CARDIOSAVE® IABP Operation – Transport

Quick Reference Guide

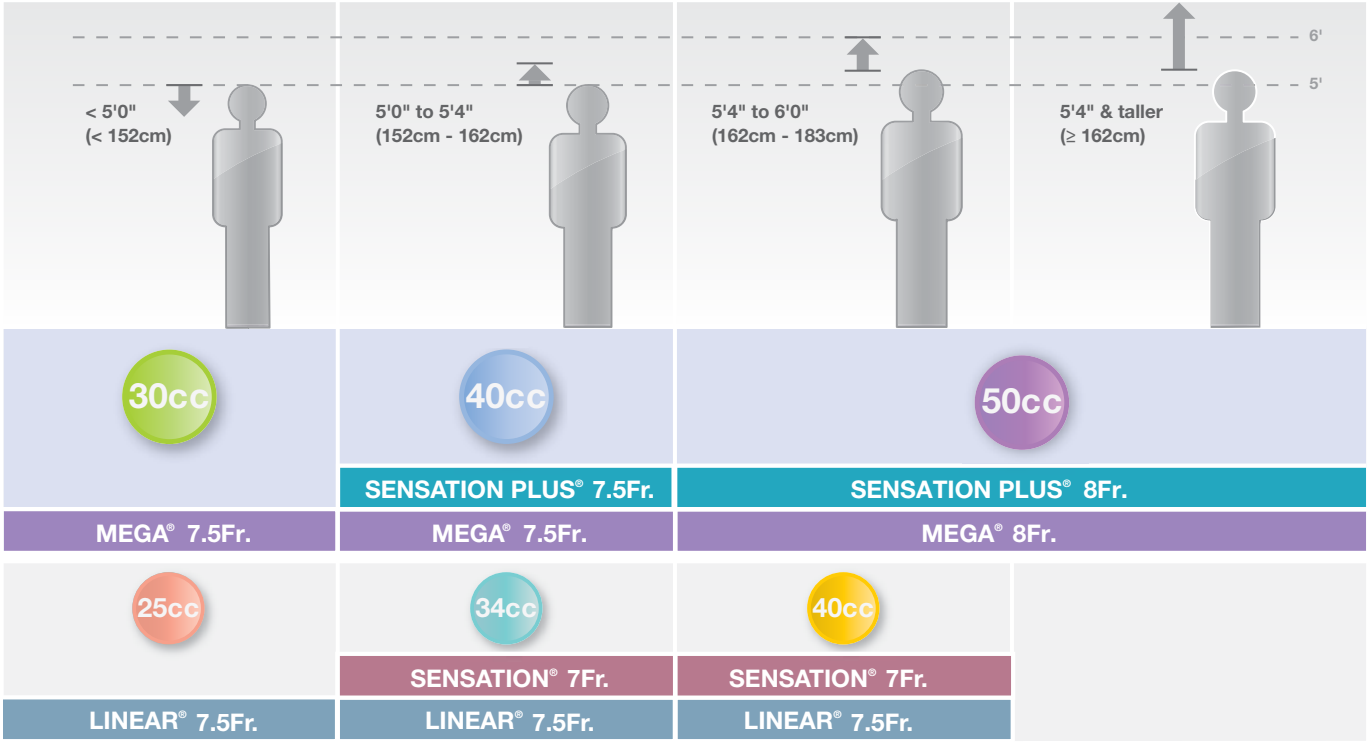
MAQUET
GETINGE GROUP



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

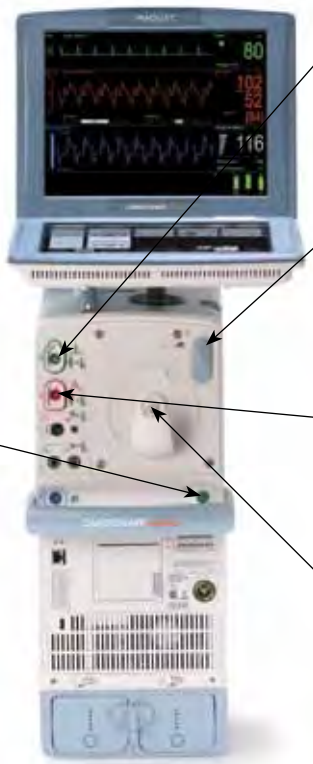
Intra-aortic Balloon

Reference 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.

