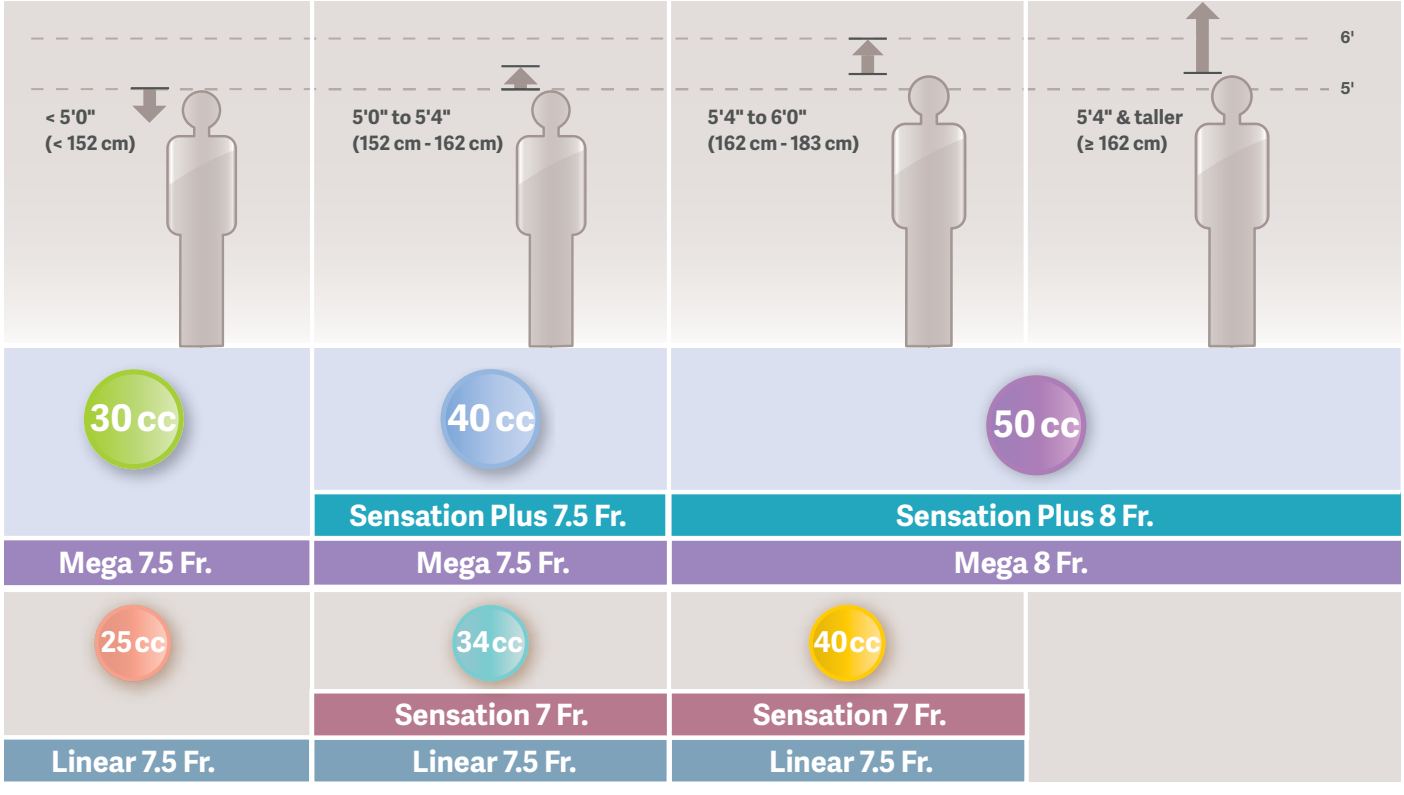
IAB Insertion / Cardiosave IABP Operation

Quick Reference Guide/Cardiosave IABP software C.06

(For use outside the US only)

Note: This is an abbreviated guide. For complete instructions, refer to IAB Instructions for Use and Cardiosave Operating Instructions.

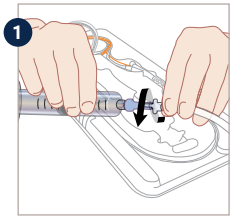
Intra-aortic Balloon Sizing Guide



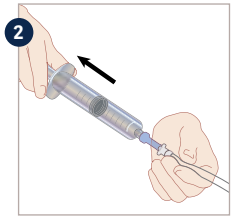
Note: This information is to be used as a guidance only. Clinical information and patient factors such as torso length should be considered when selecting the appropriate balloon size. Sensation and Sensation Plus are fiber-optic IAB catheters.

Sensation Plus and Sensation IAB Catheter

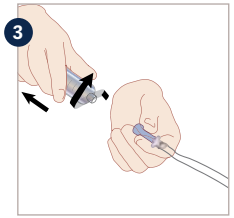
Preparing the IAB Catheter



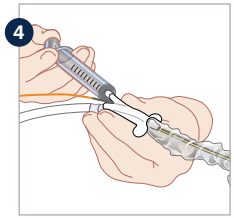
Firmly attach one-way valve to male luer fitting of IAB catheter.



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.

Sensation Plus and Sensation IAB Catheter

Sheathless insertion

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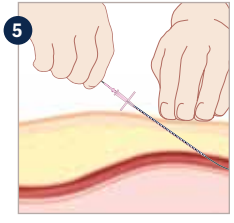
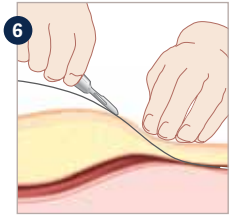


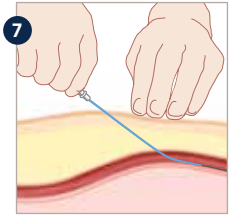
Insert needle at 45˚ angle or less, then insert guidewire – 7.5 Fr./8 Fr. IAB: 0.025" (0.06 cm) / 7 Fr. IAB: 0.018" (0.05 cm).

6



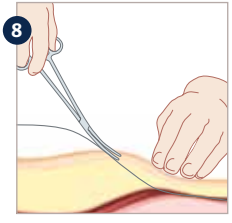
Make small incision at exit of guidewire.

7



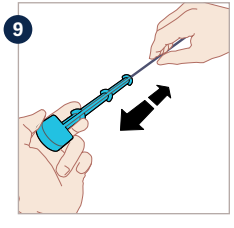
Insert vessel dilator over guidewire, tapered end first, then remove.

