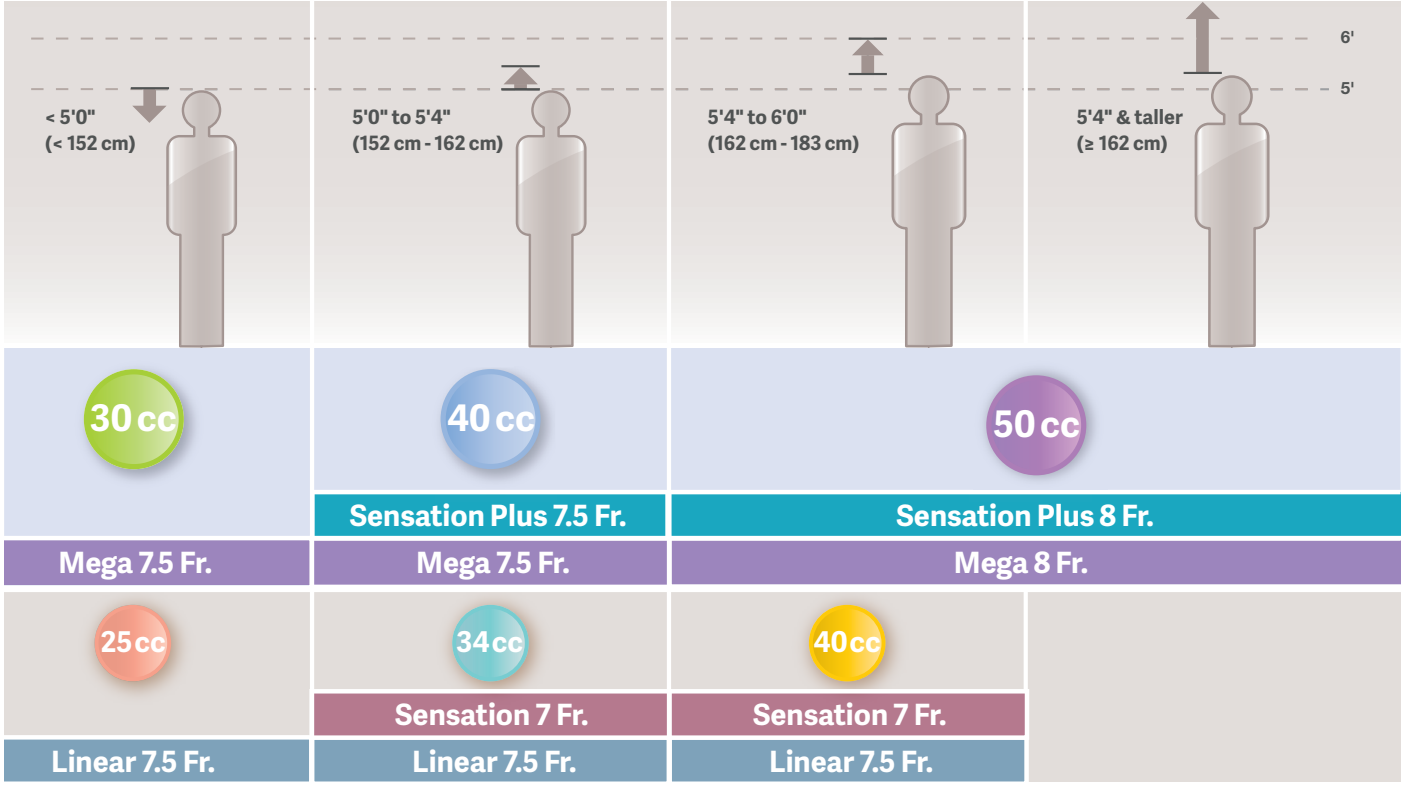
IAB Insertion / Cardiosave IABP Operation

Quick Reference Guide/Cardiosave IABP software D.00/D.01

(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.

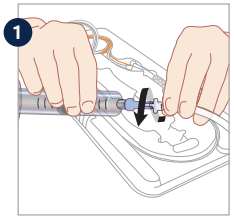
Intra-aortic Balloon Sizing Guide



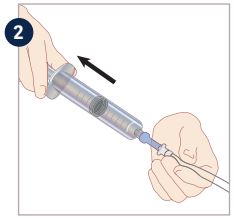
Note: This information is to be used as a guidance only. Clinical information and patient factors such as torso length should be considered when selecting the appropriate balloon size. Sensation and Sensation Plus are fiber-optic IAB catheters.

Sensation Plus and Sensation IAB Catheter

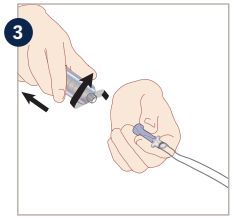
Preparing the IAB Catheter



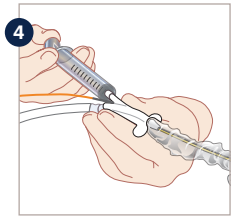
Firmly attach one-way valve to male luer fitting of IAB catheter.



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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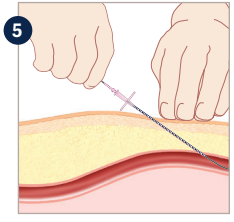
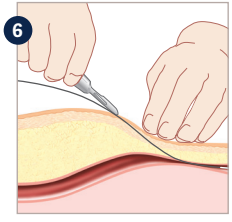


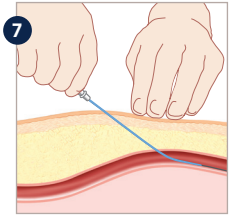
Insert needle at 45˚ angle or less, then insert guidewire – 7.5 Fr./8 Fr. IAB: 0.025" (0.06 cm) / 7 Fr. IAB: 0.018" (0.05 cm).

6



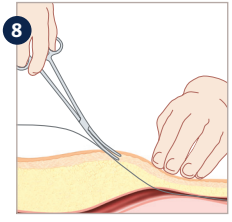
Make small incision at exit of guidewire.

7



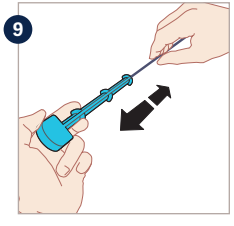
Insert vessel dilator over guidewire, tapered end first, then remove.

8



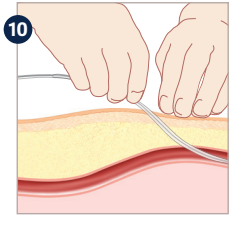
Spread tissue at incision to facilitate sheathless insertion.

9



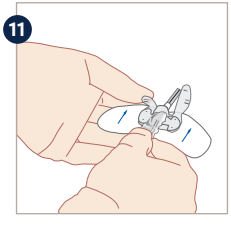
Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.

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

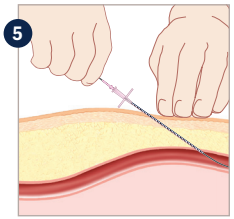


Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures (Sensation Plus includes StatLock® in IAB box).

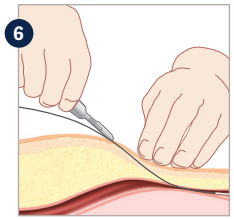
Note: Continue on page 6, step #13.

Sensation Plus and Sensation IAB Catheter

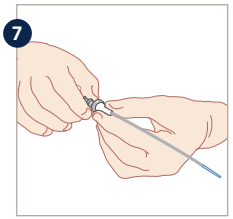
Sheathed insertion



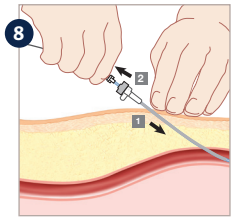
Insert needle at 45˚ angle or less, then insert guidewire – 7.5 Fr./8 Fr. IAB: 0.025" (0.06 cm) / 7 Fr. IAB: 0.035" (0.09 cm).



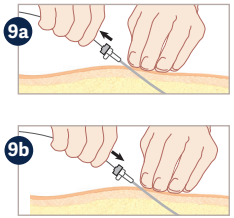
Make small incision at exit of guidewire.



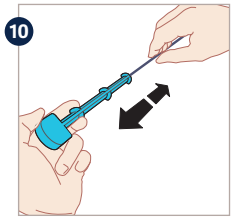
Insert introducer dilator into sheath hub and twist lock in place to secure.



