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EarlySense InSight **(Model AME-01350-US/US-F)** *User Guide – USA version*

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	NAME	DATE	SIGNATURE
Written by:	Keren Hayut	22 Nov 2018	
Approved Regulatory	Ilana Band	22 Nov 2018	
Approval Product Manager	Noy Carmel	22 Nov 18	
Approval Clinical	Dalia Argaman	22 NOV. 2018	
Approval QA	Asaf Grosgold	22 Nov -18	

EarlySense
Proactive Patient Care

EarlySense Ltd.

7 Derech Ze'ev Jabotinsky, Ramat Gan, Israel

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EarlySense InSight™

User Guide

EarlySense
Proactive Patient Care

Important Notice

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EarlySense Ltd. assumes no responsibility for errors that may appear in this user guide. EarlySense Ltd. reserves the right to make changes without notice to this user guide and the products described herein.

Contact and Support Information

You may contact EarlySense at:

Israel

EarlySense Ltd. (Manufacturer)
7 Derech Ze'ev Jabotinsky
Ramat Gan 5252007, Israel

Phone: +972-3-752-2330
Fax: +972-3-752-2340

USA Office

800 West Cummings Park, Suite 6400

Woburn, Massachusetts 01801

USA

Phone: +1-781-373-3228
Fax: +1-781-373-2367

Email: support.usa@earlysense.com

www.earlysense.com

Intended Use

The EarlySense InSight System is intended for continuous measurement of Respiratory Rate, Heart Rate and Movement in an automatic contact-less manner, in hospital or clinical setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.

NOTE Definition of Age for Children: Children aged 2 and above.

About This User Guide

This user guide describes how to operate the EarlySense InSight:

- Please read this user guide thoroughly before operating the system. If any part of this user guide is not clear, you may contact EarlySense Customer Support for clarification.
- This user guide does not replace the EarlySense InSight users' training course.
- This manual provides the information necessary to setup the contact free Sensing Unit and basic operation of the EarlySense InSight Device that is placed at the patient's bedside in a safe and efficient manner. For user interface explanations, please refer to the Remote Control and Display (RCD) Unit manual. For information on InSight Cradle, please refer to EarlySense InSight Cradle User Manuals.
- This user guide must always be located near the EarlySense System so that all personnel operating the EarlySense System are aware of its location and can locate it easily.

This user guide contains the following chapters:

- **Chapter 1, Introduction,** page 15, introduces the EarlySense InSight and its components.
- **Chapter 2, Set UP,** page 24, describes how to operate the InSight and the information that it provides.

Conventions

The following conventions are used throughout this user guide:

WARNING

A warning indicates precautions and instructions, which if not followed, may result in serious bodily injury or death.

CAUTION

A caution indicates instructions or cautionary notes, which if not followed, may result in damage to the equipment or to the quality of measurements.

NOTE Notes contain helpful information and tips.

Table of Contents

List of Figures

Safety

General Safety Guidelines

WARNING

US Federal Law restricts this system for sale by or on the order of a Physician.

The data acquired by the EarlySense InSight System should be interpreted only by a Healthcare Professional.

WARNING

All changes made on an InSight Unit via remote control should only be performed by a healthcare professional.

WARNING

The installation of the remote view software on the portable device (tablet or PC) should be performed only by qualified service personnel authorized by EarlySense Ltd. in cooperation with the Enterprise IT department.

- This manual, accessory direction for use and all precautionary information and specifications should be read before use.
- Handle the InSight System with care. Do not drop, knock or shake the InSight System. Rough handling can damage the internal circuit boards.
- The system is intended for indoor operation only.
- A damaged System should not be disposed of as unsorted municipal waste. Contact your local distributor for Device disposal.
- Changes or modifications not expressly approved by EarlySense Ltd. could affect the safety or effectiveness of the EarlySense InSight System and void the system's warranty.
- The EarlySense Insight Sensing Units (the under the mattress Sensing Unit, the "chair" Sensing Unit) should be connected and used only with the EarlySense InSight Device.
- The EarlySense InSight Device is classified as IP20 Device (provides protection against access to hazardous parts and is not protected against water, should be kept dry).
- The Sensing Unit is continuously operated solid object protected and splash-proof accessory (IP24).
- Do not use a damaged system. Use of damaged components might result in malfunctioning of the system.
- The EarlySense InSight Device should be installed and serviced only by qualified service personnel authorized by EarlySense Ltd. Technical diagrams and descriptions will be available to authorized and qualified personnel. Prospective short-circuit current of installation shall not exceed 35A.

WARNING

The installation of the remote view software on the portable device (tablet or PC) should be performed only by qualified service personnel authorized by EarlySense Ltd. in cooperation and authorization of the Institution IT department.

WARNING

All changes made on an InSight Unit via remote control should only be performed by an authorized healthcare professional.

Defibrillation

The system is Defibrillation Proof with Type BF applied part.

Electromagnetic Compatibility

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in Healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this system. Medical electrical equipment needs special precautions regarding EMC and all equipment must be installed by qualified service personnel. See Appendix A: Manufacturer's Declaration tables for specific information regarding the system's compliance with IEC 60601-1-2.

InSight is intended to be used in professional healthcare facility environment and in home healthcare environment. The electromagnetic compatibility testing was performed according to the worst case scenario, which is home healthcare environment. The detailed explanation of the performed tests and the recommended precautions as for the electromagnetic interference between the EarlySense System and other RF equipment can be found in Appendix A page 28, Manufacturer's Declaration.

