USER GUIDE

ForeSite® Intelligent Surface System

This user guide covers how to install and maintain the ForeSite Intelligent Surface system and its components.

XSENSOR | Intelligent Dynamic Sensing

CE

ForeSite Intelligent Surface System
User Guide

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Introduction

The ForeSite® Intelligent Surface System (ForeSite IS) is a continuous skin monitoring mattress system for clinicians that improves patient safety and reduces staff workload. It’s powered by XSENSOR’s Intelligent Dynamic Sensing platform, which enables precise measurements and features highly detailed visualizations and smart data with AI-powered analysis — resulting in optimized performance, comfort, and safety.

ForeSite IS helps clinicians:

- Increase patient safety by validating that repositioning regimes have effectively redistributed pressures, thereby reducing the risk of injury.
- Improve staff workload by identifying highest-risk patients and body regions using detailed image visualizations.
- Individualize patient care with AI/ML to inform advanced prevention strategies to maintain healthy skin for at-risk patients.

Real-time, easy-to-understand pressure images generated by the ForeSite IS System identify areas that are experiencing elevated pressures, giving clinicians the information they need to make body position adjustments before pressure injuries occur.

The sensor array for the ForeSite IS System comes in two form factors:

- The ForeSite Intelligent Mattress, a fully integrated mattress solution; and
- The ForeSite Intelligent Overlay, a fitted mattress cover overlay designed to fit over existing hospital mattresses.

Both options are embedded with a high resolution array of over 1,500 flexible sensor cells.

The sensor surfaces connect to a touch-screen Display Terminal running the ForeSite Viewer software application.

The ForeSite Viewer continuously monitors the patient's body surface pressures and displays real-time pressure images of elevated pressures, providing actionable insights. Software features include:

- Visual display markers that clearly identify areas of the body that have been under sustained pressure;
- A patient turn clock that tracks the time since the last reposition, visually notifying the clinician that it is time to adjust the patient's body position; and
- A history of recent turns, including pressure exposure data, that allows caregivers to see at a glance the turn history of the patient and if their turn strategy needs to be modified.

Additional key features include:

- A centralized dashboard, which provides real-time, detailed injury risk and turn history for all monitored patients; and
- The cloud database, which provides access to individual and multi-patient history reports for compliance review and development of best practice.

ForeSite Reports

ForeSite Reports is an optional reporting application that integrates directly into ForeSite Viewer.

Contact XSENSOR for more details.

Intended Use

The ForeSite Intelligent Surface System is specifically intended to assist with the turn management and repositioning of patients susceptible to pressure injuries in medical, nursing and long term-care facilities. The ForeSite IS system provides continuous monitoring features that help clinical staff more effectively execute the pressure relief and patient turning schedules that are commonly included in a medical institution’s clinical pathway.

The device only measures pressure at the support surface. The device is not intended to measure:

- quantitatively a physiological or anatomical parameter
- a quantity or a measurable characteristic of energy or substances delivered to or removed from the human body

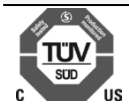
There are no known contraindications to its use. For any questions or concerns in regards to the safety of this product, do not hesitate to contact XSENSOR.

Essential Performance

There is no essential performance. The ForeSite IS system is not intended to replace current best practices for the prevention of pressure injuries. It is intended to provide additional monitoring and data collection while standard monitoring techniques and turn schedules are maintained.

Symbol Guide

The ForeSite Intelligent Surface System uses the following symbols on the components.

THIS LABEL...	IDENTIFIES THIS...
	Type B Applied Parts - Attention, consult accompanying documents
	Refer to the User Manual for important warnings and operating instructions
	Type B Defibrillator Proof
	Approved for sale in the European Economic Area
	Approved for sale in Australia and New Zealand
	Tested and approved by TUV (Technischer Überwachungs-Verein)

Compliance with Standards

The ForeSite IS System is compliant with the following standards:

- Mode of Operation: Continuous
- Class I Equipment
- Type B Applied Part. No electrical contact with patient in normal use
- Electrical/Mechanical Safety: IEC 60601-1:2005/A1:2012 Edition 3.1
- Electromagnetic Compatibility: IEC 60601-1-2:2014 Edition 4.0

For more information on compliance with emission and immunity standards, see Compliance with Emission and Immunity Standards.