CARDIOSAVE Rescue Initial Set-up



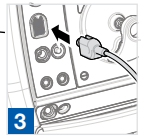


Connect ECG cable.



Connect fiber-optic sensor connector for Maquet/Datascope fiber-optic IAB.

OR



Connect pressure cable for conventional IAB.



Press POWER button to turn IABP ON.



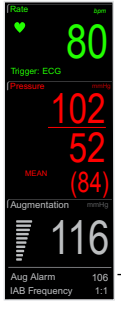
Connect IAB.

Initial Set-up using a Maquet/Datascope Fiber-optic IAB (continued)



Verify
AUTO

Press
START

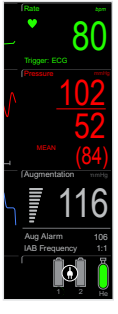


Verify Aug. Alarm is set 10mmHg below patient's augmented diastolic pressure (approx. 3 minutes after initiation of assist).

Pressing the START key

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

Note: With a Maquet/Datascope 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.



Check fill status of the helium tank.
A fully charged internal helium reservoir will provide approximately 36 fill cycles.

Initial Set-up using a Conventional IAB (continued)





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

Verify **AUTO**

Press **START**

Pressing the START key

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

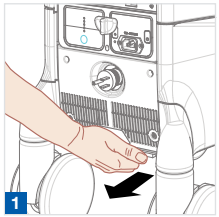
Portable Operation

Maquet/Datascope Corp. recommends:

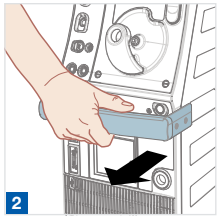
- Sufficient supply of fully charged batteries for use during transport.
- Use of the Transport Power Supply for AC operation during transport.
- Verifying internal helium reservoir is full when using the Transport System.
- System must be properly secured in the transport vehicle.



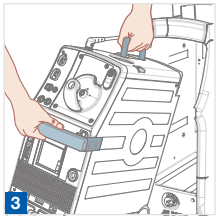
Removing Pump Console from the Cart



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



Grab handle and slowly slide console out.



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

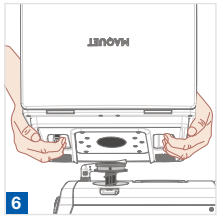




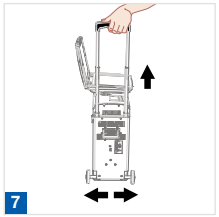
4a Push button to release pop-up mount.
4b Pull UP pop-up mount to lock in place.



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.

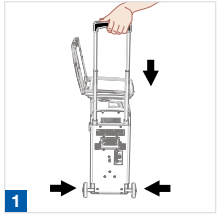


Squeeze latch below handle and lift straight up until wheels extend outward and handle locks into extended position.

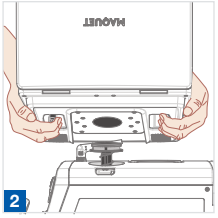


Tilt Transport System on wheels and begin transport.

Inserting the Pump Console into the Hospital Cart



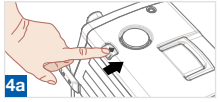
Squeeze latch below handle. Push straight down until wheels retract and handle is fully collapsed.

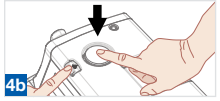


Squeeze latches located below Monitor and lift to remove from Pump Console.

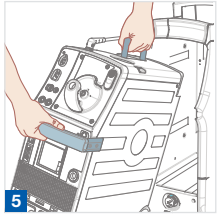


Squeeze latches and attach to display mount, then release the latches. Ensure monitor is securely attached.

