EnSite™ X EP System
Amplifier

REF ENSITE-AMP-02, ENSITE-R-AMP-02

Instructions for Use

Abbott

This warranty is given by Abbott Medical. To make inquiries regarding this warranty, use the contact information for either the manufacturer or the Australian Sponsor.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

The benefits to you given by this warranty are in addition to your other rights and remedies under the Australian Consumer Law.

Abbott Medical warrants to the buyer that the goods, for a period equal to the validated shelf life of the goods (the "Warranty Period"), shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. Unless otherwise obligated by law or mandatory consumer guarantees, under this warranty Abbott Medical will, at its option, replace or repair the goods at its factory, if the buyer, at the buyer's expense, returns the goods within the Warranty Period to Abbott Medical to the address below and after Abbott confirms that the goods are defective.

Abbott Medical

Attn: Postmarket Surveillance

One St. Jude Medical Drive

St. Paul, MN 55117 USA

+1 651 756 2000

To the maximum extent permitted by law, if a mandatory term is implied by law or a mandatory consumer guarantee applies to the goods, and the goods are not of a kind ordinarily acquired for personal, domestic or household use or consumption, Abbott Medical's liability for the breach of the term or guarantee is limited to, at Abbott Medical's option, either replacement or repair of the goods or payment of the costs of replacing or repairing the goods.

EXCEPT FOR MANDATORY TERMS IMPLIED BY LAW, MANDATORY CONSUMER GUARANTEES, OR AS EXPRESSLY PROVIDED IN THIS WARRANTY, ABBOTT MEDICAL DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED.

See the Terms and Conditions of Sale for further information.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Contents

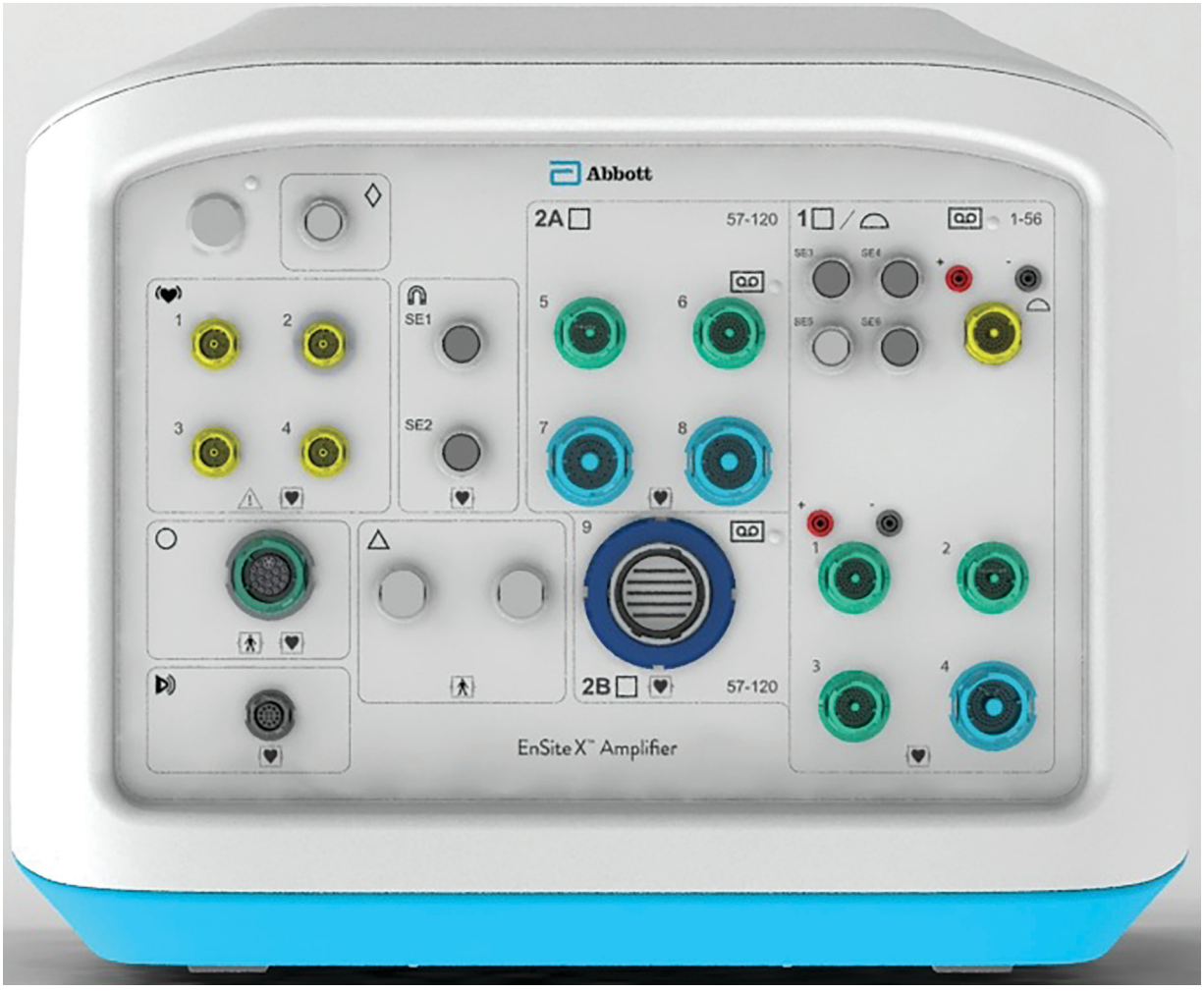
Description

The EnSite™ X Amplifier is the central element of the EnSite™ X EP System. The EnSite™ X Amplifier is used to interface catheters and other electrophysiology (EP) equipment. The amplifier generates, and measures signals associated with magnetic and impedance-based catheter navigation. The EnSite™ X Amplifier converts these signals to a secured digital format and sends them to the EnSite™ X Display Workstation (DWS) for processing and display. The EnSite™ X Amplifier is connected to the DWS through a fiber-optic cable.

The EnSite™ X Amplifier provides interfaces to the following equipment:

- Ablation catheters
- Diagnostic catheters
- EnSite™ X ECG electrodes
- EnSite™ X surface electrodes
- EnSite™ X Display Workstation (DWS)
- Ampere™ RF generator
- Pacing stimulator
- EP recording system (WorkMate™ Claris™ or a third-party recording system)
- TactiSys™ Quartz Equipment
- EnSite™ X Field Frame

Figure 1. EnSite™ X Amplifier



Indications for Use

The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated.

The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures.

Clinical Benefit

The intended clinical benefit is to provide diagnostic information to the physician to aid in the treatment of arrhythmias.

Contraindications

There are no known contraindications.

Warnings

- Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (e.g., stimulator, defibrillator, and other devices) may create a location shift.
- Do not modify or make any additional connections to the EnSite™ X EP System, other than those described in this manual. Do not connect the system to additional multiple socket outlets or extension cords.
- Do not touch accessible connectors and the patient simultaneously.
- Only connect items that have been specified as part of the EnSite™ X EP System or compatible with the EnSite™ X EP System to the multiple socket-outlets.
- When using the EnSite™ X EP System, full protection against the effects of cardiac defibrillator discharge and other leakage currents is dependent upon the use of appropriate cables.
- For patient safety, any connections that directly connect the patient to the EnSite™ X EP System must be routed through the appropriate modules: EnSite™ X EP System SurfaceLink Module, EnSite™ X EP System 20-pin Catheter Input Module, EnSite™ X EP System 80-pin Catheter Input Module and Direct Connect Ports on the EnSite™ X EP System Amplifier.
- The ECG display is not to be used as the primary/sole patient monitor during an Electrophysiology study. The EnSite™ X EP System contains no alarms for indicating inoperative conditions.
- EnSite™ X EP System components should be connected to power through an isolation transformer or the multiple socket outlet supplied with the system carts. Connecting equipment directly to a wall outlet may result in excessive leakage current.
- The multiple socket outlets provided with the EnSite™ X EP System should only be used for supplying power to EnSite™ X EP System components. Failure to do so may result in excessive leakage current. The maximum permitted loads for the multiple socket outlets are:

System Component	Input Current	Output Current
Power strip on carts	12A	N/A

System Component	Power (Max)	Output Current (Max)
Amplifier or DWS Isolation Transformer	US: 1000VA EU: 1000VA JPN: 840VA	US: 8.4A EU: 4.17A JPN: 8.4A
Remote Monitor Isolation Transformer	US/JPN: 720VA EU: 750VA	US/JPN: 6A EU: 3.12A

- Use of accessories, transducers and cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EnSite™ X EP System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Precautions

- Ensure that surface electrodes, Patient Reference Sensors, and associated connectors do not contact one another, electrical ground, or metallic objects.
- When the EnSite™ X Amplifier is turned off, it can affect ECG signals viewed on the recording system. When the EnSite™ X Amplifier is turned off and a recording system is in use, it is recommended that the cables to the EnSite™ X EP System be disconnected from the EnSite™ X Amplifier.
- Do not clean the system components with disinfectants that contain surfactants.
- Do not clean system components with bleach.
- Do not apply cleaners while the system is warm to the touch.
- Do not sterilize system components.
- Do not immerse system components in liquid.
- Do not expose or immerse the EnSite™ X EP System to liquids or allow fluid to enter the equipment in any way. Exposing the EnSite™ X EP System to liquids may result in equipment damage, produce a fire or shock hazard, and result in possible personal injury.
- Do not place multiple socket-outlets on the floor.
- Do not connect the system to additional multiple socket-outlets or extension cords.

- Non-patient environment system components are not suitable for use within the patient environment where intentional or unintentional contact can occur between a patient and these components or between a patient and other person touching parts of these components.
- Do not use aerosol sprays near the equipment as these sprays can damage circuitry.
- Use of this equipment adjacent to or stacked with other equipment other than as specified in this IFU should be avoided because it could result in improper operation. If adjacent or stacked use is necessary, this product should be observed to verify that they are operating normally.
- Do not leave system components where they can be damaged, particularly on the floor, where they can easily be stepped on and damaged.
- Remove cables by gripping the connector. Do not tug on the cable as this can damage the connecting cable. Never force a connection or a disconnection.

Adverse Events

- Cardiac Perforation
  - Cardiac effusion / tamponade
- Cardiovascular Injury, which might include but not limited to,
  - Vascular injury
  - Damage to the coronary vasculature
  - Valvular damage
  - Cardiac effusion / tamponade
- Organ Injury, which might include but not limited to,
  - Esophageal lesion
  - AE Fistula
  - Puncture of surrounding organs
  - Hemothorax
  - Pneumothorax
- Arrhythmias, which might include but not limited to,
  - Recurrent arrhythmia
  - Non-sustained ventricular tachycardia
  - Recurrence of atrial fibrillation
- Peripheral Nerve Damage
  - Phrenic nerve (PN) palsy
- Superficial Tissue Injury
- Electric Shock
- Thermal Injury

Important Safety Information

WARNING: A Warning indicates a situation which, if not avoided, could result in death or serious injury.