Wireless Communication

The system incorporates an off-the-shelf certified Wi-Fi (802.11b/g/n) communication Module (complies with FCC part 15).

For proper wireless communication, maximum operating distance between InSight device and router should be up to 18 m, the minimal separation distance between InSight and other wireless interfering devices should be not less than 20 cm (8 inch).

This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter

Electrical Fire

Avoid splashing liquids on any part of the system, keep it dry. Do not allow conductive fluids to leak into the active circuit components of the system as this may cause a short circuit which could result in an electrical fire. In such an event, only fire extinguishers approved for use on electrical fires should be used. The system is not intended for use in the presence of flammable mixtures.

Classification

The EarlySense InSight Device is an internally, continuously powered ordinary non-transit operable portable equipment with type BF applied part. The EarlySense InSight Device is classified as IP20 device, provides protection against access to hazardous parts. The Device is not protected against water, and should be kept dry. Sensing Unit is a continuously operated solid object protected and splash-proof accessory (IP24)).

Only equipment specified in this manual and complying with requirements of IEC 60601 should be connected to the system. The system complies with IEC 60601-1 and IEC 60601-1-2.

Electrical Shock

The EarlySense InSight Device contains no user serviceable parts. Do not open the Device's covers.

The EarlySense InSight Device is not waterproof. Keep the InSight Device dry to avoid electrical shock or malfunction.

Contraindications for Use

The EarlySense InSight System is contraindicated for use in:

- Patients whose proper positioning cannot be achieved or maintained.
- Patients who do not meet the weight limits tested or specified.
- Situations where a dry environment cannot be ensured.
- An MR environment.
- An explosive atmosphere.

Warning and Cautions

- EarlySense InSight System should be installed and serviced only by qualified service personnel authorized by EarlySense.
- Mounting the InSight Device to the Power Socket should be performed while exercising utmost caution. DO NOT place the InSight Device over the patient's head to avoid safety related conditions.
- If no readings are received from the InSight Device, check that it is fully inserted into the Power Socket.
- Mounting the InSight Device to the Power socket should be performed by mechanical experts of the institution (e.g. Biomed/Engineering) to make sure they are safely attached. EarlySense Ltd is not responsible for any harm or damage related to the wrongful placement of the InSight Device.
- The connection of the InSight Devices and the Remote Control and Display (RCD) Unit to the LAN /WLAN should be performed only by qualified personnel, authorized by EarlySense Ltd. in cooperation with the Biomedical/ IT Engineering Departments of the hospital.
- Configuration of the LAN/WLAN for correct communication between the RCD and the InSight Devices requires the support of hospital's Biomedical / IT Engineering Department, as well as an authorized EarlySense Representative to ensure correct definitions and final testing of the complete system and proper communication between the InSight Devices and the RCD Unit.
- The data acquired by EarlySense InSight System should be interpreted only by a Healthcare Practitioner.
- In the event that the EarlySense InSight System does not operate properly, contact EarlySense Inc. Support Services: (781) 373-3228.
- Never open the InSight Device's housing as this may damage the system. Refer all servicing to an Authorized Technician.
- Only equipment specified in this manual and complying with requirements of IEC 60601 should be connected to the system.
- EarlySense Chair Sensing Unit should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EarlySense Chair Sensing Unit should be observed to verify normal operation in the configuration in which it will be used.
- Measurements may be affected by cable lengths. Do not shorten or extend the lengths.
- The use of accessories, transducers and cables other than those specified by the system's specifications could result in increased emissions or decreased immunity.
- Changes or modifications not expressly approved by EarlySense Ltd. could affect the safety or effectiveness of the EarlySense InSight System and void the system's warranty.

- The system should be operated within a temperature range of 5-40°C (41-104°F). The non-condensing relative humidity conditions allowed for Sensing Units are 30-95% and 15-93% for the Insight Device, atmospheric pressure: 700-1060 hPa for the whole system including Sensing Units.
- Do not use a damaged system. The use of damaged components might result in the malfunctioning of the system.
- Avoid splashing liquids on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system as this may cause a short circuit, which could result in an electrical fire. In this event, only fire extinguishers approved for use on electrical fires should be used. Care should be taken when an EarlySense Sensing Unit is placed under the mattress for patients with poor bladder function or control, including small children.
- Do not share the bed with another person or pet during the EarlySense InSight System recording session. Sharing the bed could affect the effectiveness of the system and the accuracy of the measurements.
- Avoid using heating blankets. Use of heating blankets could affect the safety or effectiveness of the EarlySense InSight System and void the system's warranty.
- Do not use the EarlySense InSight System for patients who weigh more than 200 kg (440 Pounds). Usage of the system for such patients might result in malfunction of the Sensing Unit
- The patient should not have direct contact with the Sensing Unit. A mattress, pad or mattress cover should always be placed as a barrier between the Sensing Unit of the EarlySense InSight System and the patient. Patients should be frequently checked to ensure direct contact does not occur.
- If used by multiple patients, the Chair Sensing Unit should be covered by clean bed sheet to prevent cross-contamination of the users.
- Careful oversight should be provided when EarlySense InSight System is used with children.
- False alerts may occur in some situations. The alert must be identified and understood. The cause(s) of the false alerts must be addressed whenever possible to eliminate the possibility of repeated false alerts and alert fatigue which might result in a failure to respond to an actual alert situation.
- All wireless systems are prone to intermittent signal dropout. Make sure that the patient only has conditions which can tolerate intermittent monitoring interruptions. The InSight Device is the alerting monitor. Alert delays were measured between the InSight Device and RCD and the same alert from the RCD to the InSight Device. Delays are less than 10 total seconds, not including any hold-off settings set by the clinical facility. However, network speeds vary and the system's performance may vary, depending on the speed of clinical facility network.
- Alert limit settings are patient- or facility-specific. The clinician must set and verify on the RCD Unit that alert limits are appropriate for each patient. Failure to set alert limits properly can lead to false alerts or failure to alert. Alerting will only work properly if set up properly.
- The usage of EarlySense InSight System on the bed or chair, close to any adjacent source of vibration, might influence the accuracy of the system's measurements or create periodic interferences with the measurements.
- The InSight System does not support life & nurses are required to continue their standard practice The EarlySense InSight System is not intended for monitoring high risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.
- It is strongly recommended that the InSight Unit be installed with redundant power supplies.
- External wireless alerting devices as used by the hospital should be used as secondary to the alerts as provided by the EarlySense system.
- When utilizing EarlySense CDS as the Remote Control and display device (RCD), configuring the possibility to remotely access the CDS via tablets or other portable devices should be performed by EarlySense authorized technicians and requires authorization from the facility's IT/Biomed for network setup.
- EarlySense InSight should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the InSight System should be observed to verify normal operation.

