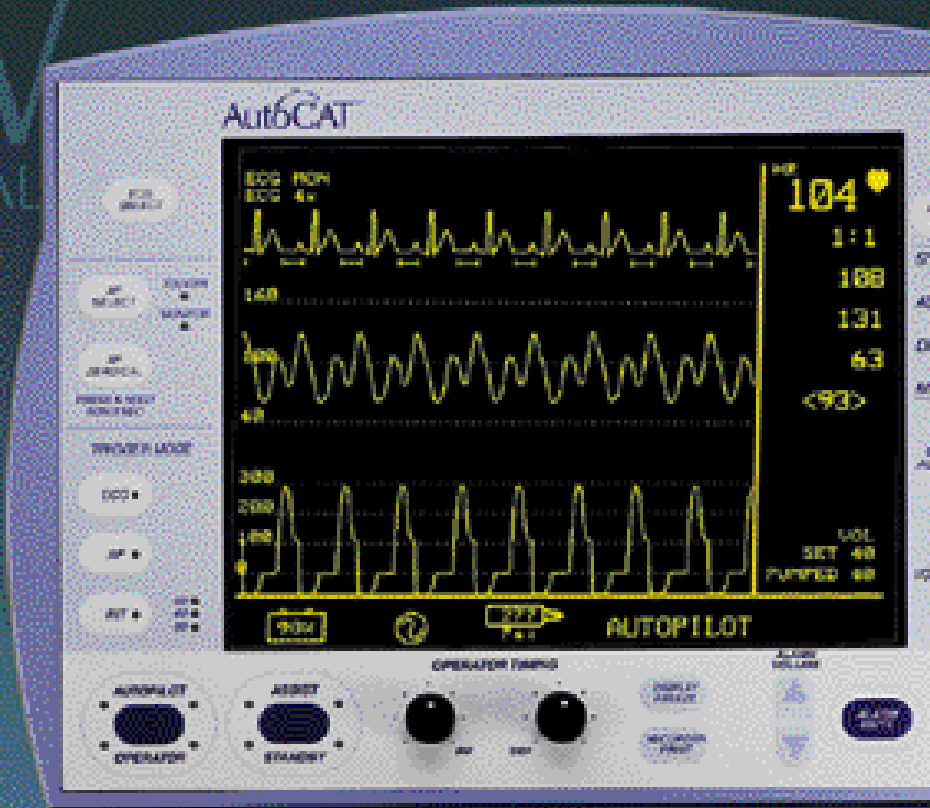
Abbreviated Operation and Troubleshooting Guide for the AutoCAT™ IABP System



24 Hour Intra-Aortic Balloon Product Support:

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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 currently selected lead is lost, the console will select the next clear ECG lead.
2. AP source is selected by the console but can be changed by the operator.
3. If trigger is lost, console will select alternate trigger.
4. All timing settings and adjustments are under the control of the console.
5. The console continuously assesses correlation of IAB diameter to patient's aortic diameter. If the IAB is found to be too large or too small for the patient's aorta, the console will adjust the IAB volume to the maximum allowed in order to correct this condition.
6. All control keys and knobs, whose functions are adjusted by the console in AUTOPILOT™ mode, will not function when this mode is selected.

If, at any time, the operator prefers to take control of trigger, ECG source, timing, etc. this can be accomplished by selecting OPERATOR mode.

OPERATOR MODE

This is the mode of operating all other models of intra-aortic balloon pumps use. The operator makes all choices regarding ECG source, AP source, trigger, timing, and IAB volume.

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

AUTOPILOT™ MODE INITIAL SET-UP

1. Establish Power
2. Check Helium Tank
3. Connect ECG Source
4. Connect AP Source
5. Connect IAB Catheter
6. Initiate Pumping

TRIGGER MODES

Trigger is the event the pump uses to identify the onset of the cardiac cycle (systole). The pump must have a consistent trigger in order to provide patient assist. If the selected trigger signal can no longer be detected, counterpulsation will be interrupted.

Three different trigger selections are available.

1. ECG: **Note: trigger of choice**

   The R-wave of the ECG is the trigger event. Automatic pacer spike rejection. ESIS (electrosurgical interference suppression) is active with skin leads. If no R-wave detected the pump will automatically look for the ventricular pacer spike of an AV pacer.

