EpiAccess Control Unit

Instructions For Use

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

EPIEP, INC
195 Church Street
17th Floor
New Haven, CT 06510
USA
Telephone: (434) 951-0444
Fax: (434) 951-0478

CE
0297

European Representative:

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CONTACT INFORMATION

For any questions related to the EpiAccess Control Unit, please contact EpiEP Customer Service Department.

Address: 195 Church Street
17th Floor
New Haven, CT 06510
USA
Office: (434) 951-0444
Fax: (434) 951-0478

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Introduction

The EpiAccess System has two components: the EpiAccess Control Unit, which is used in conjunction with the A0006 or 0399-13950 EpiAccess Needle (L0034 or L0007 Instructions For Use). The EpiAccess Needle is a 14 gauge (.078 inch OD), 12.6 cm Tuohy type needle with an integrated a fiber optic sensor housed within a stainless steel tube in the inner lumen of the needle. The Control Unit contains instrumentation that captures the pressure signal from the sensor and delivers that signal to a computer.

Indications For Use

The EpiAccess System with introducer needle and integrated needle tip pressure transducer is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate guidewire placement in electrophysiology procedures in adult patients.

Description

The EpiAccess Needle is placed under fluoroscopic imaging. The system provides pressure measurements taken at the needle tip and via a commercially available (not provided) A-line catheter with pressure transducer that is also connected to the EpiAccess Control Unit. These pressure measurements are provided to the user by the EpiAccess Control Unit through a custom and ergonomic graphical user interface (GUI). The interface is displayed via a cable connection to a hospital or surgical suite monitor (not provided).

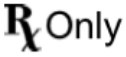
Changes and differences in pressure measurements within the human body are known to be indicative of specific anatomies and therefore can be used by the physician to identify the location of the device tip within the body during the electrophysiology procedure. The pressure measurements are adjunctive information provided for user convenience.

Contraindications

Not intended for use in patients with any of the following conditions:

- Congenital absence of the pericardium
- Absence of a free pericardial space

Symbol Legend

	Manufacturer
	Catalog number
	Serial Number
	Date of manufacture
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Keep away from rain
	Consult instructions for use
	General Warning Sign
	Caution
	Type CF Applied Part
	cETLus Classified mark (Conforms To AAMI STD ES 60601-1 and Certified To CSA STD C22.2 # 60601-1)

Warnings and Precautions

Read and follow all instructions and labeling during setup, installation, and equipment preparation. Not doing so can cause damage to equipment and injury to user or patient. Not following instructions may prevent the device from being able to perform its intended actions.

	**Warning!** Warning statements describe conditions or actions that can result in personal injury or loss of life.
	**Caution!** Caution statements describe conditions or actions that can result in damage to the equipment or software.
Note:	Notes contain additional information on device usage.

Electrical Shock

Warning!

To ensure the patient's safety and your own, observe the following:

- Never connect or disconnect the power cable when the system is on.
- When operating the system, be sure it and all other electrical equipment connected to or near the patient are effectively grounded.
- Use only the power cord included with the system.
- Do not use extension cords or three-prong to two-prong adapters. This could cause damage to the device and injury to the user or patient.
- Connect all the cables before plugging the system into the wall outlet.
- Do not disassemble any system component; it contains no user serviceable parts. Contact EpiEP, Inc. for maintenance assistance.
- Do not touch or alter any internal component during storage or use.
- Always disconnect power before cleaning or moving your system.
- Do not immerse any portion of this system in water or other fluids.
- Avoid spilling any fluids on the system.
- To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
- Only items that have been specified/supplied with your EpiAccess System are part of the system. Do not use any additional items in conjunction with the system.
- Use the power plug as mains disconnect in case of emergency.

Fire or Explosion

Warning!

- Risk of explosion exists if used in the presence of flammable anesthetics, or other flammable gases or liquids.
- Do not clean this system with flammable agents.

Trip or Fall Hazard

Warning!

- Risks of falls are increased if system cables are not properly placed during use and while being stored.

Control Unit Damage

Caution!