8



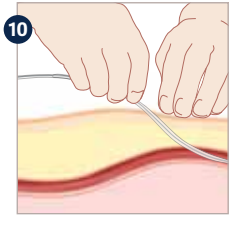
Spread tissue at incision to facilitate sheathless insertion.

9



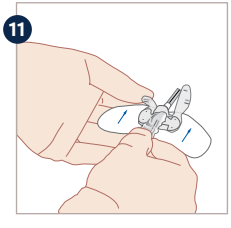
Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.

10



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

11

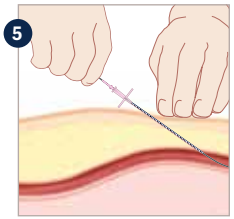


Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures (Sensation Plus includes StatLock® in IAB box).

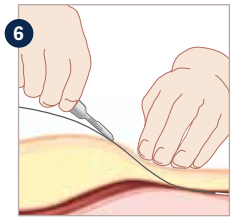
Note: Continue on page 6, step #13.

Sensation Plus and Sensation IAB Catheter

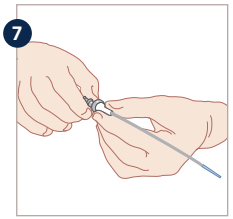
Sheathed insertion



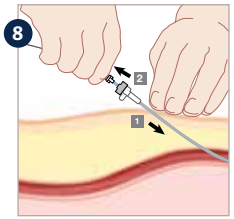
Insert needle at 45˚ angle or less, then insert guidewire – 7.5 Fr./8 Fr. IAB: 0.025" (0.06 cm) / 7 Fr. IAB: 0.035" (0.09 cm).



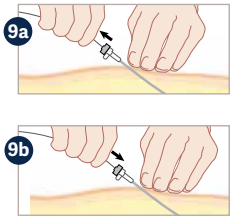
Make small incision at exit of guidewire.



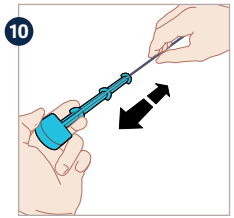
Insert introducer dilator into sheath hub and twist lock in place to secure.



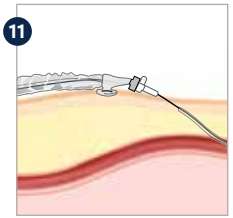
1 Advance sheath over guidewire into artery using a rotary motion.
2 Withdraw introducer dilator leaving sheath in place.



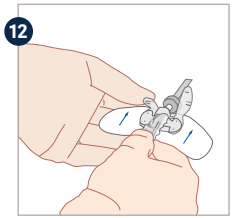
7Fr. IAB only:
9a Remove 0.035" (0.09 cm) guidewire and
9b Replace with 0.018" (0.05 cm) guidewire.



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



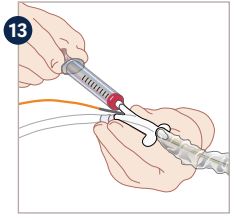
Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



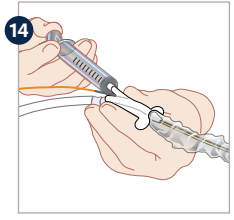
Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures (Sensation Plus includes StatLock® in IAB box).

Sensation Plus and Sensation IAB Catheter

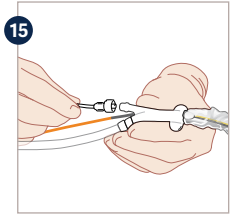
Pressure monitoring set-up



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



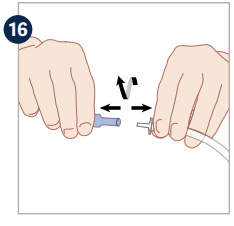
Manually flush inner lumen with 3-5 cc of flush solution.



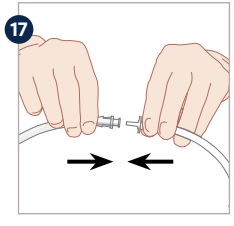
Attach a standard arterial pressure monitoring apparatus.

Note: With Sensation Plus, a reliable pressure signal may be obtained via the inner lumen, if needed.

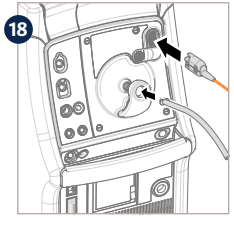
Connection to IABP



Remove one-way valve from IAB catheter.



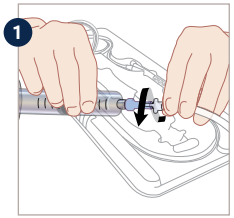
Connect IAB catheter's male luer fitting to female luer fitting of catheter extender.



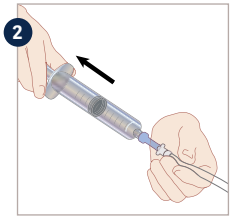
Connect male luer fitting of catheter extender to Pneumatic Module of IABP. Insert fiber-optic sensor connector into IABP's sensor input receptacle until it clicks.

Mega and Linear IAB Catheter

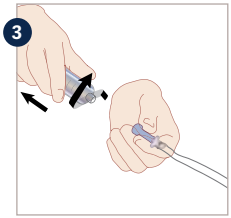
Preparing the IAB Catheter



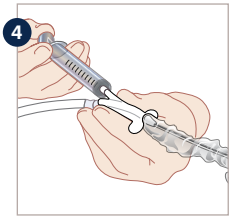
Firmly attach one-way valve to male luer fitting of IAB catheter.



Apply a 30 cc vacuum.



Remove syringe while keeping one-way valve in place.

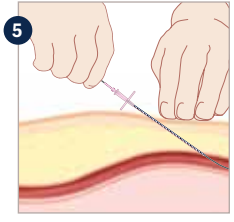


Manually flush inner lumen with 3-5 cc of flush solution.

Mega and Linear IAB Catheter

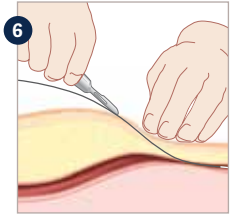
Sheathless insertion

5



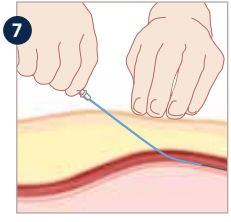
Insert needle at 45˚ angle or less, then insert 0.025" (0.06 cm) guidewire.

