

QUICK REFERENCE GUIDE
IAB INSERTION / CS300™ OPERATION

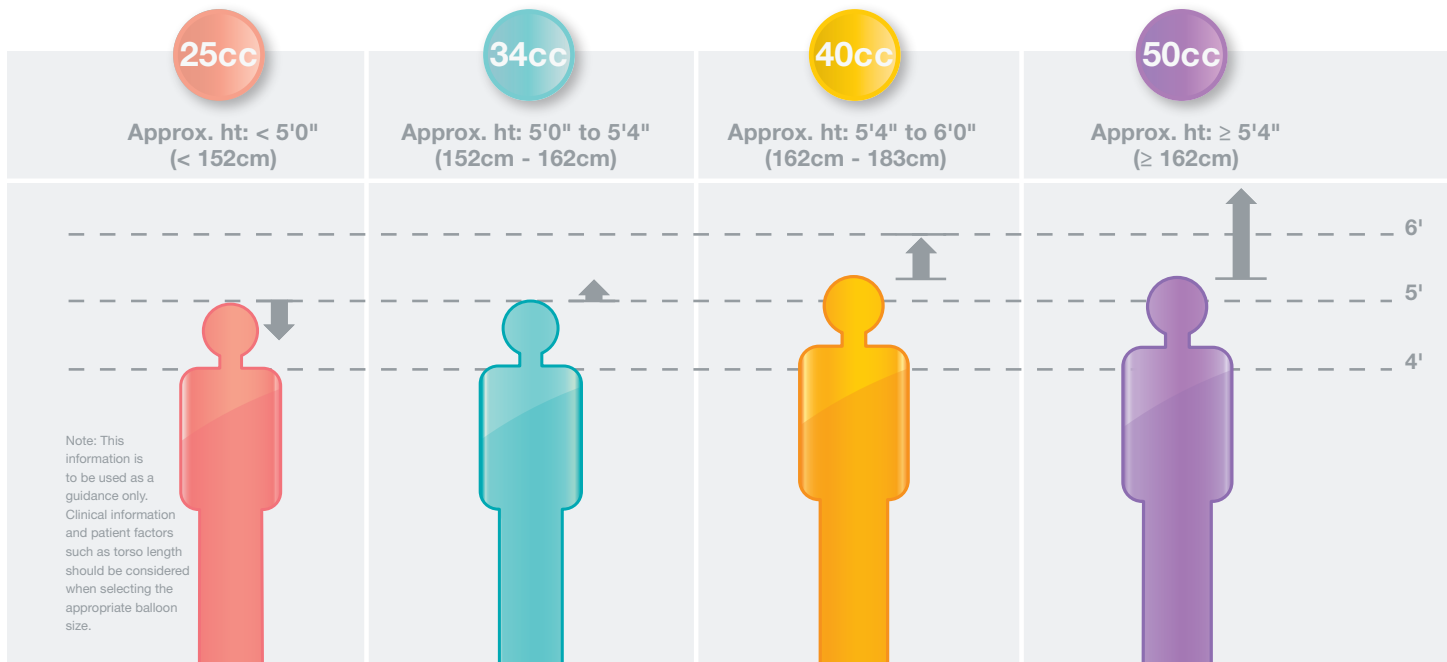
MAQUET
GETINGE GROUP

CARDIOVASCULAR



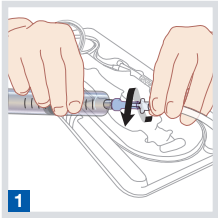
*Note: This is an abbreviated guide.
For complete instructions, refer to IAB
Instructions for Use and CS300 Operating
Instructions.*

INTRA-AORTIC BALLOON REFERENCE SIZING GUIDE

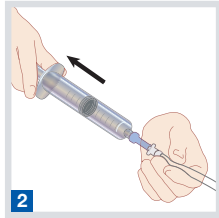


MEGA® AND LINEAR® IAB CATHETER

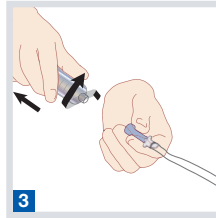
Preparing the IAB Catheter



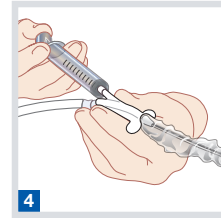
Firmly attach one-way valve to male luer fitting of IAB catheter.



Apply a 30cc vacuum.



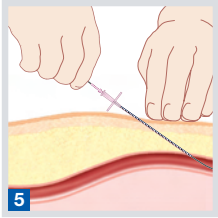
Remove syringe while keeping one-way valve in place.



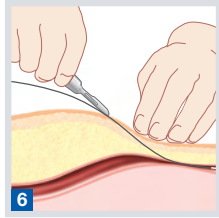
Remove stylet, then manually flush inner lumen with 3-5cc of flush solution.