- Portable RF communications equipment, including antennas, such as mobile phones, Walkie-Talkie, mobile radios, etc. should not be used closer than 30 cm (12 inches) to any part of EarlySense System, including its cables, as it can negatively affect its performance

WARNING

Due to the small size of the system's label it can be read only from the intended position of the user - from the user's hand.

WARNING

Configuring the possibility to remotely access the bedside via tablets, computers or other portable devices should be performed by EarlySense authorized technicians, and requires authorization from the hospital IT/Biomedical department for network setup.

WARNING

All wireless systems are prone to intermittent signal dropout due to communication lost. Make sure that the patient only has conditions that can tolerate intermittent monitoring interruptions. Do not pause or turn off an alert remotely if patient safety might be compromised.

WARNINGS

Patient harm risk. Do not pause or turn off an audible alert remotely if patient safety may be compromised. Do not adjust a patient's alert limits as a way to silence an alarm.

Remote monitoring is not a substitution for frequent patient assessment by attending clinicians, or a substitute for the alerting that occurs at the patient monitor.

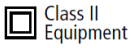
Alerts and other events can go unnoticed if clinical personnel are not present at the bedside or if interruptions occur in power, network connections or Monitoring Units operation.

Explanation of System Labels

The following provide a description of the graphical symbols which appear on the EarlySense InSight System components and package.

Table 1: System Label Description

	Warning
	Caution
	Consult accompanying documents
	Defibrillation proof, type BF applied part
	Fragile, handle with care
	Keep dry

	Indoor operation only
	Class II equipment (double insulated electrical Device, does not require a safety connection to electrical earth)
	Non-ionizing Electromagnetic Radiation
IP24	Solid object protected and splash-proof accessory
IP20	Solid object protected
	Sorted disposal
	Manufactured by:
	Date of manufacture:
	MR Unsafe- Keep away from magnetic resonance imaging (MRI) equipment
Rx Only	US Federal Law restricts this Device to sale by or on the order of a physician.
	Temperature Range
	Relative Humidity
	Atmosphere Pressure

Compliance with Standards

The EarlySense InSight System was tested and found to be in compliance with the following standards:

Standard	#
Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	IEC 60601-1:2005+CORR.1:2—6+CORR 2:2007+A1:2012
Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability	IEC 60601-1-6:2010 + A1:2013
Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; Electromagnetic Compatibility -Requirements and Tests	IEC 60601-1-2:2014 (Fourth edition) and 2007+I-SH 01:2010 (third edition)
Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services	EN 301 489-1 V1.9.2:11; EN 301 489-7 V1.3.1:05; EN 301 489-17 V2.2.1:12

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems, ESD Air Discharge was tested to ± 2kV, ± 4kV, ± 8kV only.
See Appendix A for Manufacturer's declaration and tables for specific information regarding compliance with IEC 60601-1-2.

Supplying InSight Unit

The EarlySense InSight Device is shipped in a protective package. The Device should be unpacked and installed only by an authorized EarlySense Technician.

The EarlySense InSight Device can only be operated by connecting to a Cradle. The Cradle is suppled separately. For further explanation refer to EarlySense Cradle User Guide.

Supplying Sensors

The EarlySense Bed Sensing Units are supplied in a separate package. Each Sensing Unit is isolated to ensure safe transport.

The EarlySense InSight System may also be provided with optional Chair Sensing Unit/s.

The EarlySense InSight System should be unpacked and installed only by an authorized EarlySense Technician.

