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# User Guide

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## ForeSite SS User Guide Revision



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**ASY-05-00005-02**

# Introduction

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## The ForeSite SS System: Overview

Thank you for purchasing the ForeSite SS Pressure Imaging System! The ForeSite SS sensor is embedded with thousands of sensor cells that continuously measure the level of pressure between two solid objects. For clinical purposes, this may be the level of pressure between a wheelchair and a client's body surface. The sensor connects to a touch screen tablet that displays live pressure information and statistics on a colour-coded scale. The resulting pressure images may be rotated, captured as snapshots, recorded as a series of frames, and even displayed in 3D.

ForeSite SS is designed to be intuitive and user-friendly in an effort to help wheelchair seating professionals make more informed clinical decisions



### The ForeSite SS System: Intended Use

Wheelchair users are at an increased risk of developing pressure ulcers which can form when muscles and soft tissue press against surfaces such as a chair or a bed. As such, preventative measures must be taken in order to reduce these risks. ForeSite SS provides clinicians with the tools they need to help their clients reduce the risk of developing pressure ulcers. By utilizing ForeSite SS, clinicians are able to create an image of the relative pressure distribution over a surface. The dynamic pressure images then allow them to evaluate the pressure distribution, and, if necessary, take appropriate measures to enhance the pressure distribution for that particular surface.

ForeSite SS is calibrated at the factory to improve the overall accuracy of the pressure distribution images. However, the system is not intended to replace current best practices for prevention of pressure ulcers. It is intended to provide additional monitoring and data collection while standard monitoring techniques and turn schedules are maintained.

This system is designed in compliance with medical safety standards and is intended for the use of clinicians only. It is not recommended for private use or client use without the assistance of a trained medical professional. 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 (see Appendix 4).

## Product Compliance: Safety Standards

The XSENSOR Pressure Imaging System complies with the following standards:

- ✓ IEC 60601-1:2005, CSA C22.2 No. 60601-1:2008, ANSI/AAMI ES 60601-1/A2:2010, UL 60601-1:2003
- ✓ Mode of Operation
- ✓ Class I Medical Equipment
- ✓ Type B Applied Part. Only the sensor(s) touch the patient in normal use.

The ForeSite SS is intended for use by healthcare professionals only. ForeSite SS must be installed and used as described in this user manual.

## Product Compliance: Emission & Immunity Standards

The ForeSite SS is a class A digital device suitable for business, industrial and commercial environments. It is not intended for residential use. The ForeSite SS may cause radio interference or may disrupt the operation of nearby equipment. Portable and mobile RF communications equipment can also affect ForeSite SS. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.

The ForeSite SS should not be used adjacent to or stacked with other equipment. If adjacent or stacked operation is necessary, the Pressure Imaging System should be observed to verify normal operation in the configuration in which it will be used.

Use of accessories and cables other than those provided by XSENSOR may result in increased emissions or decreased immunity.


ForeSite SS complies with Part 15 of the FCC Rules. Operation is subject to the following 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.

### Standards Compliance:

- ✓ EN 60601-1-2:2007 (Ed3.0) Medical Electrical Equipment – Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility (Non-life-supporting, Group 1, Class A Equipment)
- ✓ FCC 15.107/CISPR 11 (Class A) Conducted Emissions
- ✓ FCC 15.109/CISPR 11 (Class A) Radiated Emissions
- ✓ Industry Canada ICES-003(A)/NMB-3(A) Compliant
- ✓ IEC 61000-3-2:2005 Harmonics Emissions
- ✓ IEC 61000-3-3:2008 Flicker Emissions
- ✓ IEC 61000-4-2:2008 Electrostatic Discharge
- ✓ IEC 61000-4-3:2008 Radiated Susceptibility
- ✓ IEC 61000-4-4:2007 Electrical Fast Transients
- ✓ IEC 61000-4-5:2005 Surge Susceptibility
- ✓ IEC 61000-4-6:2006 Conducted Susceptibility
- ✓ IEC 61000-4-8:2001 Magnetic Susceptibility
- ✓ IEC 61000-4-11:2007 Dips & Interrupts

| Guidance and manufacturer's declaration – electromagnetic emissions  |            |  |
|--|------------|--|
| The <b>ForeSite SS</b> system is intended for use in the electromagnetic environments specified below. <b>ForeSite SS</b> system users should ensure that it is used in such an environment. |            |  |
| Emissions Test   | Compliance | Electromagnetic Environment Guidance   |
| RF emissions CISPR 11  | Group 1    | The <b>ForeSite SS</b> 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 the nearby electronic equipment.                     |
| RF emissions CISPR 11  | Class A    | The <b>ForeSite SS</b> system is suitable for use in all establishments other than domestic and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2   | Class A    |  |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3  | Complies   |  |

| Recommended separation distances between portable and mobile RF communications equipment and the ForeSite SS   |   |  |  |
|--|---|--|--|
| The <b>ForeSite SS</b> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>ForeSite SS</b> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>ForeSite SS</b> as recommended below, according to the maximum output power of the communications equipment. |   |  |  |
| Rated maximum output power of transmitter W  | Separation distance according to frequency of transmitter M |  |  |
|  | 150 kHz to 80 MHz   | 80 MHz to 800 MHz                          | 800 MHz to 2.5 GHz                       |
|  | $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$                  | $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ | $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 0.01   | 0.12  | 0.12                                       | 0.24                                     |
| 0.1  | 0.37  | 0.37                                       | 0.74                                     |
| 1  | 1.17  | 1.17                                       | 2.34                                     |
| 10   | 3.69  | 3.69                                       | 7.38                                     |

| The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment 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 | 3 V              | Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br><br>$d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup><br><br>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:  |
| Radiated RF IEC 61000-4-3  | 3 V/m 80 MHz to 2,5 GHz  | 3 V/m            |  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment<br>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. |                          |                  |  |

| The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment 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   | ±6 kV contact<br>±8 kV air                                | ±6 kV contact<br>±8 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 ±1 kV for input/output lines | ±2 kV for power supply lines ±1 kV for input/output 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)<br>±2 kV line(s) to earth        | Mains power quality should be that of a typical commercial or hospital environment.  |




## Warnings & Cautions

|   |  |  |  |
|---|--|--|--|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11<br>UT = 230 Vac | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery. |
| Power frequency (50 Hz) magnetic field<br>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.  |

The ForeSite SS 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 the System product life, please contact XSENSOR for safe disposal instructions (see Appendix 4).

1. **Warning:** Use only approved power supplies (Magtech part number 26-2704 and Glob Tek Part number WR9QD2000MSB-N-MED) with the ForeSite SS 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.
2. **Warnings:** ForeSite SS should only be configured as indicated in the hardware section of the User Guide. Modification of this equipment is prohibited.
3. **Warning:** The ForeSite SS Sensor should be cleaned between each use. Unplug all product components from the wall outlet before cleaning. See the Maintenance section of the User Guide for information on cleaning.
4. **Warning:** The ForeSite SS System is not intended for long term use.
5. **Warning:** The ForeSite SS System is intended for use by health care professionals only.
6. **Warning:** To reduce risk of electric shock, connect the Magtech 26-2704 to supply mains with protective earth. Where available, connect the equipment to a receptacle marked "Hospital Only," "Hospital Grade," or an equivalent.
7. **Warning:** Always completely disconnect the power cord from your chassis whenever you work with the hardware. Do not make connections while the power is on. Sensitive electronic components can be damaged by sudden power surges.
8. **Warning:** Do not connect any external accessories, including computers, cables, or peripherals, to the ForeSite SS Display Tablet input/output ports (USB, Ethernet, and HDMI) which is part of a wired (USB Sensor Pack) system during client pressure monitoring. If using the ForeSite SS Tablet Wireless System (Wireless Sensor Pack), please note that the ForeSite SS tablet is no longer medically compliant when connected to any external accessory. As such, please ensure the tablet and any accessory equipment are kept at least 1.83m (6') away from the subject when connected.