- Unpacking a cold system and exposing it to a warm room may cause condensation to form that can damage the system if it is connected immediately. Allow the system to adjust to room temperature before use. Never connect the system until moisture from condensation has completely dried.
- If the EpiAccess System is delivered and appears damaged, do not use the device. Contact EpiEP, Inc. for maintenance assistance.
- Never open the control unit case! The Control Unit must be serviced by properly trained personnel.
- Do not disassemble any system components.
- Contact EpiEP, Inc. for maintenance assistance.
- Store the EpiAccess Control Unit properly so that accessories are not lost and the device can be used again.
- Connect the EpiAccess Needle to the EpiAccess Control Unit correctly. Not doing so may cause the pressure readings to not be transferred to the EpiAccess Control Unit.
- Do not spill anything on the EpiAccess Control Unit. This may cause damage to the control unit device.

- Follow the shutoff process to ensure unit performs properly when started for next usage.

Other Precautions

Warning!

- Exposed metal surfaces of internal parts may be hot. Do not touch internal metal surfaces for more than 10 seconds.
- No modification of this equipment is allowed.

Caution!

The following steps should be taken before moving the system:

- The unit should be moved by AUTHORIZED PERSONNEL who have read and understand the operating instructions. DO NOT allow children to move the unit.
- Make sure the power cord is disconnected from the wall outlet and secured on the control unit and off the ground.
- Loosen the Pole clamp only as the final step of removing the EpiAccess Control Unit from the standard IV Pole.

Caution!

The following steps should be taken for stationary use:

- The EpiAccess Control Unit SHOULD NOT be used as a stool or ladder.
- Be sure that all persons operating this system have been trained and fully understand the operating instructions.
- DO NOT place food or beverage on the Control Unit or any component.
- Place your EpiAccess System in such a manner as to allow direct and easy access to operate the appliance coupler or separable plug to be used as an isolation means.

Potential Complications

Potential adverse effects that might be associated with the EpiAccess Needle are similar to those associated with any interventional procedure; particularly those accessing the pericardium from a subxiphoid approach, and include the following:

- Bleeding from the site of access
- Vascular rupture and perforation
- Hematoma
- Embolization
- Pain
- Epicardial irritation
- Local and systemic infection
- Neurological deficits including stroke and death
- Urticaria or ulceration may occur at the site of injection
- Thrombus formation
- Cardiac perforation
- Cardiac tamponade
- Pericarditis
- Hemopericardium
- Esophageal injury
- Coronary artery injury
- Abdominal bleeding
- Pneumopericardium
- Atrial fibrillation (AF)
- Ventricular tachycardia (VT) requiring cardioversion
- Ventricular fibrillation (VF)

System Description

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

Warning!

Please read all information carefully. Failure to properly follow the instructions may lead to patient injury.

Note:
This manual is designed to provide instructions for use of the EpiAccess Control Unit with the EpiAccess Needle. This manual is not a reference to surgical technique.

How Supplied

The EpiAccess Control Unit is supplied non-sterile and for multiple-patient use. The EpiAccess Control Unit is for use outside the sterile field in electrophysiology suites.

- **EpiAccess Needle**

This system is comprised of an EpiAccess Needle, which is a Tuohy Needle with a fiber optic pressure sensor housed within a stainless steel tube, integrated inside the lumen of the access needle. The instrumentation and usage is described in the EpiAccess Needle Instructions for Use (L0034 or L0007).

- **EpiAccess Control Unit**

Auxiliary instrumentation includes instrumentation, which captures the pressure signal from the sensor and displays the signals on a monitor. The data is displayed in a manner, which provides guidance to the physician on the position of the needle. The instrumentation and usage is described in this manual, the EpiAccess Control Unit Instructions for Use (L0038) and the EpiAccess System Quick Reference Guide (L0040).

