Cardiac Assist

Education Materials

AutoCAT®2 Series

Intra-Aortic Balloon Pump

Timing, Triggering, and Troubleshooting

ARROW INTERNATIONAL

Arrow International
AutoCAT®2 Series Intra-Aortic Balloon Pump

Timing, Triggering and Troubleshooting

The Arrow AutoCAT®2 WAVE™ Intra-Aortic Balloon Pump

U.S. Patent No. 6,258,035

Introduction to Intra-Aortic Balloon Pumping

This program is designed for experienced health care professionals directly responsible for the care of patients needing intra-aortic balloon pump (IABP) therapy. The participants should have a basic understanding of cardiac anatomy, physiology and hemodynamics. Participants should have experience with hemodynamic monitoring and its implications.

Information and instructions given in this manual in no way supersede established medical procedures concerning patient care. Best practice as determined by the medical community is always to be observed. In each case, the user must determine whether the application of the information provided is appropriate to his/her particular clinical setting.

Hands-on time will be provided to allow participants to set up the console and troubleshoot various alarm situations.

Participants are also provided with a competency performance checklist and a post test to assist in maintaining proficiency.

Document Specification

When making reference to or requesting additional copies of this document, please note the following Part Number: A2W-TG, Revision 2.

U.S. Patent No. 6,258,035

Caution: U.S. Federal Law limits this device to sale by or on order of a physician. Contents of unopened, undamaged package are sterile. Disposable. Refer to package insert for current warnings, indications, contraindications, precautions, and instructions for use.

1. Two Hour Program Schedule: AutoCAT®2 Series IABP

8:00 – 8:05 Registration and Welcome

8:05 – 8:15 Start-up Operations

8:15 – 8:45 Timing

8:45 – 9:00 Triggering

9:00 – 9:30 Utilizing the Balloon Pressure Waveform in Troubleshooting

9:30 – 9:50 Set-up and Operations

9:50 – 10:00 Post test and Evaluation

2. Program Description

The primary focus of this two hour session is the technical aspects, operation and troubleshooting of the AutoCAT®2 Series Intra-Aortic Balloon Pump (IABP). Participants should have previous IABP experience and a sound working knowledge of the anatomy, physiology and theory of IABP therapy.

3. Program Objectives

1. Review FiberOptix™ IAB preparation, zeroing and insertion.

2. Identify the differences between AutoPilot™ and Operator modes.

3. Identify improper timing and appropriate corrective action.

4. Identify the most appropriate trigger signal selection for a given patient situation.

5. Identify the alterations that would occur in the Balloon Pressure Waveform for two alarm conditions.

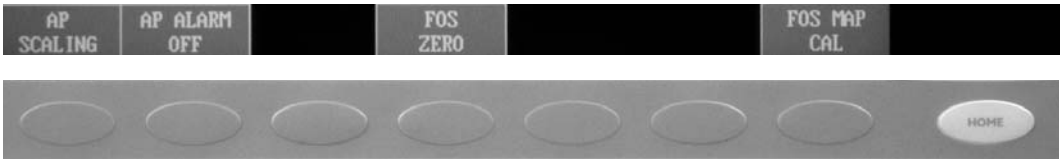
6. Demonstrate the set-up and operation of the IABP utilizing the skills checklist.

FiberOptix™ IAB Preparation, Zeroing and Insertion

Insertion of the FiberOptix™ intra-aortic balloon catheter should be performed as any other IAB catheter with the exception to ZERO the fiber optic sensor to atmosphere immediately prior to insertion.

The Sterile Operator should hand off the fiber optic sensor connector and CAL Key **prior to arterial insertion.** The IAB will automatically zero; continue catheter insertion as usual. (Note: The Fiber Optic status indicator, on the left side of the screen, will turn green when the sensor has been zeroed.)

Alternately, the fiber optic may be manually zeroed by pressing AP SELECT (verify the FIBER OPTIC indicator next to the key is illuminated). Then press the soft key, at the bottom of the screen, under the message FOS ZERO.



Light bulb Icon Legend

Black light bulb with blue square
- FiberOptix™ IAB not connected

Blue light bulb
- FiberOptix™ IAB not zero'd prior to insertion

Green light bulb
- FiberOptix™ IAB zero'd prior to insertion

White light bulb
- FiberOptix™ IAB cal value manually adjusted

Red "X" through light bulb
- FiberOptix™ unavailable

Preparation of IAB for insertion

- Attach the one-way valve to the IAB quick connector.
- Connect the syringe to the one-way valve.
- Apply full vacuum.
- DO NOT remove the one-way valve until IAB is fully inserted into the patient.
- Do not remove IAB from tray until time to insert into patient.
- Do not remove stylet from central lumen until IAB is removed from tray.
- Flush through central lumen with heparinized saline just prior to insertion.
- If IAB is to be inserted through a sheath, remove pre-mounted hemostasis device.

Zeroing the FiberOptix™ (FiberOptic Sensor)

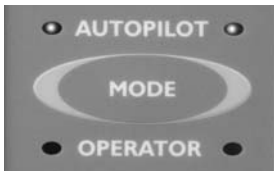
- Pass the blue slide connector and CAL Key to the non-sterile IABP operator.
- Connect the blue slide connector and CAL Key to the pump.
- Confirm the IAB is exposed to room air.
- Wait for Auto Zero to occur (average time: approximately 15 seconds).
    - **Alternately, press AP Select, select fiber optic, press FOS Zero.**
- Confirm FOS icon turns green.
- Insert IAB.

Note: If FOS icon does not turn green or the IAB must be inserted urgently, skip the zeroing step and proceed to IAB insertion.

After IAB is positioned in the patient

- Aspirate blood from central lumen and gently flush with approximately 3cc heparinized saline.
- Immediately connect pressurized heparinized saline flush system to central lumen.
- Remove one-way valve and attach drive line tubing.
- Connect IAB to pump.
- Suture at both the sheath hub and catheter site.
- Tape fiber optic cable to driveline tubing in several places.

The AutoCAT®2 Series IABP offers two distinct modes of operation:



AutoPilot™ MODE

In AutoPilot™ mode the console selects the ECG source, AP source, trigger, and timing.

1. Console scans all available ECG leads continuously. If the current lead selected is lost or noisy, the console will select another available lead. If another lead is significantly better for triggering than the current lead, the pump will change leads. If the clinician desires, he/she can change the ECG lead, source, or gain.
2. AP source is selected by the console but can be changed by the clinician. On the AutoCAT®2 WAVE™, if the Fiber Optic sensor is connected and available, it will always be selected since it has the most optimal waveform and allows for WAVE timing to be selected.
3. Console selects the available trigger modes based on patient condition and signal availability.
4. All timing settings and adjustments are under control of the console.

If, at anytime, the clinician prefers to take control of trigger selection or timing this can be accomplished by selecting OPERATOR mode.

OPERATOR MODE

This is the mode of operating common to all other models of intra-aortic balloon pumps. The clinician makes all the choices regarding ECG source and lead, AP source, triggering, and timing.

1. Once the initial timing is set, the console will automatically adjust for changes in heart rate.

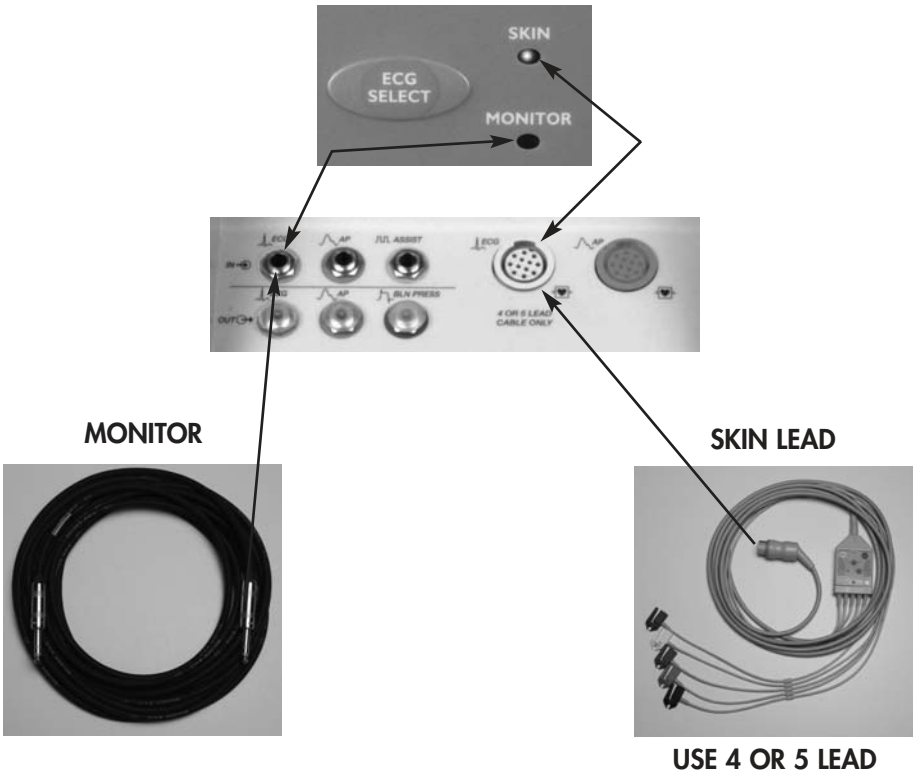
1. Power ON

a. Applies power to the system.

