

# Instructions for Use and Technical Description



## SafeSense® 3

## **Monitoring System**

Stand-alone Version, Version for Image 3 and Version for Eleganza 2



D9U001SFS-0101

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## SafeSense® 3 Monitoring System

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## 1 Symbols and Definitions

## 1.1 Warning Notices

## 1.1.1 Types of Warning Notices

Warning notices are differentiated by the type of danger using the following key words:

- ► CAUTION warns about the risk of material damage.
- ▶ **WARNING** warns about the risk of physical injury.
- ► **DANGER** warns about the risk of fatal injury.

## 1.1.2 Structure of Warning Notices



SIGNAL WORDS!

Type and source of danger!

► Measures to avoid the danger.

## 1.2 Instructions

#### Structure of instructions:

► Perform this step. Results, if necessary.

## 1.3 Lists

#### Structure of bulleted lists:

- List level 1
  - □ List level 2
  - List level 3



## 1.4 Symbols on the Package

	FRAGILE, HANDLE WITH CARE	
	THIS WAY UP	
	DO NOT POLLUTE THE ENVIRONMENT	
PAP	PAPER RECYCLING SYMBOL	



## 1.5 Symbols and Labels on the Product

	READ INSTRUCTIONS FOR USE	
U	ACTIVATION BUTTON (TO ACTIVATE SafeSense® 3)	
	PLAY OR STOP BUTTON (TO ACTIVATE OR DEACTIVATE SELECTED MONITORING)	
	SELECT AND TIME BUTTON (SELECT TYPE OF MONITORING OR SET PERIOD OF SELECTED MONITORING)	
	WEEE SYMBOL (RECYCLE AS ELECTRONIC WASTE, DO NOT PUT INTO THE HOUSEHOLD WASTE)	
	MANUFACTURER	
	MANUFACTURING DATE	
	ON	
	OFF	
<u>^</u>	WARNING	
	ONLY SUITABLE FOR INDOOR USE	



*	APPLIED PARTS TYPE <b>B</b>
REF	REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON CONFIGURATION)
SN	SERIAL NUMBER
( <del>+</del> -	BATTERY (HUB)
	PLAY ICON (ON)
	STOP ICON (OFF)
	DECUBITUS/MOVEMENT NOTIFICATION
	MOTION MONITORING
٦	BED EXIT MONITORING
	WETNESS MONITORING



DO NOT ORBIT	CHECKED BY AUTHORIZED SERVICE DEPARTMENT
	DO NOT WASH (AIR PAD)
	DO NOT BLEACH (AIR PAD)
	DO NOT TUMBLE DRY (AIR PAD)
	DO NOT WRING (AIR PAD)
	DO NOT IRON (AIR PAD)
P	PROFESSIONAL CHEMICAL CLEANING - MODERATE PROCEDURE (AIR PAD)
PHENOL	DO NOT USE PHENOL (AIR PAD)
	DRY NATURALLY (AIR PAD)
6 (H <sub>2</sub> O)	RINSE WITH WATER (AIR PAD)



NaCIO ≤1,000ppm 1	DISINFECT USING SOLUTION CONTAINING LESS THAN 1000 ppm OF CHLORINE (REFER TO INSTRUCTIONS FOR USE) (AIR PAD)
	HANDWASH WITH DETERGENT (INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50°C) (AIR PAD)
BS 7175  BS 7175  5 5  RESISTANT	COVER MATERIALS ARE FIRE RESISTANT TO BS7175, SOURCE 0, 1 AND 5 (AIR PAD)
CE	CE MARKING
MD	MEDICAL DEVICE (COMPATIBLE WITH MEDICAL DEVICE REGULATION)

## 1.6 Product Labels

Serial label of the SafeSense 3 Monitoring System is placed on the Hub bottom side. The serial label contains information about manufacturer's address, manufacturing date, product reference number and product serial number. Hub serial label is also placed on the Hub bottom side. The Hub serial label contains information about manufacturer's address, manufacturing date, component reference number, component serial number, symbols and electrical specification.



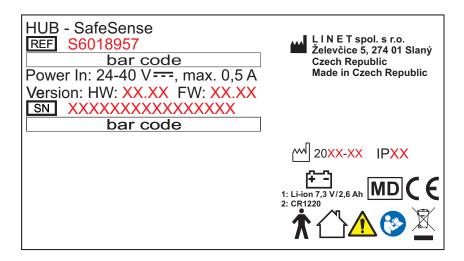


Fig. SafeSense® 3 Hub Serial Label (example)



Fig. SafeSense® 3 Air Pad Type Label

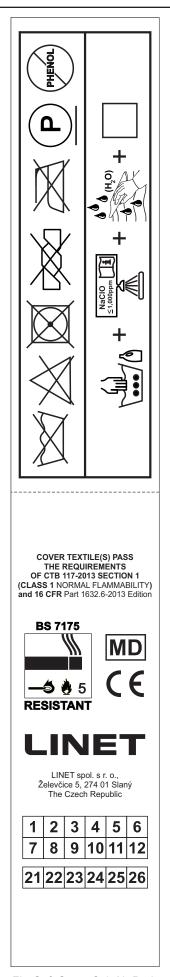


Fig. SafeSense® 3 Air Pad Wash Label



## 1.7 Visual signalisation

## 1.7.1 LEDS ON THE HUB CONTROL PANEL

SIGNALISATION		MEANING
ACTIVATION LED	GREEN	SafeSense® 3 ON - battery charged to more than 75%
	LIGHT BLUE	SafeSense® 3 ON - battery charged to 25 - 75%
	RED	SafeSense® 3 ON - battery fault
Ch	LED OFF	SafeSense® 3 OFF
PLAY/STOP LED	GREEN	monitoring ON
	BLUE	monitoring OFF
ERROR LED	RED	internal error
ERROR	LED OFF	no error detected

## 1.8 Definitions

Adult	Patient having a physical size equal to or more than 146 cm, a mass equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17 (according to IEC 60601-2-52).
Alert	Information signal (other than alarm signal)
MQTT Broker	MQTT Broker is a software part of the SafeSense® 3 system. MQTT (Message Queuing Telemetry Transport) represents a light- weight communication protocol for the internet of things according to the standard ISO/IEC 20922. The MQTT Broker consists of software components running on the server allowing to share mes- sages among connected devices (clients with SafeSense Applica- tion and Hubs). The MQTT Broker is configured to use encrypted communication in a network to eliminate vulnerable and insecure client connections.



## 1.9 Abbreviations

Alternating Current	
Attendant Control Panel	
European Conformity	
Cardiopulmonary Resuscitation	
Sound Intensity Unit	
Direct Current	
Electromagnetic Compatibility	
High Frequency	
Hardware	
Intensive Care Unit	
Ingress Protection	
Intravenous	
Light Emitting Diodes	
Medical Electrical (Equipment)	
Activation	
Deactivation	
parts per million, millionth (1000 ppm = 0,1%)	
Reference Number (product type depending on configuration)	
Serial Number	
Software	
Safe Working Load	
Universal Serial Bus	
Waste Electrical and Electronic Equipment	



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## **2 Safety Instructions**



#### **WARNING!**

You cannot rely unconditionally on alert notifications! This medical device is not intended to be used as an alarm system! SafeSense® 3 was not developed or tested as a diagnostic tool and must not be considered as such or as another instrument of that type.



#### WARNING!

This medical device is portable medical electrical equipment!



#### **WARNING!**

Inappropriate handling of the power supply cord, e. g. by kinking, shearing or other mechanical damages is hazardous!



#### **WARNING!**

When routing cables from SafeSense® 3 in a medical bed avoid squeezing those between parts of the medical bed!



#### **WARNING!**

No modification of this equipment is allowed.



#### **WARNING!**

An additional multiple socket-outlet or extension cord shall not be connected to the medical electrical system.



### WARNING!

Only authorised and trained person using the tool is allowed to change Hub battery!



#### WARNING!

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



#### WARNING!

This medical device is not intended for oxygen enriched environment!



#### WARNING!

Incompatible mattresses can put system functions out of order.



#### **WARNING!**

This medical device is not intended for use with flammable substances!



#### **WARNING!**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!



#### Additional instructions for correct use:

- Follow the instructions for use carefully.
- Ensure any user has read and understood the instructions for use completely before operating the product.
- Use the system exclusively if it is in perfect working order.
- If necessary, check the system functions daily or at each shift change.
- Use the system exclusively with the correct mains supply.
- ▶ Ensure that the system is operated exclusively by qualified personnel who have been trained according to the instructions for use.
- ▶ Ensure that the patient (health permitting) has been informed about the operation of the system and all applicable safety instructions.
- ► Contact service department of the manufacturer immediately to let it replace any damaged parts by the original spare parts.
- ▶ Ensure that maintenance and installation are performed exclusively by qualified personnel who have been trained by the manufacturer.
- To avoid injury or crushing, take extra caution when operating any moving parts of the bed.
- Never use the system in areas where there is a hazard of explosion.
- Never handle the mains plug with wet hands.
- Disconnect the product from the mains exclusively by pulling the mains plug.
- When pulling the mains plug, always hold the plug, not the cable.
- Position the mains cable so that there are no loops or kinks in the cable; protect the cable from mechanical wear and tear.
- Improper handling of mains cable can cause an electric shock hazard and other serious injuries or damages.
- ► To prevent failures, use exclusively the manufacturer's original accessories and mattresses in perfect working order.
- Do not hang anything on any cable.
- Select a suitable location for the placement of bed accessories and other objects to prevent involuntary activation of buttons or controls which may result in the adjustment of bed positioning.
- Replace the Air Pad once every 2 years to ensure its full functionality!



## 3 Intended Use (Stand-alone Version, Version for Image 3 and Version for Eleganza 2)

The SafeSense® 3 Monitoring System is intended to use for the automated, contactless and unobtrusive continuous mobility detection of patients in bed, bed exit and continuous wetness detection in the context of healthcare and nursing facilities.

## 3.1 User population

- Not specific. Indication is limited by limitation of hospital/nursing bed patients (weight ≥ 40 kg and ≤ 180kg , height >= 146 cm, BMI >= 17)
- ► Caregivers (nurses, doctors, technical personnel, transport personnel, cleaning personnel)

## 3.2 Contraindications

- ▶ Patients in whom proper positioning cannot be achieved or maintained.
- ▶ Patients who do not meet the weight limits tested or specified.
- ▶ An explosive atmosphere or in the presence of flammable anesthetics or gases.

## 3.3 Operator

► Health care professional (nurses, doctors)

## 4 Mattresses compatible with SafeSense® 3



#### WARNING!

Following mattresses are manufactured in versions with different dimensions. Use only mattresses whose dimensions are compatible with corresponding medical bed!

#### **Compatible Mattresses:**

- EffectaCare 10
- EffectaCare 20
- PrimaCare 10
- PrimaCare 20
- CliniCare 10CliniCare 20
- CliniCare 30
- Universal mattress Wulff
- ViskoMatt Comfort
- MicroMatt 7
- HeavyMatt 270
- ViskoMatt 2
- ViskoMatt 3
- ViskoMatt 5
- ViskoMatt 3 bariatric



## **5 Product Description**

Based on the functional principle of ballistocardiography, patients are monitored by a bed-side hardware unit of the SafeSense® 3 Monitoring System. This system consists of an electronic-free pad (SafeSense® 3 Air Pad) located under the mattress, which is connected to a hardware unit (SafeSense® 3 Hub) through an air hose. From there, the data is sent to remote devices via (W) LAN. The data is visualized using an SafeSense Application. Targeted and efficient patient care is also supported by an integrated notification function.

## **5.1 System Desciption**

## 5.1.1 Stand-alone Version

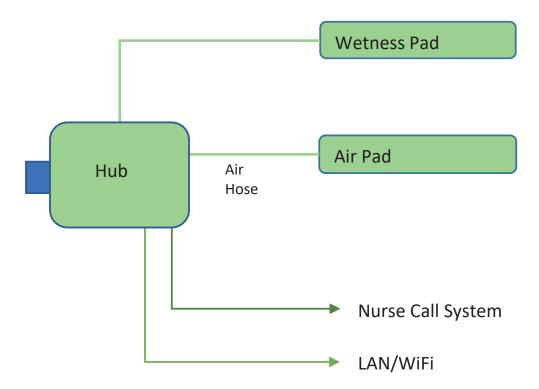


Fig. Diagram of the SafeSense® 3 Stand-alone system



## 5.1.2 Version for Image 3 (Image 3 bed with SafeSense® 3)

## $\triangle$

#### **WARNING!**

SafeSense® 3 Monitoring System in Version for Image 3 is compatible only with Image 3 medical bed and depends on the specific configuration of the Image 3 bed because Image 3 bed must be SafeSense® 3 ready for use with SafeSense® 3!

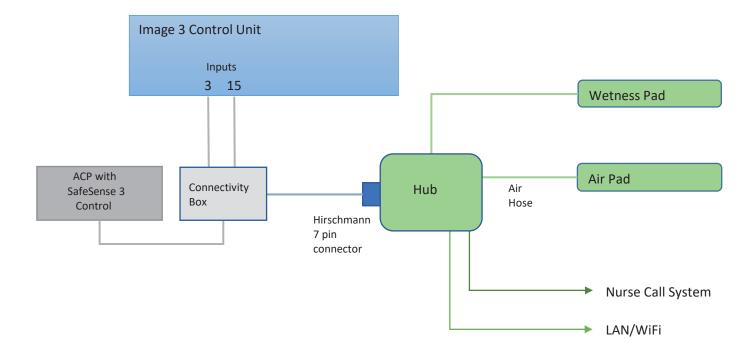


Fig. Diagram of the SafeSense 3 system with Image 3 bed



## 5.1.3 Version for Eleganza 2 (Eleganza 2 bed with SafeSense® 3)

## $\triangle$

#### **WARNING!**

SafeSense® 3 Monitoring System in Version for Eleganza 2 is compatible only with Eleganza 2 medical bed and depends on the specific configuration of the Eleganza 2 bed because Eleganza 2 bed must be SafeSense® 3 ready for use with SafeSense® 3!

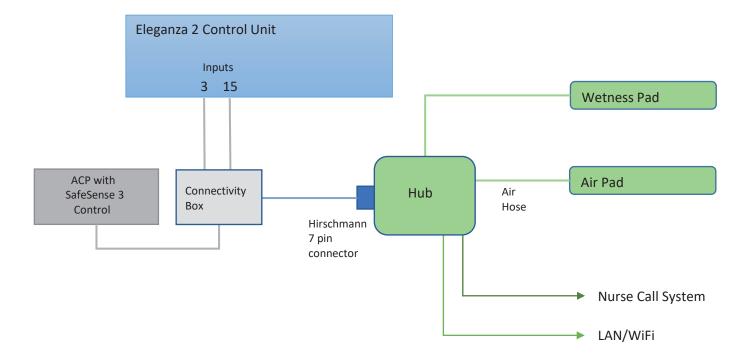
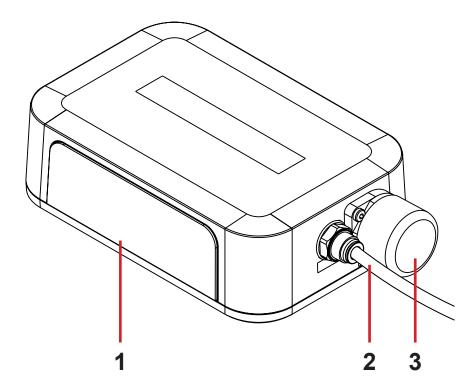


Fig. Diagram of the SafeSense 3 system with Eleganza 2 bed



## **5.2 Hub**

Hub interconnects parts of the SafeSense® 3 system and enables communication between the SafeSense® 3 system installed on a medical bed and CareMonitor user interface.



- 1. Hub Control Panel
- 2. Air Hose
- 3. Attendant Control Panel Connector with plug (only for Image 3 and Eleganza 2 medical bed)



## 5.3 Air Pad

Air Pad connected to the Hub via Air Hose enables Bed Exit Monitoring and Motion Monitoring.

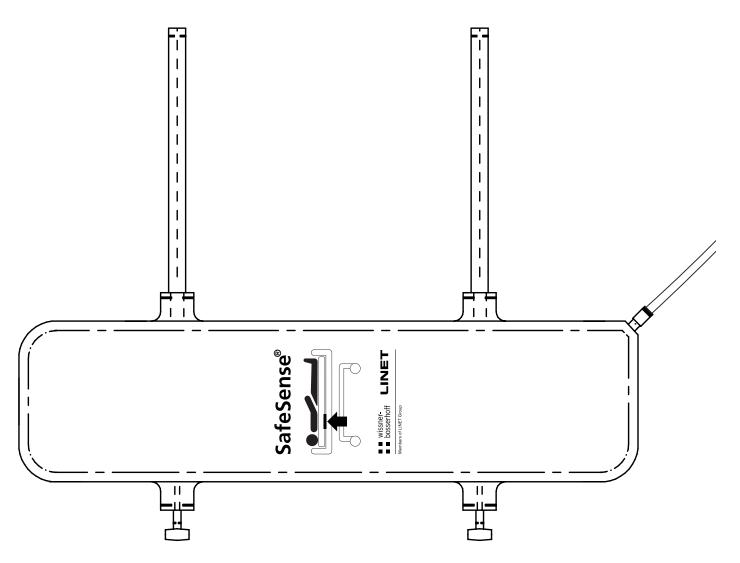


Fig. Air Pad with Air Hose



## 5.4 Wetness Pad



#### **CAUTION!**

## Risk of incorrect Wetness Monitoring due to incorrect cleaning of the Wetness Pad!

- For maximum sensitivity of Wetness Monitoring, wash the used Wetness Pad before use under another patient.
- Follow the instructions for cleaning the Wetness Pad to achieve the maximum lifetime of the Wetness Pad.

Wetness Pad connected to the Hub via Wetness Pad Cable enables Wetness Monitoring.

