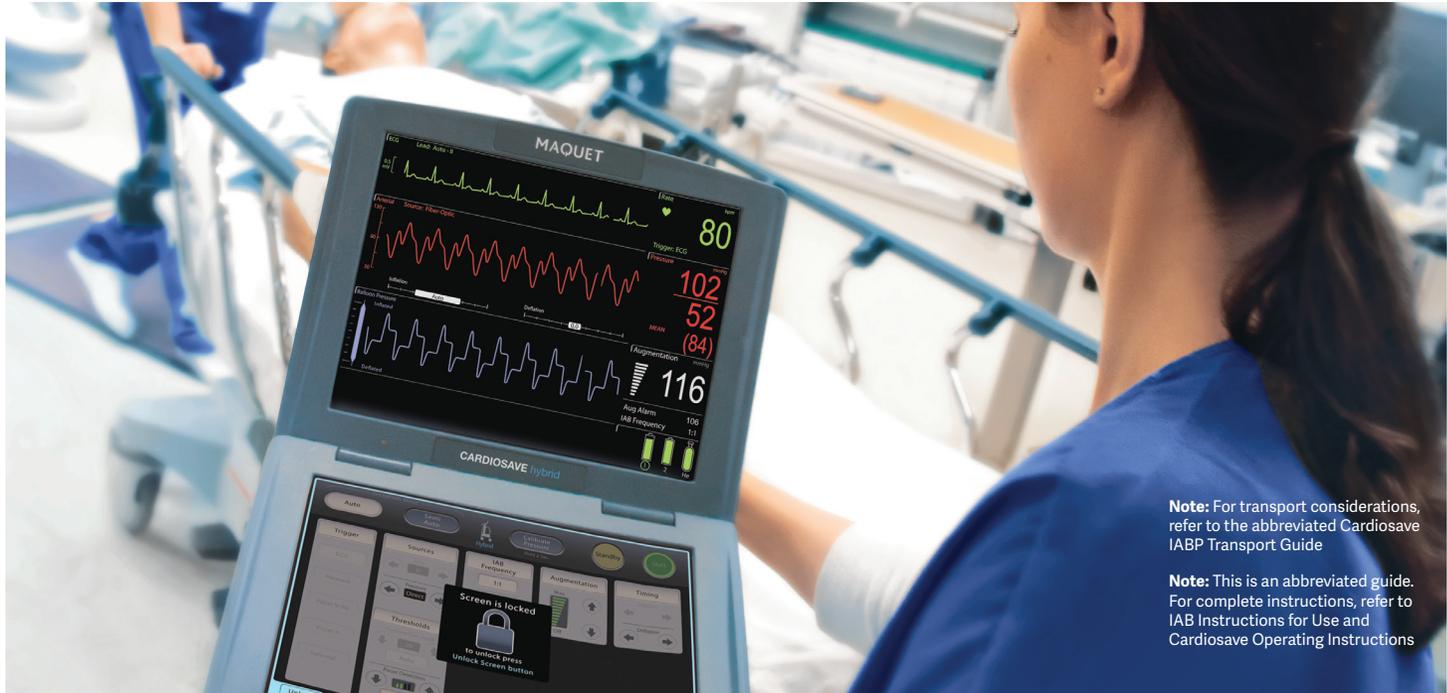


Cardiosave IABP Quick Reference Guide

Software Version D.03

(For use outside the US only)

GETINGE 



Note: For transport considerations, refer to the abbreviated Cardiosave IABP Transport Guide

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

Cardiosave Configurations



Pump Console + Hospital Cart

=



Hybrid



Pump Console Only = Rescue



Cardiosave Hybrid:

- Pump Console is docked into the Hospital Cart
- Used primarily in hospital settings
- Operates on AC power or battery power



Cardiosave Rescue:

- Pump Console is undocked from Hospital Cart
- Used primarily in transport settings
- Operates on battery power or AC power with Transport Power Supply

Note: To minimize risk of fluid entering the IABP, maintain the Pump Console in the Hospital Cart when transporting within the hospital

Verify Cardiosave IABP Configuration

Cardiosave Configuration Icons

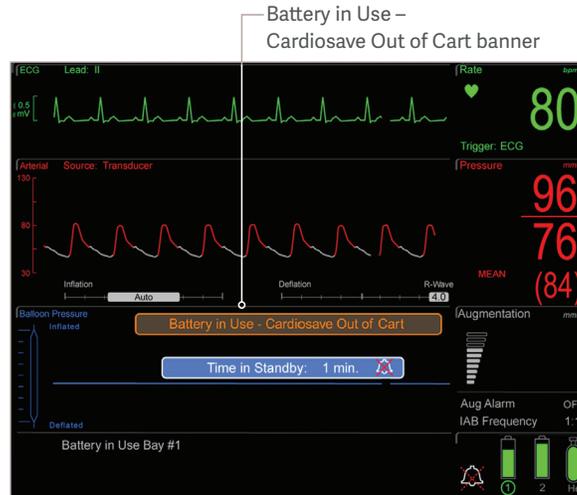
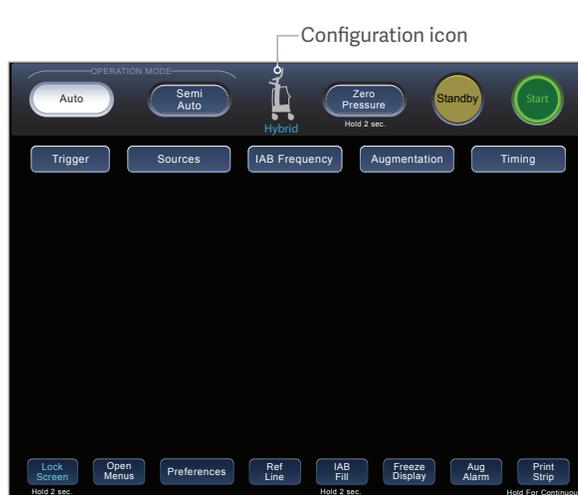
- The Cardiosave configuration icon shows the current configuration of the IABP – Hybrid (Hospital) or Rescue (Transport)



Determining Power Source

- A visual alert “Battery in Use – Cardiosave Out of Cart” will be displayed to inform users whenever the Pump Console is undocked and relying on battery power

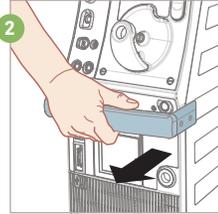
Note: The Cardiosave must be in the Hybrid configuration to charge the batteries



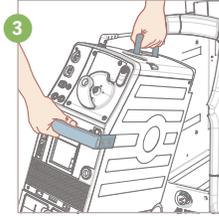
Removing Pump Console from the Cart



1 Release latch located below Pump Console (ensure wheels are locked)



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

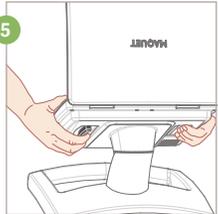


3 Grab handles located on top and front of console, then remove from Hospital Cart

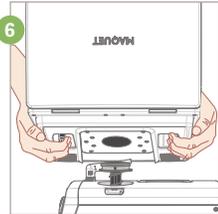


4a Push button to release pop-up mount

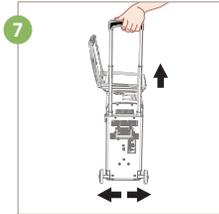
4b Pull UP pop-up mount to lock in place



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



6a Squeeze latches and attach to pop-up mount, then release latches
6b Ensure Monitor is securely attached



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

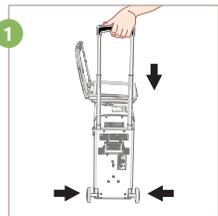


8 Tilt Transport System on wheels and begin transport

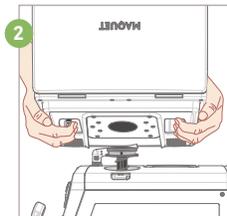


"Battery in Use – CardioSave Out of Cart" Informs users whenever the console is undocked and relying on battery power

Inserting the Pump Console into the Hospital Cart



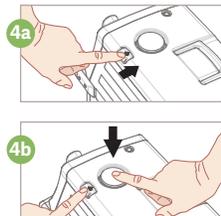
- 1a** Squeeze latch below handle
1b Push straight down until wheels retract and handle is fully collapsed



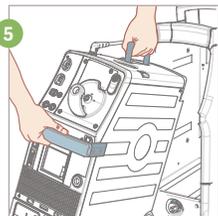
- 2** Squeeze latches located below Monitor and lift to remove from Pump Console



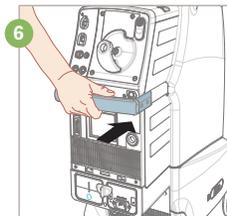
- 3a** Squeeze latches and attach to display mount, then release the latches
3b Ensure monitor is securely attached