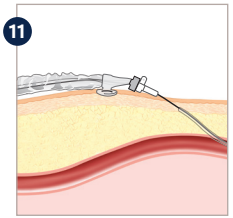
1 Advance sheath over guidewire into artery using a rotary motion.
2 Withdraw introducer dilator leaving sheath in place.



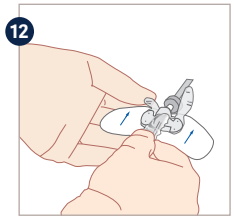
7Fr. IAB only:
9a Remove 0.035" (0.09 cm) guidewire and
9b Replace with 0.018" (0.05 cm) guidewire.



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



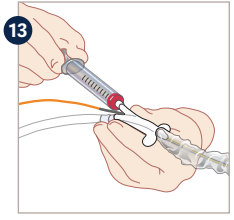
Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



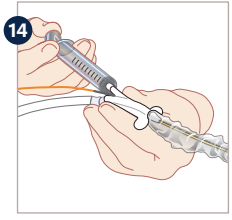
Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures (Sensation Plus includes StatLock® in IAB box).

Sensation Plus and Sensation IAB Catheter

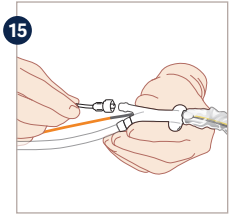
Pressure monitoring set-up



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

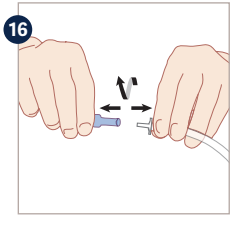


Manually flush inner lumen with 3-5 cc of flush solution.

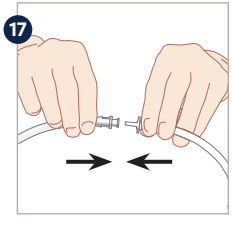


Attach a standard arterial pressure monitoring apparatus.

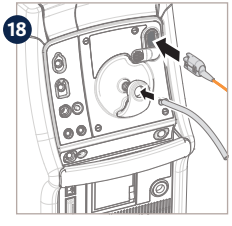
Connection to IABP



Remove one-way valve from IAB catheter.



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



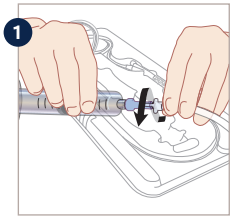
Connect male luer fitting of catheter extender to Pneumatic Module of IABP. Insert fiber-optic sensor connector into IABP's sensor input receptacle until it clicks.

Note: Using current hospital protocol, connect a standard arterial pressure flush apparatus to inner lumen for ALL Getinge/Maquet IAB catheters (conventional and fiber-optic).

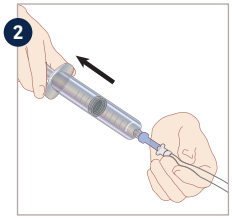
A continuous 3 cc/hour flow through the inner lumen is recommended for ALL Getinge/Maquet IAB catheters (conventional and fiber-optic).

Mega and Linear IAB Catheter

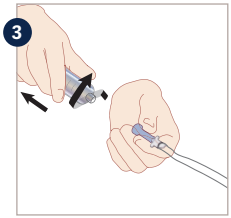
Preparing the IAB Catheter



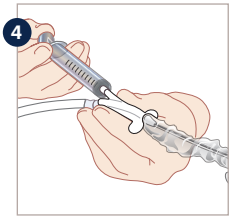
Firmly attach one-way valve to male luer fitting of IAB catheter.



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

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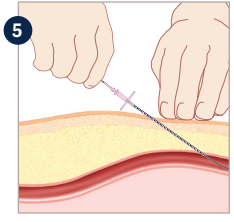
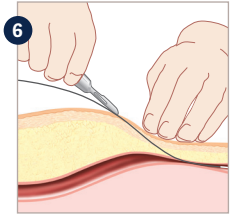


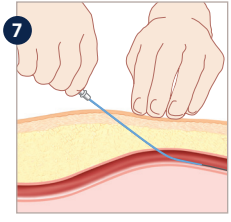
Insert needle at 45˚ angle or less, then insert 0.025" (0.06 cm) guidewire.

6



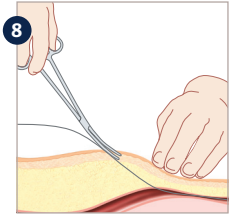
Make small incision at exit of guidewire.

7



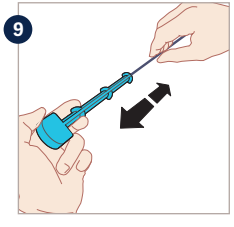
Insert vessel dilator over guidewire, tapered end first, then remove.

8



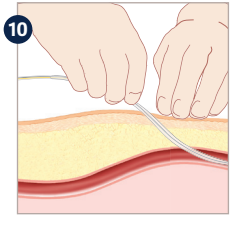
Spread tissue at incision to facilitate sheathless insertion.

9



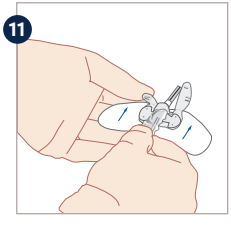
Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.

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

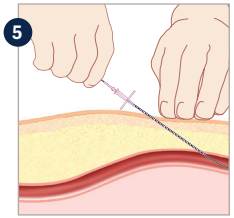


Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures.

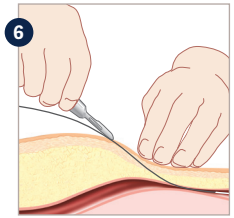
Note: Continue on page 10, step #12.

Mega and Linear IAB Catheter

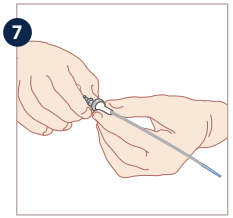
Sheathed insertion



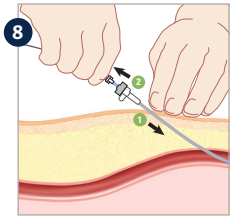
Insert needle at 45˚angle or less, then insert 0.025" (0.06 cm) guidewire.



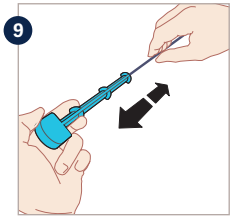
Make small incision at exit of guidewire.



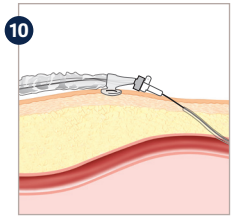
Insert introducer dilator into sheath hub and twist lock in place to secure.



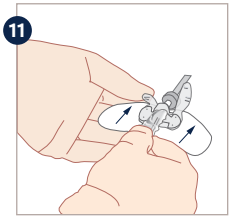
1 Advance sheath over guidewire into artery using a rotary motion.
2 Withdraw introducer dilator leaving sheath in place.



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



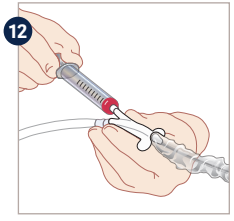
Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



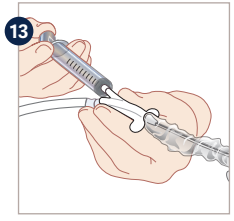
Secure IAB catheter to patient's leg using StatLock® IAB Stabilization Device or sutures.

Mega and Linear IAB Catheter

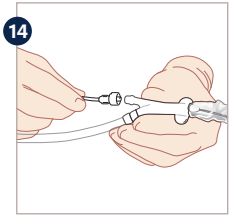
Pressure monitoring set-up



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

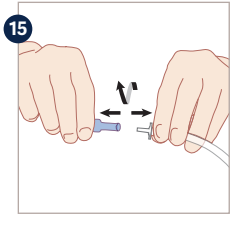


Manually flush inner lumen with 3-5 cc of flush solution.

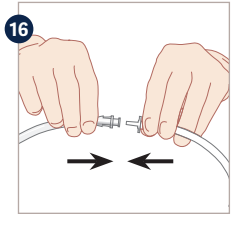


Attach a standard arterial pressure monitoring apparatus.

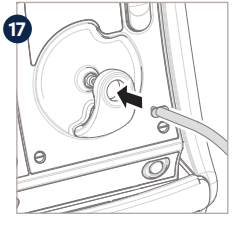
Connection to IABP



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.