Warnings and Cautions

The ForeSite Intelligent Surface System has been designed and tested in accordance with the previously mentioned safety standards. To ensure safe use of the product, follow all safety and operating instructions in this guide. At the end of your system's product life, please contact XSENSOR for instructions for safe disposal.

The ForeSite IS System is intended for use by healthcare professionals only. ForeSite IS must be installed and used as described in this User Guide.

1. ⚠ Warning: Use only the supplied power supply (Model Delta Electronics MDS-060AAS19 B) and cable with the ForeSite IS System. Power supplies specified are part of the equipment. Do not position any part of the equipment to keep it from disconnecting from the mains, should the need arise. In case of emergency, unplug the device to isolate it from the mains.
2. ⚠ Warning: ForeSite IS should only be configured as indicated in the hardware section of the User Guide. Modification of this equipment is prohibited. To ensure grounding reliability, connect the equipment to a receptacle with proper electrical grounding. For medical applications, connect the equipment to a receptacle marked “Hospital Only,” “Hospital Grade,” or an equivalent.
3. ⚠ Warning: Do not attach or connect any external accessories, including computers, cables, or peripherals, to the ForeSite IS Display Terminal input/output ports (USB, Ethernet, serial, and power).
4. ⚠ Warning: Do not use the ForeSite IS System if any of the cables to and from any of the enclosed units are damaged or visibly separating from the enclosures. This includes the power supply, or sensor USB cable.
5. ⚠ Warning: Do not use the equipment in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
6. ⚠ Warning: The ForeSite IS System is intended for use by health care professionals only.
7. ⚠ Warning: The ForeSite IS Display Terminal may become hot with extended use in a hot environment. Handle with care and avoid contact with hot surfaces. Do not place tablet on any body surface. Place on a hard surface and do not impede airflow.
8. ⚠ Warning: Administrative options settings must be reviewed and selected by a qualified medical practitioner.
9. ⚠ Warning: Do not use the ForeSite IS Sensor to lift the patient or to help remove the patient from the bed.
10. ⚠ Warning: The ForeSite IS Sensor is not intended for direct contact with the patient and must be covered with a fitted cotton sheet.
11. ⚠ Warning: The sensor is not defibrillator-proof unless covered with a fitted cotton sheet, minimum 0.01 in. (0.254 mm) thick, or equivalent.
12. ⚠ Warning: Do not attempt to service or maintain the ForeSite IS equipment when in use with a patient.
13. ⚠ Caution: The ForeSite Intelligent Overlay and ForeSite Intelligent Mattress with embedded sensors should be cleaned between each use. Unplug all product components from the wall outlet before cleaning. Never intentionally expose the system to moisture other than the specified cleaning agents. Refer to Maintenance and Cleaning for more information.
14. ⚠ Caution: The side of the system with labeling must face towards the patient’s body for medical safety compliance.
15. ⚠ Caution: Do not use the ForeSite IS System if the system's covering material is visibly damaged or punctured. Ensure that patients making contact with the sensor do not have sharp objects on their person, and that no sharp objects make contact with the sensor, as it may puncture the sensor during use.
16. ⚠ Caution: The ForeSite IS System is designed for indoor use only.

17. ⚠ Caution: For information regarding the safe disposal of your ForeSite IS Display Terminal, contact your local XSENSOR representative or XSENSOR directly.
18. ⚠ Caution: Only use the USB communication cable provided with the ForeSite IS System. The USB cable length cannot exceed 10 feet (3 meters).
19. ⚠ Caution: Ensure power cords do not trail on the ground, to avoid tripping hazards.
20. ⚠ Caution: Avoid damage to the Display Terminal. Never place or rest another object on it while it is not in use.

If any of these warnings or cautions are unclear, please contact XSENSOR Technology Corporation immediately for more information.