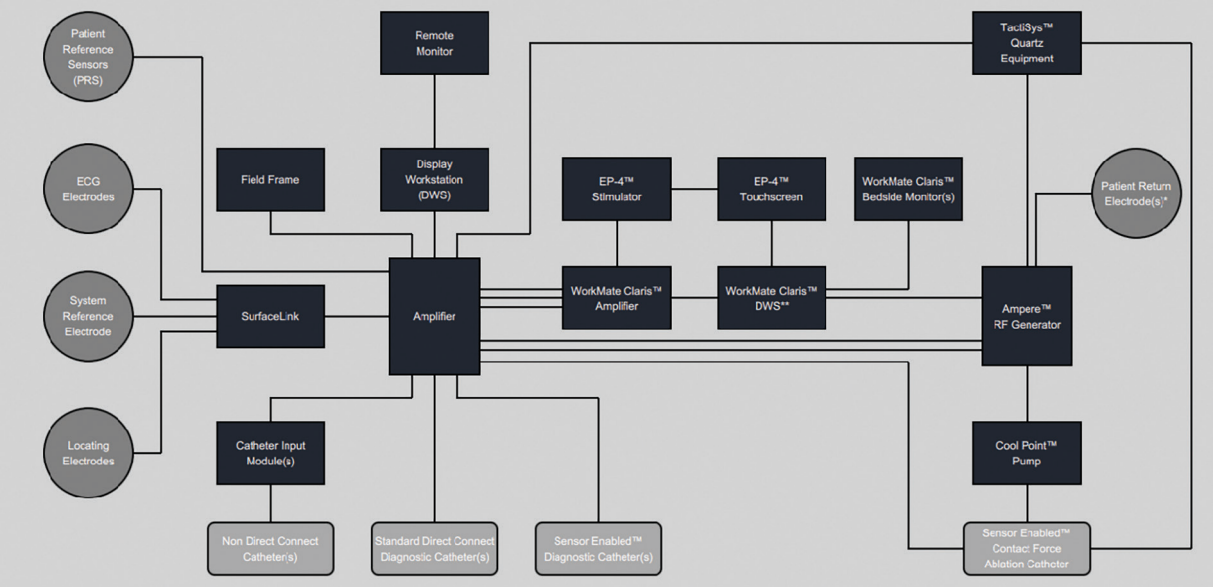
CAUTION: A Caution indicates a situation which, if not avoided, could result in minor or moderate injury or damage to the equipment or other property.

NOTE: A Note provides additional information.

System Overview

EnSite™ X EP System Diagram

Figure 2. Typical EnSite™ X EP System Setup



EnSite™ X Amplifier Panels Description

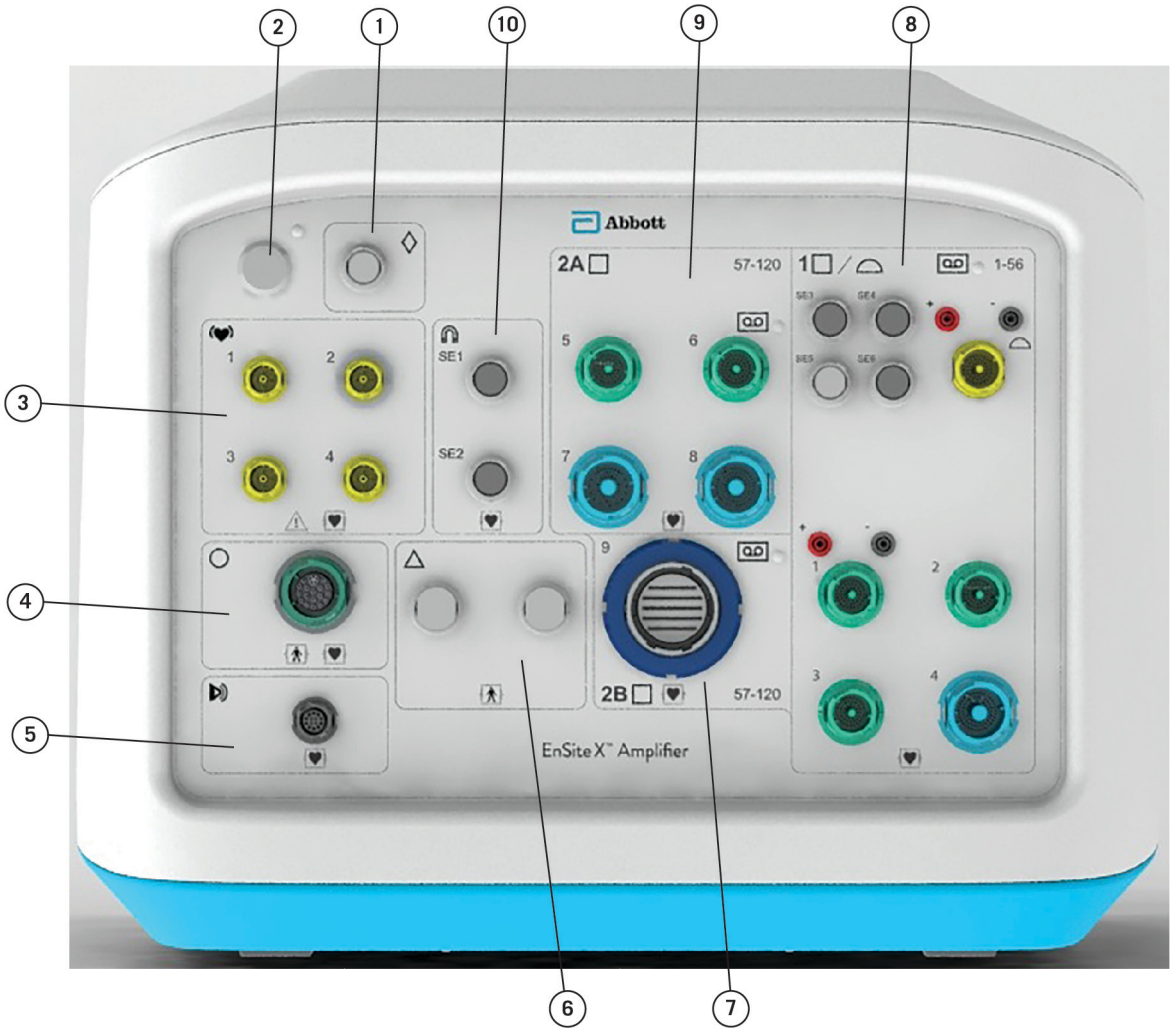
EnSite™ X Amplifier Front Panel

This panel allows the user to turn on/off the EnSite™ X Amplifier and to connect catheters and system hardware components. Specifically, it allows for the connection of:

- EnSite™ X SurfaceLink (EnSite™ X locating electrodes, EnSite™ X RL ECG electrode, EnSite™ X system reference electrode, and ECG connections).
- EnSite™ X Patient Reference Sensors (PRS) when using magnetic Sensor Enabled™ catheters.
- Connection to the Ampere™ RF Generator.
- Sensor Enabled™ ablation catheters.
- Direct connect catheters (for more information refer to the EnSite™ X Catheter Cables Instructions for Use).
- EnSite™ X Catheter Input Module (CIM) -- for non-direct connect catheters.
- Direct stimulation ports.

The catheter ports are grouped and labeled to provide users with the ability to determine how the ports on the EnSite™ X Amplifier front panel are mapped to the channels of a recording system amplifier (whose connection ports are on the EnSite™ X Amplifier back panel). LED indicators on the EnSite™ X Amplifier front panel indicate the physical banks of channels the EnSite™ X Amplifier is connected to on the recording system.

Figure 3. EnSite™ X Amplifier Front Panel



	Icon	Element	Notes
1		Future use	Future Use, external Reference.
2		Power Button and LED	Provides ability to turn on/off amplifier and LED indicates when it is on/off.
3		Future use	Future use.
4		EnSite™ X SurfaceLink port	Connects to EnSite™ X SurfaceLink (EnSite™ X surface electrodes, EnSite™ X system reference electrode, EnSite™ X RL ECG electrode and ECG electrodes).
5		Future use	Future use.
6		Magnetic PRS	Provides connection for EnSite™ X Patient Reference Sensors (PRS).
7	2B	High Density (HD) catheter port	Connects High Density (HD) catheters (greater than 20 pins) to the recording amplifier channels. Catheters connected in this section also connect to channels 57-120 on the EnSite™ X Amplifier back panel represented by this icon: The LED indicator will show if there is a recording system connection cable plugged in the EnSite™ X Amplifier back panel, connector labeled 2B. NOTE: Only the first 64 pins are sent to the recording system.

	Icon	Element	Notes
8		Catheter ports	Connects catheters to the recording amplifier channels. Catheters connected in this section also connect to channels 1-56 on the EnSite™ X Amplifier back panel represented by this icon:  The LED in this section is lit when there is a recording system connection cable plugged in the EnSite™ X Amplifier back panel, connector labeled 1. 
9		Catheter ports	Connects catheters to the recording amplifier channels. Catheters connected in this section also connect to channels 57-120 on the EnSite™ X Amplifier back panel represented by this icon:  The LED indicator will show if there is a recording system connection cable plugged in the EnSite™ X Amplifier back panel, connector labeled 2A. 
10		Magnetic Tools ports	Provides connection for Sensor Enabled™ catheters.

