the provisions of the medical device directive (MDR) 2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur la directive sur les dispositifs médicaux (MDR) 2017/745 et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva sui dispositivi medici (MDR) 2017/745 e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d'évaluation de la conformité: / Procedura di valutazione della conformità: Klasse I, MDR 2017/745 gemäß Artikel 19 und Anhang IV Class I, MDR 2017/745 according to Article 19 and Annex IV Classe I, MDR 2017/745 visés à l'article 19 et à l'annexe IV Classe I, MDR 2017/745 di cui all'articolo 19 e all'allegato IV

Weitere mitgeltende Richtlinien: / Other applicable directives: / Autres directives applicables: / Altre directive applicabili: RoHS II, 2011 / 65 / EU

Wickede (Ruhr) 08.06.2021

Ort, Datum / Place, date / Lieu, date / Luogo, data Thomas Erbslöh, CEO

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