Terms, Abbreviations and Definitions

Table 2: Terms, Abbreviations and Definitions

Term/Abbreviation	Definitions
°C	Degrees Centigrade
°F	Degrees Fahrenheit
AC	Alternating Current
AM	Ante Meridiem (L) – Before Noon
BF	Type BF applied part – medical device classification
BPAP	Bi-level Positive Airway Pressure
BPM	The number of heartbeats per unit of time (beats per minute)
Br./min	Breaths per minute
Braden Score	A scale for predicting pressure sore risk
CPAP	Continuous Positive Airway Pressure
CSV	Comma Separated Values (text file format)
ECG	Electrocardiography
EMC	ElectroMagnetic Compatibility
F	Female
FCC	Federal Communications Commission
FDA	US Food and Drug Administration
HIS	Hospital Information System
HR	Heart Rate
ID	Identification number
IEC	International Electrotechnical Commission
IFU	Instructions For Use
IP24	Solid object protected and splash-proof accessory
IT	Information Technology
Kg	Kilogram = 2.2 pounds weight
kHz	Kilohertz
LAN	Local Area Network
LED	Light Emitting Diode
M	Male
MHz	Megahertz
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
MRN	Medical Record Number
OEM	Original Equipment Manufacturer
PDF	Portable Document Format
PIN	Personal Identification Number
PM	Post Meridiem (L) – After Noon
RCD UNIT	Remote Control and Display Device which can be EarlySense Central Display Station (CDS) or other regulatory-approved central monitoring station
Q	Turn Interval
RR	Respiratory Rate
RF	Radio Frequency
Wi-Fi	Local area wireless technology

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1 Introduction

This chapter introduces the EarlySense InSight and its components.

1.1 What Is the EarlySense InSight System?

The EarlySense InSight System developed by EarlySense Ltd. is designed for continuous and contact-free measurement of Heart and Respiratory Rate. In addition, the System tracks body motion; monitors patient movement and can notify users when the patient exits the bed. The device can communicate numerical data on Heart Rate, Respiratory Rate and Movement. The System can notify the Remote Control and Display (RCD) Unit when Heart or Respiratory Rates averaged over time, passes above or below predefined limits.

Setting, viewing and adjusting the parameters of the InSight is managed by the Remote Control and Display (RCD) Unit that can communicate with the InSight device according to its predefined standard communication protocol.

Providing contact-free, passive monitoring capabilities, with no need for patient activation, the EarlySense InSight System enables continuous monitoring of patients in hospitals or clinical settings. The InSight Device has no display. The display of patients' measurements, as well as the individual setting is only available with the EarlySense CDS System or other regulatory-approved[1] central monitoring station (i.e. Remote Control and Display - RCD Unit) that complies with the minimum requirement specifications for the central monitoring station (See RCD Unit's documents). For detailed information of using InSight with EarlySense CDS, please see EarlySense CDS User Manual.

The basic System includes a Sensing Unit which is placed beneath the bed mattress or between the mattress and a mattress pad/cover, a Chair Sensing Unit, a Cradle and an InSight Device itself which processes the information detected by the Sensing Unit and sends it to the Remote Control and Display (RCD) Unit. Monitoring of the patient may begin automatically as soon as the sensor under the mattress detects bed entry. The data acquired by the System is continuously logged into the InSight Device that is placed at the patient's bedside. The data provided by the System is intended to aid in the evaluation process of a patient's clinical status and should be interpreted only by a Healthcare Practitioner.

The InSight device will communicate with the Remote Control and Display (RCD) Unit via LAN or Wi-Fi communication protocol.

NOTE	The EarlySense InSight System has not been studied on any specific patient group, nor has it been studied as a diagnostic tool for any specific disease or medical condition. It is meant only as an adjunctive tool for measuring Respiratory Rate, Heart Rate and Movement.

[1] The regulatory approval depends upon the geographic area of usage of the system- CE approval is needed for European countries, FDA clearance for the USA market, etc.

1.2 System Components

The system consists of a Sensing Unit, a Cradle and InSight Device, connected by a cable.

Figure 1: EarlySense InSight Components

1.2.1 Sensing Units

Bed Sensing Unit

The Bed Sensing Unit is placed under the mattress (See Positioning the InSight Device and Sensing page 24) and detects physiological and motion signals generated by the patient. A solid base plate is designed to be fixed to the bed's frame for convenience during placement.

Chair Sensing Unit (Optional)

The Sensor is inserted into a cushion so that it is not in contact with the patient. The cushion can be placed on a chair and is able to detect the patient's Heart Rate, Respiratory Rate, and Motion while seated.

Only one Sensigs device can be connected to the EarlySense InSight Device, either the Bed Sensing Unit or the Chair Sensing Unit

If using an accessory switch (provided by Earlysense), Both Sensing units can be connected to the InSight Device together.

Figure 2: Chair Sensing Unit- a cushion with a sensor incorporated inside

1.2.2 Sensing Unit Extension Cable

An optional extension cable for the Sensing Unit is available, if required.

NOTE Use total length of extension cable which should not exceed 12 meters (39.36 ft.).

1.2.3 InSight Device

The display of patients' measurements, as well as the individual setting is only available on the Remote Control and Display (RCD) Device. For more elaborated explanation and user interface details, please refer to the Remote Control and Display (RCD) Unit's User Manual.

Figure 3: InSight Device Indicators and Keys

NOTE	The EarlySense InSight System has not been studied on any specific patient group, nor has it been studied as a diagnostic tool for any specific disease or medical condition. It is meant as an adjunctive tool only for measuring Respiratory Rate, Heart Rate and Movement.

NOTE	***Sorted Disposal*** Do not discard this product. Contact your local authorized representative for additional information for collection and recovery programs available for this product and for appropriate facilities for recovery and recycling.

