IAB Insertion / Cardiosave IABP Operation

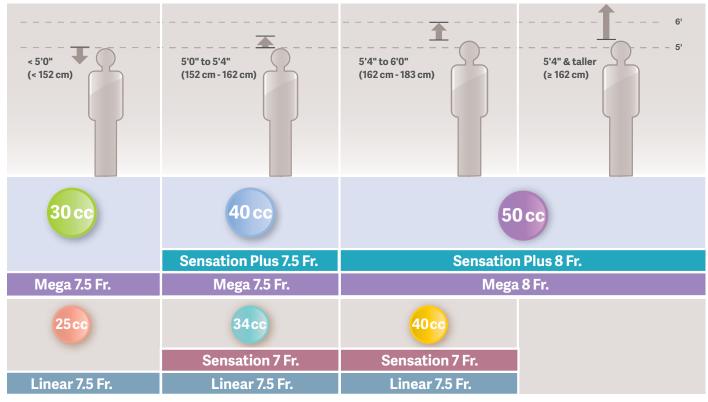


Quick Reference Guide/Cardiosave IABP software D.00

(For use outside the US only)



Intra-aortic Balloon Sizing Guide



Note: This information is to be used as a guidance only. Clinical information and patient factors such as torso length should be considered when selecting the appropriate balloon size. Sensation and Sensation Plus are fiber-optic IAB catheters.

Preparing the IAB Catheter



Firmly attach one-way valve to male luer fitting of IAB catheter.



Apply a 30 cc vacuum.



Remove syringe while keeping one-way valve in place.



Manually flush inner lumen with 3-5 cc of flush solution.

Sheathless insertion



Insert needle at 45° angle or less, then insert guidewire – 7.5 Fr./8 Fr. IAB: 0.025" (0.06 cm) / 7 Fr. IAB: 0.018" (0.05 cm).



Make small incision at exit of guidewire.



Insert vessel dilator over guidewire, tapered end first, then remove.



Spread tissue at incision to facilitate sheathless insertion.



Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.



Advance IAB catheter into artery using short strokes until correct placement is achieved, then advance sheath seal as close to insertion site as possible.



Secure IAB catheter to patient's leg using StatLock' IAB Stabilization Device or sutures (Sensation Plus includes StatLock' in IAB box).

Note: Continue on page 6, step #13.

Sheathed insertion



Insert needle at 45° angle or less, then insert guidewire – 7.5 Fr./8 Fr. IAB: 0.025" (0.06 cm) / 7 Fr. IAB: 0.035" (0.09 cm).



Make small incision at exit of guidewire.



Insert introducer dilator into sheath hub and twist lock in place to secure.



- **1** Advance sheath over guidewire into artery using a rotary motion.
- 2 Withdraw introducer dilator leaving sheath in place.



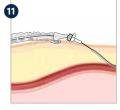


7Fr. IAB only:

- 9a Remove 0.035" (0.09 cm) guidewire and
- **9b** Replace with 0.018" (0.05 cm) guidewire.



Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.



Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



Secure IAB catheter to patient's leg using StatLock' IAB Stabilization Device or sutures (Sensation Plus includes StatLock' in IAB box).

Pressure monitoring set-up



Remove guidewire and aspirate 3 cc of blood from inner lumen.



Manually flush inner lumen with 3-5 cc of flush solution.



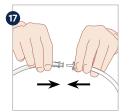
Attach a standard arterial pressure monitoring apparatus.

Note: With Sensation Plus, a reliable pressure signal may be obtained via the inner lumen, if needed. Maintain the inner lumen according to Hospital policy for arterial line management.

Connection to IABP



Remove one-way valve from IAB catheter.



Connect IAB catheter's male luer fitting to female luer fitting of catheter extender.



Connect male luer fitting of catheter extender to Pneumatic Module of IABP. Insert fiber-optic sensor connector into IABP's sensor input receptacle until it clicks.

Preparing the IAB Catheter



Firmly attach one-way valve to male luer fitting of IAB catheter.



Apply a 30 cc vacuum.



Remove syringe while keeping one-way valve in place.



Manually flush inner lumen with 3-5 cc of flush solution.

Sheathless insertion



Insert needle at 45° angle or less, then insert 0.025" (0.06 cm) guidewire.



Make small incision at exit of guidewire.



Insert vessel dilator over guidewire, tapered end first, then remove.



Spread tissue at incision to facilitate sheathless insertion.



Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.



Advance IAB catheter into artery using short strokes until correct placement is achieved, then advance sheath seal as close to insertion site as possible.



Secure IAB catheter to patient's leg using StatLock' IAB Stabilization Device or sutures.

Note: Continue on page 10, step #12.

Sheathed insertion



Insert needle at 45° angle or less, then insert 0.025" (0.06 cm) guidewire.



Make small incision at exit of guidewire.



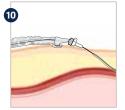
Insert introducer dilator into sheath hub and twist lock in place to secure.



- 1 Advance sheath over guidewire into artery using a rotary motion.
- 2 Withdraw introducer dilator leaving sheath in place.



Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.



Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



Secure IAB catheter to patient's leg using StatLock' IAB Stabilization Device or sutures.

Pressure monitoring set-up



Remove guidewire and aspirate 3 cc of blood from inner lumen.



Manually flush inner lumen with 3-5 cc of flush solution.



Attach a standard arterial pressure monitoring apparatus.

Connection to IABP



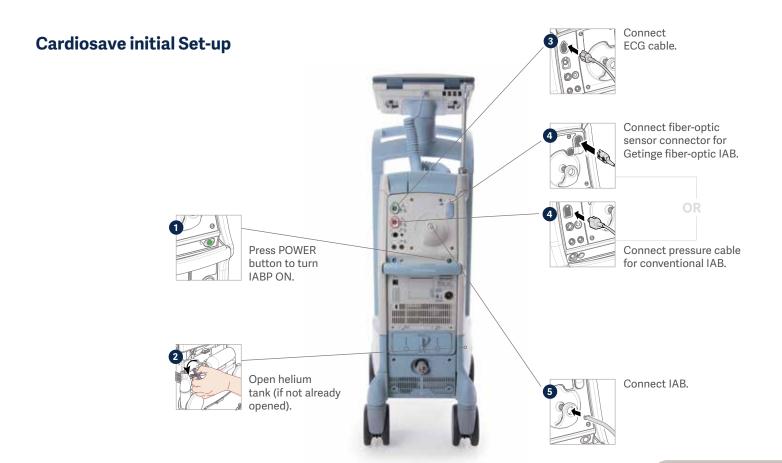
Remove one-way valve from IAB catheter.



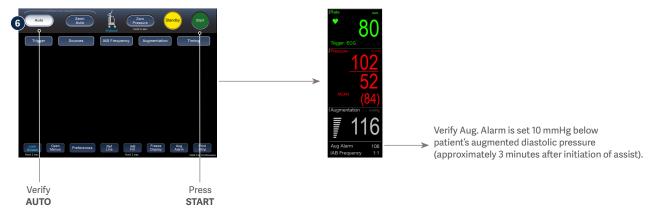
Connect IAB catheter's male luer fitting to female luer fitting of catheter extender.



Connect male luer fitting to Pneumatic Module of IABP.



Initial set-up using a Getinge Fiber-optic IAB (continued)



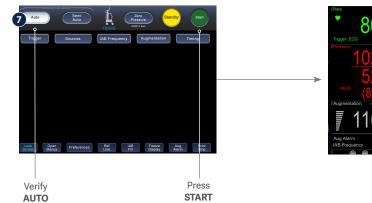
Pressing the START key

- · Automatically purges and fills IAB
- Automatically performs an in vivo calibration
- Automatically selects most appropriate lead and trigger
- · Automatically sets inflation and deflation timing

Note: With a Getinge fiber-optic IAB, there is no need to zero. Calibration occurs automatically after pressing START. Operator may invoke a calibration anytime by pressing and holding CALIBRATE PRESSURE key for 2 seconds, while assisting. The power button is disabled for 10 seconds after a shutdown to allow for a full reset.

Initial Set-up using a Conventional IAB (continued)





Verify Aug. Alarm is set 10 mmHg below

→ patient's augmented diastolic pressure
(approximately 3 minutes after initiation of assist).

Pressing the START key

- · Automatically purges and fills IAB
- · Automatically selects most appropriate lead and trigger
- · Automatically sets inflation and deflation timing

Note: The power button is disabled for 10 seconds after a shutdown to allow for a full reset.

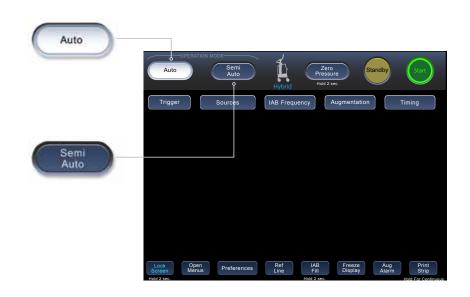
Cardiosave Operation Modes

Auto Operation Mode

- · Automatic lead and trigger selection
- Automatic and continuous inflation and deflation timing management
- User has ability to fine-tune deflation timing
- · Automatic management of irregular rhythms
- Automatic in vivo calibration (when using a Getinge fiber-optic IAB)

Semi-Auto Operation Mode

- Operator selects most appropriate lead and trigger source
- Operator establishes timing, then Cardiosave automatically adjusts timing with heart rate and rhythm changes
- · Automatic management of irregular rhythms
- Automatic in vivo calibration (when using a Getinge fiber-optic IAB)



Cardiosave Monitor Display and Touchscreen



Monitor Display



Touchscreen

Cardiosave Lock Screen Feature



Touchscreen Unlocked

Touchscreen will Lock:

- · Automatically after 2 minutes of inactivity
- When operator presses LOCK SCREEN key for 2 seconds





Touchscreen Locked

Touchscreen will Unlock:

- Automatically with any Technical, High, Medium, or Low Priority Alarm
- When operator presses UNLOCK SCREEN key