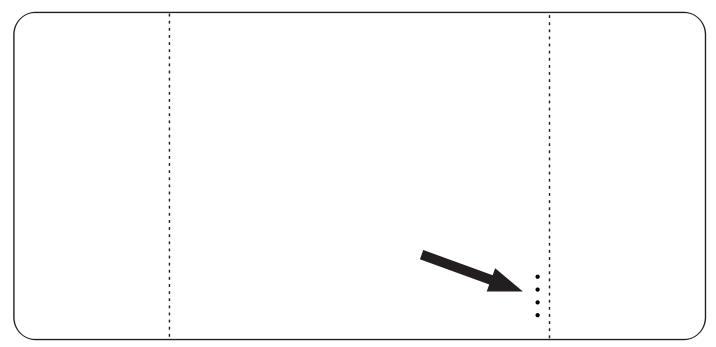


Fig. Wetness Pad with 4 connectors



## **6 Technical Specification**

All technical data are rated data and are subject to construction and manufacturing tolerances.

## **6.1 Mechanical Specifications**

Parameter	Value
Dimensions of Air Pad (length x width x height)	66 cm x 17 cm x 2 cm
Dimensions of Wetness Pad (length x width)	177 cm x 59,7 cm
Dimensions of Hub Box (length x width x height)	16,5 cm x 10,6 cm x 4,5 cm
Length of Air Hose (Stand-alone Version)	1,2 m
Length of Air Hose (Version for Image 3)	1,2 m
Length of Air Hose (Version for Eleganza 2)	1,4 m
Length of Power Supply cable (Stand-alone Version)	1,8 m
Length of LAN cable (Stand-alone Version)	1,4 m
Length of LAN cable (Version for Image 3)	1,4 m
Length of LAN cable (Version for Eleganza 2)	0,34 m
Length of Nurse Call cable (Stand-alone Version)	1,4 m
Length of Nurse Call cable (Version for Image 3)	1,4 m
Length of Nurse Call cable (Version for Eleganza 2)	0,34 m
Length of Wetness Pad cable	0,7 m
Minimum Patient Weight	40 kg
Maximum Patient Weight	180 kg
Weight of Hub Box	0,5 kg
Weight of Stand-alone Version Set	2,6 kg
Weight of Image 3 Version Set	2,4 kg
Weight of Eleganza 2 Version Set	2,2 kg

## **6.2 Technical Requirements on the Part of the Customer**

Parameter	Value
Tablets	CPU 2 GHz, 3GB RAM, 64 GB eMMC
PCs	Dual Core CPU 3 GHz, 4 GB RAM, 128 GB SSD (free space: 300 MB), Intel UHD 630
Broker Station	Dual Core CPU 2,4 GHz, 4 GB RAM, 128 GB SSD (free space: 1 GB)
Operating System for Tablets (running CareMonitor)	Android 5.0
Operating System for PCs (running CareMonitor)	Windows 10
Operating System Broker PC	Windows 10 or Linux (Debian based)
Necessary SW on Broker PC	TeamViewer or alternative remote Desktop solution
LAN	IEEE 802.3
WLAN	IEEE 802.11 (802.11b/g, 2.4 GHz, WPA/WPA2-PSK)
Network Speed	10/100 Mbit
Open Network Ports	1883 8883 (Standard) (MQTT) 22666 (SSH-Hub) 5938 (TeamViewer)
Maximum Number of Hubs connected to a one SafeSense® 3 Monitoring System	50 pieces



## **6.3 Environment conditions**

## **6.3.1 Use Conditions**

Parameter	Value	
Ambient Temperature	10°C — 40°C	
Relative Humidity	30% — 75 %	
Atmospheric Pressure	795 hPa — 1060 hPa	

## **6.3.2 Storage and Transport Conditions**

Parameter	Value	
Ambient Temperature	-20°C — 50°C	
Relative Humidity	20% — 90 %	
Atmospheric Pressure	795 hPa — 1060 hPa	

## **6.4 Electrical Specifications**

Parameter	Value
Input Voltage, Frequency (Adaptor)	100 — 240 V AC, 50/60 Hz
Maximum Power Input (Adaptor)	max. 60 VA
Ingress Protection according to EN 60529 (Adaptor)	IPX4
Protection Class (Adaptor)	Class II
Input Voltage, Frequency (Hub)	100 — 240 V AC, 50/60 Hz
Maximum Power Input (Hub)	max. 10 W
Ingress Protection according to EN 60529 (Hub)	IPX4
Protection Class (Hub)	Class III
Batteries (Hub)	CL18650-29E/2S1P 7,3V / 2,67 Ah CR1220 3V / LFT 1A
Battery Operation	max. 3 h
Time to full charge	8 h



## 6.5 Electromagnetic Compatibility

Monitoring system is intended for hospitals except for near active HF surgical equipment and the RF shielded room of a medical system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Monitoring system has defined no essential performance.



#### WARNING!

It is recommended to avoid the use of this device next to or in block with other device, because it could lead to improper operation. If such use is needed, this device and the other equipment should be under surveillance to verify proper operation.

#### List of used cables:

- ► AC/DC Adaptor Cable, maximum length 1,8 m
- ► Wetness Pad Cable, maximum length 0,7 m
- ► Nurse Call Cable, maximum length 1,4 m
- ► LAN Cable, maximum length 1,4 m



#### WARNING!

Use of the accessories, converters and other cables, than specified and provided by manufacturer of this monitoring system could lead to increase of electromagnetic emission or lower the electromagnetic immunity of this monitoring system and lead to improper operation.



### WARNING!

Mobile RF communication device (including end use devices like antenna cables and external antenna) should not be used closer than 30 cm (12 inches) from any part of this monitoring system SafeSense® 3, including cables specified by manufacturer. Otherwise this could lead to deterioration of functionality of this monitoring system.



#### **WARNING!**

Consider chapter 14 Maintenance in order to maintain the basic safety with regard to electromagnetic disturbances for the expected service life.

## 6.5.1 Manufacturer instructions - electromagnetic emissions

Emission Test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies

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## 6.5.2 Manufacturer instructions - electromagnetic susceptibility

Immunity Tests	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV for contact discharge ± 15 kV for contact discharge
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 1
Fast electrical transients / burst IEC 61000-4-4	±2 kV for power line repetition frequency 100 kHz
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground
Conducted RF IEC 61000-4-6	3 V (0,15 MHz – 80 MHz) 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m
Voltage dips, short interruptions on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycle Single phase: at 0° 0 % UT; 250/300 cycle

Table 1 - IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level V/m
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710 745 780	704 - 787	LTE band 13, 17	Pulse modulation 217 Hz	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28
1 720 1 845 1 970	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	28
5 240 5 500 5 785	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

NOTE There are applied no deviations to requirements of IEC 60601-1-2 ed. 4

**NOTE** There are no known other measures for keeping the basic safety based on EMC phenomena.

**NOTE** Hub is equipped with communication module in compliance with standard IEEE 802.11 b/g/n (2400,0 MHz – 2483,5 MHz, modulation DSSS (IEEE 802.11 b ), OFDM (IEEE 802.11 g/n) 20MHz bandwidth, EIRP = 0,34 W).



## **7 Use and Storage Conditions**



#### **WARNING!**

A source of air flow near to the installed SafeSense® 3 system can affect the information functions of the system!

▶ Before and during the use of this system check the possible sources of air flow (e.g. air-conditioner) to ensure you will be informed about statuses whose detection can help you in care for a patient and not about environmental conditions.



#### **WARNING!**

Do not manipulate the bed if the SafeSense 3 Monitoring System is activated on it!



#### **WARNING!**

SafeSense 3 Monitoring System consists of the parts whose simultaneous working is necessary for the proper functioning of the whole system! Unless the CareMonitor Application is activated, outputs from the Hub could not be displayed correctly later in the CareMonitor Application!

SafeSense® 3 is designed for use in rooms for medical purposes. Electrical installations must therefore meet local norms laying down the necessary conditions for electrical installations.

Disconnect the system from the mains in exceptional cases (i.e. lightnings, earthquake).

Respect values of the parameters connected with environment conditions in the chapter Technical Specification during use and storage of the product.

SafeSense® 3 is not suitable for indoor environments containing flammable gases (except oxygen cylinders).

## 8 Scope of Delivery and Product Variants

## 8.1 Delivery

- Upon receipt, check that the shipment is complete as specified on the delivery note.
- Notify the carrier and supplier of any deficiencies or damages immediately as well as in writing or make a note on the delivery note.

## 8.2 Scope of Delivery

- SafeSense® 3 Monitoring System
- Instructions for use



## 8.3 SafeSense® 3 Variants

## 8.3.1 Stand-alone Version

### **Basic Configuration:**

- SafeSense® 3 Hub
- Comb-like part securing connectors connected to the Hub
- SafeSense® 3 Air Pad
- Air Hose
- AC/DC Adaptor

#### **Optional Features:**

Wetness Pad with Wetness Pad Cable

## 8.3.2 Version for Image 3

#### **Basic Configuration:**

- SafeSense® 3 Hub
- Comb-like part securing connectors connected to the Hub
- Hub Holder
- SafeSense® 3 Air Pad
- Air Hose
- Cables (Nurse Call cable, LAN cable)
- Holder of the interconnecting elements for Nurse Call cable and LAN cable

## **Optional Features:**

Wetness Pad with Wetness Pad Cable

## 8.3.3 Version for Eleganza 2

#### **Basic Configuration:**

- SafeSense® 3 Hub
- Comb-like part securing connectors connected to the Hub
- Hub Holder
- SafeSense® 3 Air Pad
- Air Hose
- Cables (Nurse Call cable, LAN cable)

#### **Optional Features:**

Wetness Pad with Wetness Pad Cable



## 9 Putting into Service

Installation of the SafeSense® 3 Monitoring system consists of the hardware installation and the software installation. The hardware installation can be performed by a hospital technician. The software installation must be performed by the authorized LINET service technician.

## 9.1 Stand-alone SafeSense® 3



#### **WARNING!**

Risk of injury and risk of material damage due to incorrectly installed Stand-alone SafeSense® 3 system!

- Ask manufacturer of the SafeSense® 3 system for the approval of your installation method on a medical bed if any of the following installation requirements could not be met (e.g. original Hub Holder is not used with the Hub Box)!
- Each alternative installation method that differs from the following installation requirements and that is approved by the manufacturer must comply with the general installation principles according to which Hub Box must be safely placed on the bed, Air Pad must be fixed on the backrest of a medical bed and under the compatible mattress, Wetness Pad must be placed on the seat section of a compatible mattress and each cable must be safely installed!



#### WARNING!

Risk of injury and risk of material damage due to incorrectly installed Hub box!

- SafeSense® 3 Hub must be placed on the Hub holder and these two components must be fixed on an accessory rail on the right bed side towards the thigh rest!
- Respect dimensions of the C-shape upper part of the Hub holder and dimensions of the accessory rail during placement of the Hub with Hub holder on the compatible accessory rail!
- Avoid collisions between Hub holder and movable parts of the bed and collisions between Hub box and movable parts of the bed!
- Avoid collisions between Hub holder and accessories of the bed and between Hub box and accessories of the bed!
- Ensure the indispensable cables are correctly and safely connected to the Hub box!



#### **WARNING!**

Risk of injury and risk of material damage due to incorrect installation of cables and incorrect installation of the Air Hose!

- ► Ensure the cables leading to the SafeSense® 3 Hub are not kinked or sheared or otherwise machanically damaged during bed positioning or during manipulation with accessories of the bed!
- ▶ When routing cables from SafeSense® 3 system in a medical bed avoid squeezing those cables between parts of the medical bed!
- ▶ Cables of the SafeSense® 3 system and Air Hose must not be tensioned!
- ▶ Ensure the Air Hose is correctly connected to the Hub box and to the Air Pad!
- Avoid squeezing, kinking, shearing of the Air Hose or other mechanical damage to the Air Hose!
- ▶ Use only original power supply cord with original adaptor!



#### **WARNING!**

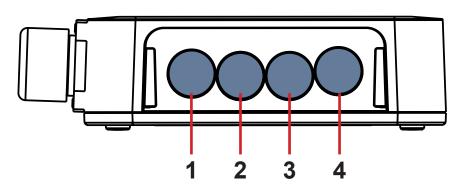
Risk of injury and risk of material damage due to incorrect installation of Air Pad and Wetness Pad!

- Use only mattress compatible with SafeSense® 3 system!
- ▶ Air Pad must be fixed on the backrest of a medical bed. Prevent the Air Pad from moving on the backrest under the mattress!
- ▶ Ensure the Air Hose is correctly connected to the Air Pad fixed on the backrest of a medical bed!
- ▶ Wetness Pad must be placed on the seat section of the compatible mattress and the ends of the Wetness Pad must be put under the seat section of the compatible mattress.
- ▶ Wetness Pad must not be covered with a plastic foil!
- ► Ensure the cable connecting Wetness Pad with SafeSense® 3 Hub is correctly connected to the SafeSense® 3 Hub and to the Wetness Pad.



#### **Initial Instructions:**

- ► Ensure the SafeSense® 3 Hub is placed correctly to the Hub Holder by the raised latch.
- Connect LAN cable, Nurse Call cable, Wetness Pad cable and Power Supply cable to the Hub box.
- ► Tighten grommets of the connected cables on the back side of the Hub box by turning or by pushing in the case of the Power Supply cable.
- Secure the connected cables by inserting comb-like part.
- Fix the Hub connected with the Hub holder on the accessory rail of a bed. There is a C-shape upper part of the Hub holder that must be fixed to the compatible accessory rail and secured with safety bolt. Respect dimensions of the C-shape upper part of the Hub holder and dimensions of the accessory rail during placement of the Hub with Hub holder on the compatible accessory rail!
- ► Tighten the safety bolt to fix Hub holder on the accessory rail. Check if SafeSense® 3 Hub is safely installed on the accessory rail.
- ► Connect SafeSense® 3 Hub to the mains power using the compatible cable with adaptor.
- ► Connect SafeSense® 3 Hub to the hardware where CareMonitor Application is installed using LAN cable or remote WiFi connection.
- Place Air Pad under the compatible mattress to the correct position on the backrest.
- Connect Air Pad to the SafeSense® 3 Hub using Air Hose.
- ▶ Place Wetness Pad on the mattress under the sheet to the correct position in the seat section of the patient. Four connectors on the Wetness Pad are facing a surface of the compatible mattress.
- ► Connect Wetness Pad cable to the Wetness Pad.
- ► Connect SafeSense® 3 Hub to the Nurse Call system using Nurse Call cable if the use of the Nurse Call system with SafeSense® 3 system is required.
- Open the CareMonitor Application.
- Activate the Hub and check if the corresponding bed is visible on the CareMonitor Screen.
- ▶ Perform the same steps to activate the other Hubs and to display the corresponding beds on the CareMonitor Screen.



- 1. Power Supply cable
- 2. Nurse Call cable
- 3. Wetness Pad cable
- 4. LAN cable

Fig. 4 Hub Connectors (back side)

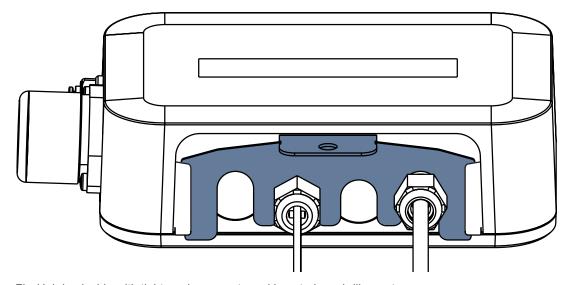


Fig. Hub back side with tightened grommets and inserted comb-like part



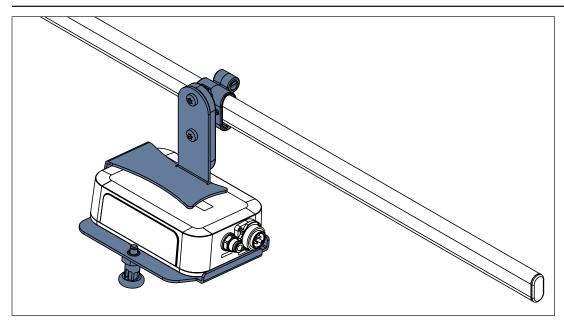
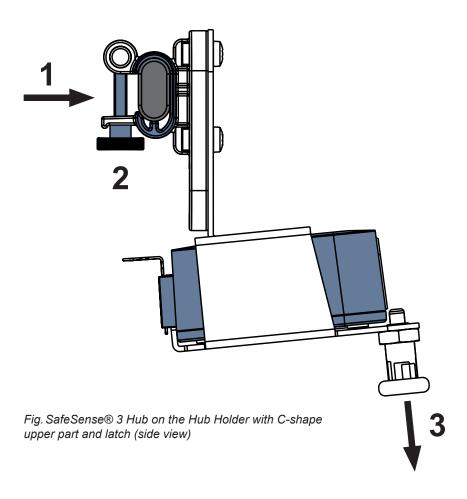


Fig. SafeSense® 3 Hub with Hub Holder on the accessory rail



## To fix Hub Holder on an accessory rail:

- ► Mount Hub Holder on an accessory rail. (1)
- Tighten the safety bolt (2) to fix Hub Holder on the accessory rail.

#### To fix Hub in the Hub Holder:

- ► Hold a latch of the Hub Holder pulled down (3).
- Place Hub to the Hub Holder.
- ► Ensure the Hub is fixed in the Hub Holder by the raised latch.