9. **Warning:** Do not use the ForeSite SS System if any of the cables to and from any of the enclosed units are damaged or frayed. This includes the power supply and Sensor USB cable. Contact XSENSOR to replace damaged cables (see Appendix 4 of the User Guide).
10. **Warning:** Do not use the ForeSite SS System if the Sensor pad's covering material is visibly damaged or punctured. Ensure that clients 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. Contact XSENSOR for a replacement Sensor if it becomes damaged; do not attempt to repair with cheap materials such as tape or glue.
11. **Warning:** Do not use the equipment in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
12. **Warning:** Do not use the ForeSite SS Sensor to lift the client or to help remove the client from a seated position.
13. **Warning:**  ForeSite SS Tablet 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.
14. **Warning:** Always lay the Tablet on a flat, sturdy surface when not in use to prevent damages from falling.
15. **Warning:** Do not allow clients to handle the Tablet or Sensor cables; these should be handled only by registered health care professionals.
16. **Warning:** Do not attempt to service this product by yourself, as opening or removing covers may expose you to dangerous voltage points or other risks and will void the warranty. Refer all servicing to qualified service personnel.
17. **Warning:** Do not touch the LCD panel surface with sharp or hard objects.
18. **Warning:** The ForeSite SS Sensor is not intended for direct contact with the client's skin and should be covered with a sheet or clothing.
19. **Warning:** The Sensor is not defibrillator-proof.
20. **Caution:** Administrative options and settings must be reviewed and selected by a qualified medical practitioner.

21. **Caution:** Never intentionally expose the Sensor pad to moisture besides the specified cleaning agents. Refer to the Maintenance section of the User Guide for more information on cleaning.
22. **Caution:** For the Sensor, labeling and grid marks must face towards the client's body; do not use the flip side of the Sensor against a client's body.
23. **Caution:** The ForeSite SS System is designed for indoor use only.
24. **Caution:** For information regarding the safe disposal of the ForeSite SS Display Tablet or Sensor at the end of product life, contact a local XSENSOR representative or XSENSOR directly (see Appendix 4 of the User Guide).
25. **Caution:** Only use the cables provided with the ForeSite SS System.
26. **Caution:** Ensure power cords do not trail on the ground, to avoid tripping hazards.
27. **Caution:** Avoid damage to the Display Tablet by never setting or resting another object on it while it is not in use.

If any of these warnings or cautions are unclear, do not hesitate to contact XSENSOR immediately for more information (see Appendix 4).



# ForeSite SS Hardware



Note: For information on using ForeSite SS Desktop Systems, please see Appendix#2.

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## ForeSite SS Tablet Wireless System

### Single Pad Sensor System



### Components

- A ForeSite SS Tablet (with software installed)
- B ForeSite SS Tablet power supply (and power cord)
- C Pressure Imaging Sensor Pad
- D Wireless Sensor Pack with battery (X4)
- E X4 Power Supply (for recharging)
- F Documentation USB Flash Drive
  - ForeSite SS Desktop Software\*\*
  - ForeSite SS User Guide
- G ForeSite SS Quick Start Guide (not shown)
- H ForeSite SS Carry Case (not shown)

\* See Appendix 2 for the ForeSite SS Desktop System Set-Up

**Warning:** To ensure operator and subject safety and compliance with regulations detailed on Page 5, connect and operate ForeSite SS only as described here.

## Set-Up Instructions

1. Begin by ensuring both the ForeSite SS tablet and the X4 are fully charged. Recommended charge time to ensure a full charge is 2-3 hours for both devices. For the X4, connect the micro-USB on the X4 power supply to the micro-USB input on the X4, as shown in Figure 1. For the ForeSite SS tablet, connect the tablet power supply and cord to the tablet as shown in Figure 2.

Figure 1



Figure 2



**Warning:** Use only XSENSOR approved power supplies with ForeSite SS. Do not connect any other USB device or cable to the X4.

2. Inspect the sensor pad covering material and cable for signs of damage. These include, but are not limited to, tears, punctures, cracked enclosures, and/or exposed wiring. If damage is identified or suspected, contact XSENSOR for repair (see Appendix #4)

**Warning:** Do not attempt live pressure imaging if the sensor pad is damaged or soiled. Refer to the Maintenance section of this user guide for more information on cleaning.

3. Connect the X4 to the sensor pad for Wired Set-up, plug the micro USB into the X4 enclosure and the other end into the tablet.
4. For wireless setup, connect the X4 to the sensor pad via bluetooth settings. On the tablet, go to Bluetooth devices and ensure Bluetooth is on. Your tablet will search for discoverable Bluetooth devices. Pair it with the sensor (device will start with WSPK).

Figure 3



If the sensor has one of the following markings, it is cleanable as per the Cleanable Sensor Instructions section of this User Guide.

For sensors WITHOUT this label, place sensor in the approved protective sleeve provided by XSENSOR before placing on the desired surface. Ensure that the protective sleeve separates the portions of the sensor pad that may come into direct continuous contact with the subject. The cabling from the sensor to the sensor pack should exist from the open end of the sensor protective sleeve.

5. Power ON the X4 by pressing the ON/OFF button for at least two seconds (Figure 4). The power light will glow green.
6. Power ON the tablet by pressing the ON/OFF button for at least 3 seconds (Figure 5). The power LED indicator on the display panel will turn blue. See the ForeSite SS Software section of this guide for details on using the software.
7. The ForeSite SS system is now ready for use. Before the subject makes contact with the sensor, ensure that they do not have any sharp objects or protrusions that may puncture/tear the sensor pad covering material.

Figure 4



**Warning:** Neither sensor pads nor protective sleeves are intended for contact with bare skin.

Figure 5



## ForeSite SS Tablet System











### Dual Sensor Pad Systems

Dual sensor pad systems include all the same components as listed above for the single pad systems with the exception of:

- 1 additional Pressure Imaging Sensor Pad
- 1 additional Wireless Sensor Pack (X4)

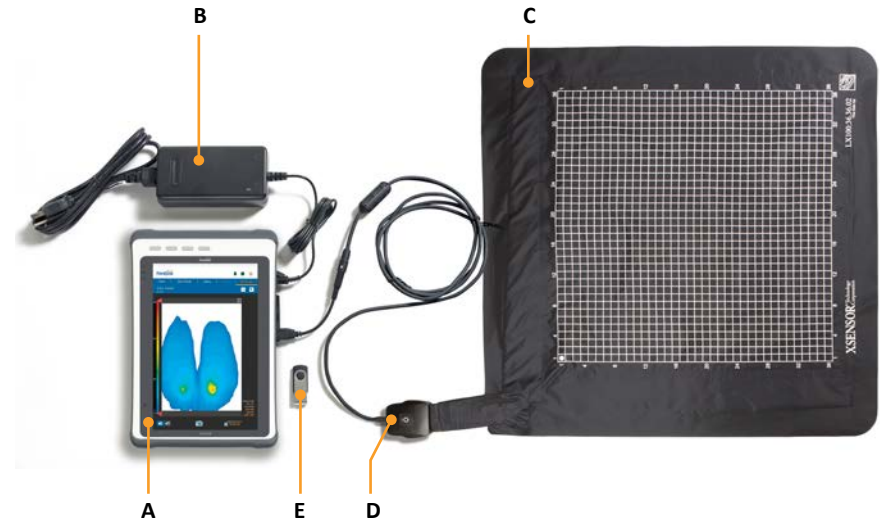
The dual sensor pad system is set-up the same way as the single sensor pad system with the exception that it requires you to repeat the instructions above for charging, connecting and powering ON your second X4.