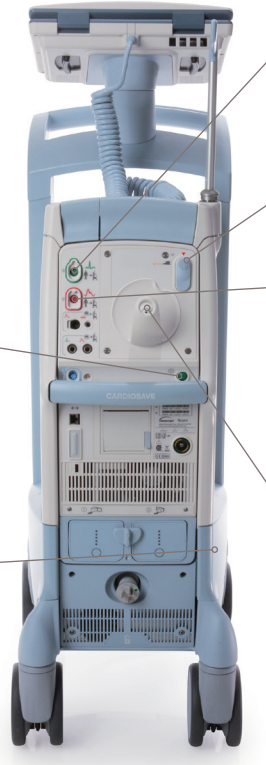
Note: Using current hospital protocol, connect a standard arterial pressure flush apparatus to inner lumen for ALL Getinge/Maquet IAB catheters (conventional and fiber-optic).

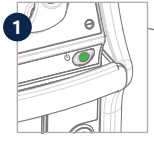
A continuous 3cc/hour flow through the inner lumen is recommended for ALL Getinge/Maquet IAB catheters (conventional and fiber-optic).

Cardiosave Checklist prior to initiating therapy

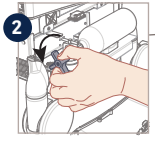
1. Plug the IABP power cord into a live AC power outlet.
2. Verify that two batteries are installed and have an adequate charge level.
3. Press the POWER button to turn the IABP on.
4. Verify that the “Hybrid” icon is displayed on the touchscreen (if the console is in the hospital cart).
5. Verify that the message “Batteries in Use“ is not displayed on the monitor.
6. Ensure that the helium tank is open and has a sufficient supply.
7. Verify that ECG trunk cable and lead wires are damage free, and intended for use with Cardiosave (Getinge/Maquet).
8. Ensure that the electrodes are placed correctly on the patient.
9. Verify that an arterial flush apparatus is set up and attached to the inner lumen of the IAB after insertion (this is required for all IABs).
10. Verify the catheter extender tubing is the correct size.
11. Only one extender tubing is attached.

Cardiosave initial Set-up

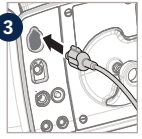




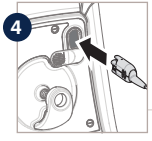
1 Press POWER button to turn IABP ON.



2 Open helium tank (if not already opened).

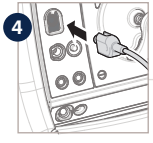


3 Connect ECG cable.

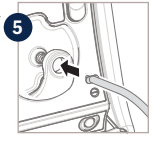


4 Connect fiber-optic sensor connector for Getinge/Maquet fiber-optic IAB.

OR

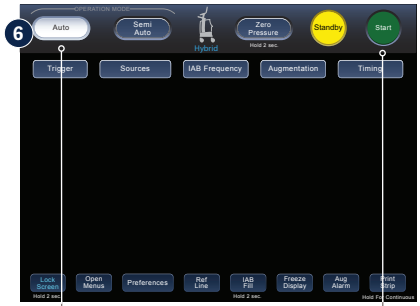


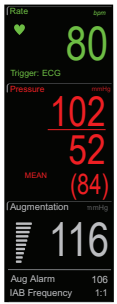
4 Connect pressure cable for conventional IAB.



5 Connect IAB.

Initial set-up using a Getinge/Maquet Fiber-optic 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

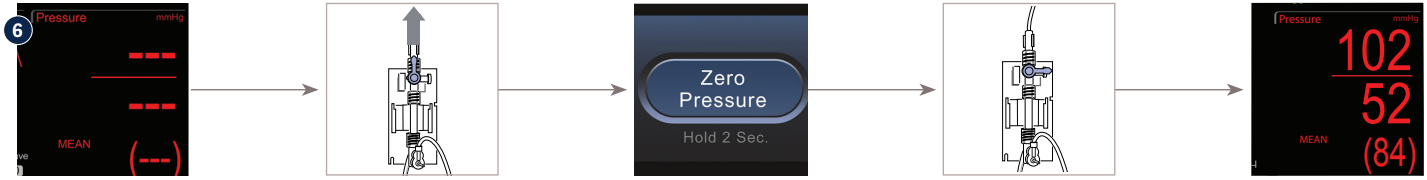
Pressing the START key

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

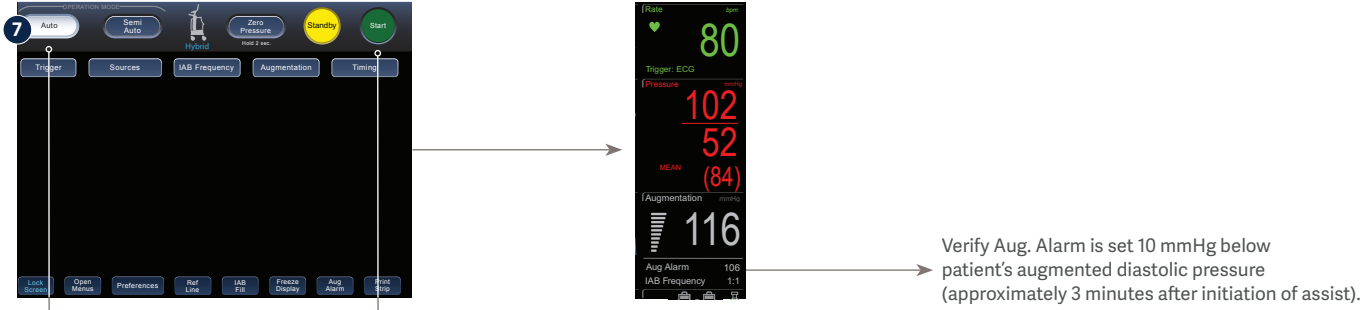
Note: With a Getinge/Maquet fiber-optic IAB, there is no need to zero. Calibration occurs automatically after pressing START. Operator may invoke a calibration anytime by pressing and holding CALIBRATE PRESSURE key for 2 seconds, while assisting.

Note: 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)



Zero Transducer



Verify
AUTO

Press
START

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

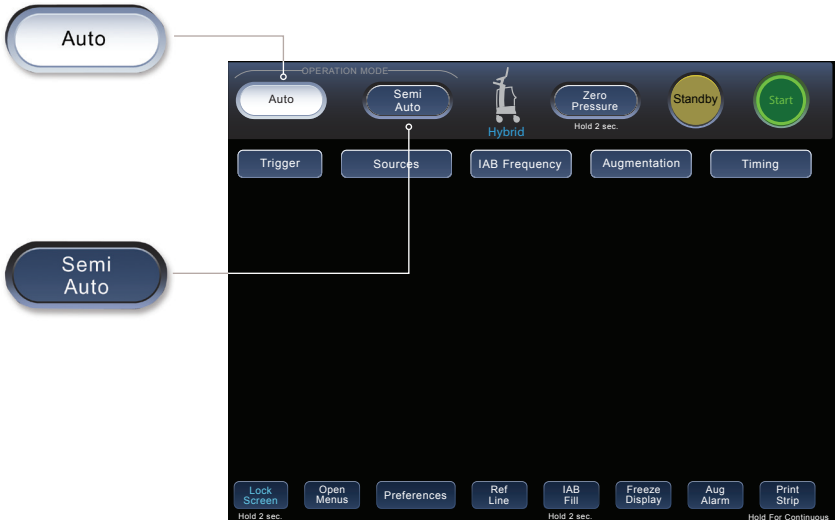
Auto Operation Mode

- 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/Maquet fiber-optic IAB)

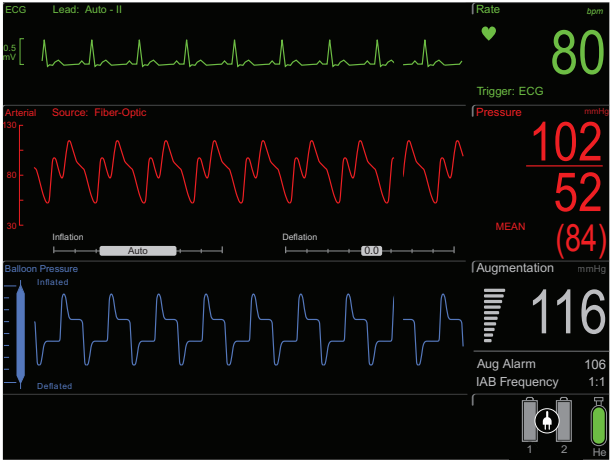
Semi-Auto Operation Mode

- 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/Maquet fiber-optic IAB)