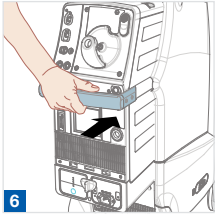




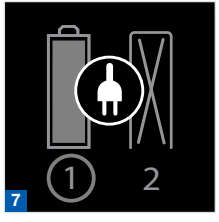
4a Push and hold button on console to unlock monitor mount.
4b Push down to lock into place, then release button.



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.

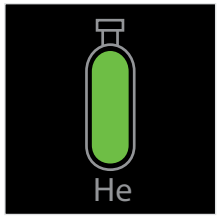


To ensure console was successfully installed into cart, plug Hospital Cart power cord into a compatible grounded AC receptacle. Confirm AC operation by presence of AC Plug Icon in the Battery Icon Display Area. If AC Plug Icon is not present:

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

Helium Supply

Ensure the internal helium reservoir is full before using CARDIOSAVE for transport.



Helium tank icon displays a full tank.

If the helium icon is not showing full, the following actions should be taken:

CARDIOSAVE Hybrid:

- Return the pump console to the hospital cart for a minimum of 30 seconds.
- Ensure the helium icon indicates full.
- Remove pump console from cart and continue with transport (refer to page 6).

CARDIOSAVE Rescue:

- Attach the Helium Refilling Station for a minimum of 30 seconds.
- Ensure the helium icon indicates full.
- Disconnect Helium Refilling Station and continue with transport.

Caution: The Helium Refilling Station is not intended for use in transport. It is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.



Helium Refilling Station

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

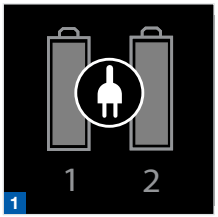
Note: The supply of helium in the internal helium reservoir will deplete more rapidly when an autofill is performed when the system is powered on, when the catheter is disconnected and reconnected or when an autofill is performed due to a gas loss, catheter disconnect, or autofill failure alarm.

Effects of altitude changes during air transportation

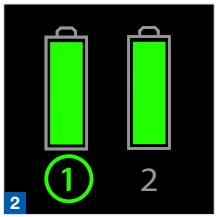
For proper operation during air transport, IABP balloon pressure must adapt to local atmospheric pressure. The system will automatically purge and fill the IAB when local atmospheric pressure decreases by 25mmHg or increases by 50mmHg.

These pressure changes occur approximately every 1,000 feet (305 meters) of increase in altitude or 2000 feet (610 meters) of decrease in altitude.

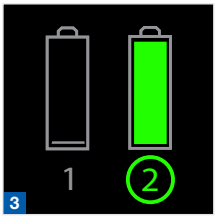
Viewing Battery Status on Monitor Display (examples)



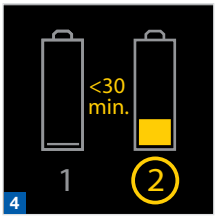
Plugged into AC power outlet and batteries are fully charged.



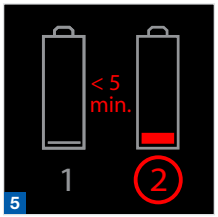
Lit green circle indicates battery 1 is in use. Battery 2 is fully charged and available for use when battery 1 is depleted.



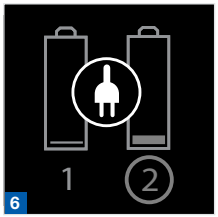
Battery 1 is depleted, thus battery 2 is currently being used.



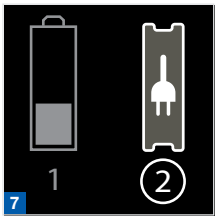
Battery 2 has less than 30 minutes of charge remaining (Low Battery message is displayed).



Battery 2 has less than 5 minutes of charge remaining.

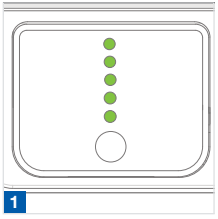


IABP has been plugged into AC power outlet and battery 2 is being charged.