Pump should be plugged into an AC outlet. The green indicator LED below the power switch denotes AC power is being received by the pump. The amber indicator LED denotes that the battery is at least 80% charged.

2. Patient Connections

ECG



ECG Cables

a. Skin Lead Cable

1. In use when SKIN selected on keypad, next to ECG Select.

2. Must use either a 4 or 5 lead cable.

3. For 4-lead cable, the lead choices are I, II or III.

4. For 5-lead cable AutoPilot™ will select either I, II, III or V. AVR, AVL and AVF may be selected by the clinician.

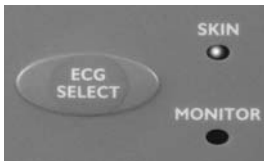
5. Lead selected is highlighted in white and displayed in upper left corner of LCD screen.

b. Phono to Phono Cable (Monitor Cable)

1. In use when MONITOR selected on keypad.

2. Actual lead choice is made on the bedside monitor.

ECG SELECT

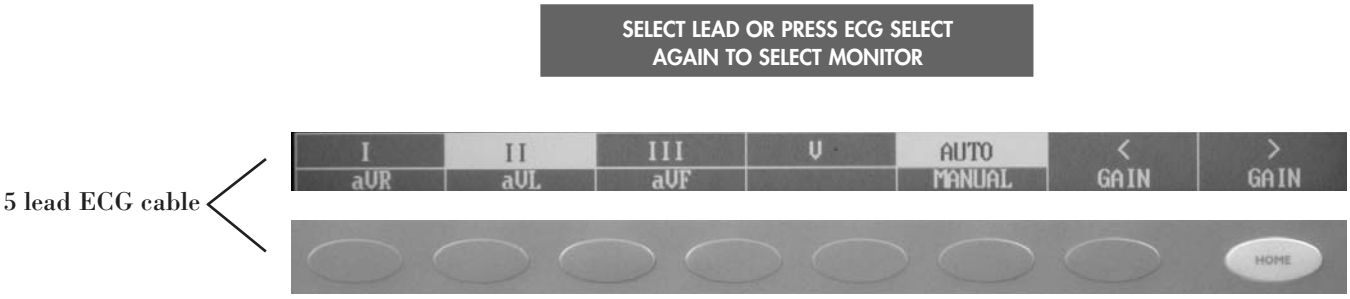


a. ECG SELECT provides selection for LEAD, input source, gain mode and level.

b. This key can be used in either AutoPilot™ or Operator mode. If you select a lead that is not good or not available, in AutoPilot™, your choice will be overridden.

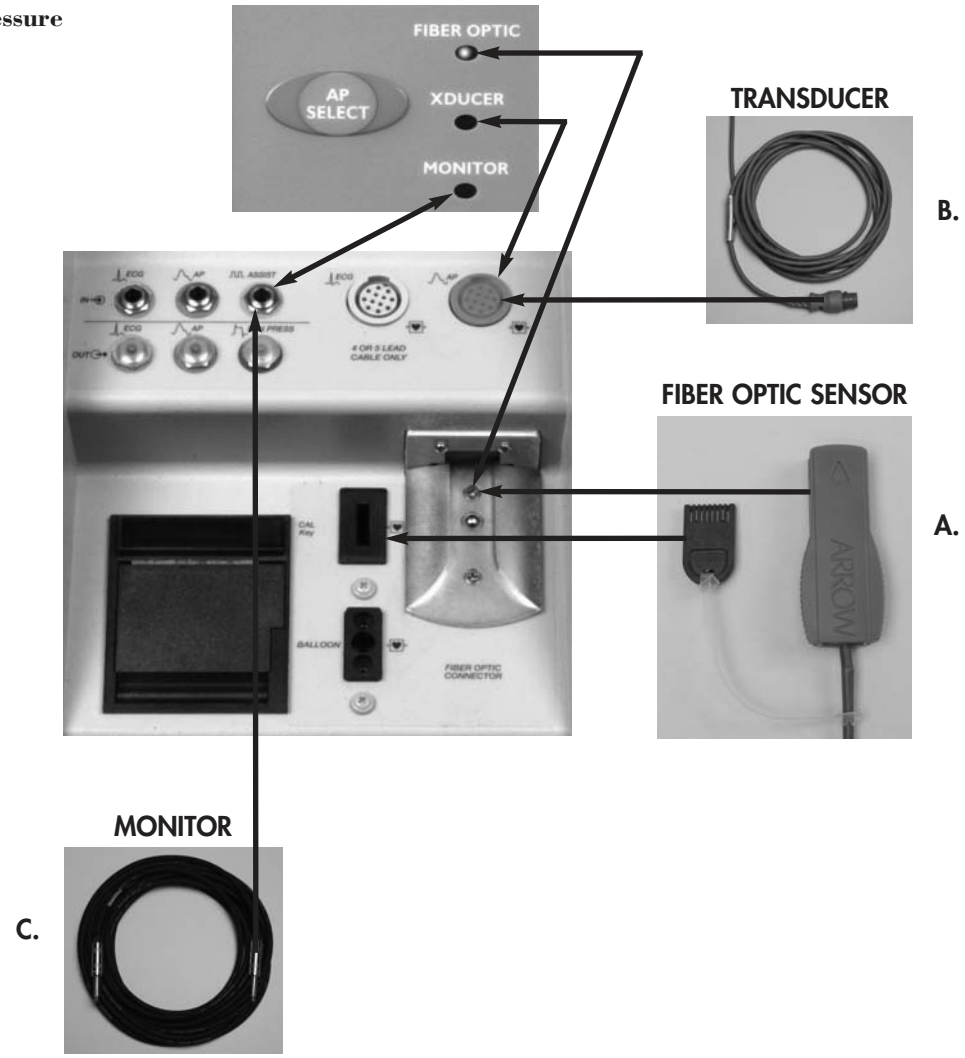
1. To change input source press ECG SELECT twice.

2. To change lead, press ECG SELECT once. Press key under desired LEAD label. To select the alternate lead II/AVL, press the key under the desired lead again. To switch gain mode press key under desired label. DECREASE/INCREASE GAIN keys can be used with AUTO or MANUAL GAIN. If AUTO is selected, the GAIN change is only valid until lead is changed.



Note: It is highly recommended to use ECG skin leads when AP fiber optic is selected.

Arterial Pressure



AP Cables

A. Fiber Optic Cable

1. Exclusive to the AutoCAT®2 WAVE™ IABP.

2. In use when FIBER OPTIC is selected on the keypad.

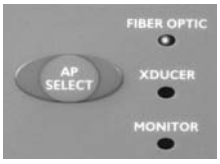
B. Transducer Cable

1. In use when XDUCER is selected on the keypad.

C. Monitor Cable

1. In use when MONITOR is selected on the keypad.

AP SELECT

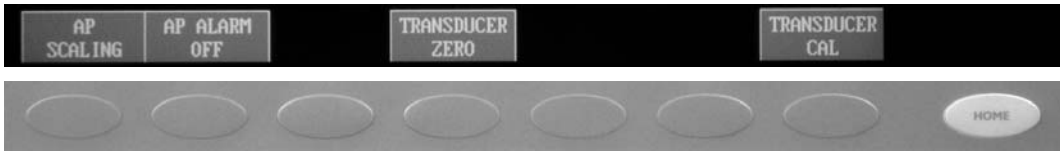


a. AP SELECT provides selection for AP SOURCE, SCALE, AP ALARM, ZERO and CAL.

b. This key can be used in either AutoPilot™ or Operator mode. If you select an alternate AP source while the fiber optic sensor is connected to the pump, AutoPilot™ will return to FIBER OPTIC after a brief time.