Cardiosave Triggers

Triggering

- A Trigger is the signal that Cardiosave uses to identify the beginning of the next cardiac cycle
- When Cardiosave recognizes the trigger event, it will deflate the balloon if not already deflated
- Trigger Source keys are only active while in Semi-Auto operation mode



Cardiosave Triggers

ECG

Trigger event is the R-Wave

- Trigger of choice when an adequate R-Wave is present
- · Pacer spikes are automatically rejected

Pressure

Trigger event is the systolic upstroke

- Trigger of choice (with a regular rhythm) when an adequate R-Wave is not present
- A fixed pressure threshold can be manually set while in Semi-Auto operation mode

Pacer V/AV

Trigger event is the Ventricular pacer spike

- Typically used when ECG triggering is unsuccessful and a V or AV pacer is being used
- Must be 100% paced
- · Only available in Semi-Auto operation mode

Pacer A

Trigger event is the R-Wave

- Recommended only if atrial pacer tails are interfering with R-Wave detection while in ECG trigger
- · Only available in Semi-Auto operation mode

Internal

Trigger event is asynchronous at a fixed rate of 80 BPM

- Only used when there is no mechanical cardiac cycle (i.e.: cardiopulmonary bypass or asystole)
- Rate can be adjusted from 40 to 120 BPM
- Only available in Semi-Auto operation mode





Theory of Counterpulsation Therapy



Inflation: increases supply of oxygen to the myocardium.

How it works

- Balloon inflates at onset of diastole (when aortic valve closes)
- Displaces blood, causing an increase in aortic pressure

Benefits

- Increases coronary artery perfusion
- · Increases mean arterial pressure



Deflation: decreases demand for oxygen by the left ventricle.

How it works

- Balloon deflates just prior to systolic ejection (before aortic valve opens)
- Results in a rapid decrease in aortic pressure

Benefits

- · Decreases afterload
- · Decreases cardiac workload
- · Increases cardiac output

Timing

Timing refers to the positioning of inflate and deflate points on the arterial pressure waveform.

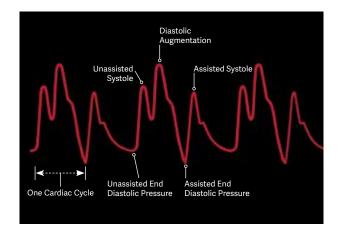
Proper IABP Timing

Inflation

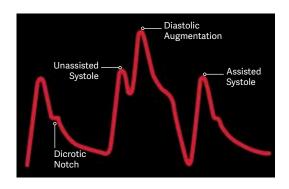
- · Occurs at the dicrotic notch
- · Appears as a sharp "V"
- Ideally diastolic augmentation rises above systole

Deflation

- Occurs just prior to systolic ejection
- Results in a reduction in assisted end diastolic pressure
- Results in a reduction in assisted systolic pressure



Timing Errors



Early Inflation

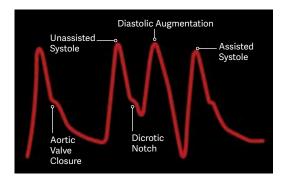
Inflation of IAB prior to aortic valve closure.

Waveform characteristics

- Inflation of IAB prior to dicrotic notch
- Diastolic augmentation encroaches onto systole (may be unable to distinguish)

Physiologic Effects

- Potential premature closure of aortic valve
- Potential increase in LVEDV/LVEDP/PCWP
- Increased left ventricular wall stress or afterload
- · Aortic regurgitation
- · Increased MVO2 demand



Late Inflation

Inflation of IAB markedly after closure of aortic valve.

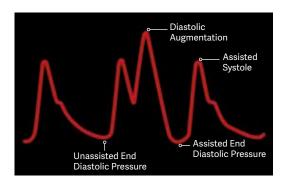
Waveform characteristics

- · Inflation of IAB after dicrotic notch
- · Absence of sharp "V"
- Sub-optimal diastolic augmentation

Physiologic Effects

Sub-optimal coronary artery perfusion

Timing Errors



Early Deflation

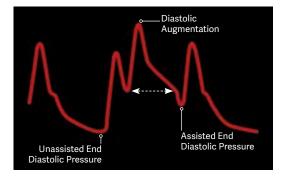
Premature deflation of IAB during diastolic phase.

Waveform characteristics

- Deflation of IAB is seen as a sharp drop following diastolic augmentation
- · Sub-optimal diastolic augmentation
- Assisted end diastolic pressure may be equal to or less than unassisted end diastolic pressure
- · Assisted systolic pressure may rise

Physiologic Effects

- · Sub-optimal coronary perfusion
- Potential for retrograde coronary and carotid blood flow
- Angina may occur as a result of retrograde coronary blood flow
- · Sub-optimal afterload reduction
- Increased MVO2 demand



Late Deflation

Deflation of IAB after aortic valve has opened.

