1. Table of contents

2. Introduction

2.1 About these instructions for use

In this section, you will find information about the structure of these instructions for use and a description of the signs and symbols used.
This document contains instructions for the use of the SafeSense® Bed-Exit System.
These instructions for use may contain inaccuracies and typographical errors. The information provided in these instructions for use are updated at regular intervals, and changes resulting from product maintenance are implemented in future editions. Changes or improvements are possible at any time without previous notice. Contact our customer service in case you have any questions.
The instructions for use must be read and observed by every person operating the Bed-Exit System.
Apart from the instructions for use and the accident prevention regulations valid for the respective country and area of use, the commonly accepted regulations for safe and professional work must also be adhered to.

2.2 Symbols used in the text

In these instructions for use, the following terms and symbols are used for important notes:

Caution!
This symbol precedes warnings when there is the danger of damage to the equipment or other things.

This symbol precedes additional helpful advice.

- A hyphen preceding the text means: This is part of an itemization.

2.3 Intended use

SafeSense® Bed-Exit System is a Class I medical device. It is exclusively for medical use and only in conjunction with wissner-bosserhoff nursing home beds made since 2002.

This system is a medical product in the sense of the regulations and standards specified in the later chapter “Product safety/excerpt of applied standards.” Accordingly, this product may only be used under medical supervision. The decisive factor in whether nursing is medically supervised or not depends on whether nursing takes place under the instructions of medical personnel or not. Children under the age of twelve must not use the Bed-Exit System.

In the nursing sector, it serves the purpose of informing nursing staff when the resident leaves the bed and of assisting the resident in moving about at night, by means of an automatic underbed light. Any other application must be agreed beforehand in writing with wissner-bosserhoff GmbH.

SafeSense® informs nursing staff as soon as the resident leaves the bed or does not return to the bed when expected. Please note that this entails an intrusion into the resident’s right to privacy.
The use of this system can be approved in either of two ways:
- with the resident’s consent;
- with the consent of the resident’s legal representative (caregiver, precautionary agent, parents).

The SafeSense® Bed-Exit System may only be used by persons who can guarantee correct operation on the basis of their training or knowledge and practical experience. The users of the system must have received instructions for correct use and must have familiarized themselves with the equipment with the help of these instructions. The product may only be used in complete accordance with the instructions for use.

We assume no liability for potential product damage or personal injuries caused by unapproved accessories or mutual cancellation of the intended use.
The specified use is the intended use. Its sole source for the operator or user is the labeling and the instructions for use.

Please note that SafeSense is not designed to be used as an emergency call or a lifesaving call for help. It is rather a product that helps to facilitate the daily work in a nursing home.

2.4 General safety notes

The SafeSense® Bed-Exit System was designed in accordance with state-of-the-art technology and approved safety regulations.

Use SafeSense® only when it is in perfect working order. Only use it in for its intended purpose, safely, risk-consciously and in accordance with these instructions for use. Malfunctions that may affect safety must be eliminated immediately in particular!

Always keep these instructions for use ready to hand at the location where the Bed-Exit System is used. In addition to the instructions for use, please observe the generally applicable standards and commonly ac-cepted regulations on accident prevention and environmental protection!

Do not carry out any changes, extensions or conversions without the manufacturer's approval. Spare parts have to comply with the manufacturer's requirements. For original spare parts, this is always guaranteed.

Make sure that operating and auxiliary materials and replacement parts are recycled safely and in an environment-friendly manner.

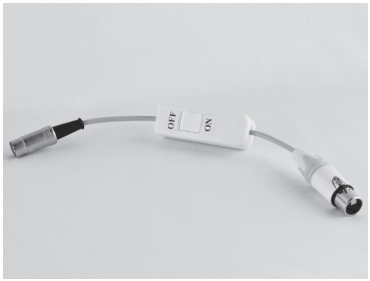
3. Components

The SafeSense® Bed-Exit System is available in a cable version or a wireless version and consists of the following components:

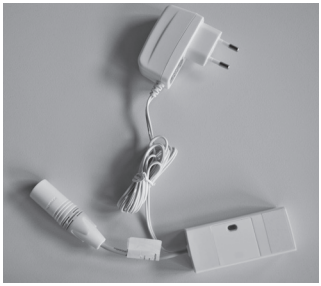
Bed-Exit Box

Sensor mat, 50 x 50 cm for backrest

Sensor mat, 80 x 20 cm for seat section



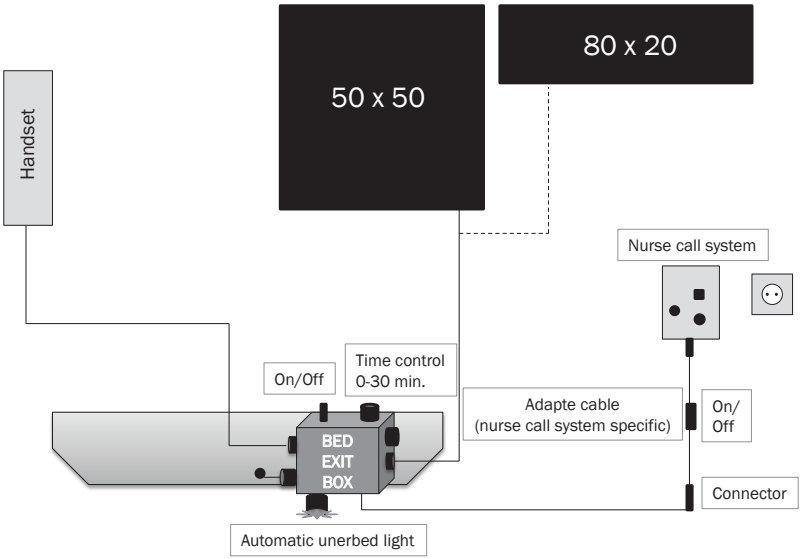
Customer-specific adapter cable with connec-tion to the nurse call system (with optional on/off switch)



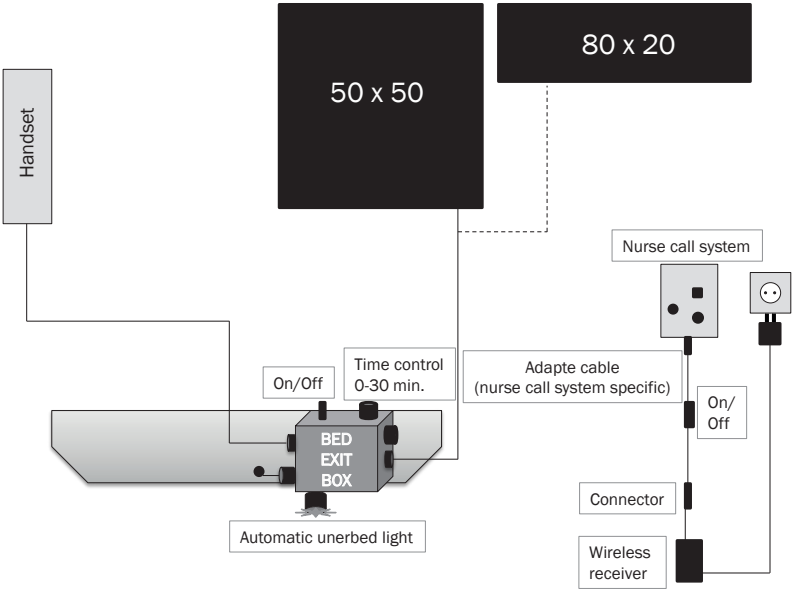
Wireless receiver (wireless version only)

4. System structure

4.1 Cable version



4.2 Wireless version



5. General usage information

When using SafeSense®, please be aware that there are various circumstances that could lead to malfunctions or complete loss of function in the system. The following points should therefore be observed before start-up and during use:

- Check that all plugs are connected correctly to ensure that all signals can be transmitted.

- Make sure the system is switched on

- Ensure that all cables are undamaged

- The sensor mat must be positioned correctly and secured with the appropriate equipment to pre-vent it from slipping (see “Securing the sensor mats”)

- It must always be ensured that the resident is positioned correctly in the bed (e.g. not facing back-wards)

- Please observe the relevant minimum weights associated with the various mattress types (see “Sensor mats and mattresses”)

- If incontinent patients occupy the bed, incontinence protection must be used on the mattress.

- Please note that the sensor mats are not to be used in combination with alternating pressure mattresses. Otherwise, the system will not be able to transmit reliable signals.

- Consider that the sensor mats are also subject to wear and tear consistent with their use, and must be replaced after five years or when they begin to show signs of wear and tear

- Keep the sender and receiver together if possible. If this is not possible, delete the receiver’s programming (the exact steps can be found in its usage instructions) and reconfigure it

To identify possible errors, please also note the error-cause matrix given later in the instructions for use (see chapter “Troubleshooting”). This lists faults that may occur along with their possible causes.

6. Start-up

6.1 Delivery

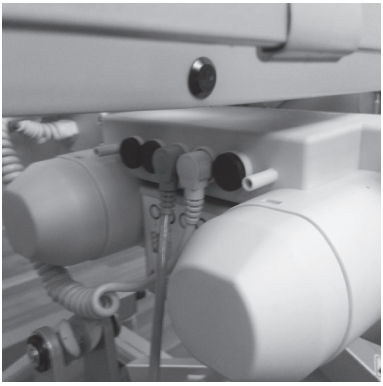
The SafeSense® Bed-Exit System is generally delivered as individual components, or is assembled by specialists on site.