**NOTE:** Ensure that the power adaptor corresponds to the plug as provided in your country (see chart). XSENSOR is **not** responsible for damages that may sustain if an incorrect power source is used.

|   |                      |   |         |
|---|----------------------|---|---------|
|    | North American       |    | Danish  |
|    | Australian           |    | Indian  |
|   | British              |   | Israeli |
|  | Continental European |  | Italian |
|  | Japanese             |  | Swiss   |

If a different power adaptor is required for your country, please contact XSENSOR for a replacement (see Appendix 4). For medical applications, only use a “Hospital Grade” power cord (or equivalent) to connect the power supply to receptacles marked “Hospital Grade” or equivalent.

### Single Pad Sensor System



### Components

- A ForeSite SS Tablet (with software installed)
- B ForeSite SS Tablet power supply (and power cord)
- C Pressure Imaging Sensor Pad
- D Sensor Pack (SPK) (with SPK adaptor)
- E Documentation USB Flash Drive
  - ForeSite SS Desktop Software\*
  - ForeSite SS User Guide
- F ForeSite SS Quick Start Guide (not shown)
- G ForeSite SS Carry Case (not shown)

\* See Appendix 2 for information on ForeSite SS Desktop Systems

### Set-Up Instructions

**Warning:** To ensure operator and subject safety and compliance with regulations detailed on Page 5, connect and operate ForeSite SS only as described here.



Figure 1

1. Begin by ensuring the ForeSite SS tablet is fully charged. Recommended charge time to ensure a full charge is 2-3 hours. To charge, connect the tablet power supply and cord to the tablet as shown in Figure 1.

**Warning:** Use only XSENSOR approved power supplies with ForeSite SS.

2. Inspect the sensor pad covering material and cable for signs of damage. These include, but are not limited to, tears, punctures, cracked enclosures, and/or exposed wiring. If damage is identified or suspected, contact XSENSOR for repair (see Appendix 4)

**Warning:** Do not attempt live pressure imaging if the sensor pad is damaged or soiled. Refer to the Maintenance section of this user guide for more information on cleaning.

3. Connect the SPK to the sensor pad cable connection point (aka CONN) as shown in Figure 2. The SPK and CONN are connected correctly when the labels on each are both aligned, as shown. The alignment between the two connections is stiff to ensure reliable electrical connectivity. As such, press the two together gently but firmly until you hear a “click”. This indicates that you have a secure and reliable connection.

4. Connect the SPK adaptor (connected to the SPK) to the tablet USB port as shown in Figure 2.

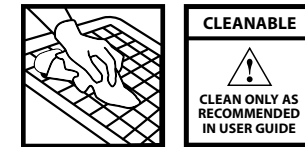
**Warning:** The SPK adaptor must only be used with the ForeSite SS Tablet. Do not connect to any other USB device.

5. Place the sensor pad on the desired supporting surface, such as a chair or a bed. Ensure that the sensor’s grid is facing towards the subject applying the pressure.

Figure 2



If the sensor has one of the following markings, it is cleanable as per the Cleanable Sensor Instructions section of this User Guide.



For sensors WITHOUT this label, place sensor in the approved protective sleeve provided by XSENSOR before placing on the desired surface. Ensure that the protective sleeve separates the portions of the sensor pad that may come into direct continuous contact with the subject. The cabling from the sensor to the sensor pack should exist from the open end of the sensor protective sleeve.

6. Power ON the tablet by pressing the ON/OFF button for at least 3 seconds (Figure 3). The power LED indicator on the display panel will turn blue. Once the tablet is powered ON, the green power light on the SPK will turn green. See the ForeSite SS Software section of this guide for details on using the software.

7. The ForeSite SS system is now ready for use. Before the subject makes contact with the sensor, ensure that they do not have any sharp objects or protrusions that may puncture/tear the sensor pad covering material.

**Warning:** Neither sensor pads nor protective sleeves are intended for contact with bare skin.

Figure 3



## Dual Sensor Pad Systems

Dual sensor pad systems include all the same components as listed above for the single pad systems with the exception of:

- ✓ 1 additional Pressure Imaging Sensor Pad
- ✓ 1 additional Sensor Pack (SPK)
- ✓ 1 Dual USB Hub

The dual sensor pad system is connected as shown in Figure 4.

Figure 4

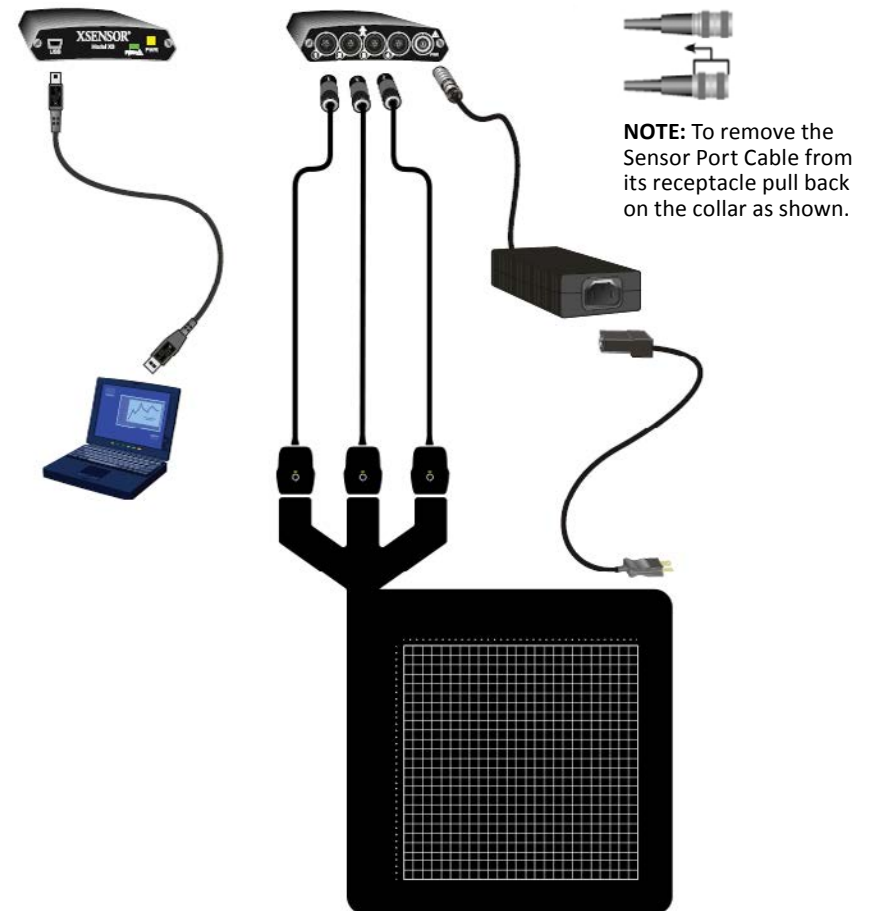


**Warning:** The dual hub is for use only with the ForeSite SS Tablet System (USB SPK). It allows connection of two USB SPKs to the tablet.