6



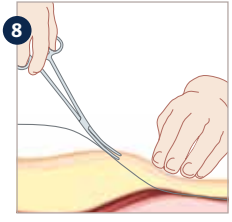
Make small incision at exit of guidewire.

7



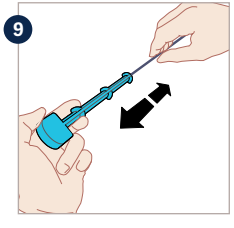
Insert vessel dilator over guidewire, tapered end first, then remove.

8



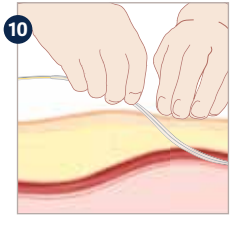
Spread tissue at incision to facilitate sheathless insertion.

9



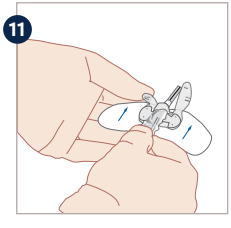
Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.

10



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

11

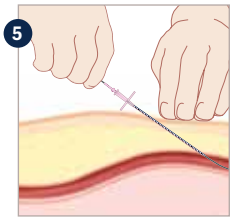


Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures.

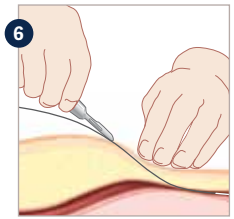
Note: Continue on page 10, step #12.

Mega and Linear IAB Catheter

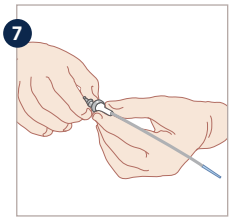
Sheathed insertion



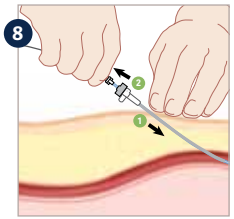
Insert needle at 45˚angle or less, then insert 0.025" (0.06 cm) guidewire.



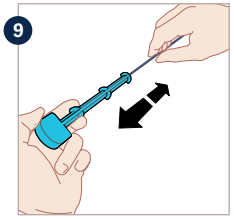
Make small incision at exit of guidewire.



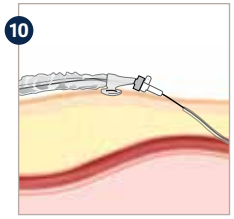
Insert introducer dilator into sheath hub and twist lock in place to secure.



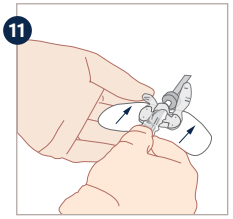
1 Advance sheath over guidewire into artery using a rotary motion.
2 Withdraw introducer dilator leaving sheath in place.



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



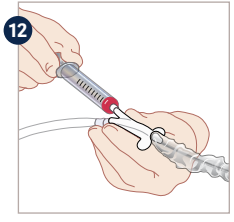
Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



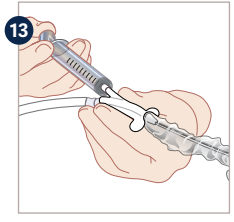
Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures.

Mega and Linear IAB Catheter

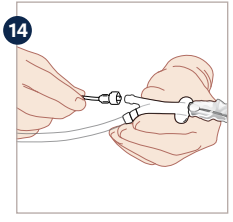
Pressure monitoring set-up



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

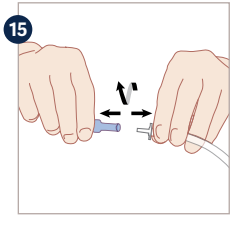


Manually flush inner lumen with 3-5 cc of flush solution.

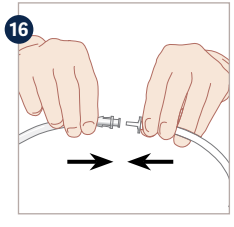


Attach a standard arterial pressure monitoring apparatus.

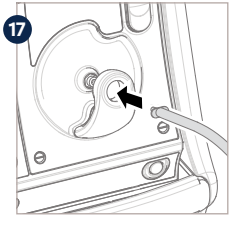
Connection to IABP



Remove one-way valve from IAB catheter.