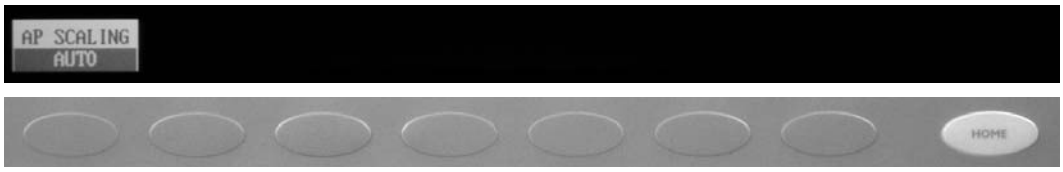
1. To change input source press AP SELECT twice.

2. To change scale, set AP alarm, zero or calibrate, press AP SELECT once. Press key under desired label to select function.



AP SCALING

- AUTO is the preset.
- To set scale manually press AP SCALING once.
- Press AP SCALING AUTO to select MANUAL scaling.
- Press MANUAL SCALES.
- Press soft key under desired scale.

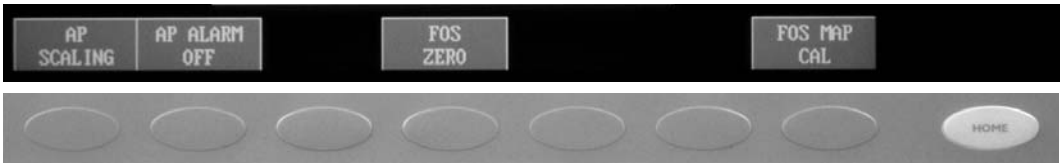


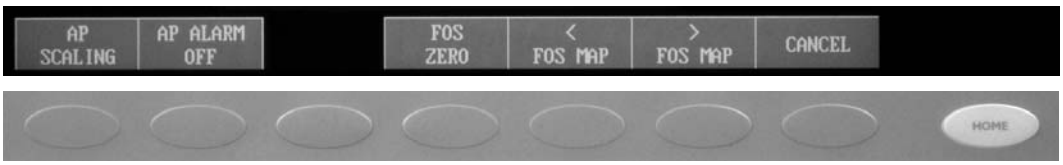
AP ALARM

- Press AP ALARM OFF key. This will toggle the alarm system to ON.
- Select AP parameter for alarm: MAP or AUG.
- Preset MAP limit is 70mm Hg. Preset AUG limit is 100mm Hg.
- Verify alarm limit. Alarm limit can be adjusted in 5mmHg increments.

FiberOptix™ ZERO and MAP CAL

- The fiber optic sensor will zero automatically if it is connected to the pump prior to insertion.
- To zero manually, connect FOS sensor and CAL key then press FOS ZERO before the catheter is inserted into the patient.
- For Auto Zero to occur (average time: approximately 15 seconds), the FOS icon (light bulb) will turn green after the ZERO is complete.
- If the fiber optic sensor was not zeroed before insertion, the MAP value may be adjusted to match the pressure from a transduced arterial pressure source.
  - Select FOS CAL.
  - Use either the <FOS MAP or >FOS MAP to adjust the MAP value in the hemodynamic section of the display screen to the desired value. The MAP can be adjusted in increments of 5mmHg. The waveform is adjusted as the < > keys are pressed.
  - If the adjustment was made in error, press the CANCEL key.
  - If the FOS MAP value is changed, the FOS icon will change to white.





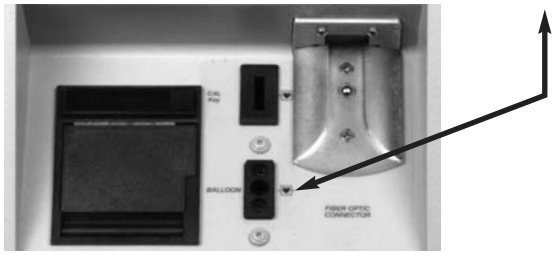
ZERO Transducer

- Verify level of the transducer to the patient's phlebostatic axis; open transducer to air.
- Press AP SELECT key once, then press soft key under XDUCER ZERO.
- Close transducer; observe for return of arterial pressure waveform.

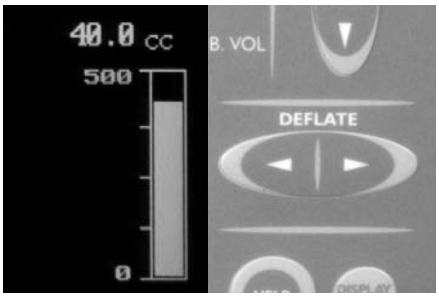
(Note: Transduced AP does NOT need to be zeroed to use as a trigger source.)

Balloon

a. Push balloon connector in firmly, right side up or upside down – it does not matter.
   - 30cc IAB - white connector
   - 40cc IAB - blue connector
   - 50cc IAB - orange connector



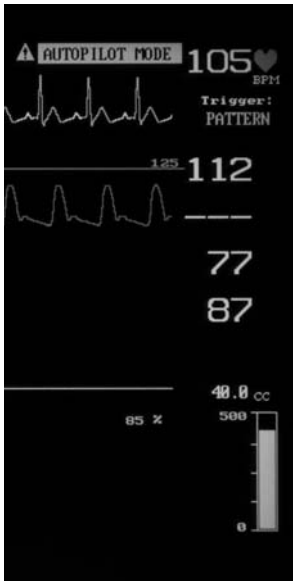
b. Balloon volume is displayed above the helium bar display.



3. Pump ON

Verify:

- The console can not pump without a trigger. Trigger acceptance is indicated by the white overlay on the ECG, flashing heart symbol and accurate Heart Rate.
- Trigger mode displayed below HR.
- Helium gauge to ensure adequate amount of helium to fill the drive system.

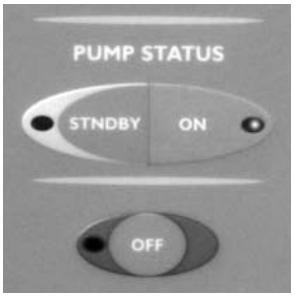


Helium Status

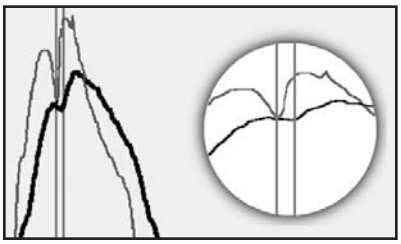
Initiate Pumping

Press PUMP ON

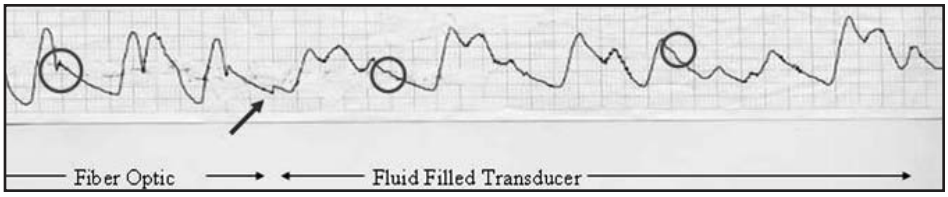
The first time ON is pressed after power up, the pump will fill the drive with helium, perform one purge cycle followed by nine mixing beats. This will be repeated two times to optimize helium concentration. Pumping will continue uninterrupted.