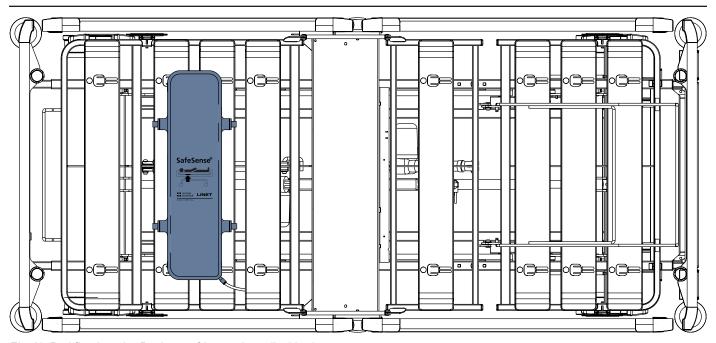


Fig. Air Pad fixed on the Backrest of Image 3 medical bed

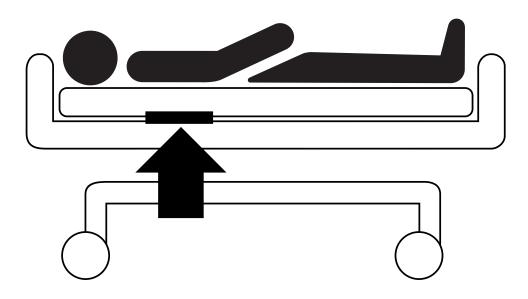
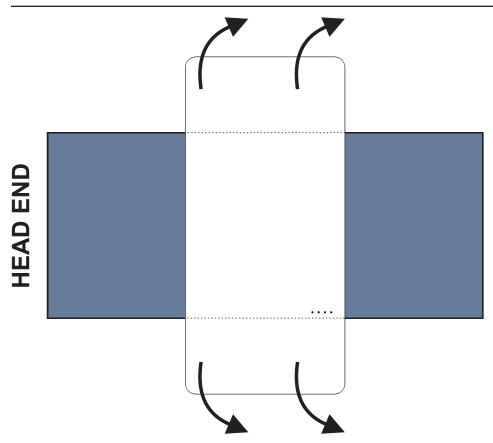


Fig. Position of the Air Pad under the mattress with patient





## To place Wetness Pad on a mattress:

- Put Wetness Pad over the mattress seat section to have 2 overlapping ends of the Wetness Pad on the sides of the mattress. Four connectors on the Wetness Pad are facing a surface of the compatible mattress.
- Connect Wetness Pad
  Cable to the 4 connectors on the
  Wetness Pad. There are two correct
  ways of connecting the Wetness
  Pad Cable to the Wetness Pad
  depending on the starting position of
  the Wetness Pad connectors.
- ► Slip the overlapping ends of the Wetness Pad under the sides of the mattress.

Fig. Position of the Wetness Pad on the compatible mattress

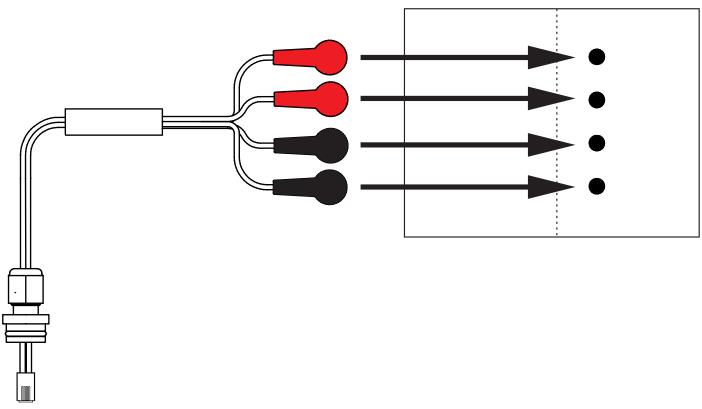


Fig. Wetness Pad Cable connecting Hub to Wetness Pad



#### To connect Wetness Pad to the SafeSense® 3 system:

- ► Connect the RJ connector on the opposite side of the Wetness Pad cable to the Hub (connector in the position 3).
- ► Connect 4 connectors of the Wetness Pad cable to the four connectors on the Wetness Pad according to labels on the cable.

#### ORDER OF THE CONNECTION OF THE FOUR WETNESS CABLE CORES

Order	1	2	3	4
Cable core marked by this label	0000	0000	0000	000

## 9.2 Image 3 with SafeSense® 3



#### **WARNING!**

#### Risk of injury and risk of material damage due to incorrectly installed Hub box!

- SafeSense® 3 Hub must be placed on the Hub holder and these two components must be fixed on the accessory rail on the right bed side towards the thigh rest!
- Avoid collisions between Hub holder and accessories of the bed and between Hub box and accessories of the bed!
- Ensure the indispensable cables are correctly and safely connected to the Hub box!



#### **WARNING!**

## Risk of injury and risk of material damage due to incorrect installation of cables and incorrect installation of the Air Hose!

- ▶ Ensure the cables leading to the SafeSense® 3 Hub are not kinked or sheared or otherwise machanically damaged during bed positioning or during manipulation with accessories of the bed!
- ▶ When routing cables from SafeSense® 3 system in the Image 3 medical bed avoid squeezing those cables between parts of the medical bed!
- ► Cables of the SafeSense® 3 system and Air Hose must not be tensioned!
- ► Ensure the Air Hose is correctly connected to the Hub box and to the Air Pad!
- Avoid squeezing, kinking, shearing of the Air Hose or other mechanical damage to the Air Hose!



### WARNING!

#### Risk of injury and risk of material damage due to incorrect installation of Air Pad and Wetness Pad!

- Use only mattress compatible with SafeSense® 3 system!
- ▶ Air Pad must be fixed on the Backrest of the Image 3 medical bed. Prevent the Air Pad from moving on the Backrest under the mattress!
- ▶ Ensure the Air Hose is correctly connected to the Air Pad fixed on the Backrest of the Image 3 medical bed!
- ▶ Wetness Pad must be placed on the seat section of the compatible mattress and the ends of the Wetness Pad must be put under the seat section of the compatible mattress.
- ▶ Wetness Pad must not be covered with a plastic foil!
- ► Ensure the cable connecting Wetness Pad with SafeSense® 3 Hub is correctly connected to the SafeSense® 3 Hub and to the Wetness Pad.



#### **WARNING!**

#### Material damage due to machine washing with SafeSense® 3 installed on the bed!

- ▶ Remove each part of the SafeSense® 3 Monitoring System from the Image 3 bed before each machine washing!
- ▶ Plug the connector of the Power Supply/Data cable to the safety position behind the accessory rail on the right side of the Image 3 bed!

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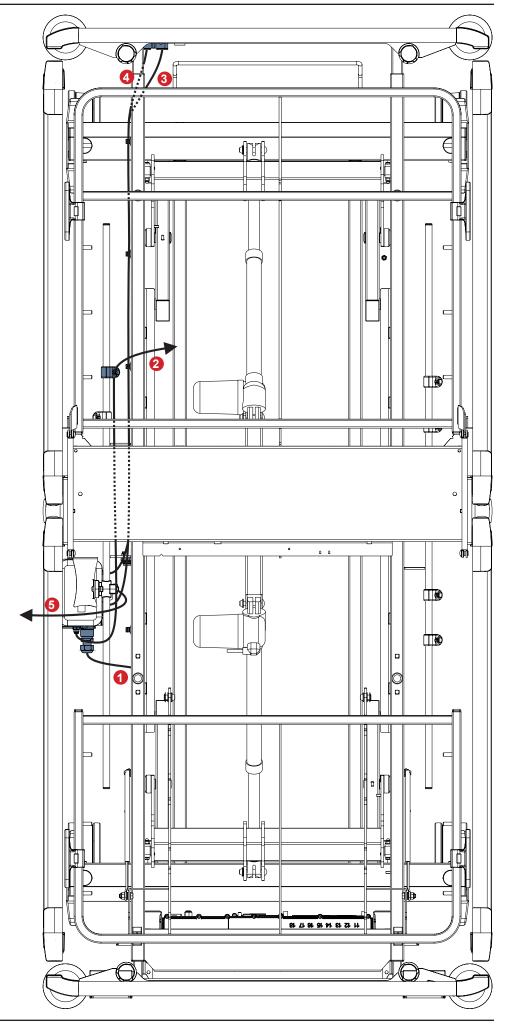
## 9.2.1 Instructions for putting into service

- Place the Hub Holder on the accessory rail on the right side of the Image 3 bed.
- ► Tighten the safety bolt to fix Hub Holder on the accessory rail. Check if the Hub Holder is safely installed on the accessory rail.
- ▶ Bolt the Holder of the interconnecting elements for Nurse Call cable and LAN cable to the crossbar at head end of the Image 3 bed.
- ▶ Insert both interconnecting elements for Nurse Call cable and LAN cable to the Holder of the interconnecting elements in any order.
- Connect LAN cable, Nurse Call cable and Wetness Pad cable to the back side of the Hub box.
- ► Tighten grommets of the connected cables on the back side of the Hub box by turning.
- Secure the connected cables by inserting comb-like part.
- Place the Hub to the Hub Holder and ensure the Hub is fixed in the Hub Holder by the raised latch.
- Disconnect the Power Supply/Data cable from the safety position behind the accessory rail.
- Remove the plug covering the connector on the right side of the Hub.
- Connect Power Supply/Data cable to the connector on the right side of the Hub.
- ▶ Route LAN cable and Nurse Call cable above the accessory rail towards the head end of the bed. Place both cables to the plastic holders on the frame of the mattress support platform.
- ► Connect LAN cable and Nurse Call cable to the interconnecting elements for Nurse Call cable and LAN cable at head end of the Image 3 bed according to the size of the connectors.
- ▶ Raise the Backrest of the Image 3 bed to the highest position.
- ► Fix the Air Pad on the Backrest so that the 2 middle plastic sections of the Backrest are surrounded by the straps of the Air Pad Cover.
- ► Connect the Air Hose to the right side of the Hub.
- Route the Air Hose along the two cables above the accessory rail towards the head end of the bed.
- ▶ Run the Air Hose from below up through the hole in the hook on the accessory rail. The hook selected for this purpose must be put on the accessory rail in the other way around so it is not possible to use this hook for carrying any accessory. The position of the selected hook must be adjusted with respect to the Air Pad position on the Backrest in the highest position.
- Run the Air Hose upwards through the plastic sections of the Backrest.
- Connect the Air Hose to the Air Pad fixed on the Backrest.
- ► Ensure the Backrest adjustment does not damage the Air Hose and the Air Hose is not squeezed in any position of the Backrest.
- Place a compatible mattress on the mattress support platform of the Image 3 bed.
- ▶ Place Wetness Pad on the mattress without any sheet to the correct position in the seat section of the patient. Four connectors on the Wetness Pad are facing a surface of the compatible mattress.
- Connect Wetness Pad cable to the Wetness Pad according to the four labels on the Wetness Pad cable. There are two ways of connection depending on the starting position of the Wetness Pad that are in accordance with the correct use. Slip the overlapping ends of the Wetness Pad on the both sides of the Image 3 bed under the mattress.
- Place a sheet on the mattress.
- Connect the cable connected to the local Nurse Call system to the interconnecting element for Nurse Call cable at head end of the Image 3 bed, if the use of the Nurse Call system with SafeSense® 3 system is required.
- Connect the local LAN cable to the interconnecting element for LAN cable at head end of the Image 3 bed, if wireless signal from Hub is not used for communication between Hub and a hardware with installed CareMonitor Application.
- Place patient on the Image 3 bed.
- Activate Hub according to the instructions for use.
- **▶** Open the CareMonitor Application.
- Activate the Hub and check if the corresponding bed is visible on the CareMonitor Screen.
- ▶ Perform the same steps to activate the other Hubs and to display the corresponding beds on the CareMonitor Screen.

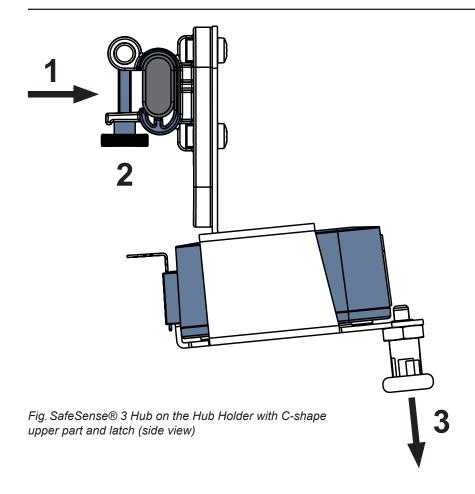


## SafeSense® 3 system on the right side of the Image 3 bed

- 1. Power Supply/Data cable
- 2. Air Hose
- 3. LAN cable
- 4. Nurse Call cable
- 5. Wetness Pad cable







### To fix Hub Holder on the accessory rail:

- ► Mount Hub Holder on the accessory rail. (1)
- Tighten the safety bolt (2) to fix Hub Holder on the accessory rail.

### To fix Hub in the Hub Holder:

- ► Hold a latch of the Hub Holder pulled down (3).
- Place Hub to the Hub Holder.
- ▶ Ensure the Hub is fixed in the Hub Holder by the raised latch.

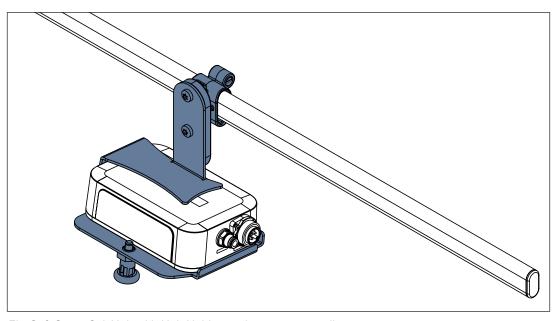


Fig. SafeSense® 3 Hub with Hub Holder on the accessory rail

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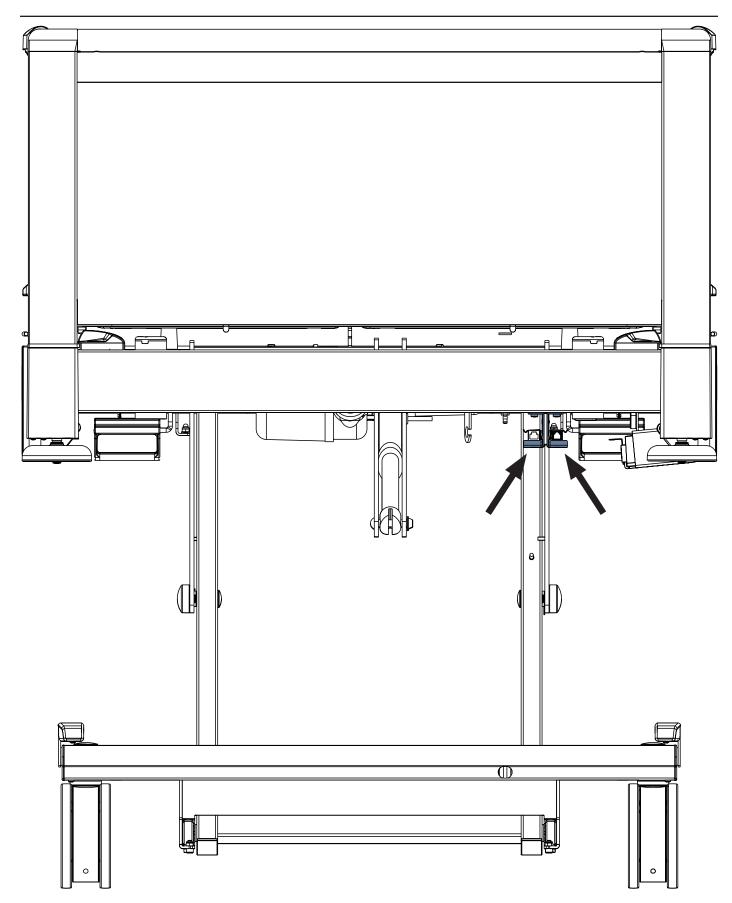


Fig. Interconnecting elements for Nurse Call cable and LAN cable at head end of the Image 3 bed



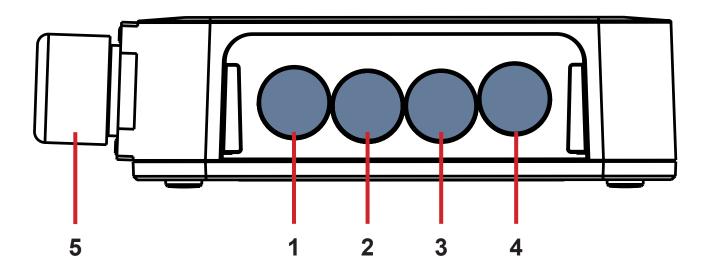


Fig. Hub Connectors (back side)

- 1. NOT AVAILABLE CONNECTOR
- 2. Nurse Call cable
- 3. Wetness Pad cable
- 4. LAN cable
- 5. Power Supply/Data cable