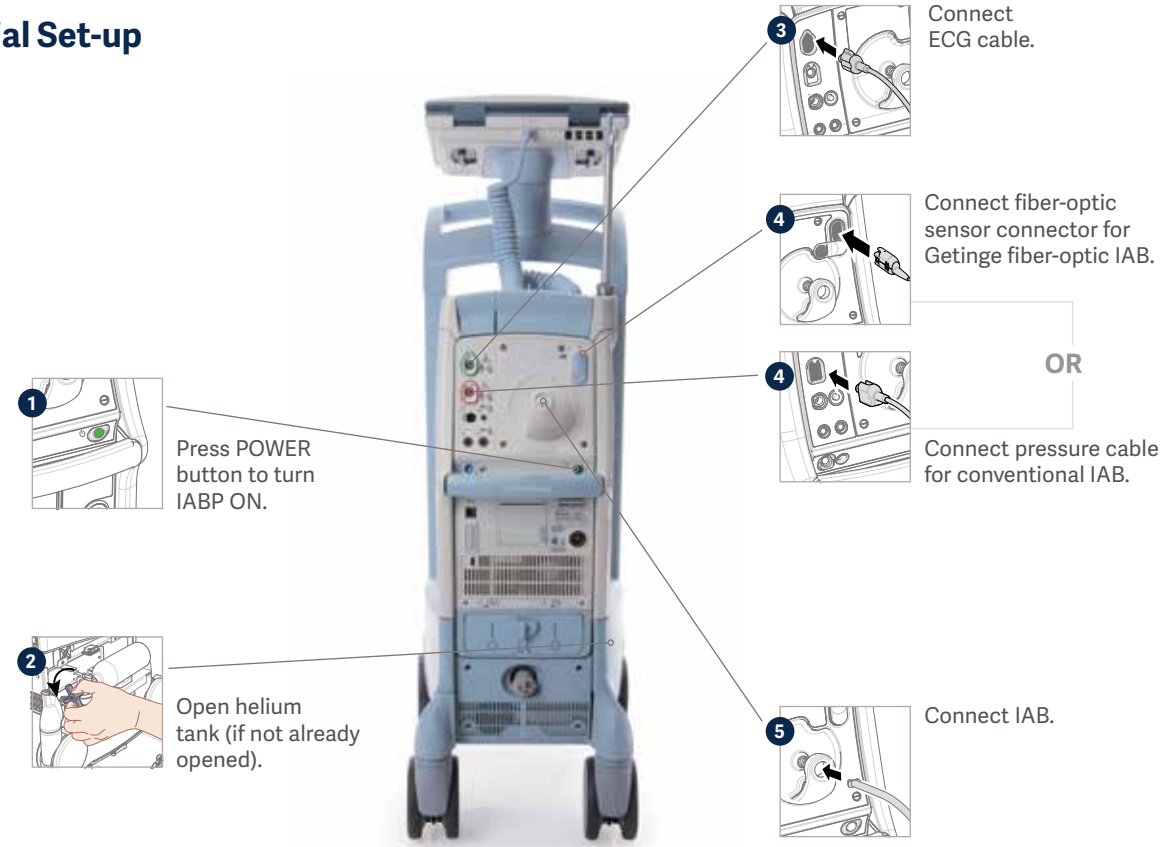


Connect IAB catheter's male luer fitting to female luer fitting of catheter extender.

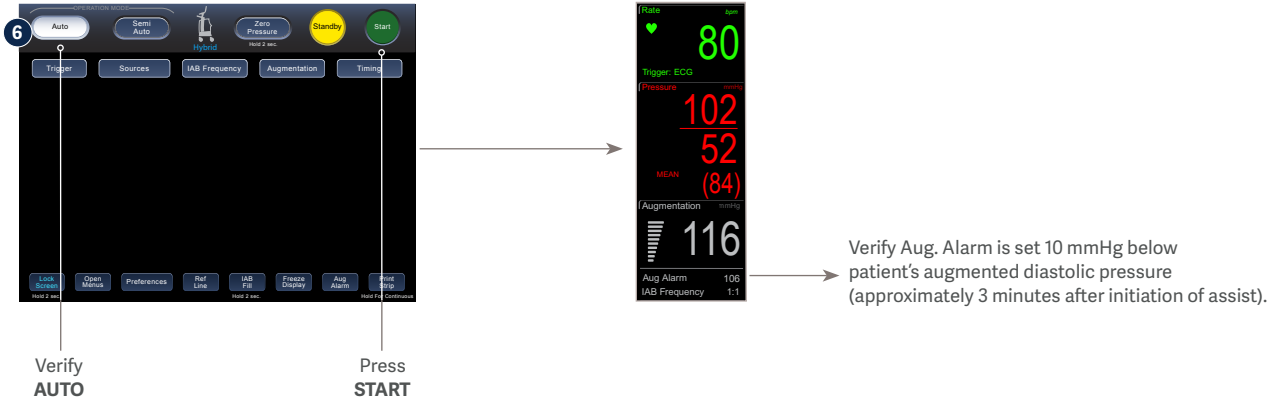


Connect male luer fitting to Pneumatic Module of IABP.

Cardiosave initial Set-up



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



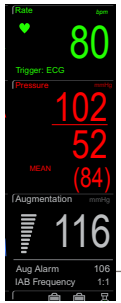
Verify Aug. Alarm is set 10 mmHg below patient's augmented diastolic pressure (approximately 3 minutes after initiation of assist).

Pressing the START key

- Automatically purges and fills IAB
- Automatically 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.

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).

Verify **AUTO**

Press **START**

Pressing the START key

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

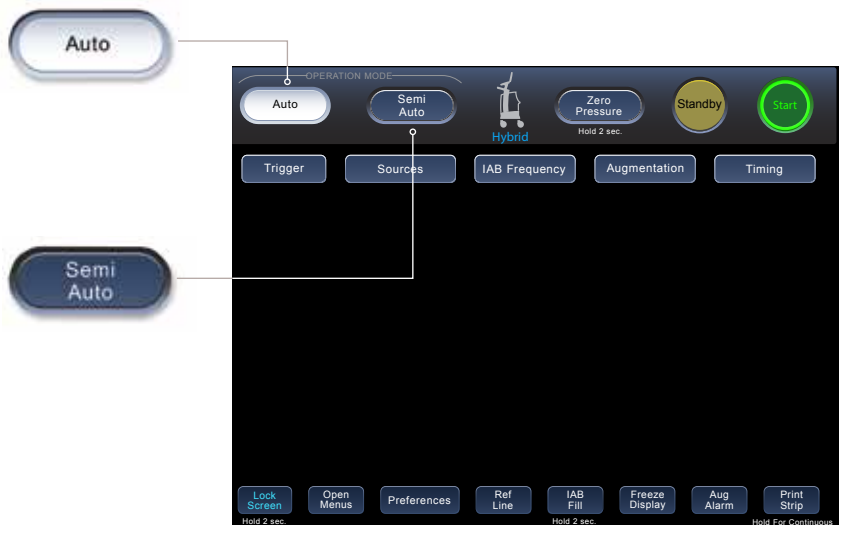
Cardiosave Operation Modes

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)

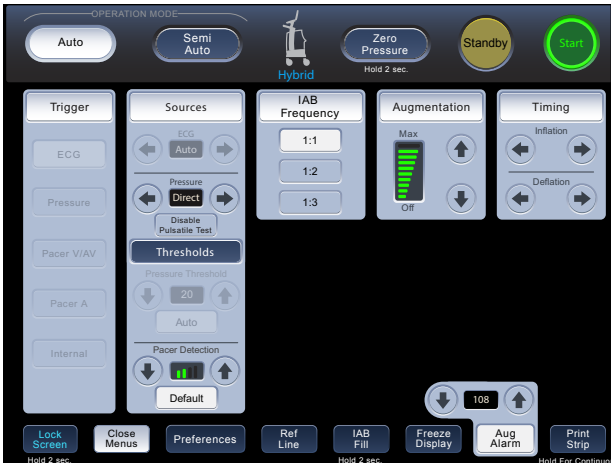
Semi-Auto Operation Mode

- 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)