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



- 5** Grab handles located on top and front of console, then lift into Hospital Cart



- 6** 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



- 7a** 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 power source
 - 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

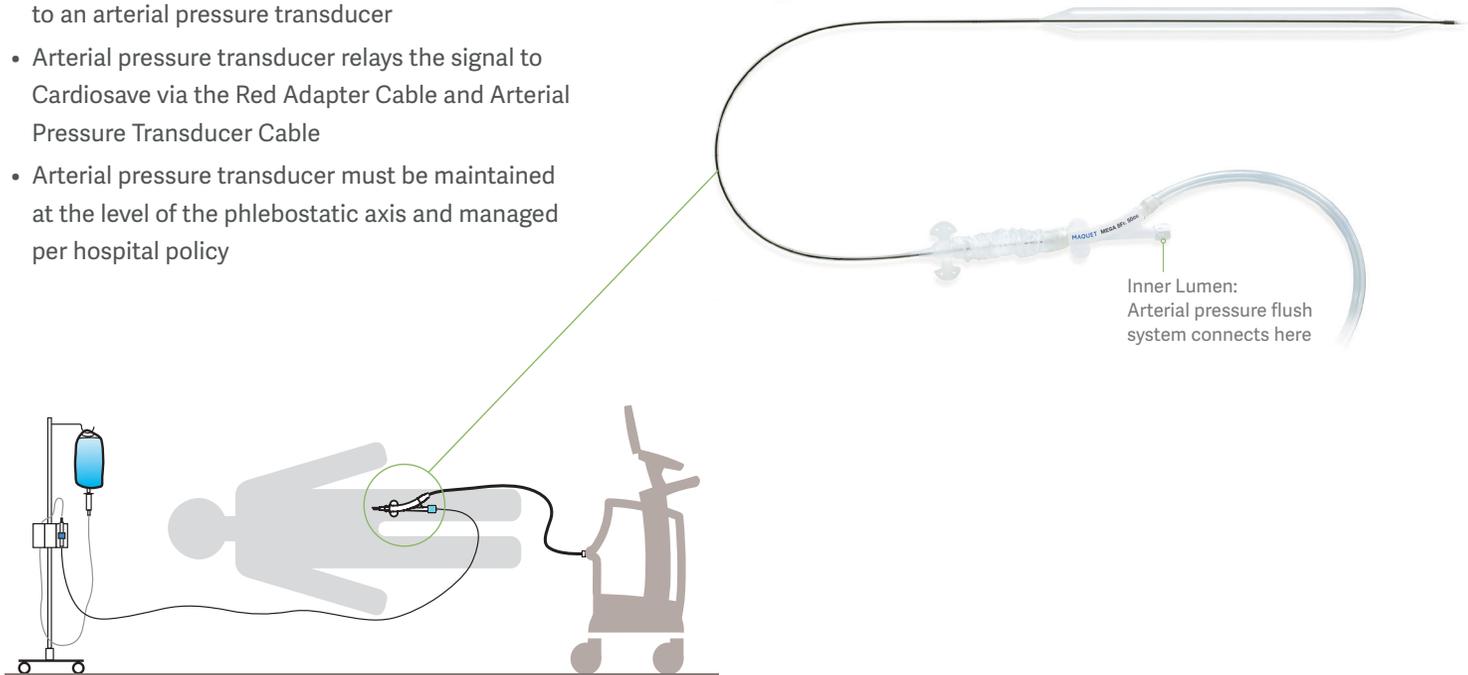


Note: If the cart is not properly docked, a banner that states “Battery in Use - Cardiosave out of Cart” will appear on the Monitor Display

Intra-Aortic Balloon (IAB) Catheters

Conventional IAB Catheters

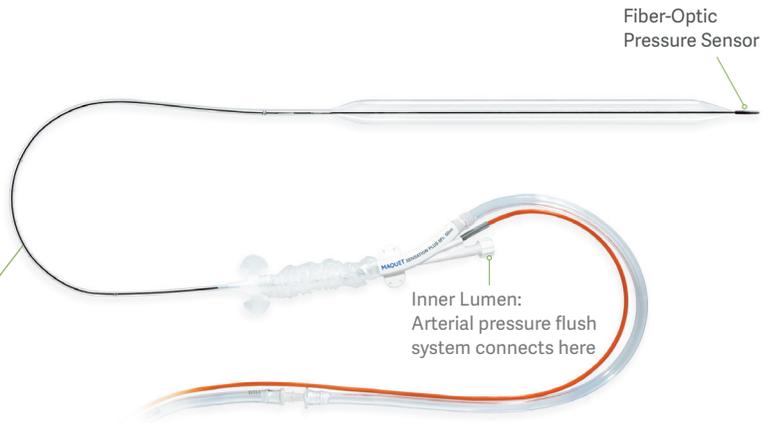
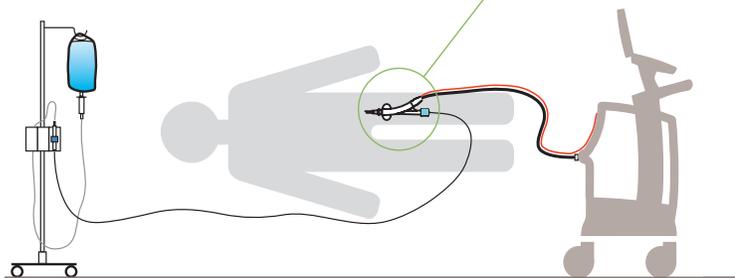
- Arterial pressure is transmitted through a fluid-filled inner lumen within the IAB catheter to an arterial pressure transducer
- Arterial pressure transducer relays the signal to Cardiosave via the Red Adapter Cable and Arterial Pressure Transducer Cable
- Arterial pressure transducer must be maintained at the level of the phlebostatic axis and managed per hospital policy



Intra-Aortic Balloon (IAB) Catheters

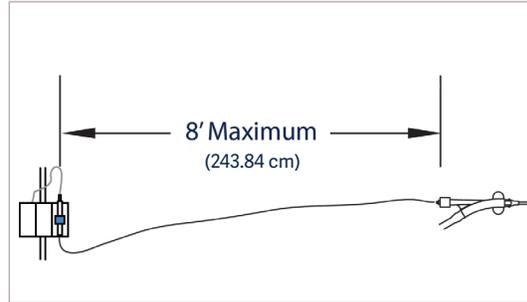
Getting Fiber-Optic IAB Catheters

- Transmits arterial pressure directly from the Fiber-Optic Pressure Sensor (transducer) in the IAB catheter tip to Cardiosave
- Transducer moves as patient moves, eliminating need to level an external arterial pressure transducer
- Automatically calibrates (zeroes) inside patient (in-vivo) at regular intervals
- Fiber-Optic IAB catheters require the arterial flush system setup to maintain patency of the inner lumen and to prevent blood clot formation



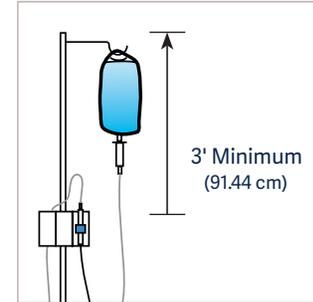
Proper Care of Inner Lumen

- Minimize length of pressure tubing
- **Only** use low compliance pressure tubing
- Elevate flush bag at least 3' (91.44 cm) above the transducer on a standard IV pole
- A 3 mL/hour continuous flow through inner lumen is recommended
- If inner lumen becomes damped
 - Aspirate and discard 3 mL 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 in **Standby**)
- **Do not** sample blood from inner lumen



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

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



Initial Setup

- 1**
Plug power cord into live AC power source



- 2**
Press IABP Power button to turn IABP on
• Check batteries are installed and charged adequately



- 3**
Open Helium Tank (if not already opened)



- 4**
Connect green ECG cable
• Verify the ECG Trunk Cable and Lead Wires are damage free



- 5**
Connect Fiber-Optic Sensor Connector for Getinge Fiber-Optic IAB catheter



- 5**
OR
Connect Red Adapter Cable and Arterial Pressure Transducer Cable for conventional IAB catheter



- 6**
Connect IAB helium extender tubing
• Verify helium extender tubing is correct size and only one is attached



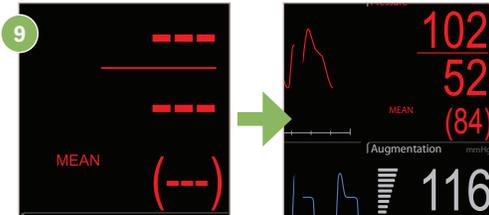
Starting IABP with a Getinge Fiber-Optic IAB Catheter