1.2.4 EarlySense InSight Device Controls and Indicators

The InSight Device contains the following controls and indicators:

1. Operational Buttons- located at the side panel, and can be configured to fulfill various functions
2. **LEDs** -

   A. Alert LED- indicates either a technical or a clinical active alert at this InSight Device. Further information regarding Clinical Alerts can be found in "*Clinical Alerts*" section on page 27

   B. Communication LED - indicates if communication with external control and display device is intact or not. Orange when connected and OFF when disconnected

   C. Power indication - confirms that the InSight Device is plugged to the power socket. Green when connected and OFF when disconnected.

3. Responding to an Active Alert key- is made by pressing on the InSight Device (the entire exterior shell operates as a button).

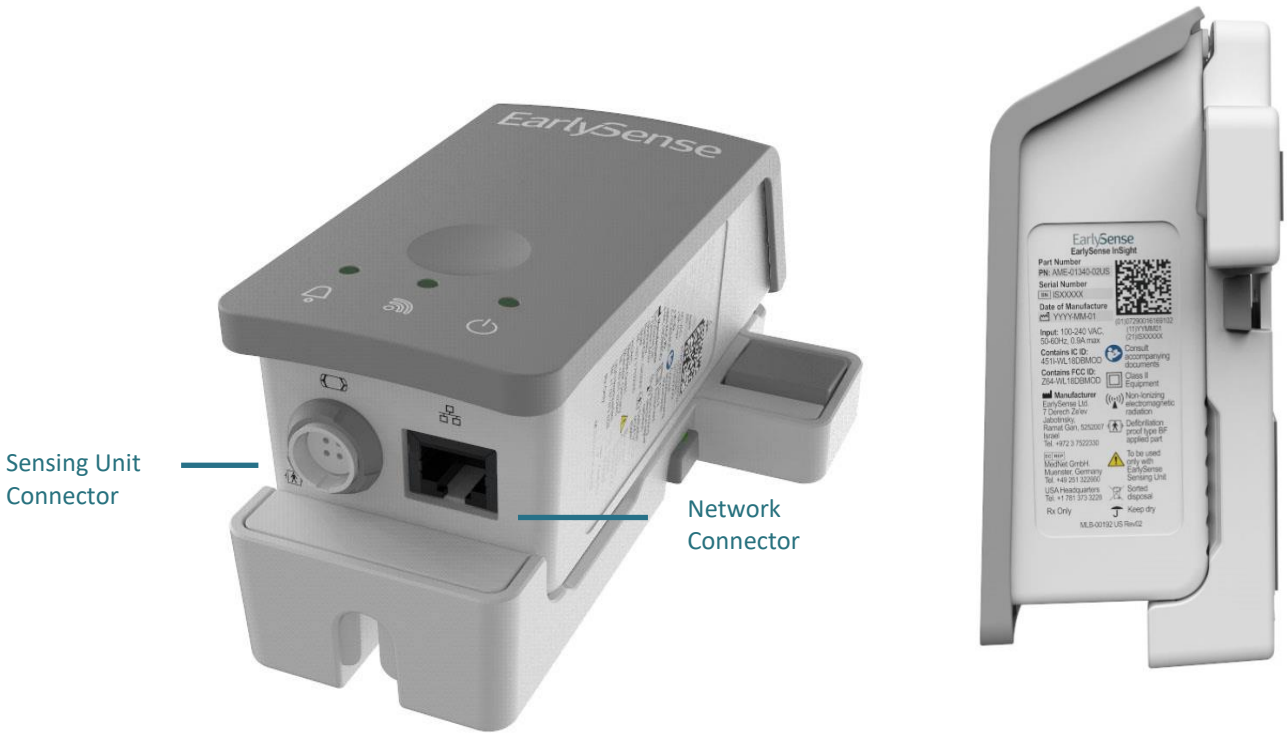

Figure 4: InSight Device- Side View

1.3 InSight Device Specifications

Physical Characteristics

Table 3: Physical Characteristics

Characteristic	Bed Sensing Unit	Chair Sensing Unit	InSight Unit
Dimensions	Sensor: 300 X 210 X 6.45 mm With handles: 420.7 X 210 X 13.8 mm	300 X 210 X 6.45 mm	145.6 x 62 x 65.07 mm
Weight	730 gr	482 gr	238.7gr
Materials	ABS + Polycarbonate	ABS + Polycarbonate Inserted into cushion: **Cushion:** Visco elastic (dimension: 400 X 450 X 60 mm)	ABS + Polycarbonate

Electrical

Table 4: Electrical

Voltage Input Range	100−240 VAC, 50−60 Hz, 0.9A maximum

Communication modules

The system contains wireless LAN module which enables wireless communication to the network. The module can transmit at either 2.4 GHZ or 5 GHz.
The system also contains a BLE module (for AME-01350-EU-B Module only), and an RFID module which enables identification of the cradle.
All relevant FCC IDs:
FCC ID: 2AQ32-INSIGHT
Contains FCC ID: TFB-BT2
Contains FCC ID: Z64-WL1835MOD
Contains FCC ID: PD98260NGU

This device complies with Part 15 of the FCC Rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation

Operating Conditions

Table 5: Operating Conditions

Relative Humidity	Sensing Unit 30%–95% Non-condensing InSight Device 15%–93% Non-condensing
Ambient Operating Temperature	Sensing Unit and InSight Device: 5–40°C (41–104°F)
Atmospheric Pressure	InSight Device 700–1,060 hPa Sensing Device 500–1,060 hPa