## High Resolution Sensor Pad Systems

- High Resolution sensor pad systems require 3 SPKs to be connected to an X3 Pro Platform.
- The high resolution sensor pad system is connected as shown in Figure 5. Turn on the X3 Pro Platform by pressing the power button until the LED turns on. The LED on the sensor pack should also turn on at the same time











Figure 5



**NOTE:** To remove the Sensor Port Cable from its receptacle pull back on the collar as shown.

# Display Tablet Specifications

**NOTE:** Ensure that the power adaptor corresponds to the plug as provided in your country (see chart). XSENSOR is **not** responsible for damages that may sustain if an incorrect power source is used.

|   |                      |   |         |
|---|----------------------|---|---------|
|  | North American       |  | Danish  |
|  | Australian           |  | Indian  |
|  | British              |  | Israeli |
|  | Continental European |  | Italian |
|  | Japanese             |  | Swiss   |

If a different power adaptor is required for your country, please contact XSENSOR for a replacement (see Appendix 4). For medical applications, only use a “Hospital Grade” power cord (or equivalent) to connect the power supply to receptacles marked “Hospital Grade” or equivalent.

|                                   |   |
|-----------------------------------|---|
| <b>I/O Connectors</b>             |   |
| Bottom I/O Port                   | USB 3.0/2.0, Full size SD slot, HDMI                |
| <b>Display</b>                    |   |
| Size                              | 26 cm (10.1”) LCD Display                           |
| Resolution                        | 1280 x 800 pixels                                   |
| <b>Mechanical and Environment</b> |   |
| Weight                            | 1.2 kg  |
| Shock                             | Rugged mobile-shock                                 |
| Vibration                         | Rugged mobile-vibration                             |
| Drop                              | 1.2m (4')   |
| Certifications                    | CE, FCC, EN 60601-1                                 |
| <b>Power Management</b>           |   |
| Power Input                       | 12 VDC<br>Note: use only with approved power supply |
| Battery                           | 7.4V/6300 mAh Li-ion                                |
| Operating time                    | 5 Hours   |
| <b>Wireless Communication</b>     |   |
| WLAN                              | IEEE 802.11 a/b/g/n/ac                              |
| Bluetooth                         | Bluetooth 4.0                                       |



**Tablet Terminal Light Indicators:**

| # | COMPONENTS        | FUNCTION                                    |
|---|-------------------|---|
| 1 | Docking Connector | Not applicable for ForeSite SS              |
| 2 | USB               | For connectivity and/or USB storage devices |
| 3 | LAN / HDMI        | LAN & HDMI Out combo connector              |
| 4 | Mic-in/Line-Out   | Not applicable for ForeSite SS              |
| 5 | DC - Jack         | For Power Supply connectivity               |

## Power Supply Specifications

|        |                        |
|--------|------------------------|
| Input  | 100-240 V AC, 47-63 Hz |
| Output | 12V DC, 2.5A max       |

## X4 Lithium-Ion Battery Specifications

| Molicel MCR-1821J |          |
|-------------------|----------|
| Nominal Voltage   | 7.4 VDC  |
| Nominal Capacity  | 2400 mAh |

**Caution:** Risk of fire, explosion or burns. Do not short circuit, crush, heat above 100C, incinerate, or disassemble the battery.

**Caution:** Charge only using the XSENSOR X4 and Globtek WR9QD2000MSB-N-MED.

The battery contains recyclable materials and recycling is encouraged. Some jurisdictions require recycling.

Please consult and obey local battery disposal laws.

## Maintenance

### The Tablet Terminal

If proper precautions are met in accordance to provided warnings and cautions to protect the Display Terminal, there should be no regular maintenance required. If damages occur, contact XSENSOR as soon as possible. **Do not** attempt repairs on your own.

### The Sensor

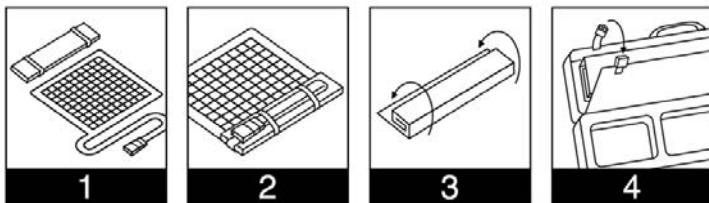
The Sensor pad does not require regular maintenance, but periodic calibration may be required for optimum accuracy. Repairs may **ONLY** be performed by the manufacturer or the manufacturer's authorized representative. The device may still be used successfully if it is not calibrated; the frequency of calibration is at the discretion of the user.

### Wireless Sensor Pack (X4) Battery

The X4 battery is maintenance free. It is recommended that batteries be kept at room temperature (25°C +/- 5°C). Elevated temperatures can result in shortened battery life.

## Storage/Transport

Only health care professionals should handle storage and cleaning of the system components. All pieces of the system should be stored according to the following instructions which also appear on the ForeSite SS carry case insert.



### Storage Steps

1. Place the sensor pad on a flat surface.
2. Place the carry case insert along the edge of the sensor pad and secure the sensor cable using the attached elastic straps.
3. Roll, wrapping the sensor pad around the carry case insert.
4. Store the wrapped sensor pad in the designated sensor carry case compartment and secure it with the attached straps.

### 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          |

Do not place heavy objects on top of a folded sensor. Store the system components in the provided protective case(s) when not in use, and avoid leaving pieces of the system lying unprotected or in a place where there may be a tripping hazard or danger of the system components being damaged. If the system is required to be transported to another location, ensure all components are folded and/or safely put away into their protective cases during transport.

## Cleaning

Cleaning may be performed if a part of the system becomes accidentally dirty or smudged. It is strongly recommended that only health care professionals attempt to perform any type of cleaning on any part of the system, as follows:

### Tablet Terminal

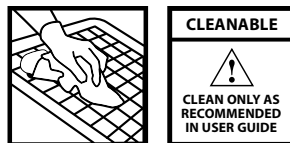
- ✓ The Display Terminal may be wiped gently with a computer cleaning cloth or clean towel to remove smudges from the touch screen.
- ✓ Do not use liquid or aerosol cleaners, abrasive cleaners, waxes or solvents as these may cause permanent damage to the screen.
- ✓ NEVER immerse in water or other fluids.

### Power Cords/Connectors

- ✓ No electrical device should come in contact with water or other fluids. This applies to the connector ends of USB cords and any other electrical connector. A clean, dry cloth may be used to clean these portions of the cords only, but ONLY while they are unplugged.
- ✓ The non-connector portions of power cords and connectors may be cleaned with a spray disinfectant. The following choices are recommended:
  - ED Everyday Disinfectant by Wood Wyant, 4 ml/litre, 10 min. contact
  - MetriGuard® by Metrex, 3 min. contact
- ✓ After applying a light spray to non-electrical portions of power cords, wait the recommended contact time for the particular spray, and wipe clean with a lightly damp, clean cloth. Allow to air dry completely before attempting to plug in or use the cables again.

### Sensor

If the sensor has one of the following markings, it is cleanable as per the Cleanable Sensor Instructions section of this User Guide.



For sensors WITHOUT this, protective sleeves are provided by XSENSOR to shield against soiling. The sensor should not be exposed to moisture and should never be immersed in water. In the case that something is accidentally spilled on the sensor:

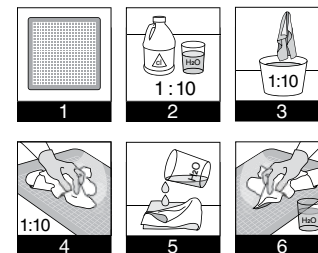
- Wipe carefully with a damp cloth and isopropyl alcohol if absolutely necessary
- NEVER use a steam cleaner on the sensor
- After cleaning the sensor, allow to air dry COMPLETELY before returning to use.