- Please check whether all components have been delivered by consulting the delivery papers.
- Write down potential defects or damage on the delivery note.
- Inform your service partner immediately about potential transport damage or defects. The address and phone number are noted on the last page of this manual.

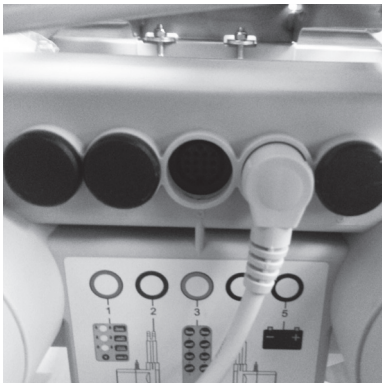
6.2 Installing on a bed with no battery

The SafeSense® system is quick and easy to install. To do so, please follow the steps below:

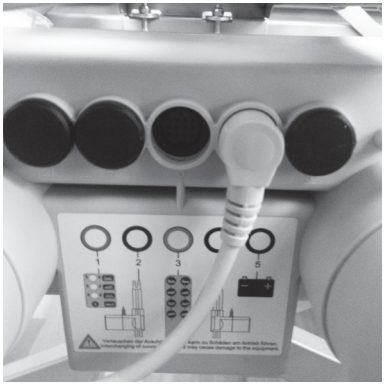
1. Use a screwdriver to remove the drive cap. There is one screw on the left side and one on the right side.



2. Remove the handset from the third socket from the right.

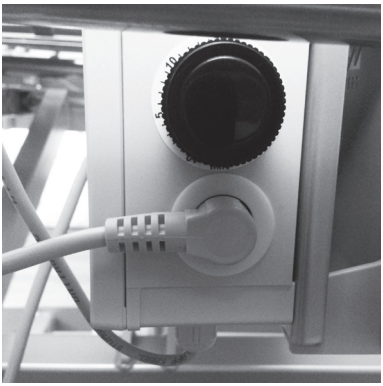


3. Now connect the bed's handset to the Bed-Exit box. To do this, plug the handset plug into the empty socket on the left side of the box. Fasten the strain relief.



4. Connect the Bed-Exit box to the bed drive. To do this, plug the connector plug (on the left of the box) into the now empty slot on the drive (see point 2).

5. Clip the Bed-Exit Box into the holder. For this, the under-bed light must be pointing downward and the alarm interval adjustment wheel must be on the right. The box will sit securely once it has audibly slotted into place. For a bed with a battery, the box is screwed to the battery and slotted together with it.



6. Connect the sensor mat to the Bed-Exit box. For this purpose, the mat plug must be plugged into the free socket underneath the alarm interval adjustment wheel. Then connect the mat under the seat section or to the backrest of the bed.

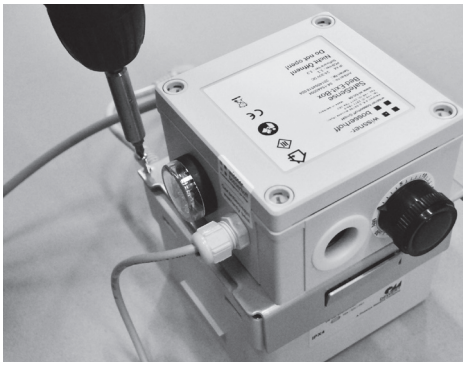
7. The final step is to connect the SafeSense® system to your nurse call system. For the cable version, this is done by connecting the plug on the SafeSense® system to the socket on your call system.

For the wireless version (see photo), please plug the wireless receiver's power supply into a power socket and connect the plug to your call system. The wireless receiver must then be calibrated to the SafeSense® system.

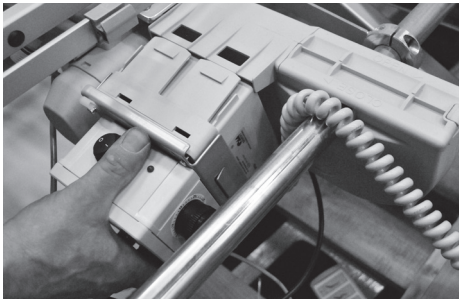
6.3 Installing on a bed with a battery

To install SafeSense® on a bed with a battery, follow the steps below:

1. Remove the battery pack from the bed and remove the two diagonally opposite screws.



2. Secure the Bed-Exit Box to the battery using the two screws supplied.



3. Clip the battery into the holder on the bed.

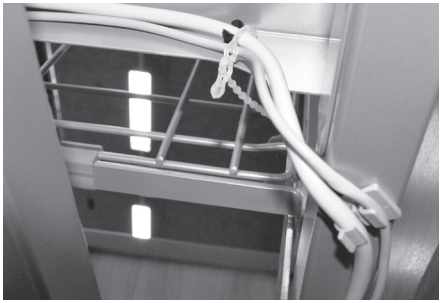
4. The remaining installation steps are identical to those for beds with no battery.