Storage and Transportation Conditions

Table 6: Storage and Transportation Conditions

Temperature Range	-20–50°C (-4–122°F)
Relative Humidity	InSight Device:15%–90% Non-condensing Sensing units:10%-90% Non -condensing
Atmospheric Pressure	InSight Device 700–1,060 hPa Sensing Device 500–1,060 hPa

Cables Used with the Sensing Units and EarlySense InSight Device

Table 7: Cables

Connector Name	Connector Type	Type of Cable	Length (m)	# of Identical Connectors
Sensing Unit Extension Cable	Sensor Extension Cable	Unshielded	≤12	2
LAN	RJ45	Shielded	>3	1

1.4 Additional Specifications

1.4.1 System Performance – Sensing Unit

Table 8: Performance Specifications

Respiratory Rate	Heart Rate	Movement
Range		
6–45 Br./min.	30–170 BPM	0, L, M, H, EH
Averaging Period		
1 Min.	1 Min.	15 Seconds
Accuracy		
±4% or ±1.5 Br./min., whichever is greater	±4% or ±5 BPM, whichever is greater	
±4% or ±1.5 Br./min., whichever is greater	±4% or ±5 BPM, whichever is greater	

Respiratory Rate	Heart Rate	Movement
The system detects HR that is > 1.8 times the RR Total system accuracy, including undetected signals 90% for RR and for HR. The total system accuracy was measured as +/- 10% of the predicate device.		
Alert Thresholds		
Default: Low=8 Br./min. High=32 Br./min.	Default Alert: Low=40 BPM High=130 BPM	Default: Low=0% High=Extremely High movement > 1 min.
Min. – Max. Settable Alert Thresholds		
Low: 8 Br./min. High: 44 Br./min.	Low: 35 BPM High: 150 BPM	

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2 Set UP

This chapter describes the initial setup and configuration of the InSight Device and Sensor.

2.1 Positioning the InSight Device and Bed Sensing Unit

The InSight Device should be positioned close to the patient's bed. When an InSight Device is attached to the Cradle, and then is connected to the power socket, it is ready to be used. If moving an InSight Device from another location, ensure proper connection to Cradle to allow operation. The Sensing Unit cable should be connected to the InSight Device on the bottom. Please make sure the Sensing Unit cable is not trailing on the floor.

Place the Bed Sensing Unit horizontally under the patient's mattress (at least 7cms/3 inches thick) and locate it underneath the chest area. Position the Sensing Unit so the top surface is facing upwards (See Figure 5). Ensure that the Sensing Unit's cord is secured at the top of the bed, to prevent tripping while patient exits the bed. If the Sensing Unit is placed on a framework which does not allow solid support, please consult your authorized EarlySense Representative.

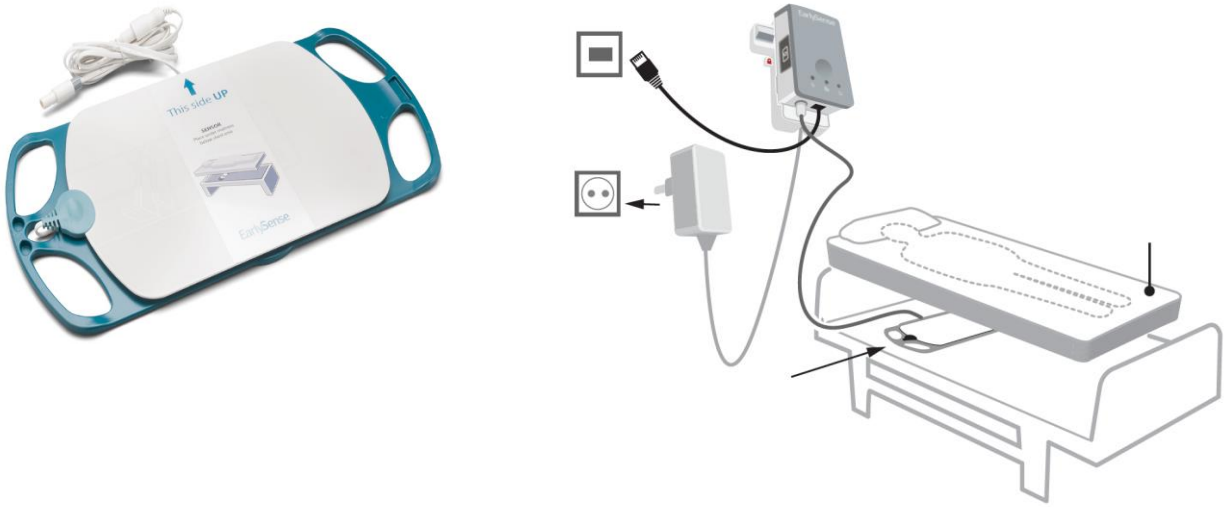

Figure 5: Positioning the Sensing Unit and the InSight Device

2.2 Positioning the Chair Sensing Unit on a chair

Place the Chair Sensing Unit on a chair so that the top surface is facing upwards. Secure the cushion to the chair's back, using the strap. Position the cable so that it will not interfere with patient or staff movement in the room.