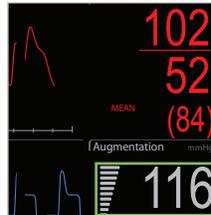
Verify **Auto** Operation



Press **Start** to initiate therapy

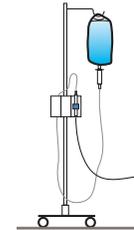


- The IABP will automatically fill the balloon (autofill) and calibrate (zero) the Fiber-Optic Pressure Sensor (transducer)
- Once process is complete, arterial blood pressure values will be displayed



Clinical Requirements

- Augmentation Alarm automatically sets after 3 minutes of continuous pumping
- Verify alarm is 8-10 mmHg below the patient's augmented diastolic pressure
- Adjust as needed

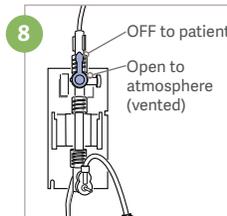


The arterial pressure flush system is required for all Getinge catheters to minimize risk of clot formation in the arterial inner lumen

Starting IABP with a Conventional IAB Catheter



Verify **Auto** Operation

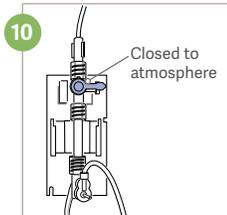


Verify arterial pressure flush system is connected to inner lumen of IAB catheter

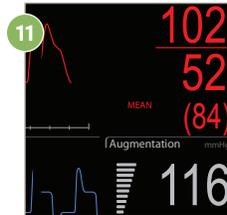
- Vent arterial pressure transducer to atmosphere



Press and hold the **Zero Pressure** key for 2 seconds



Close the arterial pressure transducer



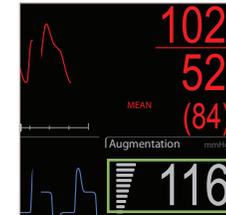
Arterial blood pressure values will be displayed on the pump



Press the **Start** key

- The IABP will automatically fill the balloon (autofill) and initiate therapy

Clinical Requirement

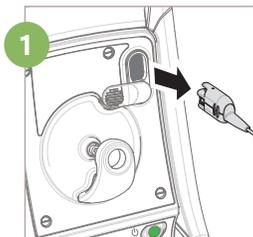


- Augmentation Alarm automatically sets after 3 minutes of continuous pumping
- Verify alarm is 8-10 mmHg below the patient's augmented diastolic pressure
- Adjust as needed

Note: Arterial blood pressure values will not be displayed until the arterial pressure transducer has been zeroed on the IABP

Setup with Alternate Direct Arterial Pressure Source

- An alternate arterial pressure source (e.g., radial arterial line) should only be used when the fiber-optic pressure signal is unavailable, not connected, and the IABP catheter inner lumen is not patent



1 Disconnect Fiber-Optic Sensor Connector from IABP if in use

- The IABP ignores alternate sources when the Fiber-Optic Sensor Connector is connected



2 Connect (if not already) the Red Adapter Cable to IABP



- Connect IABP Arterial Pressure Transducer Cable to alternate source (i.e., radial arterial line)
- Connect IABP Arterial Pressure Transducer Cable to Red Adapter Cable

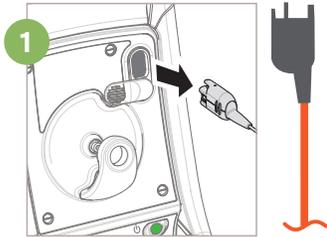


- 4 Press and **hold Zero Pressure** key for 2 seconds
- Refer to page 11 for instructions

Setup with Alternate External Arterial Pressure Source

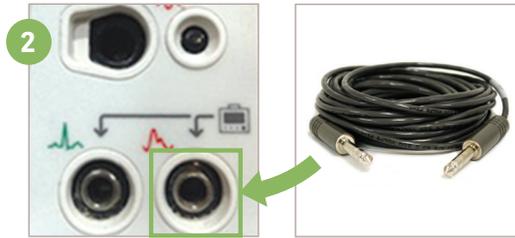
External Patient Monitor Pressure Source

- An alternate arterial pressure source (e.g., radial arterial line) should only be used when the fiber-optic pressure signal is unavailable, not connected, and the IAB catheter inner lumen is not patent
- This assumes an arterial line is in place and zeroed on the external patient monitor



Disconnect Fiber-Optic Sensor Connector from IABP if in use

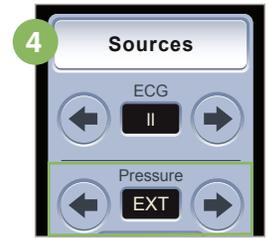
- The IABP ignores alternate sources when the Fiber-Optic Sensor Connector is connected



Connect Interface Cable from external patient monitor to IABP



Open **Sources** menu



Select or confirm that **EXT** is the **Pressure** source displayed

Note:

- Femoral arterial lines are not recommended as an alternate pressure source
- Check your hospital's policy regarding use of external pressure sources and availability of interface cables

Operation Modes

Auto Operation Mode

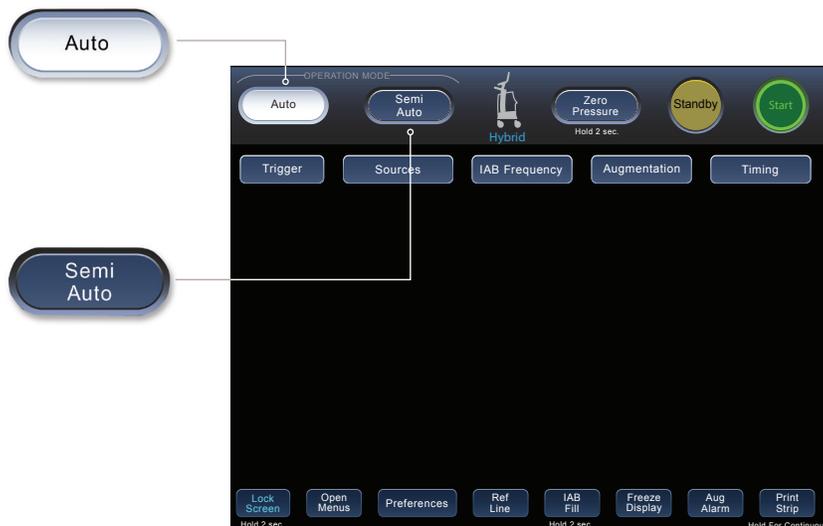
- Automatic lead and trigger selection
- Automatic and continuous inflation and deflation timing management
 - User has ability to fine-tune deflation timing
- Automatic management of irregular rhythms

Semi Auto Operation Mode

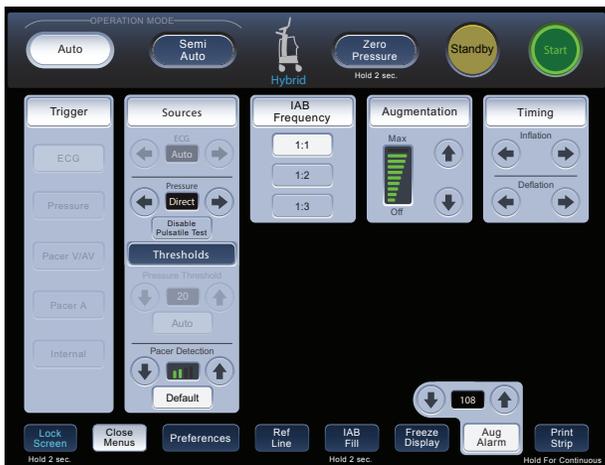
- User selects most appropriate lead and trigger source
- User establishes timing, then Cardiosave automatically adjusts timing with heart rate and rhythm changes
- Automatic management of irregular rhythms

Note:

- When switching from **Auto** to **Semi Auto** Operation Mode, the IABP is placed in Standby and pumping is suspended
- Press the **Start** key to resume therapy



Lock Screen Feature



Touchscreen Unlocked

Touchscreen will lock:

- Automatically after 2 minutes of inactivity
- When user presses **Lock Screen** key for 2 seconds



Touchscreen Locked

Touchscreen will unlock:

- Automatically with any High, Medium, or Low Priority Alarm
- When user presses **Unlock Screen** key



Hemodynamic Effects of Counterpulsation Therapy



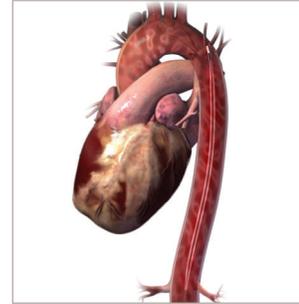
Inflation: increases supply of oxygen to the myocardium

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

Mean Arterial Pressure (MAP)

Mean Arterial Pressure (MAP)