MEGA AND LINEAR IAB CATHETER

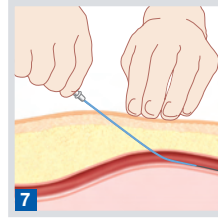
Sheathless Insertion



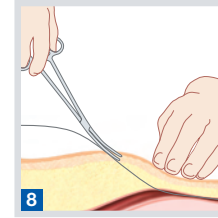
Insert needle at 45° angle or less, then insert 0.025" (0.06cm) guidewire.



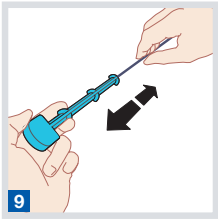
Make small incision at exit of guidewire.



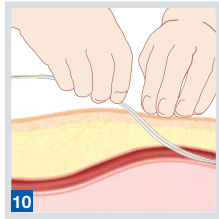
Insert vessel dilator over guidewire, tapered end first, then remove.



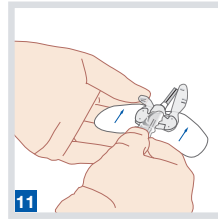
Spread tissue at incision to facilitate sheathless insertion.



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



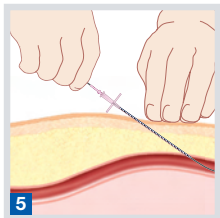
Advance IAB catheter into artery using short strokes until correct placement is achieved, then advance sheath seal as close to insertion site as possible.



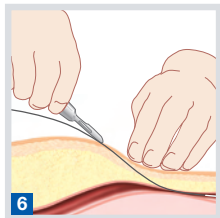
Secure IAB catheter to patient's leg using STATLOCK® Stabilization Device or sutures.

MEGA AND LINEAR IAB CATHETER

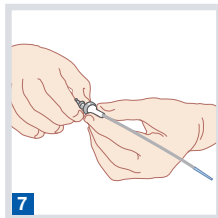
Sheathed Insertion



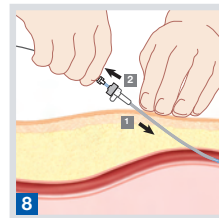
5 Insert needle at 45° angle or less, then insert 0.025" (0.06cm) guidewire.



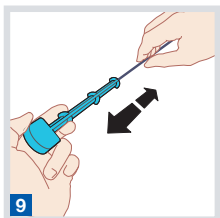
6 Make small incision at exit of guidewire.



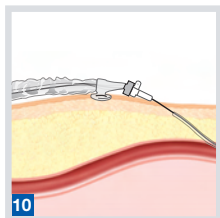
7 Insert introducer dilator into sheath hub and twist lock in place to secure.



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



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



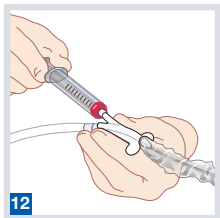
10 Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



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

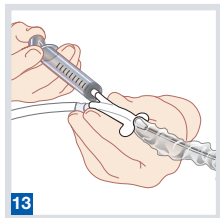
MEGA AND LINEAR IAB CATHETER

Pressure Monitoring Set-Up



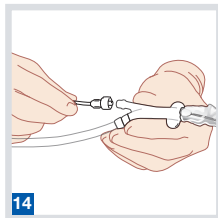
12

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



13

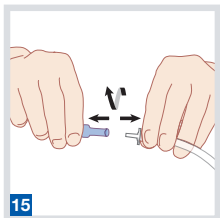
Manually flush inner lumen with 3-5cc of flush solution.



14

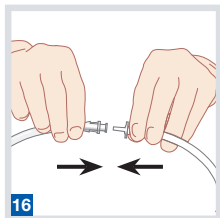
Attach a standard arterial pressure monitoring apparatus.

Connection to IABP



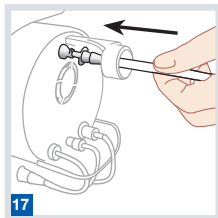
15

Remove one-way valve from IAB catheter.



16

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

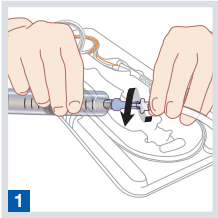


17

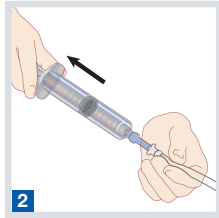
Connect male luer fitting to Safety Disk of IABP.

SENSATION PLUS™ AND SENSATION® IAB CATHETER

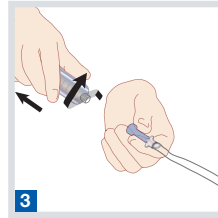
Preparing the IAB Catheter



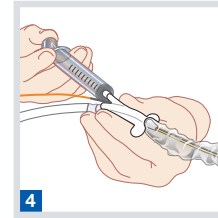
Firmly attach one-way valve to male luer fitting of IAB catheter.