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

## Cleanable Sensor Instructions

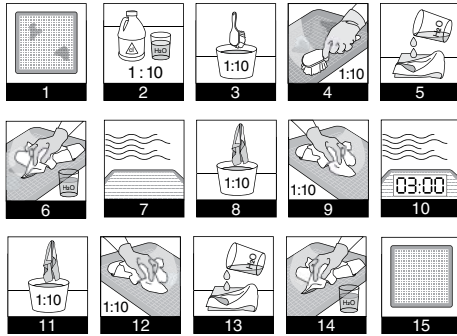
### For an UNSOILED Sensor:

→ NOTE: the sensor should never be immersed in water



1. Lay the unsoiled sensor on flat surface
2. Prepare a 1:10 cleaning solution (1 bleach : 10 water).
3. Dip a soft cloth into 1:10 cleaning solution.
4. Clean sensor with soft cloth moistened with cleaning solution.
5. Wet clean soft cloth with tap water.
6. Clean residual solution off with wet cloth.

### For a SOILED Sensor:



1. Lay the soiled sensor on a flat surface.
2. Prepare a 1:10 cleaning solution (1 bleach : 10 water).
3. Dip a soft bristle (M16) brush into cleaning solution.
4. Scrub surface with the brush.
5. Wet a soft cloth with tap water.
6. Wipe off residual cleaning solution with the wet cloth.
7. Allow surface to dry.
8. Wet a soft cloth with 1:10 cleaning solution.
9. Wipe the sensor with a soft cloth moistened with cleaning solution.
10. Allow sensor to dry for 3 minutes.
11. Dip a fresh, clean soft cloth into 1:10 cleaning solution.
12. Clean sensor with clean, moist cloth until all visible debris removed.
13. Wet a clean, soft cloth with tap water.
14. Wipe residual solution off with wet cloth.
15. Allow sensor to dry.

### ForeSite SS Label Symbols



Warning – ForeSite SS tablet 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.



Approved for sale in the European Economic Area



RCM (Regulatory Compliance Mark) - approved for sale in Australia and New Zealand.



Tested and approved by TUV (Technischer Überwachungs-Verein)



Refer to the User Manual for important warnings and operating instructions



# ForeSite SS Software



|                                  |           |
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## Introduction

This section of the User Guide is intended to provide you with a simple overview of some of the key features and functions of the ForeSite SS software.

## Quick Start

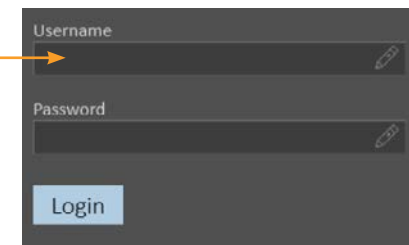
These 6 steps will help you get started pressure imaging with your ForeSite SS software quickly and easily. Once your hardware has been properly setup as per the instructions in the Hardware section of the guide, you are ready to get started with your ForeSite SS software.


1. Ensure your ForeSite SS tablet is fully charged
2. Turn the tablet on by pressing and holding the power button at the top of the tablet until the power indicator light on the display flashes blue

Display flashes blue



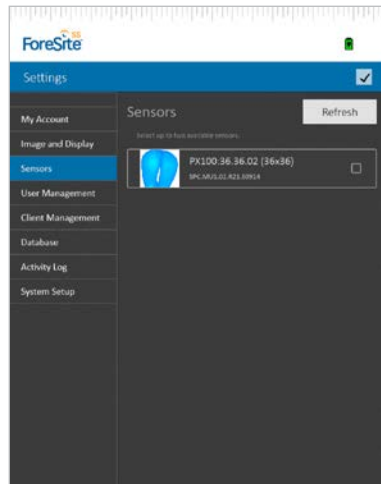
3. The first time you use ForeSite SS, you'll log into the software by entering the Username "Admin" and selecting the Login button. No password is required.




4. For security purposes, we recommend you create a password as soon as possible.
  - Select the icon  in the top right hand corner, and select Settings from the dropdown menu.
  - From the **My Account** tab, select the “Change Password” button and complete the required fields.

→ Note: you do not need to enter anything in the “old password” field the first time you create a password.
5. Before closing out of Settings, select the Sensors tab to ensure your sensor is connected and active. If your hardware was properly configured, your sensor will appear in the list and a pressure image will be live, as shown in the image to the right. Ensure the sensor(s) you are using are selected before you save and close out of settings.
 

→ If you do not see your sensor(s) in the sensor list, click “Refresh” to search for an available sensor connection. See Appendix #1 for further sensor connectivity trouble shooting.




6. From the main Clients tab, select  to create a new client file. Once you have created a new client, select the Live Image tab to begin pressure imaging.

## User Roles & Security

ForeSite SS was designed with role-based security in order to meet the unique security needs of your organization. Role-based security allows administrators to create users with specific permissions to both allow and restrict access to different functionality within the software.


There are two user roles in ForeSite SS; Standard User and Administrator. As new users are created in the software, they are given a unique username, a password and a user role which defines their accessibility within the software. As such, all ForeSite SS users, regardless of their role, must provide a username and password in order to access the system. New users can only be created by the Administrator user role. This, and other administrative features, are discussed in more detail below.

## Administrative Settings

The following Settings can be accessed by an Administrator only. Open Settings from the main dropdown menu icon  on the upper right-hand corner of any screen.

### User Management

#### To Create New Users

1. Select  to launch the user creation screen
- For increased security, new users should change their password upon first logging into ForeSite SS.

#### To Edit User Account Information

1. Select the user to open the user profile
2. Select the field you wish to edit

### To Change/Reset a User's Password

1. Select the user to open the user profile
  2. Select **Change Password**
  3. Enter the new password and select **Save**
- For increased security, users whose passwords have been changed/reset by an admin should change their password upon logging in with the new password.

### To Change a User's Language Preference

→ This feature is user-specific and is not a system-wide setting.


1. Select the user to open the user profile
2. Select the preferred language from the Language dropdown

### To Delete Users

1. Select the user to open the user profile
  2. Select the Delete User button at the bottom of the screen
- All client files associated with a user account must be transferred to another user or deleted before the user account can be deleted. See Client Management under Administrative Settings for more information.

## Client Management

### To Transfer Client Files Between Users

1. Select a user from the dropdown menu
2. Select the client file you wish to transfer
3. Select 
4. Select the user to whom you wish to transfer the client file
5. Select **OK**

### To Delete Client Files

1. Select a user from the dropdown menu
2. Select the client file you wish to delete
3. Select the delete icon

## Database

### To Backup your Data to an External Storage Device

1. Insert a USB memory stick into the tablets USB port
2. Select **Backup...**
3. Select the external storage device where you would like to backup your data
4. Select **Open**

### To Restore your System

1. This feature will overwrite your current database with the contents of the database imported.
2. Insert the USB memory stick containing the ForeSite SS database you would like to import into the tablets USB port
3. Select **Restore...**
4. Select the database file from which you would like to restore your database.
5. Select **Open**

## Activity Log

### To Export your Activity Log

1. Insert a USB memory stick into the tablets USB port
2. Select **Export**

### To Clear your Activity Log

→ This feature will clear your **entire activity history and cannot be undone.**

1. Select **Clear**
2. Select **Yes**

### To Enable/Disable Activity Logging

1. Select/deselect the checkbox

### Set the Maximum Log Size/Time Span

1. Enter the maximum number of activities you would like to log in your log file



## System Setup

These settings allow admins to customize ForeSite SS to suit the needs of your organization and apply settings across all users.