6.4 Cable routing

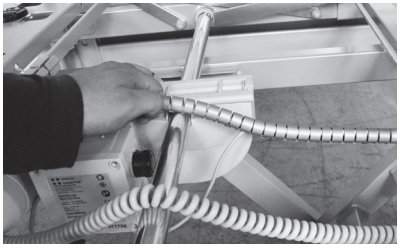
When installing SafeSense® please take care to ensure that the cables are not pinched or damaged in any way. For this reason, the steps below are to be followed to ensure proper cable routing:

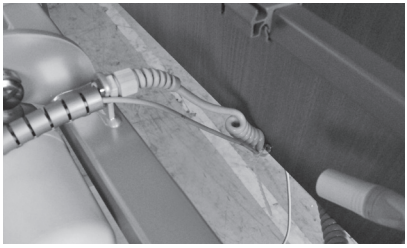
1. Cable routing for beds with cable opening on the side (movita, carisma, contempora):

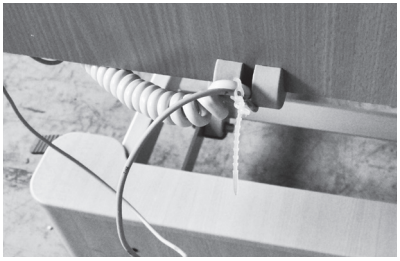
Use a cable clip to attach the nurse call cable to the power cable.
Always run the nurse call cable along the power cable to the head end of the bed and attach it to the power cable using a cable clip.



2. Cable routing for beds with cable opening at the head end:

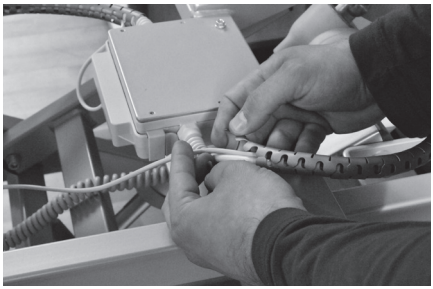


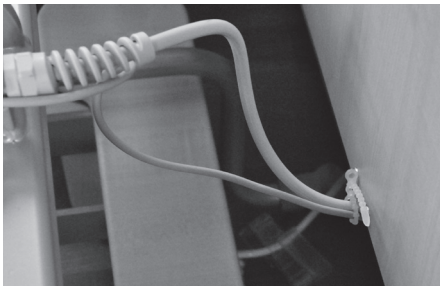




Run the nurse call cable from the Bed-Exit Box into the cable conduit, which also contains the power cable. Use a cable clip to attach it to both the inside of the head end and the cable relief at the head end.

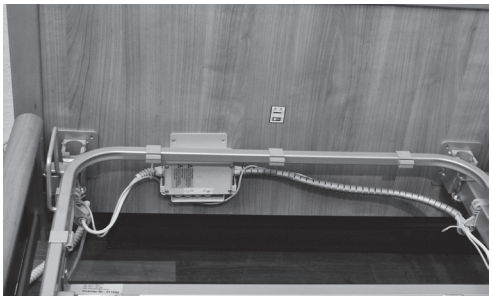
3. Cable routing for beds with a D-Box on the frame (sentida):





Run the nurse call cable from the D-Box into the cable conduit, which also contains the power cable. Use a cable clip to attach it to both the end of the cable conduit and the cable relief at the head end.

4. Cable routing for beds with a D-Box at the head end (movita):



Run the nurse call cable along the power cable and attach it to the holder in front of the cable conduit, which contains the power cable. Then run the nurse call cable through the cable conduit and below or above the D-Box. Use a cable clip to attach the cable. Continue running it alongside the power cable and attach it for the last time at the point where the cable spirals.

→ Please note: Gather the remaining cable together to avoid the risk of tripping and cable damage.

6.5 Calibrating the wireless receiver

The first time the wireless SafeSense® is connected to your nurse call system, the wireless receiver must be calibrated. This is done in three steps:

1. Press the button on the front of the wireless receiver. The light will start to blink.

2. Trigger an alarm by setting the time interval to 0 seconds and putting pressure on the sensor mat with your hand. After three seconds, remove your hand from the sensor mat. The blinking of the light on the wireless receiver will change.

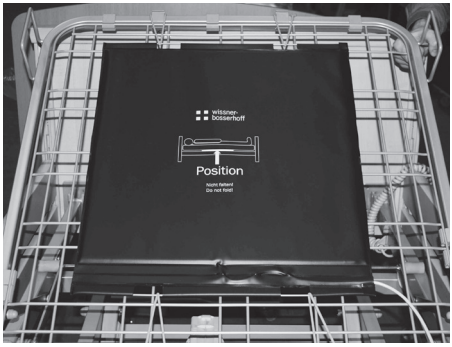
3. Press the button on the front of the wireless receiver again. This is now calibrated to the SafeSense® system and will transmit the signal to the nurse call system.