Apply a 30cc vacuum.



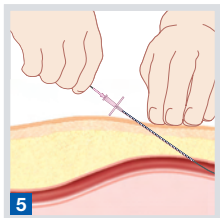
Remove syringe while keeping one-way valve in place.



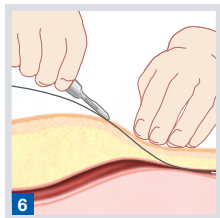
Remove stylet, then manually flush inner lumen with 3-5cc of flush solution.

SENSATION PLUS AND SENSATION IAB CATHETER

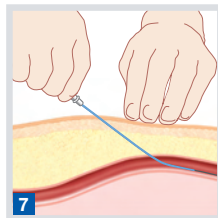
Sheathless Insertion



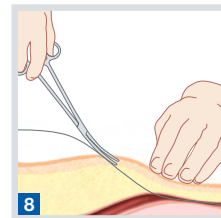
5
Insert needle at 45° angle or less, then insert guidewire (8Fr. IAB: 0.025" (0.06cm) / 7Fr. IAB: 0.018" (0.05cm).



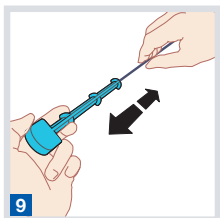
6
Make small incision at exit of guidewire.



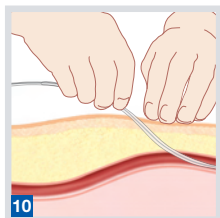
7
Insert vessel dilator over guidewire, tapered end first, then remove.



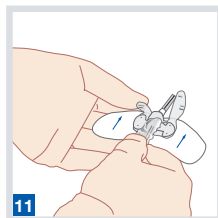
8
Spread tissue at incision to facilitate sheathless insertion.



9
Remove IAB catheter from T-handle by pulling STRAIGHT out to avoid damaging it. Do not dip, wipe, or handle membrane prior to insertion.



10
Advance IAB catheter into artery using short strokes until correct placement is achieved, then advance sheath seal as close to insertion site as possible.

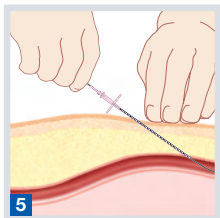


11
Secure IAB catheter to patient's leg using STATLOCK® Stabilization Device or sutures (SENSATION PLUS includes STATLOCK® in IAB box).

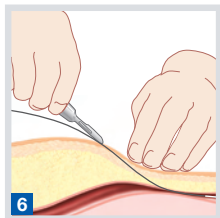
Note: Continue on page 10, step #13.

SENSATION PLUS AND SENSATION IAB CATHETER

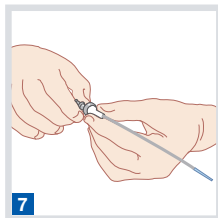
Sheathed Insertion



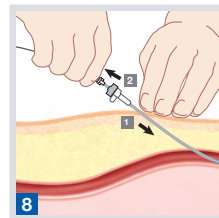
Insert needle at 45° angle or less, then insert guidewire (8Fr. IAB: 0.025" (0.06cm) / 7Fr. IAB: 0.035" (0.09cm)).



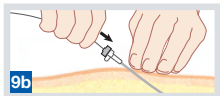
Make small incision at exit of guidewire.



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

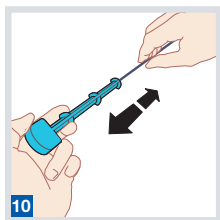


- 1 Advance sheath over guidewire into artery using a rotary motion.
- 2 Withdraw introducer dilator leaving sheath in place.

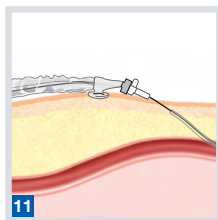


7Fr. IAB only:

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



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



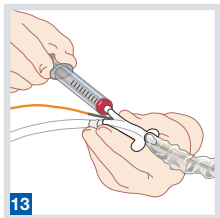
Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.



Secure IAB catheter to patient's leg using STATLOCK® Stabilization Device or sutures (SENSATION PLUS includes STATLOCK® in IAB box).

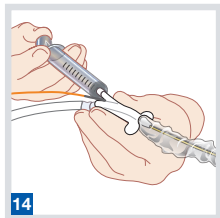
SENSATION PLUS AND SENSATION IAB CATHETER

Pressure Monitoring Set-Up



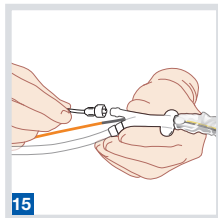
13

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



14

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

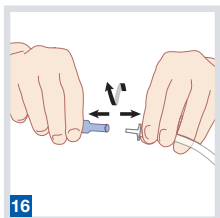


15

Attach a standard arterial pressure monitoring apparatus.