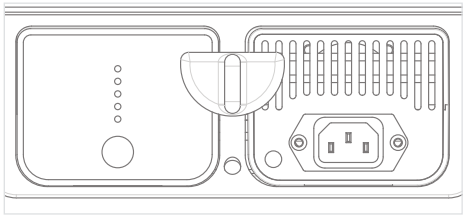
Transport Power Supply installed in Battery Bay #2 is plugged into AC receptacle and is in use. The battery in Battery Bay #1 is not being charged.

Viewing Battery Status on Battery



Battery is approximately 100% charged.

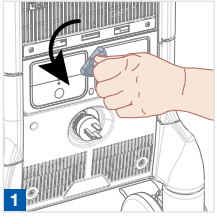
Note: Each LED represents a charge of approximately 20%. Battery run time: approximately 90 minutes each.



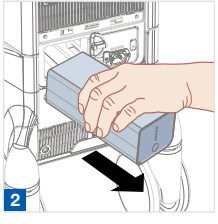
Battery installed in Battery Bay 1.

Transport Power Supply installed in Battery Bay 2.

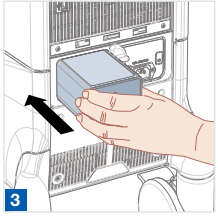
Changing the Battery



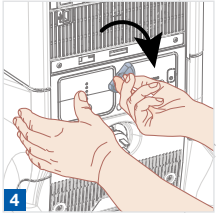
Turn knob to remove battery from Battery Bay.



Slide battery OUT.

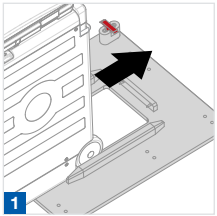


Slide charged battery IN.

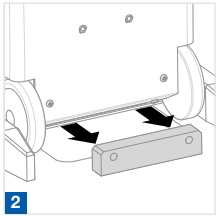


While holding battery in bay, turn knob to lock battery in place.

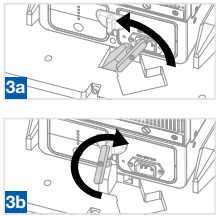
IAB Transport Fixation with the Mounting Plate



Center CARDIOSAVE on open end of Transport Mounting Plate. Ensure pump's wheels are fully retracted before rolling into position on the plate.



Roll CARDIOSAVE into Transport Mounting Plate between guide tracks until seated on guide pins and firmly braced against rear track.



Lift swing bolt into upright position.

Turn bolt clockwise until tight. Ensure CARDIOSAVE is firmly locked in place.

Technical Specifications

Weight*

	kg	lbs
Monitor	3.6	8
Battery Pack (0146-00-0097)	1.4	3
Pump Console	17.7	39
Transport Configuration (including monitor and pump console with 2 batteries)	24.1	53

* *All weights ± 5%*

Dimensions

Transport and Display	
Display Closed	57.2cm H x 40.6cm D x 33.0cm W 22.5" H x 16" D x 13" W
Display Open 90°	78.0cm H 30.7" H

Operating Ambient

Operating Temperature	10° C to 40° C (50° F to 104° F)
Operating Humidity	15% to 85% Relative Humidity (non-condensing)
Operating Altitude	-1250 feet to 12,000 feet (795 mmHg to 483 mmHg) (1060 hPa to 644 hPa)

CARDIOSAVE Operation Modes

Auto Operation Mode

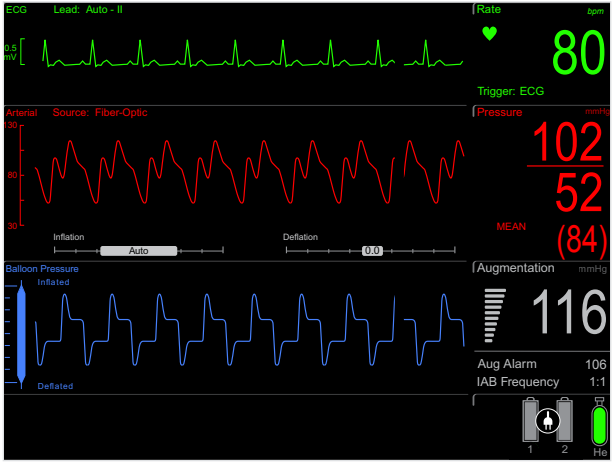
- Automatic lead and trigger selection
- Automatic and continuous inflation and deflation timing management
  - User has ability to fine-tune deflation timing
- Automatic management of irregular rhythms
- Automatic *in vivo* calibration (when using a Maquet/Datascope fiber-optic IAB)