Difference between Fiber Optic Arterial Pressure Signal and Transducer



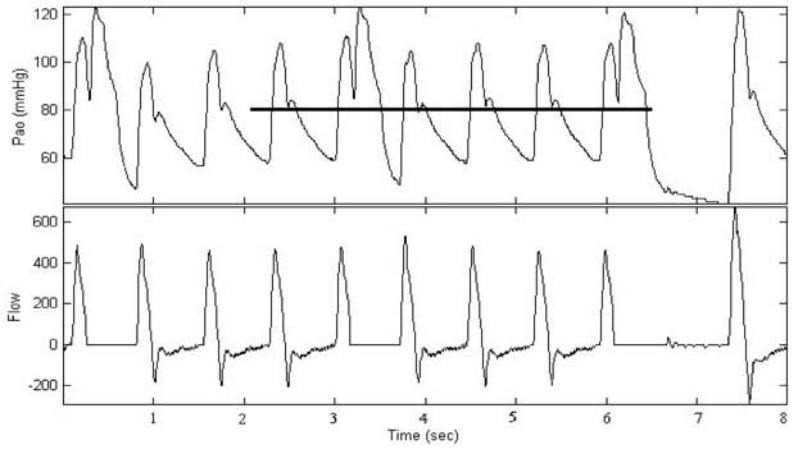
38msec delay



The Fiber Optic AP Signal produces a high fidelity waveform that is available to the IABP earlier than fluid filled AP signals. When the inflation timing is correct on the fiber optic arterial pressure waveform it may look early on the fluid filled line because of the transmission delay in fluid systems. Since the fiber optic AP waveform is a real time signal, there is no delay.

WAVE™ Inflation Timing

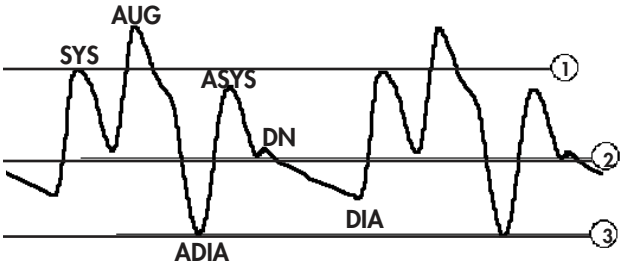
Windkessel Aortic Valve Equation (WAVE™) is exclusive to the AutoCAT®2 WAVE™ IABP in AutoPilot™ mode. The fiber optic arterial pressure signal is converted to an aortic flow signal inside the pump. The aortic flow waveform is then used to set inflation of the balloon in synchrony with Aortic Valve closure.



Compare inflation to the most unassisted beat Dicrotic Notch.

Comparison of Arterial Pressure Signal: Fiber Optic and Transducer

Timing Guidelines for assessment and setting timing in Operator Mode.



SYS	Systole
AUG	Augmented Diastolic Pressure
ADIA	Assisted Diastole
ASYS	Assisted Systole
DN	Dicrotic Notch
DIA	Diastole

The Timing Three

Inflation

GOAL: To produce a rapid rise in aortic pressure (optimize AUG), thereby increasing O_2 supply to coronary circulation.

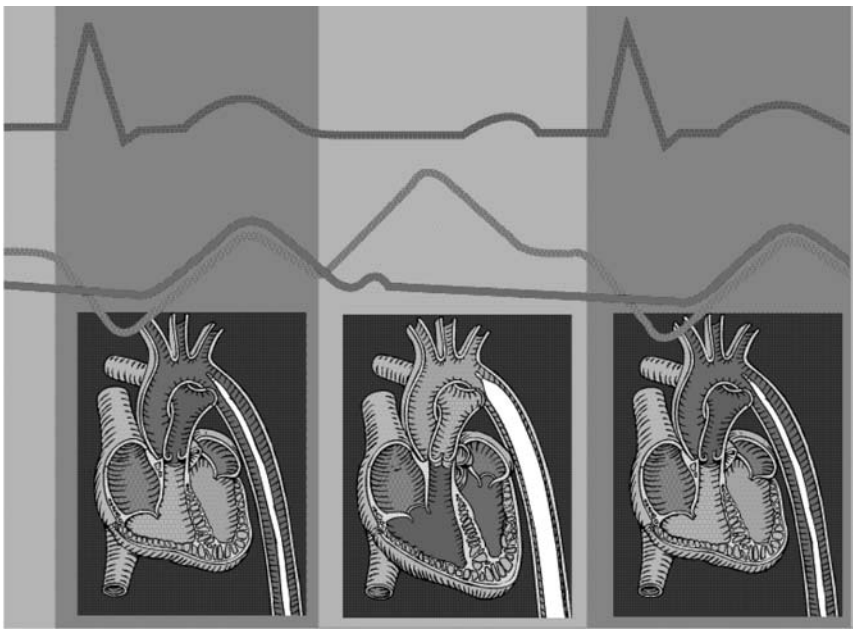
Rule #1. Inflate just prior to the DN (this should result in AUG>SYS).

Deflation

GOAL: To reduce aortic end diastolic pressure (afterload), thereby decreasing MVO_2 while improving CO (cardiac output).

Rule #2. ADIA≤DIA

Rule #3. ASYS<SYS



Balloon Inflation and Deflation

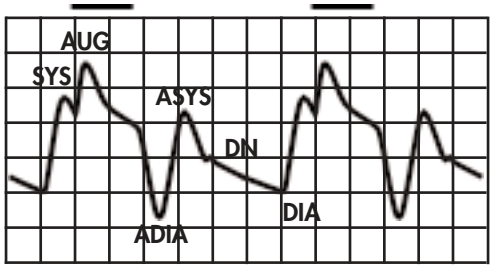
Electrical and Mechanical Relationship

Timing Errors

Early Inflation

IAB is inflated well before actual DN (Aortic Valve closure). Violates Rule 1 for inflation.

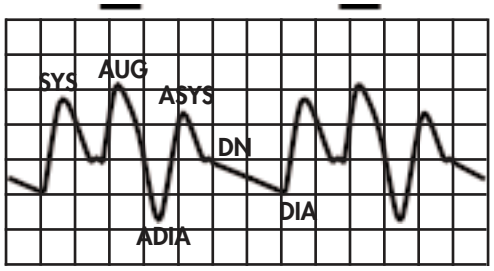
Result: Premature closure of Aortic Valve. Reduced stroke volume/CO. Increased LVED volume. Increased workload of the left ventricle, related to increased wall tension.



Late Inflation

DN is visible between points SYS and AUG. Violates Rule 1 for inflation.

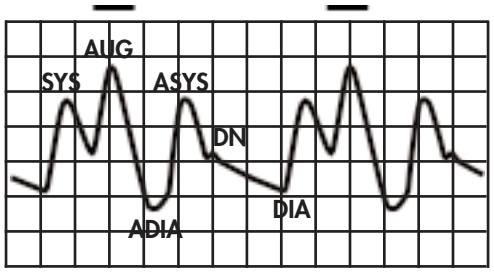
Result: AUG less than optimum. Decreased perfusion pressure and volume to coronary arteries. Reduced augmentation time.



Early Deflation

ASYS = SYS Violates Rule 3 for deflation. May see "U" shape at ADIA

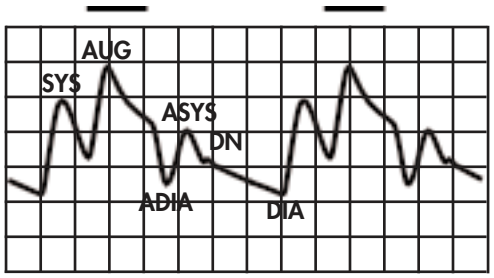
Result: No afterload reduction.



Late Deflation

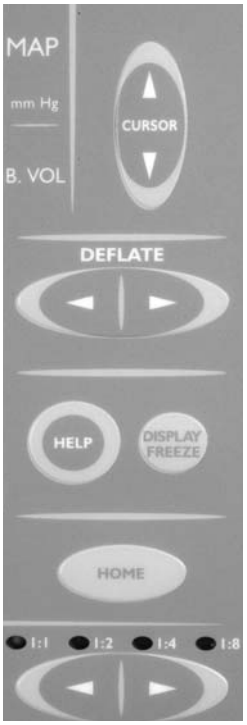
ADIA>DIA Violates Rule 2 for deflation.

Result: Increased workload of the left ventricle. Increased MVO2.



Timing can only be adjusted by the clinician when the pump is in Operator mode.

earlier *later*



Other control keys used in timing assessment:

CURSOR moves magenta line up and down the screen to aid in comparing timing landmarks.