Description of Components

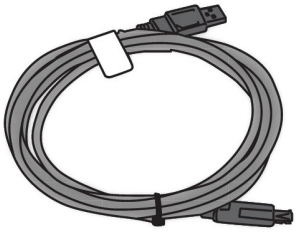
The ForeSite IS System includes the following components:

ForeSite IS Display Terminal

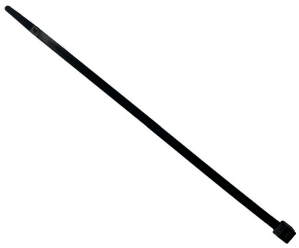
ForeSite Intelligent Overlay or ForeSite Intelligent Mattress with embedded sensors

19 VDC, 3.15 A AC/DC power supply

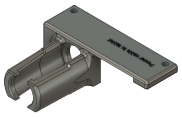
Power adapter cord



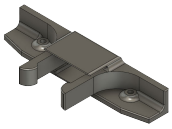
USB extension cable (sensor to display terminal)



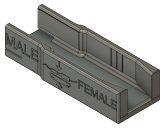
Reusable cable tie (zip tie)



Power cord brace



USB adapter brace



USB-USB connector brace

Note: The brace components are not supplied with all systems. Contact XSENSOR Support if you need the braces but they were not supplied with your system.

Display Terminal Status Lights

The two lights on the front of the Display Terminal show the following states:

- Power (Top LED): Green when on. Off when off.
- Battery Charging (Bottom LED): Red when low battery. Flashing white when charging. Solid white when battery is fully charged. Off when off.

Power Supply and Power Cord

Use only the ForeSite IS System supplied power supply with the ForeSite IS System. Before using the ForeSite IS system, verify that the power supply is model Delta Electronics MDS-060AAS19 B.

POWER CORD REQUIREMENTS:

Warning: To ensure the grounding reliability of the ForeSite IS System, connect the equipment to a receptacle with proper electrical grounding. The type of attachment plug can vary according to the country in which it is being used.

Following are examples of attachment plugs used in different countries:

	North America		Denmark	NOTE: Contact your distributor if you require a power cord with an attachment plug other than the type supplied with your system.
	Australia		India	
	Great Britain		Israel	
	Continental Europe		Italy	
	Japan		Switzerland	

For medical applications, only use a “Hospital Grade” power cord (or equivalent) to connect the power supply to receptacles marked “Hospital Grade,” ”Hospital Only,” or an equivalent.

Installation

Inspect ForeSite IS Components Before Using

1. Inspect the ForeSite IS System for signs of damage including, but not limited to, tears, punctures, cracks, and/or exposed inner layers. If damage to the system is identified or suspected, return it immediately to XSENSOR for repair or replacement.
2. Inspect USB cable and power supply cables for signs of damage including, but not limited to, tears, cracks, and/or exposed wiring. If damage to system cables is identified or suspected, return them immediately to XSENSOR for repair or replacement.
3. Inspect the Display Terminal and power supply for signs of damage including, but not limited to, cracks, punctures, damaged connectors or enclosures, and/or exposed wiring or electronic components. If damage to the Display Terminal or power supply is identified or suspected, return it immediately to XSENSOR for repair or replacement.

Installing the ForeSite IS Overlay

The Strapped ForeSite Intelligent Surface Overlay is a fitted mattress cover designed to fit over existing hospital mattresses that strap to their bed frames.

1. Unroll the overlay and place it so the zippered pocket is on the top left of the mattress and the **Foot End** label is face up.

2. Drape the top half of the overlay over the top half of the mattress. Ensure that the corners align.

3. Grab the bottom edge of the overlay and tug on it gently to ensure that the top half of the overlay is flush with the top edge of the mattress.

4. Push down the flap at the bottom edge of the mattress so the overlay is fitted nicely over the mattress.

5. Each corner has a strap originating from the short ends of the overlay. Grab that strap with one hand. Feed the overlay strap under any mattress-to-frame straps.

6. Lift up the long edge of the overlay about 2.5 feet from the corner. A buckle will be located on the underside.

7. Feed the strap through the backside of the top buckle slot.

8. Feed the strap through the front of the bottom buckle slot and tighten till snug. Overtightening is not required and not recommended. Let the edge of the overlay return to its natural position.