Control Unit Components

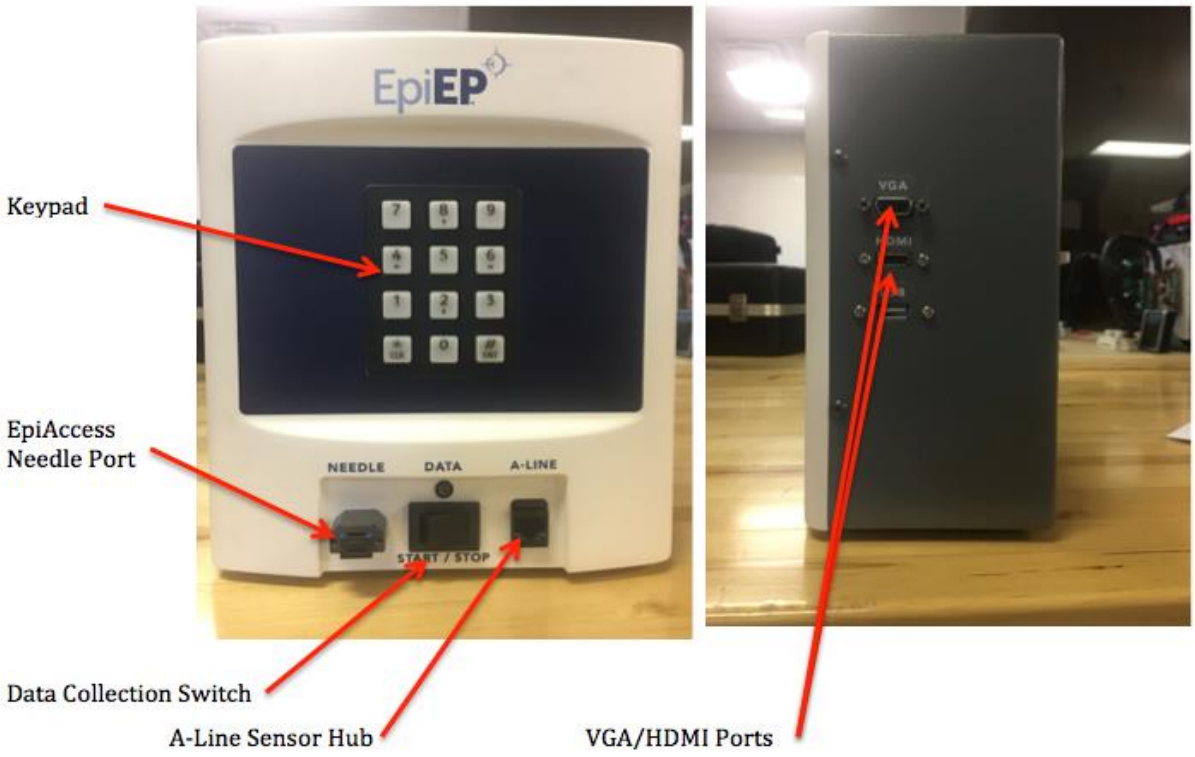


Figure 1 - Control Unit Components

The EpiAccess Control Unit is delivered in generic shipping packaging. It is recommended that the original shipping box and foam inserts be saved for future storing and transporting of the system. Care should be taken when removing the system from the box so as to not damage any of the box parts. The EpiAccess Needle will be shipped separately from the EpiAccess Control Unit.

Warning!

The EpiAccess Control Unit is not a sterile device. The Control Unit should be placed outside the sterile field, with a screen clearly visible to the user.

Installing the System

Transporting Control Unit

Caution!

The following steps should be taken before moving the system:

- The unit should be moved by AUTHORIZED PERSONNEL who have read and understand the operating instructions. DO NOT allow children to move the unit.
- Make sure the electrical cord is disconnected from the wall outlet and off the ground.

Preparing the Control Unit for Use

1. Review the EpiAccess System Quick Reference Guide (L0040) prior to proceeding with setting up your EpiAccess Control Unit.
2. Remove all components from the shipping box.
3. Mount the provided pole mount to the back of the Control Unit by sliding fully into place and tightening the thumbscrew securely (Figure 2)
4. Mount the control unit to a standard IV Pole using the provided pole mount and tightening the screw knob securely.
5. Connect an external monitor to the device using the HDMI or VGA ports (Connecting cables are not supplied with the device). Monitor resolution of 1424 x 1048 or higher is recommended.