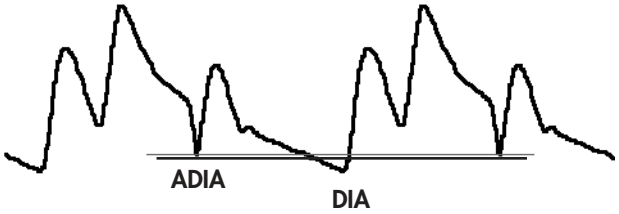
DISPLAY FREEZE key freezes and unfreezes the waveforms.

ASSIST RATIO

R Wave Deflation

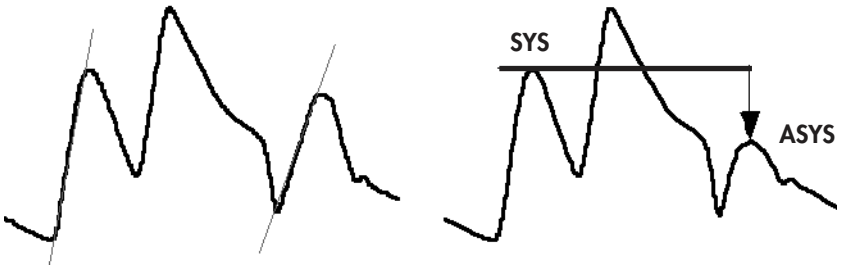
R wave deflation (also known as "real time" deflation) uses the next occurring R wave on the ECG to deflate the balloon. It provides the most consistent deflation in irregular rhythms. The AutoCAT®2 Series IABPs utilize R wave deflation when AFIB trigger is selected.

R wave deflation generally deflates the IAB later than conventional deflation. This may sometimes result in ADIA > DIA.



To assess if deflation is late compare the systolic upstroke of the assisted beat with that of the unassisted beat. If they are equal and the hemodynamics are stable then deflation is generally OK.

If the assisted systole has less of a slope than the unassisted systole or the assisted systole is severely depressed then deflation is late. If the pump is in AutoPilot™ turn ARRHYTHMIA TIMING off. If the pump is in Operator mode, select Peak trigger and adjust deflation as desired.



Trigger Modes
It is necessary to establish a reliable trigger signal before balloon pumping can begin. The computer in the IAB console needs a stimulus to cycle the pneumatic system which inflates and deflates the balloon. The trigger signal tells the computer that another cardiac cycle has begun. In most cases it is preferable to use the R wave of the ECG as the trigger signal. Back-up options are the arterial pressure waveform and pacer spikes.

AutoPilot™ automatically selects the best available trigger. If control of the trigger mode is desired, select Operator mode.

ECG Pattern
Pattern analyzes the height, width and slope of a positively or negatively deflected QRS complex. The width of the R wave must be between 25-135msec. Widened QRS complexes may not be recognized, such as bundle branch blocks. Rejection of pacer spikes is automatic. This is AutoPilot™'s trigger of choice when the rhythm is regular, the HR is less than 130bpm and the QRS complex is normal width.
AutoPilot™: HR < 130 and no arrhythmia.

ECG Peak
Peak analyzes the height and slope of a positively or negatively deflected QRS complex. Rejection of pacer spikes is automatic. This is AutoPilot™'s choice when the rhythm is regular and the QRS is wide or the HR is greater than 130bpm. It will also select Peak if the rhythm is irregular and ARRHYTHMIA TIMING is turned OFF.
AutoPilot™: HR > 130 and/or arrhythmia with arrhythmia timing off.

AFIB
AFIB analyzes the QRS in the same manner as Peak mode. Deflation cannot be controlled by the operator as the balloon will automatically be deflated whenever an R wave is sensed. Rejection of pacer spikes is automatic. This is AutoPilot™'s choice when a rhythm is irregular and ARRHYTHMIA TIMING is ON. This will also be AutoPilot™'s choice when R WAVE DEFLATION is ON.
AutoPilot™: Any HR > with arrhythmia and arrhythmia timing on.

AP
Arterial pressure mode uses the systolic upstroke of an arterial pressure waveform as the trigger signal. It is not recommended for irregular rhythms. AutoPilot™ will choose this trigger when there are no QRS complexes seen or the ECG is obscured by artifact.
AutoPilot™: Noisy or no ECG present.

VPACE
VPACE utilizes the ventricular spike as the trigger signal. This mode may be used with V or AV paced rhythms. Because the pump will only initiate an inflate/deflate cycle when a ventricular spike is sensed, it is ESSENTIAL that the patient's rhythm is 100% paced. AutoPilot™ will only choose this trigger if there are no QRS complexes or arterial pressure waveforms seen but pacer spikes are present.
AutoPilot™: Single or dual pacer spikes with no ECG/AP.

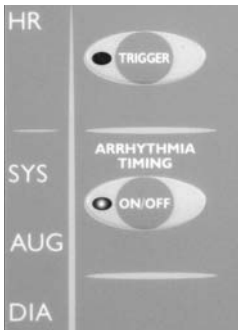
APACE
APACE uses the atrial pacing spike as the trigger signal. This mode can only be used with 100% atrial paced rhythms. AutoPilot™ will select this mode when an ECG or AP is present but not stable and the pacer is more than 100msec before the R wave on the ECG.
AutoPilot™: Single pacer with R wave > 100msec after pacer.

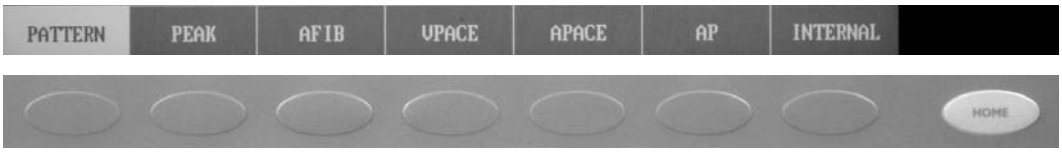
Internal (Operator Mode only)

The balloon inflates and deflates at a preset rate regardless of the patient's cardiac activity. This mode is only to be used in situations where there is no cardiac output and no ECG, such as cardiopulmonary bypass. The preset rate is 80 bpm but may be adjusted in increments of 5 between 40 and 120 bpm. Selection of this trigger is only available in Operator mode and must be confirmed by an additional keystroke. AutoPilot™ will NEVER choose this trigger.

To access trigger modes the pump must be in Operator mode.

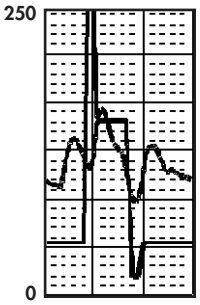
1. **Press the TRIGGER key.**
2. **Select the desired trigger mode by pressing the softkey under that trigger.**





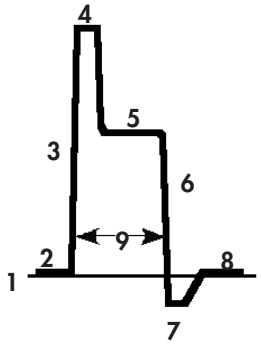
Balloon Pressure Waveform

1. Description
   The Balloon Pressure Waveform (BPW) represents the helium movement between the console and the IAB catheter. It is displayed as a calibrated, continuous waveform which allows objective assessment of counterpulsation.

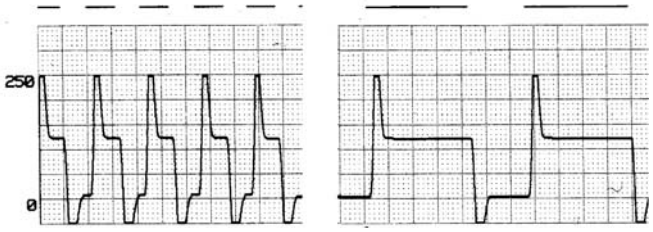


2. BPW Height
   Reflects the pressure in the aorta, therefore the plateau pressure on the BPW should be within ±25mmHg of the AUG pressure.

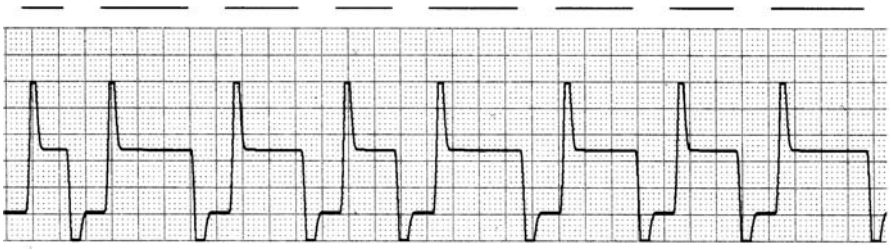
3. BPW Width
   It is approximately the duration in which the balloon is inflated.