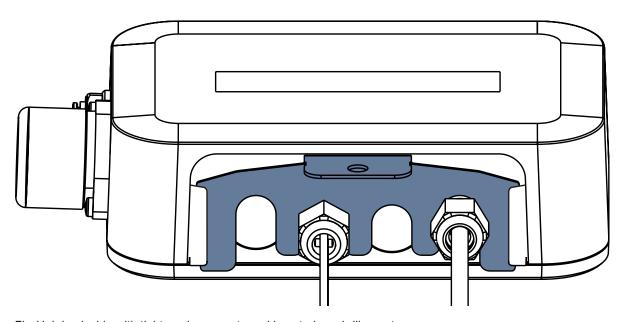


Fig. Hub back side with tightened grommets and inserted comb-like part



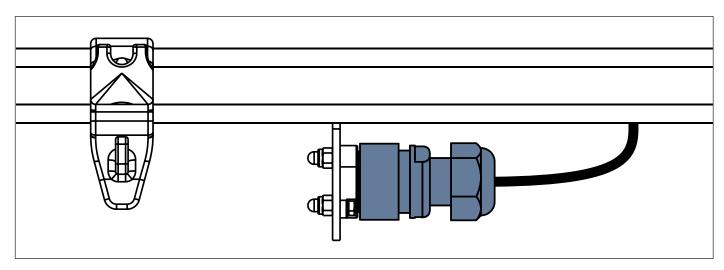


Fig. Power Supply/Data cable in the safety position behind the accessory rail

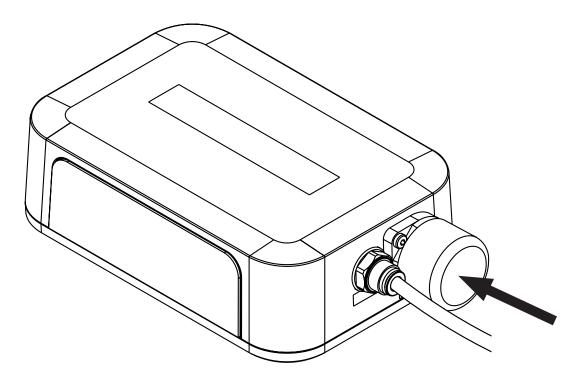


Fig. Covered connector for Power Supply/Data cable



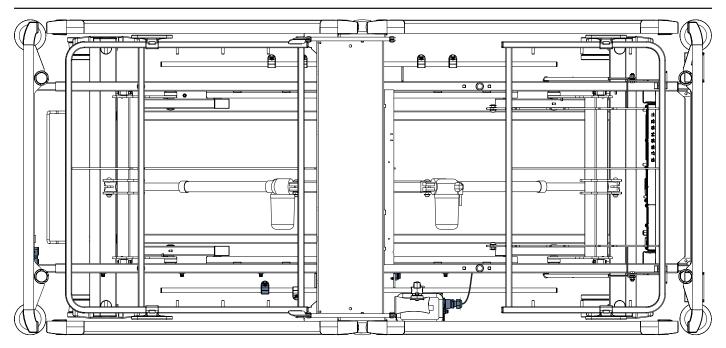


Fig. Power Supply/Data cable connected to the Hub

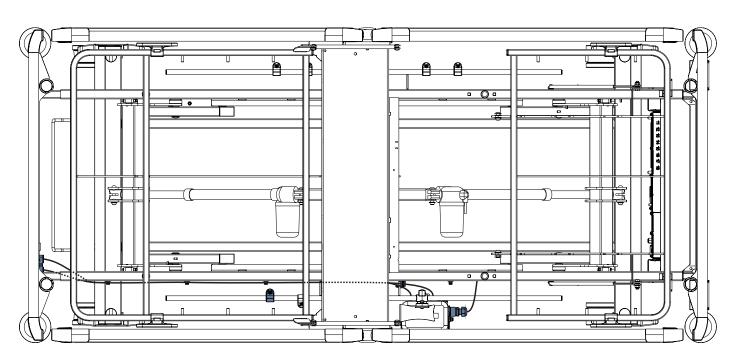


Fig. LAN cable and Nurse Call cable connected to the interconnecting elements for Nurse Call cable and LAN cable



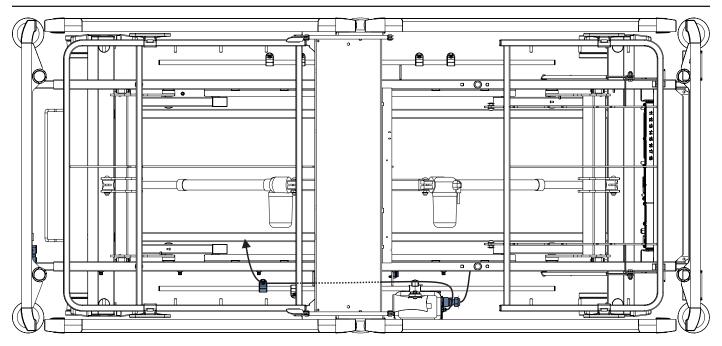


Fig. Air Hose connected to the Hub

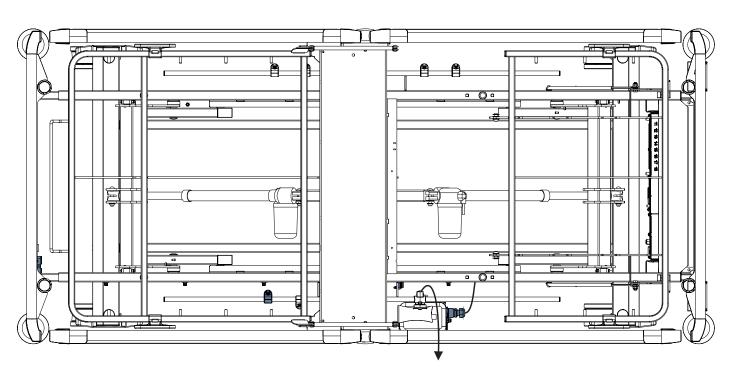


Fig. Wetness Pad cable connected to the Hub



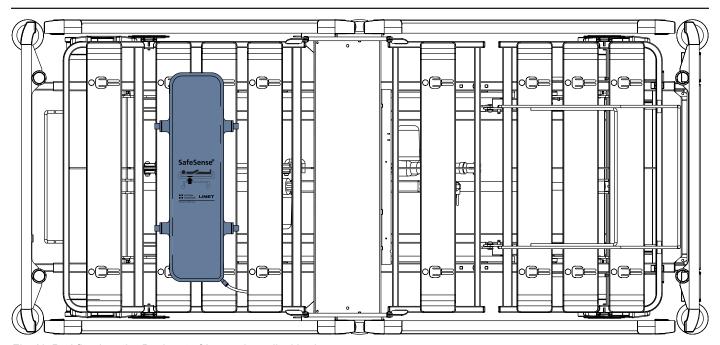


Fig. Air Pad fixed on the Backrest of Image 3 medical bed

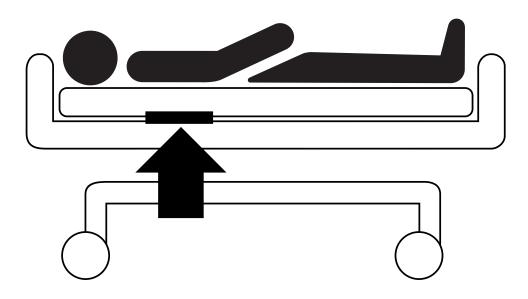
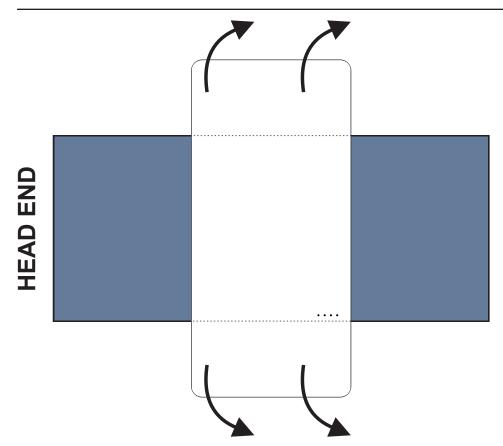


Fig. Position of the Air Pad under the mattress with patient





# To place Wetness Pad on a mattress:

- Put Wetness Pad over the mattress seat section to have 2 overlapping ends of the Wetness Pad on the sides of the mattress. Four connectors on the Wetness Pad are facing a surface of the compatible mattress.
- Connect Wetness Pad
  Cable to the 4 connectors on the
  Wetness Pad. There are two correct
  ways of connecting the Wetness
  Pad Cable to the Wetness Pad
  depending on the starting position of
  the Wetness Pad connectors.
- ► Slip the overlapping ends of the Wetness Pad under the sides of the mattress.

Fig. Position of the Wetness Pad on the compatible mattress

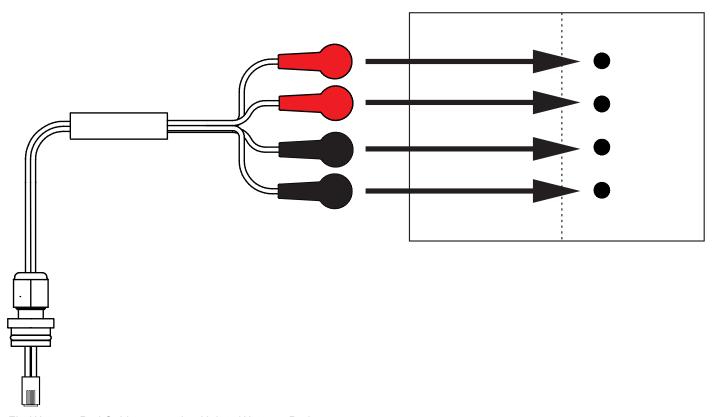


Fig. Wetness Pad Cable connecting Hub to Wetness Pad



#### To connect Wetness Pad to the SafeSense® 3 system:

- Connect the RJ connector on the opposite side of the Wetness Pad cable to the Hub (connector in the position 3).
- ► Connect 4 connectors of the Wetness Pad cable to the four connectors on the Wetness Pad according to labels on the cable.

#### ORDER OF THE CONNECTION OF THE FOUR WETNESS CABLE CORES

Order	1	2	3	4
Cable core marked by this label	000	0000	0000	000

## 9.3 Eleganza 2 with SafeSense® 3



#### **WARNING!**

#### Risk of injury and risk of material damage due to incorrectly installed Hub box!

- SafeSense® 3 Hub must be placed on the Hub holder and these two components must be fixed on the accessory rail on the right bed side under the seat section!
- Avoid collisions between Hub holder and accessories of the bed and between Hub box and accessories of the bed!
- Ensure the indispensable cables are correctly and safely connected to the Hub box!



#### WARNING!

# Risk of injury and risk of material damage due to incorrect installation of cables and incorrect installation of the Air Hose!

- ► Ensure the cables leading to the SafeSense® 3 Hub are not kinked or sheared or otherwise machanically damaged during bed positioning or during manipulation with accessories of the bed!
- ▶ When routing cables from SafeSense® 3 system in the Eleganza 2 medical bed avoid squeezing those cables between parts of the medical bed!
- Cables of the SafeSense® 3 system and Air Hose must not be tensioned!
- ▶ Ensure the Air Hose is correctly connected to the Hub box and to the Air Pad!
- Avoid squeezing, kinking, shearing of the Air Hose or other mechanical damage to the Air Hose!



#### WARNING!

#### Risk of injury and risk of material damage due to incorrect installation of Air Pad and Wetness Pad!

- ▶ Use only mattress compatible with SafeSense® 3 system!
- ▶ Air Pad must be fixed on the Backrest of the Eleganza 2 medical bed. Prevent the Air Pad from moving on the Backrest under the mattress!
- ▶ Ensure the Air Hose is correctly connected to the Air Pad fixed on the Backrest of the Eleganza 2 medical bed!
- ▶ Wetness Pad must be placed on the seat section of the compatible mattress and the ends of the Wetness Pad must be put under the seat section of the compatible mattress.
- Wetness Pad must not be covered with a plastic foil!
- ► Ensure the cable connecting Wetness Pad with the SafeSense® 3 Hub is correctly connected to the SafeSense® 3 Hub and to the Wetness Pad.



#### **CAUTION!**

#### Risk of material damage due to steam cleaning of the SafeSense 3 Monitoring System!

Always remove the components of the SafeSense® 3 Monitoring System (Hub Box, Air Pad, Wetness Pad and cables) from the Eleganza 2 medical bed on which the system has been installed!



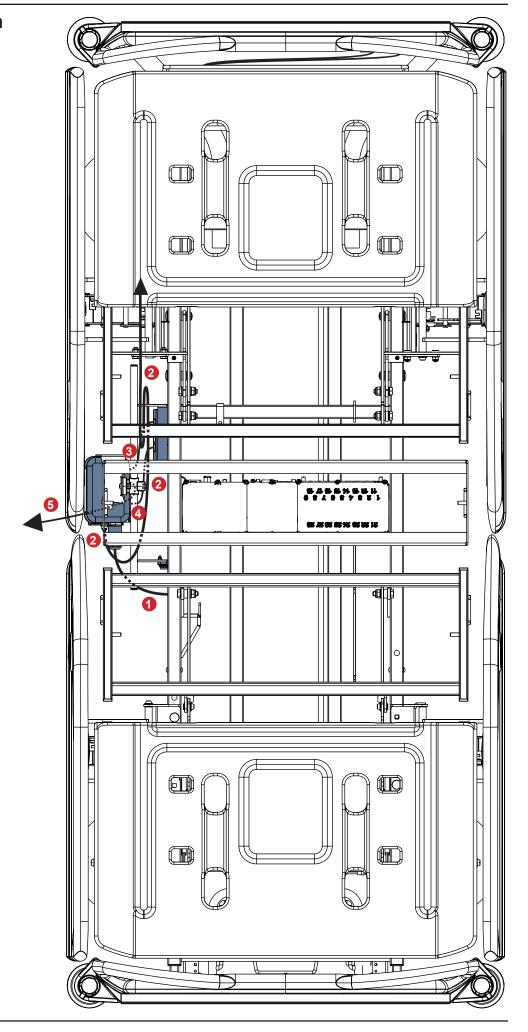
## 9.3.1 Instructions for putting into service

- Place the Hub Holder on the accessory rail on the right side of the Eleganza 2 bed so that the holder with interconnecting elements for Nurse Call cable and LAN cable will be accessible next to the left side of the Hub Holder.
- Tighten the safety bolt to fix Hub Holder on the accessory rail. Check if the Hub Holder is safely installed on the accessory rail.
- Connect LAN cable, Nurse Call cable and Wetness Pad cable to the back side of the Hub box.
- Tighten grommets of the connected cables on the back side of the Hub box by turning.
- ▶ Secure the connected cables by inserting comb-like part.
- Place the Hub to the Hub Holder and ensure the Hub is fixed in the Hub Holder by the raised latch.
- Disconnect the Power Supply/Data cable from the safety position behind the accessory rail.
- Remove the plug covering the connector on the right side of the Hub.
- Connect Power Supply/Data cable to the connector on the right side of the Hub.
- ► Connect LAN cable and Nurse Call cable to the interconnecting elements for LAN cable and Nurse Call cable in the holder next to the left side of the Hub. LAN cable must be connected to the left white socket. Nurse Call cable must be connected to the right black socket.
- ▶ Raise the Backrest of the Eleganza 2 bed to the highest position.
- Fix the Air Pad on the Backrest so that the Air Pad will be placed over the space between the 2 plastic parts on the Backrest and the fixing straps will be led through the 4 holes in the 2 different plastic parts.
- Connect the Air Hose to the right side of the Hub.
- Route the Air Hose above the accessory rail towards the head end of the bed.
- ► Run the Air Hose through the hole in the left accessory rail holder next to the holder with interconnecting elements for Nurse Call cable and LAN cable.
- ▶ Run the Air Hose upwards and then back above the accessory rail in order to run the Air Hose between the Backrest and the Seat section.
- ▶ Run the Air Hose towards the head end of the bed in groove of the Backrest plastic part.
- ► Connect the Air Hose to the Air Pad fixed on the Backrest.
- ▶ Ensure the Backrest adjustment does not damage the Air Hose and the Air Hose is not squeezed in any position of the Backrest.
- Place a compatible mattress on the mattress support platform of the Eleganza 2 bed.
- ▶ Place Wetness Pad on the mattress without any sheet to the correct position in the seat section of the patient. Four connectors on the Wetness Pad are facing a surface of the compatible mattress.
- ► Connect Wetness Pad cable to the Wetness Pad according to the four labels on the Wetness Pad cable. There are two ways of connection depending on the starting position of the Wetness Pad that are in accordance with the correct use. Slip the overlapping ends of the Wetness Pad on the both sides of the Eleganza 2 bed under the mattress.
- ► Place a sheet on the mattress.
- Connect the cable connected to the local Nurse Call system to the interconnecting element for Nurse Call cable at head end of the Eleganza 2 bed, if the use of the Nurse Call system with SafeSense® 3 system is required.
- ► Connect the local LAN cable to the interconnecting element for LAN cable at head end of the Eleganza 2 bed, if wireless signal from Hub is not used for communication between Hub and a hardware with installed CareMonitor Application.
- ▶ Place patient on the Eleganza 2 bed.
- ► Activate Hub according to the instructions for use.
- Open the CareMonitor Application.
- Activate the Hub and check if the corresponding bed is visible on the CareMonitor Screen.
- ▶ Perform the same steps to activate the other Hubs and to display the corresponding beds on the CareMonitor Screen.

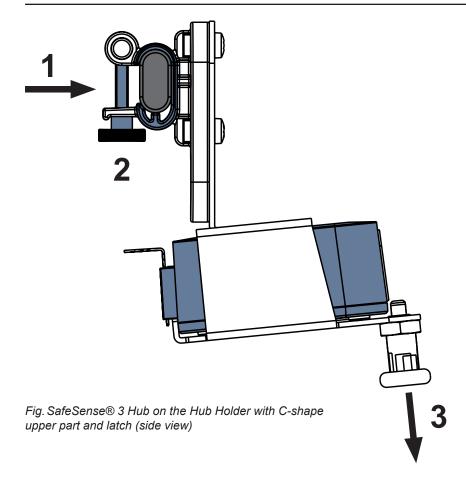


# SafeSense® 3 system on the right side of the Eleganza 2 bed

- 1. Power Supply/Data cable
- 2. Air Hose
- 3. LAN cable
- 4. Nurse Call cable
- 5. Wetness Pad cable







#### To fix Hub Holder on the accessory rail:

- ► Mount Hub Holder on the accessory rail. (1)
- ► Tighten the safety bolt (2) to fix Hub Holder on the accessory rail.

#### To fix Hub in the Hub Holder:

- ► Hold a latch of the Hub Holder pulled down (3).
- ▶ Place Hub to the Hub Holder.
- ► Ensure the Hub is fixed in the Hub Holder by the raised latch.