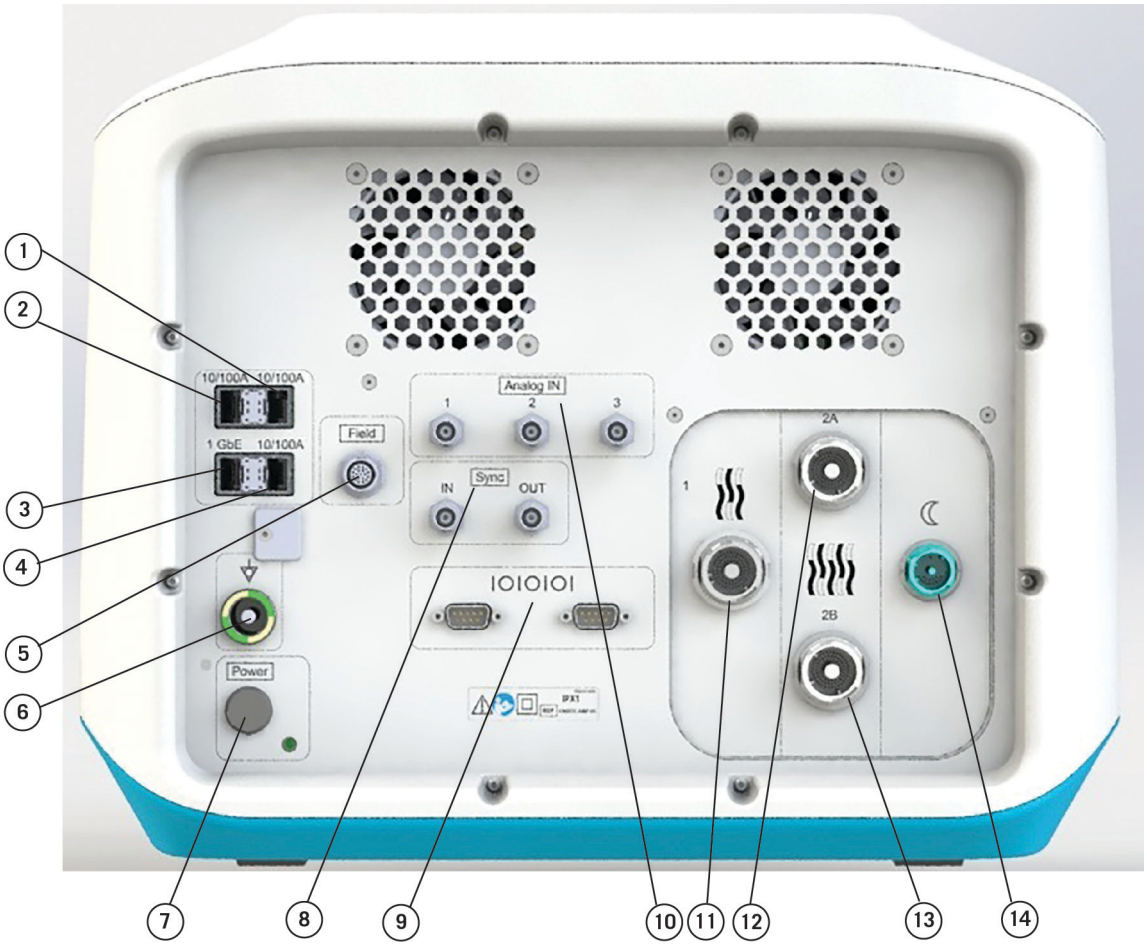
EnSite™ X Amplifier Back Panel

This panel allows the user to connect the following hardware components to the EnSite™ X Amplifier:

- Ampere™ RF generator (via a data port)
- EnSite™ X Display Workstation (DWS)
- Recording system amplifier (WorkMate™ Claris™ or a third-party recording system)
- TactiSys™ Quartz equipment (via a data port)
- EnSite™ X Field Frame
- Equipotential (i.e. GROUND)
- Power Supply

The ports are grouped and labeled to provide users with the ability to determine how the recording amplifier ports on the back panel are mapped to the catheter ports on the front panel.

Figure 4. EnSite™ X Amplifier Back Panel



	Icon	Element	Notes
1	10/100A	Future use	Future use.
2	10/100A	Ampere™ RF generator	10/100A, fiber optic connection.
3	1 GbE	EnSite™ X Display Workstation (DWS)	Fiber optic provides connection between the EnSite™ X Amplifier and the EnSite™ X DWS.
4	10/100A	TactiSys™ Quartz equipment	10/100A, copper Ethernet cable provides connection between the EnSite™ X Amplifier and TactiSys™ Quartz equipment.
5	**Field**	EnSite™ X Field Frame port	Provides connection between the EnSite™ X Amplifier and the EnSite™ X Field Frame.
6		Equipotential ground	Provides the connection between the EnSite™ X Amplifier and ground. (Optional)
7	**Power**	EnSite™ X Amplifier power	Power connection to the EnSite™ X Amplifier power module. Green LED will light when external power is applied.
8	**Sync**	Sync	Future use.
9	IOIOI	Serial IN	Future use.
10	**Analog IN**	Analog IN	Future use.

	Icon	Element	Notes
11		Bank 1 port	Provides connection between the EnSite™ X Amplifier and the recording system amplifier for the catheters connected to the Bank 1 port on the EnSite™ X Amplifier front panel. Connection has 56 channels. Connection color is grey. NOTE: Catheters connected to Bank 1 Input on the EnSite™ X Amplifier front panel will be output to Bank 1 on the EnSite™ X Amplifier back panel.
12		Bank 2A port	Provides connection between the EnSite™ X Amplifier and the recording system for the catheters connected to the Bank 2A ports on the front panel. Connection has 64 channels. Connection color is white. NOTE: Catheters connected to Bank 2A Input on the EnSite™ X Amplifier front panel will be output to Bank 2A on the EnSite™ X Amplifier back panel.
13		Bank 2B port	Provides connection between the EnSite™ X Amplifier and the recording system for the catheters connected to the Bank 2B port on the front panel. Connection has 64 channels. Connection color is white. NOTE: Catheters connected to Bank 2B Input on the EnSite™ X Amplifier front panel will be output to Bank 2B on the EnSite™ X Amplifier back panel.
14		ECG OUT port	Provides connection between the EnSite™ X Amplifier and the recording system for the ECG connected to the EnSite™ X SurfaceLink port on the front panel. NOTE: When connecting to a third-party recording system, this port will connect to the ECG Output Module.

EnSite™ X Amplifier Ports and Connections

Direct Connect Catheter Connections

Direct Connect Diagnostic Catheters can be connected to the following Direct Connect Ports on the EnSite™ X Amplifier front panel.

Refer to the EnSite™ X Catheter Cables Instructions for Use for a list of compatible catheters and direct connect cables for the EnSite™ X EP System.

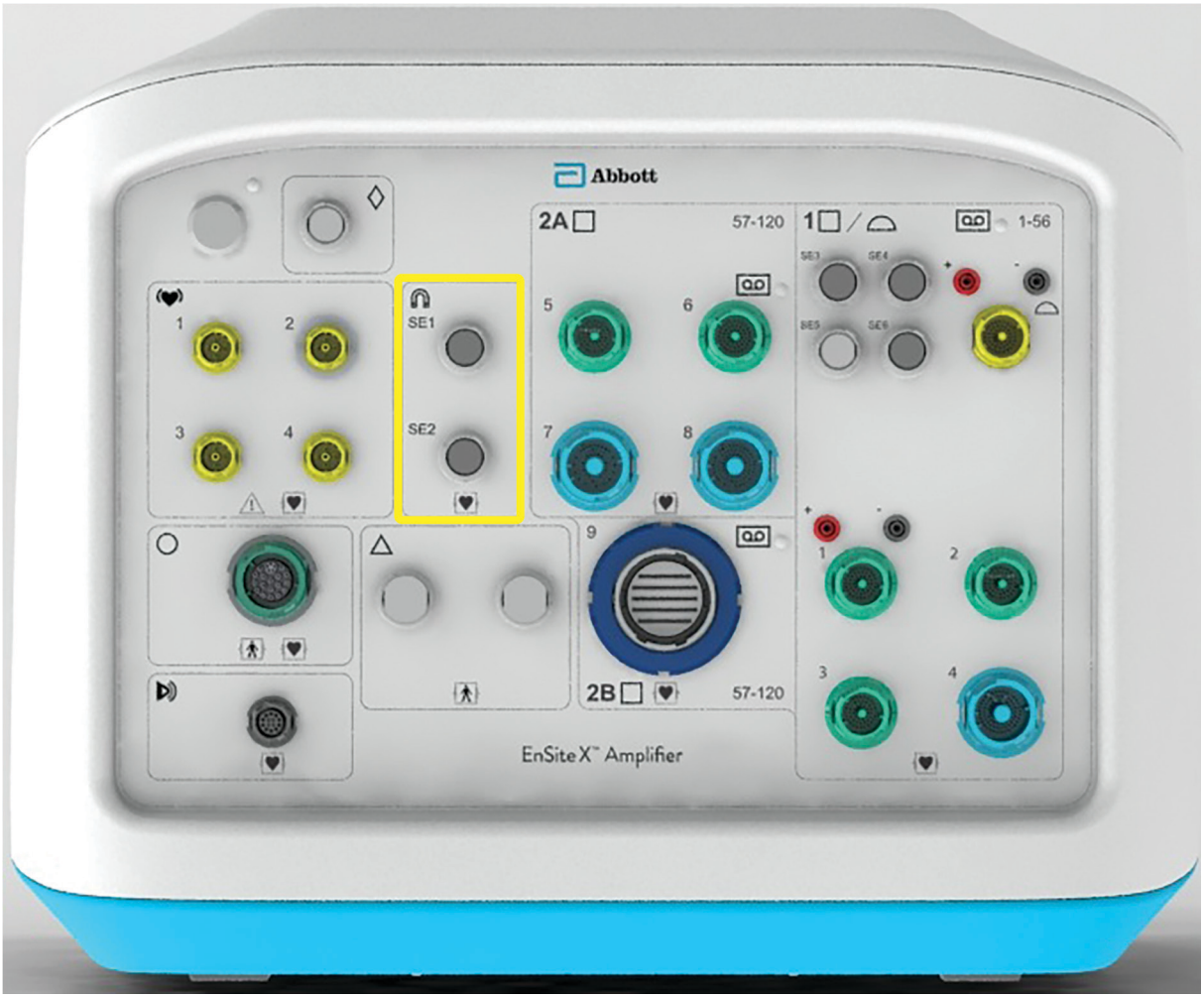
Figure 5. EnSite™ X Direct Catheter Connections on Front Panel

Icon	Color	Element	Notes
	Green	Catheter ports	There are five GREEN color-coded catheter connectors on the EnSite™ X Amplifier front panel (ports 1-3 and 5-6). Each contains 10 pins and can be used to connect catheters with 10 or fewer electrodes.
	Light Blue	Catheter ports	There are three LIGHT BLUE color-coded catheter connectors on the EnSite™ X Amplifier front panel (ports 4 and 7-8). Each contains 22 pins and should be used to connect catheters with 11-22 electrodes. A 20-pin CIM can be plugged into any LIGHT BLUE connection.
	Dark Blue	High Density (HD) port	There is one DARK BLUE color-coded High Density (HD) port on the EnSite™ X Amplifier front panel. This is for the 80-pin CIM only.

Connecting Sensor Enabled™ Ablation Catheters to the EnSite™ X Amplifier

When using a Sensor Enabled™ ablation catheter, connect the sensor lead of a catheter to either one of the magnetic ports on the EnSite™ X Amplifier.