Semi-Auto Operation Mode

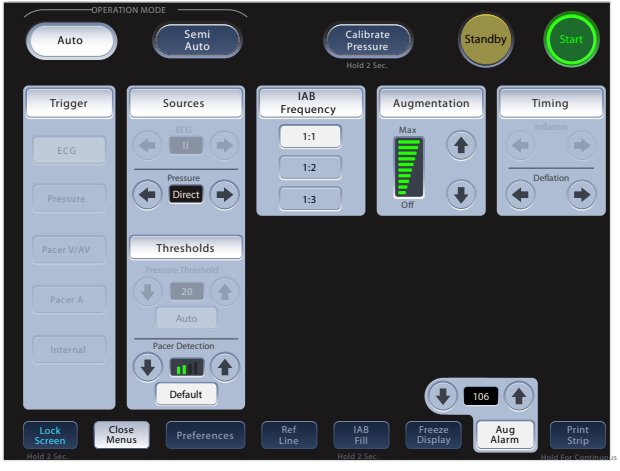
- Operator selects most appropriate lead and trigger source
- Operator establishes timing, then CARDIOSAVE automatically adjusts timing with heart rate and rhythm changes
- Automatic management of irregular rhythms
- Automatic *in vivo* calibration (when using a Maquet/Datascope fiber-optic IAB)



CARDIOSAVE Monitor Display and Touchscreen

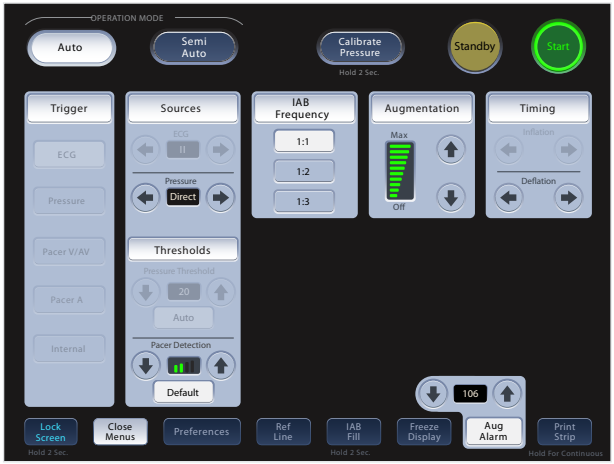


Monitor Display



Touchscreen

CARDIOSAVE Lock Screen Feature



Touchscreen Unlocked

Touchscreen will **Lock**:

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





Touchscreen Locked

Touchscreen will **Unlock**:

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



CARDIOSAVE Triggers

Triggering

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



CARDIOSAVE Triggers



ECG

Trigger event is the R-Wave

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



Pressure

Trigger event is the systolic upstroke

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

Pacer V/AV

Trigger event is the Ventricular pacer spike

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

Pacer A

Trigger event is the R-Wave

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

Internal

Trigger event is asynchronous at a fixed rate of 80 BPM

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

Theory of Counterpulsation Therapy



Inflation: increases supply of oxygen to the myocardium.

How it works

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

Benefits

- Increases coronary artery perfusion
- Increases mean arterial pressure



Deflation: decreases demand for oxygen by the left ventricle.