### USER PERMISSIONS


#### To Allow Users to Share Client Files

→ This feature makes all client files accessible to all users

1. Select the Enable Client Sharing Between All Users checkbox

### EMAIL

#### To Set Up Email Sharing

→ When enabled, this icon  will be displayed when sharing client files

1. Select the **Share client images and notes by email** checkbox
2. Enter your outgoing email server
3. Enter the email address to use as the “sender” for file sharing
4. Enter the password for the above email address

### NETWORK CONFIGURATIONS

#### To Disable/Enable Bluetooth Connectivity

→ This feature allows seamless connectivity to wireless SPKs and is ON by default. If you do not have a wireless SPK, disable this feature to extend battery life.

1. Select/deselect the Enable Bluetooth Adapter checkbox

#### To Pair ForeSite with a sensor connected via wireless SPK

→ This feature is used to pair sensors connected to ForeSite via a wireless SPK. It should be used if your sensor does not appear in the sensor list on the Sensor tab. See the Trouble Shooting section in this User Guide for more information.

1. Select the Pair Sensors button

### DATE AND TIME

#### To Set the Date and Time

1. Select Set Date/Time

## Standard Settings

The following settings are accessible to both Standard Users and Administrators

### My Account

#### To Edit Account Information

1. Select the field you wish to edit

#### To Change Your Password

1. Select Change Password
2. Enter the new password and select Save
3. Complete the fields and select Save

#### To Change Your Preferred Language

1. Select your preferred language from the Language dropdown

### Image and Display

These settings allow you to customize your pressure imaging experience.

### PRESSURE IMAGE LEGEND AND SCALE

#### To Change the Pressure Unit of Measurement

1. Select the preferred unit of measurement from the Pressure Units dropdown menu

#### To Set the Upper and Lower Pressure Limits

→ The threshold affects the range of pressure values displayed in the image. These can also be adjusted by touching the pressure legend beside the image (unless it is locked in settings).

1. Enter the desired lower/upper pressure values next to Image Threshold

#### To Lock the Upper and Lower Pressure Limits

1. Select the checkbox under the lower and upper pressure value fields
- Locking the upper and lower pressure limits will prevent you from adjusting them on the live pressure image and pressure image gallery items (snapshots/recordings)

## PRESSURE IMAGE STATISTICS

### To Turn Off/On Pressure Calculations

1. Select the checkboxes for the calculations you wish to view on the live pressure image and pressure image gallery items (snapshots/recordings)  
→ *Coefficient of Variation and Dispersion Index* are calculations which depend on the usage and placement of anatomical markers.

### To Change the Contact Area Unit of Measurement

1. Select the preferred unit of measurement from the Contact Area dropdown menu

## PRESSURE VIDEO RECORDING

### To Set the Maximum Recording Time

1. Enter the desired lower/upper recording time in minutes next to Maximum Recording Time

## TOUCHSCREEN DISPLAY

### To Calibrate the Touchscreen Display

1. Select Calibrate

### To Adjust the Screen Brightness

1. Drag the Screen Brightness slider to the right to brighten the display backlight, and left to dim it.



### To Turn On/Off the Tablet Power Saving Mode

- To conserve battery life, this feature will automatically turn off the display when the user is inactive
1. Select the Power Saving Mode checkbox

## Sensors

*Your ForeSite SS sensors are designed to connect automatically to ForeSite SS so that you can begin pressure imaging quickly and easily. In some instances, however, you may experience connectivity issues, or wish to use two sensors for pressure imaging. The following features address these scenarios.*

### To Re-Connect a Sensor that has Lost Connection with ForeSite SS

- If the sensor connectivity icon at the top of your screen indicates you have lost your connection , manually scan for your sensor and reconnect.
1. Ensure your sensor is configured and connected per the instructions in the Hardware section of this user guide.
  2. Select Refresh to scan for a sensor connection
  3. If ForeSite finds your sensor, it will appear in the list and display a live thumbnail of the pressure image. Select the checkbox of the sensor(s) you wish to connect.
  4. After closing out of Settings, the sensor connectivity icon should now show as connected. 

### To Connect to Two Sensors (e.g. back and seat)

1. Ensure your sensors are configured and connected per the instructions in the Hardware section of this user guide.
2. If ForeSite finds your sensors, they will appear in the list and display a live thumbnail of the pressure image. Select the checkbox of the sensor(s) you wish to connect.  
→ To disconnect a sensor, simply deselect the checkbox next to the sensor in the list and exit from Settings.

## System Information

### To Check for Software Updates


1. Select Check For Updates

## Client Management

The Clients feature is designed to help you organize your pressure image data. All pressure image snapshots and recordings are associated with a client file which is listed alphabetically for ease of retrieval and efficient record-keeping. The Clients feature also allows users to create and attach notes to a client file chronologically.

Creating/opening a client file is the first-step in beginning pressure imaging. The Live Image tab will be inactive until a client file is created and opened. Begin by selecting the main Clients tab.


### To Create a New Client File

1. Select 
2. Complete the relevant fields

### To Search for an Existing Client File

1. Enter the name or ID of the client file you wish to retrieve in the Clients search field  
→ You can filter the list of client files by selecting the Sort list and toggling to sort by First Name, Last Name, Client ID or date of Last Visit.

### To Edit a Client File

1. Select the client file (Opens file on the Client Details tab)
2. Select 

## Pressure Imaging

Once a client file is opened, the **Live Image** tab will become active. To view the live pressure image, select the main **Live Image** tab.



### To Rotate the Pressure Image

1. Select  until the pressure image rotates to the desired orientation





### To View the 3x3 Peak Pressure Index (PPI)

1. Select an area of the pressure image and hold

### To Take a Pressure Image Snapshot

1. Select  directly below the live pressure image (opens snapshot on the Review tab)
2. Enter a title for your snapshot
3. Select  to capture notes for your snapshot  
→ Snapshots are automatically saved to Gallery as soon as they are taken

### To Take a Pressure Image Recording

1. Toggle the camera/recorder icon   to the recorder icon (it will turn blue)
2. Select  to begin recording
3. Select the red stop button when you wish to stop recording
4. Enter a title for your recording
5. Select  to capture notes for your recording  
→ Recordings are automatically saved to Gallery as soon as they are taken

### To Reset the Settling Time

1. Select the refresh icon next to the digital timer


### To Adjust the Upper and Lower Pressure Thresholds

1. Select the upper/lower red arrows and drag them to the desired pressure values

### To View the Pressure Image in 3D

1. Select the **3D** icon  
→ Re-select the icon to return to 2D

### To Pin a Note or Anatomical Marker to the Pressure Image

1. Select 
2. Select and hold the area on the pressure image where you would like to place it
3. Select the desired type from the list  
→ Note (Select the text area below the Note selection to enter text)
  - Coccyx
  - LIT: left ischial tuberosity
  - RIT: right ischial tuberosity
  - RGT: right greater trochanter
  - LGT: Left greater trochanter  
→ Selecting both the LIT and RIT anatomical markers will invoke a line of symmetry on the pressure image

### To Delete a Note or Anatomical Marker

1. Select the previously placed note or anatomical marker
2. Select the delete icon



## Gallery Management

Pressure image snapshots and recordings are automatically saved to the Gallery and organized chronologically beginning with the most recent snapshot or recording.


### To Open a Gallery Item

1. Select the item from the list



### To Share/Export Gallery Items

1. Select 
2. Select the items you wish to share/export
3. Select 
4. On the share/export screen, choose the pressure image data you would like to share/export
5. Select the envelop icon to email or disc icon to save to an external drive  
→ The email option will only be displayed if this administrative setting is turned on. All shared/exported items are in PNG format.