Figure 6. Magnetic Ports on the EnSite™ X Amplifier (highlighted in yellow)



EnSite™ X Amplifier front panel

Connecting Standard Diagnostic Catheters to the EnSite™ X Amplifier

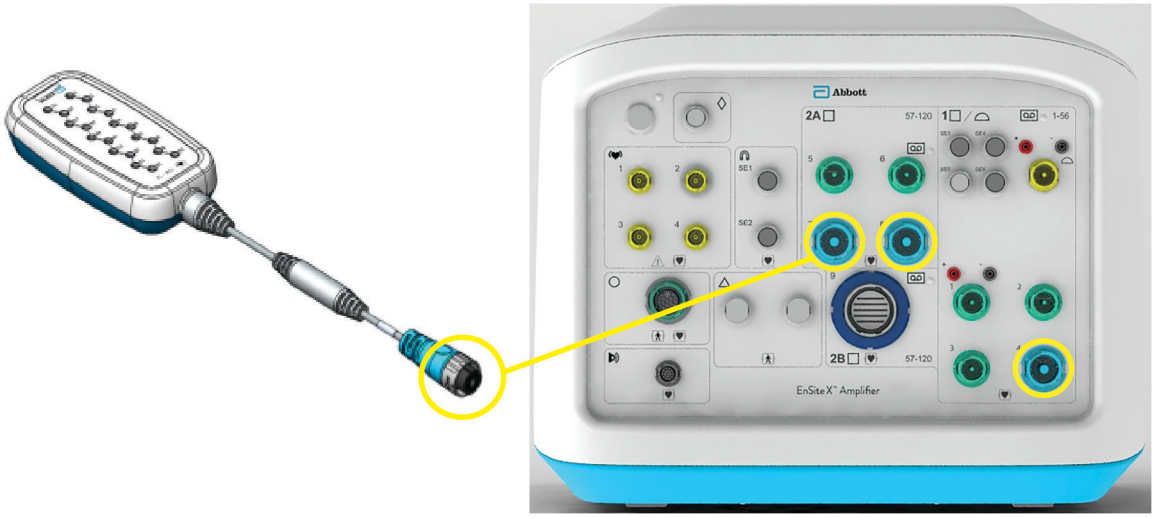
The EnSite™ X EP System provides one 20-pin catheter input module (CIM) and one 80-pin CIM for connecting standard diagnostic catheters to the system using 2 mm pin jacks.

CAUTION: Do not connect ablation catheters to CIM modules. The CIMs are low voltage components and ablation catheters are high voltage. Equipment damage may occur.

Connect standard diagnostic catheters with up to 20 electrodes to the 20-pin CIM using 2 mm pin jacks.

Connect the 20-pin CIM cable into any of the three LIGHT BLUE port on the EnSite™ X Amplifier front panel.

Figure 7. 20-pin CIM Connection Ports on the EnSite™ X Amplifier (highlighted in yellow)



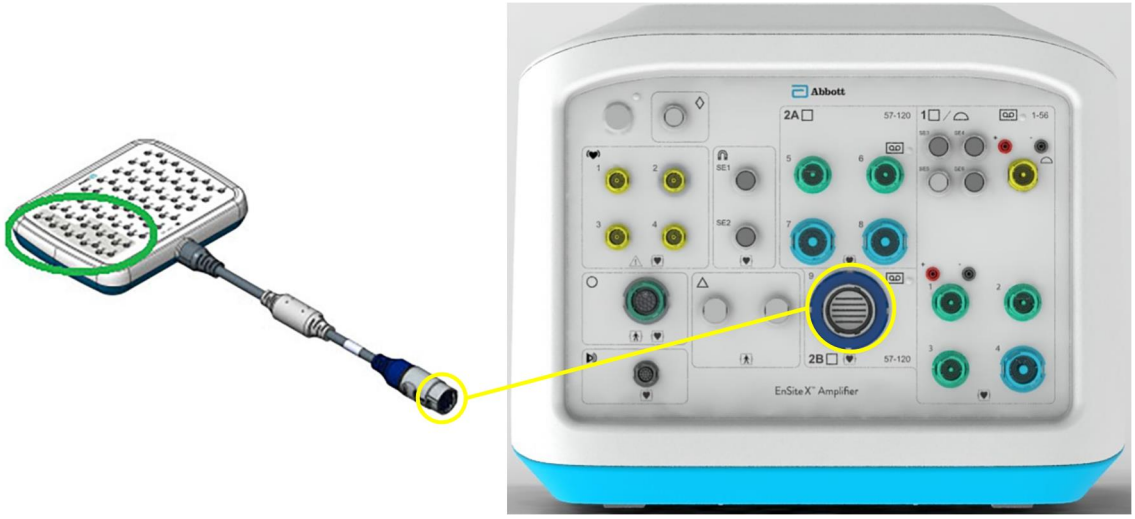
20-pin CIM EnSite™ X Amplifier front panel

Use the 80-pin CIM to connect standard diagnostic catheters to the EnSite™ X Amplifier using 2 mm pin jacks.

NOTE: Pins 65 through 80 (the grey area circled in green in the following figure) are not routed to a recording system.

Connect the 80 pin CIM cable to the DARK BLUE port on the EnSite™ X Amplifier front panel.

Figure 8. 80-pin CIM Connection Port on the EnSite™ X Amplifier (highlighted in yellow)



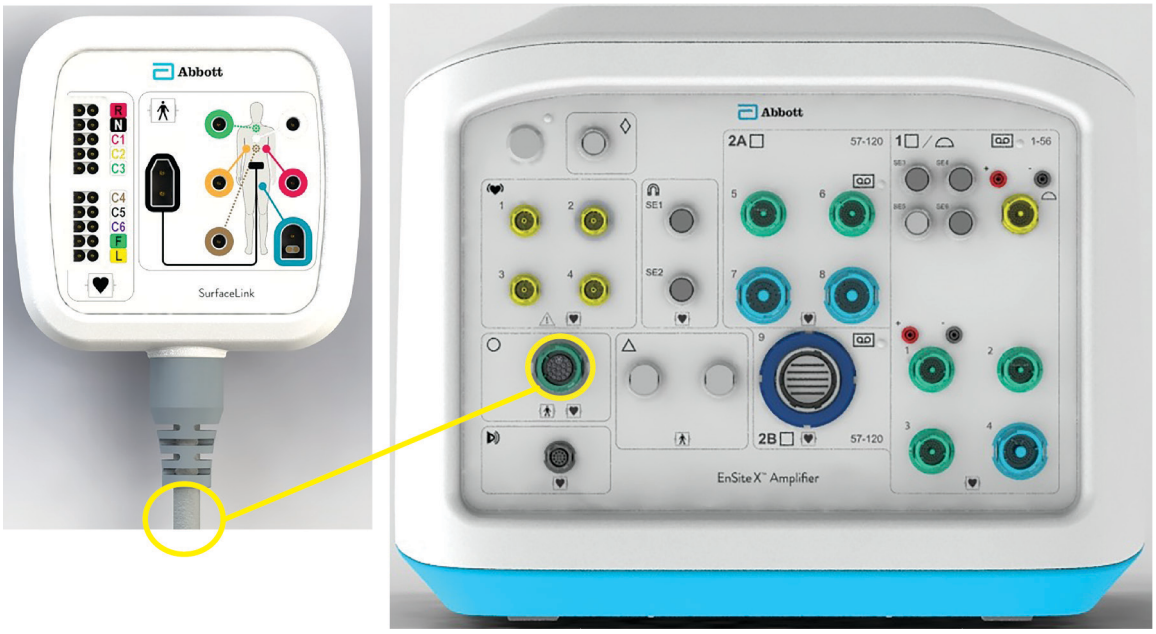
80-pin CIM EnSite™ X Amplifier front panel

Connecting ECG and EnSite™ X Surface Electrodes to the EnSite™ X Amplifier

The EnSite™ X SurfaceLink module is used to connect the 12-lead ECG cable, the EnSite™ X surface electrodes, the EnSite™ X RL ECG electrode, and the EnSite™ X system reference electrode to the EnSite™ X Amplifier. The EnSite™ X surface electrodes are color-coded to match the connection points on the module.

Plug the EnSite™ X SurfaceLink module cable into the front of the EnSite™ X Amplifier at the connector marked with the circle symbol. Use the symbol on the cable to match to the correct connection point on the EnSite™ X Amplifier.

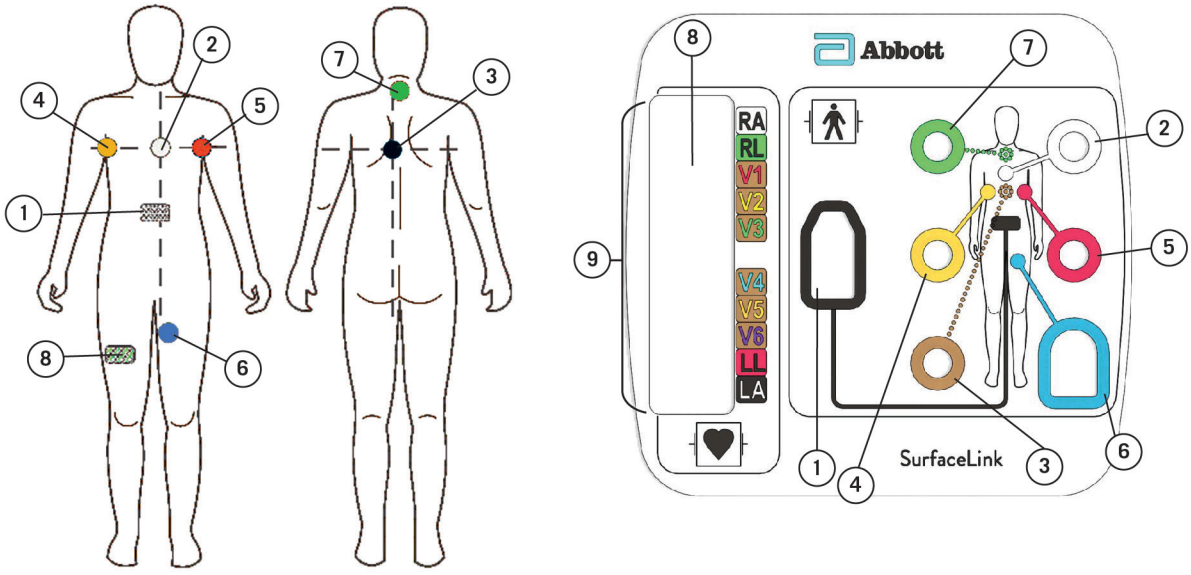
Figure 9. EnSite™ X SurfaceLink Module Connection Port on the EnSite™ X Amplifier (highlighted in yellow)



EnSite™ X SurfaceLink module (OUS shown) EnSite™ X Amplifier front panel

EnSite™ X SurfaceLink Module Connections (US Only)

Figure 10. EnSite™ X SurfaceLink Module Connections (US Only)



Place surface electrodes on patient (left graphic) and connect surface electrode leads to EnSite™ X EP System SurfaceLink Module (right graphic).