- MAP is the average pressure in a patient's arteries during one cardiac cycle and is used to assess organ perfusion
- With an arterial line, the MAP is calculated by the area under the pressure curve during the cardiac cycle
- With a non-invasive blood pressure cuff, the MAP is calculated by $[SBP + (2 \times DBP)] / 3$

Assisted MAP

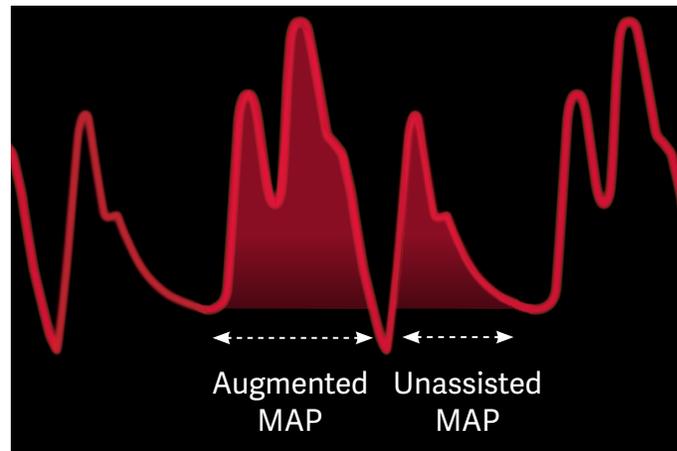
- Diastolic augmentation increases MAP by increasing pressure and time under the pressure curve

Unassisted MAP

- MAP will be lower during unassisted beats due to less pressure and time under the pressure curve

IABP samples the arterial pressure every 4 msec to calculate a MAP

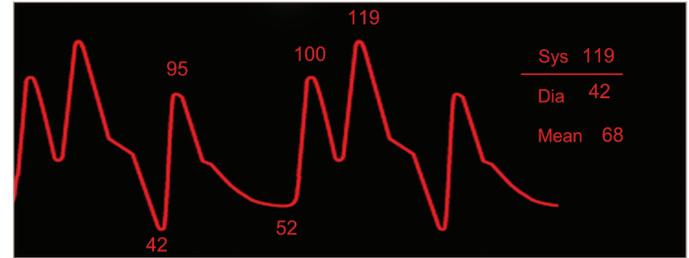
Source: Parissis V, Graham S et al. IABP: History-evolution-pathophysiology-indications: What We Need To Know. Journal of Cardiothoracic Surgery (2016) 11:122



IABP Monitor Display vs. External Patient Monitor



Cardiosave IABP Monitor Display



External Patient Monitor

- External patient monitors review the arterial waveform for several seconds and show the highest and lowest pressures during that time
 - Most monitors are not programmed to distinguish between the patient's systolic pressure and diastolic augmentation
 - This results in augmentation being incorrectly labeled as systolic pressure on the external patient monitor
- It is recommended that the assisted blood pressure values and MAP displayed on the IABP Monitor Display be utilized to guide clinical decision making
- Non-invasive blood pressure readings are unreliable during IABP therapy and should not be used for patient management

Triggers

Trigger

- 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
- Cardiosave IABP has 5 trigger sources

Mode	Trigger Sources Available	IABP/User Action
Auto	ECG Pressure	IABP automatically switches between ECG and Pressure trigger. The IABP will select the Trigger based on the most reliable signal
Semi Auto	ECG Pressure Pacer V/AV Pacer A Internal	User must select Trigger source

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

- Used when ECG and Pressure triggers are unsuccessful and a V or AV pacemaker is used
- Must be 100% V-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

IABP Timing

Timing

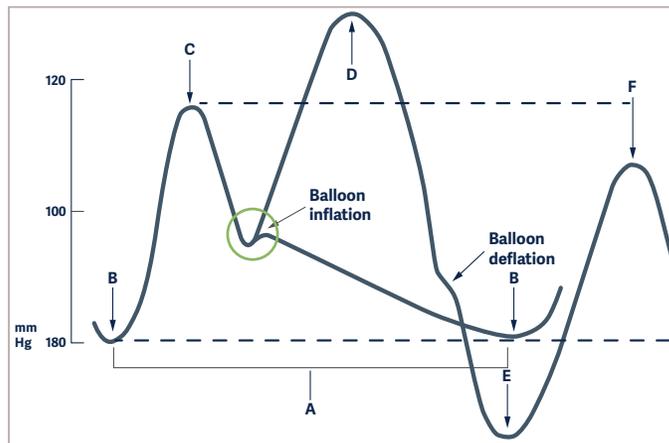
Timing refers to the positioning of inflate and deflate points on the arterial pressure waveform

Proper Inflation Timing

- Occurs at dicrotic notch on the arterial waveform
- Appears as a sharp "V"
- Ideally diastolic augmentation rises above systole
 - The peak after the "V" is referred to as diastolic augmentation

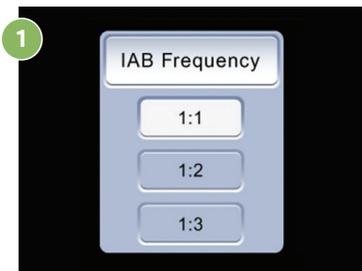
Proper Deflation Timing

- Occurs just prior to systolic ejection
- Results in a reduction of:
 - Assisted systolic pressure
 - Assisted end diastolic pressure

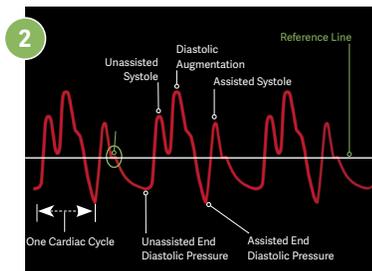


- A** - One cardiac cycle
- B** - Unassisted end diastolic pressure
- C** - Unassisted systolic pressure
- D** - Diastolic augmentation
- E** - Assisted end diastolic pressure
- F** - Assisted systolic pressure

Timing Assessment

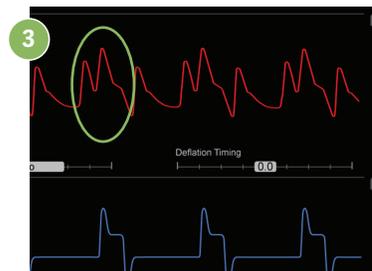


1 Place the IABP in 1:2 or 1:3 frequency

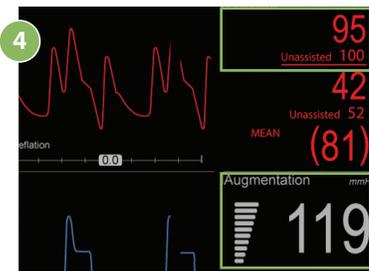


2 Does balloon inflation occur at the dirotic notch?

- Line up **Reference Line** on the dirotic notch where there is no balloon inflation
- Inflation should align with the dirotic notch

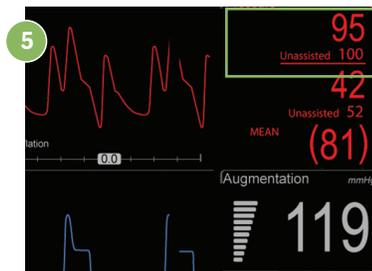


3 Does inflation result in a sharp "V"?



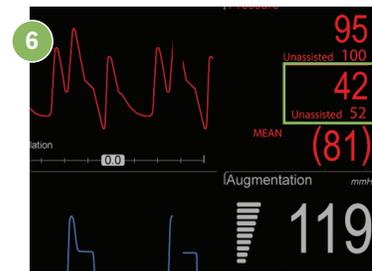
4 Is diastolic augmentation higher than the patient's systolic pressure?