Figure 6: Example of Chair Sensing Unit attached to a chair

WARNING

Do not place the InSight Device attached to Cradle above the patient's head. Do not obstruct access to the InSight Device. There should be a possibility to easily access the InSight's front panel as well as access to disconnect InSight Device from the Cradle in case of necessity or malfunction.

CAUTION

The patient should not be in direct contact with the Sensing Unit. A mattress cover should always be placed as a barrier between the Sensing Device of the EarlySense InSight System and the patient.

CAUTION

Handle the InSight System with care.

Do not drop, bang or shake the InSight System. Rough handling can break the internal circuit boards.

NOTE

Please ensure Sensor's correct positioning under the mattress. Misplacement of the Sensor might result in wrong readings and notifications.

2.3 Visual and Audial Alerts

The following table explains the audial and visual alerts displayed by the InSight Device:

LED position	LED description	Definition
Alerts LED	Flashes blue	Indication that there is one of the following technical problems: • A need to check the Sensing Device (connection, position or location) • System malfunction- technical alert indication that the system is malfunctioning
	Flashes red	Indication that there is Bed Exit or Vital Sign related Alert
	Flashes yellow	Indication that there is a Motion related Alert (Turn Counter exceeded, Low/High Motion detected)
	The LED is blinking in rotation between the colors (Red, Blue, Yellow)	All alerts are suspended (no alerts will be activated in the next 15 minutes)
Communication with RCD LED	Solid Yellow	Device Indication when communication with RCD Unit is intact
	No light	The system is disconnected from the RCD
Power indication LED	Solid Green	The system is connected to AC power and working
	No light	The system is disconnected from the AC power, re-connect the system to the AC plug

Each visual alert (LED flashing) will be accompanied by the audial alert (one tone alert). The alerts can be muted with the help of the button on the InSight Device or on the Remote Control and Display (RCD) Unit.

The complete information regarding the alerts mentioned above is available on the RCD User manual.

2.4 Electrical Failure

The InSight Device is powered by the Cradle that is connected to the power socket. In case of an electrical failure, the InSight System will shut down.

NOTE The InSight System does not include a battery. In order to maintain the constant operation, make sure that the system is always plugged in to the electrical socket. In case of power failure, monitoring will not be available.

2.5 After Electrical Power is restored

1. Make sure that the InSight Device is attached to the Cradle.
2. Make sure the Cradle is connected to the power socket.
3. The system automatically starts operating
4. Ensure that the InSight Device's details are appearing correctly upon the RCD Unit Screen.

2.6 Clinical Alert

Alerts are used to notify personnel of situations which may require attention. The EarlySense InSight Device alert's the user that an Alert is active by flashing a LED light, or/and by making an audible sound. The color of the LED light indicates the type of alert (alert types are specified in the RCD Unit's User Guide). To understand the nature of an Active Alert, the user must view the RCD Unit's User Guide.

An active Alert can be acknowledged either by pressing on the InSight Device Front Panel, or via the RCD Unit. The InSight System can be also preset to acknowledge alerts via the InSight Device only.

Vital Signs Alerts are generated by the system if heart rate or respiratory rate averages exceed predefined thresholds for the amount of time listed below:

	Low Heart Rate	**High Heart Rate**
Time to alert for change in HR	90 seconds	90 seconds
	Low Respiratory Rate	**High Respiratory Rate**
Time to alert for change in RR	180 seconds	180 seconds

The InSight System can also be configured to provide a "Multi Parameter Alert". This Alert is generated if both HR and RR exceeds predefined thresholds, as set by the EarlySense technical support representative, according to the Healthcare practitioner's instructions.

WARNING

The Audible and Visual Alerts in the EarlySense InSight System are not intended for monitoring high risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

2.7 Technical alerts

Technical Alerts are managed differently than other alerts. Technical Alerts indicate that there is a technical problem. Please refer to the Remote Control and Display (RCD) Unit User Manual to understand the nature of the alert.

2.8 Maintenance and cleaning

The EarlySense InSight System is designed to provide trouble free operation. The system should be kept clean and dry, and the user should verify that there is no physical damage to the InSight Device and to the Bed/Chair Sensing Units.

The Bed and Chair Sensing Units should be replaced on an annual basis to ensure proper functionality of the system. No restriction for sensing Unit storage time exists.

Minimal expected service life of the InSight Device is 5 years; however, the service can still be provided after this term. Please, contact your local distributor for more details.

2.8.1 Cleaning and disinfecting the InSight Device

Please follow your institution guidance for bed mattress cleaning, in order to clean the InSight Device. Cleaning detergents such as soft, wipes containing alcohol, Chlorhexidine, Peroxide and bleach material or slightly damp cloth/wipes containing anti-septic substances can be used. Please ensure that the sensor is dry before re-use. Avoid excessive liquids.

CAUTION

Never open the InSight Device housing as this may damage the system.

Handle the InSight Device with care. Do not drop, knock, or shake the InSight Device. Rough handling can damage internal circuit boards.

Do not clean the InSight Device while in use, first detach it form the mains supply.

2.8.2 Cleaning and disinfecting the Sensing Unit

Please follow your institution guidance for bed mattress cleaning, in order to clean the contact-less Bed Sensing Unit, that is placed under the bed mattress. Cleaning detergents such as soft, wipes containing alcohol, Chlorhexidine, Peroxide and bleach material or slightly damp cloth/wipes containing anti-septic substances can be used. Please ensure that the sensor is dry before re-use. Avoid excessive liquids.