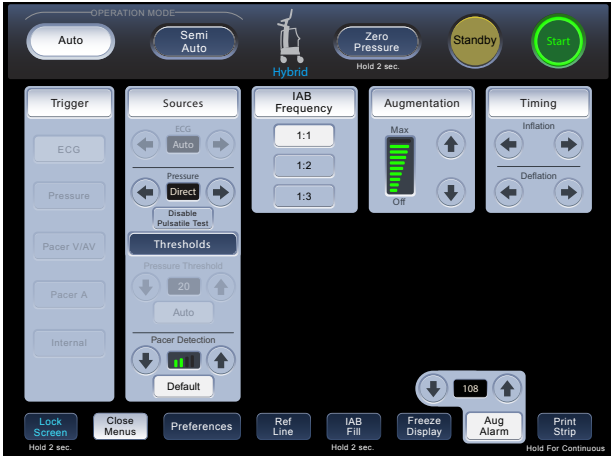
Cardiosave Monitor Display and Touchscreen

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

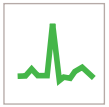
Cardiosave Triggers

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

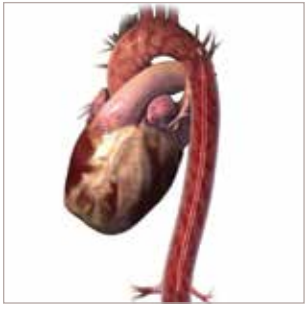
Inflation: increases supply of oxygen to the myocardium.

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.

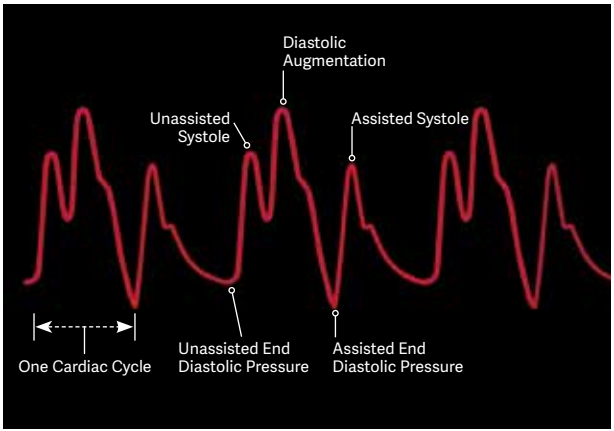
Proper IABP Timing

Inflation

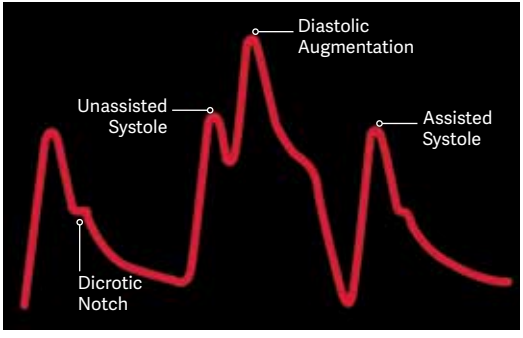
- Occurs at the dicrotic notch
- Appears as a sharp "V"
- Ideally diastolic augmentation rises above systole

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

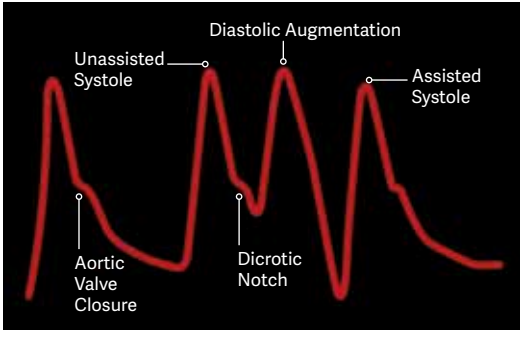
Inflation of IAB prior to aortic valve closure.

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 MVO_2 demand



Late Inflation

Inflation of IAB markedly after closure of aortic valve.

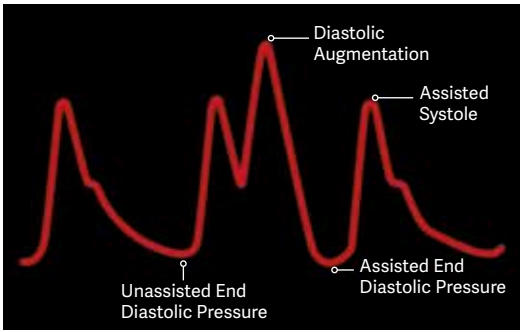
Waveform characteristics

- 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

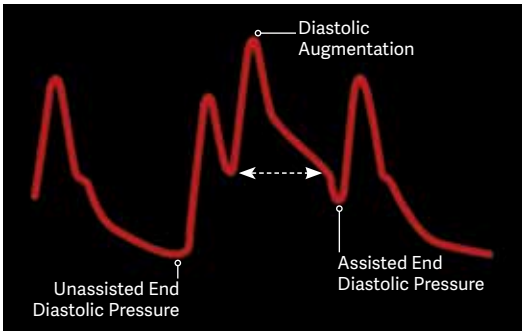
Premature deflation of IAB during diastolic phase.

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 MVO_2 demand



Late Deflation

Deflation of IAB after aortic valve has opened.

Waveform characteristics

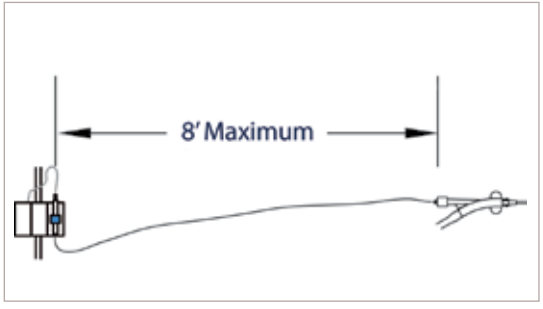
- Assisted end diastolic pressure may be equal to or higher than unassisted end diastolic pressure
- Rate of rise of assisted systole is prolonged
- Diastolic augmentation may appear widened

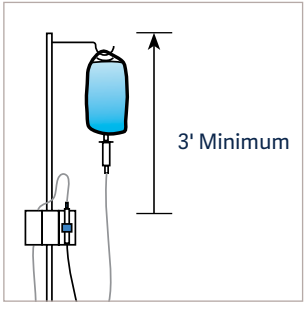
Physiologic Effects

- Afterload reduction is essentially absent
- Increased MVO_2 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