- Compare augmentation pressure to systolic pressure



5 Does deflation reduce assisted systolic pressure?

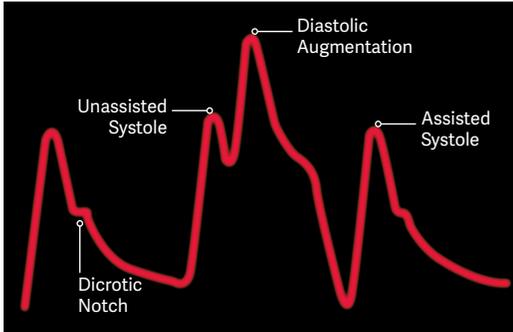
- Assisted systolic pressure should be lower than unassisted systolic pressure



6 Does deflation reduce assisted end diastolic pressure?

- Assisted end diastolic pressure should be lower than unassisted end diastolic pressure

Timing Errors



Early Inflation

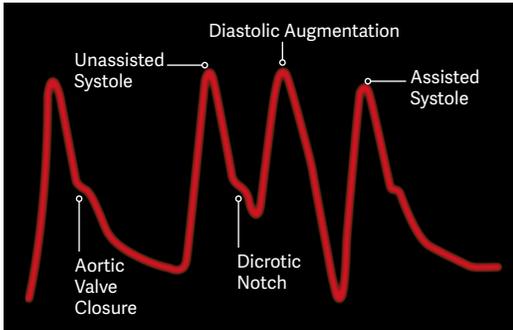
Inflation of IAB prior to aortic valve closure

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

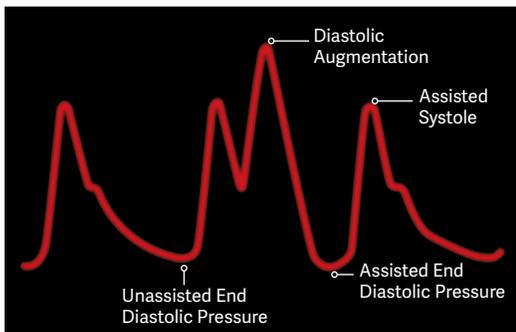
Waveform characteristics

- 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

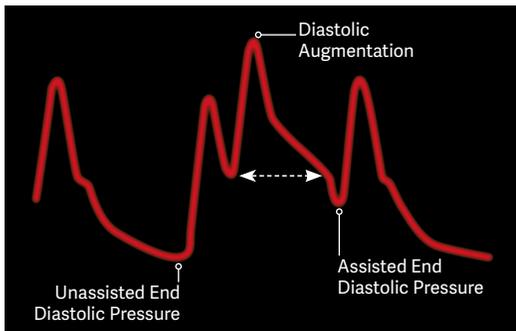
Premature deflation of IAB during diastolic phase

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

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

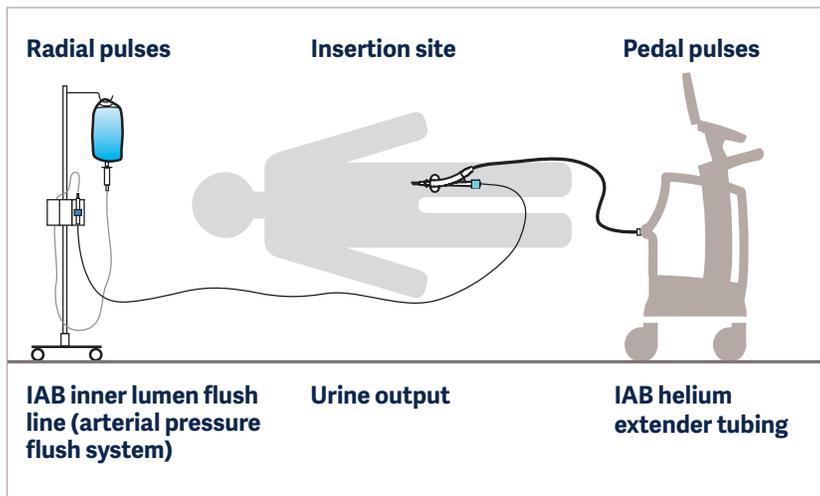
Waveform characteristics

- 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

Patient Assessment



Assessment

Corrective Action

Radial pulses

Left radial pulse weak or left arm ischemia

Check position of IAB catheter

Insertion site

Excessive bleeding from insertion site

Apply pressure, ensure distal flow

Pedal pulses

Limb ischemia

Consider removing IAB catheter, 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 in Standby)

Urine output

Urine output low

Check position of IAB catheter

IAB catheter and/or helium extender tubing

• Blood observed in tubing

STOP pumping and prepare for IAB catheter removal

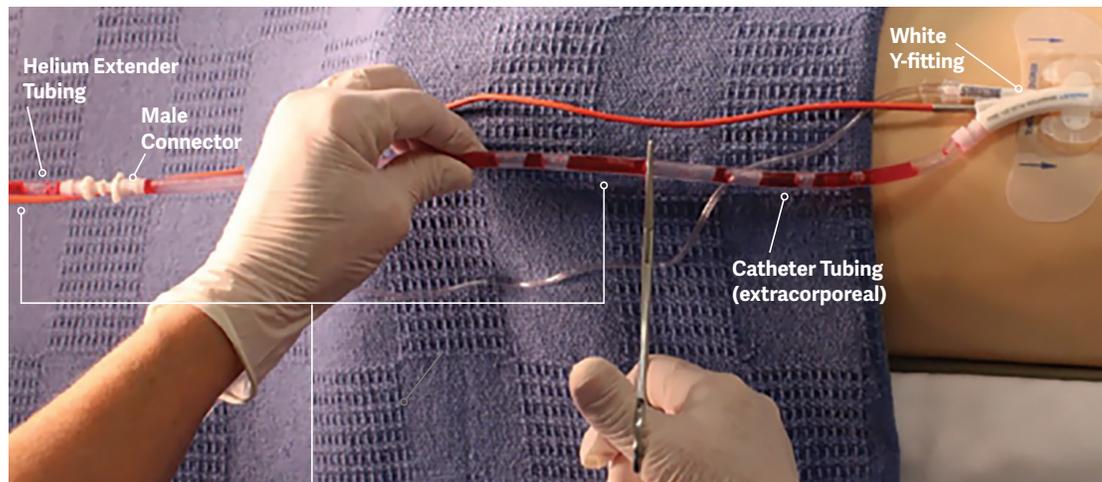
Suspected IAB Catheter Perforation Indicators

Evidence of IAB Catheter Perforation

- Blood or fluid may be seen in IAB catheter tubing (extracorporeal) and/or helium extender tubing
- Sudden change in diastolic augmentation pressure
- IABP alarms

Alarms that *may* indicate IAB Catheter Perforation

- Blood Suspected – Check Catheter and Tubing
- Autofill Failure
- Gas Loss in IAB Circuit
- Gas Gain in IAB Circuit
- IAB Catheter Restriction



Blood or fluid may be seen in IAB catheter tubing (extracorporeal) and/or helium extender tubing as evidenced by:

- **Bright red blood**
- **Dried blood particles**
- **Serosanguineous fluid**

Suspected IAB Catheter Perforation Management

If blood is seen, or if the alarm “Blood Suspected – Check Catheter and Tubing” is active, follow these steps immediately:

1 Standby



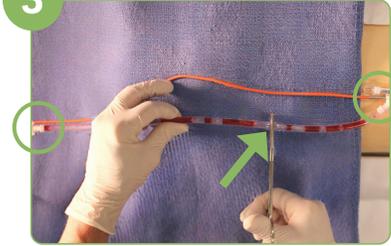
If not in Standby, press Standby key to stop pumping

2 Disconnect



Disconnect helium extender tubing from back of pump

3 Clamp



Clamp IAB catheter tubing between white Y-fitting and male connector

4 Notify

Notify physician and prepare for removal and IAB catheter replacement if patient condition warrants

5 Next Steps

If blood is suspected of entering the IABP:

- To continue therapy, replace IAB catheter and obtain a new IABP

If blood is not suspected of entering the IABP:

- Replace IAB catheter if patient condition warrants

- To continue using the **same IABP**, reset the “Blood Suspected - Check Catheter and Tubing” alarm:
 - Power off IABP
 - Wait 10 seconds, power on IABP
 - Press Start to resume pumping

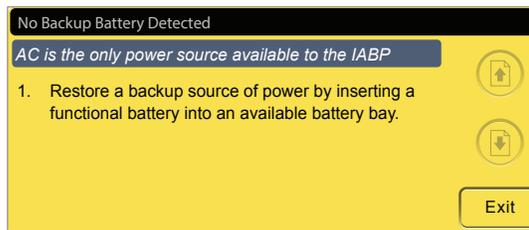
Alarms and Troubleshooting

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



Pause Audio

- Press **Pause Audio** to temporarily suspend a 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 causes and corrective actions for the alarm

Alarms and Troubleshooting

Types of Alarms	Alarm Icon	Alarm Information
Technical Alarms		<ul style="list-style-type: none"> Indicates an IABP electrical hardware failure and are the highest priority alarms Pumping suspended and sounds a continuous alarm tone
High Priority Alarms		<ul style="list-style-type: none"> Indicates a situation that requires immediate intervention Pumping suspended for most High Priority Alarms
Medium Priority Alarms		<ul style="list-style-type: none"> Indicates a situation that requires prompt intervention Pumping is not suspended but may indicate a need for corrective action
Low Priority Alarms		<ul style="list-style-type: none"> Indication that user awareness is required
Informational Messages		<ul style="list-style-type: none"> Provides information to the user and displays textual messages Some messages include an audio tone