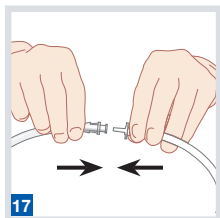
Note: With SENSATION PLUS, a reliable pressure signal may be obtained via the inner lumen, if needed.

Connection to IABP



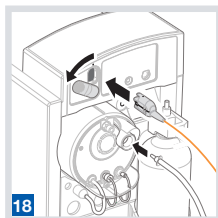
16

Remove one-way valve from IAB catheter.



17

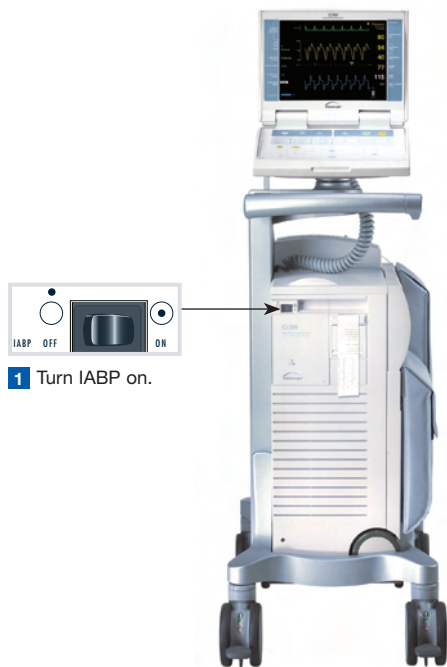
Connect IAB catheter's male luer fitting to female luer fitting of catheter extender.



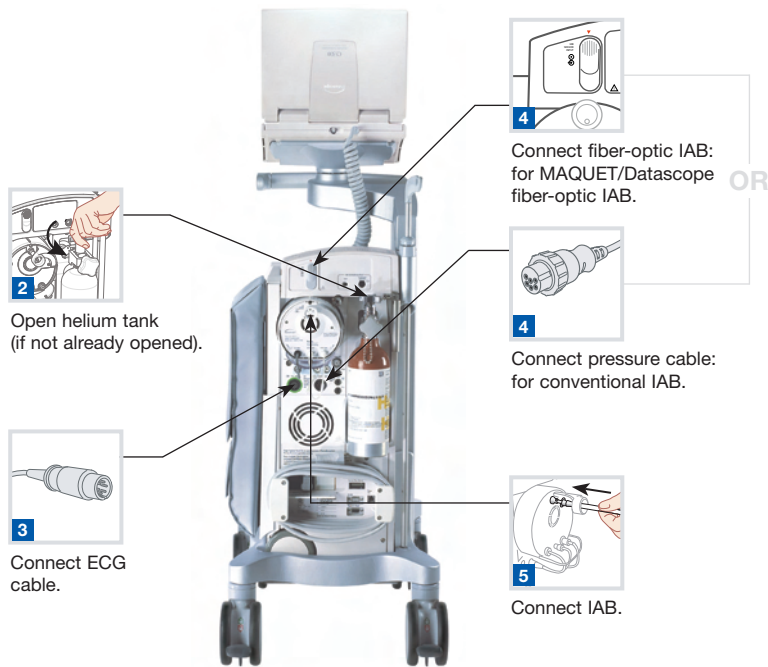
18

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

CS300 INITIAL SET-UP



1 Turn IABP on.



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.

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 ZERO PRESSURE key for 2 seconds, while assisting.

INITIAL SET-UP USING A CONVENTIONAL IAB (CONTINUED)



Verify
AUTO

Press
START



Verify Aug Alarm is set 10mmHg below patient's augmented diastolic pressure.

Pressing the START key

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

CS300 OPERATION MODES

Auto Operation Mode

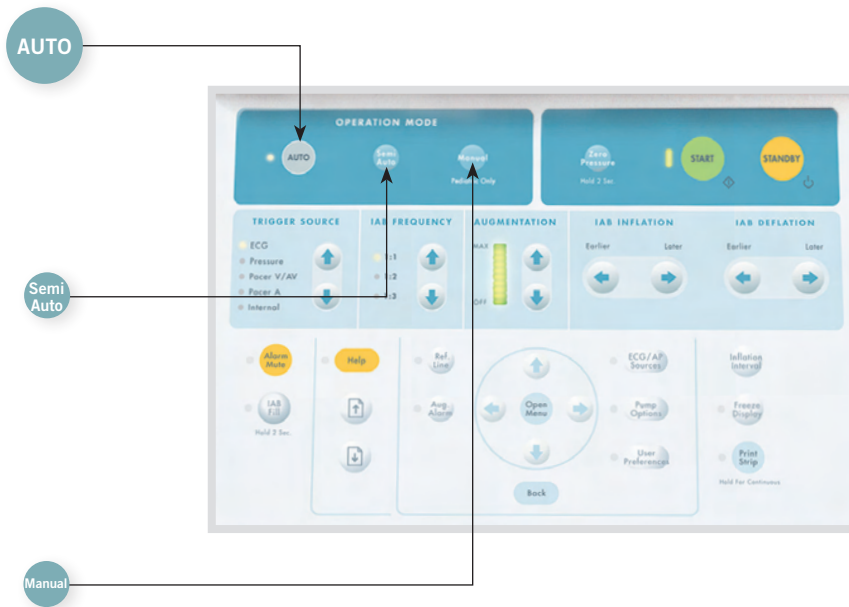
- Automatic lead and trigger selection
- Automatic and continuous inflation and deflation timing management
 - User has ability to fine-tune deflation timing
- Automatic management of irregular rhythms
- Automatic *in vivo* calibration (when using a MAQUET/Datascope fiber-optic IAB)