How it works

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

Benefits

- Decreases afterload
- Decreases cardiac workload
- Increases cardiac output

Timing

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

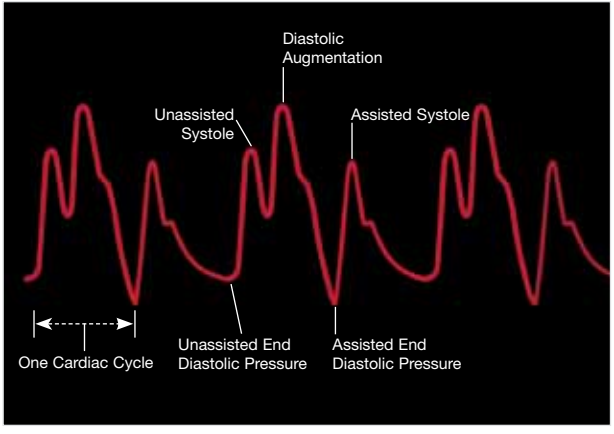
Proper IABP Timing

Inflation

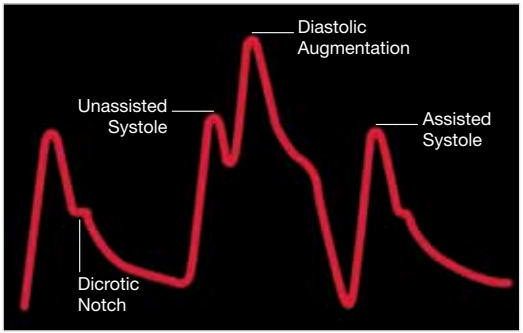
- Occurs at the dicrotic notch
- Appears as a sharp “V”
- Ideally diastolic augmentation rises above systole

Deflation

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



Timing Errors



Early Inflation

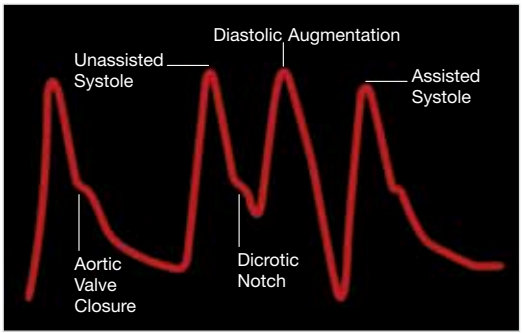
Inflation of IAB prior to aortic valve closure.

Waveform characteristics

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

Physiologic Effects

- Potential premature closure of aortic valve
- Potential increase in LVEDV/LVEDP/PCWP
- Increased left ventricular wall stress or afterload
- Aortic regurgitation
- Increased MVO_2 demand



Late Inflation

Inflation of IAB markedly after closure of aortic valve.

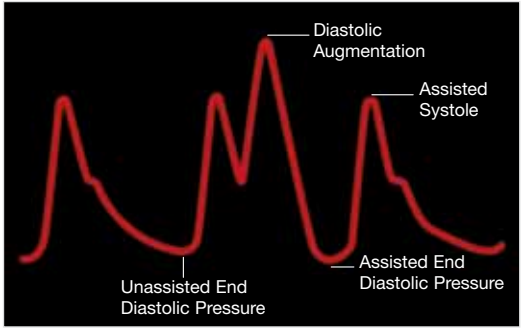
Waveform characteristics

- Inflation of IAB after dicrotic notch
- Absence of sharp “V”
- Sub-optimal diastolic augmentation

Physiologic Effects

- Sub-optimal coronary artery perfusion

Timing Errors



Early Deflation

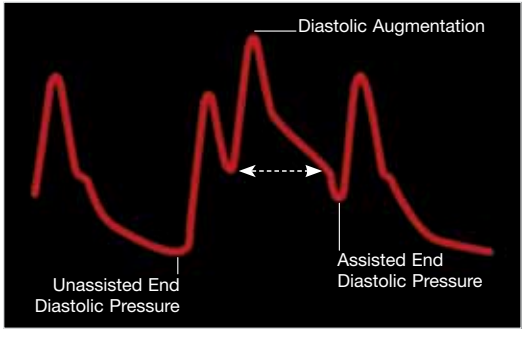
Premature deflation of IAB during diastolic phase.

Waveform characteristics

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

Physiologic Effects

- Sub-optimal coronary perfusion
- Potential for retrograde coronary and carotid blood flow
- Angina may occur as a result of retrograde coronary blood flow
- Sub-optimal afterload reduction
- Increased MVO_2 demand



Late Deflation

Deflation of IAB after aortic valve has opened.