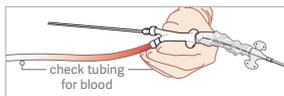
Technical Alarm



Pump Failure – Service Required

Probable Cause

IABP inoperable due to blood entering the IABP console, blood seen in IAB catheter tubing (extracorporeal) and/or helium extender tubing



Corrective Action

- Disconnect the helium extender tubing from IABP console to allow the balloon to deflate
- Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector
- Notify physician and prepare for IAB catheter removal
- Consider IAB catheter replacement if the patient condition warrants
- Remove affected pump from service and have it evaluated by biomedical or technical service before using it on another patient

IABP inoperable, no blood seen

- Therapy may continue with a replacement IABP
- Remove affected pump from service and have it evaluated by biomedical or technical service
- The IABP cannot be used on another patient until serviced

Technical Alarm



System over Temperature

Probable Cause	Corrective Action
The system has detected an over temperature condition	<ul style="list-style-type: none">• Turn the IABP OFF by pressing and holding the 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 biomedical or technical service

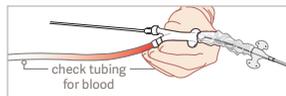
High Priority Alarm



Blood Suspected – Check Catheter and Tubing

Probable Cause

IAB catheter perforation, blood seen in IAB catheter tubing (extracorporeal) and/or helium extender tubing



Corrective Action

- Disconnect the helium extender tubing from IABP console to allow the balloon to deflate
- Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector
- Notify physician and prepare for IAB catheter removal
- Consider IAB catheter replacement if the patient condition warrants
- If blood is suspected of having entered the pump, remove affected pump from service and have it evaluated by biomedical or technical service before using it on another patient

Alarm triggered without blood seen in IAB catheter tubing (extracorporeal) and/or helium extender tubing

- Turn IABP OFF by pressing and holding the green IABP **Power** Button for 2 seconds
- Wait 10 seconds, then turn the IABP ON by pressing and releasing green IABP **Power** Button
- Press the **Start** key to initiate an Autofill and resume therapy
- If another “Blood Suspected – Check Catheter and Tubing” alarm is activated, there is a likelihood the IAB is perforated even if blood is not seen in the IAB catheter tubing (extracorporeal) and/or helium extender tubing
 - Therapy should be stopped or the IAB catheter replaced as deemed appropriate by the clinician

Catheter is replaced, and blood is not suspected of entering the IABP console

- Turn IABP OFF by pressing and holding green IABP **Power** Button for 2 seconds
- Wait 10 seconds, then turn the IABP ON by pressing and releasing the green IABP **Power** Button
- Press the **Start** key to fill the IAB catheter and resume pumping

High Priority Alarm

Augmentation Below Limit Set

Probable Cause

Change in the patient's hemodynamic status

Corrective Action

- 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

Timing error

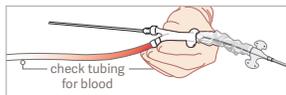
- Assess for late inflation and/or early deflation and correct if necessary

High Priority Alarm

Augmentation Below Limit Set (continued)

Probable Cause

Potential IAB catheter perforation



Corrective Action

Check for evidence of blood in the tubing. If blood is seen or perforation is suspected, perform the following procedure:

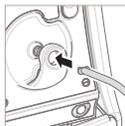
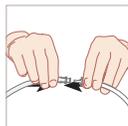
- Disconnect the helium extender tubing from the IABP console to allow the balloon to deflate
- Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector
- Notify physician and prepare for IAB catheter removal
- Consider IAB catheter replacement if the patient condition warrants
- If blood suspected of having entered the pump, take affected pump out of service and have it evaluated by biomedical or technical service before using it on another patient

High Priority Alarm

IAB Disconnected

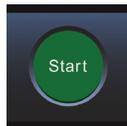
Probable Cause

IAB catheter (extracorporeal) or helium extender tubing is disconnected



Corrective Action

- Reattach IAB catheter tubing (extracorporeal) or helium extender tubing, press **Start**



High Priority Alarm

IAB Catheter Restriction

Probable Cause

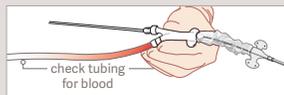
There is a restriction or kink in the IAB catheter or tubing



Corrective Action

- Check the IAB catheter tubing (extracorporeal) and helium extender tubing for restriction or kink, and relieve if possible
- If no kink or restriction is noted in tubings, consider an internal catheter kink or restriction
 - Obtain a radiographic examination to confirm
- Press the **Start** key to resume pumping

Potential IAB catheter perforation



If blood is seen or perforation is suspected, perform the following procedure:

- Disconnect the helium extender tubing from the IABP console to allow the balloon to deflate
- Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector
- Notify physician and prepare for IAB catheter removal
- Consider IAB catheter replacement if the patient condition warrants
- If blood suspected of having entered the pump, take affected pump out of service and have it evaluated by biomedical or technical service before using it on another patient

High Priority Alarm



IAB Catheter Restriction (continued)

Probable Cause	Corrective Action
IAB membrane is not completely unfolded immediately after insertion	<ul style="list-style-type: none">• Aspirate to assure blood is not drawn into the IAB catheter tubing (extracorporeal)• Using a syringe, manually inflate and deflate the IAB with 30 mL of air through the male luer of the IAB catheter tubing (extracorporeal)• Press the Start key to initiate an Autofill and initiate pumping
IAB catheter remains in the sheath immediately after insertion	<ul style="list-style-type: none">• Check the markings on the IAB catheter to confirm the balloon has fully exited the sheath<ul style="list-style-type: none">– 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

High Priority Alarm



Autofill Failure

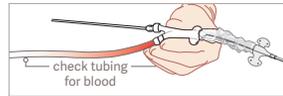
Probable Cause

IABP cannot fill the IAB catheter system

Corrective Action

Check for evidence of blood in the tubing. If blood is seen or perforation is suspected, perform the following procedure:

- Disconnect the helium extender tubing from the IABP console to allow the balloon to deflate
- Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector
- Notify physician and prepare for IAB catheter removal
- Consider IAB catheter replacement if the patient condition warrants
- If blood suspected of having entered the pump, take affected pump out of service and have it evaluated by biomedical or technical service before using it on another patient



If blood is not seen, perform the following procedure:

- Ensure only one correctly sized helium extender tubing is connected to the IAB catheter and the IABP
- Ensure there are no restrictions in the IAB catheter tubing (extracorporeal) or helium extender tubing
- Press **Start** to initiate an Autofill and resume pumping
- If alarm persists, replace IABP and remove affected pump from service to be evaluated by biomedical or technical service before use on another patient

High Priority Alarm



Gas Loss in IAB Circuit

Probable Cause	Corrective Action
A helium loss has been detected due to a potential IAB catheter perforation	<p>Check for evidence of blood in the tubing. If blood is seen or perforation is suspected, perform the following procedure:</p> <ul style="list-style-type: none">• Disconnect the helium extender tubing from the IABP console to allow the balloon to deflate• Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector• Notify physician and prepare for IAB catheter removal• Consider IAB catheter replacement if the patient condition warrants• If blood suspected of having entered the pump, take affected pump out of service and have it evaluated by biomedical or technical service before using it on another patient
A helium loss has been detected due to a leak or high rate of diffusion in the IAB Circuit	<ul style="list-style-type: none">• Ensure the IAB helium extender tubing is tightly connected to the IAB catheter tubing (extracorporeal) 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 <div data-bbox="495 735 631 871"></div> <div data-bbox="647 735 784 871"></div> <div data-bbox="800 735 937 871"></div>

Medium Priority Alarm

No Pressure Source Available

Probable Cause	Corrective Action
No DIRECT or EXTERNAL arterial pressure source connected	<ul style="list-style-type: none"> • Ensure Fiber-Optic Sensor Connector is connected • If transducer in use, ensure Red Adapter Cable is connected to Arterial Pressure Transducer Cable and IABP • If arterial pressure source unavailable from catheter, connect an alternate arterial source (e.g., radial arterial line) or connect an interface cable from an external patient monitor to IABP
Arterial Pressure transducer vented to atmosphere for more than 10 seconds	<ul style="list-style-type: none"> • Check stopcock to ensure transducer is closed to atmosphere
Pressure monitoring tubing has become disconnected	<ul style="list-style-type: none"> • Verify monitoring tubing is securely connected
Pressure monitoring lumen may be clotted	<ul style="list-style-type: none"> • Attempt to aspirate • If unable to aspirate, discontinue use of IAB inner lumen <ul style="list-style-type: none"> – Cap off lumen to prevent further attempts to use – Connect an alternate arterial source (e.g., radial arterial line) or connect an interface cable from an external patient monitor to IABP • If alternate arterial pressure source is not available, override the alarm by pressing the Disable Pulsatile Test in the Sources Menu
Defective pressure transducer or transducer cable	<ul style="list-style-type: none"> • Replace transducer or transducer cable • If alarm persists, provide an alternate arterial pressure source • If an alternate arterial pressure source is not available, override the alarm by pressing the Disable Pulsatile Test key in the Sources menu <ul style="list-style-type: none"> – For more information on the Disable Pulsatile Test, refer to the Cardiosave Operating Instructions