→ Please note: The wireless receiver can be programmed to up to 30 senders. Therefore, for safety reasons, only one SafeSense® system may be calibrated to one wireless receiver at any time. If you wish to move the system to another location (e.g. another room), you will need to take the wireless receiver as well.

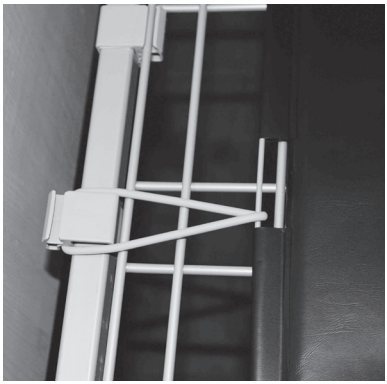
6.6 Securing the sensor mat for the backrest (50 x 50 cm)

The square sensor mat is designed for use on the bed's backrest. It is fixed to the backrest using the at-tached rubber rings and the supplied fastening clips. Securing works as follows:
1. Place the sensor mat in the middle of the backrest.

2. Secure the two large clips to the top of the backrest so that the slot is facing backward (directly opposite the clips securing the patient surface).



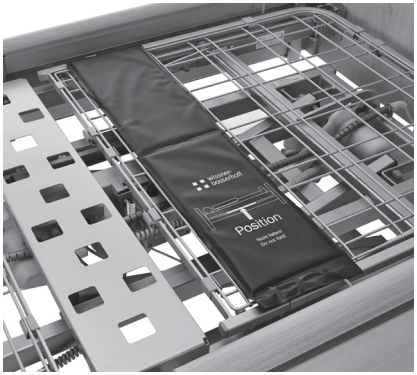
3. Secure the two smaller clips to the bottom of the backrest so that the slot is facing backward (directly opposite the clips securing the patient surface).
4. Hook the rubber rings into the clips.

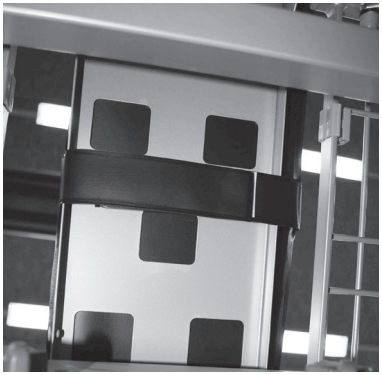


5. The sensor mat should now be sitting securely on the backrest and is protected against slipping.

6.7 Securing the sensor mat for the seat section (80 x 20 cm)

The 80 x 20 cm sensor mat is designed for use on the bed's seat section. The mat is equipped on either side with fastening straps, which can be joined together under the seat section using a Velcro fastener.





7. Handling the sensor mats

The sensor mats must not be bent, as this may stop them from functioning. For this reason, they may not be positioned in the transition zone between the seat section and backrest, since this would inevitably cause them to fold when the backrest is raised. In addition, the mats are not suitable for use on the wissner-bosserhoff comfort surface.

7.1 Cleaning the sensor mats

The sensor mats, including the connection cable, must be cleaned regularly. To do this, wipe the mat down, preferably with a slightly damp cloth. The moisture should then be completely removed with a dry cloth. The mat must not be cleaned in the laundry or with water spray.

7.2 Sensor mats and mattresses

The senor mats react to the removal of weight. To ensure safe and trouble-free detection when the resident leaves the bed, minimum weights associated with various mattress types must be observed. However, these are only rough guides. The functionality must therefore be tested with the resident before each use.

Mattress	**Art. no.**	**50 x 50 cm sensor mat**	**80 x 20 cm sensor mat**
Universalmatratze RG40	50-0084	mind. 62 kg	mind. 62 kg
MicroMatt 7	50-0565	mind. 62 kg	mind. 57 kg
ViskoMatt Komfort	50-0317	mind. 62 kg	mind. 57 kg
HeavyMatt 160	50-0315	mind. 70 kg	mind. 80 kg
HeavyMatt 230	50-0355	mind. 75 kg	mind. 90 kg
ProphyMatt	50-0126	mind. 65 kg	mind. 65 kg
ViskoMatt 3	50-0577	mind. 65 kg	mind. 60 kg

If the resident is lighter than the specified weight, the sensor mat may not detect his/her leaving the bed, meaning that no signal will be sent to the nurse call system.

Please consider that the sensor mats should not be used in combination with alternating pressure mattresses. Otherwise, the system cannot transmit reliable signals.