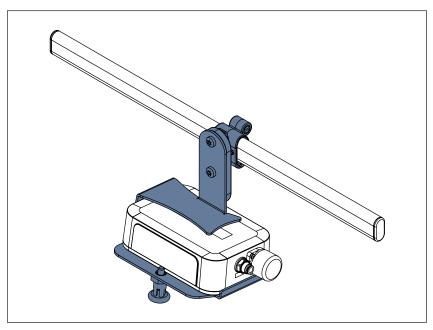


Fig. SafeSense® 3 Hub with Hub Holder on the accessory rail



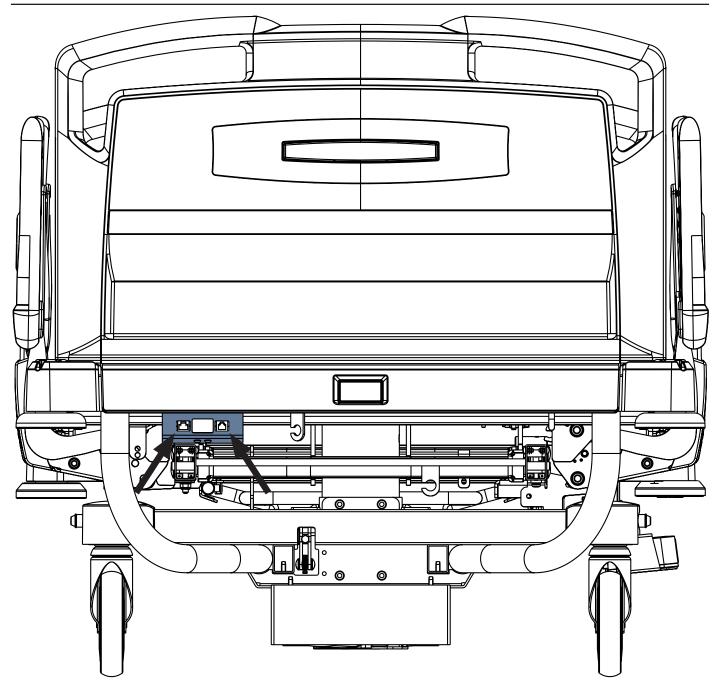


Fig. Interconnecting elements for Nurse Call cable and LAN cable at head end of the Eleganza 2 bed



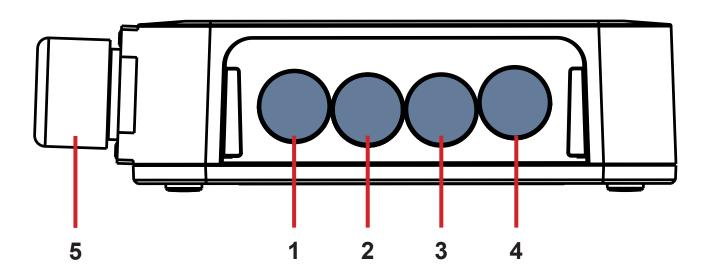


Fig. Hub Connectors (back side)

- 1. NOT AVAILABLE CONNECTOR
- 2. Nurse Call cable
- 3. Wetness Pad cable
- 4. LAN cable
- 5. Power Supply/Data cable

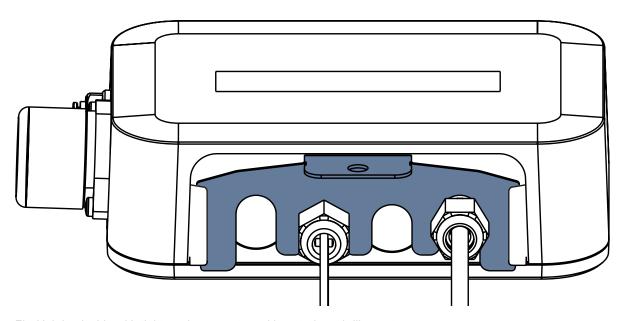


Fig. Hub back side with tightened grommets and inserted comb-like part



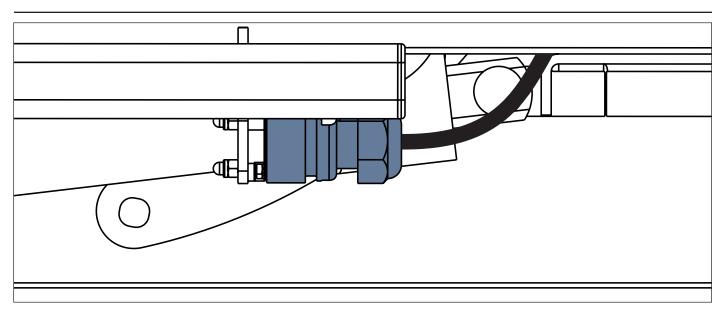


Fig. Power Supply/Data cable in the safety position behind the accessory rail

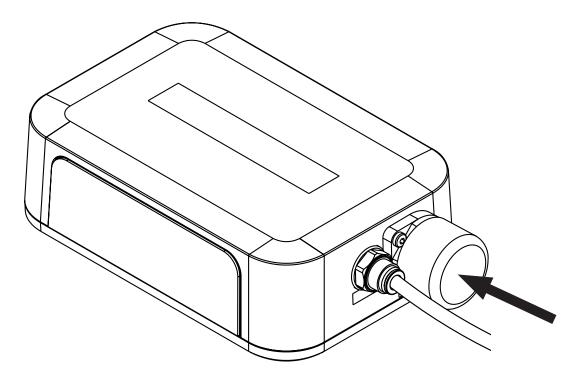


Fig. Covered connector for Power Supply/Data cable



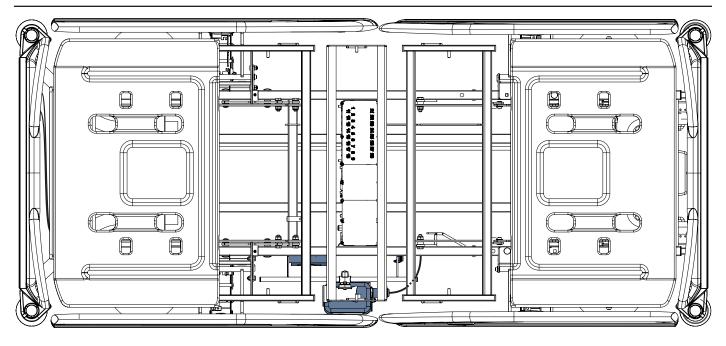


Fig. Power Supply/Data cable connected to the Hub

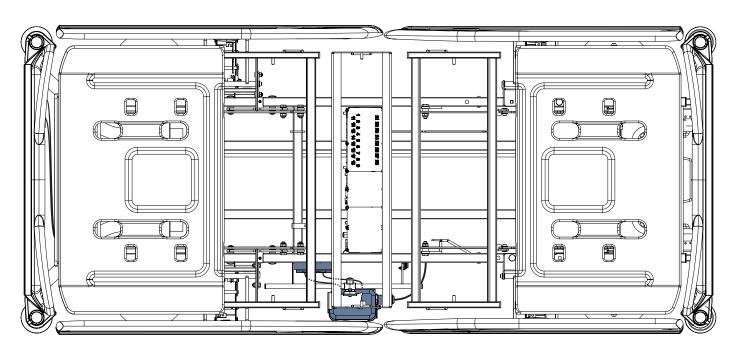


Fig. LAN cable and Nurse Call cable connected to the interconnecting elements for Nurse Call cable and LAN cable



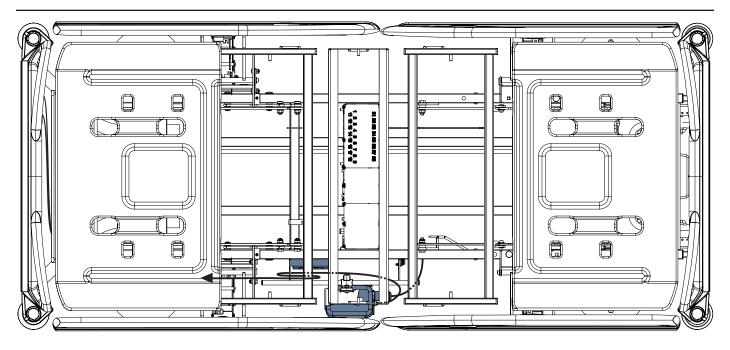


Fig. Air Hose connected to the Hub

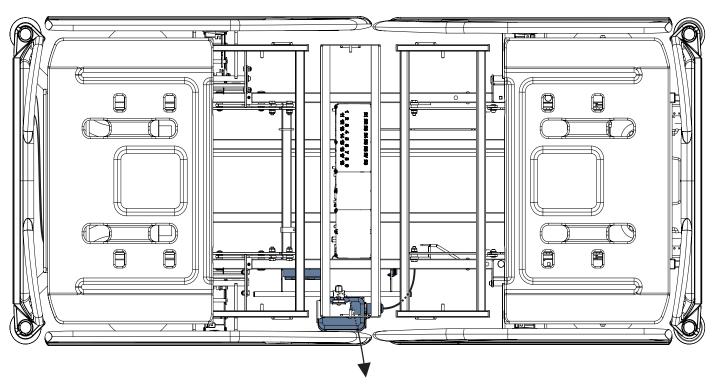


Fig. Wetness Pad cable connected to the Hub



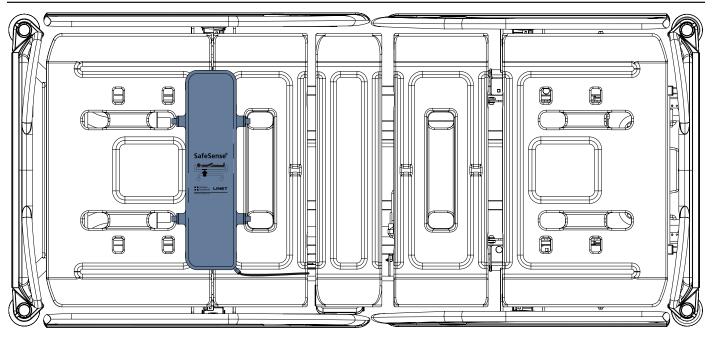


Fig. Air Pad fixed on the Backrest of Eleganza 2 medical bed

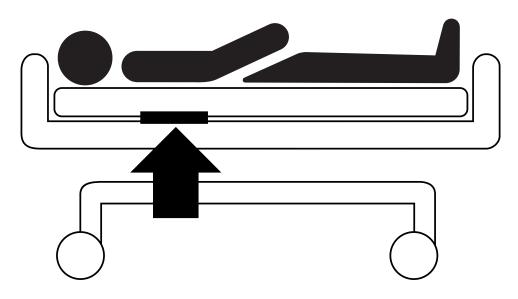
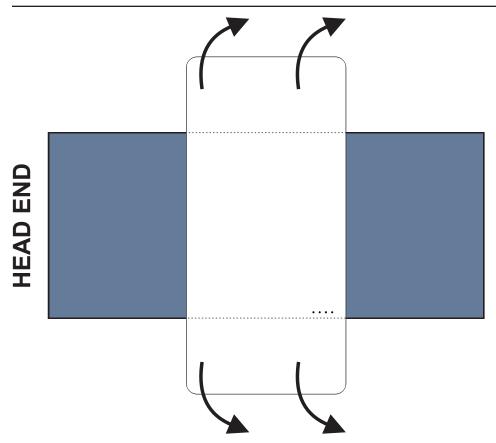


Fig. Position of the Air Pad under the mattress with patient





# To place Wetness Pad on a mattress:

- Put Wetness Pad over the mattress seat section to have 2 overlapping ends of the Wetness Pad on the sides of the mattress. Four connectors on the Wetness Pad are facing a surface of the compatible mattress.
- Connect Wetness Pad
  Cable to the 4 connectors on the
  Wetness Pad. There are two correct
  ways of connecting the Wetness
  Pad Cable to the Wetness Pad
  depending on the starting position of
  the Wetness Pad connectors.
- ► Slip the overlapping ends of the Wetness Pad under the sides of the mattress.

Fig. Position of the Wetness Pad on the compatible mattress

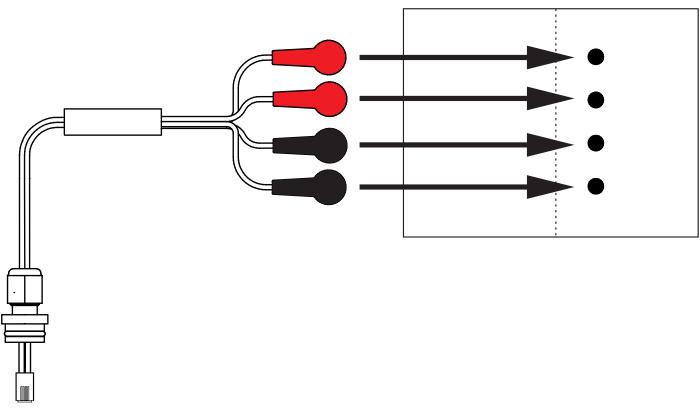


Fig. Wetness Pad cable connecting Hub to Wetness Pad



#### To connect Wetness Pad to the SafeSense® 3 system:

- ▶ Connect the RJ connector on the opposite side of the Wetness Pad cable to the Hub (connector in the position 3).
- Connect 4 connectors of the Wetness Pad cable to the four connectors on the Wetness Pad according to labels on the cable.

## ORDER OF THE CONNECTION OF THE FOUR WETNESS CABLE CORES

Order	1	2	3	4
Cable core marked by this label	000	0000	0000	000



# 10 AC/DC Adaptor (only for Stand-alone Version)



#### **WARNING!**

Where the integrity of the external protective conductor in the installation or its arrangement is in doubt

use the other power source that is not in doubt.



#### **WARNING!**

Inappropriate handling of the power supply cord, e. g. by kinking, shearing or other mechanical damages is hazardous!



#### WARNING!

When routing cable from AC/DC Adaptor in a medical bed avoid squeezing the cable between parts of the medical bed!



#### WARNING!

An additional multiple socket-outlet or extension cord shall not be connected to the SafeSense® 3 system.

Attachment plug is means of connecting and disconnecting SafeSense® 3 system from the mains.

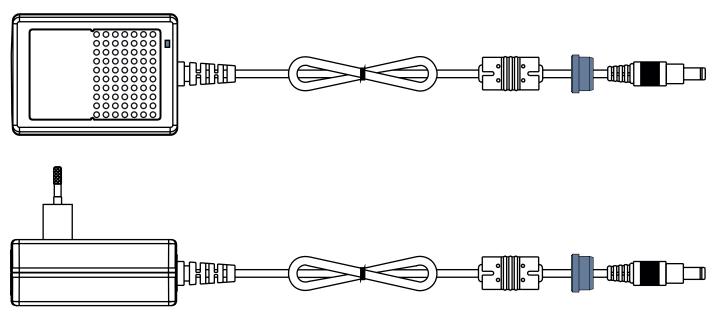


Fig. AC/DC Adaptor connecting Hub to the mains power (with grommet on the Power Supply cable)

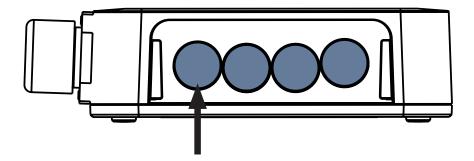


Fig. Connector for Power Supply cable (back side of the Hub Box)

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# 11 Manipulation



#### **WARNING!**

A source of air flow near to the installed SafeSense® 3 system can affect the information functions of the system!

▶ Before and during the use of this system check the possible sources of air flow (e.g. air-conditioner) to ensure you will be informed about statuses whose detection can help you in care for a patient and not about environmental conditions



#### **WARNING!**

Do not manipulate the bed if the SafeSense 3 Monitoring System is activated on it!



#### **WARNING!**

SafeSense 3 Monitoring System consists of the parts whose simultaneous working is necessary for the proper functioning of the whole system! Unless the CareMonitor Application is activated, outputs from the Hub could not be displayed correctly later in the CareMonitor Application!

SafeSense® 3 provides 4 main functions: Bed Exit Monitoring, Motion Monitoring, Decubitus/Movement Notification and optionally Wetness Monitoring.



## 11.1 Bed Exit Monitoring

Bed Exit Monitoring is intended to notify nursing personnel that the monitored patient has left the bed.

Bed Exit alert is indicated by an acoustic signal when patient is out of the supporting bed.

Bed Exit alert is also indicated visually on the display of Attendant Control Panel with SafeSense® 3 Control and on the CareMonitor user interface.

Nursing personnel can set delayed reaction of the Bed Exit Monitoring system so the patient can return before Bed Exit alert is triggered. Periods for Bed Exit Monitoring are **early** (about **3** seconds) or **10** seconds or **20** seconds or **30** seconds or **40** seconds or **50** seconds or **1** minutes or **10** minutes or **15** minutes or **30** minutes.

Bed Exit acoustic alert is automatically muted when patient correctly returns to the bed during triggered Bed Exit alert.

#### To set Bed Exit Monitoring use:

- ▶ CareMonitor
- ▶ Attendant Control Panel with SafeSense 3 Control (only for Image 3 and Eleganza 2)

## 11.2 Motion Monitoring

Motion Monitoring is intended to notify nursing personnel of the patient's motions on the bed.

Nursing personnel can set a period during which the absence of patient movement on the bed is tolerated.

Periods for Motion Monitoring are multiples of 5 minutes from 10 minutes to 100 minutes.

Countdown to the end of selected period starts again from the beginning after patient movement on the mattress.

CareMonitor shows chart of the patient movements if it is allowed in the Display settings.

Alert is triggered if no patient movement occurs before the set period has elapsed.

#### To set Motion Monitoring use:

- CareMonitor
- ▶ Attendant Control Panel with SafeSense 3 Control (only for Image 3 and Eleganza 2)

#### 11.3 Decubitus/Movement Notification

Decubitus/Movement Notification provides timer which triggers an acoustic signal alerting the nursing personnel.

Nursing personnel can set a period after which notification to check position of the patient is triggered.

Periods for Decubitus/Movement Notification are 2 hours or 3 hours or 4 hours or 5 hours or 6 hours.

Visual and acoustic alert is triggered after the set period has elapsed depending on the current setting.

#### To set Decubitus/Movement Notification use:

- CareMonitor
- ▶ Attendant Control Panel with SafeSense 3 Control (only for Image 3 and Eleganza 2)

# 11.4 Wetness Monitoring

Wetness Monitoring is intended to notify nursing personnel of the bodily fluids on the bed sheet or directly on the mattress (e.g. urine).

Nursing personnel can set sensitivity of the Wetness Monitoring on the CareMonitor.

Limits of the wetness sensitivity are 25% or 50% or 75% or 100%.

Alerts are triggered after the set wetness sensitivity has been exceeded.