Waveform characteristics

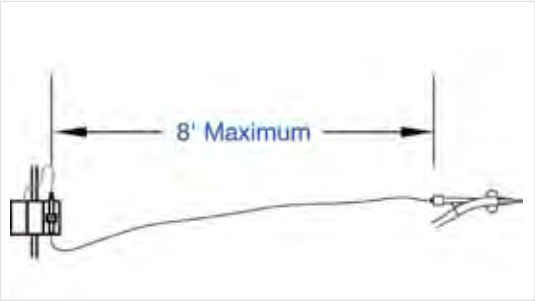
- Assisted end diastolic pressure may be equal to or higher than unassisted end diastolic pressure
- Rate of rise of assisted systole is prolonged
- Diastolic augmentation may appear widened

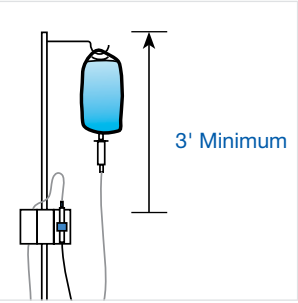
Physiologic Effects

- Afterload reduction is essentially absent
- Increased MVO_2 consumption due to left ventricle ejecting against a greater resistance and a prolonged isovolumetric contraction phase
- IAB may impede left ventricular ejection and increase afterload

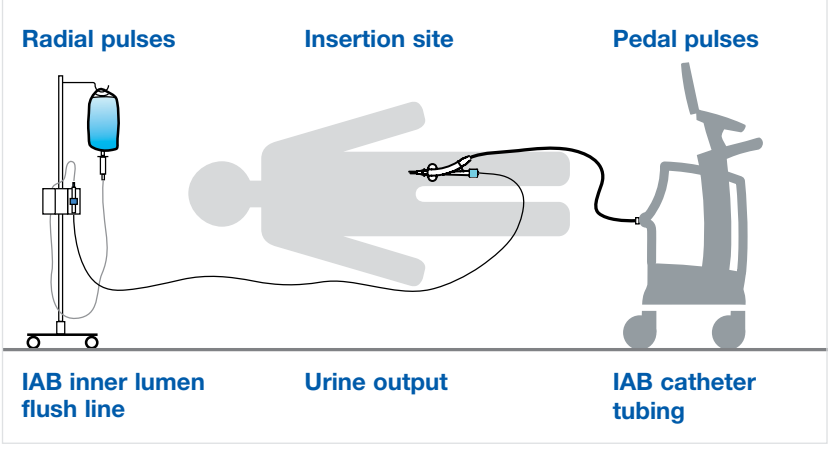
Proper Care of Inner Lumen

- Minimize length of pressure tubing
- Use **only** low compliance pressure tubing
- Elevate flush bag at least 3′ (91.44cm) above transducer
- A 3cc/hour continuous flow through inner lumen is recommended
- If inner lumen becomes damped
  - Aspirate and discard 3cc of blood
  - If **unable** to aspirate blood, consider inner lumen clotted, cap lumen, provide alternate pressure source
  - If **able** to aspirate blood, fast flush to clear pressure tubing for **at least 15 seconds** (with IABP on Standby)
- **Do not** sample blood from inner lumen





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.

Alarms

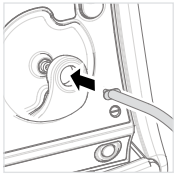
Augmentation Below Limit Set

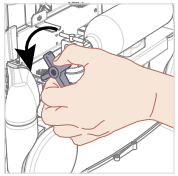




Probable Cause	Corrective Action
Hemodynamic status has changed: ↑HR, ↓SV, ↓MAP.	Attempt to optimize patient's hemodynamic status.
Alarm limit set too high.	Press AUG. ALARM key, decrease limit.