Semi-Auto Operation Mode

- Operator selects most appropriate lead and trigger source
- Operator establishes timing, then CS300 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)

Manual Operation Mode

- For pediatric use only



CS300 MONITOR AND KEYPAD



TRIGGER SOURCE

- ECG
- Pressure
- Pacer V/AV
- Pacer A
- Internal

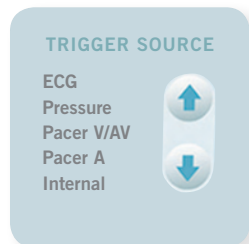
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CS300 TRIGGERS

Triggering

- A Trigger is the signal the CS300 uses to identify the beginning of the next cardiac cycle
- When the CS300 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



CS300 Triggers

ECG

Trigger event is the R-Wave

- Trigger of choice when an adequate R-Wave is present
- Pacer spikes are automatically rejected
- Gain can be adjusted while in Semi-Auto or Manual operation mode



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 or Manual 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 or Manual 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 or Manual 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 or Manual operation mode

THEORY OF COUNTERPULSATION THERAPY



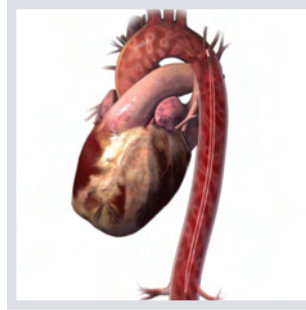
Inflation: increases supply of oxygen to the myocardium.

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.

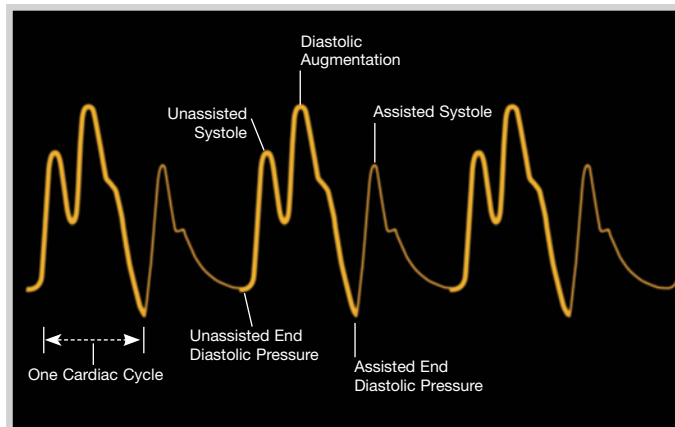
Proper IABP Timing

INFLATION

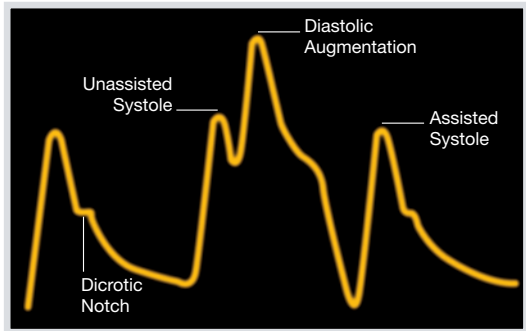
- Occurs at the dicrotic notch
- Appears as a sharp “V”
- Ideally diastolic augmentation rises above systole

DEFLATION

- Occurs just prior to the next systolic event
- Results in a reduction in assisted end diastolic pressure
- Results in a reduction in assisted systolic pressure



TIMING ERRORS



Early Inflation

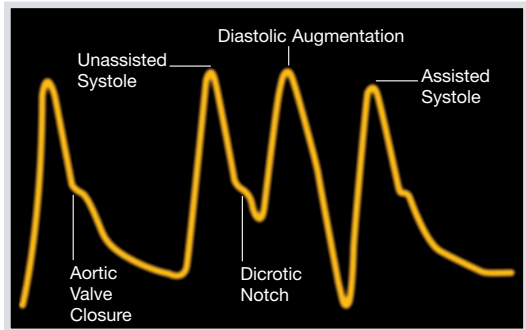
Inflation of IAB prior to aortic valve closure.