The data explicitly relates to wissner-bosserhoff mattresses. We offer no guarantee for these values if other mattresses are used. If you are using a different mattress, please check its functionality and compatibility with the SafeSense® Bed-Exit System in advance.

8. Operation of the Bed-Exit box

8.1 On/off switch

The on/off switch is located on the top of the Bed-Exit box and is labeled with the numbers 0 and 1. To activate the system you will need to set the switch to 1. All the SafeSense® Bed-Exit System's functions will then be active. To deactivate the complete system, set the switch to 0.

8.2 LED status light

Also on the top of the box is a small LED light that shows the system's current status. It will either light up green, orange or red:

Green: Resident is in bed, system is in monitoring mode

Orange: If a time interval has been set and the resident has left the bed, the LED will light up orange. If the resident returns to bed within the set time period, it will switch back to green. If the resident does not come back in time, the LED will light up red and a signal will be sent to the nurse call system.

Red: As soon as a call is triggered, the LED will light up red.

8.3 Setting a time interval

Using the black control dial on the right side of the box, you can set a time interval for triggering the alarm. The adjustment can be made in continuous one-minute steps, from immediately to up to approximately 30 minutes. Time markings help to set the time accurately. Please note that the markings only provide a rough guide for orientation purposes and cannot guarantee a specific time setting. The tolerance between the time set and the actual time of the call can be up to 20%.

8.4 Underbed light

The Bed-Exit Box is equipped with an under-bed light to assist the resident in moving about at night. It is automatically activated as soon as the resident leaves the bed, regardless of whether or not a time inter-val has been set. As soon as the resident lies down again, the under-bed light will switch off.

The under-bed light can also be controlled using the bed handset. However, this will only work if the Bed-Exit Box is activated. If the box is switched off, the under-bed light cannot be controlled with the handset. The underbed light is controlled with the handset as follows:

Activate the backrest with the following button:

Press the two arrow buttons (up and down) at the same time:

In this way, the under-bed light can be switched on or off.

→ The underbed light cannot be switched off using the handset if it is on because of a call signal. In this case, it will only turn off if the Bed-Exit box is completely switched off or the resident returns to bed.

9. Connecting to the nurse call system or other signal receivers

So that full use can be made of the SafeSense® Bed-Exit System, it must be connected to your nurse call system. All required components (with the exception of any Y adapter that may be necessary) are supplied with the system. In order to ensure that the system functions smoothly with your nurse call system, certain things must be noted:

The adapter cable must be laid out individually for the call systems installed in the building; if not available, it can be ordered from wissner-bosserhoff. Connect the system to the nurse call system by attaching the nurse call cable to the adapter cable through the XLR connector and the other end to the call system.

To allow you to continue using the handheld switch on your nurse call system and also to connect SafeSense®, two sockets are necessary. If your nurse call system does not have a socket, a Y-adapter is required. You can obtain one from your call system manufacturer. Please also ask the manufacturer about any risks and other information that should be noted.

If there is a Y cable for the corresponding call system, both connectors on the Y cable may need to be occupied (e.g. by a handheld switch).

wissner-bosserhoff is not responsible for the incorrect use of Y adapters or any possible damage to the call system that may result, and accepts no liability for such damage. Furthermore, wissner-bosserhoff accepts no liability for untransmitted or incorrectly transmitted signals to the nurse call system. Before installing the SafeSense® Bed-Exit System, therefore, please contact the manufacturer to check the compatibility of your nurse call system and any other information that may need to be taken into account.

10. Maintenance and service

The SafeSense® Bed-Exit System requires minimal servicing. This is because, during product development, attention was paid to ensure that servicing work was reduced to a minimum, keeping operating costs low.

In daily use, however, experience shows that products are also sometimes handled carelessly, and rough handling can also contribute to them aging more quickly and to the wear of certain components, on which the manufacturer can have no direct influence.
For this reason, routine maintenance checks should be performed by the operator – this should also be done to guarantee the availability of the system, which is in the operator's own interest. We recommend servicing the Bed-Exit System once a year, together with the service of the nursing home bed.

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

Only trained operators and maintenance technicians can ensure proper handling and use. wissner-bosserhoff's technical customer service offers servicing and necessary training on all aspects of the product.

If a function check, an inspection, measurement or servicing reveals serious defects that cannot be rectified, the product must be suspended from further use.
Our customer service is available to you for any inquiries and to provide training and servicing.