6. Remove the cover from the EpiAccess Needle Port and retain for future use (Figure 1).

Figure 2 - IV Pole Mount

7. Plug the provided power cord into the back of the Control Unit adjacent to the power switch (Figure 3).

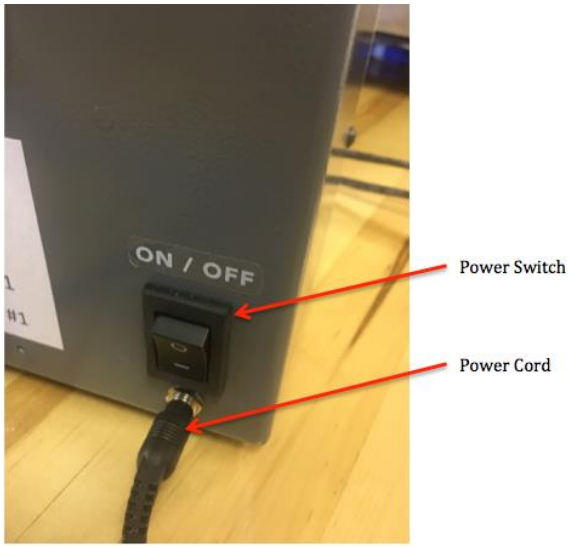


Figure 3 - Power Connection

Caution!

Failure to connect the Arterial Line Cable to the A-Line Sensor Hub prior to powering the EpiAccess System on may result in a timing lag in the waveform for the Arterial Line. Should the Arterial Line NOT be connected prior to powering the EpiAccess System on power the EpiAccess System off and proceed with step 8.

8. Connect the ICU Medical, Transpac Disposable Pressure Sensor to the Arterial Line Custom Cable by lining up the RJ11 connectors and pushing into place. (Figure 4).
9. Connect the Arterial Line Custom Cable to the front of the Control Unit by plugging into the port marked "A-Line" on the front of the Control Unit (Figure 1).

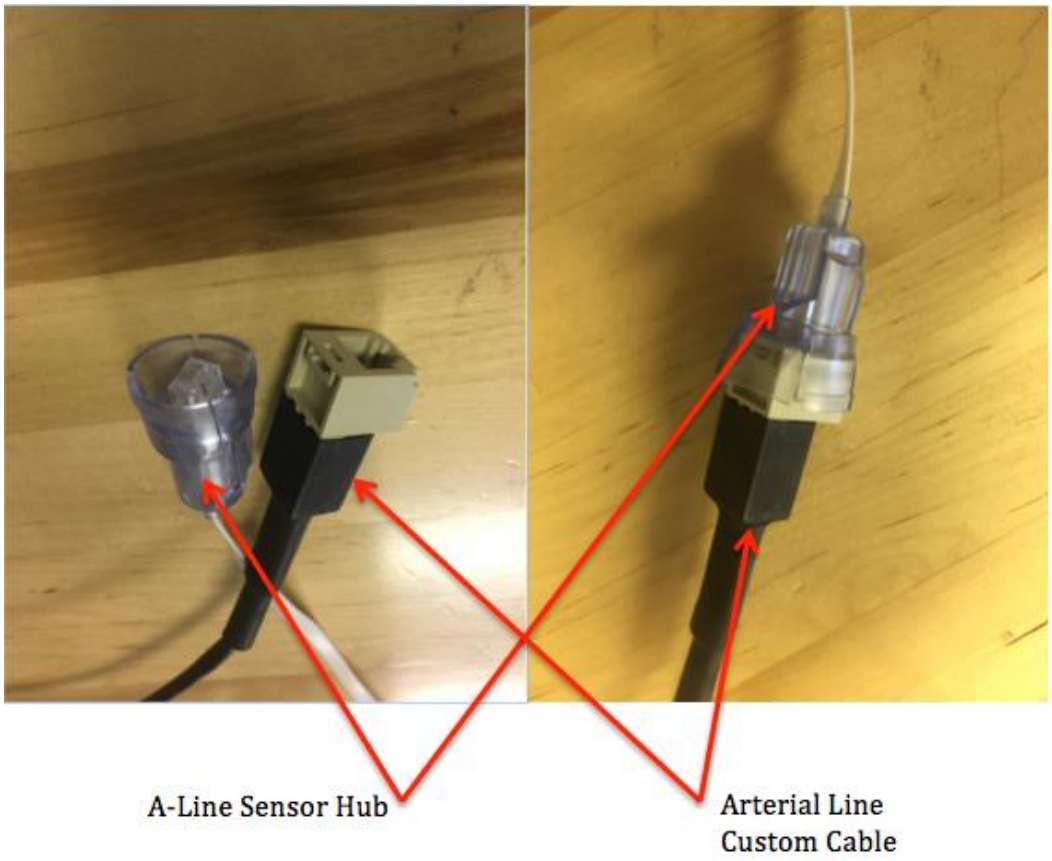


Figure 4 - Arterial Line and Sensor

Electromagnetic Emissions

When installing or placing your EpiAccess System, follow the table below regarding Electromagnetic Emissions:

Guidance and Manufacturers Declaration – Electromagnetic Emissions		
The A0005 EpiAccess Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A0005 EpiAccess Control Unit should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment**
RF Emissions CISPR 11	Group 1	The A0005 EpiAccess Control Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The A0005 EpiAccess Control Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

When installing or placing your EpiAccess System, follow the table below regarding Electromagnetic Immunity:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The A0005 EpiAccess Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A0005 EpiAccess Control Unit 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 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the A0005 EpiAccess Control Unit, including cables, than the recommended separation displacement calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation displacement 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: 
Radiated RF IEC 61000-4-3	4 V/m 80 MHz to 2.5 GHz	3 V/m	

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

NOTE 2 These guidelines may not apply to 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 A0005 EpiAccess Control Unit is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as re-orienting or relocating the A0005 EpiAccess Control Unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The A0005 EpiAccess Control Unit in intended for use in the electromagnetic environment specified below. The customer or the user of the A0005 EpiAccess Control Unit 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 ± 8 kV air	± 2 kV, 4 kV, & 6 kV contact ± 2 kV, 4 kV, & 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	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	± 0.5 kV & 1 kV differential mode ± 0.5 kV, 1 kV, & 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the A0005 EpiAccess Control Unit requires continued operation during power mains interruptions, it is recommended that the A0005 EpiAccess Control Unit be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic or a typical commercial or hospital environment,
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Powering the System

Warning!

Do not use extension cords or three-prong to two-prong adapters. The power cords should be periodically checked for damaged insulation or connectors.

- Step-by-step instructions for powering up and following on-screen prompts:
    1. Plug the EpiAccess Control Unit into a wall outlet.
    2. Toggle the power switch to the on position located on the back of the device.
        - Note: In the event of a keypad malfunction or popup software error notification, please reference the Troubleshooting section of this document.

Understanding the Graphical User Interface (GUI)

General Description:

The three graphs presented on the EpiAccess display are:

- Top: Arterial Line Signal
- Middle: Needle Tip Pressure (mmHg)
- Bottom: Algorithm Response

The arterial line signal is displayed as a raw signal on the GUI and provides the user a visual indication of proper arterial line sensor connection. The Needle Tip Pressure signal is displayed as a raw signal on the GUI for the user to interpret in determining location of the needle (e.g., diaphragm, thorax, pericardial sac, pericardial space, etc.). The Algorithm Response graph is a combination of the pressure measurements presented in a different manner for user convenience. This graph is based on an algorithm that conducts a beat-to-beat analysis of the needle tip pressure frequency using the arterial pressure signal as a gate.

Detailed Descriptions of Each Graph

Arterial Line Signal graph: The arterial line pressure tracing derived from the Arterial Line Sensor provides a visual indication of the connection status of the arterial line sensor. Proper connection is confirmed when cardiac pulsations are present in the arterial line tracing. If cardiac pulsations are not present, connections should be checked in accordance to Step 8 and 9 above under the “Preparing the Control Unit for Use” section and the ICU Medical Transpac IV Disposable Pressure Transducer Instructions for Use.

Needle Tip Pressure (mmHg) graph: The needle tip pressure tracing is derived from the pressure transducer at the tip of the EpiAccess Needle and provides the primary method of determining needle tip position.

When approaching the heart from the subxiphoid region, needle tip pressure signals with cardiac basis can provide an indication that the needle is close to or has entered the heart. The strength of the pulses can be indicative of certain anatomy, phase of the cardiac cycle, and physiological conditions. Thus these pressure frequencies can also be indicative of the needle tip location. For instance, pericardial pulsation may be approximately 5 mmHg, Right Ventricle pulsation may be approximately 20 mmHg, and Left Ventricle pulsations may be greater than 100 mmHg. Pressure ranges in the cardiac anatomy are well published and understood.[1] These signals can vary throughout the procedure.

The Algorithm Response graph (third graph from the top on the GUI – Figure 5 or 6) represents an analysis of the pressure-frequency patterns for potential cardiac (pressure/signal) presence. This graph is provided as an additional representation of the raw Needle Tip Pressure signal information. The algorithm calculation looks for pulsatility that has occurred. In Figure 5 there is a 1 heart beat lag between the beginning of a consistent cardiac signal on the Arterial Line Signal and the Needle Tip Pressure Signal graphs, and the algorithm response graph. A clear and consistent Pressure Tip signal pattern may not always be as visually obvious as shown in Figure 5. In these cases the additional algorithm response graph information may help clarify the raw signal information.