Waveform characteristics

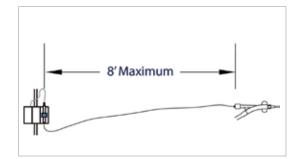
- Assisted end diastolic pressure may be equal to or higher than unassisted end diastolic pressure
- Rate of rise of assisted systole is prolonged
- Diastolic augmentation may appear widened

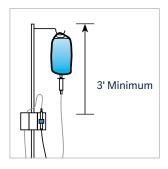
Physiologic Effects

- Afterload reduction is essentially absent
- Increased MVO₂ consumption due to left ventricle ejecting against a greater resistance and a prolonged isovolumetric contraction phase
- IAB may impede left ventricular ejection and increase afterload

Proper Care of Inner Lumen

- · Minimize length of pressure tubing
- · Use only low compliance pressure tubing
- Elevate flush bag at least 3' (91.44 cm) above transducer
- A 3 cc/hour continuous flow through inner lumen is recommended
- If inner lumen becomes damped
- Aspirate and discard 3 cc of blood
- If unable to aspirate blood, consider inner lumen clotted, cap lumen, provide alternate pressure source
- If able to aspirate blood, fast flush to clear pressure tubing for at least
 15 seconds (with IABP on Standby)
- Do not sample blood from inner lumen
- The saline pole is included with the IABP as a convenient location for the flush bag, when needed
- Never place fluids on top of the IABP and DO NOT hang flush bag and/or tubing directly over the IABP
- In case of accidental spillage, wipe clean immediately and have the unit serviced







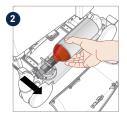
Changing the Helium Tank



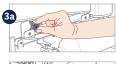


1a Grasp both sides of helium tank panel and

1b Pull out to open.



Grasp helium tank and slowly slide drawer out.





- **3a** Remove helium tank knob from Holder and
- **3b** Attach to left end of helium tank, then fully turn clockwise to close.



Slowly loosen yoke T-handle counterclockwise (some helium may escape).



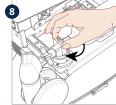
Remove helium tank.



Replace washer, if available.



Install fresh helium tank.



Fully tighten yoke T-handle clockwise.



Slowly open helium tank knob counterclockwise (listen for any escaping helium).



Slide helium tank drawer in and replace helium tank panel.



Verify full helium level via icon on Monitor Display.

Note: Once the helium alarm sounds, there are 24 Autofills remaining in tank.

Viewing Battery Status on Monitor Display (examples)



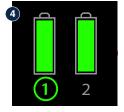
Empty battery bay. No backup battery or Transport Power Supply detected in battery bay.



Plugged into AC power outlet and batteries are fully charged.

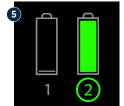


IABP has been plugged into AC power outlet, battery 1 is depleted and battery 2 is being charged.

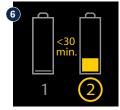


Lit green circle indicates battery 1 is in use. Battery 2 is fully charged and available for use when battery 1 is depleted.

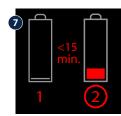
Note: The Low Battery alarm is displayed when 30 minutes or less of internal battery operating time remains. When this message is displayed, the battery symbol is displayed as empty. There is also an audible tone every 30 seconds. Additionally, a high priority Low Battery alarm message will be activated with 15 minutes of time remaining on the sole available battery in use. See the User Maintenance chapter in the Operating Instructions for additional information.



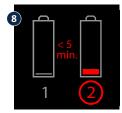
Battery 1 is depleted, thus battery 2 is currently being used.



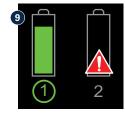
Battery 1 is depleted and battery 2 has less than 30 minutes of charge remaining (Low Battery message is displayed). **Caution:** Prompt attention is needed to either insert fully charged batteries or plug into AC source.



Battery 1 is depleted and battery 2 has less than 15 minutes of charge remaining. **Caution:** Prompt attention is needed to either insert fully charged batteries or plug into AC source.

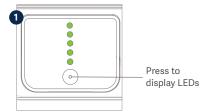


Battery 1 is depleted and battery 2 has less than 5 minutes of charge remaining. **Caution:** Prompt attention is needed to either insert fully charged batteries or plug into AC source.



IABP detects an unusable battery in a Battery Bay, the attention icon △ will be superimposed over the battery icon, with a corresponding message displayed in the Message Display Area.

Viewing Battery Status on Battery



Battery is approximately 100% charged.

Note: Each LED represents a charge of approximately 20%.

Changing the Battery



Turn knob to remove battery from Battery Bay.



Slide battery OUT.



Slide charged battery IN.



While holding battery in bay, turn knob to lock battery in place.



Use care to avoid dropping the battery.

Augmentation Below Limit Set





Probable Cause	Corrective Action
Hemodynamic status has changed: ↑HR, ↓SV, ↓MAP.	Attempt to optimize patient's hemodynamic status.
Alarm limit set too high.	Press AUG. ALARM key, decrease limit.

Autofill Failure





Probable Cause	Corrective Action
IAB disconnected.	Attach IAB catheter.
Helium tank is closed.	Open helium tank.
Helium tank is empty.	Change helium tank.
Incorrect IAB catheter extender tubing length.	Ensure only one IAB catheter extender tubing is connected from IAB to pump.