11. Spare parts

Only wissner-bosserhoff GmbH original spare parts may be used. Our customer service, sales and technical consultation department provide information concerning spare part deliveries, etc. (for the address, see the Contact section).
Please request spare parts lists, current price lists and servicing instructions with exploded diagrams as required, supplying the data from the system's identification plate or the or the appropriate article number, order number and date of delivery, to wissner-bosserhoff, Technical Customer Service Department.

wissner-bosserhoff GmbH
customer service

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

Designation	**Part No.**
Bed-Exit Box	
Bed-Exit box, cable version, for beds with no battery	04-1544-001
Bed-Exit box, cable version, for beds with a battery	04-1544-004
Bed-Exit box, wireless version, for beds with no battery	04-1544-002
Bed-Exit box, wireless version, for beds with a battery	04-1544-003
Sensor mats	
80 x 20 cm, for seat section	02-000713
50 x 50 cm, for backrest	02-000712
Adapter cable	
Customer-specific adapter cable with on/off switch for connection to the nurse call system	04-1508...
Customer-specific adapter cable without on/off switch for connection to the nurse call system	04-1608...
Wireless receiver	
Wireless receiver	02-000724
Miscellaneous	
Removable cable clip	01-003535

12. Disposal

This device falls within the scope of the EC Directive 2002/96/EC (WEEE). It is not registered for the use in private households. Disposal at municipal collection points for discarded electrical devices is not permitted. wissner-bosserhoff GmbH is responsible for legal compliance concerning the disposal of this device. For further information, please contact your responsible sales partner, or our company, if you are situated within Germany.

When transferring the equipment to an industrial third party, you are bound by contract to point out that after the end of use, proper disposal must be undertaken or arranged. If you do not point this out to the third party, you are responsible for the proper disposal of the equipment after the end of use.

The metal and plastic parts that accumulate during service and repairs must be disposed of properly and professionally in accordance with the applicable laws and regulations. The electrical controls (Bed-Exit Box) in particular may only be disposed of through specialist firms or waste management facilities authorized to do this.

13. Guarantee

By purchasing the SafeSense® Bed-Exit System, you have chosen a wissner-bosserhoff GmbH quality product. This product has been manufactured with care, using high-quality materials and modern production techniques.

We provide a 36-month guarantee for the system, starting from the date of purchase. This guarantee covers all malfunctions and defects in materials and manufacture. Malfunctions and defects arising from incorrect handling and external influences are excluded from this.

In addition, to ensure that your guarantee remains valid, make sure that the servicing and maintenance intervals are adhered to (see chapter “Maintenance and service”).
If there should be cause for justified complaints within the guarantee period, however, these will be rectified free of charge. This guarantee can be claimed with the sales receipt, which bears the date of pur-chase. Our general terms and conditions of delivery apply.

14. Technical data

Input voltage	24 – 30 V DC
Type of protection	IPX4
Protection class	3
Relative humidity	30% – 75%
Atmospheric pressure	700 hPa – 1060 hPa
Environment temperature	+10 °C – +40 °C
Manufacturer	wissner-bosserhoff GmbH Hauptstraße 4 – 6 58739 Wickede (Ruhr) GERMANY Phone +49 2377 784-0

14.1 Classification

According to Appendix IX of the Medical Devices Directive 93/42 EEC and the amending directive 2007/47/EC, the SafeSense® Bed-Exit System is a Class I medical device.

Designation	**Comment**
Directive 93/42/EEC	Medical devices directive 93/42/EEC
German law on medical products	German law on medical products (national implementation)
DIN EN ISO 14971:2013-04	Risk management applied to medical products
DIN EN 60601-1-11:2011-03 (relevant sections)	Medical electrical appliances
DIN EN 60601-2-52:2010 (applicable sections)	Medical beds
BfArM [German Federal Institute for Drugs and Medical Devices] recommendations	Recommendations of German Federal Institute for Drugs and Medical Devices
DIN EN 60529; VDE 0470-1:2000-09	Type of protection by housing IP code (protection from humidity)
DIN VDE 0834	Standard for nurse call systems in hospitals and nursing homes

14.2 Electromagnetic compatibility

Portable and mobile HF communication devices can influence medical electrical devices. Medical electrical devices are subject to special preventive measures regarding EMC. They have to be installed and put into operation in accordance with the EMC notes stated in this document.

14.3 Electromagnetic radiation

The SafeSense® Bed-Exit System is intended for operation in an electromagnetic environment as specified below. The customer or system user should ensure that it is operated in such an environment.		
Interference measurement	Compliance	EMC guideline
RF emissions in accordance with CISPR 11	Class [B]	
Harmonics emission IEC 61000-3-2	Class [A]	
Voltage fluctuations/flicker emissions IEC 61000-3-3	[Complies]	
		SafeSense® is suitable for use in all types of institutions, including residential use and similar, directly connected to the public mains grid that also supplies buildings used for residential purposes.