Via bar height and color, the algorithm response graph provides an extra visual alert to the physician that the signal has become more consistent and thus indicative of potential cardiac presence. The bar graph height (from low to high indicates an increase) and color (from gray to white indicates an increase) corresponds to the strength of the needle tip pressure signal and the degree the needle tip pressure oscillation frequency matches the heartbeat frequency (using the arterial line as a gate). Gray bars in the black section indicate a lack of cardiac signal presence.

The algorithm response graph: Consistent cardiac frequency pulsation at ~5 mmHg is indicated by white bars in the black section (lower third of the graph grid – Figure 5). As reported in the peer reviewed published literature, this pressure frequency signal may be an indication that the needle is in the pericardial space.[2] Needle position assessment using standard fluoroscopic imaging techniques should be performed if pressure frequency signals consistent with the pericardial space are observed.

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1 Mahaptra S, Tucker-L Schwartz J, Wiggins D, et al. Pressure frequency characteristics of the pericardial space and thorax during subxiphoid access for epicardial ventricular tachycardia ablation. Heart Rhythm. 2010;7: 604-609.

2 Mahapatras S, et al. Pressure frequency characteristics of the pericardial space and thorax during subxiphoid access for epicardial ventricular tachycardia ablation. Heart Rhythm. May 2010; 7(5): 604–609. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3047445/)

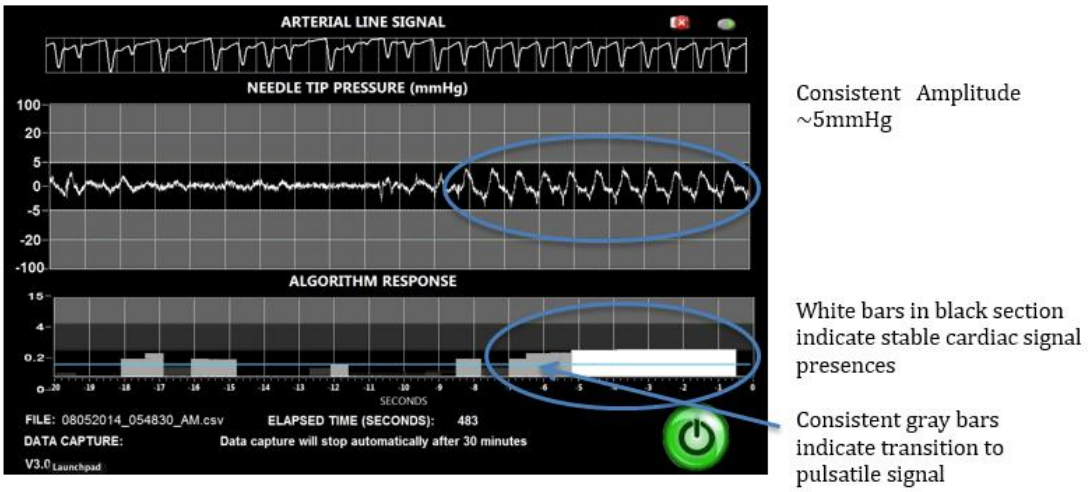
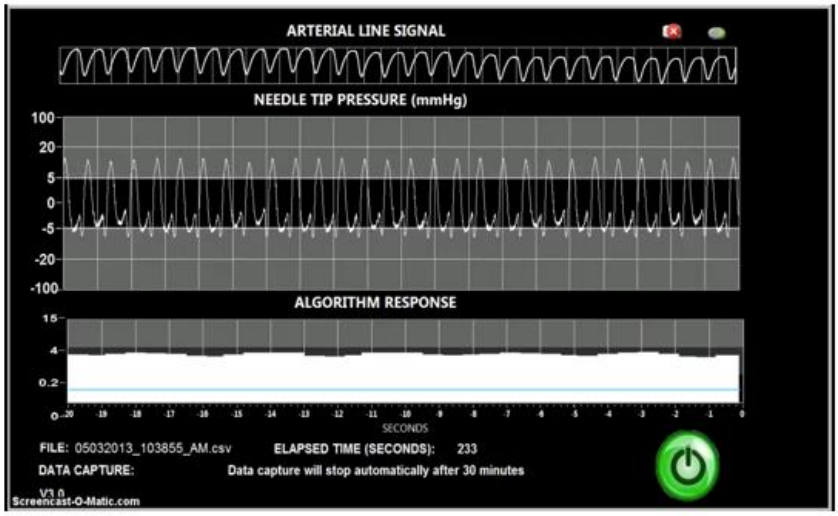