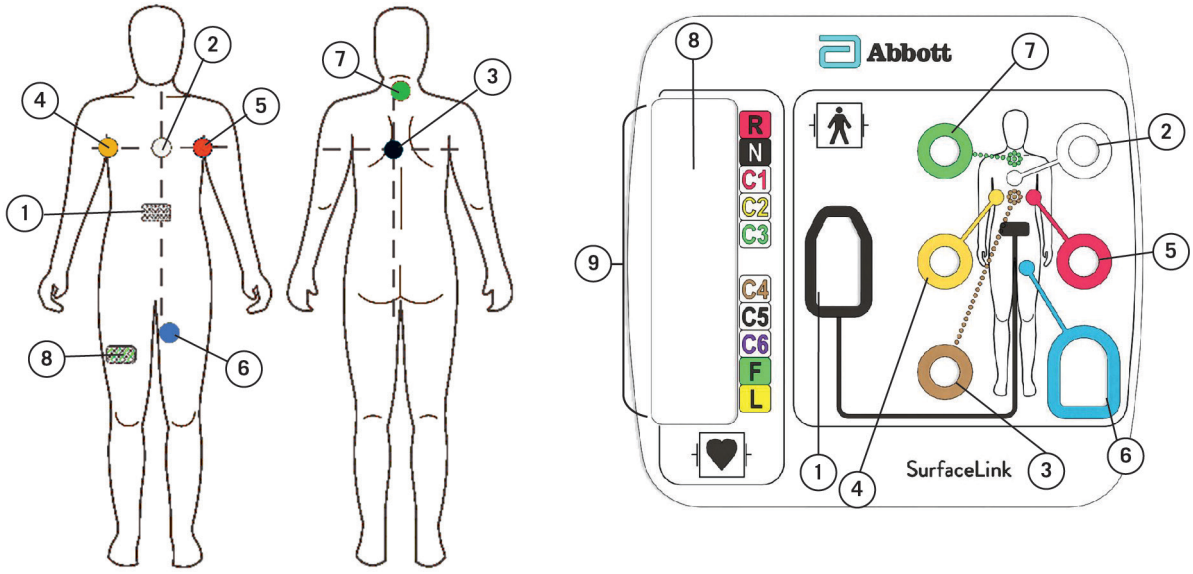
1. EnSite™ X EP System System Reference Electrode
2. EnSite™ X EP System Surface Electrode - Front
3. EnSite™ X EP System Surface Electrode - Back
4. EnSite™ X EP System Surface Electrode - Right
5. EnSite™ X EP System Surface Electrode - Left
6. EnSite™ X EP System Surface Electrode - Left Leg
7. EnSite™ X EP System Surface Electrode - Neck

8. EnSite™ X EP System RL ECG Electrode (placed as right leg ECG electrode during EnSite™ X EP System procedure)
9. ECG electrodes

   NOTE: Not shown on left graphic. Place ECG electrodes in standard 12-lead configuration for an EnSite™ X EP System procedure.

EnSite™ X SurfaceLink Module Connections (OUS Only)

Figure 11. EnSite™ X SurfaceLink Module Connections (OUS)



Place surface electrodes on patient (left graphic) and connect surface electrode leads to EnSite™ X EP System SurfaceLink Module (right graphic).

1. EnSite™ X EP System, System Reference Electrode
2. EnSite™ X EP System Surface Electrode - Front (white)
3. EnSite™ X EP System Surface Electrode - Back (brown)
4. EnSite™ X EP System Surface Electrode - Right (orange)
5. EnSite™ X EP System Surface Electrode - Left (red)
6. EnSite™ X EP System Surface Electrode - Left Leg (blue)
7. EnSite™ X EP System Surface Electrode - Neck (green)
8. EnSite™ X EP System RL ECG Electrode (placed as right leg ECG electrode during EnSite™ X EP System procedure)
9. ECG electrodes

   NOTE: Not shown on left graphic. Place ECG electrodes in standard 12-lead configuration for an EnSite™ X EP System procedure.

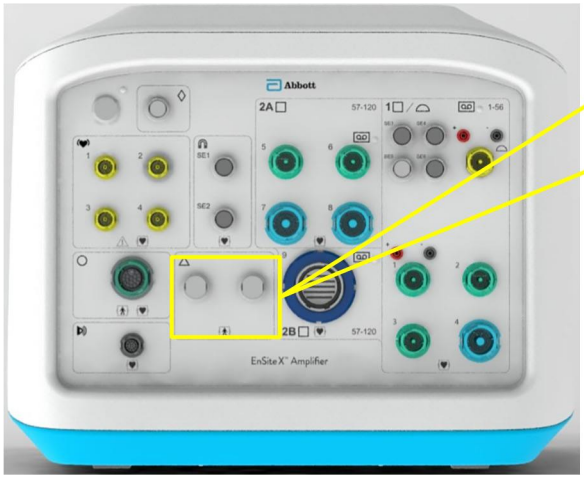
Connecting Patient Reference Sensor (PRS) Cables to the EnSite™ X Amplifier

When using Sensor Enabled™ catheters connect the two PRS cable sets to the EnSite™ X Amplifier front panel at the connector marked with the triangle symbol. There is a PRS-A cable and a PRS-P cable.

Place the PRS-A cable sensor into the PRS-A surface patch located on the patient's chest. Place the PRS-P cable sensors into the three PRS-P surface patches located on the patients back. Refer to the EnSite™ X Surface Electrode Kit Instruction for Use for appropriate PRS surface patch placement.

The PRS cables may be connected to either magnetic PRS ports on the EnSite™ X Amplifier front panel. The system will recognize which cable is connected to each port.

Figure 12. Patient Reference Sensor (PRS) Cables Connection Ports on the EnSite™ X Amplifier (highlighted in yellow)



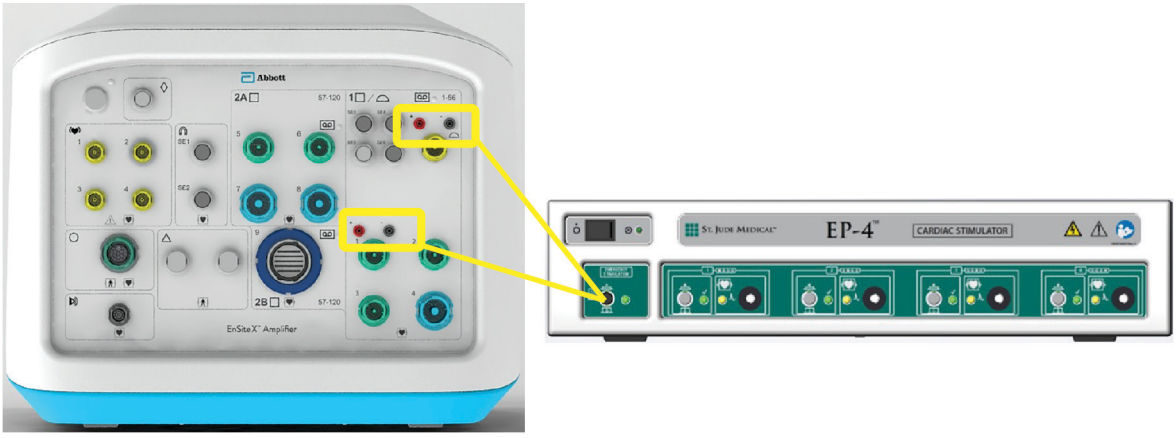
EnSite™ X Amplifier front panel

PRS-A sensor cable. (Top)
PRS-P sensor cable. (Bottom)

Catheter Stimulator Connection Points

There are two sets of 2 mm pin socket connection points in Bank 1 intended to allow direct connection of a pacing stimulator, one set for an ablation catheter and the other for a diagnostic catheter. The red socket of each connects directly to the [D] electrode and the black socket of each connects directly to the [2] electrode of an attached catheter. In case of power failure, use direct connected stimulator sockets for catheters that are used in procedures requiring pacing.

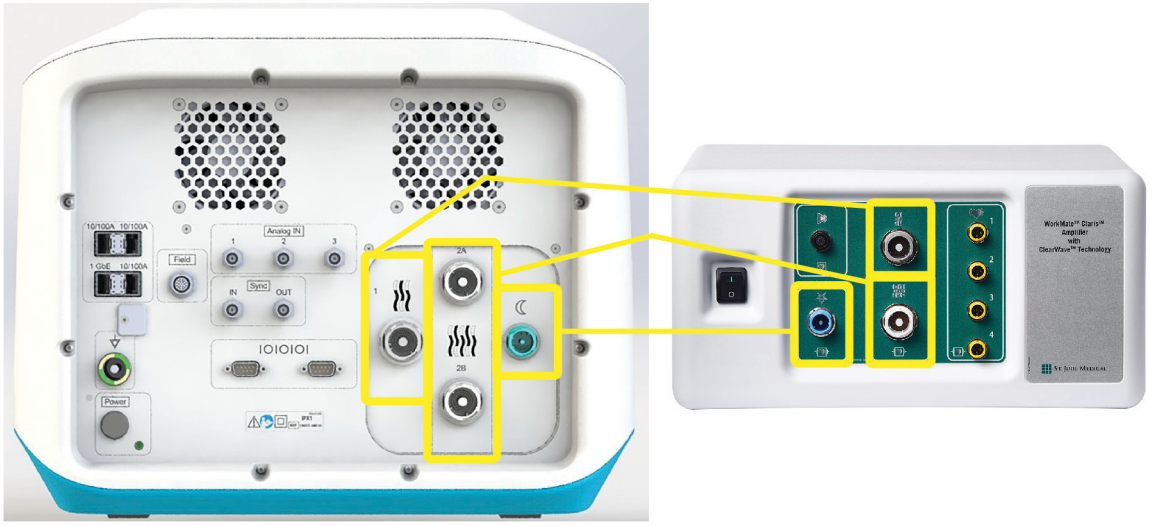
Figure 13. EnSite™ X Amplifier Stimulator Connection Points to the EP-4™ Cardiac Stimulator (highlighted in yellow)



Connecting the WorkMate™ Claris™ Recording System to the EnSite™ X Amplifier

1. Connect the gray WorkMate™ Claris™ Connect Cable IC56 (56-pin) to the Bank 1 port on the EnSite™ X Amplifier back panel.
2. Connect the white WorkMate™ Claris™ Connect Cable IC64 (64-pin) to either Bank 2A or 2B on the EnSite™ X Amplifier back panel (choose the port based on which corresponding bank of ports on the front of the amplifier will be shared with the recording system).
3. Connect both intracardiac cables to their corresponding color matched connection ports on the front of the WorkMate™ Claris™ recording system.
4. Connect blue WorkMate™ Claris™ ECG cable to the 1/4 moon port on the EnSite™ X Amplifier back panel.
5. Connect the other end of the blue WorkMate™ Claris™ ECG cable to the (STAR) symbol on the front of the WorkMate™ Claris™ recording system.