Attendant Control Panel with SafeSense® 3 Control indicates visual alerts depending on the current setting

#### To set Wetness Monitoring use:

CareMonitor



### 11.5 Control Elements

- ▶ Hub Control Panel
- CareMonitor
- ▶ Attendant Control Panel with SafeSense 3 Control (only for Image 3 and Eleganza 2)

#### 11.5.1 Hub Control Panel

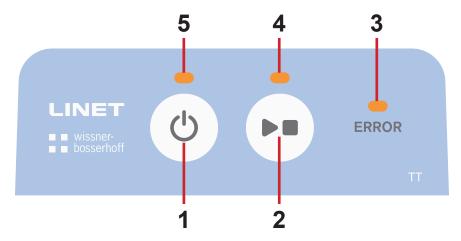


Fig. Hub Control Panel

- 1. Activation Button (to activate SafeSense® 3)
- 2. PLAY or STOP Button (to activate or deactivate monitoring)
- 3. ERROR LED (lit red internal error)
- 4. PLAY or STOP LED (monitoring ON lit green, monitoring OFF lit blue)
- 5. Activation LED (SafeSense® 3 ON and battery charged to more than 75% lit green, SafeSense® 3 ON and battery charged to 25% 75% lit light blue, SafeSense® 3 ON and battery fault lit red, SafeSense® 3 OFF not lit)

#### To activate SafeSense® 3:

► Press button ()

Activation LED (5) indicates activated SafeSense® 3 when it is lit green.

It is possible to start or stop monitoring selected by CareMonitor Application or by Attendant Control Panel with SafeSense® 3 Control.

To start monitoring selected by CareMonitor Application or by Attendant Control Panel with SafeSense® 3 Control:

PLAY or STOP LED (4) is lit green when selected monitoring is ON.

To stop monitoring selected by CareMonitor Application or by Attendant Control Panel with SafeSense® 3 Control:

▶ Press button ▶■ when monitoring is ON.

PLAY or STOP LED (4) is lit blue when selected monitoring is OFF.

#### To deactivate SafeSense® 3:

▶ Press button 🖒 .

Activation LED (5) indicates deactivated SafeSense® 3 when it is not lit.



#### 11.5.2 CareMonitor



#### **CAUTION!**

Setting confirmed on a single CareMonitor influences setting on the other CareMonitors if more SafeSense® Applications run in the same SafeSense® 3 system!

► Check the CareMonitor settings regularly to ensure you will be informed about statuses whose detection can help you in care for a patient.



#### **CAUTION!**

It is not possible to run the SafeSense® Application more than once on one device!

Check if the SafeSense Application is activated only once when it is flashing in the error mode.



#### **CAUTION!**

If SafeSense® Application is used by one user at the hardware where SafeSense® Application is installed and Attendant Control Panel with SafeSense® 3 Control is used by another user at the Image 3 bed or Eleganza 2 bed to set selected monitoring, the later setting prevails!



#### **WARNING!**

The SafeSense® Application is using the system time of a device where the Application is running. The time might differ from the Hub system time. When the time difference is greater than 5 minutes user is notified in the SafeSense® Application and "system time not found." is displayed in the Chart of Motion History!

SafeSense® Application allows setting of all SafeSense® 3 functions (Bed Exit Monitoring, Motion Monitoring, Decubitus/Movement Notification and Wetness Monitoring), indicates alerts and shows history of motion monitoring. Acoustic signalisation of the alerts can be mediated only through the CareMonitor Application. No sound indicating alerts comes out of the Hub and of the Attendant Control Panel with SafeSense® 3 Control. SafeSense® Application provides global setting of the functions in relation to all the patients and also individual setting of the functions in relation to each patient. The CareMonitor user interface could be displayed in the Dark Mode for adaptation to an ambient light conditions. It is possible to use more SafeSense® Applications on different devices simultaneously. The CareMonitor Application is the only place to check if selected bed is successfully connected to the system SafeSense® 3.

#### **SENSITIVITY**

Sensitivity settings are intended for adapting monitoring conditions with regard to the patient's mobility. If a patient is rather restless, the monitoring sensitivity can be decreased (up to the low level) based on the nursing staff expert assessment in order to avoid detection of the redundant statuses which are not useful for nursing supervision. Lowering the monitoring sensitivity increases the reaction time concerning patient's detected bed entries and bed exits. If a patient is rather still, the monitoring sensitivity can be increased (up to the high level) based on the nursing staff expert assessment in order to enable the detection of all possible statuses that could be helpful for nursing supervision.



## **CAREMONITOR SCREEN**

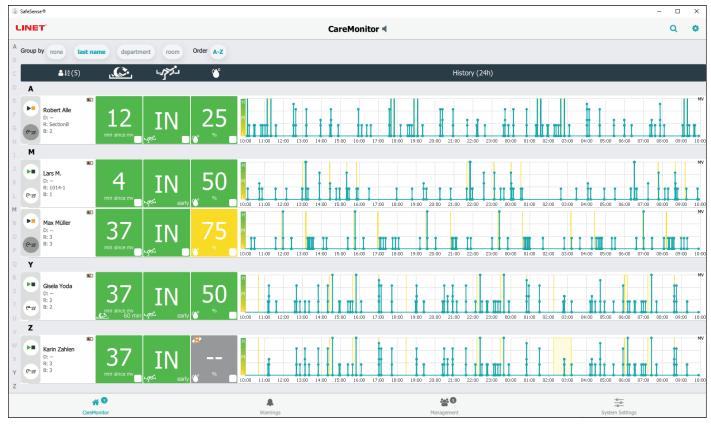


Fig. CareMonitor Screen

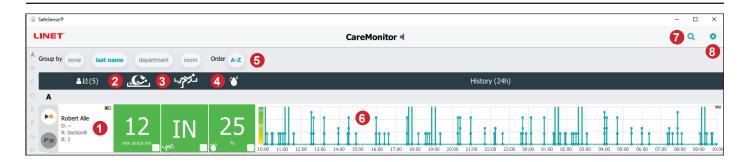
CareMonitor Screen is the default main screen of the SafeSense Application.

**GEAR Icon** in the upper right corner of the CareMonitor Screen provides **Global warnings** settings and **Display** settings.

Bottom bar of the CareMonitor Screen provides access to the 4 screens:

- CareMonitor Screen
- Warnings Screen
- Management Screen
- System Settings Screen





- 1. Tile with Patient Name
- 2. Status of Motion Monitoring or Status of Decubitus/Movement Notification (displayed or hidden)
- 3. Status of Bed Exit Monitoring (displayed or hidden)
- 4. Status of Wetness Monitoring (displayed or hidden)
- 5. Grouping of the patients/Hubs according to last name or department or room or alphabetical order from A to Z or from Z to A (none no grouping is selected)
- 6. Chart of Motion History (H HIGH, M MEDIUM, L LOW, displayed or hidden)
- 7. HAND GLASS Icon (search a selected word)
- 8. GEAR Icon (settings Global warnings or Display)

**NOTE**: Upper horizontal bar with warning notifications under the CareMonitor heading can be displayed or hidden depending on the presence of a triggered warning notification.



- 1. CareMonitor screen (with number of monitored patients)
- 2. Warnings screen (with number of notifications)
- 3. Management screen
- 4. System Settings screen

#### **COLOURS OF THE TILES**

Colour	Meaning
	<b>GREY</b> : no monitoring: either no value could be received (intentionally disabled or because of wrong values) or that Air Pad or Wetness Pad is disconnected
	GREEN: monitoring activated, status without warning: values are in between threshold ranges (OR WARNINGS TURNED OFF when monitoring is activated!)
	YELLOW: early warning: warning phase was reached, but no immediate action is required
	<b>ORANGE</b> : a severe event was detected but no immediate action is required (e.g. Decubitus/Movement Notification clock ran out of time or no movement detected for a specific amount of time during Motion Monitoring)
	<b>RED</b> : a critical event was detected and a manual action is required (e.g. Bed Exit alert indicates possible fall so the nurse should visit patient immediatly)



# **ALERTS**

Tile	Meaning
OUT 5 min	ALERT OF BED EXIT MONITORING
47 min since mv 45 min	ALERT OF MOTION MONITORING
reposition!	ALERT OF DECUBITUS/MOVEMENT NOTIFICATION
<b>50</b> %*	ALERT OF WETNESS MONITORING



# STATUSES OF BED EXIT MONITORING

Tile	Meaning
IN 5 min	BED EXIT MONITORING ACTIVATED PATIENT ON THE BED
OUT	BED EXIT MONITORING ACTIVATED PATIENT OUT OF THE BED NO ALERT INDICATED BECAUSE ALERT NOTIFICATIONS ARE DELAYED INTENTIONALLY
OUT  10 sec	EARLY WARNING
OUT 5 min	BED EXIT ALERT IMMEDIATE ACTION REQUIRED



# STATUSES OF MOTION MONITORING

	Tile		Meaning
<u>.C.</u>	min since mv	10 min	MOTION MONITORING NOT ACTIVATED
Ŀ	46 min since mv	70 min	MONITORING ACTIVATED, NO WARNING
			EARLY WARNING
۵	21 min seit mv	25 min	
<u>e</u>	47	45 min	ALERT



# STATUSES OF DECUBITUS/MOVEMENT NOTIFICATION

Tile	Meaning
2 h 0 min ∴	NOT ACTIVATED OR RESET
1 h 59 min at 16:31	DECUBITUS/MOVEMENT NOTIFICATION ACTIVATED
reposition!	ALERT



# STATUSES OF WETNESS MONITORING

Tile	Meaning
<b>←</b>	WETNESS PAD DISCONNECTED WETNESS MONITORING NOT ACTIVATED
<b>∞°</b>	
25 **	WETNESS MONITORING ACTIVATED
<b>75</b> ♣	EARLY WARNING
100 **	ALERT



#### **GLOBAL WARNINGS SETTINGS**

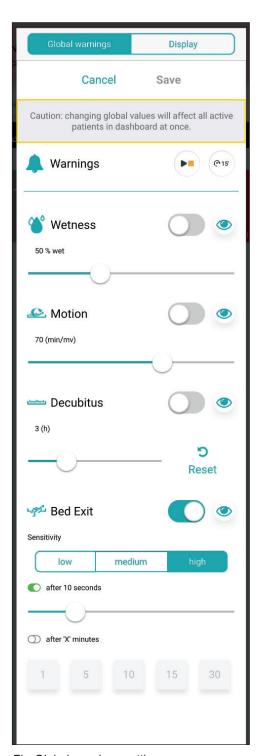


Fig. Global warnings settings

Abbreviation	Meaning
Wetness	Wetness Monitoring
Motion	Motion Monitoring
Decubitus	Decubitus/Movement Notification
Bed Exit	Bed Exit Monitoring

#### **RANGES OF VALUES**

Periods for Bed Exit Monitoring are **early** (about **3** seconds) or **10** seconds or **20** seconds or **30** seconds or **40** seconds or **50** seconds or **1** minute or **5** minutes or **10** minutes or **15** minutes.

Periods for Motion Monitoring are multiples of **5** minutes from **10** minutes to **100** minutes.

Periods for Decubitus/Movement Notification are 2 hours or 3 hours or 4 hours or 5 hours or 6 hours.

Limits of the wetness sensitivity are 25% or 50% or 75% or 100%.

#### To set Sensitivity of the Bed Exit Monitoring and Motion Monitoring:

Click on low button or medium button or high button.

Indicator	Meaning
	Warning will be triggered on each CareMonitor user interface connected to the SafeSense® 3 system when corresponding status occurs during activated monitoring (WARNINGS TURNED ON).
	Warning will <b>not</b> be triggered on any CareMonitor user interface connected to the SafeSense® 3 system when corresponding status occurs during activated monitoring (WARNINGS TURNED OFF).
	Warnings visible on a single CareMonitor user interface and audible from a single CareMonitor user interface and sent to Nurse Call system.
90	Warnings not visible on a single CareMonitor user interface and not audible from a single CareMonitor user interface, but sent to the Nurse Call system.
ි Reset	Click on this button to zero the countdown of the Decubitus/Movement Notification. If a set period is changed, the countdown related to the previous setting is not reset. RESET button serves to reset the running countdown.



#### To enter Global warnings settings:

- Click on the GEAR Icon ( .).
- ► Click on the Global warnings field.
- ► Click on the **Save** in the upper right corner of the window.

#### To enable Nurse Call alert only:

#### To change a setting of selected monitoring:

- ▶ Click on a corresponding sliding button, keep it and slide to the required position.
- ► Click on the **Save** in the upper right corner of the window.

NOTE: Setting of the Bed Exit Monitoring includes sliding button and tiles with values in minutes.



## **GLOBAL DISPLAY SETTINGS**

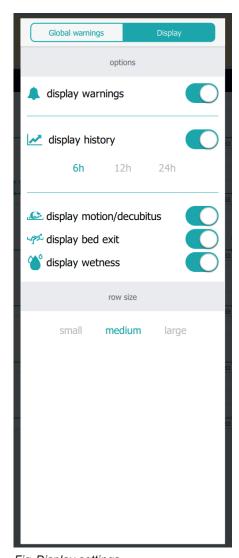


Fig. Display settings

Indicator	Meaning
	ON
	OFF

Function	Meaning
display warnings	ON: Upper horizontal bar with warning notifications is displayed on the CareMonitor screen.  OFF: Upper horizontal bar with warning notification is hidden on the CareMonitor screen.
display history	ON: Chart of Motion History is displayed on the CareMonitor screen with selected range of hours (6 hours or 12 hours or 24 hours).  OFF: Chart of Motion History is hidden.
display motion/decubitus	ON: Tiles indicating Motion Monitoring statuses or Decubitus/Movement Notification statuses are displayed on the CareMonitor screen.  OFF: Tiles indicating Motion Monitoring statuses or Decubitus/Movement Notification statuses are hidden on the CareMonitor screen.
display bed exit	ON: Tiles indicating Bed Exit Monitoring statuses are displayed on the CareMonitor screen. OFF: Tiles indicating Bed Exit Monitoring statuses are hidden on the CareMonitor screen.
display wetness	ON: Tiles indicating Wetness Monitoring statuses are displayed on the CareMonitor screen.  OFF: Tiles indicating Wetness Monitoring statuses are hidden on the CareMonitor screen.
row size	To set proportions of the displayed tiles on the Care- Monitor screen, click on a corresponding word (three sizes are available: <b>small</b> , <b>medium</b> , <b>large</b> ).

#### To enter Display settings:

- Click on the GEAR Icon ( .).
- ► Click on the **Display** field.
- ► Click anywhere outside the Global warnings window.

#### To set proportions of the displayed tiles on the CareMonitor screen:

- Click on the GEAR Icon ( ).
- ► Click on the **Display** field.
- Click on small or medium or large.

Name of the selected size will be highlighted.

Click anywhere outside the Global warnings window.



#### SINGLE PATIENT SCREEN

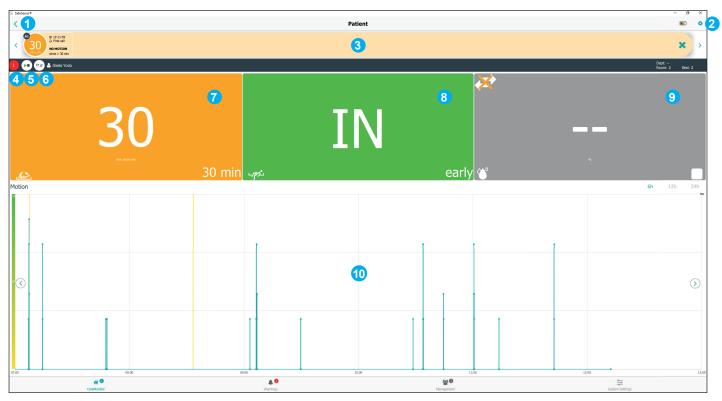


Fig. View on a single monitored patient (Patient screen)

Indicator	Meaning
•	Press the PLAY/STOP Icon to deactivate notification of warnings for the single patient.
•	Notification of warnings is OFF. Press the PLAY/STOP Icon to activate notification of warnings for the single patient. PAUSE function is disabled (grey circle).
(°15')	No type of monitoring is PAUSED. Press the white PAUSE Icon to pause all types of monitoring.
12min	All types of monitoring are PAUSED for 15 minutes (or less). Press the orange PAUSE Icon to cancel the PAUSE period.

- 1. BACK to the CareMonitor screen
- 2. GEAR Icon (settings for single patient)
- 3. Upper horizontal bar with warning notifications (left and right arrows allow transition to the other warning notifications of the same patient)
- 4. Number of warnings related to this patient
- 5. PLAY/STOP Icon (green triangle + black square: warning notifications ON; black triangle + orange square: warning notifications OFF)
- 6. PAUSE Icon (white circle: monitoring not PAUSED; orange circle: monitoring PAUSED for 15 minutes)
- 7. Status of Motion Monitoring or Status of Decubitus/Movement Notification
- 8. Status of Bed Exit Monitoring
- 9. Status of Wetness Monitoring
- 10. Chart of Motion History (H HIGH, M MEDI-UM, L LOW)

#### To enter Patient screen:

► Click on the tile with patient name or on a tile of the monitoring statuses next to the tile with patient name on the CareMonitor screen.

#### To enter settings for single patient:

Click on the GEAR Icon ( on the Patient screen.



#### SETTINGS FOR A SINGLE PATIENT

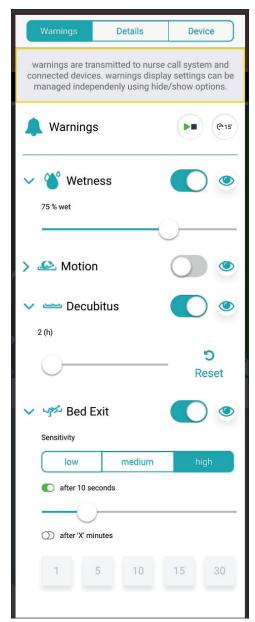


Fig. Warnings window (settings for single patient)

#### To change a setting of selected monitoring:

- ► Click on a corresponding sliding button, keep it and slide to the required position.
- ► Click anywhere outside the Warnings window.

**NOTE**: Setting of the Bed Exit Monitoring includes sliding button and tiles with values in minutes.

Abbreviation	Meaning
Wetness	Wetness Monitoring
Motion	Motion Monitoring
Decubitus	Decubitus/Movement Notification
Bed Exit	Bed Exit Monitoring

#### **RANGES OF VALUES**

Periods for Bed Exit Monitoring are early (about 3 seconds) or 10 seconds or 20 seconds or 30 seconds or 40 seconds or 50 seconds or 1 minute or 5 minutes or 10 minutes or 15 minutes or 30 minutes.