   - If triggering off a single V pacer spike is desired, select operator mode and press the ECG key once. V pacer trigger is now active.

2. AP:

   The systolic upstroke of the arterial pressure waveform is the trigger event. A 14mmHg minimum pulse pressure is required initially. Every 64th beat is unassisted and assessed by the console to ensure proper trigger. AP trigger may be used when ECG triggering is not possible.

   Note: To avoid late deflation, set the deflation point to occur prior to the systolic upstroke.

   Note: AP triggering is not recommended for use with irregular rhythms.

3. INT:

   An internally generated signal provides asynchronous assist. May be set to 40, 60, or 80 assists per minute.

   Note: Should the system detect an R-wave while in internal trigger mode, an audible alarm is sounded and the message ECG DETECTED appears on the monitor screen.

   Warning: Do not use internal trigger in the presence of any intrinsic cardiac activity; serious competitive hemodynamics will result.

In AUTOPILOT™ mode, the console will choose the ECG trigger whenever available. Should all ECG signals be lost, the console will change to AP trigger. Once the ECG is re-established, the console will return to ECG trigger after two minutes when a regular rhythm is present. If an irregular rhythm is present, the console will return to ECG trigger after one minute of recognition of the ECG signal.

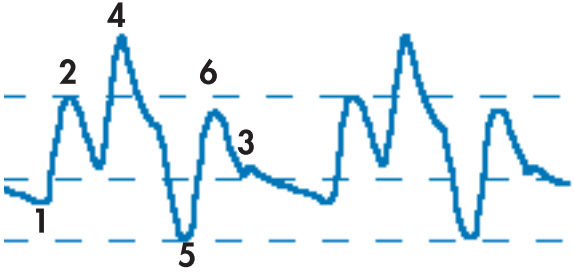
TIMING

SmarTrak® automatic timing algorithm provides beat to beat timing assessments. Automatic timing adjustments are made for heart rate and rhythm changes. The operator may adjust inflation and deflation points for the desired hemodynamic effects.

Timing refers to the positioning of inflation and deflation in relation to the period of diastole on the arterial pressure waveform. Inflation should be set to occur at the onset of diastole, which is signified by the dicrotic notch. Deflation should be set to occur prior to ventricular ejection.

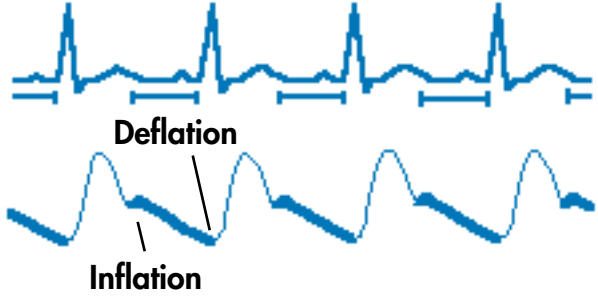
Inflation and deflation markers appear on the arterial pressure waveform whenever the pump is in standby mode. Utilizing the timing controls allows the operator to adjust the inflation and deflation points to correspond to the period of diastole. Once assist is initiated, timing effects can be assessed by selecting the 1:2 assist ratio. Assisted and unassisted blood pressures are provided on the monitor screen. The assist markers always appear underneath the ECG for every trigger event identified and can be utilized by the operator to further assist in timing assessments.

Optimal timing is illustrated below:



COMPARISON OF ASSISTED AND NATIVE PRESSURE TRACINGS.

Assist Markers:



1. Aortic end-diastolic pressure. 2. Peak systolic pressure. 3. Dicrotic notch. 4. Augmented diastolic pressure. 5. Balloon aortic end-diastolic pressure. 6. Assisted peak systolic pressure.

ARRHYTHMIA TIMING

Conventional timing becomes a challenge when the patient develops an irregular rhythm. The following options are available:

1. ECG Trigger: During an arrhythmia, such as atrial fibrillation, the length of time the balloon is allowed to stay inflated varies on a beat to beat basis. The message ARRHYTHMIA TIMING will appear on the monitor screen. In OPERATOR MODE, this specialized afib timing maximizes systolic unloading during irregular rhythms by controlling deflation. If the patient returns to a regular rhythm, the message disappears and assist returns to conventional timing.