### To Delete a Gallery Item(s)

1. Select 
2. Select the items you wish to delete
3. Select the delete icon

### To Compare Gallery Items

1. Select 
2. Select the items you wish to compare
3. Select 
4. See next section for viewing compared items  
→ You must select at least two items to activate the compare feature. Compared items open on the main **Review** tab (see below).

## Reviewing Snapshots and Recordings

Once selected, gallery items (snapshots and recordings) open on the main Review tab. From here, users can review the pressure image more carefully, make changes and also capture more pressure image-related data. Users also have many of the same features available on the Live Image tab including rotating the pressure image, viewing it in 3D, viewing the 3X3 PPI, adjusting pressure limits, and pinning notes and anatomical markers.



Select an item from the Gallery tab to view it on the main **Review** tab.

### To View Notes Captured on a Gallery Item

(where notes have been previously captured)

1. Select the note icon on the pressure image to expand and view the note


### To Edit Snapshot/Recording Title or Notes

1. Select 
2. Select item title field to make changes
3. Select  to make changes to item notes





### To Playback a Recording

1. Select the play button below the recording



### To Capture a Single Frame from a recording

1. Select the play button below the recording
2. While the recording is playing back, select  to capture a single frame  
→ Single frames are reflected in the Gallery with the same red flag icon that appears on the capture icon



### To Capture the Average Frame from a Recording

1. Toggle the single/average frame icon   to the average frame icon 
2. Drag the red arrows on the recording progress bar to the desired time frames within the recording. Time frames are indicated directly below the recording progress bar.
3. Select  to capture the average frame  
→ Average frames are reflected in the Gallery with the same red arrows icon that appears on the capture icon

### To View Compared Pressure Images as a Quadrant or in Columns

1. Once the Compare feature has been initiated from the Gallery (described above), select  for column view and  for quadrant view  
→ Column view displays the pressure image statistics below the pressure image

### To Save Compared Pressure Images

1. Select  directly below the compared images
2. Enter a title for your comparison
3. Select  to capture notes for your comparison  
→ Saved comparisons are automatically saved to Gallery

### To Share/Export Compared Pressure Images

1. Select 



# Appendixes



|   |           |
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| <b>Appendix 2 - The Desktop System</b>  | <b>58</b> |
| <b>Appendix 3 - Contact Information</b> | <b>64</b> |

## Appendix 1 - Troubleshooting

ForeSite SS software does not communicate with the X4 and sensor pad:

1. Turn off the X4 by pressing the ON/OFF button for one (1) second , then turn it back on by pressing the ON/OFF button for one (1) second.
2. Wait ten (10) seconds.
3. If the X4 indicator LED does not turn blue, contact XSENSOR Technical Support.
4. If the LED turns blue, wait for the software to begin communicating with the sensor. Once a connection is established, the sensor icon in the software will turn green.
5. If the software still does not communicate with the sensor pad, check to see if the sensor pad has been properly paired with the device.
  - Go to ForeSite Settings in the software
  - Go to System Setup
  - Under Network Configuration, ensure that the “Enable Bluetooth Adapter” option is selected
  - Under Bluetooth settings, select the “Pair Sensors” option
6. Once paired, the sensor should begin communicating with the software.
7. If the sensor still does not appear to pair with the software, contact XSENSOR Technical Support.

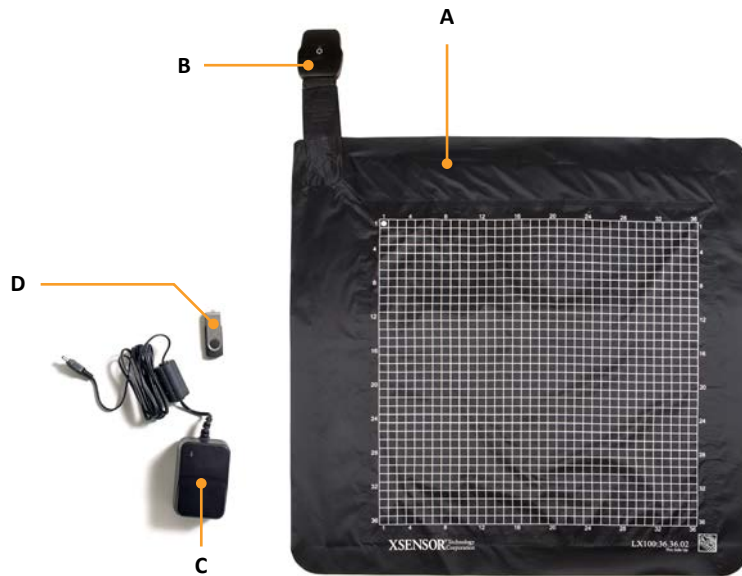
## Software Error Messages

| SOFTWARE ERROR MESSAGES   | RECOMMENDED ACTION  |
|---|---|
| The sensor last used cannot be found. Be sure it is on and charged.   | Refer to page 18 for information on charging and powering ON your X4.             |
| The battery for the sensor needs charging.  | Refer to page 18 for information on charging your X4.                             |
| A selected sensor cannot be found. Be sure it is on and charged.  | Refer to page 18 for information on charging and powering ON your X4.             |
| Lost connection to one or more of the sensors.  | Navigate to the Sensors tab in Settings to re-establish the sensor(s) connection. |
| The video capture session was interrupted at due to a sensor communication error.   | Navigate to the Sensors tab in Settings to re-establish the sensor(s) connection. |
| Lost connection with the sensor. Please connect a sensor to resume image capture.   | Navigate to the Sensors tab in Settings to re-establish the sensor(s) connection. |
| The detected hardware configuration is not medically compliant while viewing a live pressure image and may pose risks to client safety. Disconnect your sensor pad or proceed at your own risk. | Refer to Appendix 2 for medically compliant configurations for ForeSite SS.       |

## Appendix 2 - The Desktop System

### ForeSite SS Desktop Wireless System

#### I. SINGLE SENSOR PAD SYSTEMS



- A Pressure Imaging Sensor Pad
- B Wireless Sensor Pack (X4)
- C X4 Power Supply (for recharging)
- D Documentation USB Flash Drive
  - ForeSite SS Desktop Software
  - ForeSite SS User Guide
- E ForeSite SS Quick Start Guide (not shown)
- F ForeSite SS Carry Case (not shown)
- G ForeSite Bluetooth Adaptor (for computers that are not Bluetooth enabled; not shown)

#### System Set-Up

**Warning:** To ensure operator and patient safety, and compliance with regulations as detailed on connect and operate ForeSite SS only as described here.

- 1) Refer to the instructions for charging, connecting and powering ON your X4 in the Hardware section of this user guide.
- 2) Insert XSENSOR USB flash drive into PC USB port to install ForeSite SS

**Note:** for computers that are not Bluetooth enabled, please insert the ForeSite Bluetooth Adaptor into your computer's USB port to establish a Bluetooth connection.

- Follow onscreen instruction to view pre-loaded files on USB. If not automatically prompted, navigate to USB drive on PC.
  - Open folder called ForeSite SS Desktop Software and run installation file called InstallForeSiteSSDesktop.
  - Follow the onscreen installation instructions to install ForeSite SS on your desktop.
  - Launch ForeSite SS from the application icon now displayed on your desktop.
- 3) Inspect the sensor pad covering material and cable for signs of damage. These include, but are not limited to, tears, punctures, cracked enclosures, and/or exposed wiring. If damage is identified or suspected, contact XSENSOR for repair (see Appendix #4).