Figure 14. EnSite™ X Amplifier Connections to the WorkMate™ Claris™ Recording System (highlighted in yellow)



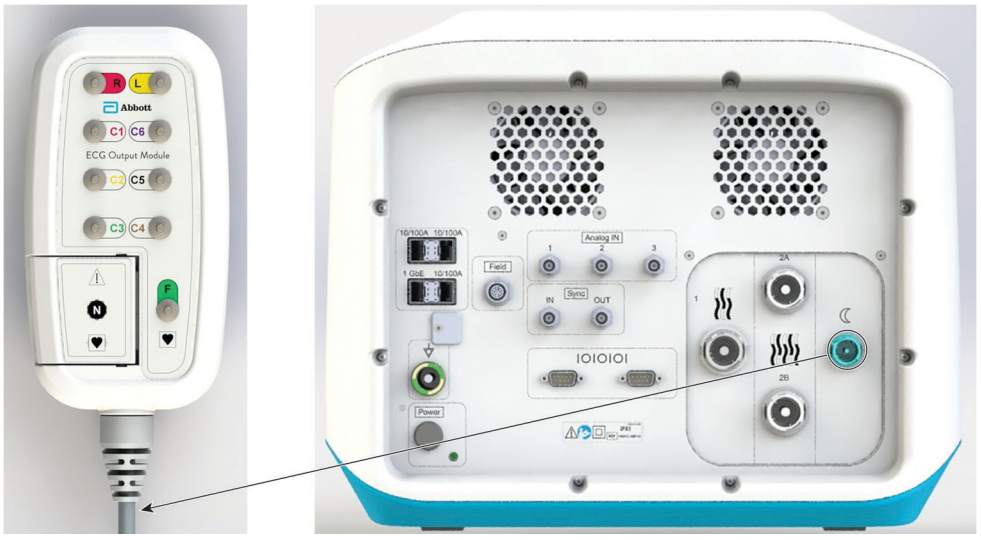
EnSite™ X Amplifier back panel

Workmate™ Claris Amplifier front panel

Connecting Third-Party Recording Systems to the EnSite™ X Amplifier

1. Connect the gray External Recording System Connect Cable IC56 (56-pin) to the Bank 1 port on the EnSite™ X Amplifier back panel.
2. Connect the white External Recording System Connect Cable IC64 (64-pin) to Bank 2A on the EnSite™ X Amplifier back panel.
3. Connect both intracardiac cables to the third-party recording system catheter input module using the 2mm pinjacks.
4. Connect the cable attached to the EnSite™ X ECG Output Module to the 1/4 moon port on the EnSite™ X Amplifier back panel.
5. Connect the third-party recording system ECG connections to the EnSite™ X ECG Output Module.

Figure 15. EnSite™ X ECG Output Module



EnSite™ X ECG Output Module

EnSite™ X Amplifier back panel

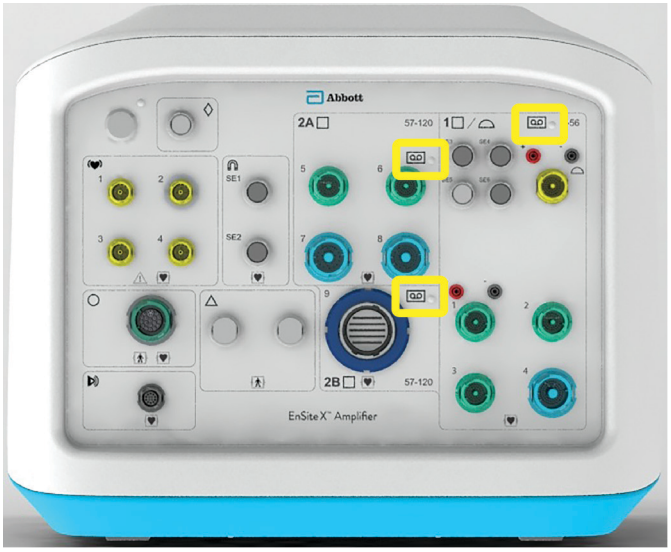
EnSite™ X ECG Output Module (OUS)

EnSite™ X ECG Output Module (US)

Recording System Connection Status LEDs

There is a Recording System Connection Status LED (highlighted in yellow) in each Bank 1, 2A, 2B identified by the recording icon. The LED is lit when there is a recording system connection cable plugged in the EnSite™ X Amplifier back panel.

Figure 16. Catheter Connections and Recording System LEDs on the EnSite™ X Amplifier (highlighted in yellow)



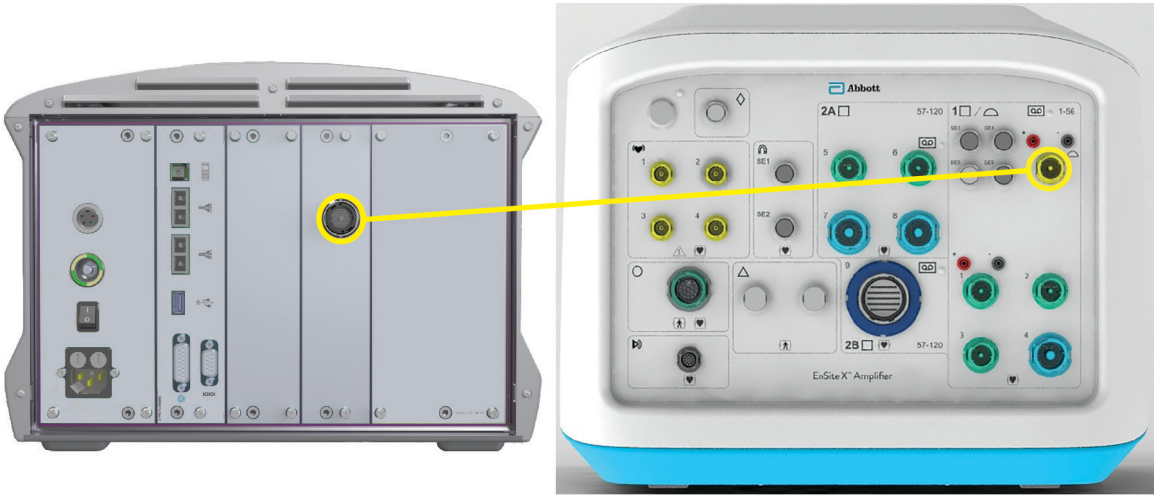
EnSite™ X Amplifier front panel

Connecting the Ampere™ RF Generator to the EnSite™ X Amplifier

NOTE: The EnSite™ X EP System is only compatible with the Ampere™ RF generator.

Connect the Ampere™ RF generator cable from the front on the EnSite™ X Amplifier at the connector marked with the half-moon symbol to back panel of the Ampere™ RF generator port on the diagram.

Figure 17. Ampere™ RF Generator Cable Connection to the EnSite™ X Amplifier Front Panel (highlighted in yellow)

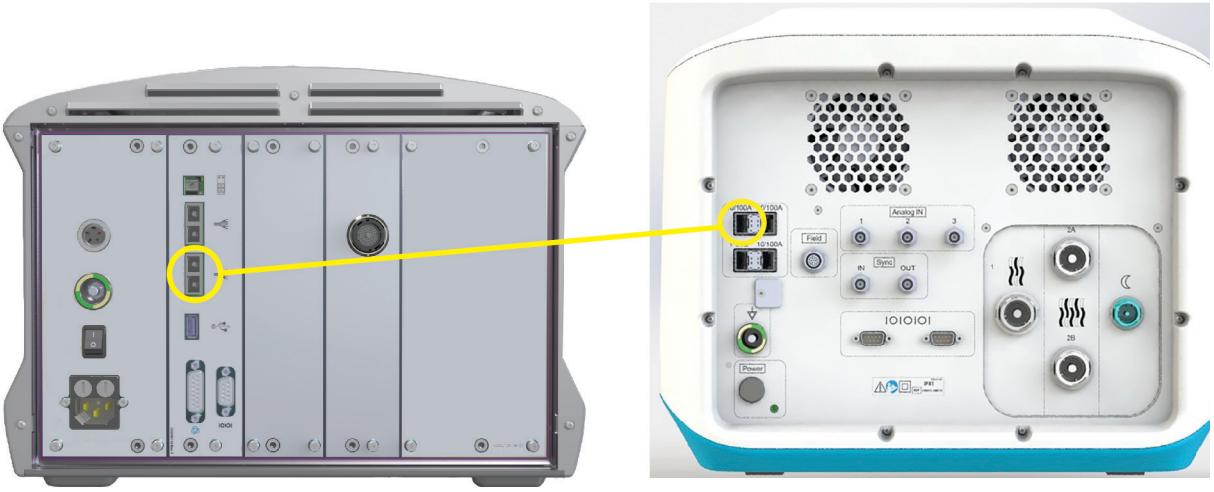


Ampere™ RF generator back panel.

EnSite™ X Amplifier front panel.

Connect a LC Fiber Optic Cable from Port 2 (10/100 port) on the EnSite™ X Amplifier back panel to the Data Port (10/100 port) on the Ampere™ RF generator back panel.

Figure 18. Ampere™ RF Generator "LC Fiber Optic Cable" Connection to the EnSite™ X Amplifier back panel in Port 2 (highlighted in yellow)



Ampere™ RF generator back panel

NOTE: Ensure connection is to the lower of the two fiber optic data ports.

EnSite™ X Amplifier back panel

Connecting the TactiSys™ Quartz Equipment to the EnSite™ X Amplifier

Connect a "10/100A" ethernet cable from Port 1 (10/100) on the EnSite™ X Amplifier back panel to the Ethernet port on the TactiSys™ Quartz equipment back panel.

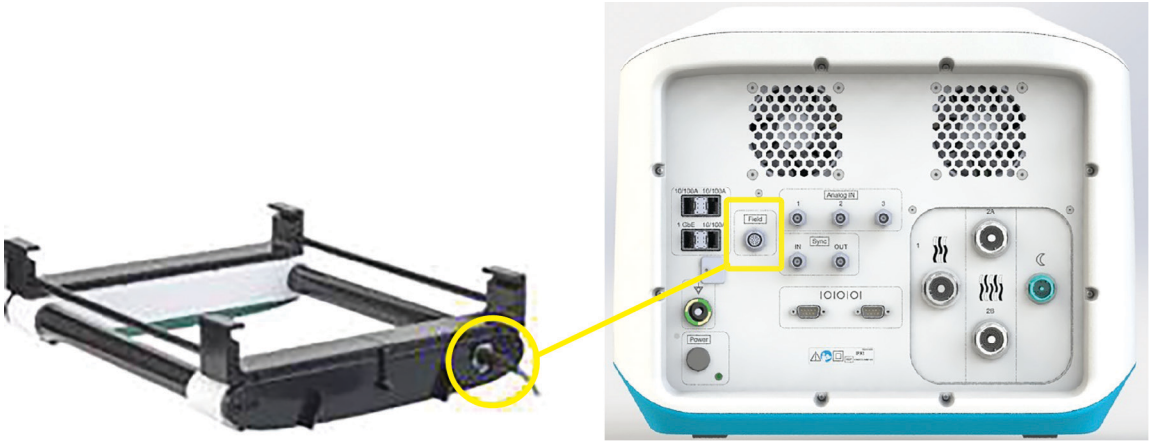
Figure 19. Tactisys™ Quartz Equipment Ethernet Cable Connection to the EnSite™ X Amplifier Port 1 on Back Panel (highlighted in yellow)

TactiSys™ Quartz equipment back panel. EnSite™ X Amplifier back panel.

Connecting the EnSite™ X Field Frame to the EnSite™ X Amplifier

Mount the EnSite™ X Field Frame to the patient table according to instructions in the EnSite™ X Field Frame Instructions for Use. Connect the EnSite™ X Field Frame cable to the FIELD connector on the EnSite™ X Amplifier back panel as shown below.