   Note: ECG trigger is the trigger of choice in the presence of irregular rhythm. If the clinician feels that ARRHYTHMIA TIMING is not in the patient's best interest, selecting the AFIB TIMING OFF key will turn off this feature. If the operator desires to control the point of deflation during an irregular rhythm, this can be accomplished in OPERATOR MODE by selecting the AFIB TIMING OFF key.

2. AP Trigger: Operator can fine tune inflation and deflation. Late deflation should always be avoided. Every 64TH beat is unassisted and assessed by the console to ensure proper trigger.

   Note: AP trigger is NOT recommended during irregular rhythms.

TROUBLESHOOTING ALARM AND ALERT CONDITIONS

The Arrow AutoCAT™ system is equipped with a comprehensive surveillance system to notify the operator of alarm and alert conditions. You have the benefit of the entire system surveillance, alarm, and message capacity in both Autopilot™ and Operator modes of operation. Alarm conditions suspend counterpulsation assist. A message is displayed on the monitor screen and an audible alarm tone is sounded. Alert conditions do not suspend counterpulsation assist, a message is displayed on the monitor screen and, in certain conditions, an audible alarm tone is sounded.

The following table provides an alphabetical listing of most of the alarm and alert messages, the pump response, possible causes and operator action to correct the condition.

MESSAGE	PUMP RESPONSE	POSSIBLE CAUSE	OPERATOR ACTION
AP TRIGGER ACTIVE	Message only	System has switched to AP trigger automatically in Autopilot™ Mode when a reliable ECG trigger cannot be obtained.	Check ECG source. Re-establish consistent ECG signal
ARRHYTHMIA TIMING	Message only	Irregular cardiac rhythm or irregular triggering.	If the rhythm is irregular, treat patient accordingly. Ensure the trigger signal is clear; pump not triggering on artifact. If desired, the automatic afib timing can be overridden by pressing AFIB TIMING OFF.
AVL FAILURE	Message only	AVL not functioning properly	Call for service. Try to reinitiate pumping by powering down and back up.
BALLOON DISCONNECT	Audible tone, message, deflate balloon; stop pumping GAS ALARMS OFF Mode: Message only	No pressure in balloon line or balloon line not connected.	Check gas tubing connections at console or at balloon connection. Call for service if all connections are tight and alarm condition persists.
CALL SERVICE	Unable to start pumping, display message.	Computer failure	Call for service. Try to reinitiate pumping by powering down and back up.

MESSAGE	PUMP RESPONSE	POSSIBLE CAUSE	OPERATOR ACTION
CHECK TIMING	Active in OPERATOR Mode only. Message. A 2 second audible alert may accompany message if enabled.	Pumping switched from AUTOPILOT™ Mode to OPERATOR Mode Assist interval set to short to fully inflate balloon.	Reminder to assess timing. Adjust as needed. Press ASSIST FREQ to 1:2 to evaluate timing. Readjust timing as necessary.
ECG DETECTED	Message and beep tone every 5 seconds.	Cardiac activity (ECG) detected while pumping in INTERNAL trigger.	Switch trigger mode according to patient's rhythm. Readjust timing.
FILL FAILURE	Audible tone, message, deflate balloon; stop pumping GAS ALARMS OFF Mode: None	Failure to fill to 6-10mmHg during fill state.	Press ASSIST key again. Check for adequate supply of helium. If alarm persists, operate in GAS ALARMS OFF override mode until another console is available.
FILL PRESSURE	Audible tone, message, deflate balloon; stop pumping.	Changing balloon volume while pumping. High helium pressure in balloon line.	If IAB volume was changed while pumping, depress ASSIST and begin pumping again. Notify service if alarm condition continues.
GAS ALARMS OFF	Message only	Pump is set to GAS ALARMS OFF Mode.	Press and hold GAS ALARMS OFF key for 3 seconds to turn this mode off (LED off) and reactivate the automatic surveillance systems.