Waveform characteristics

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

Physiologic Effects

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



Late Inflation

Inflation of IAB markedly after closure of the aortic valve.

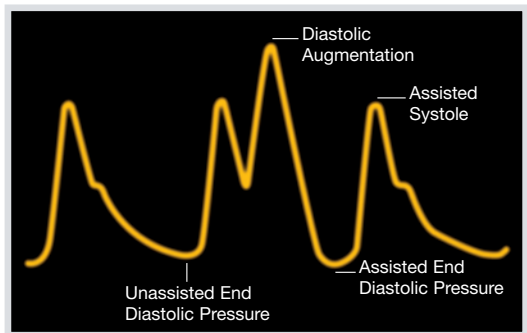
Waveform characteristics

- 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

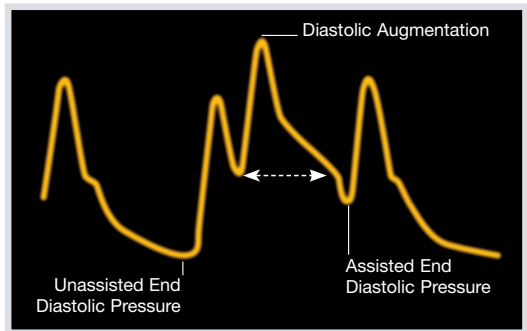
Premature deflation of IAB during diastolic phase.

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

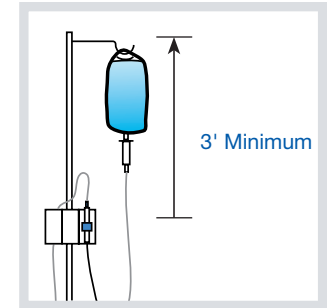
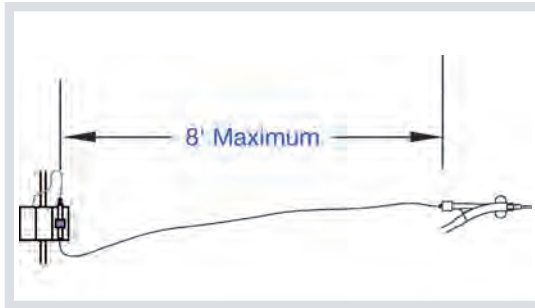
Afterload reduction is essentially absent

Increased MVO_2 consumption due to left ventricle ejecting against a greater resistance and a prolonged isovolumetric contraction phase

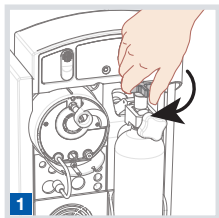
IAB may impede left ventricular ejection and increase afterload

PROPER CARE OF INNER LUMEN

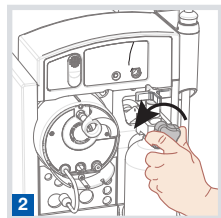
- Minimize length of pressure tubing
- Use **only** low compliance pressure tubing
- Elevate flush bag at least 3' (91.44cm) above transducer
- A 3cc/hour continuous flow through inner lumen is recommended
- If inner lumen becomes damped:
 - Aspirate and discard 3cc of blood
 - If **unable** to aspirate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



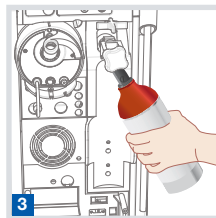
CHANGING THE HELIUM TANK



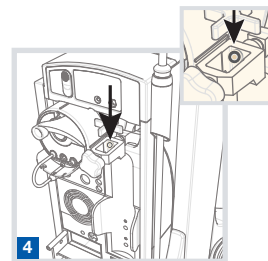
1 Fully close helium tank valve clockwise.



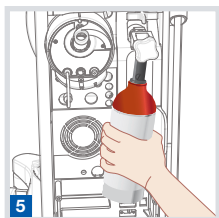
2 Slowly loosen yoke T-handle counter-clockwise.



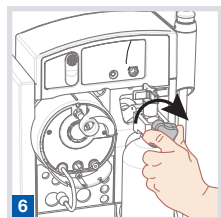
3 Remove helium tank.



4 Replace washer, if available.



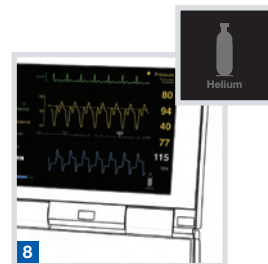
5 Install fresh helium tank.



6 Fully tighten yoke T-handle clockwise.



7 Slowly open helium tank valve counter-clockwise.

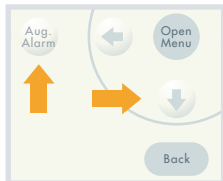
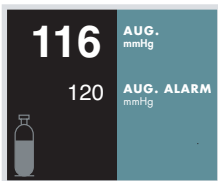


8 Verify full helium level via indicator on monitor display.

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

ALARMS

Augmentation Below Limit Set



Probable Cause

Hemodynamic status has changed: ↑HR, ↓SV, ↓MAP.