Figure 20. Field Frame Connection to the EnSite™ X Amplifier Back Panel (highlighted in yellow)



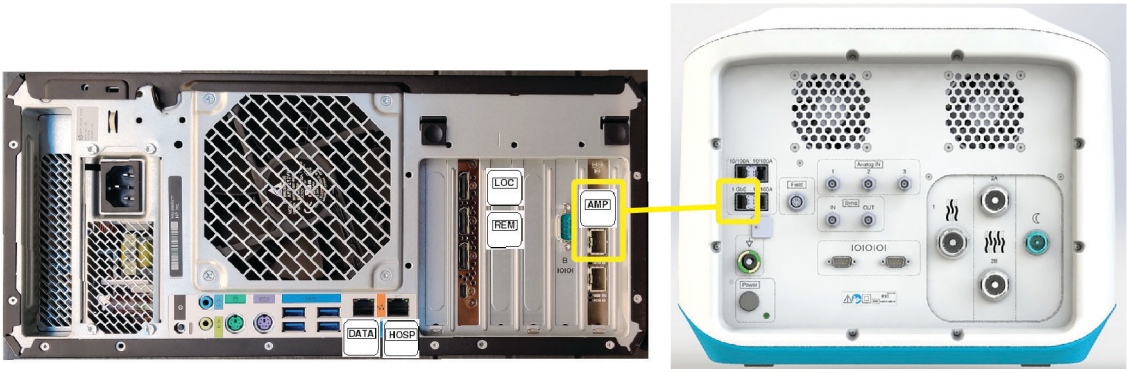
EnSite™ X Field Frame cable connection. EnSite™ X Amplifier back panel.

CAUTION: Do not coil the EnSite™ X Field Frame cable. The cable carries enough electric current that a magnetic field will be created when the cable is placed in a circular formation. This magnetic field may disturb the EnSite™ X Field Frame's magnetic field.

Connecting the EnSite™ X Display Workstation (DWS) to the EnSite™ X Amplifier

Connect a "LC to LC OM1 1Gb Fiber Optic Cable" from 1GbE connection on the EnSite™ X Amplifier back panel to the Data Port on the EnSite™ X Display Workstation (DWS) back panel.

Figure 21. Display Workstation Connection to the EnSite™ X Amplifier 1GbE connection on Back Panel (highlighted in yellow)



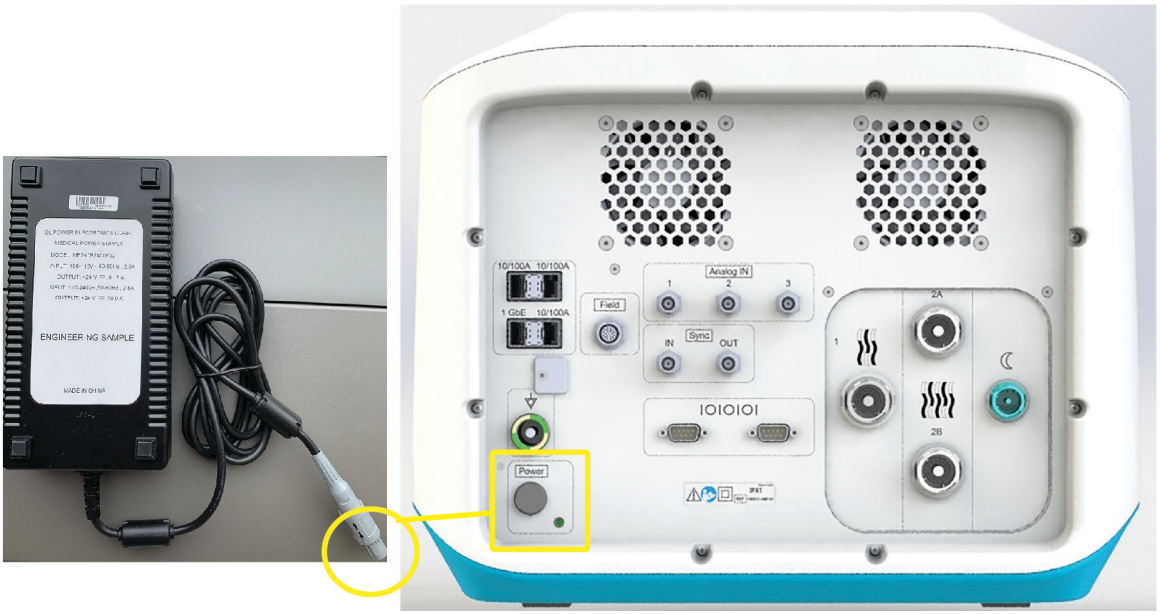
EnSite™ X Display Workstation (DWS) back panel.

EnSite™ X Amplifier back panel.

Connecting the Power Supply to the EnSite™ X Amplifier

1. Connect the EnSite™ X Amplifier external power module to the EnSite™ X Amplifier.
2. Connect the EnSite™ X Amplifier external power module into the Medical Grade Isolation Transformer.

Figure 22. Ensite™ X Amplifier Power Supply (highlighted in yellow)

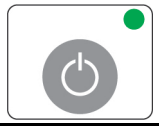
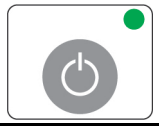
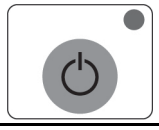


Connect the Medical Grade Isolation Transformer into the Power Outlet

Connect the grounding cable to the equipotential connector on the EnSite™ X Amplifier back panel as required by local regulations (Optional).

Power on the EnSite™ X Amplifier

1. Verify that all cables are firmly connected.
2. Power on the EnSite™ X Display Workstation (DWS).
3. Power on the EnSite™ X Amplifier.
4. The EnSite™ X Amplifier will perform a self-test. Both LEDs that comprise the status light are illuminated. Check the amplifier status lights. When the system is powered up, the amber light will stay lit for approximately two minutes while the system performs self-testing. After two minutes, the green light should come on and remain solid. See table below for amplifier status.

Color		State	Action
Orange/Green		Steady	Restart or call technical service.
Orange		Steady	Self-test running.
Orange		Flashing	Restart or call technical service.
Green		Flashing	Check fiber-optic cable between the EnSite™ X amplifier and EnSite™ X DWS is connected; verify EnSite™ X DWS is powered on.
Green		Steady	System ready.
Off		Off	System Off.

EnSite™ X Amplifier Customer-Performed Maintenance

Amplifier Cleaning

Cleaning is recommended after each use. All surfaces should be cleaned with a dry, lint free cloth, gently applied. When necessary the following solutions may be used to clean external surfaces:

- Isopropyl Alcohol (70% to 99% solution)
- Cidex‡ Solution
- Cidex OPA‡ Solution
- Sani-Cloth‡ AF3 Germicidal Disposable Wipes

CAUTION:

- **Do not clean system components with bleach.**
- **Do not apply cleaners while the system is warm to the touch.**
- **Do not sterilize system components.**
- **Do not immerse system components in liquid.**
- **Turn off and disconnect power to the EnSite™ X Amplifier before cleaning it.**
- **Do not autoclave any EnSite™ X EP System component. Autoclaving may damage the system components.**

Disinfecting

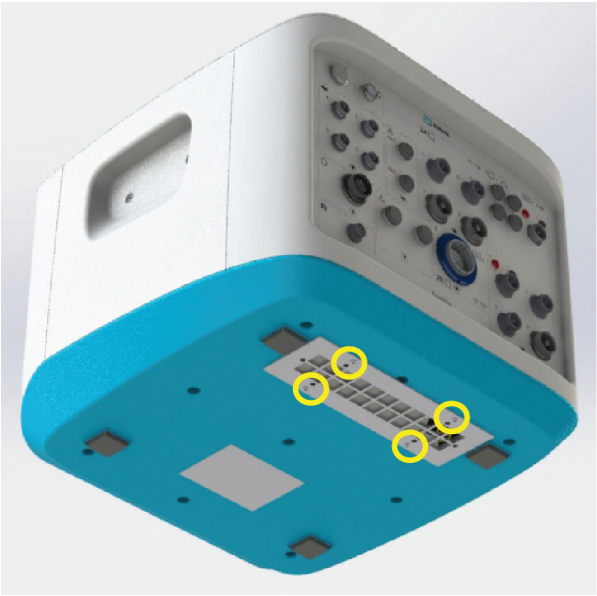
CAUTION: Do not clean the system components with disinfectants that contain surfactants.

Cleaning/Replacing the EnSite™ X Amplifier Air Filter

To Clean the Filter:

1. Use a Phillips screwdriver to remove the four screws holding the filter in place (highlighted in yellow in the following figure).

Figure 23. Filter location under the EnSite™ X Amplifier



2. Remove the filter out of the EnSite™ X Amplifier.
3. Pick off the lint layer and vacuum out the remaining dust.
4. Put the filter back in the EnSite™ X Amplifier and fasten the four screws to secure it in place.

To replace the filter:

1. Use a Phillips screwdriver to remove the four screws holding the filter in place (highlighted in yellow in the preceding figure).
2. Remove the filter out of the EnSite™ X Amplifier.
3. Discard the filter.
4. Put a new filter in the EnSite™ X Amplifier and fasten the four screws to secure it in place.

NOTE: Clean the EnSite™ X Amplifier air filter every 30 days.

Periodic Inspection

The system components should be inspected by the customer monthly:

- Ensure that any fans on system components are operating when power is on.
- Check the components, cables, and connections for mechanical damage.
- Check cables and connectors for damaged pins.
- Verify that inscriptions and labels on the system components are properly and completely fixed.
- Check the Torx security screws and discontinue use if there is visible evidence of tampering.

EnSite™ X Patient Reference Sensors (PRS)

Difference between EnSite Precision™ vs. EnSite™ X Sensors

NOTE: There exists a difference between the EnSite Precision™ PRS and the EnSite™ X PRS sensors:

- Precision PRSs sensors are all grey; and the Precision PRS-P cable has only one sensor.
- EnSite™ X PRSs sensors are green on the top and grey on the bottom; and EnSite™ X PRS-P cable has 3 sensors.

Cleaning the Sensors

The EnSite™ X Patient Reference Sensors (PRS) are intended for multiple uses. After each use, the user shall clean and maintain the sensors and cables as follows:

- Isopropyl Alcohol (70% to 99% solution)
- Cidex‡ Solution
- Cidex OPA‡ Solution
- Sani-Cloth‡ AF Germicidal Disposable Wipes

NOTE: Store in a safe place after the procedure.

NOTE: The EnSite™ X Patient Reference Sensors (PRS) should be replaced every 2 years to ensure mechanical integrity.

EnSite™ X Amplifier Cart

The EnSite™ X Amplifier cart is an optional component of the EnSite™ X EP System. The cart provides a central organized platform for all Abbott components for an EP procedure. The cart conveniently provides a location to store components of the EnSite™ X EP System such as EnSite™ X Field Frame generator and system cables.