MESSAGE	PUMP RESPONSE	POSSIBLE CAUSE	OPERATOR ACTION
GAS LOSS	Audible tone, message, deflate balloon; stop pumping GAS ALARMS OFF Mode: None	Leak in IAB catheter. Leak in balloon line connections. Insufficient helium pressure.	Inspect balloon gas tubing for blood; if observed, discontinue pumping and notify physician. Secure tubing connections. Check to see if sufficient helium is available. Replace tank if necessary.
HELIUM LOW	Message only. 1 hour autopurge is disabled.	Less than 100psi remaining in helium tank. Helium pressure transducer malfunction.	Replace helium tank. Check that helium tank is properly seated. Ensure that external supply valve is open. Call for service.
KINKED LINE	Audible tone, message, deflate balloon; stop pumping GAS ALARMS OFF Mode: Message only	Kink in balloon catheter or gas tubing.	Find kink or twist in the catheter or tubing and straighten.
LOW AIR DRIVE	Audible tone, message, deflate balloon; stop pumping GAS ALARMS OFF Mode: Message only	Insufficient air drive pressure to inflate the balloon.	Change console. Operate in GAS ALARMS OFF override mode until another console available. Call for service.
LOW VACUUM	Audible tone, message, deflate balloon; stop pumping GAS ALARMS OFF Mode: Message only	Insufficient vacuum.	Change console. Operate in GAS ALARMS OFF override mode until another console available. Call for service.

MESSAGE	PUMP RESPONSE	POSSIBLE CAUSE	OPERATOR ACTION
LOW (BATTERY)	Message "LOW" inside battery symbol flash and beep tone every 5 seconds	Battery voltage low; less than 20 minutes of battery operation remain.	Attach power cord to AC supply as soon as possible to recharge battery and maintain pumping.
MAP BELOW LIMIT	Message and beep tone every 5 seconds	Mean Arterial Pressure (AP) below operator set limit.	Decrease the AP threshold limit. Reassess patient's hemodynamics.
NOISY ECG	Audible tone, message, deflate balloon on first segment of noise. Reverts to STANDBY if more than 4 seconds of noise persists.	Oscillatory noise in ECG. Patient muscle activity. Electrocautery in use. Possible faulty ground in the AC outlet.	Change position of ECG leads. Check all connections and leads. Select another lead. Select another trigger. Change to AP trigger. Change AC source.
NO TRIGGER	Audible tone, message, deflate balloon; stop pumping Pumping resumes if trigger re-established within 5 minutes	In AUTOPILOT™ Mode: all trigger signals lost to the pump. In OPERATOR mode: the currently selected trigger has been lost. Loose or disconnected ECG leads. ECG signal too small. Monitor input disconnected. If using AP, arterial line dampened, disconnected, or turned OFF. Patient's cardiac activity ceased.	CHECK PATIENT FOR CARDIAC ACTIVITY. Check connections. Check leads and connections. Change lead selection; change trigger source. Check electrode placement. Check input from monitor and secure. Check arterial tracing; flush line; change to ECG trigger; check transducer and monitor input. CHECK PATIENT FOR CARDIAC ACTIVITY.

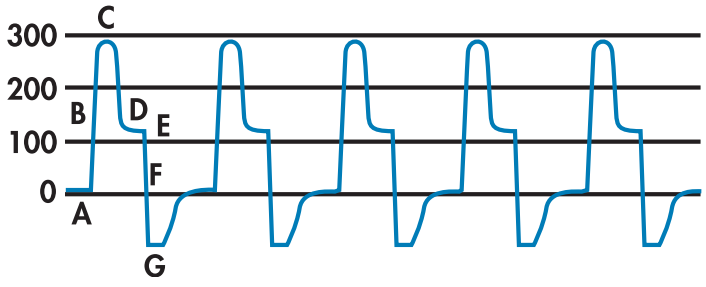
MESSAGE	PUMP RESPONSE	POSSIBLE CAUSE	OPERATOR ACTION
PUMP IN STANDBY	Message and beep tone every 5 seconds	Pump in STANDBY over 5 minutes.	Press ASSIST to resume pumping. Or press ALARMS MUTE if wish to remain in STANDBY.
REPLACE HELIUM NOW	Message and beep tone every 5 seconds	Helium tank is empty.	Replace helium tank immediately.
SYSTEM RESET	System alarms with logo; unable to start pumping	Improper computer operation.	Call for service. Try to reinitiate pumping by powering down and back up.
UNABLE TO ZERO AP	Alarm and message erase when AP ZERO/CAL button is released	Attempts to ZERO with AP signal present.	Check stopcock and line setup. ZERO/CAL with stopcock turned off to the patient.
CONSTANT ALARM TONE (NO MESSAGE)	No message, deflate balloon; stops pumping	Prolonged balloon inflation.	Call for service. Try to reinitiate pumping by powering down and back up.