Periods for Motion Monitoring are multiples of **5** minutes from **10** minutes to **100** minutes.

Periods for Decubitus/Movement Notification are 2 hours or 3 hours or 4 hours or 5 hours or 6 hours.

Limits of the wetness sensitivity are 25% or 50% or 75% or 100%.

#### To set Sensitivity of the Bed Exit Monitoring and Motion Monitoring:

Click on low button or medium button or high button.

Indicator	Meaning
	Warning will be triggered on each CareMonitor user interface connected to the SafeSense® 3 system when corresponding status occurs during activated monitoring (WARNINGS TURNED ON).
	Warning will <b>not</b> be triggered on any CareMonitor user interface connected to the SafeSense® 3 system when corresponding status occurs during activated monitoring (WARNINGS TURNED OFF).
	Warnings visible on a single CareMonitor user interface and audible from a single CareMonitor user interface and sent to Nurse Call system.
90	Warnings not visible on a single CareMonitor user interface and not audible from a single CareMonitor user interface, but sent to the Nurse Call system.
ි Reset	Click on this button to zero the countdown of the Decubitus/Movement Notification.



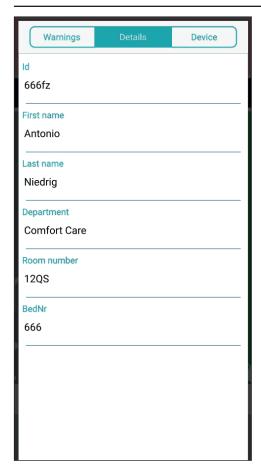


Fig. Patient Details (Id, First name, Last name, Department, Room number, BedNr)

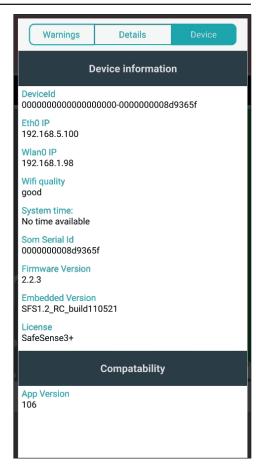


Fig. Device Specifications (DeviceId, Eth0 IP, Wlan0 IP, Wifi quality, System time, Som Serial Id, Firmware Version, Embedded Version, License, App Version)

#### To change Patient Details:

► Click on a selected line to write.



#### WARNINGS SCREEN

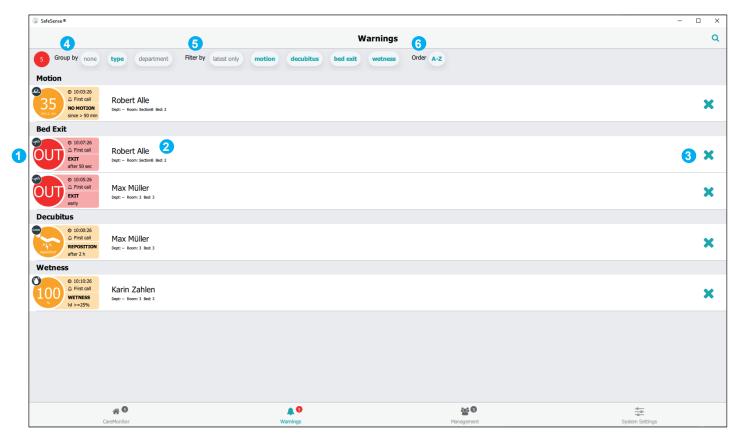


Fig. Warnings screen

- 1. Type of warning notification
- 2. Name of monitored patient
- 3. CROSS Icon (delete)
- 4. Grouping of the warnings according to type or department (none no grouping is selected)
- 5. Filter of the warnings according to warning type (motion, decubitus, bed exit, wetness) or according to newness (latest only)
- 6. Grouping of the warnings according to alphabetical order from A to Z or from Z to A

#### To enter Warnings screen:

Click on the Warnings Screen Icon ( ) on the bottom bar of CareMonitor screen.

#### To delete a bar with recorded warning notification:

▶ Click on the CROSS Icon on the right side of a bar with recorded warning notification.

#### To filter warning notifications according to the warning types:

► Click on the button with corresponding writing under the Warnings heading to select the types of warnings which should be displayed.

Buttons indicating the selected warning types are marked with green writings and the rest of warning types is not displayed.

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#### **MANAGEMENT SCREEN**

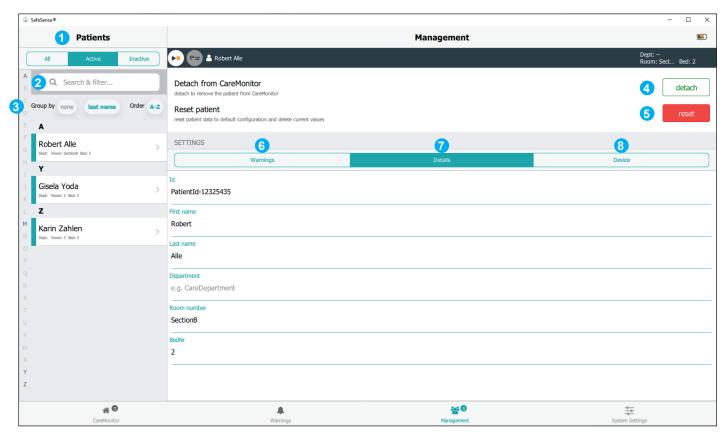


Fig. Management screen

- 1. Patients section (lists of patients according to the monitoring status: All or Active or Inactive)
- 2. Search & Filter field (search a selected word)
- 3. Grouping of the patients according to last name or alphabetical order from A to Z or from Z to A (none no grouping is selected)
- 4. Detach button (click on the button to turn off monitoring of the selected patient Detached patient is inactive and no monitoring can be set in his/her case in the SafeSense® 3 Monitoring System.)
- 5. Reset button (click on the button to reset patient data to default configuration and to delete current values of the patient in SafeSense® 3 Monitoring System)
- 6. Warnings Settings for Single Patient
- 7. Patient Details (Identification number, First name, Last name, Department, Room number, Bed number)
- 8. Device Specifications (Device identification number, Eth0 IP, Wlan0 IP, Wifi quality, System time, Som Serial Id, Firmware version, Embedded version, License, Application version)

#### To detach patient from the SafeSense® 3 Monitoring System:

- ▶ Select an active patient in the left column on the Management screen.
- ▶ Click on the Detach button in the upper right corner of the Management screen.



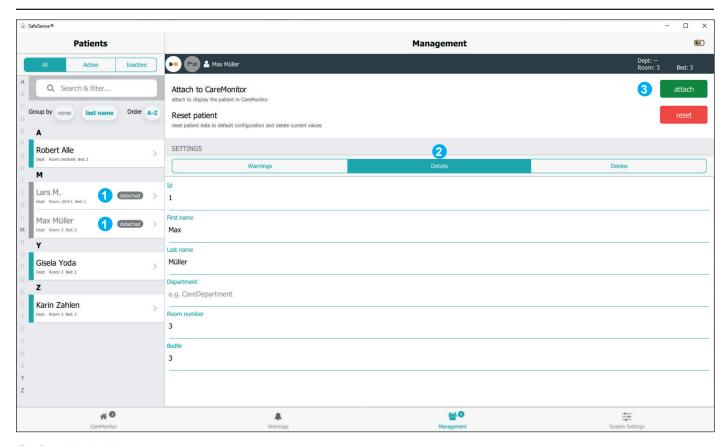


Fig. Detached patients

- 1. Detached patients (Inactive patients)
- 2. Patient Details (Identification number, First name, Last name, Department, Room number, Bed number)
- 3. Attach button (click on the button to turn on monitoring of the selected patient Attached patient is active and monitoring can be set in his/her case in the SafeSense® 3 Monitoring System.)

#### To attach patient to the SafeSense® 3 Monitoring System:

- ▶ Select a detached patient in the left column on the Management screen.
- ▶ Click on the Attach button in the upper right corner of the Management screen.



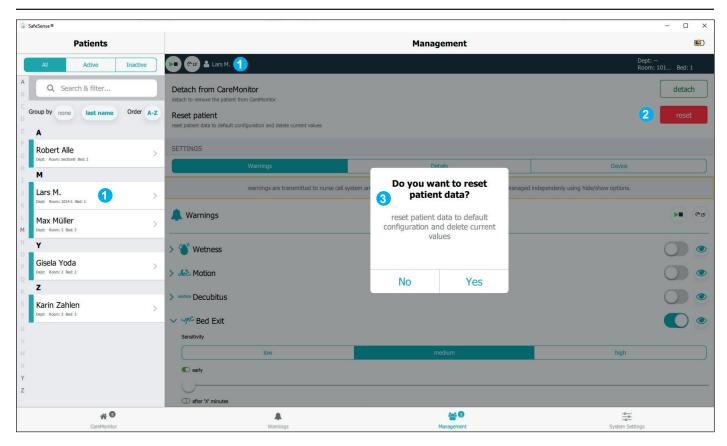


Fig. Reset confirmation window

- 1. Selected patient whose values will be reset
- 2. Reset button (click on the button to reset patient data to default configuration and to delete current values of the patient in SafeSense® 3 Monitoring System)
- 3. Reset confirmation window (press Yes to confirm the reset or No to cancel the reset)

#### To reset patient's settings and values:

- ▶ Select a patient in the left column on the Management screen.
- ▶ Click on the Reset button in the upper right corner of the Management screen.
- ▶ Confirm the reset by click on Yes on the Reset confirmation window.



#### SYSTEM SETTINGS

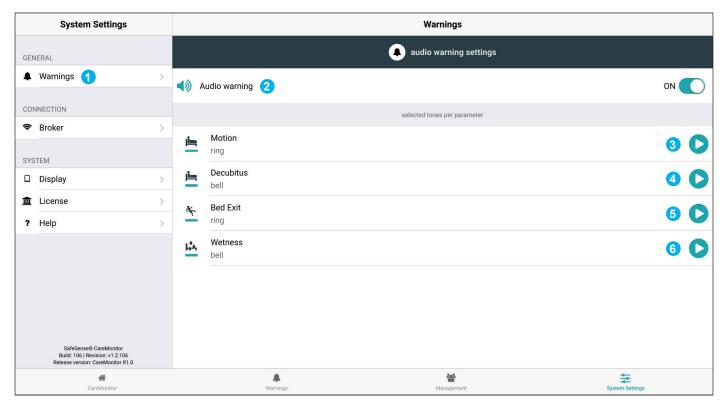


Fig. Warnings section of System Settings screen

- 1. Warnings section of System Settings
- 2. Global setting of the warning sounds (ON/OFF)
- 3. Tone indicating alerts of Motion Monitoring
- 4. Tone indicating alerts of Decubitus/Movement Notification
- 5. Tone indicating alerts of Bed Exit Monitoring
- 6. Tone indicating alerts of Wetness Monitoring

#### To sound a tone connected with a corresponding warning notification:

► Click on the corresponding PLAY Icon ( ).



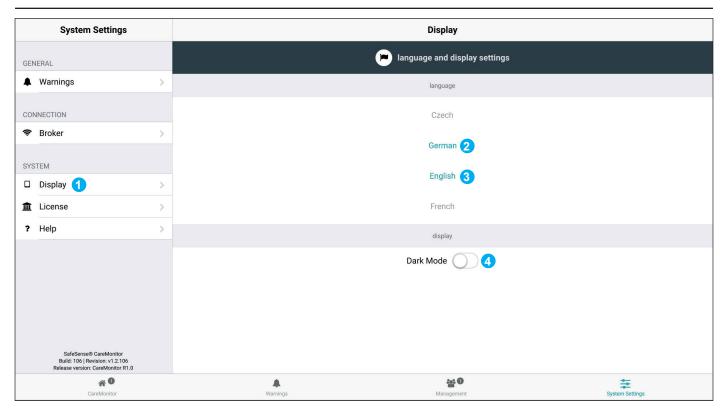


Fig. Display section of the System Settings screen

- 1. Display section of System Settings
- 2. Available language: German
- 3. Available language: English
- 4. Dark Mode Sliding Button

#### To set language of this user interface:

► Click on the name of an available language.

#### To set dark mode of this user interface:

► Slide the Dark Mode Sliding Button to the right.



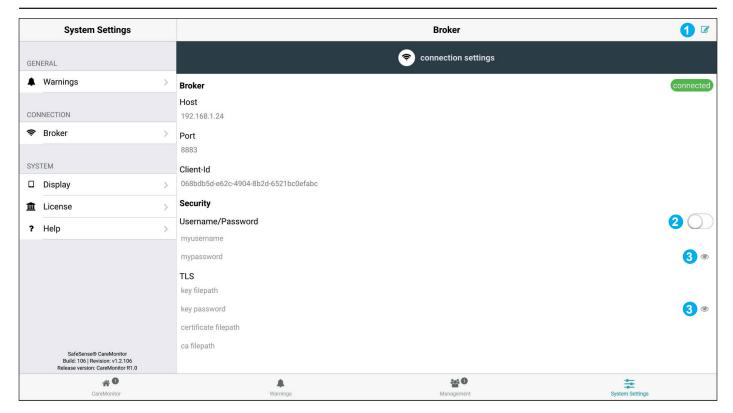


Fig. Broker section of the System Settings screen

- 1. Edit Icon
- 2. Password Activation Button
- 3. Password Display Icon (click on the icon to show the password instead of the black dots)

#### To set password:

- ▶ Click on Edit Icon (1) in upper right corner of the System Settings screen.
- ► Click on OK on the displayed Caution window.
- Set your user name and your password.
- ▶ Ensure that nothing else has been unintentionally changed.
- Click on Save Icon in place of the Edit Icon to confirm the changes.

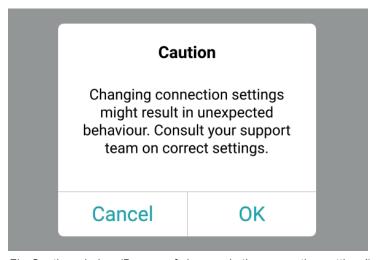


Fig. Caution window (Beware of changes in the connection settings!)



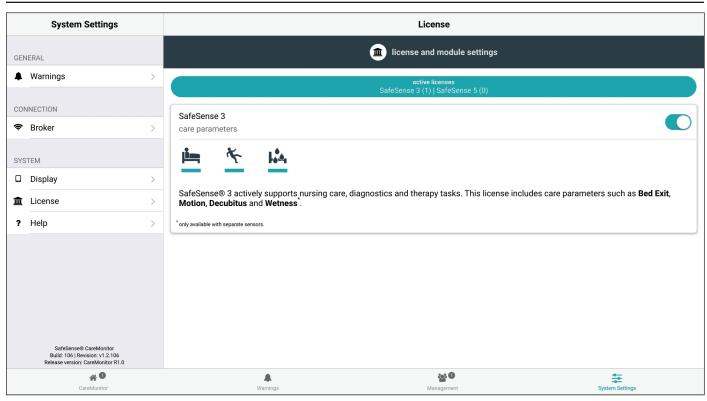


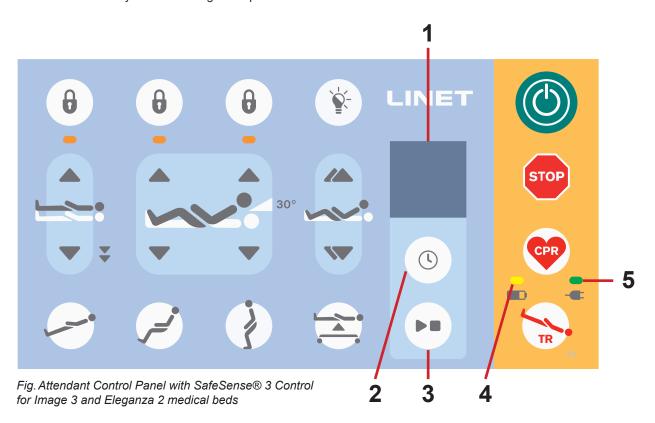
Fig. License section of the System Settings screen



# 11.5.3 Attendant Control Panel with SafeSense® 3 Control (only for Image 3 and Eleganza 2)

The Attendant Control Panel with SafeSense® 3 Control is a control element for Image 3 medical bed or Eleganza 2 medical bed. The Attendant Control Panel with SafeSense® 3 Control indicates Bed Exit Monitoring, Motion Monitoring, Decubitus/Movement Notification and Wetness Monitoring. This Attendant Control Panel can be hung on the foot board or on the siderails if required or it can be stored in the Linen Shelf. It is possible to hold this Attendant Control Panel in the hand while operating.

Ensure that exclusively trained nursing staff operates the Attendant Control Panel with SafeSense® 3 Control.



- 1. SafeSense® 3 Display
- 2. SELECT and TIME Button
- 3. PLAY and STOP Button
- 4. Accumulator Charge Status LED
- 5. Mains Power LED

### **PLAY and STOP Button**



#### CAUTION

PLAY and STOP button on the Hub Control Panel does not mute any sounding alert! Use only Attendant Control Panel with SafeSense® 3 Control and SafeSense Application to mute any sounding alert!

Unintended press of the PLAY and STOP button causes return to the default monitoring status (Bed Exit Monitoring with set **early** period and Motion Monitoring with set **1hour** period).

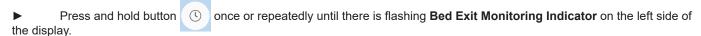
Press of the PLAY and STOP button during triggered alert causes mute of sounding alert and deactivation of the set monitoring.

### SafeSense® 3 Control

It is possible to set the other combinations of Bed Exit Monitoring, Motion Monitoring, Decubitus/Movement Notification and Wetness Monitoring at the same time. It is not possible to activate Motion Monitoring and Decubitus/Movement Notification at the same time. Display of the Attendant Control Panel with SafeSense® 3 Control indicates Wetness Monitoring but it is not control element of Wetness Monitoring. Setting order of the SafeSense® 3 functions is 1) **Bed Exit Monitoring**, 2) **Motion Monitoring** and 3) **Decubitus/Movement Notification**.