9. (Optional) If desired, roll up any excess length of strap and tuck into the nearby strap loop.

10. Repeat Steps 5-10 for all four corner straps.

Installing the ForeSite Intelligent Mattress

The ForeSite Intelligent Mattress combines a mattress and a pressure sensor into a single integrated unit.

1. Arrange the mattress such that the sloped heel zone, labelled Foot End, is on the bottom half of the bed frame.

Connecting the Power Supply

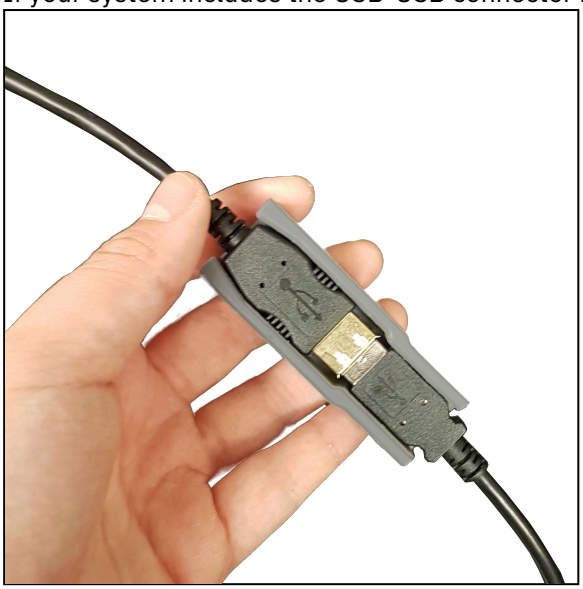
Insert the power supply connector into the charging port on the side of the Display Terminal.

If your system includes the power supply brace, align the power supply connector between the teeth on the brace. Push the connector into the brace until it is fully inserted in the charging port.

Connecting the Sensor

The USB extension cable connects the sensor to the ForeSite IS Display Terminal.

1. Plug the male end of the sensor USB connector into the female end of the USB extension cable.
2. If your system includes the USB-USB connector brace, slide it onto the two connected cable ends.



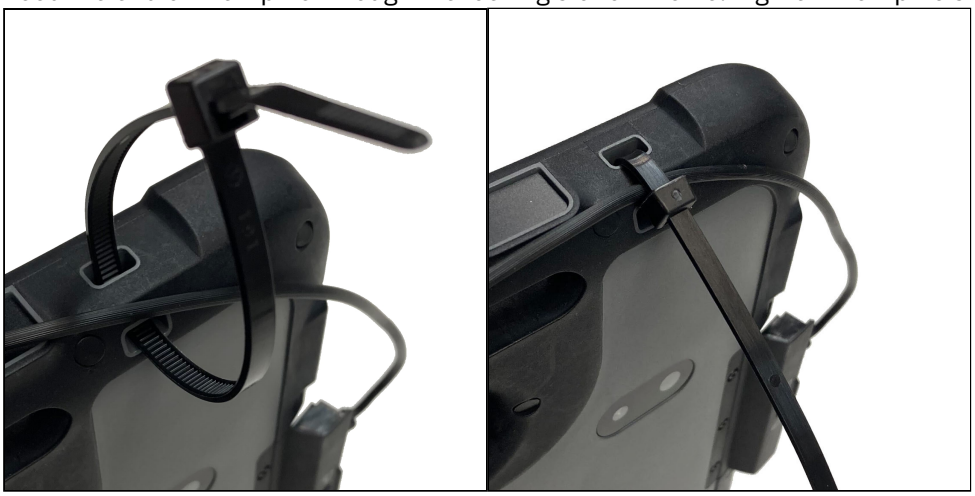
3. Insert the male end of the USB extension cable into the USB port on the Display Terminal. If your system includes the USB adapter brace, align the end of the USB extension cable between the teeth on the brace. Push the connector into the brace until it is fully inserted in the USB port.

Securing the USB-to-tablet Connection

For proper strain relief on the USB cable, secure it to the tablet with the reusable zip tie.