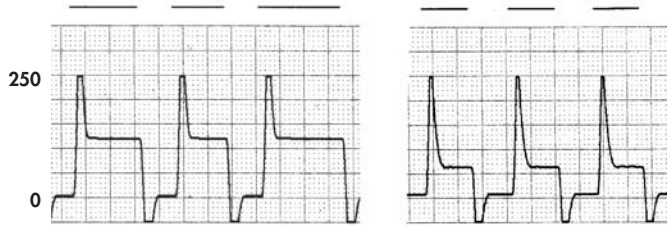
1 Zero Baseline
2 Balloon Pressure Baseline
3 Rapid Inflation
4 Peak Inflation Artifact
5 Plateau Pressure
6 Rapid Deflation
7 Deflation Artifact
8 Return to Baseline
9 Duration of Balloon Cycle



Tachycardia *Bradycardia*



Irregular Rhythm (AFIB)



Hypertension **Hypotension**

Alarms and Alerts

An alarm may cause the pump to stop pumping. The pump will display a message on the screen to assist in troubleshooting. If the alarm reappears consistently, refer to the Operator's Manual for further information. The Arrow IABP support line, 800-447-IABP, can also be utilized for troubleshooting assistance.

Class 1 Alarms (Automatic Response)

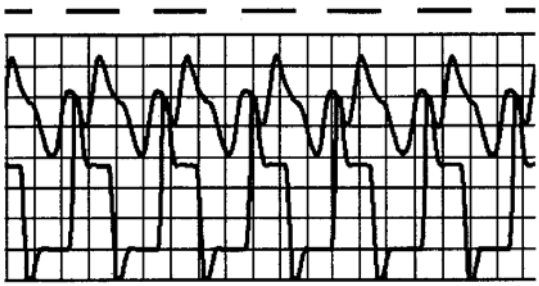
The following Class 1 alarms cause the AutoCAT®2 Series IABPs to:

1. Stop pumping (PUMP OFF key illuminates)
2. Deflate the balloon
3. Open vent valve
4. Initiate the audio alarm
5. Display an alarm message
6. Freeze the waveform display
7. Print approximately the last 10 seconds of BPW and AP on the strip chart recorder

Once the condition is corrected, to resume pumping:

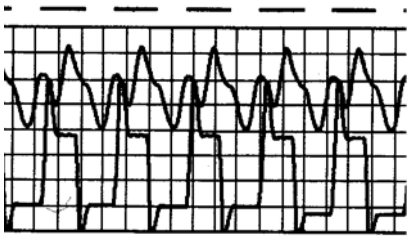
1. Press alarm RESET.
2. Press pump ON.

Unable to Refill



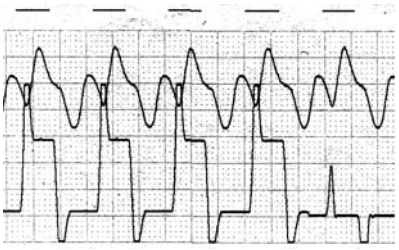
Operation Mode	Possible Cause(s)	Corrective Action
AutoPilot™ Operator	Low Helium tank pressure	Check HE tank. Change as needed.
	Fill/Drain valves malfunction	Change IABP console; call field service.
	Insufficient deflation time	Check timing. If deflation time is very short, i.e. there is no visible BPW baseline, select Operator mode.
Operator	Incorrect timing	Verify Operator mode. Adjust timing until BPW baseline is visible during IAB deflation. If problem persists, select 1:2 assist ratio. Change IABP console.

Possible Helium Loss



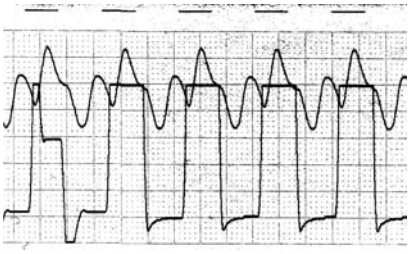
Operation Mode	Possible Cause(s)	Corrective Action
AutoPilot™ Operator	Leak in Tubing or Connections	Perform Leak test and repair tubing as needed.
	Kinked Catheter	Assess for kink and straighten out catheter.
	IAB has not fully exited the sheath	Verify IAB has exited the sheath.
	Balloon connector not properly seated	Disconnect and reconnect the IAB connector.
	Blood in catheter tubing	Remove balloon immediately and insert a new IAB catheter. Disconnect driveline tubing and clamp prior to IAB removal.
	Erratic triggering or arrhythmias	Reduce IAB volume. Select Operator mode and select PEAK trigger. Verify timing.
Operator only	Very late deflation or early inflation	Change to 1:2 assist. If alarm condition does not occur, return to 1:1 and adjust timing so BPW baseline may be observed. NOTE: If HE loss continues in 1:2 assist, perform leak test.
	Erratic triggering or arrhythmias	Change to PEAK trigger mode. Adjust deflation earlier.

Large Helium Leak



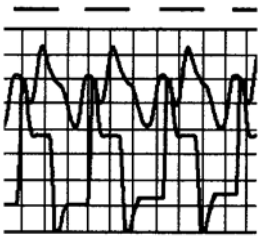
Operation Mode	Possible Cause(s)	Corrective Action
AutoPilot™ Operator	IAB tubing disconnected from console	Check all IAB connections for leak. Reconnect and/or tighten as needed.
	Gas line tubing and IAB catheter not tightly connected at catheter bifurcation	Tighten connection.
	Leak at IAB connection or in Tygon tubing between console and catheter insertion point	Verify tight connections at all drive line tubing connection points.
	Other helium leak. Check for blood in tubing. If blood is observed, remove and replace IAB. If no blood is observed, perform leak test.	Perform leak test. Replace or repair IAB as needed.

High Pressure



Operation Mode	Possible Cause(s)	Corrective Action
AutoPilot™ Operator	Kinked IAB Driveline	Check tubing for kinks. Find and straighten kink.
	IAB has not exited the sheath	Verify IAB is out of sheath. Reposition IAB as needed.
	Partially wrapped IAB	Notify physician: aspirate IAB, if no blood is present inject air into the balloon and aspirate and remove syringe from IAB connector.
	Balloon too large for the aorta	Check BPW/AP relationship. Decrease IAB volume as indicated.

High Baseline



Operation Mode	Possible Cause(s)	Corrective Action
AutoPilot™ Operator	Kinked catheter	Assess for kink and straighten out catheter.
	IAB has not exited the sheath	Verify IAB is out of sheath. Reposition IAB as needed.
	Partially wrapped balloon	Notify physician: aspirate IAB, if no blood is present inject air into the balloon and aspirate and remove syringe from IAB connector.
	Improper IAB position	Verify IAB position and reposition as needed.
	Drive System malfunction	Change console. Call Arrow International for service.

Purge Failure

Operation Mode	Possible Cause(s)	Corrective Action
AutoPilot™ Operator	No trigger or reliable trigger signal is lost	Check patient. Verify trigger bands are present on ECG. Verify flashing heart and HR corresponds to patient. Select Operator mode and choose appropriate trigger mode.
	Helium tank not open or inserted properly	Check helium tank. Change as needed.
	Helium tank empty	Replace HE tank.
	Prior alarms not reset	Verify alarms are reset. Reset alarms as needed.
	IAB not connected	Check IAB connections. Attach IAB connector.
	Drive System malfunction	Change console. Call Arrow International for service.

Problem	Operation Mode	Possible Cause(s)	Corrective Action
System Error 1-6	AutoPilot™ Operator		Press alarm RESET. Press pump ON to resume pumping. If this does not correct problem then turn power OFF then ON. If alarm persists, change IABP console. Call field service.
System Error 7 Key board controller failure Does not interrupt pumping	AutoPilot™ Operator	Umbilical cable disconnected at control head or at console	Check umbilical cable connections. Reconnect as needed. If alarm persists, power pump OFF then ON.
		Control head hardware failure	Change control heads or IABP console. Call field service.
System Error 8 (AutoCAT®2 WAVE™ only) Does not interrupt pumping	AutoPilot™ Operator	FiberOptix™ hardware failure	1. Select alternate AP Source. 2. Change console. 3. Power console OFF then ON. 4. Call field service.