Autofill Failure





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

Alarms

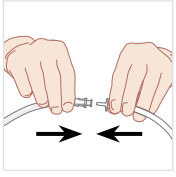
IAB Catheter Restriction

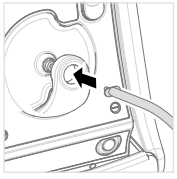




Probable Cause	Corrective Action
Restriction in IAB catheter or tubing.	Relieve restriction if possible, press START.
Membrane has not completely unfolded.	Manually inflate and deflate IAB.
IAB remains in sheath.	Check markings on IAB and if IAB has not exited sheath, refer to IFU to reposition sheath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

IAB Disconnected







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

Alarms

Prolonged Time in Standby





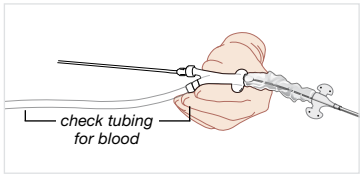
Probable Cause	Corrective Action
IABP has been in STANDBY for at least 10 minutes.	Verify whether it is appropriate to resume pumping.

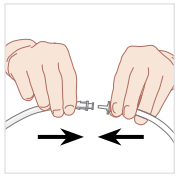
Note: The IAB catheter should not remain inactive (i.e., not inflating and deflating) for more than 30 minutes because of the potential for thrombus formation.

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

1. Detach catheter extender from IAB catheter's male luer fitting.
2. Attach the supplied 3-way stopcock and syringe to IAB catheter's male luer fitting.
3. Aspirate to assure blood is not returned through extracorporeal tubing.
4. Inflate IAB with 40cc air or helium and immediately aspirate. Repeat every 5 minutes while IAB is inactive.
5. Remove 3-way stopcock and syringe and reattach IAB catheter's male luer fitting to catheter extender and resume pumping.

Gas Loss in IAB Circuit







Probable Cause	Corrective Action
A helium loss has been detected in IAB circuit.	If blood observed - STOP pumping. Prepare for removal of IAB. If blood is not observed, verify connections are tight. If appropriate, perform an Autofill, then press START to resume pumping.

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

Alarms

Unable to Update Timing

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

Unable to Calibrate Fiber-Optic Sensor

Probable Cause	Corrective Action
Patient's pulse pressure is inadequate for calibration.	When patient's pulse pressure improves, press CALIBRATE PRESSURE key for 2 seconds while IABP is assisting. Provide alternate A.P. source (i.e.: radial).
Extender tubing or balloon catheter may be restricted.	Relieve restriction. Attempt calibration by pressing CALIBRATE PRESSURE key for 2 seconds while IABP is assisting.

Fiber-Optic Sensor Calibration Postponed

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

Alarms

Fiber-Optic Sensor Module Failure

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

Fiber-Optic Sensor Failure

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

Connecting an Arrow IAB/IABP To a Maquet/Datascope 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 Maquet/ Datascope 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 Maquet/Datascope IABP
- Set-up Maquet/Datascope IABP per abbreviated instructions on page 3 of this Quick Reference Guide

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

Transferring Facility

- This patient will have a Maquet/Datascope IAB connected to a Maquet/ Datascope IABP
- Before leaving facility, locate Arrow Pump Adapter (APA) that connects a Maquet/Datascope IAB to an Arrow IABP (may be supplied in Maquet/ Datascope 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 Maquet/Datascope IABP on Standby and disconnect IAB catheter extender tubing from back of IABP
- Connect Arrow Pump Adapter (APA) to male luer fitting of Maquet/ Datascope IAB catheter extender tubing and connect to Arrow IABP
- Adjust volume setting on Arrow IABP, according to Operating Instructions, to match IAB catheter volume

CARDIOSAVE Symbols

ICON	DESCRIPTION
	Patient
	IABP
	Alternating Current (AC)
	Battery
	On/Off
	Trainer

ICON	DESCRIPTION
	Patient Monitor
	ECG
	Pressure
	Fiber-Optic Connection Indicator
	Fiber-Optic Cable
	Vent

ICON	DESCRIPTION
	Technical Alarm
	High Priority Alarm
	Medium Priority Alarm
	Low Priority Alarm
	Audio Paused
	Alarm Inhibited (off)
	Alarm Inhibited (paused)

Notes





Notes

Notes



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