1. Position the USB cable along the side of the Display Terminal. Be sure to leave enough slack so the USB cable does not kink or put extra strain on the USB connector. Slide the zip tie, with the teeth facing up, through the slots on the Display Terminal.

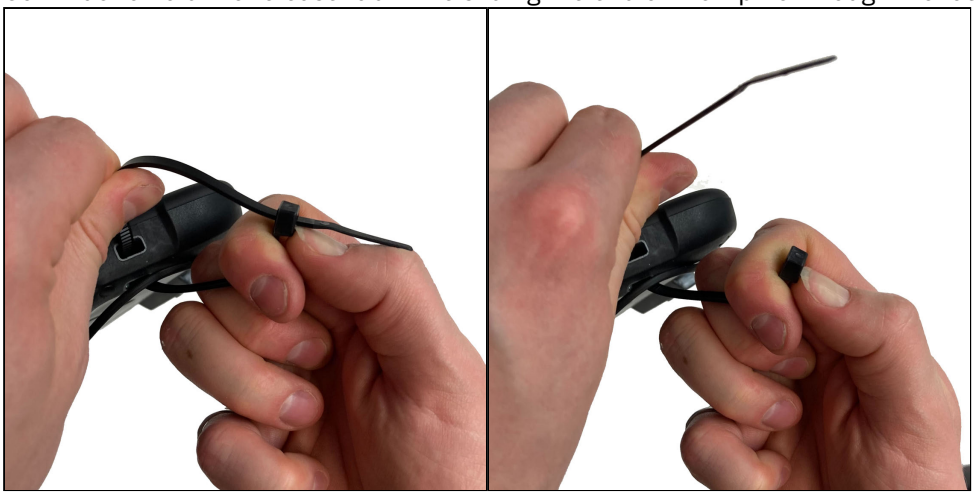
2. Feed the end of the zip tie through the locking slot on the tie. Tighten the zip tie snugly around the cable.



To remove the zip tie:

1. The underside of the locking slot on the zip tie has a release tab. Slide a fingernail or small screwdriver blade under the tab. Push the tab down, away from the teeth on the zip tie end.

2. Continue to hold the release tab while sliding the end of the zip tie through the locking slot.



Finish Making the Bed

1. Smooth out any wrinkles on the system with your hand.

2. Cover the system with a fitted cotton sheet and finish making the bed.

⚠ Warning: The ForeSite IS System is not intended for direct contact with the patient and must be covered with a fitted cotton sheet.

⚠ Warning: The sensor is not defibrillator-proof unless covered with a fitted cotton sheet, minimum 0.01 in. (0.254 mm) thick, or equivalent.

Maintenance and Cleaning

Maintenance

There are no serviceable parts on the ForeSite IS System. Refer to Contact Information for instructions on finding an authorized repair facility.

Thoroughly clean the ForeSite IS System according to the instructions in this section.

Cleaning: Cleaning the Display and Connections

⚠ Caution: Any liquid that comes in contact with the external connection ports, such as the USB port, may cause corrosion and damage. Use only a soft, dry cloth to wipe the connectors.

1. Spray a clean, absorbent, non-shedding soft cloth with one of the cleaning disinfectants listed in Cleaning and Disinfecting the Sensor Surface.
2. Wipe the mounting bracket, cords, and power supply.
3. Wipe the back and sides of the ForeSite IS Display Terminal.
4. Thoroughly wipe the Display Terminal screen.
5. Wait until the recommended contact time has passed, then wipe off disinfectant with a clean cloth dampened with water.

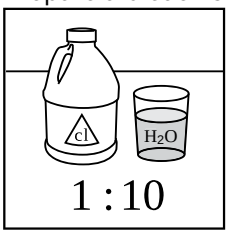
Cleaning and Disinfecting the Sensor Surface

Thoroughly clean the ForeSite IS System according to the instructions in this section.

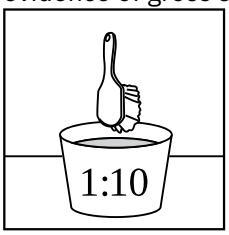
As outlined below, the sensor surface must be cleaned with two bleach-wipe-rinse cycles.