Class 2 Alarms (Automatic Response)

The following Class 2 alarms cause the AutoCAT®2 Series IABPs to:

1. Stop pumping (PUMP STANDBY key illuminates, system not vented)
2. Deflate the balloon
3. Initiate the audio alarm
4. Display alarm message

NOTE: Trigger loss alarms will automatically reset and pumping resumes when trigger is established.

Problem	Operation Mode	Possible Cause(s)	Corrective Action
Standby Alarm Disabled	AutoPilot™ Operator	Standby alarm disabled indefinitely	Press pump OFF. Press pump ON to resume counterpulsation.
Standby longer than 3 MIN	AutoPilot™ Operator	Pump in standby for longer than 3 minutes	• Press RESET to clear alarm (alarm will be re-issued in 3 minutes). • Press pump OFF. • Press pump ON to resume counterpulsation. • Press pump STANDBY twice to place pump in standby mode indefinitely.

Problem	Operation Mode	Possible Cause(s)	Corrective Action
ECG Trigger Loss	Operator only	No ECG waveform	• Check patient condition/rhythm. • Check electrode placement and change if necessary. • Check ECG cable connections; reconnect as needed. • Check external monitor and IABP input. • Check/change ECG lead. Check/change ECG source.
		Waveform erratic or noisy	Reapply electrodes. Consider using Manual gain.
		Low waveform amplitude or biphasic QRS complexes	Select another lead (if using external monitor, change lead on monitor). Increase size using gain controls.
		Inappropriate trigger mode selected	Select another trigger mode and reset timing as needed.
Pressure Trigger Loss	Operator only	No pressure waveform displayed	• Check patient condition. • Check all connections. • Verify correct AP Select source is selected. • Check pressure transducer, IAB catheter and connections for loose connections, repair/tighten if necessary. • Select another trigger mode. • Re-zero AP source.
	FiberOptix™ AP sensor (AutoCAT®2 WAVE™ only)	AP sensor cable disconnected	Check connections and reconnect as needed.
		AP sensor cable broken	Replace IAB. Select an alternate AP source.
		CAL key not inserted or corrupted	Insert CAL. Change IAB catheter. Use alternate AP source.

Problem	Operation Mode	Possible Cause(s)	Corrective Action
Pressure Trigger Loss (continued)		FiberOptix™ connector needs to be	Replace FiberOptix™ connection. Call field service.
		FiberOptix™ electronics failure	Replace console. Use an alternate AP source. Call field service.
		FiberOptix™ electronic temperature out of range	Replace console. Use an alternate AP source. Call field service.
		Altitude above 10,000 ft.	Use an alternate AP source.
ECG Lead Fault Detected	Operator only	Poor electrode connection	Re-apply electrodes.
		Loose connections	Check ECG cable connections; repair/ reconnect as needed. Replace ECG cable.
		3 lead cable detected	Use 4 or 5 lead ECG cable only
		Phono to Nicolay cable detected	Use a Phono to Phono cable for slaving
Trigger Loss	AutoPilot™ only	No ECG/AP/PACER trigger can be found	Check patient condition. Switch to Operator mode. Check ECG/AP sources and change as needed.
		Very small ECG signal	Use ECG gain to increase ECG size.

Class 3 Alerts

The following Class 3 (information only) alerts inform you of a less serious condition. Verify the condition, but immediate action may not be required. Class 3 alerts cause the AutoCAT®2 Series IABPs to:

1. Initiate the audio alarm.
2. Display an alarm message.
3. **Pumping is NOT interrupted.**

Problem	Operation Mode	Possible Cause(s)	Corrective Action
AP FOS Signal Weak	AutoPilot™ Operator	AP sensor failure	Cable is broken. Replace IAB. Select an alternate AP source.
		AP sensor dirty	Replace FiberOptix™ sensor contact.
		AP sensor partially connected	Disconnect AP FiberOptix™ sensor. Verify "click" is heard when sensor is connected.
AP FOS Sensor Out of Range	AutoPilot™ Operator	Electronics operating temperature too high or too low	Select an alternate AP source.
		Altitude above 10,000 ft.	Change altitude. Select an alternate AP source.
AP FOS Cal key Missing or Corrupted	AutoPilot™ Operator	AP FiberOptix™ key not plugged into receptacle	Reconnect CAL key
		AP FiberOptix™ CAL key damaged	Replace IAB. Select an alternate AP source.
Drain Failure	AutoPilot™ Operator	Condensate bottle full	Empty condensation bottle.
		Drain tubing kinked	Straighten drain tubing.
		Drain valve failed to open or system purge not performed	Initiate purge cycle by pressing pump OFF then STANDBY, wait 5 seconds for purge, then press pump ON to resume pumping. Replace IABP console. Call field service.
Deflate Marker beyond 100%	Operator only	Deflation set beyond the R wave	Check deflation timing. Set deflation earlier as needed.
Timing Error	Operator	Insufficient time to inflate/deflate IAB	Check timing; adjust as needed.

Problem	Operation Mode	Possible Cause(s)	Corrective Action
Warning: Battery Inoperative	AutoPilot™ Operator	The AutoCAT®2 will not run in battery mode	Do not disconnect the AutoCAT®2 from AC power source. Check circuit breaker position located in helium compartment.
		Circuit breaker turned OFF	Turn on circuit breaker.
Available Battery Power Less than 20, 10, 5 Minutes	AutoPilot™ Operator	Battery voltage low	Change to AC power as soon as possible to recharge batteries.
System Running on Battery Power	AutoPilot™ Operator	AC power disconnected	Check AC power source. Reconnect the IABP to AC power.
		AC power failure	Arrange for alternate AC power source if failure is expected to exceed 90 minutes. If AC power is connected but not available, change IABP console. Call field service.
Possible ECG Trigger Detected	Operator	QRS complex detected while in INTERNAL mode	Verify ECG is present. Change to ECG or AP trigger mode.
Weaning Step Complete	AutoPilot™ Operator	Weaning time has expired	Evaluate patient hemodynamics and set parameters for next weaning step. If weaning is complete, remove IAB.
Arterial Pressure Alarm	AutoPilot™ Operator	AP has fallen below set limit	Check patient hemodynamics. Check for AP disconnect.
Low Helium Tank Pressure	AutoPilot™ Operator	HE tank is empty	Change HE tank.
		HE tank is OFF	Open HE tank.

Class 4 Alerts

The following Class 4 (information only) alerts inform you of a less serious condition. Verify the condition, but immediate action may not be required. Class 4 alerts cause the AutoCAT®2 Series IABPs to:

1. Display an alarm message.
2. **Pumping is NOT interrupted.**

Problem	Operation Mode	Possible Cause(s)	Corrective Action
Possible Late Deflation	AutoPilot™	Electromechanical delay is less than 100msec, with IAB deflation > 250msec.	Check deflation timing. If deflation is too late and patient hemodynamics are compromised, select Operator mode and manually adjust timing.
		ECG connected from bedside monitor. Signal delay is longer than 35msec.	Consider using direct patient connection with 4 or 5 lead ECG cable.
Erratic Triggering	AutoPilot™	Multiple lead switches within 1 minute and no AP signal available	Check ECG signal quality. Change ECG electrodes. Change ECG lead. Adjust Auto gain or select Manual gain. Select Operator mode.
		Multiple trigger switches between AP and Pacer within 1 minute	Check patient condition. Select Operator mode. Select appropriate trigger mode.
No ECG Signal Available	AutoPilot™	ECG signal is not available; IABP is triggering on AP or pacer signal	Check ECG connections. Reconnect ECG cable or leads. Attach another ECG source from patient or monitor.
No AP Signal Available	AutoPilot™	AP signal is not available; IABP is triggering on ECG or pacer signal.	Check AP connections. Reconnect AP cable. Attach another AP source from patient or monitor.
ECG Lead Fault	AutoPilot™	ECG electrode disconnected	ECG lead or cable disconnected but pump is pumping in an alternate trigger mode. Check ECG lead contact. Check ECG cable/lead connections. Reconnect ECG cable/lead. Replace ECG electrodes.
		3 lead cable detected	Use 4 or 5 lead ECG cables only.
		Phono to Nicolay cable detected	Use Phono to Phono cable for slaving.