Figure 5: Algorithm Response Graph showing consistent amplitude at ~5mmHg indicated by white bars

Consistent cardiac frequency pulsation at ~20 mmHg (on average) is indicated by white bars in the medium gray section (Figure 6). This pressure frequency signal may be an indication that the needle tip is within the right ventricle, as generally 15 mmHg to 50 mmHg is within the normal right (systolic) ventricular pressure range, depending on age and other physiological factors.[3] Needle position assessment using standard fluoroscopic imaging techniques should be performed if pressure frequency signals consistent with the right ventricle are observed.

[3] Armstrong D, Tsimiklis G, Mantangi M, Factors influencing the echocardiographic estimate of right ventricular systolic pressure in normal patients and clinically relevant ranges according to age. Can J Cardiol. Feb 2010; 26(2): e35–e39. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851398/)



Consistent Amplitude ~20 mmHg

White bars in medium gray section

Figure 6: Algorithm Response Graph showing consistent amplitude at ~20 mmHg indicated by white bars

Consistent cardiac frequency pulsation at ~100 mmHg (on average) is indicated by white bars in the light gray section (Figure 7). This pressure frequency signal may be an indication that the needle tip is within the left ventricle, as generally 90 – 140 mmHg is within the normal left (systolic) ventricular pressure, depending on age and other physiological factors.[4] Needle position assessment using standard fluoroscopic imaging techniques should be performed if pressure frequency signals consistent with the left ventricle are observed.

[4] As with all normal range values, the physician should go by his/her training and institutions standard of care for these values.

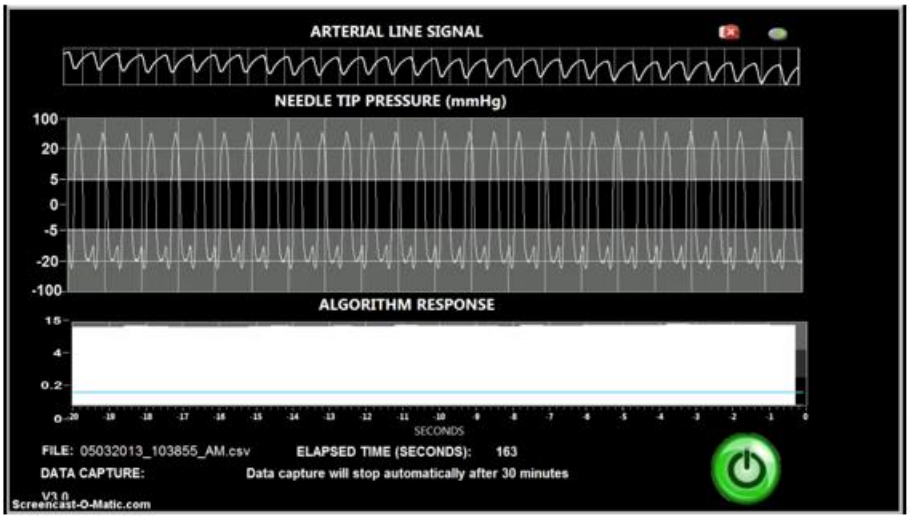


Figure 7: Algorithm Response Graph showing consistent amplitude at ~100 mmHg indicated by white bars

Using the System

Caution!

- Understand labeling and instructions so that the software is not misinterpreted.
- Should an error code arise, please first re-boot the EpiAccess Control Unit. If continued errors occur, please contact an EpiEP Representative.