1. Remove the cotton sheet covering the system prior to performing the cleaning procedure.

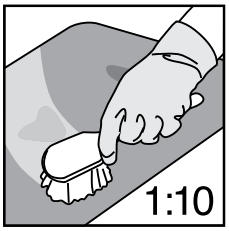
2. Prepare a bleach solution by diluting common household bleach at a 1:10 dilution.



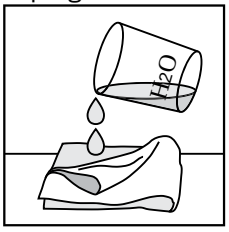
3. Using a soft bristled brush that has been dipped in the prepared bleach solution, remove all visual evidence of gross soil.



4.



5. Rinse off residual cleaning solution using a clean soft cloth that has been wetted with cool tap water by wiping until all evidence of residual cleaning solution is removed.



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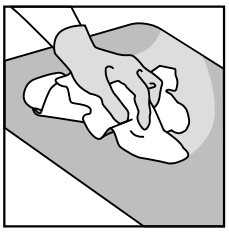
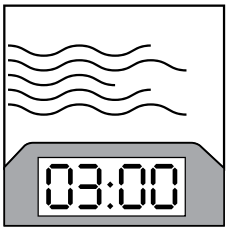
7 Using a disinfectant wipe (example CaviWipes™), wipe the sensor.

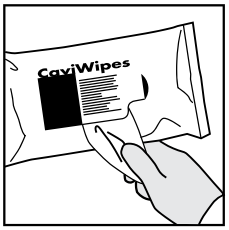
8



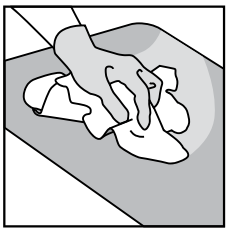
9 Allow the fabric to stay wet for 3 minutes.



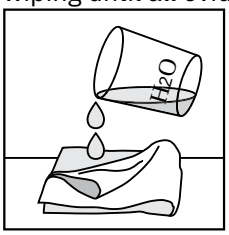
10 Using a new disinfectant wipe (example CaviWipes™), wipe the fabric until all visual evidence of debris is removed.



11



12 Rinse off residual cleaning solution using a clean soft cloth that has been wetted with cool tap water by wiping until all evidence of residual cleaning solution is removed.



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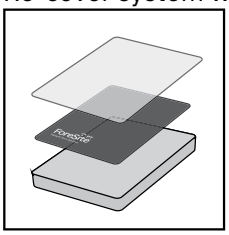
14 Repeat steps 3–13, for a total of two bleach-rinse-wipe cycles.

15 Allow the system to dry completely.

16 Re-cover system with a sheet.



⚠ Caution: Follow the specific EPA label contact times when using the disinfectant.

⚠ Caution: Solvents containing alcohol, bleaching, or abrasive material may be harmful. Contact XSENSOR before using any disinfectant not listed above.

⚠ Caution: Under no circumstances should a phenolic-based cleaning solution be used.

⚠ Warning: If the sensor becomes wet or soiled it should be cleaned immediately as described here.

⚠ Warning: Do not use excessive liquid or harsh cleaners. Do not use any steam cleaning device on the sensor. The sensor can be damaged by excessive moisture. The bleach solution must not exceed 10% bleach. Clorox Dispatch® or an equivalent bleach is recommended.

When finished cleaning, visually inspect the sensor for missed stains or soiling. Repeat cleaning process for any missed spots. Allow to dry before storage or reuse.

Cleaning the Top of the System

When there is visible soiling, clean the system as described in Cleaning and Disinfecting the Sensor Surface. If the system is about to be used for a new patient, clean with a disinfectant wipe (example CaviWipes™).

1. Remove the bedding and lower the bed rails to expose the system.
2. Using a disinfectant wipe (example CaviWipes™), wipe down the entire top surface of the system and its sides.