Cardiosave High Priority Alarm Messages – Battery/AC Power

Low Battery

There is less than 15 minutes of battery operating time remaining.

- 1. Connect system to an AC power source immediately.
- 2. If an AC power source is unavailable, insert a charged battery into the battery bay not currently in use.

Alarm Attributes:

Operation Mode: All Trigger Source: All

Detailed Cause: Cumulative reserve of both batteries falls below 15 minutes of operating time.

System Response: Unaffected.

Reset: Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.

Battery Charge Level Unavailable Bay #_

The battery in the identified bay or bays is unable to communicate the battery charge level.

- 1. Immediate battery replacement is required.
- 2. Replace the battery that is currently in use. If a fully charged battery is not available connect to an AC power source as soon as possible.
- 3. If battery operation on the indicated battery is required monitor the system closely for a system shutdown, the Low Battery Alarm will not be displayed.

Alarm Attributes:

Operation Mode: All

Trigger Source: All

Detailed Cause: The indicated battery is unable to communicate its charge level to the IABP.

System Response: None.

Reset: When battery is replaced.

Cardiosave Medium Priority Alarm Messages - Battery/AC Power

Low Battery

There is less than 30 minutes of battery operating time remaining.

- 1. Connect system to an AC power source.
- 2. If an AC power source is unavailable, insert a charged battery into the battery bay not currently in use.

Alarm Attributes:

Operation Mode: All

Trigger Source: All

Detailed Cause: Cumulative reserve

Detailed Cause: Cumulative reserve of both batteries falls below 30 minutes of operating time.

System Response: Unaffected.

Reset: Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.

Multiple AC Power Sources Detected

The IABP is connected to multiple AC power sources.

1. Disconnect the IABP from the unused AC power source (s).

Alarm Attributes:

Operation Mode: All Trigger Source: All

 $\label{eq:definition} \textit{Detailed Cause: The system has detected that multiple AC}$

power sources are connected to the IABP.

System Response: Unaffected.

Reset: Automatically, once the unused AC power source is disconnected

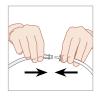
IAB Catheter Restriction





Probable Cause	Corrective Action
Restriction in IAB catheter or tubing.	Relieve restriction if possible, press START.
Membrane has not completely unfolded.	Manually inflate and deflate IAB.
IAB remains in sheath.	Check markings on IAB and if IAB has not exited sheath, refer to IFU to reposition sheath relative to IAB catheter.

IAB Disconnected







Probable Cause
IAB catheter or extender tubing is disconnected.

Corrective Action

Reattach IAB, press START.

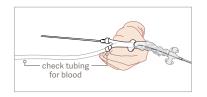
Prolonged Time in Standby

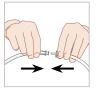




Probable Cause	Corrective Action
IABP has been in STANDBY for at least 10 minutes.	Verify whether it is appropriate to resume pumping.

Gas Loss in IAB Circuit





Corrective Action



Probable Cause

A helium loss has been detected in IAB circuit.

If blood observed - STOP pumping.

If blood is not observed, verify connections are tight.

Prepare for removal of IAB.

If appropriate, perform an Autofill, then press START to resume pumping.

Note: The IAB Catheter should not remain inactive (not inflating and deflating) for more than 30 minutes because of the potential for thrombus formation.

To keep IAB catheter active in the event of pump failure, manually inflate and deflate the IAB as follows:

- 1. Detach catheter extender from IAB catheter.
- 2. Attach 3-way stopcock and syringe to IAB catheter's male luer fitting.
- 3. Aspirate to ensure blood is not returned from catheter.
- 4. Inflate IAB with 40 cc air or helium and immediately aspirate. Repeat every 5 minutes while catheter is inactive.

Warning: Never inject air into inner lumen (female luer hub).

Arterial Pressure Surveillance Alarm Cardiosave 3rd edition Compliant^{*} / Cardiosave with select software upgrade

- System performs Flat Arterial Pressure (A.P.) Surveillance checks and monitors for sustained loss of pulsatility on A.P. trace when pulsatility is expected
- If a sustained loss of pulsatility is detected, NO PRESSURE SOURCE AVAILABLE Medium Priority Alarm will occur
- Pulsatility surveillance can be suspended by pressing DISABLE PULSATILE TEST key in the Sources menu when a well understood situation creates a nuisance alarm condition
- When zeroing a pressure transducer, press the Zero Pressure key within 7 seconds after venting the transducer to avoid a NO PRESSURE SOURCE AVAILABLE Alarm



No Pressure Source Available

Probable Cause No DIRECT or EXTERNAL arterial pressure source connected. If transducer in use, ensure pressure cable is connected to transducer and IABP. If A.P. source unavailable from catheter, provide an A.P. signal from external monitor to IABP using interface cable.

^{*}Cardiosave 3rd edition compliant systems have a serial number (located on the back of the system) that begins with the letters CB.