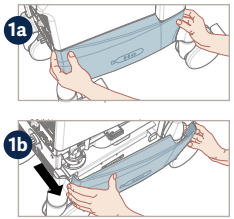
- Minimize length of pressure tubing
- Use **only** low compliance pressure tubing
- Elevate flush bag at least 3′ (91.44 cm) above transducer
- A 3 cc/hour continuous flow through inner lumen is recommended
- If inner lumen becomes damped
  - Aspirate and discard 3 cc of blood
  - If **unable** to aspirate 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



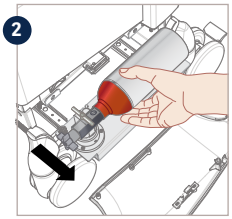


- The saline pole is included with the IABP as a convenient location for the flush bag, when needed
- Never place fluids on top of the IABP and DO NOT hang flush bag and/or tubing directly over the IABP
- In case of accidental spillage, wipe clean immediately and have the unit serviced

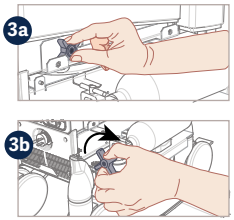
Changing the Helium Tank



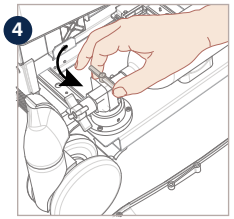
1a Grasp both sides of helium tank panel and
1b Pull out to open.



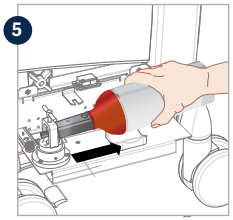
Grasp helium tank and slowly slide drawer out.



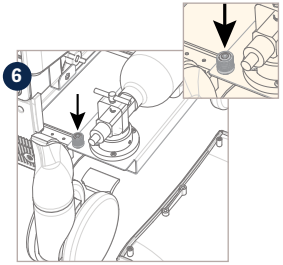
3a Remove helium tank knob from Holder and
3b Attach to left end of helium tank, then fully turn clockwise to close.



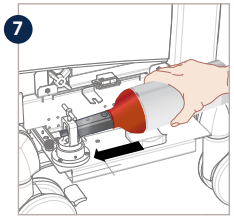
Slowly loosen yoke T-handle counter-clockwise (some helium may escape).



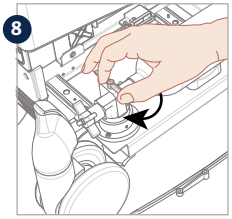
Remove helium tank.



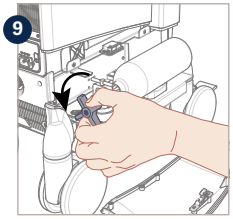
Replace washer, if available.



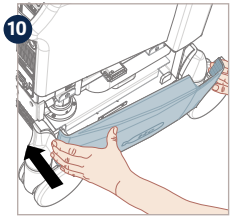
Install fresh helium tank.



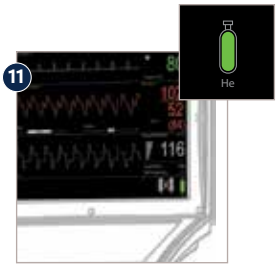
Fully tighten yoke T-handle clockwise.



Slowly open helium tank knob counter-clockwise (listen for any escaping helium).



Slide helium tank drawer in and replace helium tank panel.

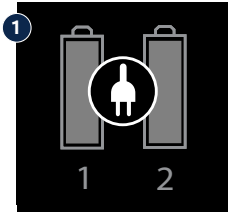


Verify full helium level via icon on Monitor Display.

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

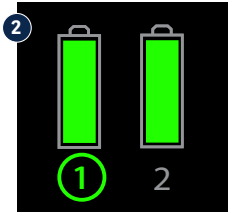
Viewing Battery Status on Monitor Display (examples)

1



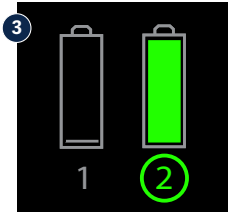
Plugged into AC power outlet and batteries are fully charged.

2



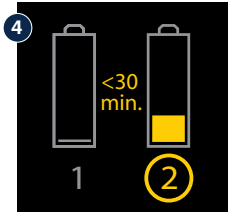
Lit green circle indicates battery 1 is in use. Battery 2 is fully charged and available for use when battery 1 is depleted.

3



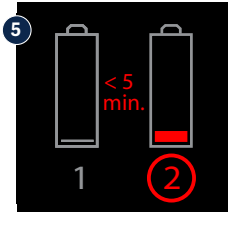
Battery 1 is depleted, thus battery 2 is currently being used.

4



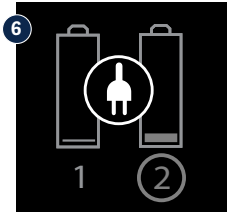
Battery 2 has less than 30 minutes of charge remaining (Low Battery message is displayed).

5



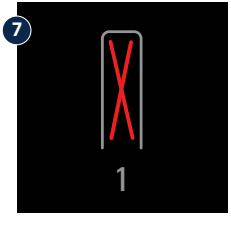
Battery 2 has less than 5 minutes of charge remaining.

6



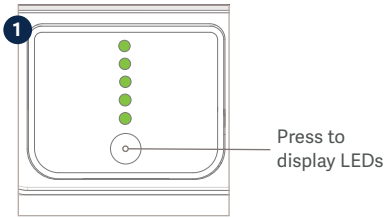
IABP has been plugged into AC power outlet and battery 2 is being charged.

7



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

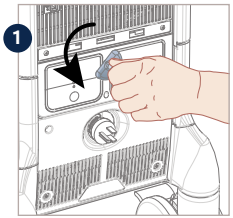
Viewing Battery Status on Battery



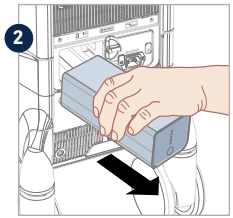
Battery is approximately 100% charged.

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

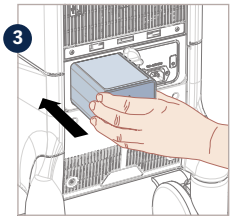
Changing the Battery



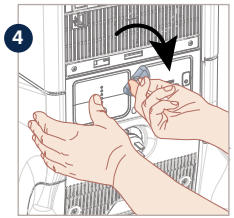
Turn knob to remove battery from Battery Bay.



Slide battery OUT.



Slide charged battery IN.