Low Priority Alarm



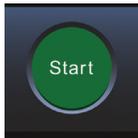
Unable to Update Timing

Probable Cause	Corrective Action
Poor waveform quality	<ul style="list-style-type: none">• Check cable connections• If transducer is in use, verify transducer stopcock is not vented and in proper position• While in Standby, aspirate and flush IAB inner lumen arterial pressure line in an attempt to improve waveform quality• If problem persists, switch to Semi Auto<ul style="list-style-type: none">– Verify trigger and proper timing, resume pumping by pressing Start
Sustained heart rate is less than 30 BPM or greater than 150 BPM	<ul style="list-style-type: none">• Switch to Semi Auto, verify Trigger Source, adjust timing, resume pumping
Poor diastolic augmentation	<ul style="list-style-type: none">• If diastolic augmentation is poor, when Augmentation level is set to MAX, attempt to improve patient's hemodynamic status

Informational Messages

Prolonged Time in Standby

Probable Cause	Corrective Action
IABP has been in Standby mode for an extended period of time	<ul style="list-style-type: none">• Verify whether it is appropriate to resume pumping• Press the Start key to resume pumping



Note: Getinge 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

Informational Messages

Checking for Balloon Perforation

Probable Cause

IAB is evaluating the IAB catheter and tubing for the loss of helium during Autofills, most high priority alarms, and while in Standby

Corrective Action

- No corrective action needed
- If a loss of helium is suspected, a check for balloon perforation will be completed

Informational Messages

No Balloon Perforation Detected

Probable Cause

The IABP did not detect a balloon perforation at the time of the check

Corrective Action

- If “Gas Loss in IAB Circuit” occurred, press and hold the IAB fill key for 2 seconds
 - Then press START to resume pumping
- or
- For all other alarms, press START to resume pumping

Medium Priority Alarm



Fiber-Optic Sensor Failure

Probable Cause	Corrective Action
There is a failure in the communication of the Fiber-Optic Sensor signal with the IABP	<ul style="list-style-type: none">• 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 arterial pressure source (e.g., radial arterial line)

Informational Messages

Fiber-Optic Sensor Module Failure

Probable Cause	Corrective Action
There has been a failure of the internal Fiber-Optic Sensor Module in the IABP	<ul style="list-style-type: none">• 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/Maquet IABP that supports the Fiber-Optic IAB• If replacement IABP is not available, provide alternate arterial pressure source (e.g., radial arterial line)• Contact biomedical or technical service for Fiber-Optic Sensor Module repair

Informational Messages

Unable to Calibrate Fiber-Optic Sensor

Probable Cause	Corrective Action
Patient's pulse pressure is inadequate for calibration	<ul style="list-style-type: none"> When patient's pulse pressure improves, press Calibrate Pressure key for 2 seconds while IABP is assisting Provide alternate arterial pressure source (e.g., radial arterial line)
Extender tubing or balloon catheter may be restricted	<ul style="list-style-type: none"> Relieve restriction Attempt calibration by pressing Calibrate Pressure key for 2 seconds while IABP is assisting

Informational Messages

Fiber-Optic Sensor Calibration Postponed

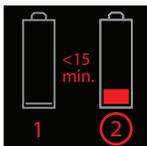
Probable Cause	Corrective Action
A non-scheduled calibration update has been intentionally postponed because either patient's mean arterial pressure may be too low to pause assist or less than 15 minutes have elapsed since last calibration	<ul style="list-style-type: none"> Assess patient to determine if a brief pause in assist would be tolerated, and if so, press Calibrate Pressure key for 2 seconds while IABP is assisting
Pump is in Standby	<ul style="list-style-type: none"> Resume pumping, then press Calibrate Pressure key for 2 seconds to initiate a calibration

High Priority Alarm



Icon displayed

Battery icon turns red when less than 15 minutes of battery operated time remains



Action

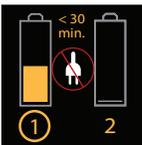
- Connect to AC power source immediately
- If AC power source unavailable, insert a new charged battery

Medium Priority Alarm



Icon displayed

Battery icon turns yellow when less than 30 minutes of battery operation time remains



Action

- Connect to AC power source immediately
- If AC power source unavailable, insert a new charged battery

High Priority Alarm

Battery Charge Level Unavailable Bay #__

Probable Cause	Corrective Action
The battery in the identified bay or bays is unable to communicate the battery charge level	<ul style="list-style-type: none"> Immediate battery replacement is required Replace the battery that is currently in use <ul style="list-style-type: none"> – 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

Medium Priority Alarm

Multiple AC Power Sources Detected

Probable Cause	Corrective Action
The IABP is connected to multiple AC power sources	<ul style="list-style-type: none"> Disconnect the IABP from the unused AC power source

Battery Informational Messages

Battery Maintenance Required Bay #___

Probable Cause

The battery in the identified bay requires maintenance

Corrective Action

- 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 Informational Messages

Battery Replacement Required Bay #___

Probable Cause

The battery in the identified bay or bays has become unreliable and requires replacement

Corrective Action

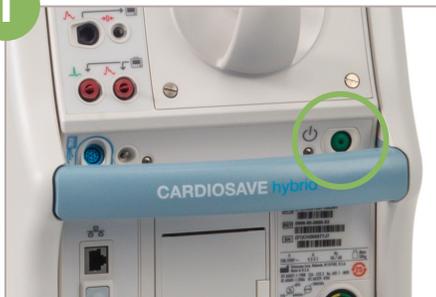
- Battery replacement is required
- Continue operation on AC power
- If battery operation on the indicated battery is required, the battery run time will be reduced
 - Monitor the system for a Low Battery alarm
- If a Low Battery alarm occurs, immediately replace the battery or return to AC power
- Contact Getinge Service to obtain a new battery

Alarm Related Suspension or Unexpected Shutdown

Do not proceed if IAB catheter perforation is suspected. If blood is seen in IAB catheter tubing (extracorporeal) and/or helium extender tubing refer to page 26 for IAB catheter perforation management

If pressing the Start key did not resume therapy after an alarm:

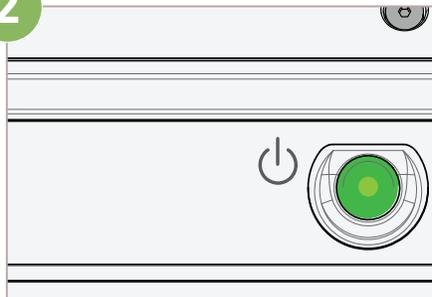
1 Power off



Press and hold power button for 2 sec.

- The LED will flash for 10 seconds
- Once the LED stops flashing, the unit is ready for use

2 Power on



Press power button

3 Alarm reoccurs



If alarm reoccurs, replace IABP if available

- Take affected pump out of service and have it evaluated by biomedical or technical service before using it on another patient

If pump has unexpectedly shutdown and unable to power on:

- Obtain a replacement IABP if available
- Take affected pump out of service and have it evaluated by biomedical or technical service before using it on another patient

Warnings:

In hospital settings, a backup Cardiosave should be available in case the device in use is compromised, as is common practice with life-saving equipment

Helium Alarms

Low Helium

Probable Cause

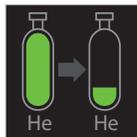
The Helium Tank is closed

Corrective Action

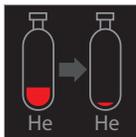
- Open the Helium Tank

There are fewer than 24 Autofills of helium remaining in the tank

- Replace the Helium Tank



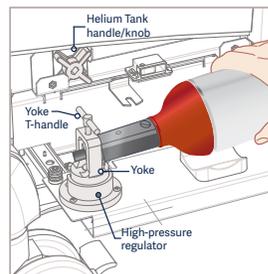
Adequate helium supply



Low helium supply

Helium Tank General Maintenance

- Ensure Cardiosave 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

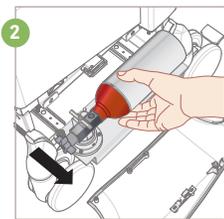


Changing the Helium Tank



1a Grasp both sides of Helium Tank panel and

1b Pull out to open

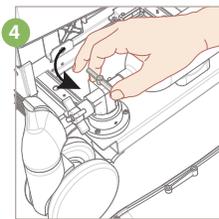


2 Grasp Helium Tank and slowly slide drawer out

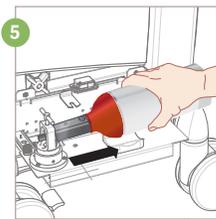


3a Remove Helium Tank knob from holder and

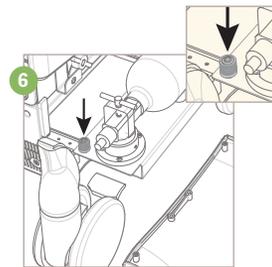
3b Attach to Helium Tank and turn to close