Arterial Pressure Surveillance Alarm, (continued)

No Pressure Source Available

Probable Cause	Corrective Action
A.P. transducer vented to atmosphere for more than 10 seconds.	Check stopcocks to ensure transducer is closed to atmosphere.
Pressure monitoring tubing has become disconnected.	Verify monitoring tubing is securely connected.
Pressure monitoring lumen may be clotted.	Attempt to aspirate.
	If unable to aspirate, discontinue use of arterial lumen and provide an alternate A.P. source.
	If alternate A.P. source is not available, override the alarm by pressing the DISABLE PULSATILE TEST in the Sources Menu.
Defective pressure transducer or transducer cable.	Replace transducer or transducer cable.
	If alarm persists, provide an alternate A.P. source.
	If an alternate A.P. source is not available, override the alarm by pressing the DISABLE PULSATILE TEST key in the Sources menu.

Unable to Update Timing

Probable Cause	Corrective Action
Poor waveform quality.	Check cable connections. Verify transducer was not left vented, if in use.
	If transducer is in use, aspirate and flush arterial pressure line.
	If problem persists, switch operation mode to SEMI-AUTO, verify TRIGGER SOURCE, adjust timing, resume pumping.
Sustained heart rate is less than 30 BPM or greater than 150 BPM.	Switch to SEMI-AUTO, verify TRIGGER SOURCE, adjust timing, resume pumping.
Poor diastolic augmentation.	If diastolic augmentation is poor, when AUGMENTATION level is set to MAX, attempt to improve patient's hemodynamic status.

Unable to Calibrate Fiber-optic Sensor

Corrective Action
Provide alternate A.P. source (i.e.: radial).
Relieve restriction.
Attempt calibration by pressing CALIBRATE PRESSURE key for 2 seconds while IABP is assisting.

Fiber-Optic Sensor Calibration Postponed

Probable Cause	Corrective Action
A non-scheduled calibra- tion update has been intentionally postponed because either patient's mean arterial pressure may be too low to pause assist	Assess patient to determine if a brief pause in assist would be tolerated, and if so, press CALIBRATE PRESSURE key for 2 seconds while IABP is assisting.
or less than 15 minutes have elapsed since last calibration.	Provide alternate A.P. source (i.e.: radial).
Pump is in STANDBY.	Resume pumping, then press CALIBRATE PRESSURE key for 2 seconds to initiate a calibration.

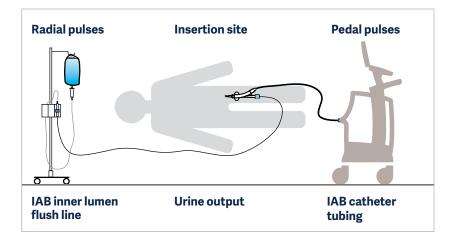
Fiber-optic Sensor Module Failure

Probable Cause There has been a failure If a fiber-optic IAB is NOT in of the internal Fiber-Optic use, continue normal IABP Sensor Module in the IABP. use. If a Getinge fiber-optic IAB is in use, replace IABP with another Getinge IABP that supports the fiber-optic IAB. If replacement IABP is not available, provide alternate A.P. source (i.e.: radial). Contact Maquet Service for Fiber-Optic Sensor Module repair.

Fiber-optic Sensor Failure

Probable Cause	Corrective Action
There is a failure in communication of the	Unplug Fiber-Optic Sensor Connector and reconnect.
fiber-optic sensor signal with the IABP.	Relieve any visible kinks in orange fiber-optic cable.
	If problem persists, disconnect Fiber-Optic Sensor Connector and provide alternate A.P. source (i.e.: radial).

Patient Assessment



Assessment Corrective Action Radial pulses Left radial pulse weak or left arm ischemia.
Left radial pulse weak or left
Insertion site Apply pressure, ensure Excessive bleeding from insertion site.
Pedal pulses Consider removing IAB Limb ischemia detected. consider insertion via opposite limb.
IAB inner lumen flush line Pressure waveform damped (if using a conventional IAB). Aspirate inner lumen. If line patent, flush for 15 seconds (with IABP on Standby).
Urine output Check position of IAB. Urine output low.
IAB catheter tubing STOP pumping and Blood observed in catheter tubing.

Suspected IAB perforation

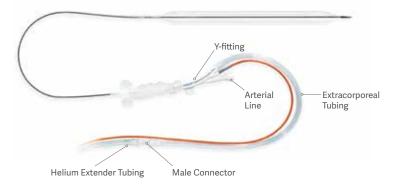
Evidence of IAB perforation

- Blood or fluid may be seen in extracorporeal tubing or catheter extender as evidenced by:
 - Bright red blood
 - Dried blood particles
 - Serosanguineous fluid
- · Sudden change in diastolic augmentation pressure
- · Potential IAB pump alarms

Potential IABP Alarms

Periodically check IAB catheter tubing for blood both throughout therapy and when the below alarms occur. Do not bypass these alarms, and please pay close attention to alarm notifications listed below, as these alarms may help identify a perforated balloon earlier, preventing any blood from traveling into the IABP.