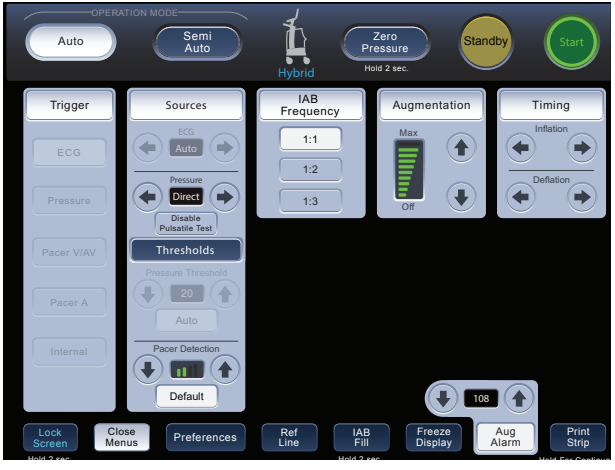
Note: When switching from **Auto** to **Semi Auto** OPERATION MODE: The IABP is placed in **Standby** mode and assist is suspended. Pressing the **Start** key will resume.



Cardiosave Monitor Display and Touchscreen

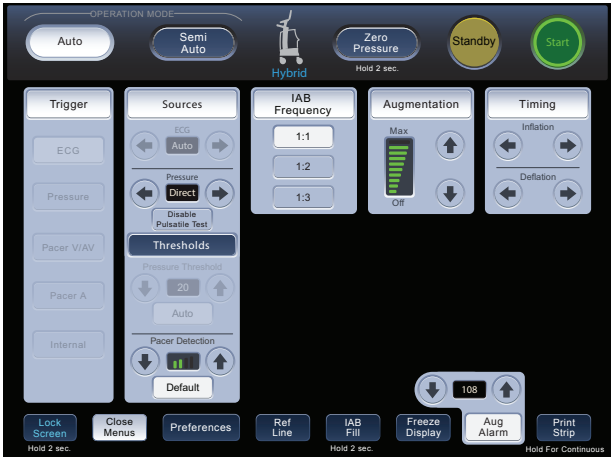


Monitor Display



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

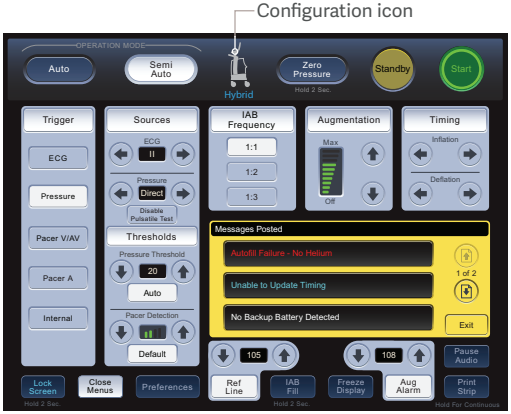
Touchscreen will **Unlock**:

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

To verify if the Cardiosave IABP is in hospital or transport mode

Docking the IABP Console in the Hospital Cart

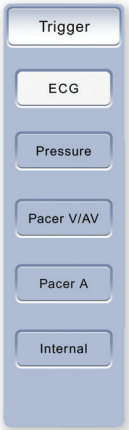
- The Cardiosave Configuration icon shows the current mode of configuration for the IABP, Hybrid (Hospital) Mode or Rescue (Transport) Mode.
- The Cardiosave must be in the Hybrid Mode to charge the batteries.



Cardiosave Triggers

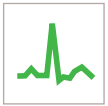
Triggering

- 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

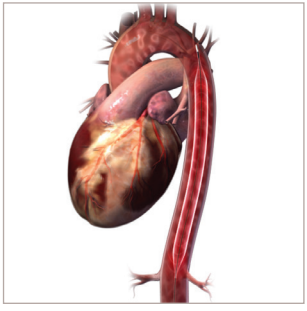
- Recommended only if atrial pacer tails are interfering with R-Wave detection while in ECG trigger
- Only available in Semi-Auto operation mode

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



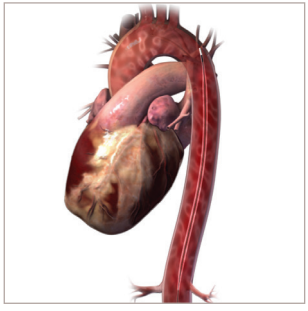
Inflation: increases supply of oxygen to the myocardium.

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.

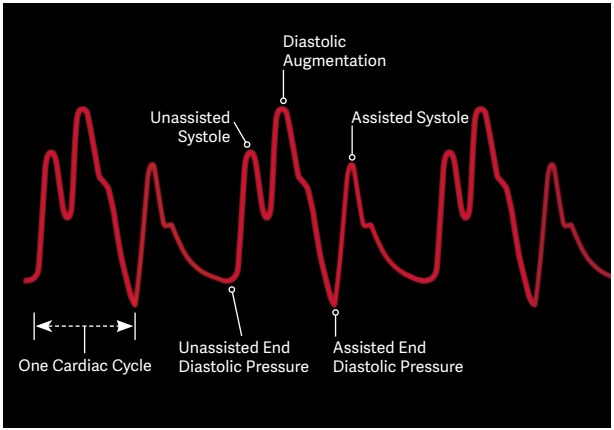
Proper IABP Timing

Inflation

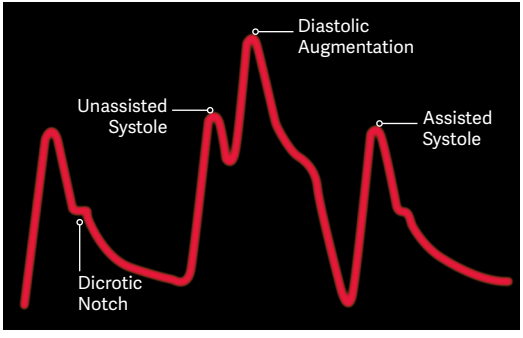
- Occurs at the dicrotic notch
- Appears as a sharp "V"
- Ideally diastolic augmentation rises above systole

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

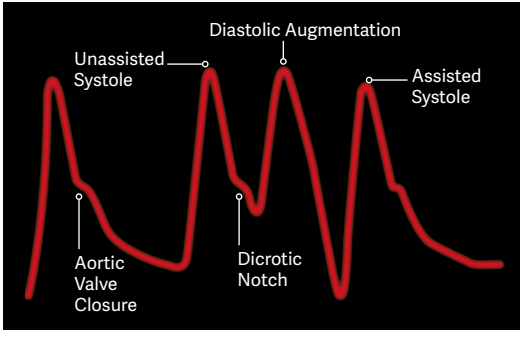
Inflation of IAB prior to aortic valve closure.

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.

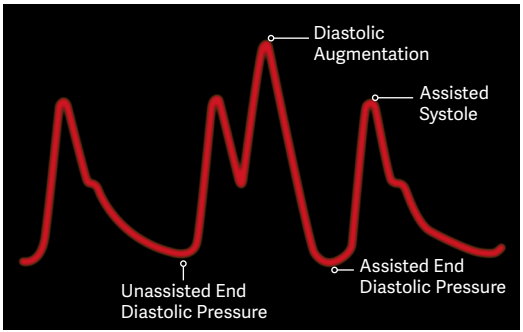
Waveform characteristics

- 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

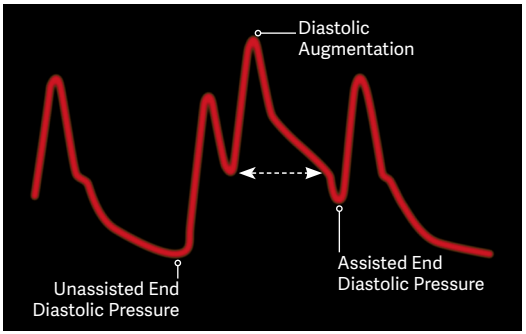
Premature deflation of IAB during diastolic phase.