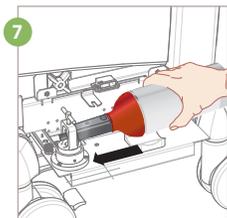
4 Slowly loosen Yoke T-handle counter-clockwise (some helium may escape)



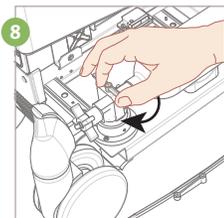
5 Remove Helium Tank



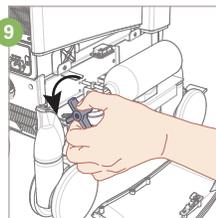
6 Replace washer, if available



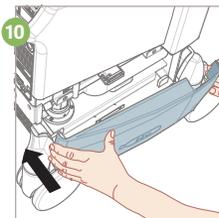
7 Install new Helium Tank



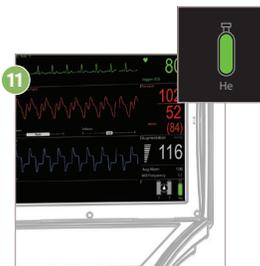
8 Fully tighten Yoke T-handle clockwise



9 Slowly open Helium Tank knob counter-clockwise (listen for any escaping helium)



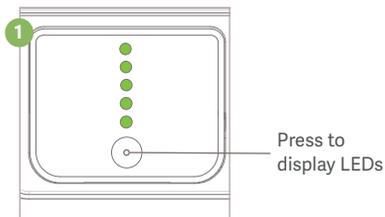
10 Slide Helium Tank drawer in and replace Helium Tank Panel



11 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 Battery



Battery is approximately 100% charged

Note: Each LED represents a charge of approximately 20%

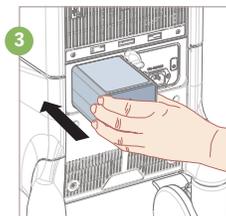
Changing the Battery



Turn knob to remove battery from Battery Bay



Slide battery out



Slide charged battery in

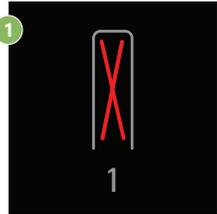


While holding battery in bay, turn knob to lock battery in place

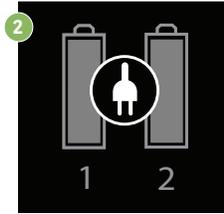


Use care to avoid dropping the battery

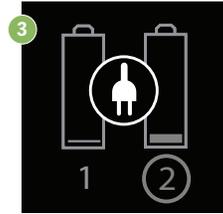
Viewing Battery Status on Monitor Display (examples)



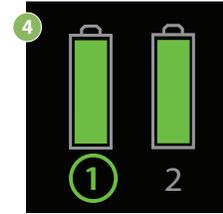
Empty Battery Bay, no backup battery or Transport Power Supply detected in Battery Bay



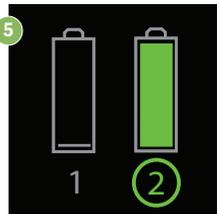
Plugged into AC power source and batteries are fully charged



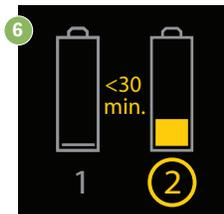
IABP has been plugged into AC power source, battery 1 is depleted and battery 2 is being charged



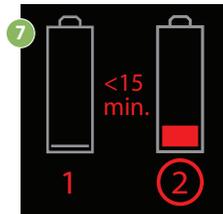
Lit green circle indicates battery 1 is in use, battery 2 is fully charged and available for use when battery 1 is depleted



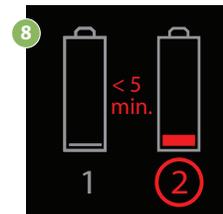
Battery 1 is depleted, thus battery 2 is currently being used



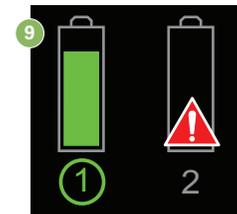
Battery 1 is depleted and battery 2 has less than 30 minutes of charge remaining (Low Battery message is displayed)
Caution: Prompt attention is needed to either insert fully charged batteries or plug into AC power source



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



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



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

Note: Low Battery alarm appears when 30 minutes or less of battery life remains. The battery icon shows empty and an audible tone sounds every 30 seconds. When only 15 minutes remain on the battery currently in use, a High Priority Low Battery alarm activates. Refer to the User Maintenance section in the Operating Instructions for details

Connecting an Arrow IAB 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/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 – Refer to the Arrow Operating Instructions

Connecting a Getinge IAB 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 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/Maquet IABP in Standby and disconnect IAB helium extender tubing from back of IABP
- Connect Arrow Pump Adapter (APA) to male luer fitting of Getinge IAB helium extender tubing and connect to Arrow IABP
- Refer to the Arrow Operating Instructions for the appropriate balloon settings

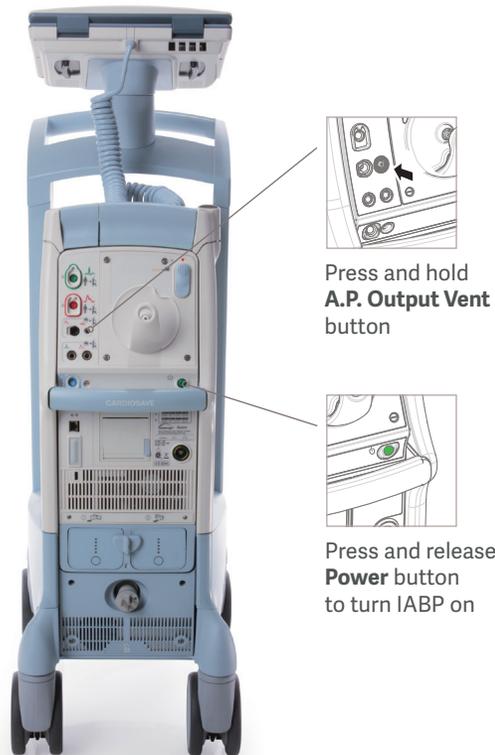
Note: The APA will not connect to other types of pumps

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 the setup 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 Service



Cardiosave Cleaning Instructions

For detailed guidance on cleaning Cardiosave, refer to the Cleaning section of Cardiosave Operating Instructions

This process applies to all surfaces of the device, and followed between each use. This includes:

The Pump Console • Hospital Cart • Accessory Cables • Transport Accessories

Approved Cleaning Products:

Note:

- Replace wipes or swabs. Use only quaternary-based disinfectants that are free from alcohol, bleach, acid, phenol, acetone, and ammonia – such as Sani-Cloth AF3
- Replace wipes or swabs when dry or soiled

Phase I: Pre-Cleaning

1. Ensure IABP is powered off
2. Unplug from AC power source
3. Remove all batteries
4. Release latch on Hospital Cart and remove Pump Console

If contaminated or visibly soiled:

5. Remove all gross soil and clean all surfaces with germicidal wipes.
6. Use low-lint swabs with disinfectant, for tight spaces, crevices, buttons, seams, and vent grates

Phase II: Pre-disinfection Cleaning

1. Clean all surfaces again with fresh germicidal wipes and low-lint swabs using a top-to-bottom, clean-to-dirty method
2. Inspect and repeat if visible soil remains
3. Remove disinfectant residue with a lint-free cloth moistened with warm deionized water
4. Allow to air dry completely

Phase III: Disinfection

1. Clean all surfaces again with fresh germicidal wipes using an "S" pattern for larger areas
2. Use fresh low-lint swabs with disinfectant for tight spaces, crevices, buttons, seams, and vent grates
3. Let disinfectant remain wet on surfaces for at least three minutes
4. Remove remaining disinfectant residue with a lint-free cloth moistened with warm deionized water

Post Disinfection and Air Drying

1. Allow to air dry completely before proceeding
2. Reinsert Pump Console into hospital cart
3. Reinstall batteries
4. Plug into AC power and verify batteries are charging

Warning:

Always use standard precautions (i.e., protective eye wear and gloves) when cleaning and disinfecting the system to prevent contact with blood or other potentially infectious materials

Caution: Do not apply cleaner/disinfectant directly on the unit. Use pre-moistened lint free wipes or cloths instead

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