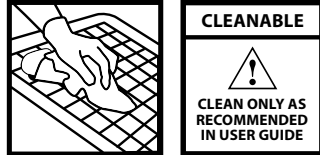
**Warning:** Do not attempt live pressure imaging if the sensor pad is damaged or soiled. Refer to the Maintenance section of this user guide for more information on cleaning.



- 4) Place the sensor pad on the desired supporting surface, such as a chair or a bed. Ensure that the sensor's grid is facing towards the subject applying the pressure.

The following label on the sensor indicates it is cleanable as described:

If the sensor has one of the following markings, it is cleanable as per the Cleanable Sensor Instructions section of this User Guide.



- 5) The ForeSite SS Desktop system is now ready for use. Before the subject makes contact with the sensor, ensure that they do not have any sharp objects or protrusions that may puncture/tear the sensor pad covering material.

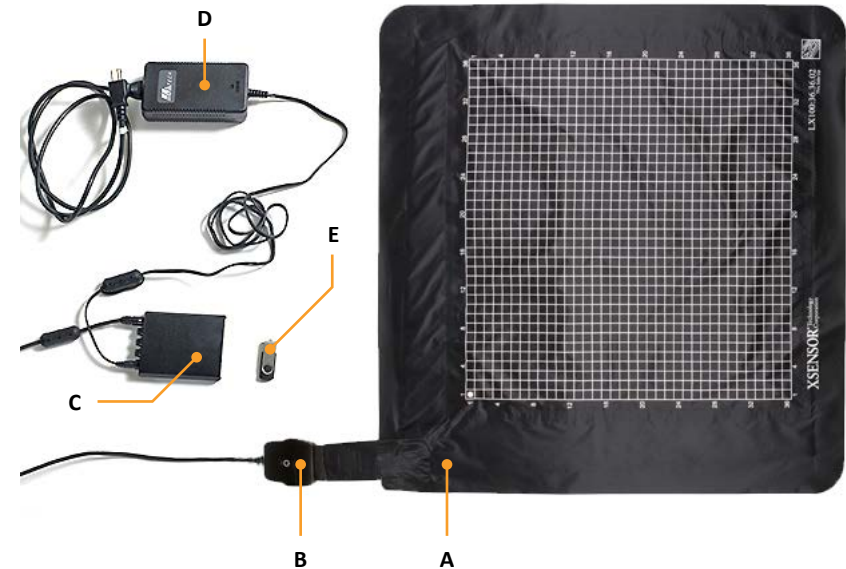
**Warning:** Neither sensor pads nor protective sleeves are intended for contact with bare skin.

## II. DUAL SENSOR PAD SYSTEMS

- Dual sensor pad systems include all the same components as listed above for the single pad systems with the exception of:
  - › 1 additional Pressure Imaging Sensor Pad
  - › 1 additional Wireless Sensor Pack (X4)
- The dual sensor pad system is set-up the same way as the single sensor pad system with the exception that it requires you to repeat the instructions above for charging, connecting and powering ON your second X4.

## ForeSite SS Desktop Systems

### I. SINGLE SENSOR PAD SYSTEMS



- A Pressure Imaging Sensor Pad
- B Sensor Pack (SPK)
- C X3 Pro Platform and USB cable (cable not shown)
- D X3 Pro Platform Power Supply and Power Cord
- E Documentation USB Flash Drive
  - ForeSite SS Desktop Software
  - ForeSite SS User Guide
- F ForeSite SS Quick Start Guide (not shown)
- G ForeSite SS Carry Case (not shown)

## System Set-Up

**Warning:** To ensure operator and patient safety, and compliance with regulations, connect and operate ForeSite SS only as described here:

- 1) Insert XSENSOR USB flash drive into PC USB port to install ForeSite SS
  - Follow onscreen instruction to view pre-loaded files on USB. If not automatically prompted, navigate to USB drive on PC.
  - Open folder called ForeSite SS Desktop Software and run installation file called InstallForeSiteSSDesktop.
  - Follow the onscreen installation instructions to install ForeSite SS on your desktop.
  - Launch ForeSite SS from the application icon now displayed on your desktop.
- 2) Inspect the sensor pad covering material and cable for signs of damage. These include, but are not limited to, tears, punctures, cracked enclosures, and/or exposed wiring. If damage is identified or suspected, contact XSENSOR for repair (see Appendix 4)

**Warning:** Do not attempt live pressure imaging if the sensor pad is damaged or soiled. Refer to the Maintenance section of this user guide for more information on cleaning.

- 3) Connect the SPK to the sensor pad cable connection point (aka CONN) as shown in Figure 1. The SPK and CONN are connected correctly when the labels on each are both aligned, as shown. The alignment between the two connections is stiff to ensure reliable electrical connectivity. As such, press the two together gently but firmly until you hear a “click”. This indicates that you have a secure and reliable connection.
- 4) Connect the system components as shown in Figure 1.

**Warning:** To ensure operator and subject safety, only connect the sensor pack to the X3 Pro Platform. Do not attempt to directly connect the sensor pack to an unapproved PC.

- 5) Turn on the X3 Pro Platform by pressing the power button until the LED turns on. The LED on the sensor pack should also turn on at the same time.
- 6) Place the sensor pad on the desired supporting surface, such as a chair or a bed. Ensure that the sensor’s grid is facing towards the subject applying the pressure.

Pressure sensor pads are available in several performance classes, sizes, pressure ranges, and resolutions to suit a variety of applications:

- PX100 class – basic performance for most applications. Accuracy is  $\pm 10\%$  full scale.
- LX100 class – higher accuracy, high repeatability, low hysteresis, and low creep characteristics. Accuracy is  $\pm 5\%$  full scale.
- IX100 class – higher pressure range (can be used to see foot pressure distribution while standing). Accuracy is  $\pm 10\%$  full scale.

### For use with ForeSite SS:

| Sensor Pad      | Sensing Area | Resolution | Pressure Range     | Cleanable? |
|-----------------|--------------|------------|--------------------|------------|
| PX100 48.144.02 | 24"x72"      | 0.5"       | 5-50 & 10-200 mmHg | No         |
| PX100 64.160.02 | 32" x 80"    | 0.5"       | 5-50 & 10-200 mmHg | No         |
| PX100 26.64.01  | 32" x 80"    | 1 ¼"       | 5-50 & 10-200 mmHg | No         |
| LX100 36.36.02  | 18"x18"      | 0.5"       | 5-200 mmHg         | Cleanable  |
| LX100 40.40.02  | 20" x 20"    | 0.5"       | 5-200 mmHg         | Cleanable  |
| LX100 40.64.02  | 24"x24"      | 0.5"       | 5-200 mmHg         | Cleanable  |
| LX100 48.48.02  | 20"x20"      | 0.5"       | 5-200 mmHg         | Cleanable  |
| LX100:28.28.02  | TBD          | 0.2"       | 5-200 mmHg         | Cleanable  |
| LX100:10.64.05  | 2" x 12.8"   | 0.2"       | 5-200 mmHg         | Cleanable  |
| IX500 64.64.04  | 16" x16"     | 0.25"      | 51-4,137 mmHg      | No         |

## Appendix 3 - Contact Information

Please contact XSENSOR with any questions or concerns in regards to any of the following:

- √ Safe handling/transportation of the ForeSite SS System
- √ Safe cleaning of the ForeSite SS System
- √ Use/misuse of the ForeSite SS System
- √ Replacement of damaged/lost system components
- √ Replacement power cords designed for different countries
- √ Software troubleshooting
- √ General concerns, questions, or comments about this manual and its contents

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