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

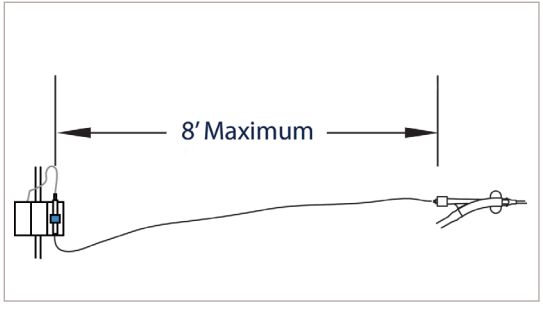
- Assisted end diastolic pressure may be equal to or higher than unassisted end diastolic pressure
- Rate of rise of assisted systole is prolonged
- Diastolic augmentation may appear widened

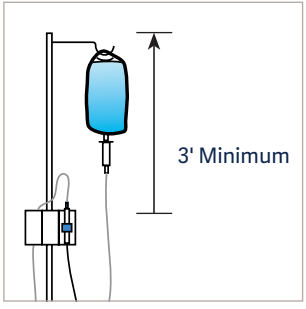
Physiologic Effects

- 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 the transducer on a standard IV pole.
- 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)





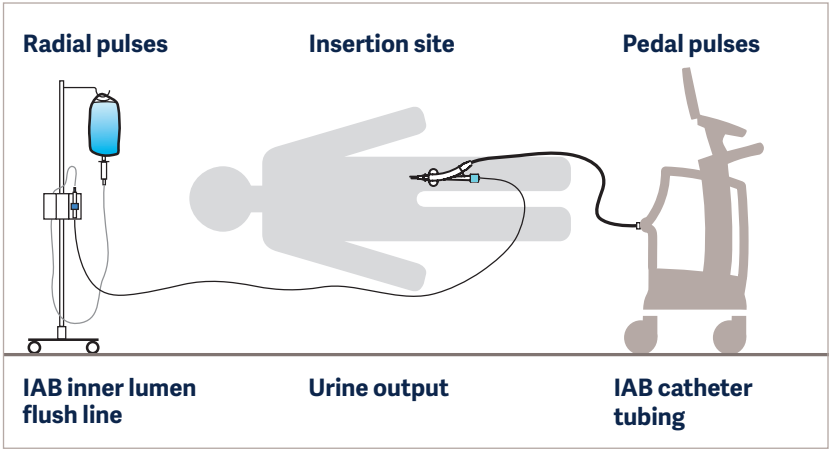
Note: Using current hospital protocol, connect a standard arterial pressure flush apparatus to inner lumen for ALL Getinge/Maquet IAB catheters (conventional and fiber-optic).

A continuous 3cc/hour flow through the inner lumen is recommended for ALL Getinge/Maquet IAB catheters (conventional and fiber-optic).

Proper Use of Cardiosave saline pole

- The saline pole is included with the IABP as a convenient location for the flush bag and is intended for temporary use during TRANSPORT ONLY.
- 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.
- The Saline Pole is not intended for use as a handle or lift point. When transporting or moving the System, use only the cart handle.

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

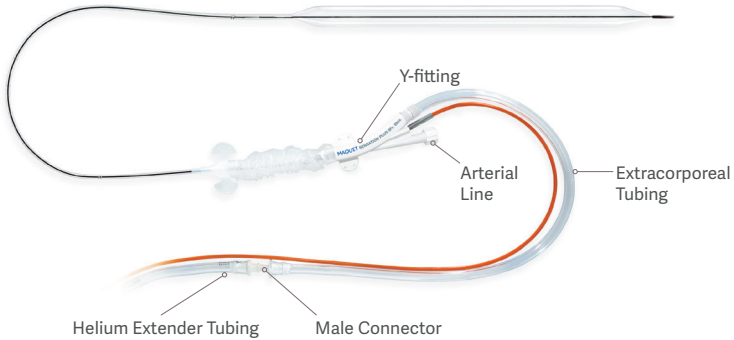
Evidence of IAB perforation

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

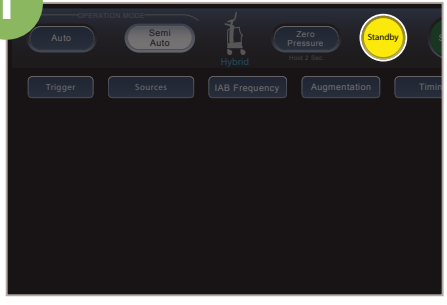


Suspected IAB perforation

Blood detected management

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

1 Standby

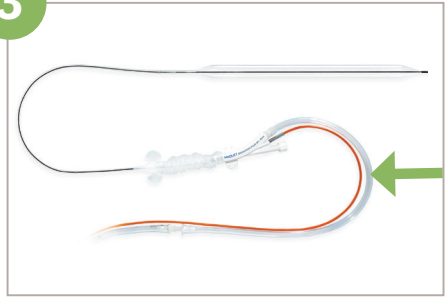


Stop pumping by placing IABP console in Standby.

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:

- 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.

Resuming IABP Therapy after Alarm related Suspension or unexpected shutdown

If there is no evidence of blood in the catheter tubings and unable to resume therapy by pressing the START key:

1. Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds.
2. Wait 10 seconds.
3. Turn the IABP ON by pressing and releasing the green IABP Power Button.
4. If the alarm message persists, switch to a replacement Getinge/Maquet IABP if available.
5. Take the pump out of service immediately. Biomed or technical service should evaluate the pump before considering its use with another patient.

If there is no evidence of blood in the catheter tubings and unable to resume therapy after turning off and restarting the IABP:

1. Obtain a replacement Getinge/Maquet IABP if available.
2 Take the pump out of service immediately.
3. Biomed or technical service should evaluate the pump before considering its use with another patient.

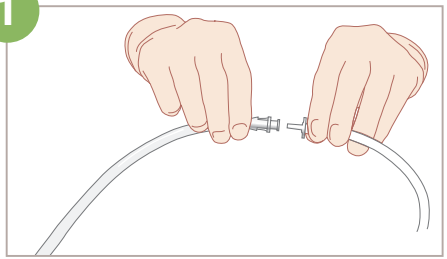
If you encounter an unexpected shutdown of the IABP and there is evidence of blood in the IAB tubings:

1. If blood is suspected of having entered the pump, take pump out of service.
2 It should be evaluated before use in another patient by Biomed/Technical Service to determine if replacement of contaminated components is necessary.
3 If IAB catheter replacement is anticipated, obtain a replacement Getinge/Maquet IABP.

Manual Inflation and Deflation of IAB

If restarting the IABP is not successful and a replacement Getinge/Maquet IABP is NOT available, the IAB catheter should not remain inactive (i.e., not inflating and deflating) for more than 30 minutes due to the risk of thrombus formation. To keep the IAB catheter active in case of pump failure, follow these steps: ***Do not manually inflate the IAB if IAB membrane perforation is suspected.***

1

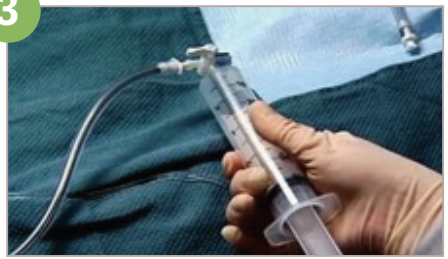


Disconnect the catheter extender from the IAB catheter's extracorporeal tubing.

2

Attach a 3-way stopcock and a 60 cc syringe to the IAB extracorporeal tubing's male luer fitting.

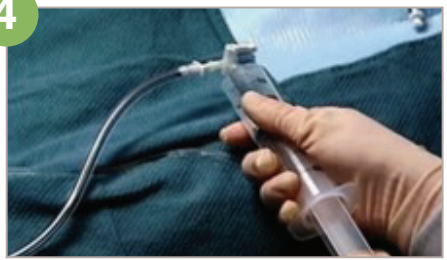
3



Aspirate to ensure no blood returns through the extracorporeal tubing.

Warning: If blood is aspirated from the male luer fitting of the extracorporeal tubing, remove the IAB catheter immediately, as this is indicative of an IAB perforation.

4



Inflate the IAB with 40 cc of air or helium and immediately aspirate. Repeat every 5 minutes while the IAB is inactive.