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

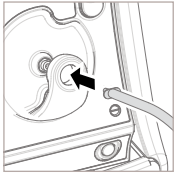
Use care to avoid dropping the battery.

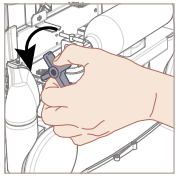
Alarms

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





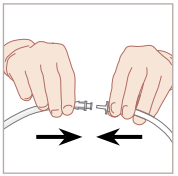
Probable Cause	Corrective Action
IAB disconnected.	Attach IAB catheter.
Helium tank is closed.	Open helium tank.
Helium tank is empty.	Change helium tank.
Incorrect IAB catheter extender tubing length.	Ensure only one IAB catheter extender tubing is connected from IAB to pump.

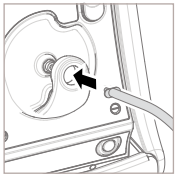
Alarms

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





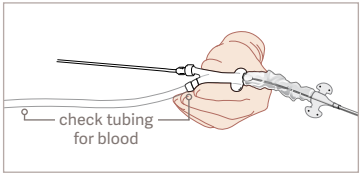
Probable Cause	Corrective Action
IAB catheter or extender tubing is disconnected.	Reattach IAB, press START.

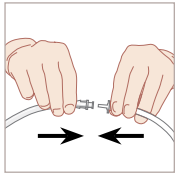
Alarms

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





Probable Cause	Corrective Action
A helium loss has been detected in IAB circuit.	If blood observed - STOP pumping. Prepare for removal of IAB. If blood is not observed, verify connections are tight. 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 PULSATILITY 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	Corrective Action
No DIRECT or EXTERNAL arterial pressure source connected.	Ensure fiber-optic sensor cable is 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.

Alarms

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.

Alarms

Unable to Calibrate Fiber-optic Sensor

Probable Cause	Corrective Action
Patient's pulse pressure is inadequate for calibration.	When patient's pulse pressure improves, press CALIBRATE PRESSURE key for 2 seconds while IABP is assisting. Provide alternate A.P. source (i.e.: radial).
Extender tubing or balloon catheter may be restricted.	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 calibration update has been intentionally postponed because either patient's mean arterial pressure may be too low to pause assist or less than 15 minutes have elapsed since last calibration.	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. 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.

Alarms

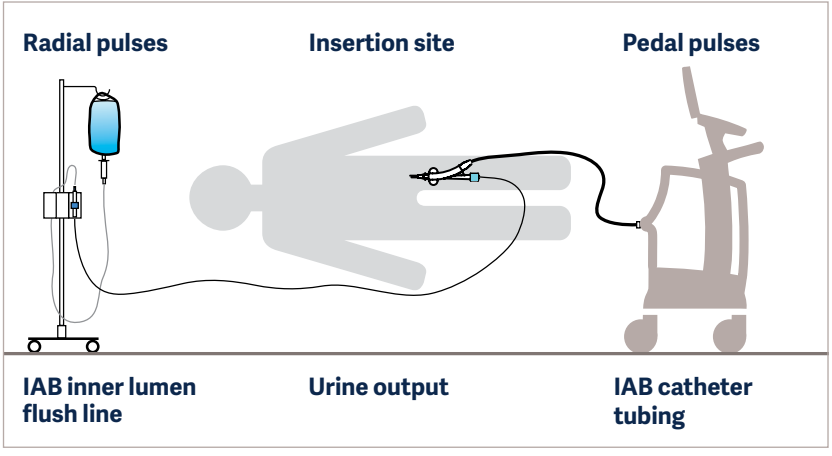
Fiber-optic Sensor Module Failure

Probable Cause	Corrective Action
There has been a failure of the internal Fiber-Optic Sensor Module in the IABP.	If a fiber-optic IAB is NOT in use, continue normal 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 fiber-optic sensor signal with the IABP.	Unplug Fiber-Optic Sensor Connector and reconnect. 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.	Check position of IAB.
Insertion site Excessive bleeding from insertion site.	Apply pressure, ensure distal flow.
Pedal pulses Limb ischemia detected.	Consider removing IAB, 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 Urine output low.	Check position of IAB.
IAB catheter tubing Blood observed in catheter tubing.	STOP pumping and prepare for IAB removal.

Suspected IAB perforation

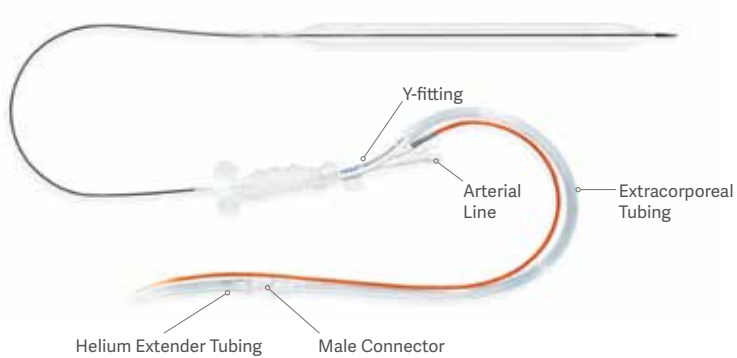
Evidence of IAB perforation

- 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 Suspected	• Gas Loss in IAB Circuit
• Autofill Failure	• Gas Gain in IAB Circuit
	• IAB Catheter Restriction

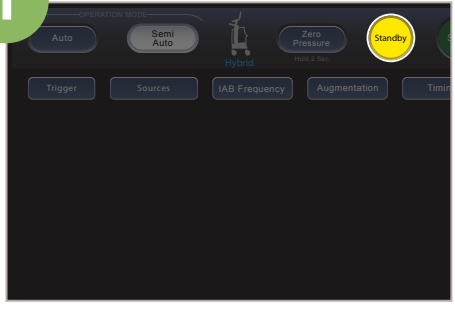


Suspected IAB perforation

Blood detected management

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

1 Standby

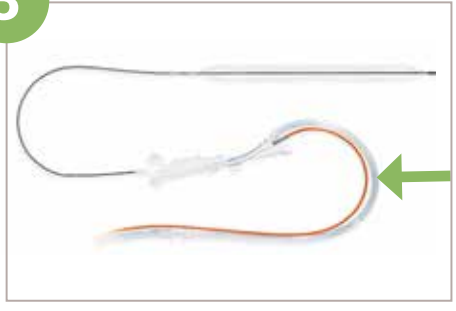


Stop pumping by placing IABP console in Standby

2 Disconnect

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

3 Clamp



Clamp extracorporeal tubing between white y-fitting and male connector

Clinical Considerations:

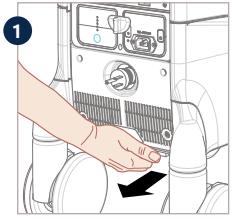
- Place patient in Trendelenburg as tolerated to guide any residual helium to travel away from the head vessels.
- Notify physician, and prepare for IAB catheter removal.
- Consider IAB catheter replacement, if patient's condition warrants.
- If blood is suspected of having entered the pump, take pump 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

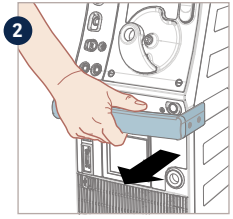
Getinge recommends:

- 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

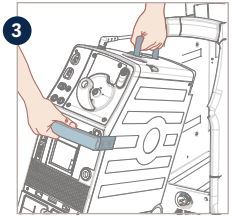


Release latch located below pump console (ensure wheels are locked).

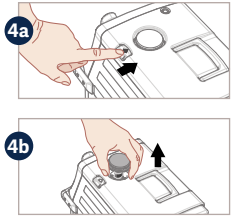


Grab handle and slowly slide console out.

Note: 3 audio tones will sound.

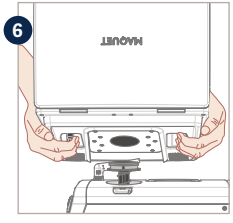


Grab handles located on top and front of console, then remove from Hospital Cart.

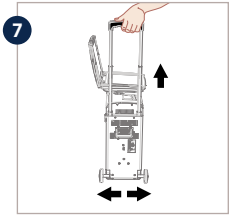


4a Push button to release pop-up mount.
4b Pull UP pop-up mount to lock in place.

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.

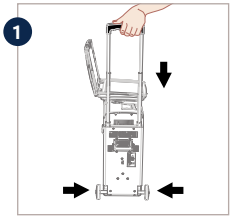


Squeeze latch below handle and lift straight up until wheels extend outward and handle locks into extended position.

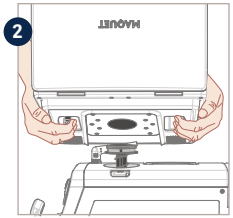
Tilt Transport System on wheels and begin transport.

Rescue icon will be displayed on Touchscreen

Inserting the Pump Console into the Hospital Cart

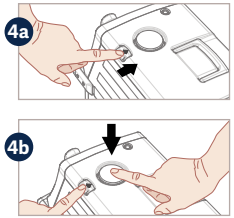


Squeeze latch below handle. Push straight down until wheels retract and handle is fully collapsed.

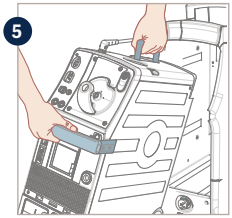


Squeeze latches located below Monitor and lift to remove from Pump Console.

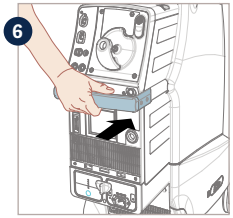
Squeeze latches and attach to display mount, then release the latches. Ensure monitor is securely attached.



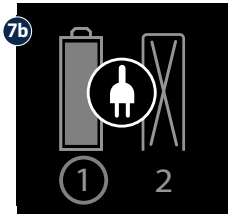
4a Push and hold button on console to unlock monitor mount.
4b Push down to lock into place, then release button.



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



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.



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

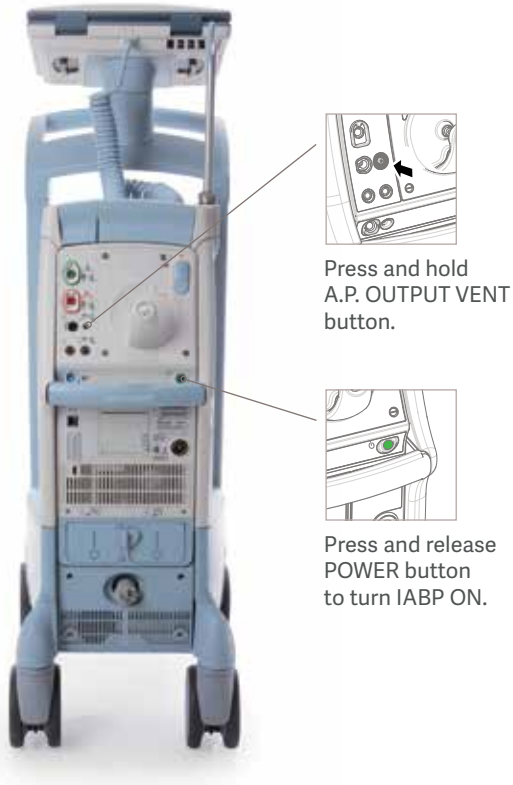
- When arriving at receiving facility, place Getinge IABP on Standby and disconnect IAB catheter extender tubing from back of IABP
- Connect Arrow Pump Adapter (APA) to male luer fitting of Getinge IAB catheter extender tubing and connect to Arrow IABP
- Adjust volume setting on Arrow IABP, according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



Press and hold A.P. OUTPUT VENT button.

Press and release POWER button to turn IABP ON.

Cardiosave Symbols

Icon	Description
	Attention, refer to Operating Instructions
	Warning of Potential Injury or Health Risk
	Alternating Current (AC)
	Battery
	Doppler
	Helium Tank
	ECG
	Pressure
	Fiber-optic Connection Indicator

Icon	Description
	IABP
	Do not place fluids on top of unit
	Patient
	Patient Monitor
	Vent
	Fiber-optic cable
	Trainer
	On/Off

Icon	Description
	Technical Alarm
	High Priority Alarm
	Medium Priority Alarm
	Low Priority Alarm
	Audio Paused
	Alarm inhibited (off)
	Alarm inhibited (paused)
	Audio Alarms Off

Notes

Notes

Notes

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GETINGE

Getinge · 45 Barbour Pond Drive, Wayne, NJ 07470 · USA
Datascope Corp. · 1300 MacArthur Blvd., Mahwah, NJ 07430 · USA

www.getinge.com