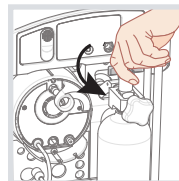
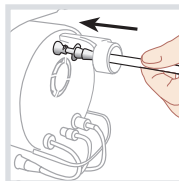
Alarm limit set too high.

Corrective Action

Treat patient, adjust alarm limit as appropriate.

Press AUG. ALARM key, change limit.

Autofill Failure



Probable Cause

IAB disconnected.

Helium tank is closed.

Helium tank is empty.

Incorrect IAB catheter extender tubing length.

Corrective Action

Attach IAB catheter.

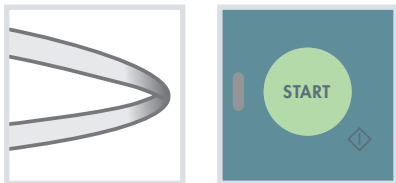
Open helium tank.

Change helium tank.

Ensure only one IAB catheter extender tubing is connected from IAB to pump.

ALARMS

Check IAB Catheter



Probable Cause

Kink in IAB catheter or tubing.

Corrective Action

Relieve kink if possible, press START.

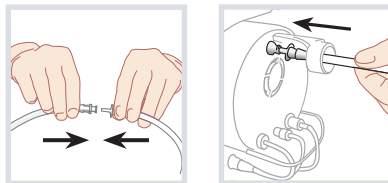
Membrane has not completely unfolded.

Manually inflate and deflate IAB.

IAB remains in sheath.

Check the markings of the IAB and withdraw sheath if indicated.

IAB Disconnected



Probable Cause

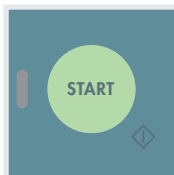
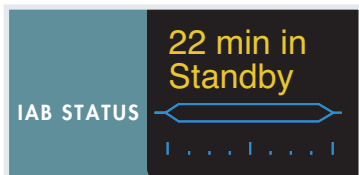
IAB catheter or extender tubing is disconnected.

Corrective Action

Reattach IAB, press START.

ALARMS

Prolonged Time in Standby



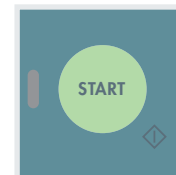
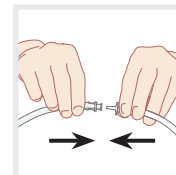
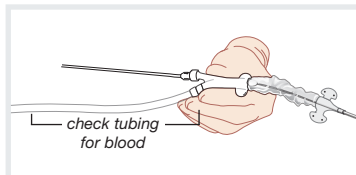
Probable Cause

IABP has been in STANDBY mode for an extended period of time.

Corrective Action

Verify whether it is appropriate to resume pumping.

Rapid Gas Loss or Leak in IAB Circuit



Probable Cause

Gas loss has been detected in IAB circuit.

Corrective Action

If blood observed - STOP pumping. Prepare for removal of IAB.

If blood is not observed, verify connections are leak-free.

With Rapid Gas Loss, resume pumping by pressing START key.

With Leak in IAB Circuit, press IAB FILL key for 2 seconds to initiate an AUTOFILL, then resume pumping by pressing START key.

ALARMS

Unable to Calibrate IAB Optical Sensor

Probable Cause	Corrective Action
Patient's pulse pressure is inadequate for calibration.	When patient's pulse pressure improves, press ZERO PRESSURE key for 2 seconds while the 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 ZERO PRESSURE key for 2 seconds while IABP is assisting.
IAB FILL mode is set to MANUAL.	If appropriate, set IAB FILL mode to AUTO via PUMP OPTIONS menu.

IAB Optical Sensor Calibration Expired

Probable Cause	Corrective Action
A 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 ZERO PRESSURE key for 2 seconds while IABP is assisting. Provide alternate A.P. source (i.e.: radial).
Pump is either in STANDBY or the IAB FILL mode is set to MANUAL.	Verify that IAB FILL mode is set to AUTO. Resume pumping, then press ZERO PRESSURE key for 2 seconds to initiate a calibration.

ALARMS

A.P. Optical Sensing Module Failure

Probable Cause

There has been a failure of the A.P. Optical Sensing Module in the pump console.

Corrective Action

Replace CS300, if available.

If replacement pump not available, an alternate A.P. source (i.e.: radial) must be provided.

Contact MAQUET Service for optical module repair.

IAB Optical Sensor Failure

Probable Cause

There has been a failure of the Optical Sensor in the IAB.

Corrective Action

Unplug Sensor Connector and reconnect.

If problem persists, provide alternate A.P. source (i.e.: radial).

Unable to Update Timing

Probable Cause

Poor waveform quality.

Corrective Action

Check cable connections. Verify transducer was not left vented, if in use.