When a replacement IABP is available:

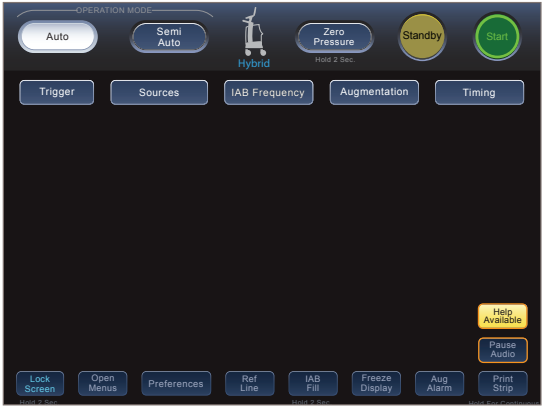
1. Remove the 3-way stopcock and syringe and reattach the extracorporeal tubing to the catheter extender.
2. Resume pumping by pressing the START key.

Alarms and Troubleshooting

Types of Alarms	Alarm Icon	Alarm Information
Technical Alarms		• Indicates an IABP electrical hardware failure and are the highest priority alarms. • Pumping suspended and sounds a continuous alarm tone.
High Priority Alarms		• Indicates a situation that requires immediate intervention. • Pumping suspended for most High Priority Alarms.
Medium Priority Alarms		• Indicates a situation that requires prompt intervention. • Pumping is not suspended but may indicate a need for corrective action.
Low Priority Alarms		• Indication that operator awareness is required.
Informational Messages		• Provides information to the Operator and displays textual messages. • Some messages include an audio tone.

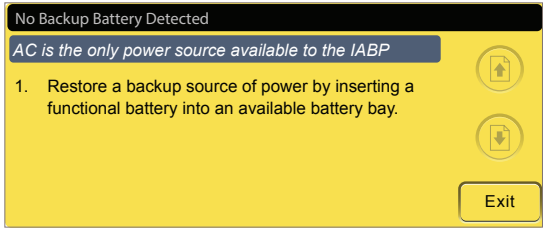
Alarms and Troubleshooting

With an alarm condition, the Help Screen and Pause Audio keys will appear on the Touchscreen.



Pause Audio

- Press Pause Audio to temporarily suspend an active audible alarm for 60 seconds.



Help Screen

- Pressing the Help Available key will display the Help Screen area for single and multiple alarms.
- The Help Screen will provide information on Probable Cause and Corrective Actions for the Alarm.

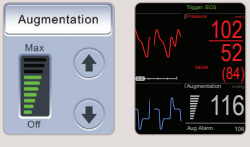
Alarms and Informational Messages

System over Temperature

Probable Cause	Corrective Action
The system has detected an over temperature condition.	• Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds. • Wait 10 seconds. • Turn the IABP ON by pressing and releasing the green IABP Power Button. • If the alarm message persists, switch to another Getinge/Maquet IABP if available and contact Getinge/Maquet Service.

Alarms and Informational Messages

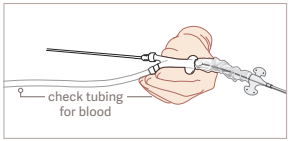
Augmentation Below Limit Set

Probable Cause	Corrective Action
There is a change in the patient's hemodynamic status.	• Assess patient's hemodynamics and attempt to optimize. • Decrease augmentation alarm limit to 8-10mmHg below patient diastolic augmentation.
Augmentation alarm limit set too high. 	• Decrease augmentation alarm limit to 8-10mmHg below patient diastolic augmentation. • Press Aug Alarm key and use down arrow key to decrease alarm limit.
Augmentation level set too low.	• Use Augmentation menu to increase IAB Augmentation to Max. 
IAB positioned incorrectly.	• Verify placement and reposition if necessary.
There is a timing error.	• Assess for late inflation and/or early deflation and correct if necessary.

Alarms and Informational Messages

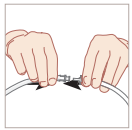
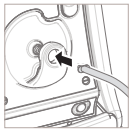
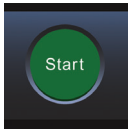
Augmentation Below Limit Set, (continued)

High Priority Alarm

Probable Cause	Corrective Action
There is a balloon leak. 	**Check for evidence of blood in the tubing. If any blood is visualizedor perforation is suspected, perform the following procedure:** • Stop pumping by placing IABP console in Standby. • Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate. • Clamp extracorporeal tubing between white y-fitting and male connector. • Notify physician and prepare for IAB catheter removal. • Consider IAB catheter replacement if the 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 is necessary.

IAB Disconnected

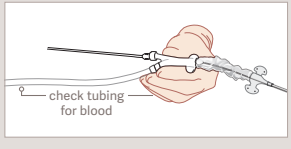
High Priority Alarm

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

Alarms and Informational Messages

IAB Catheter Restriction

High Priority Alarm

Probable Cause	Corrective Action
There is a restriction or kink in the IAB catheter or tubing. 	• Check the IAB catheter shaft, extracorporeal tubing, and extender tubing for restriction or kink, and relieve if possible. • Press the START key to resume pumping.
Check for evidence of blood in the tubing. 	**If any blood is visualized or perforation is suspected, perform the following procedure:** • Stop pumping by placing IABP console in Standby. • Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate. • Clamp extracorporeal tubing between white y-fitting and male connector. • Notify physician and prepare for IAB catheter removal. • Consider IAB catheter replacement if the 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 is necessary.

Alarms and Informational Messages

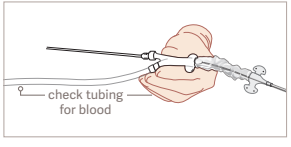
IAB Catheter Restriction, (continued)

Probable Cause	Corrective Action
The IAB membrane is not completely unfolded immediately after insertion.	• Aspirate to assure blood is not drawn into the extracorporeal tubing. • Using a syringe, manually inflate and deflate the IAB with 30 cc of air through the male Luer of the IAB extracorporeal tubing. • Press the START key to initiate an Autofill and initiate pumping.
The IAB remains in the sheath immediately after insertion.	• Check the markings on the IAB catheter to confirm the balloon has fully exited the sheath. If the balloon has not fully exited the sheath, refer to the IAB catheter manufacturer's instructions for use to reposition the sheath relative to the IAB catheter. • Press the START key to initiate an Autofill and initiate pumping.

Alarms and Informational Messages

Autofill Failure

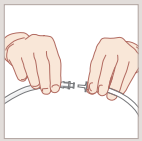
High Priority Alarm

Probable Cause	Corrective Action
IABP cannot fill the IAB catheter system.	**Check for evidence of blood in the tubing. If any blood is visualized or perforation is suspected, perform the following procedure:** • Stop pumping by placing IABP console in Standby. • Disconnect catheter extender from IABP and clamp extracorporeal tubing between white y-fitting and male connector. • Notify physician, prepare for removal of the IAB. • Consider IAB catheter replacement, if the patient's condition warrants. • If blood is suspected of entering the pump, take pump out of service to be evaluated before use in another patient by Biomed/Technical Service to determine if replacement of contaminated components is necessary before use on another patient.  **If blood is not visualized, perform the following procedure:** • Ensure only one correctly sized IAB extender tubing is connected to the IAB catheter and the IABP. • Ensure there are no restrictions in the catheter shaft, extracorporeal tubing, or extender tubing. • Press START to initiate an Autofill and resume pumping. • If alarm persists, change to another Getinge IABP and remove pump from service to be evaluated by Biomed/Technical service before use on another patient.

Alarms and Informational Messages

Gas Loss in IAB Circuit

High Priority Alarm

Probable Cause	Corrective Action
A Helium loss has been detected due to a leak or high rate of diffusion in the IAB Circuit.	**Check for evidence of blood in the tubing. If any blood is visualized or perforation is suspected, perform the following procedure:** • Stop pumping by placing IABP console in Standby. • Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate. • Clamp extracorporeal tubing between white y-fitting and male connector. • Notify physician and prepare for IAB catheter removal. • Consider IAB catheter replacement if the 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 is necessary.
A Helium loss has been detected due to a leak or high rate of diffusion in the IAB Circuit.	**If blood is not visualized, perform the following procedure:** • Ensure the IAB extender tubing is tightly connected to the IAB and IABP. • Press and hold the IAB FILL key for 2 seconds. • Press START to resume pumping. • If the patient is febrile or tachycardic, consider initiating an Autofill by pressing the IAB Fill key before the scheduled 2-hour interval.   

Alarms and Informational Messages

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.
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. For more information on the Disable Pulsatile Test, refer to the Cardiosave Operating Instructions.