14.4 Electromagnetic interference immunity

The SafeSense® Bed-Exit System is intended for operation in an electromagnetic environment as specified below. The customer or SafeSense® user should ensure that it is operated in such an environment.			
Interference immunity checks	IEC 60601 test level	Compliance level	EMC guidelines
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transi-ent¬/burst (IEC 61000-4-4)	± 2 kV for power cables ± 1 kV for input and output lines	± 2 kV for power cables ± 1 kV for input and output lines	Grid power quality should be that of a typical commercial or hospital environment
Surge (IEC 61000-4-5)	± 1 kV voltage line-line ± 2kV voltage line-earth	± 1 kV voltage line-line ± 2 kV voltage line-earth	Grid power quality should be that of a typical commercial or hospital environment.
Voltage dips, short in-terruptions and voltage variations on power supply lines (IEC 61000-4-11)	< 5% UT (> 95% dip in UT) for ½ cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (95% dip in UT) for 5 sec.	< 5% UT (> 95% dip in UT) for ½ cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 sec	Grid power quality should be that of a typical commercial or hospital environment. If the user requires SafeSense® to continue to function even in the event of interruptions to the power supply, we recommend connecting the Bed-Exit System to an uninterruptible power supply or a battery.
Magnetic field power frequency (50/60 Hz) (IEC 61000-4-8)	3 A/m	3 A/m	The magnetic field power frequency should be at levels characteristic for a commercial or hospital environment.
NOTE: UT is the AC supply voltage prior to application of the test level			

14.5 Electromagnetic interference immunity for non life-sustaining equipment

The SafeSense® Bed-Exit System is intended for operation in an electromagnetic environment as specified below. The customer or system user should ensure that it is operated in such an environment.			
Interference immunity checks	IEC 60601 test level	Compliance level	EMC guidelines
Conducted RF (IEC 61000-4-6)	3 $_{VRMS}$ value 150 kHz to 80 MHz	*U1 = 3 $_{VRMS}$ value*	Portable and mobile communication devices should not be used when any closer to SafeSense®, including the cables, than the recommended separation distance calculated according to the applicable equation for the transmission frequency. Recommended separation distance $d = \frac{3,5}{E_1}\sqrt{P}$ $d = \frac{3,5}{U_1}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{E_1}\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	E1 = 3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strength from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot theoretically be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the field strength measured at the location where the SafeSense® Bed-Exit System is used exceeds the above compliance levels, the product should be monitored to verify that it is functioning as intended. If unusual performance is observed, additional steps may be required such as a change in orientation or a different location for the system.
b For frequencies between 150 kHz and 80 MHz, the field strength should be lower than 3 V/m.

14.6 Recommended separation distances

Recommended separation distances between portable and mobile RF telecommunications devices and the SafeSense® Bed-Exit System.

The SafeSense® Bed-Exit System is intended for operation in an electromagnetic environment where RF interference is controlled. The customer or SafeSense® user can therefore help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunications devices (senders) and the Bed-Exit System, depending on the communications device's power output as specified below.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = \frac{3,5}{E_1}\sqrt{P}$	80 MHz to 800 MHz $d = \frac{3,5}{U_1}\sqrt{P}$	800 MHz to 2,5 GHz $d = \frac{7}{E_1}\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the manufacturer.

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

NOTE 2: These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15. Troubleshooting

	Errors/faults	possible cause	Solution
1.	No call is triggered and the under-bed light does not switch on	Bed-Exit box is switched off	Switch the box on
		Sensor mat cable is not secure	Plug the cable securely into the Bed-Exit Box
		Bed-Exit box is defective	Contact WiBo service
		No mains power (for beds with a battery: battery is empty)	Netzkabel in die Steckdose stecken
		Time interval is not set correctly	Check and correct interval setting
		On/off switch on the adapter is off	Set the switch to “on”
		Sensor mat is worn/defective	Replace sensor mat
2.	No call is triggered, but the under-bed light is on	The plug to the nurse call system is not secure	Check the plug connections, otherwise call WiBo service
3.	Call is triggered in the wrong room	For wireless version: the sender is calibrated to the wrong receiver	Delete programming and recalibrate
4.	The call is triggered, but the under-bed light does not switch on	Light source defective	Contact WiBo service
		Bed-Exit box is defective	Contact WiBo service
5.	Calls are triggered incorrectly	The patient is not posi-tioned correctly in the bed	Position patients correctly
		The sensor mat is not positioned correctly	Correct the position of the sen-sor mat and secure it in place
		The time interval set is too short	Adjust the time interval using the control dial

16. Declaration of conformity

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

Wissner-Bosserhoff GmbH
Hauptstraße 4-6
58739 Wickede (Ruhr)
Germany

We declare under our sole responsibility that

the medical device: **„SafeSense“ Model No.: 04-1544**
of the class: **Class I**

according to annex IX of Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.: **No. 12 100 45814 TMS**

Notified Body:

TÜV Süd Management Service GmbH
Ridlerstrasse 65
80 339 München
Germany

Wickede (Ruhr) 07.03.2014
Place, date

CEO
Name and function