Figure 24. EnSite™ EP System and Cart

Moving the EnSite™ X EP System

Do not disconnect any cables other than those mentioned below. These are not user-serviceable connections. If the system must be moved, adhere to the following guidelines:

1. Disconnect external equipment (EnSite™ X Field Frame cable, EnSite™ X SurfaceLink module, WorkMate Claris™ recording system cables, third-party recording system cables, EnSite™ X ECG Output module supporting third-party recording systems, and the Ampere™ RF generator cable (from Ampere™ RF generator) from the EnSite™ X Amplifier.
2. Disconnect any catheters and catheter cables, external stimulator, EnSite™ X system reference electrode, EnSite™ X ECG electrodes, from the EnSite™ X Amplifier.
3. Disconnect power cords from external power sources. Power cords connected to an isolation transformer secured to a cart can remain connected.
4. Disconnect the fiber-optic cable from the EnSite™ X Amplifier.
5. For dual monitor systems, disconnect the second monitor cables from the EnSite™ X DWS.
6. Secure all cables on the carts to which they are attached.
7. After moving the system, inspect all connections for damage, reconnect the system per instructions in this IFU as well as the EnSite™ X EP System Software IFU. Damaged cables or components must be replaced.

Service and Technical Support

The EnSite™ X Amplifier should be tested annually. These tests require specialized equipment and training. Contact Abbott Technical Support to schedule testing.

CAUTION: Only a qualified service representative can perform maintenance or service the system.

Service can be contacted at:

Local Number: 651-756-6985

Toll Free: 855-478-5833

Email: USDTechSupport@abbott.com

Technical Specifications

Environmental Specifications

Component	Operating Temp.	Operating Humidity	Operating Altitude	Storage and Transport Temp.	Storage and Transport Humidity	Storage and Transport Altitude
Amplifier	Ambient Temperature: +10°C to +30°C	Relative Humidity, non-condensing: 30% to 75%	Altitude: 0 m to 3000 m	Ambient Temperature: -10°C to +50°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 5574 m
ECG Lead Set	Ambient Temperature: +10°C to +35°C, inclusive	Relative Humidity, non-condensing: 20% to 90%	Altitude: up to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
AmpereConnect Cable	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
Claris Intracardiac Output Cable	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
Claris ECG Cable	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
Recording System IC Output Cables	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
EnSite™ X ECG Output Monitor	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
PRS	Ambient Temperature: +10°C to +43°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C, inclusive	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
SurfaceLink	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
CIM	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m

Component	Operating Temp.	Operating Humidity	Operating Altitude	Storage and Transport Temp.	Storage and Transport Humidity	Storage and Transport Altitude
Cart	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m
Mounting Bracket	Ambient Temperature: +10°C to +35°C	Relative Humidity, non-condensing: 20% to 90%	Altitude: 0 m to 3000 m	Ambient Temperature: -25°C to +60°C	Relative Humidity, non-condensing: 10% to 90%	Altitude: 0 m to 7620 m

Power Specifications

Supply Voltage	100-240VAC, 50/60 Hz
Maximum Output Power Rating	24 VDC @ 10 Amps
Maximum Output Current	10 Amps
Safety Classification	Class II, Equipment with functional earth, Defibrillation Proof Type CF, IPX0 (as defined in IEC/EN 60601-1)

Description of Equipment

Leakage	Conforms to IEC 60601-1
Defibrillator	Conforms to IEC 60601-1
Protection	Type CF, Type BF Defibrillator-Proof Applied Parts
Isolation	Conforms to IEC 60601-1
PRS IPX Rating	IPX4
Amplifier IPX Rating	IPX0
Identification of Applied Part Types are displayed on the Amplifier.	

Physical Characteristics

Dimensions	Height: 362 mm (14.25")
	Width: 455 mm (17.94")
	Depth: 432 mm (17")
Weight	12.25 kg (27 lbs.)

Electromagnetic Compatibility

Electromagnetic Emission Declaration

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy for its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than residential environments and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity Declaration

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN61000-4-2 (IEC 1000-4-2)	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±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 EN61000-4-4 (IEC 1000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN61000-4-5 (IEC 1000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variation on power supply input lines. IEC61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; for 5 sec @ 60 Hz (300 cycles) 0% U_T; 250/300 cycles	100% dropout in VNOM for 0.5 cycle at listed phase angles 100% dropout in VNOM for 1 cycle at 0° 30% dropout in VNOM for 25/30 cycles at 0° 100% dropout in VNOM for 5 sec 100% interrupt in VNOM for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms [V1 = 3]	Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [1.2]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.7GHz	3 V/m [E1 = 3]	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [1.2]\sqrt{P}$ $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz $d = [2.3]\sqrt{P}$

			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 
Immunity to Proximity Fields from RF wireless communications equipment IEC 60601-1-2 (Clause 8.10)	385-5785 MHz	9-27 V/m	Per IEC 60601-1-2 (Table 9)

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	.117	.117	.233
.10	.369	.369	.737
1	1.167	1.167	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.33

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

Standards of Compliance

ETL CLASSIFIED
Intertek
3166204

Conforms to EN 60601-1, EN 60601-1-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366-1; Certified to CAN/CSA 22.2 No.60601-1.

All configurations should comply with the system standard EN 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is, therefore, responsible that the system complies with the requirements of the system standard EN 60601-1-1. If in doubt, consult the technical services department or your local representative.

Simplified RED Compliance Statement

CE 2797

Hereby, St. Jude Medical declares that the radio equipment type EnSite™ X is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.cardiovascular.abbott/int/en/hcp/resources/product/declarations-of-conformity.html

EnSite™ X EP System (Model ENSITE-PRSFRNT-01, ENSITE-PRSBACK-01, ENSITE-AMP-02, and ENSITE-R-AMP-02)

Frequency Range	3200 Hz
Type	Oscillating Magnetic Field (Inductive)
Radiated Power	1 Amp/meter at 30 cm Less than 30.7 µT, RMS at 30 cm
Range	Up to 0.6 meters
Delay Time	<250 ms

Isolation Transformer

EN 60601-1, Ed. 3.1 approved Isolation Transformer models ISB-1462 (US), ISB-1499 (JPN), or ISB-1520 (EU) to be used for connection of the EnSite™ X Amplifier and Medical Electrical (ME) System equipment installed on the Amplifier and DWS carts. A total of two (2) Isolation Transformers are used for a complete EnSite™ X EP System.

NOTE: Do not position the isolation transformer so that it is difficult to disconnect from power.

Recording System Input Impedance

External recording equipment must meet the safety requirements of BS EN 60601-1 "Medical electrical equipment Part 1: General requirements for basic safety and essential performance".

Input impedance should be greater than 2.5 megohms when measured at 40Hz. Additionally, to optimize EnSite NavX™ performance, input impedance should be greater than 25k ohms channel-to-channel when measured at 8kHz.

Patient Environment Information

Non-Patient Environment

EnSite™ X EP System Display Workstation (DWS) Cart including: EnSite™ X EP System DWS, Keyboard, Mouse, Printer, Local Monitor, Isolation Transformer, Fiber Optic Video Extender and associated cabling.

NOTE: The EnSite™ X EP System DWS Cart is an optional component. Components are considered to be a part of the non-patient environment regardless of if they are on a cart.

Patient Environment

EnSite™ X EP System Amplifier Cart including: EnSite™ X EP System Amplifier, EnSite™ X EP System ECG Output Module, EnSite™ X EP System 20-pin Catheter Input Module, EnSite™ X EP System 80-pin Catheter Input Module, EnSite™ X EP System Field Frame, EnSite™ X EP System SurfaceLink Module, EnSite™ X EP System Patient Reference Sensors, and associated cabling.

NOTE: The EnSite™ X EP System Amplifier Cart is an optional component. Components are considered to be a part of the patient environment regardless of if they are on a cart.

EnSite™ X EP System Remote Monitor Stand including: Remote Monitor, Isolation Transformer, and Fiber Optic Video Extender, and associated cabling.

NOTE: The EnSite™ X EP System Remote Monitor Stand is an optional component. Components are considered to be a part of the patient environment regardless of if they are on a cart.

NOTE: The Remote Monitor is an optional component. If included, it can reside on the EnSite™ X EP System Remote Monitor Stand or the EnSite™ X EP System Amplifier Cart.

Disposal

- The IFU is recyclable.
- After use, device(s) and packaging should be appropriately classified for disposal, e.g. electrical equipment, non-hazardous waste, etc. and carefully disposed of in compliance with facility procedures and applicable laws and regulations. Discard any unused components after the procedure.

Reporting Device Incidents

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

Cybersecurity

- The site controlling the device should have policies in place prescribing the physical safety and security of the devices in the electrophysiology laboratory. For example, physically securing devices and information should include policies that limit physical access, securing equipment in locked rooms, managing access to secured rooms, and restricting the ability to remove devices from a secure area.
- It is the responsibility of the hospital/clinic to implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision. (Source: 45CFR Subpart C §164.310(a)(2)(iii))
- In the event of a suspected cybersecurity issue, discontinue use of the EnSite™ X EP System and contact Abbott Technical Support.
- This device must be operated by, or under the supervision of, an electrophysiologist trained in the operation of this device and supported by other qualified personnel trained in the field of cardiac EP.
- EnSite™ X EP System Amplifier is not intended to be used as a networked device. All remote network access protocols into the amplifier are disabled/not installed.

Cybersecurity Responsibilities of the Customer

As part of our assessments, we have identified risks that are dependent on how the product is maintained in the customer environment. The securing of the products we provide to our customers is a shared responsibility among all stakeholders. Based on the assessment conducted on the EnSite™ X EP System, we request the customer to ensure the following general security practices to protect the product in use at the customer location:

- **Physically secure the product and its operating environment** - Protect the physical security of the EnSite™ X EP System and operate it in a secure manner. Control and monitor physical access to the instrument using mechanisms such as security cameras, security badges, mantraps, keypads, and biometrics.
- **Securely operate and protect the product network** - Secure your network using network intrusion detection and prevention mechanisms, using adequately hardened network/application firewalls and network segmentation.
- **Limit access to authorized users** - Restrict access to the EnSite™ X EP System in accordance with your organization's security policies and through the user account security settings maintained by the EnSite™ X EP System.
- **Manage and protect your sensitive data** - Reports or other data exported from the EnSite™ X EP System should be controlled with appropriate clinical security practices.

Limited Warranty

Abbott Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products is set forth in the related "Instructions for Use" that accompany each product. Abbott Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. Abbott Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Abbott Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. Abbott Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete Abbott Medical warranty policy available from Abbott Medical or on the back of an Abbott Medical invoice.

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://medical.abbott/manuals.

Symbol	Definition
	Medical Device
	Unique device identification number
	Importer
	Consult instructions for use on this website
	Affixed to this device in accordance with European Council Directive 2012/19/EU. This directive calls for separate collection and disposal of electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem.

Symbol	Definition
	Intertek Safety Agency Certification Mark
MEDICAL ELECTRICAL EQUIPMENT	Medical Electrical Equipment
CE 2797	Conformité Européenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC (NB 2797) and 2011/65/EU. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
Rx ONLY	USA only: Federal law restricts this device to sale by or on the order of a Physician

St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117-9913 USA
+1 855 478 5833
+1 651 756 5833

EC REP
St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

www.abbott.com

Abbott

2020-11
ARTEN600155277 B

600155277

CE
2797