During an autofill	Outside an autofill		
Potential alarms	Potential alarms		
Autofill Failure – Blood SuspectedAutofill Failure	Gas Loss in IAB CircuitGas Gain in IAB CircuitIAB Catheter Restriction		



Suspected IAB perforation

Blood detected management

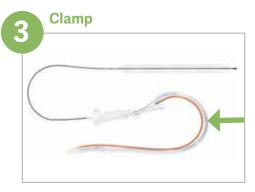
If any blood is noted or perforation is suspected, the following procedure must be performed immediately.



Stop pumping by placing IABP console in Standby



Disconnect catheter extender tubing from IABP console to allow balloon to deflate



Clamp extracorporeal tubing between white y-fitting and male connector

Clinical Considerations:

- Place patient in Trendelenburg as tolerated to guide any residual helium to travel away from the head vessels.
- Notify physician, and prepare for IAB catheter removal.
- Consider IAB catheter replacement, if patient's condition warrants.
- If blood is suspected of having entered the pump, take pump out of service. It should be evaluated before use in another patient by Biomed/Technical Service to determine if replacement of contaminated components are necessary.

Portable Operation

Getinge recommends:

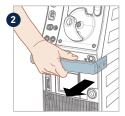
- Sufficient supply of fully charged batteries for use during transport.
- Use of the Transport Power Supply for AC operation during transport.
- Verifying internal helium reservoir is full when using the Transport System.
- System must be properly secured in the transport vehicle.



Removing Pump Console from the Cart



Release latch located below pump console (ensure wheels are locked).



Grab handle and slowly slide console out. **Note:** 3 audio tones will sound.



Grab handles located on top and front of console, then remove from Hospital Cart.





4a Push button to release pop-up mount. **4b** Pull LIP pop-up mount

4b Pull UP pop-up mount to lock in place.



Squeeze latches located below Monitor and lift to remove from Hospital Cart.



Squeeze latches and attach to pop-up mount, then release latches. Ensure Monitor is securely attached.



Squeeze latch below handle and lift straight up until wheels extend outward and handle locks into extended position.



Tilt Transport System on wheels and begin transport.



Rescue icon will be displayed on Touchscreen

Inserting the Pump Console into the Hospital Cart



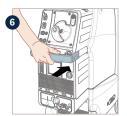
Squeeze latch below handle. Push straight down until wheels retract and handle is fully collapsed.



Grab handles located on top and front of console, then lift into Hospital Cart.



Squeeze latches located below Monitor and lift to remove from Pump Console.



Grab handle and slowly slide console into Hospital Cart until it locks into place.

Note: An audible click will be heard when console is locking into cart and 3 audio tones will sound.



Squeeze latches and attach to display mount, then release the latches. Ensure monitor is securely attached.







- **4a** Push and hold button on console to unlock monitor mount.
- **4b** Push down to lock into place, then release button.



Note: If the cart is not properly docked, a banner that states "Battery in Use - Cardiosave out of Cart" will appear on the waveform screen.

Ensure Hybrid icon (7a) is displayed on Touchscreen when console has been successfully installed into cart. Plug Hospital Cart power cord into a compatible grounded AC receptacle. Confirm AC operation by presence of AC Plug icon (7b).

If Hybrid icon/AC Plug icon are not present after installing console into the cart:

- Release latch on Hospital Cart located below Pump Console
- Grab handle and slowly slide Console out approximately one quarter of the way
- Repeat steps 6-7a-b to ensure Pump Console was successfully installed into Hospital Cart

Helium use from Internal Reservoir

The internal helium reservoir contains sufficient helium to provide approximately 36 fill cycles at full capacity. With every Autofill, helium will be depleted in the following approximate amounts:

Autofill Condition	Helium Used
Pump is powered off, powered on, and IAB fill performed to restart therapy	6 Autofill cycles
IAB disconnected and reconnected and IAB fill performed to restart therapy	6 Autofill cycles
Autofill performed due to a Gas Gain in IAB Circuit alarm, IAB Disconnected alarm, or an Autofill Failure alarm	6 Autofill cycles
Autofill every 2 hours	1 Autofill cycle
Autofill every 1000 feet (305 meters) of altitude increase during ascent	1 Autofill cycle
Autofill every 2000 feet (610 meters) of altitude decrease during descent	1 Autofill cycle

Note: The supply of helium in the internal helium reservoir will deplete more rapidly when an autofill is performed when the system is powered on, when the catheter is disconnected and reconnected or when an autofill is performed due to a gas loss, catheter disconnect, or autofill failure alarm.

Effects of altitude changes during air transportation

For proper operation during air transport, IABP balloon pressure must adapt to local atmospheric pressure. The system will automatically purge and fill the IAB when local atmospheric pressure decreases by 25 mmHg or increases by 50 mmHg. These pressure changes occur approximately every 1,000 feet (305 meters) of increase in altitude or 2000 feet (610 meters) of decrease in altitude.