Problem	Operation Mode	Possible Cause(s)	Corrective Action
Arrhythmia Timing not Available	AutoPilot™	Arrhythmia detected but AFIB trigger cannot be selected	R wave deflation cannot be implemented due to user selection or patient condition. Check timing. If R wave deflation is desired, turn Arrhythmia Timing ON. Select Operator mode. Select AFIB trigger mode. Check timing.
Warning: Dead Clock Battery	AutoPilot™ Operator	Internal clock battery malfunction	Call field service. Pump can remain on patient.
Warning: Low Battery for Static RAM	AutoPilot™ Operator	Internal Static RAM battery malfunction	Call field service. Pump can remain on patient.

Intra-Aortic Balloon Pumping Reference List

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10. Reference List

ARROW INTERNATIONAL

Intra-Aortic Balloon Insertion
Procedure Competency Checklist

Name:_____ **Date:**_____

	SKILL	YES
1.	**Balloon Sizing Recommendations**	
	30cc 4' 10" – 5' 4"	
	40cc 5' 4" – 6'	
	50cc > 6'	
2.	**Sheath Options**	
	A. Sheaths with side-port	
	B. Sheaths without side-port	
	C. Sheathless (hemostasis device available for post insertion bleeding)	
3.	**Interface Fiberoptic IAB connections to the IABP**	
	A. Slide blue fiberoptic connection in the IABP	
	B. Insert calibration key (black key)	
	C. Verify light bulb change from blue to green	
	D. Describe how to do a manual zero	
4.	**Balloon Preparation**	
	A. Place IAB guidewire on the field	
	B. *Attach one-way valve to Gas lumen* (do not remove until IAB is in position)	
	C. Pull vacuum on IAB	
	D. Remove IAB from the tray (immediately prior to insertion)	
	E. Remove the packing stylet (if present)	
	F. Flush IAB central lumen with heparinized NS solution before insertion	
5.	**Arterial Pressure Source**	
	A. To zero Fiberoptic source manually:	
	a) Press AP select to highlight fiber optic	
	b) Press soft key under "FOS ZERO"	
	B. To calibrate Fiberoptic source, if FOS was not zero'd prior to insertion and MAP value is erroneous:	
	a) Press AP select to highlight fiber optic	
	b) Press soft key under "FOS CAL"	
	c) Adjust FOS MAP to actual MAP (from another AP source)	
	C. To zero Fluid Transducer:	
	a) Press AP select to highlight Xducer	
	b) Open stopcock to air and off to patient	
	c) Press soft key under "TRANSDUCER ZERO" (DO NOT press CAL key)	
6.	**Identify proper IAB positioning**	
	A. 2nd to 3rd Intercostal Space (anterior ribs) on Fluoro/X-ray	
	B. Left radial (or ulner) pulse present	
	C. Urine output present (if Foley in place)	

Performance Checklist for Arrow International AutoCAT®2 Series IABP

Name: _____

Instructor: _____ **Date:** _____

Skill	Observed	Completed with Assistance	Completed without Assistance
AUTOPILOT™ MODE			
Initial Set-up			
1. Establish Power			
a. Plug Power Cord to Wall Outlet	_____	_____	_____
b. Press Power On Switch	_____	_____	_____
2. Connect Patient ECG			
a. Skin Cable	_____	_____	_____
b. Phono-Phono Cable (Slave)	_____	_____	_____
3. Verify Trigger Acceptance			
a. Assist Marker on ECG	_____	_____	_____
b. Flashing Heart and Heart Rate	_____	_____	_____
4. Connect Arterial Pressure			
a. Transducer Cable	_____	_____	_____
b. Phono-Phono Cable (Slave)	_____	_____	_____
c. FOS (if available)	_____	_____	_____
5. Connect IAB Catheter	_____	_____	_____
a. Verify IABP Volume Setting	_____	_____	_____
6. Initiate Pumping	_____	_____	_____
7. Change Assist Interval (Starts in 1:1)	_____	_____	_____
Recorder			
1. Record Timing Strip	_____	_____	_____
2. Change Recorder Paper	_____	_____	_____
ECG			
1. Adjust ECG Gain	_____	_____	_____
2. Change ECG Source	_____	_____	_____
Arterial Pressure			
1. Zero FOS	_____	_____	_____
2. Zero Arterial Pressure Transducer	_____	_____	_____
3. Change AP Scale	_____	_____	_____
4. Set AP Alarm (optional)	_____	_____	_____
Assess Balloon Pressure Waveform Characteristics	_____	_____	_____

11. Skills Checklist

Skill	Observed	Completed with Assistance	Completed without Assistance
Assess Patient Response			
1. Assess Diastolic Augmentation	_____	_____	_____
2. Assess Pressures/Timing			
a. SYS	_____	_____	_____
b. ASYS	_____	_____	_____
c. DIA	_____	_____	_____
d. ADIA	_____	_____	_____
3. Assess IAB Sizing	_____	_____	_____
Alarms			
Verify Alarms On	_____	_____	_____
Helium			
1. Assess Helium Tank Level on Screen	_____	_____	_____
2. Change Helium Tank	_____	_____	_____
Empty Condensation Bottle	_____	_____	_____
Initiate Battery Operation	_____	_____	_____
Adjust Balloon Volume	_____	_____	_____
OPERATOR MODE			
Activate Appropriate Trigger For:			
1. Clear ECG, QRS Normal, Rate 90	_____	_____	_____
2. Clear ECG, QRS Wide, Rate 110	_____	_____	_____
3. Noisy ECG with Excessive Interference	_____	_____	_____
4. AV Sequential Pacemaker-Fixed Rate	_____	_____	_____
5. Atrial Pacemaker-Fixed Rate	_____	_____	_____
6. Irregular Rhythm	_____	_____	_____
7. CPR	_____	_____	_____
Timing			
Assess Inflation and Deflation adjust as necessary	_____	_____	_____

____ **1.** The landmark on the arterial pressure waveform used to time the inflation point is
- A. The dicrotic notch
- B. The systolic peak
- C. The end diastolic pressure
- D. Diastolic augmentation

____ **2.** A physiological effect of early inflation of the balloon may be
- A. Potential premature closure of the aortic valve
- B. Suboptimal diastolic augmentation
- C. Potential retrograde coronary and carotid blood
- D. Potential renal artery hypoperfusion

____ **3.** The waveform characteristics of late inflation include
- A. Inflation prior to the dicrotic notch
- B. Diastolic augmentation encroaches into systole
- C. Rate of rise of assisted systole is prolonged
- D. Inflation of the balloon after the dicrotic notch

____ **4.** A trigger is defined as
- A. Adjustment of inflation and deflation
- B. Pressure exerted to inflate IAB
- C. Event that purges console automatically
- D. Signal to identify the onset of the next cardiac cycle

____ **5.** The trigger of choice for a HR < 130bpm with a normal QRS width is
- A. AP (arterial pressure)
- B. Peak
- C. A Pace
- D. Pattern

____ **6.** The following represents a cause of a HELIUM LOSS alarm
- A. Kinked line
- B. IAB abrasion
- C. IAB malpositioned
- D. All of the above

Answers:

1. A
2. A
3. D
4. D
5. D (or B)
6. D

Arrow International – Timing, Triggering and Troubleshooting

Please help us evaluate this program so that we may better meet the needs of future participants.
Check the appropriate box.

Instructor: _____

Date: _____

Hospital: _____

AutoCAT®2 Series IABP	4 Excellent	3 Good	2 Fair	1 Poor	NA
Program Evaluation					
1. Program met the stated objectives					
2. Content covered topic adequately					
3. Rate overall quality of this program					
4. Rate overall quality of speaker(s)					
5. Rate the program facilities					
6. How well did this program meet you personal objectives?					
7. I can incorporate program content into my practice					
Speaker Evaluation					
1. *Objectives* – Stated Objectives Met					
2. *Audiovisual* – Contributed to Presentation					
3. *Content* – Relevance of Content to Objectives					
4. *Practice* – Validate/Change Practice					

Comments:

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