CAUTION

Avoid splashing liquids on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system as this may cause a short circuit, which could result in an electrical fire. In such an event, only fire extinguishers approved for use on electrical fires should be used.

2.9 Troubleshooting

Problem	Possible Cause	Solution
The system is not functioning	System is unplugged from the electrical socket	Reconnect the Device to the Cradle.

A Appendix: Manufacturer declaration

This appendix describes the system's compliance with applicable IEC and RF standards.

A.1 Overview

See the following tables for specific information regarding the system's compliance with the IEC 60601-1-2 standards.

The EarlySense InSight System is intended for use in the electromagnetic environment specified below. The customer or the user of the EarlySense InSight should ensure that it is used in such an environment.

Table 9: System Compliance Information – Electromagnetic Emissions

The EarlySense InSight System is intended for use in the electromagnetic environment specified below. The customer or the user of the EarlySense System should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The EarlySense InSight System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EarlySense InSight System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 10: System Compliance Information – Enclosure Port Immunity to RF Wireless communications equipment

Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance(m)	Immunity Level (V/m)	Compliance Level (V/m)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Table 11: Electromagnetic Immunity for Non-Life-Supporting Systems

The EarlySense InSight System is intended for use in the electromagnetic environment specified below. The customer or the user of the EarlySense system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV ±1 kV ± 2 kV	± 0.5 kV ±1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips 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 cycles Single phase at 0°	0 % UT; 0.5 cycle At 0%, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the EarlySense InSight System be powered from an uninterruptible power supply.
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
Rated Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment and are not expected to affect the EarlySense InSight System.

NOTE U_T is the AC Mains voltage prior to application of the test level.

Table 12: System Compliance Information – Immunity

The EarlySense InSight is intended for use in the electromagnetic environment specified below. The customer or the user of the EarlySense InSight System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[3] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Portable and mobile RF communications equipment should be used no closer to any part of the InSight including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=0.58\sqrt{P}$ $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 MHz Where **P** is the maximum output power rating of the transmitter, in watts (W), according to the transmitter manufacturer and **d** is the recommended separation distance, in meters (m)[4]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[5], should be less than the compliance level in each frequency range[6] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz to 2,5 GHz	

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

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

3 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

4 The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

5 Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

6 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 13: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the EarlySense System (Non-Life-Supporting)

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)			
	150 kHz to 80 MHz outside ISM bands $d=0.58\sqrt{P}$	150kHz to 80MHz in ISM bands $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0,01	0.06	0.12	0.12	0.2
0,1	0.2	0.3	0.3	0.7
1	0.6	1.2	1.2	2.3
10	1.8	3.7	3.7	7.2
100	5.8	12	12	23

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

NOTE At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

NOTE The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

NOTE An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

B Appendix:

FCC Compliance Standard Statement

EarlySense
Proactive Patient Care

EarlySense Ltd.
Derech Ze'ev Jabotinsky 7,
Ramat Gan, 5252007 Israel
Tel +972 3 7522330
Fax +972 3 7522340

Compliance Information Statement

(For products assembled from modular components that are themselves SDoC or Certified

We EarlySense Ltd. declare:

Type of equipment: The EUT is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, at home, hospital or clinic setting
Brand name or trademark: Insight (AME-01350-EU/EU-B/US/US-F)
Product Identification number: FCC ID- 2AQ32-INSIGHT
Applicable Compliance Statements: (e.g. for part 15 devices see §15.19(a)(3))
Copies of Compliance Statements for each SDoC modular component used:

- Modular 1, FCC ID TFB-BT2, BLE Module
- Modular 2, FCC ID Z64-WL1835MOD, Wi-Fi module
- Modular 3, FCC ID PD98260NGU, Wi-Fi module

Country of origin: Israel
Manufacturer: EarlySense Ltd.
Responsible Party name (in USA): EarlySense Inc.(USA Office)
Address: 800 West Cummings Park Suite 6400, Woburn, MA 01801
Telephone: +1-781-373-3228
Fax: +1-781-373-2367
Internet E-Mail: Vladimir.Lechaness@earlysense.com
Standards applied:

- FCC Part 15B - For Unintentional radiators
- FCC Part 15C - For Intentional radiators

Test reports/ certificates issued by: GTS, EMTEK
Telecom Certification Body by: GTS, EMTEK

As manufacturer/ manufacturer's authorized representative within the USA, we declare under our sole of responsibility that the equipment follows the provisions of FCC Equipment Authorization Procedures under CERTIFICATION (47 CFR Section 2.907) and / or SUPPLIER'S DECLARATION OF CONFORMITY (47 CFR Section 2.906) as stated above.

Thus, FC is placed on the product

Date of issue: November 19 2018
Place of issue: Israel
Avner Halperin
CEO

Earlysense Ltd.
51-360955-2

The FCC Wants You to Know

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

a) Reorient or relocate the receiving antenna.
b) Increase the separation between the equipment and receiver.
c) Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
d) Consult the dealer or an experienced radio/TV technician.

CAN ICES-3 (B) / NMB-3 (B)

This Class B digital apparatus complies with Canadian ICES-003.
Cet appareil numérique de classe B est conforme à la norme canadienne ICES-00

EarlySense
Proactive Patient Care

EarlySense.com

800 West Cummings Park Suite 6400
Woburn, Massachusetts 01801
USA
Phone: 781.373.3228

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