1. Power on the EpiAccess System by toggling the on/off switch.
    - Note: In the event of a keypad malfunction or popup software error notification, please reference the Troubleshooting section of this document.
2. The software will boot directly to the EpiAccess software program. To gain access, log into the software through use of the keypad on the front of the device. The code for access is 123456. Press each number on the keypad and then press “ENT”.
3. Connect the A0006 or 0399-13950 EpiAccess Needle into the front of the Control Unit (Figure 1).
4. Verify the ICU Medical, Transpac Disposable Pressure Sensor is connected to the custom cable connector for the Arterial Line signal as shown in the “preparing the control unit for use” section.

5. Toggle the start/stop data collection switch to the Start position located on the front of the control unit to begin collecting data (Figure 1).
    - Note: In the event of a keypad malfunction or popup software error notification, please reference the Troubleshooting section of this document.
6. To stop data collection, toggle the data collection switch to the Stop position.
7. To power down the EpiAccess System toggle the on/off switch to the off position.
8. Disconnect all external cables and store the device in a secure and safe location

Warning!

It is important that the system be properly shut down. Failure to do so may cause the unit to not start properly.

Troubleshooting

The EpiAccess Control Unit does not have any user serviceable parts. Please contact EpiEP customer service for any questions.

Caution!

In the event of a keypad malfunction or popup software error notification, please restart the device. If the problem persists, please contact EpiEP customer service for additional support.

Technical Specifications

The EpiAccess Control Unit should be operated in a hospital environment with an ambient temperature between 20°C and 28°C with a relative humidity between 30% and 60%.

The EpiAccess Control Unit should be stored in a safe and dry location with the following ambient conditions:

- Temperature: 10°C – 40°C
- Humidity: 10% – 90%
- Pressure: 70 kPa – 105 kPa

Input Voltage: DC 12 V 2.5 A

Preventative Maintenance and Cleaning

Recommended Care

Regular maintenance and cleaning can enhance the performance and longevity of the EpiAccess Control Unit. The Control Unit should be maintained and cleaned. The following section contains information about caring for the device.

Care and Cleaning

Warning!

Follow the cleaning method in the instructions so that the equipment is not damaged. Before cleaning any components shut down the system and unplug the power cord.

The outside surfaces of the EpiAccess Control Unit and its accessories (except the EpiAccess Needle) are designed to be cleaned with mild soap and water or isopropyl alcohol.

Cleaning the EpiAccess Control Unit

- Shut down the system and unplug the power cord.
- Wipe the external surfaces of the systems components with a soft cloth dampened with mild soap and water or isopropyl alcohol.

Caution!

- Avoid applying cleaning fluids to cable connectors.
- **Do not** use any strong solvents or abrasive cleaning materials such as:
  - Acetone
  - Iodine based cleaners
  - Phenol based cleaners
  - Ethylene Oxide Sterilization
  - Chlorine Bleach
  - Ammonia based cleaners
- **Do not** immerse any components in liquids.
- **Do not** spill any liquids on the system's components.

Caution!

Immediately have the system serviced if any liquids spill on any components.

Cleaning External, Computer Components

Before cleaning any components shut down the system and unplug the power cord. Follow local facilities guidelines or wipe external surfaces of components with a soft cloth dampened with mild soap and water or isopropyl alcohol.

Moving the Unit

Caution!

The following steps should be taken before moving the system:

- The unit should be moved by AUTHORIZED PERSONNEL who have read and understand the operating instructions. DO NOT allow children to move the unit.
- Make sure unit has been properly shut down prior to disconnecting the electrical cords.
- Make sure the power cord is disconnected from the wall outlet and secured with the Control Unit and off the ground. Unsecured cables could cause damage to the device or user.
- Loosen the Pole clamp only as the final step of removing the EpiAccess Control Unit from the standard IV Pole.

Disposal

Do not dispose or recycle the device components. Please return the device to EpiEP for proper recycling or disposal.

Service Life Agreement

The EpiAccess Control Unit has a useful service life of five years from the date of manufacture.

Limited Warranty

EpiEP, Inc. provides this limited warranty that the product has been manufactured and released for use in accordance with its specifications and tested using its established test methods. EpiEP makes no other express or implied warranties, including the implied warranties of merchantability and fitness for a particular purpose. EpiEP specifically does not make any representation or warranty about the use or performance of this device used in conjunction with any other intervention devices. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond EpiEP's control may directly affect the device and the results obtained from its use. EpiEP makes no warranty, expressed or implied, including but not limited to the warranties of merchantability or fitness for a particular use with respect to devices reused, reprocessed, or sterilized.