#### To set Bed Exit Monitoring:



Press button uring flashing of the **Bed Exit Monitoring Indicator** once or repeatedly to set required period during

which no Bed Exit Alert will be triggered unless patient is on the bed.

Periods for Bed Exit Monitoring are: early (Bed Exit Alert will be triggered in 3 - 5 seconds), 1 min, 5 min, 10 min, 15 min or 30 min.

#### To set Motion Monitoring:

- Press and hold button once or repeatedly until there is flashing **Motion Monitoring Indicator** on the right side of the display.
- ▶ Press button ③ during flashing of the **Motion Monitoring Indicator** once or repeatedly to set required period during

which the absence of patient movement on the bed is tolerated.

Periods for Motion Monitoring are: 10 minutes, 30 minutes, 60 minutes or 90 minutes.

Countdown to the selected time limit (e.g. 4 hours) starts again from the beginning after patient movement on the mattress. CareMonitor shows chart of the patient movements if it is allowed in the settings.

Alert is triggered if no patient movement occurs before the set period has elapsed.

#### To set Decubitus/Movement Notification:

- Press and hold button the right side of the display.

  Once or repeatedly until there is flashing **Decubitus/Movement Notification Indicator** on the right side of the display.
- Press button (5) during flashing of the **Decubitus/Movement Notification Indicator** once or repeatedly to set required

period after which nursing staff is notified to check position of the patient.

Periods for Decubitus/Movement Notification are: 2 hour, 3 hours, 4 hours, 5 hours or 6 hours.

Alert is triggered after the set period has elapsed.

#### To deactivate selected monitoring:

- Press and hold button () repeatedly until the indicator of the selected monitoring is flashing.
- ▶ Press button (⑤) repeatedly until there is a cross over the indicator of the selected monitoring.

Selected monitoring is deactivated.

#### **OR**

Select Motion Monitoring when Decubitus/Movement Notification is selected or select Decubitus/Movement Notification when Motion Monitoring is selected.

Selected monitoring is deactivated and another monitoring is selected.

#### OR

▶ Press button ▶■ to turn OFF the SafeSense® 3 system.

All monitorings are deactivated.

#### To mute triggered acoustic signal (Bed Exit Alert) or accept the triggered alert:

▶ Press button ▶ when acoustic signal sounds or alert is displayed.

Acoustic signal is muted, triggered alerts are accepted and set monitoring is deactivated.

#### To return to the main screen:

▶ Press and hold button ▶ when another screen is displayed.



### SafeSense® 3 Display (main screen)

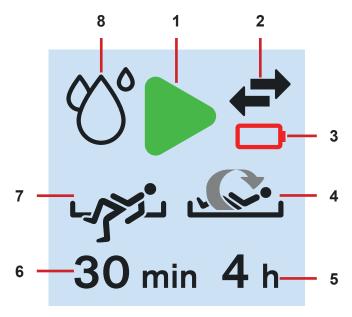


Fig. SafeSense® 3 Display - monitoring ON

- 1. Activation Symbol (selected type (or types) of monitoring is (are) activated)
- 2. Indicator of communication between Hub and Attendant Control Panel (black arrows communication works, orange cross over black arrows communication does not work)
- 3. Indicator of discharged Hub battery
- 4. Indicator of activated Motion Monitoring
- 5. Period during which the absence of patient movement on the bed is tolerated. Countdown to the selected time (e.g. 4 hours) starts again from the beginning after patient movement on the mattress.
- 6. Period during which the Bed Exit alerts are not triggered unless patient is on the bed (e.g. no alert during 30 minutes)
- 7. Indicator of activated Bed Exit Monitoring (patient presence on the mattress is monitored)
- 8. Indicator of Wetness Monitoring (Wetness Monitoring is activated)

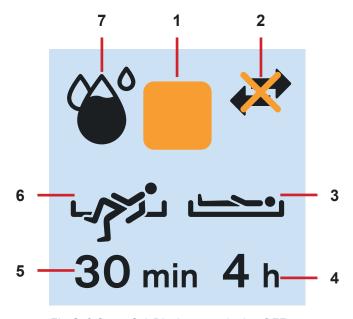


Fig. SafeSense® 3 Display - monitoring OFF

- 1. Deactivation Symbol
- 2. Indicator of communication between Hub and Attendant Control Panel (black arrows communication works, orange cross over black arrows communication does not work)
- 3. Indicator of activated Decubitus/Movement Notification
- 4. Period after which nursing staff is notified to check position of the patient
- 5. Period during which the Bed Exit alerts are not triggered unless patient is on the bed (e.g. no alert during 30 minutes)
- 6. Indicator of activated Bed Exit Monitoring (patient presence on the mattress is monitored)
- 7. Indicator of Wetness Monitoring (Wetness Monitoring is activated The more black symbol of drop, the higher degree of the wetness is monitored.)

Orange square symbol is displayed instead of the green activation symbol when no monitoring is activated. Indicator of Wetness Monitoring is not displayed when Wetness Monitoring is not activated. Indicator of Wetness Monitoring changes according to the degree of monitored wetness. The more black symbol of drop, the higher

Indicator of Wetness Monitoring changes according to the degree of monitored wetness. The more black symbol of drop, the higher degree of the wetness is monitored.





Fig. Bed Exit Alert (monitored patient is not present on the mattress)



Fig. Motion Monitoring Alert (expired period during which the absence of patient movement on the mattress was tolerated)



Fig. Decubitus/Movement Notification Alert (nursing staff is notified to check position of the patient)



# **Mains Power LED Signalisation**

MAINS POWER LED	MEANING
lit	connected to the mains
flashing: 0,6s lit / 0,6s not lit	keyboard error (flashing inverted to Lock LED)
	error (first fault)
flashing: 0,1s lit / 0,1s not lit	service mode
not lit	disconnected from the mains power
	transformer switching error

# **Accumulator Charge Status LED Signalisation**

ACCUMULATOR INDICATOR	MEANING
lit	accumulator disconnected or faulty
flashing: 1,6s lit / 0,2s not lit	accumulator deeply discharged
flashing: 0,1s lit / 0,1s not lit	accumulator discharged
flashing: 0,2s lit / 1,6s not lit	accumulator is charging
not lit	accumulator charged



# 12 Cleaning/Disinfection



#### **WARNING!**

#### Risk of injury due to accidental bed movement!

Always disable the function buttons of a medical bed when cleaning SafeSense® 3 system components (Hub Box, Air Pad, Wetness Pad and cables) installed on the medical bed.



#### **CAUTION!**

#### Risk of material damage due to cleaning of the SafeSense® 3 system in a washing machine!

▶ Before machine washing of a medical bed, always remove the components of the SafeSense® 3 system (Hub Box, Air Pad, Wetness Pad and cables) from the medical bed on which the system is installed!



#### **CAUTION!**

#### Risk of material damage due to steam cleaning of the SafeSense 3 Monitoring System!

Always remove the components of the SafeSense® 3 Monitoring System (Hub Box, Air Pad, Wetness Pad and cables) from the Eleganza 2 medical bed on which the system has been installed!



#### **CAUTION!**

#### Risk of material damage due to incorrect washing of the Wetness Pad!

- ► It is recommended to wash the Wetness Pad at temperature of 60°C.
- ▶ Do not tumble dry for maximum lifetime of the Wetness Pad (50 washes). Washing of the Wetness Pad at temperature of 85°C with medium heat tumble dry causes shorter lifetime of the Wetness Pad (30 washes).
- Do not use fabric softener. Do not make the Wetness Pad waterproof.
- Hang Wetness Pad to dry after washing.



#### CAUTION

#### Material damage due to incorrect cleaning/disinfection!

- Do not use washing machines.
- Do not use pressure or steam cleaners.
- ► Follow the instructions and observe the dosages recommended by the manufacturer.
- Ensure that disinfectants are selected and applied exclusively by qualified hygiene experts.
- ► Check if used cleaning agents and disinfectants are compatible with materials that the product consists of! For information see the following table.

PRODUCT COMPONENTS THAT ARE INTENDED TO BE CLEANED	MATERIALS (SURFACES OF THE MENTIONED COMPONENTS)
Do not clean what is not mentioned in this column!	Competent user is responsible for check if used cleaning agents and disinfectants are compatible with mentioned materials!
Air Pad	Polyester (PES)
Air Hose	Polyvinylchlorid (PVC)
Wetness Pad	Cotton
Hub box	Acrylonitrile butadiene styrene (ABS)
Hub holder	Lacquered steel + Polyamide (PA)
Cables (LAN cable, Nurse Call cable, Wetness Pad cable)	Polyvinyl chloride (PVC)



# 13 Troubleshooting

Problem	Possible Cause	Proposed Solution
Patients/residents do not appear in the Care-Monitor.	The respective terminal is not connected to the correct WLAN. Error message Connection established.	Select the "WLAN" tab under the settings of the terminal and check the WLAN connection.     Select the correct WLAN network and connect to it by entering a password.
	CareMonitor Application is not properly connected to the broker. Connection problem (Yellow connection error bar).	<ol> <li>Open the Broker field under the "System Settings" tab.</li> <li>Note host computer, user &amp; password.</li> <li>Check if broker is reachable.</li> <li>Contact the service technician to access the Hub Box and synchronise the data.</li> </ol>
	Patients/residents have been set to "inactive" in the patient overview.	Click on "Inactive" under the tab "Patients".     Select patient/resident.     Move the patient's/resident's tab to the left.     Click on the "Eye" icon to reactivate the patient/resident.
	Hub Box is not properly connected to the Broker. Connection problem.	Contact the service technician to access the Hub Box and synchronise the data.
No values are displayed or a patient/resident in the bed is displayed who is not lying in it.	Things were placed on the bed or the mattress was lifted and then placed back on the lying surface.	<ol> <li>Switch off the Hub Box once by pressing and holding the power button until the box switches off.</li> <li>Wait approx. 10 seconds and switch the box on again (briefly press the power button again).</li> <li>Make sure that the mattress lies properly on the lying surface.</li> <li>Check the position of Air Pad or Wetness Pad.</li> </ol>
	Air Pad or Wetness Pad is not placed or connected correctly.	<ol> <li>Check the position of the Air Pad or Wetness Pad and the correct attachment.</li> <li>Make sure that the Air Hose or Wetness Pad Cable is not disconnected.</li> <li>Check that the Air Hose is correctly plugged into both the Hub Box and the Air Pad.</li> </ol>
(W)LAN connection not available.	Network malfunction or connection problems WLAN.	Contact your in house technical support. If the system does not work again after the repair, please contact LINET customer support or make an appointment with LINET service technician.
The Hub Box does not switch ON.	Problems with the power supply.	Stand-alone version: Check the power supply and pull the plug out of the socket.     Reconnect the plug after a short pause (approx. 10 sec.).     Check whether all plugs are still inserted in the Hub Box.
In the CareMonitor view, only the Motion Monitoring is displayed or, the other way round, only the Bed Exit monitoring.	Display fields have been hidden.	Click on the GEAR Icon in the upper right corner of the CareMonitor screen.     Make sure that Display settings are set as required.     If this is not the case, change the Display settings.



# 13.1 Error Codes

Error Code	Meaning	Action to Eliminate Error
0	Unknown Error	
1	Socket Connection Refused Error	
2	Socket Remote Host Closed Error	
3	Socket Host Not Found Error	
4	Socket Access Error	
5	Socket Resource Error	
6	Socket Timeout Error	
7	Socket Datagram Too Large Error	
8	Socket Network Error	
9	Socket Address In Use Error	
10	Socket Address Not Available Error	
11	Socket Unsupported Socket Operation Error	
12	Socket Unfinished Socket Operation Error	
13	Socket Proxy Authentication Required Error	Check connection settings.
14	Socket Ssl Handshake Failed Error	If an error status remains, contact service department
15	Socket Proxy Connection Refused Error	approved by manufacturer. Report the error code
16	Socket Proxy Connection Closed Error	displayed on the CareMonitor screen if needed.
17	Socket Proxy Connection Timeout Error	
18	Socket Proxy Not Found Error	
19	Socket Proxy Protocol Error	
20	Socket Operation Error	
21	Socket Ssl Internal Error	
22	Socket Ssl Invalid User Data Error	
23	Socket Temporary Error	
24	Mqtt Unacceptable Protocol Version Error	
25	Mqtt Identifier Rejected Error	
26	Mqtt Server Unavailable Error	
27	Mqtt Bad User Name Or Password Error	
28	Mqtt Not Authorized Error	
29	Mqtt No Ping Response	



### 14 Maintenance



#### **WARNING!**

#### Risk of injury when working on the system!

- ▶ Ensure that the system is disconnected from the mains power prior to installation, putting into service, maintenance and deinstallation of the SafeSense® 3 system.
- ▶ Ensure that the bed castors are locked prior to installation, putting into service, maintenance and deinstallation of the SafeSense® 3 system.



#### **WARNING!**

#### Risk of injury due to defective system!

- Have a defective SafeSense® 3 system repaired immediately.
- ▶ If the defect cannot be repaired, do not use the SafeSense® 3 system.



#### **CAUTION!**

#### Material damage due to incorrect maintenance!

- ► Ensure that maintenance is performed exclusively by manufacturer's customer service or by authorised service personnel certified by the manufacturer.
- ▶ If the defect cannot be repaired, do not use the SafeSense® 3 system.

### 14.1 Regular maintenance

- Perform regularly visual check of the product (with delivery note if necessary).
- Ask service department of the manufacturer for addition of the original spare parts if some product parts are missing.
- Ask service department of the manufacturer for replacement of any damaged product parts by the original spare parts.

### 14.2 Spare Parts

The serial label contains information for claims and ordering replacement parts.

#### Information about spare parts is available from:

- Manufacturer's customer service
- Sales department

## 14.3 Safety Technical Checks



#### **WARNING!**

#### Risk of injury due to incorrect safety technical checks!

- ▶ Ensure that safety technical checks are performed exclusively by manufacturer's customer service or by authorised service personnel certified by the manufacturer.
- Ensure that the safety technical checks are recorded in the service and maintenance log.

#### Safety technical check of the SafeSense® 3 system must be performed at least once every 12 months.

The procedure for performing the safety technical check is stipulated in EN 62353:2014.

**NOTE** On request, the manufacturer will provide service documentation (e.g. circuit diagrams, component part lists, descriptions, calibration instructions etc.) for service personnel for the repair of ME equipment designated by the manufacturer as repairable by service personnel.



# 15 Disposal

#### 15.1 Environment Protection

The company LINET® is aware of the importance of environmental protection for future generations. Within this company the environmental management system is applied in accordance with the internationally agreed standard ISO 14001. The compliance with this standard is annually tested by the external audit executed by an authorised company. Based on the Directive No. 2002/96/EC (Directive WEEE - Waste, Electric and Electronic Equipments) the company LINET, s. r. o. is registered in the List of Electric and Electronic Equipment Producers (Seznam výrobců elektrozařízení) on the Ministry of the Environment of the Czech Republic (Ministerstvo životního prostředí).

Materials used in this product are not environmentally hazardous. LINET® products meet valid requirements of national and European legislation in the areas of **RoHS** and **REACH**, so they do not contain any prohibited substances in excess quantities. None of the wooden parts is made of tropical wood (such as mahogany, rosewood, ebony, teak etc.) or made of timber from the Amazon region or from similar rainforests. Product noise (sound pressure level) meets requirements of the regulations for the protection of public health against undesirable effects of noise and vibration in protected interior spaces of buildings (according to standard IEC 60601-2-52). Used packaging materials are in accordance with requirements of the Packaging Act (**Zákon o obalech**). For disposal of packaging materials after installation of products contact your sales representative or manufacturer's customer service about the possibility of a free take-back of packaging through an authorized company (more details on **www.linet.cz**).

# 15.2 Disposal

The main objective of the obligations arising from the European Directive No. 2012/19/EU on Waste, Electric and Electronic Equipments (nationally regulated in Act No. 185/2001 Coll. as amended. On Waste and in Decree of the Ministry of the Environment No. 352/2005 Coll. as amended), is to increase the re-use, material recovery and recovery of electric and electronic equipment at the required level, thereby avoiding the production of waste and thereby avoiding the possible harmful effects of hazardous substances contained in electric and electronic equipment on human health and the environment. LINET® electric and electronic equipments that have a built-in battery or accumulator are designed so that the used batteries or accumulators can be safely removed by LI-NET® qualified service technicians. There is an information about its type on the built-in battery.

### 15.2.1 Within Europe

To dispose of the electric and electronic equipment:

- The electric and electronic equipment must not be disposed of as household waste.
- ▶ Dispose of this equipment at designated collection points or take-back points.

#### To dispose of the other equipment:

- ► The equipment must not be disposed of as household waste.
- Dispose of this equipment at designated collection points or take-back points.

LINET® participates in a collective system with take-back company REMA System (see **www.remasystem.cz/sberna-mista/**). By bringing electric and electronic equipment to a take-back point, you participate in recycling and you save primary raw material resources while protecting your environment from effects of unprofessional disposal.

## 15.2.2 Outside Europe

- Dispose of the product or its components in accordance with local laws and regulations!
- Hire an approved waste disposal company for disposal!



# 16 Warranty

LINET ® will only be held responsible for the safety and reliability of products that are regularly serviced, maintained and used in accordance with the safety guidelines, especially in the instructions for use.

#### Should a serious defect arise that cannot be repaired during maintenance:

Do not continue to use the SafeSense® 3 system.

This product is covered by a 24-month warranty from the date of purchase. The warranty covers all material and manufacturing-related failures and errors. Failures and errors caused by incorrect use and external effects are not covered. Justified complaints will be fixed free of charge during the warranty period. Proof of purchase, with the date of purchase, is required for all warranty service. LINET standard terms and conditions apply.

# 17 Standards and Regulations

Apllied norms are stated on Declaration of Conformity.

The manufacturer adheres to a certified quality management system in compliance with the following standards:

- ISO 9001
- ISO 14001
- ISO 13485
- MDSAP (Medical Device Single Audit Program)