3. If the ForeSite IS System has any additional flaps, buckles, or straps, use a disinfectant wipe (example CaviWipes™) to wipe down the these parts.

Cleaning the Mattress Underneath the ForeSite Intelligent Overlay

1. Remove the system, or push it to the side, and wipe the mattress underneath using a disinfectant wipe (example CaviWipes™).

Cleaning the Underside of the System

1. Wipe the entire underside of the system using a disinfectant wipe (example CaviWipes™). If working with the ForeSite Intelligent Overlay, the system can be folded in half or completely flipped over to access the underside. If working with the ForeSite Intelligent Mattress, the system can be flipped over to access the underside.

2. Disconnect the system's USB cable from the USB extension cable connected to the ForeSite IS Display Terminal and wipe down the cable using a disinfectant wipe (example CaviWipes™).

3. If the overlay has any additional flaps, buckles, or straps, use a disinfectant wipe (example CaviWipes™) to wipe down the these parts.

Storing the System and Display Terminal

If using the ForeSite Intelligent Mattress, simply unplug the USB cable from the Display Terminal and the ForeSite Intelligent Mattress and place cable and Display Terminal in original packaging. The USB cable attached to the mattress can be coiled up and tucked into the pouch on the mattress cover near the mattress indicator light.

If using the Strapped ForeSite Intelligent Overlay, safely store the system using the following instructions:

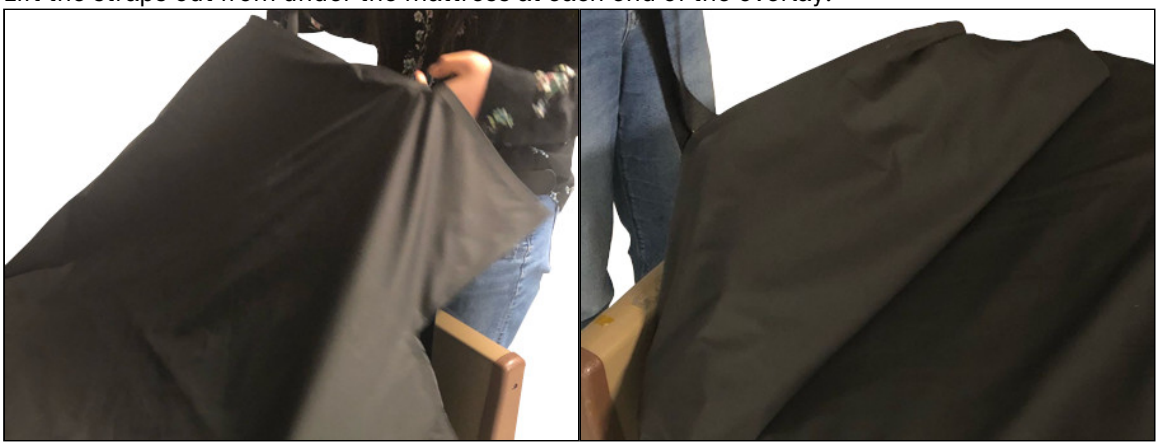
1. Fold up the long edge of the overlay at the location of a buckle.

2. Pull upwards on the tab of the buckle to loosen the strap.

3. Pull the strap up out of the bottom buckle slot.

4. Pull the strap to remove it from the buckle entirely.

5. Repeat steps 1-4 for each corner strap.
6. Lift the straps out from under the mattress at each end of the overlay.



7. Flip the overlay upside down and place the provided foam block at the foot end.

8. Bring the foot edge and straps over the foam block.

9. Place the straps inside and fold the edges inward.

10. Fold the bottom edge over the foam block to start rolling the overlay around the foam block. Roll completely and place into the accompanying XSENSOR storage bag.

Storage and Transport Conditions

Environmental conditions for system storage and transportation:

Ambient Temperature	-4 to 140˚F (-20 to 60˚C)
Relative Humidity	10 to 90%, non-condensing
Atmospheric Pressure	0.50 to 1.06 bar

Fold the ForeSite overlay as described in Storing the System and Display Terminal.