Connecting an Arrow IAB/IABP to a Getinge IABP

Transferring Facility

- This patient will have an Arrow IAB connected to an Arrow IABP
- Before leaving facility, locate IAB catheter extender tubing supplied in Arrow IAB box, which connects an Arrow IAB to a Getinge IABP
- Take this IAB catheter extender tubing on transport with patient, for use when arriving at receiving facility

Receiving Facility

- When arriving at receiving facility, remove current IAB catheter extender tubing that connects an Arrow IAB to an Arrow IABP
- Connect appropriate end of IAB catheter extender tubing (that was brought from transferring facility) to Arrow IAB, then connect male luer fitting of IAB catheter extender tubing to back of Getinge IABP
- Set-up Getinge IABP per abbreviated instructions on page 11 of this Quick Reference Guide

Connecting a Getinge IAB/IABP to an Arrow IABP

Transferring Facility

- This patient will have a Getinge IAB connected to a Getinge IABP
- Before leaving facility, locate Arrow Pump Adapter (APA) that connects a Getinge IAB to an Arrow IABP (may be supplied in Getinge IAB box or separately)
- Take the APA on transport with patient, for use when arriving at receiving facility

Receiving Facility

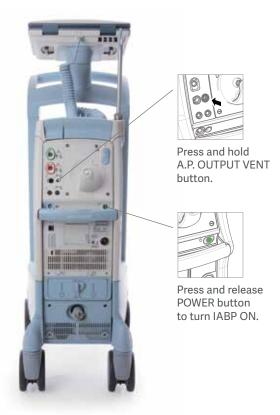
- When arriving at receiving facility, place Getinge IABP on Standby and disconnect IAB catheter extender tubing from back of IABP
- Connect Arrow Pump Adapter (APA) to male luer fitting of Getinge IAB catheter extender tubing and connect to Arrow IABP
- Adjust volume setting on Arrow IABP, according to Operating Instructions, to match IAB catheter volume

Pneumatic Module Leak Test

This test measures pneumatic leak rate(s) of the Pneumatic Module and is recommended to be performed before or after each IABP use.

WARNING: Pneumatic Module Leak Test MUST NOT be performed with the pump connected to a patient's IAB.

- Press and release POWER button while continuously holding A.P. OUTPUT VENT button until SPECIAL ACTIVATION MENU appears on Touchscreen
- Press PNEUMATIC MODULE LEAK TEST key, then press START PNEUMATIC MODULE LEAK TEST key
- Using a non-locking luer cap, tightly plug Pneumatic Module outlet when message PLEASE PLUG IAB PORT appears on Touchscreen in INSTRUCTIONS field
- STATUS field will display pneumatic tests that are currently being executed. When tests are complete (in approx. 3 minutes), the message PIM LEAK TESTS COMPLETE will be displayed
- If system passes test, the message PASS in green will be displayed in RESULTS field. Remove non-locking luer cap and press and hold POWER button for 2 seconds to exit SPECIAL ACTIVATION MENU. If IABP therapy is being started, then proceed with set-up of pump
- If system fails test, the message FAIL in red will be displayed in RESULTS field. Check to ensure that non-locking luer cap is tight, then repeat leak test. If test fails again, contact Maquet Service

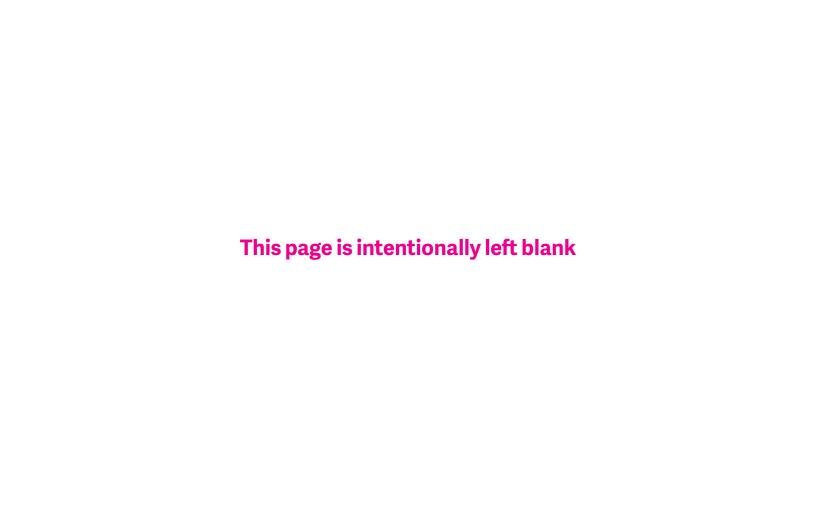


Cardiosave Symbols

Icon	Description	Icon	Description	Icon	Description
\triangle	Attention, refer to Operating Instructions	Á	IABP	\triangle	Technical Alarm
<u> </u>	Warning of Potential Injury or Health Risk		Do not place fluids on top of unit	⊘ !!!	High Priority Alarm
\sim	Alternating Current (AC)	Ť	Patient	△!!	Medium Priority Alarm
-+	Battery		Patient Monitor	△!	Low Priority Alarm
DOPPLER	Doppler	→ 0←	Vent	X	Audio Paused
He A	Helium Tank		Fiber-optic cable	×	Alarm inhibited (off)
1	ECG		Trainer		Alarm inhibited (paused)
\mathcal{N}	Pressure	(h	On/Off	\bowtie	Audio Alarms Off
V	Fiber-optic Connection Indicator				

Notes		





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