Alarms and Informational Messages

Unable to Update Timing

Low Priority Alarm

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.

Prolonged Timing in Standby

Informational Message

Probable Cause	Corrective Action
The IABP has been in Standby mode for an extended period of time.	• Verify whether it is appropriate to resume pumping. • Press the Start key to resume pumping.

Note: Getinge/Maquet recommends that the IAB should not remain inactive (i.e. not inflating and deflating) for more than 30 minutes because of the potential for thrombus formation.

Fiber-optic Alarms and Informational Messages

Fiber-optic Sensor Failure

Medium Priority Alarm

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).

Fiber-optic Sensor Module Failure

Informational Message

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

Fiber-optic Alarms and Informational Messages

Unable to Calibrate Fiber-optic Sensor

Informational Message

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

Informational Message

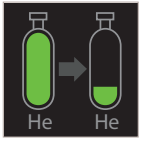
Probable Cause	Corrective Action
A non-scheduled calibration update has been intentionally postponed because either patient's mean arterial pressure may be too low to pause assist or less than 15 minutes have elapsed since last calibration.	• Assess patient to determine if a brief pause in assist would 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.

Helium Alarms and Informational Messages

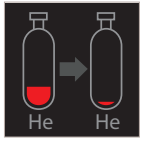
Low Helium

Informational Message

Probable Cause	Corrective Action
The Helium tank is closed.	• Open the Helium tank.
There are fewer than 24 Autofills of Helium remaining in the tank.	• Replace the Helium tank.



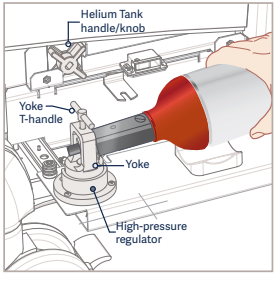
Adequate helium supply



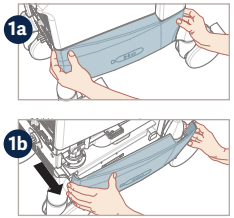
Low helium supply

Helium Tank General Maintenance

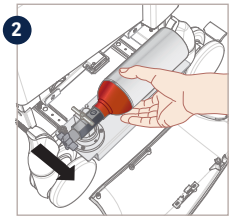
- Ensure the Cardiosave's helium supply is monitored to prevent depletion.
- Check the helium pressure regulator for any impairments and address any issues promptly.
- Be aware of the potential risk of therapy interruption if the helium supply is depleted.
- Be prepared for therapy interruption by paying attention to the advanced notice for low helium provided (at least approximately 24 hours) to plan accordingly.
- If helium replacement is not feasible or another IABP console is unavailable, initiate alternative means of providing hemodynamic support.



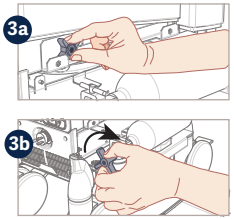
Changing the Helium Tank



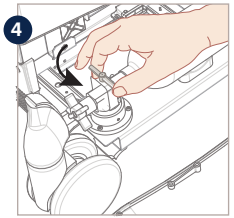
1a Grasp both sides of helium tank panel and
1b Pull out to open.



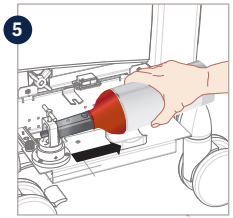
Grasp helium tank and slowly slide drawer out.



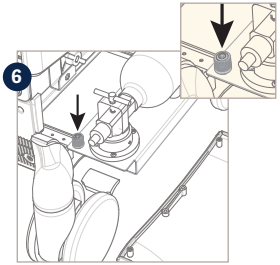
3a Remove helium tank knob from Holder and
3b Attach to left end of helium tank, then fully turn clockwise to close.



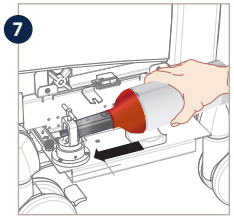
Slowly loosen yoke T-handle counter-clockwise (some helium may escape).



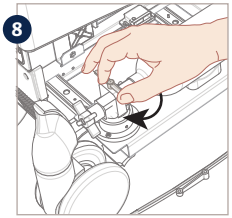
Remove helium tank.



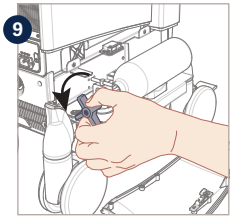
Replace washer, if available.



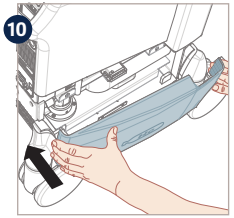
Install fresh helium tank.



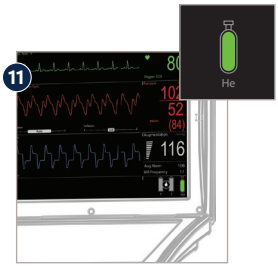
Fully tighten yoke T-handle clockwise.



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.

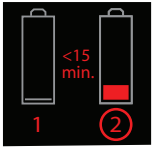
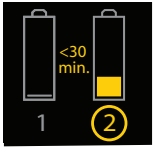
Note: Once the helium alarm sounds, there are 24 Autofills remaining in tank.

Battery Alarms and Informational Messages

Low Battery

High Priority Alarm

Medium Priority Alarm

Icon displayed	Icon displayed	Corrective Action
Battery icon turns red when less than 15 minutes of battery operation time remains, and alarm becomes a High Priority Alarm. 	**Battery icon turns yellow when less than 30 minutes of battery operation time remains, and Medium Priority Alarm occurs.** 	• Connect system to AC power source immediately. • If AC power source unavailable, insert a new charged battery.

Battery Alarms and Informational Messages

Battery Charge Level Unavailabe Bay #___

Probable Cause	Corrective Action
The battery in the identified bay or bays is unable to communicate the battery charge level.	• Immediate battery replacement is required. • 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. • 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.

Multiple AC Power Sources Detected

Probable Cause	Corrective Action
The IABP is connected to multiple AC power sources.	• Disconnect the IABP from the unused AC power source.

Battery Alarms and Informational Messages

Battery Maintenance Required Bay #___

Informational Message

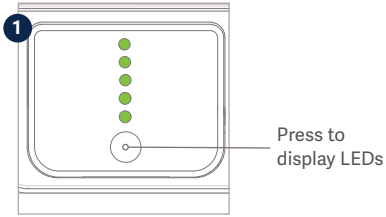
Probable Cause	Corrective Action
The battery in the identified bay requires maintenance.	• Continue operation on AC power. • If battery operation is required, the battery run time may be reduced. Monitor the system closely for a Low Battery alarm. • If a Low Battery alarm occurs, immediately connect the system to AC power or install a fully charged battery. • As soon as possible, execute the Battery Maintenance.

Battery Replacement Required Bay #___

Informational Message

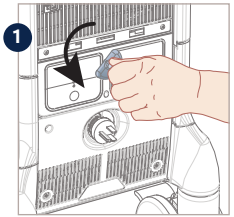
Probable Cause	Corrective Action
The battery in the identified bay or bays has become unreliable and requires replacement.	• Battery replacement is required. • Continue operation on AC power. • If battery operation on the indicated battery is required, the battery run time will be reduced. Monitor the system for a Low Battery alarm. • If a Low Battery alarm occurs, immediately replace the battery or return to AC power. • Contact Getinge/Maquet Service to obtain a new battery.

Viewing Battery Status on Battery

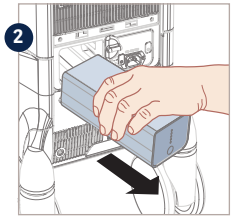


Battery is approximately 100% charged.
Note: Each LED represents a charge of approximately 20%.

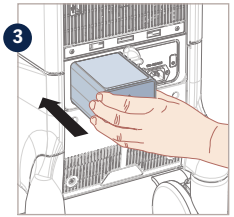
Changing the Battery



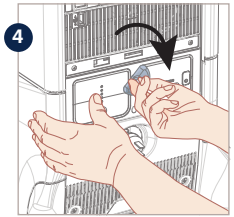
Turn knob to remove battery from Battery Bay.



Slide battery OUT.



Slide charged battery IN.