⚠ Do not place heavy objects on top of a folded ForeSite Intelligent Overlay or a ForeSite Intelligent Mattress when placed in storage. Store and/or transport the ForeSite IS System components in the provided protective case.

End of a System's Product Life

When a system has been damaged or reached the end of its product life, please contact XSENSOR or your local XSENSOR representative for next steps for your system.

Specifications

SENSOR ELECTRONICS

Sensor electronics (X4 SPK, P/N ASY-27-00118) are enclosed in the system.

Dimensions	64 mm x 50 mm x 21 mm
Weight	0.2 kg
Input power	USB
Power consumption	2 W

POWER SUPPLY

Model	Delta Electronics MDS-060AAS19 B
Dimensions	62 mm x 135 mm x 34.1 mm
Weight	360 g
Input	100–250 VAC, 50–60 Hz, 1.5–0.75 A
Output	19 VDC, 3.15 A
Case Material	Plastic

SENSOR

	ForeSite IS
Sensor array	26 x 64 sensels
Sensing area	825.5 mm x 2032 mm
Sensor resolution	31.75 mm
Pressure range	5 mmHg to 200 mmHg

DISPLAY TERMINAL

Note: use only with approved power supply.

Display Size	26 cm
Resolution	1920 x 1200 pixels
Weight	1.1 kg
Battery	11.1 V, 3700 mAh
Bluetooth	Built-in Bluetooth

SYSTEM

Risk Management	EN ISO 14971
Electrical/ Mechanical Safety	IEC 60601-1:2005/A1:2012 Edition 3.1
Electromagnetic Compatibility	IEC 60601-1-2:2014 Edition 4.0

Compliance with Emission and Immunity Standards

The equipment generates (and can radiate) radio-frequency energy. It can cause interference with adjacent equipment if it is not installed and used in accordance with the instructions in this manual. Even with adequate precautions, there is no guarantee that interference will not occur. To determine if the ForeSite IS System causes interference, move the system away from adjacent equipment.

Portable and mobile RF communications equipment can affect the operation of electrical equipment. Precautions should be taken to minimize the potential of this occurrence. Such precautions include, but are not limited to, separation of the RF communication equipment and the ForeSite IS System.

Standards IEC 60601-1-2:2014

ANSI C63.4:2014	American National Standard for Methods of Measurement of Radio-Noise Emissions from Low- Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz
IEC 60601-1-2:2014	Medical Electrical Equipment - Electromagnetic Compatibility
CISPR 11:2009+A1:2010	Industrial, scientific and medical equipment - Radio- frequency disturbance characteristics
IEC 61000-3-2:2014	Limits for Harmonic Current Emissions (equipment input current ≤ 16A per phase)
IEC 61000-3-3:2013	Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for equipment with rated current ≤ 16A per phase and not subject to conditional connection
IEC 61000-4-2:2008	Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
IEC 61000-4-3:2010	Testing and Measurement Techniques - Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2012	Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2014	Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6:2006	Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio- Frequency Fields
IEC 61000-4-8:2009	Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004	Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
ISO 17025	General requirements for the competence of testing and calibration laboratories

*XSENSOR declares that the ForeSite IS complies with the European Communities Council Medical Device Directive 93/42/EEC amended by 2007/47/EC. This declaration will be deemed invalid should any

unauthorized modifications be made to the systems. Follow this User Guide when setting-up and operating the system.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The ForeSite IS 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 ForeSite IS System is suitable for use in all establishments except domestic. However, it may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes if the following warning is heeded: ⚠ Warning: This equipment/ system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ForeSite IS System or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class B	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

IEC 60601-1-2:2014
The ForeSite IS System is intended for use in the electromagnetic environment specified below. The customer or the user of the ForeSite IS 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 ±15 kV Air	±8 kV Contact ±15 kV Air	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 for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 60601-1-2:2014

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	10 V/m, 1 kHz AM at 80% depth, 80 MHz to 2.7 GHz	10 V/m, 1 kHz AM at 80% depth, 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the ForeSite IS System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 

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

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

a) Field 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 ForeSite IS System is used exceeds the applicable RF compliance level above, the ForeSite IS 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 ForeSite IS System

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

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