BALLOON PRESSURE WAVEFORMS: USE IN TROUBLESHOOTING ALARM CONDITIONS

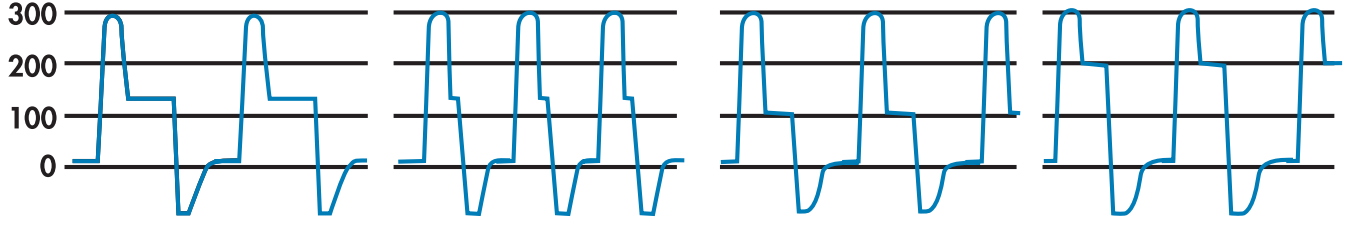
The BPW is obtained from a built-in pressure transducer attached to the patient side of the isolator assembly. Alarm conditions are detected by a change of pressure in the closed system on the patients side.

Normal Balloon Pressure Waveform:

A. Balloon pressure baseline
B. Rapid inflation
C. Pressure overshoot (peak inflation artifact)
D. Balloon plateau
E. Plateau endpoint
F. Deflation
G. Zero-undershoot (peak deflation artifact)

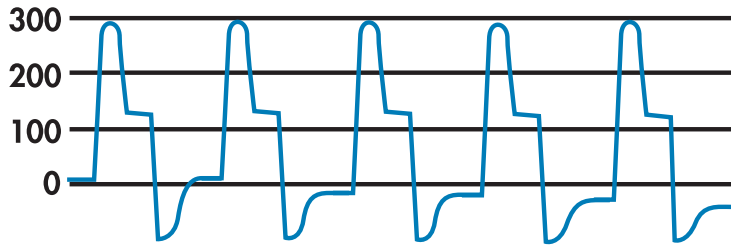


Normal Variations:

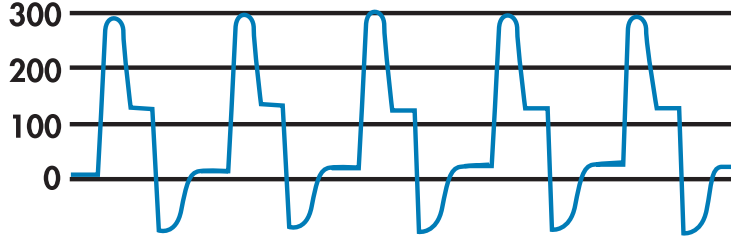


Abnormal Balloon Pressure Waveforms:

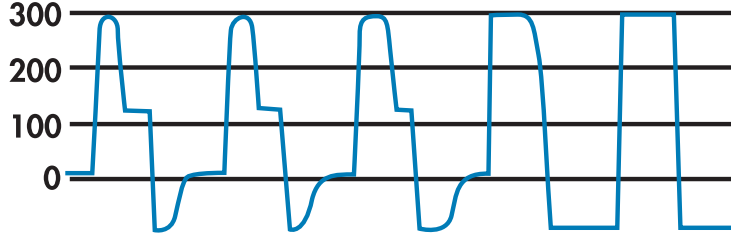
Low or Falling Baseline
Possible Alarm: GAS LOSS



High Balloon Pressure Baseline
Possible Alarm: FILL PRESSURE



Plateau Lost or Distorted
Possible Alarm: KINKED LINE, GAS LOSS



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ARROW 24 HOUR INTRA-AORTIC BALLOON PRODUCT SUPPORT:

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