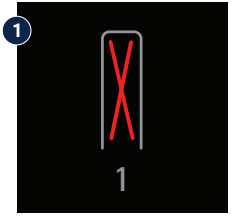


While holding battery in bay, turn knob to lock battery in place.

Use care to avoid dropping the battery.

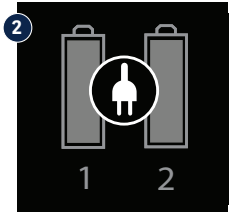
Viewing Battery Status on Monitor Display (examples)

1



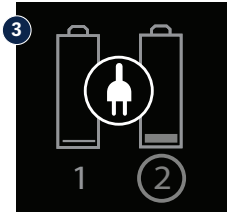
Empty battery bay.
No backup battery or Transport Power Supply detected in battery bay.

2



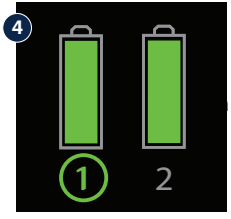
Plugged into AC power outlet and batteries are fully charged.

3



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

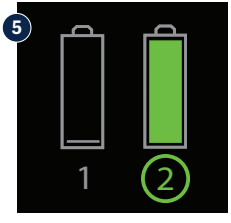
4



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

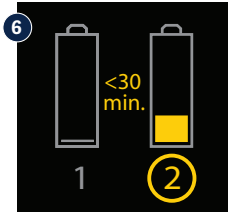
Note: The Low Battery alarm is displayed when 30 minutes or less of internal battery operating time remains. When this message is displayed, the battery symbol is displayed as empty. There is also an audible tone every 30 seconds. Additionally, a high priority Low Battery alarm message will be activated 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.

5



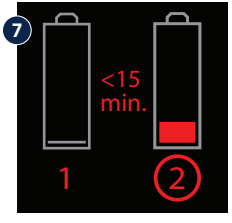
Battery 1 is depleted, thus battery 2 is currently being used.

6



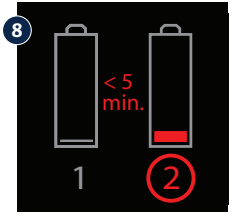
Battery 1 is depleted and battery 2 has less than 30 minutes of charge remaining (Low Battery message is displayed).
Caution: Prompt attention is needed to either insert fully charged batteries or plug into AC source.

7



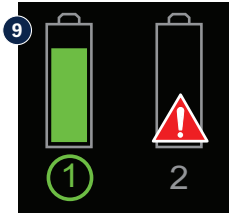
Battery 1 is depleted and battery 2 has less than 15 minutes of charge remaining.
Caution: Prompt attention is needed to either insert fully charged batteries or plug into AC source.

8



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.

9



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.

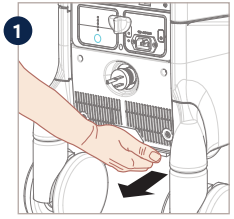
Portable Operation

Getinge/Maquet recommends:

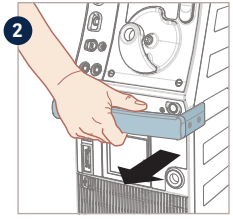
- Sufficient supply of fully charged batteries for use during transport.
- Use of the Transport Power Supply for AC operation during transport.
- Verifying internal helium reservoir is full when using the Transport System.
- System must be properly secured in the transport vehicle.

Warning: It is advised not to transport a patient receiving counterpulsation therapy via Cardiosave unless the clinician deems the benefit of transport outweighs the risk of unexpected shutdown.

Removing Pump Console from the Cart

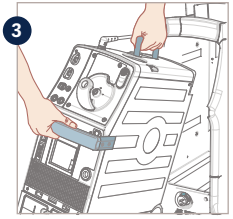


Release latch located below pump console (ensure wheels are locked).

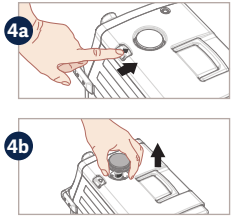


Grab handle and slowly slide console out.

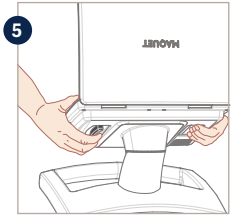
Note: 3 audio tones will sound.



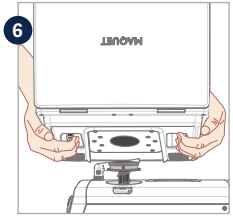
Grab handles located on top and front of console, then remove from Hospital Cart.



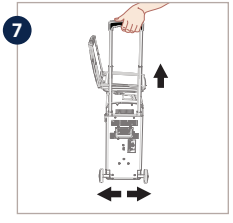
4a Push button to release pop-up mount.
4b Pull UP pop-up mount to lock in place.



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.

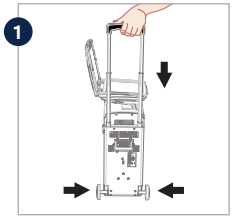


Squeeze latch below handle and lift straight up until wheels extend outward and handle locks into extended position.

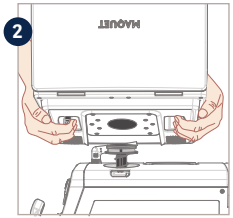
Tilt Transport System on wheels and begin transport.

Battery in Use – Cardiosave Out of Cart" Informs users whenever the console is undocked and relying on battery power.

Inserting the Pump Console into the Hospital Cart

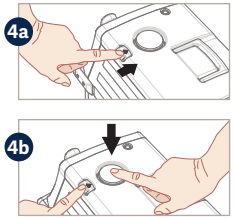


Squeeze latch below handle. Push straight down until wheels retract and handle is fully collapsed.

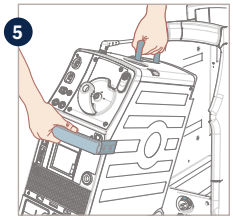


Squeeze latches located below Monitor and lift to remove from Pump Console.

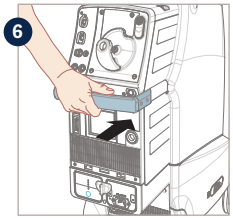
Squeeze latches and attach to display mount, then release the latches. Ensure monitor is securely attached.



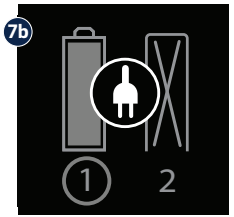
4a Push and hold button on console to unlock monitor mount.
4b Push down to lock into place, then release button.



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

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.

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/Maquet 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/Maquet 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/Maquet IABP.
- Set-up Getinge/Maquet IABP per abbreviated instructions on page 11 of this Quick Reference Guide.

Connecting a Getinge/Maquet IAB/IABP to an Arrow IABP

Transferring Facility

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

Receiving Facility

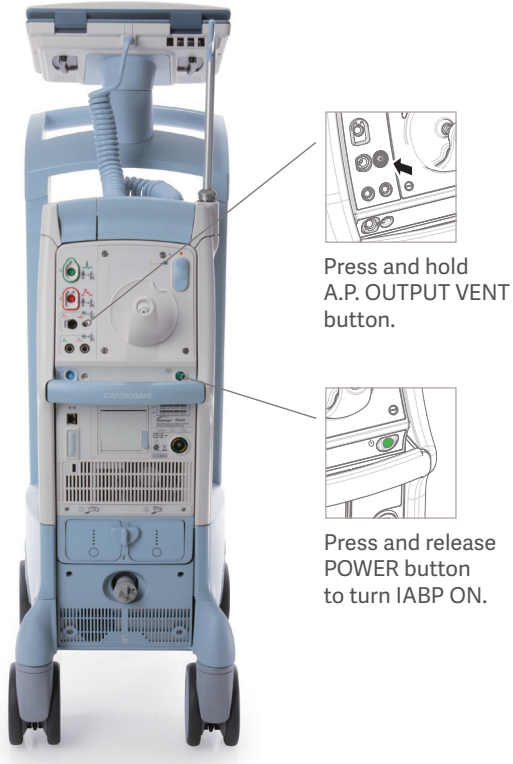
- When arriving at receiving facility, place Getinge/Maquet IABP on Standby and disconnect IAB catheter extender tubing from back of IABP.
- Connect Arrow Pump Adapter (APA) to male luer fitting of Getinge/Maquet IAB catheter extender tubing and connect to Arrow IABP.
- Adjust volume setting on Arrow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

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GETINGE

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