If transducer is in use, aspirate and flush fluid circuit.

If problem persists, switch operation mode to SEMI AUTO, verify TRIGGER SOURCE, adjust timing, resume pumping.

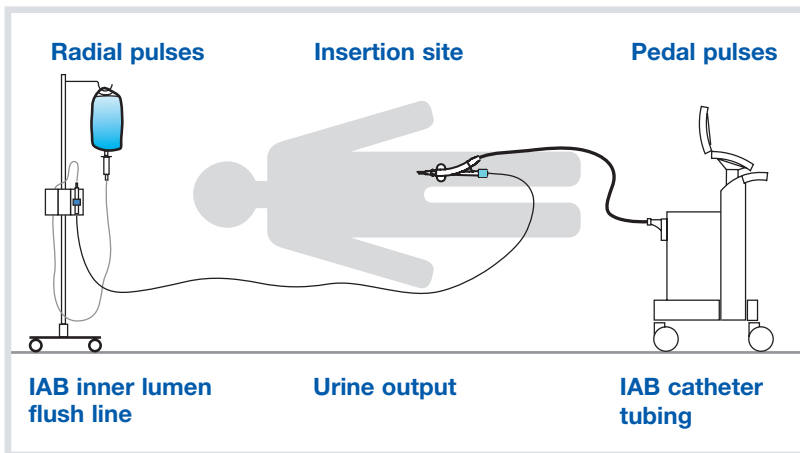
Sustained heart rate is less than 30 BPM or greater than 150 BPM.

Switch to SEMI AUTO, verify TRIGGER SOURCE, adjust timing.

Poor diastolic augmentation.

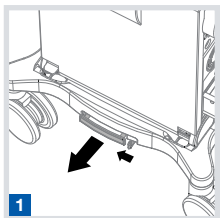
If diastolic augmentation is poor, when AUGMENTATION level is set to MAX, attempt to improve patient's hemodynamic status.

PATIENT ASSESSMENT



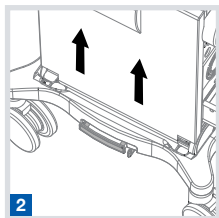
Assessment	Corrective Action
<p>Radial pulses Left radial pulse weak or left arm ischemia.</p>	Check position of IAB.
<p>Insertion site Excessive bleeding from insertion site.</p>	Apply pressure, ensure distal flow.
<p>Pedal pulses Limb ischemia detected.</p>	Consider removing IAB, consider insertion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

REMOVING PUMP CONSOLE FROM THE CART



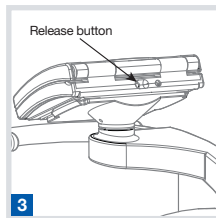
1

Unlock console by pressing tab to right of console release handle and pull handle straight out.



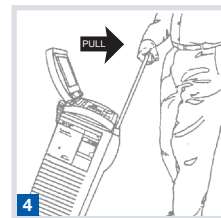
2

Lift pump console straight up and off cart.



3

Detach monitor from cart handle by pressing button on rear of monitor.



4

Attach monitor to top of pump console. Extend console handle until it locks, tilt pump and pull to transport.

PORTABLE OPERATION

Datascope Corp. recommends

- A fully charged battery
- Helium tank is at least 25% full

Effects of altitude changes during air transportation

For proper operation during air transport, IABP balloon pressure must adapt to local atmospheric pressure. In the AUTO FILL mode, the system will automatically purge and fill the IAB when local atmospheric pressure decreases or increases by 25 or 50mmHg, respectively. These pressure changes occur approximately every 1,000 feet of rise or 2,000 feet of drop in altitude.

WARNING: The Auto Fill mode should be used during air transport. If the Auto Fill mode cannot be used and the Manual Fill mode is required, ensure that a Manual Fill is performed at each interval and altitude that an Auto Fill would occur.



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 11 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 this IAB catheter extender tubing 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

SAFETY DISK LEAK TEST

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

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

- Press and hold IAB Fill key while switching IABP ON/OFF to ON. Release IAB Fill key when message LEAK TESTING SAFETY DISK appears in advisory section of screen.
- Using supplied Luer plug, cap IAB Catheter Extender Input when message PLUG DISK OUTLET appears on display. If message UNPLUG DISK OUTLET appears, remove any connections that may exist to IAB Catheter Extender Input.
- A double beep will sound at end of Safety Disk test. If system passes test, the message SYSTEM TEST OK is displayed in advisory section of screen. Remove Luer plug.
- If IABP therapy is being started, then proceed with set-up of pump.
- If Safety Disk Leak Test fails, inspect all pneumatic connections and press the IAB Fill key for two (2) seconds to repeat test. If in doubt about integrity of Safety Disk, replace it. See “Safety Disk/Condensate Removal Module” on page 7-7 of the CS300 Operating Instructions.

MAQUET

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