

ARROW AutoCAT® 2 WAVE™ IABP Abbreviated Operation and Troubleshooting Guide

ARROW 24-HOUR INTRA-AORTIC BALLOON PRODUCT SUPPORT:

US and Canada

(800)-447-IABP

(800)-447-4227



Modes of Operation

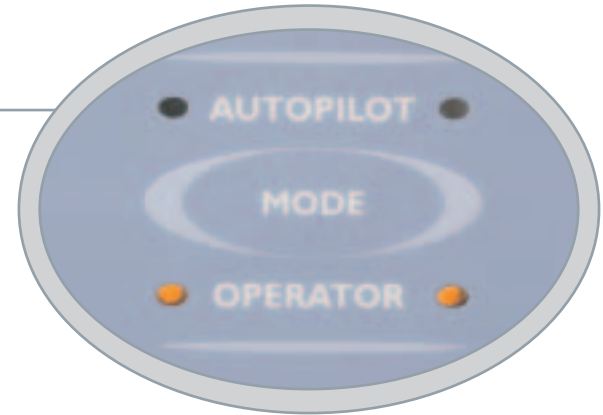
AutoPilot™

- **Pump Selects ECG / AP source lead**
 - Continuously monitors all available ECG signals and selects an alternate lead if current ECG signal is lost or noisy
- **Pump Sets Timing**
 - Automatically sets inflation and deflation based on current patient condition and timing method selected
- **Automatic Trigger Selection**
 - Selects and changes trigger mode based on patient condition. Selects next best trigger source if present one is lost



Operator

- User selects ECG and AP sources and adjusts as needed
- User sets Timing
- User selects Trigger

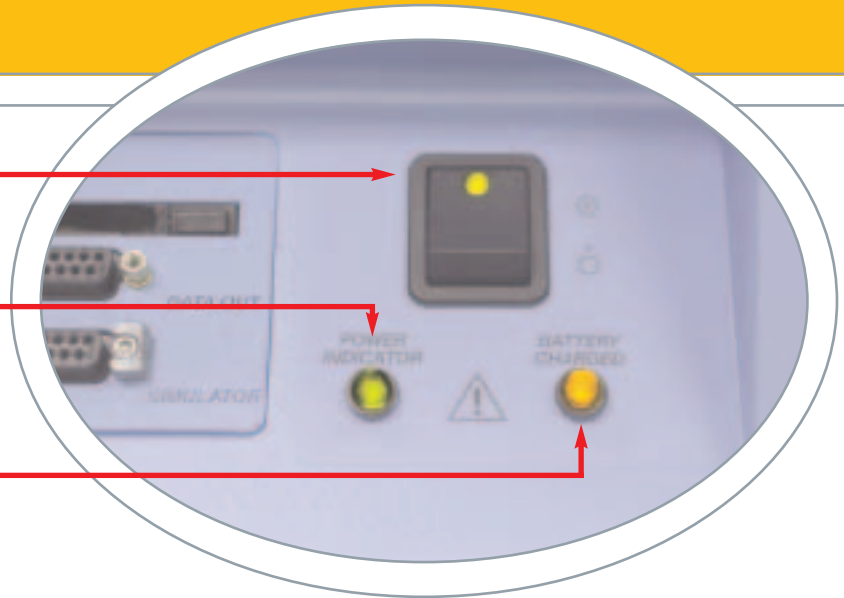


Power On

■ Power on.

■ LED indicates the pump is plugged in.

■ LED indicates 80% charge on the battery.

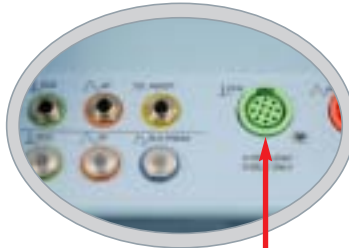


ECG Patient Connections

■ BEST Connection Method



- 5 lead ECG Cable (offers 12 lead capability)



- Skin lead connection



- SKIN selection is preset

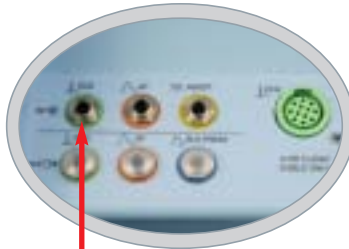


- Lead selected is displayed

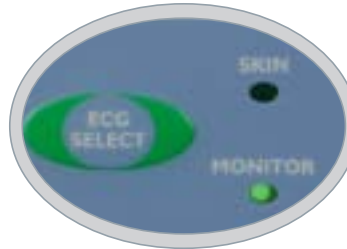
■ Alternate ECG Signal Option



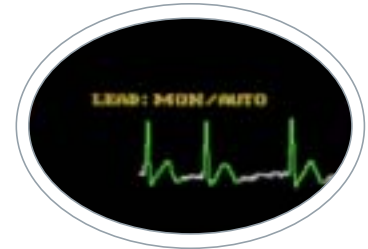
- Standard 1/4" phono cable



- Phono to Phono connection



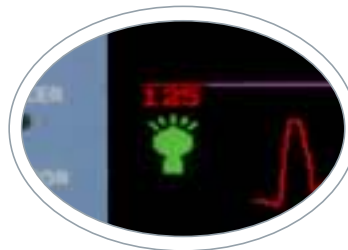
- AutoPilot™ will automatically select if first ECG source available



- Monitor source displayed

Arterial Pressure Patient Connections

■ BEST OPTION via FiberOptix™ IAB



- Connect blue sensor and Cal Key PRIOR to insertion

- Verify Auto Zero via audible tone, green light bulb and AP FOS Zero'd message appears

■ To perform manual Zero of FiberOptix™ IAB



- Press AP select once

- Press soft key under fiber optic sensor for Zero

- Verify green light display and AP FOS Zero'd message appears

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

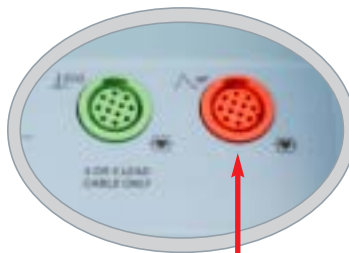
Arterial Pressure Patient Connections (cont.)

Alternate arterial pressure signal options:

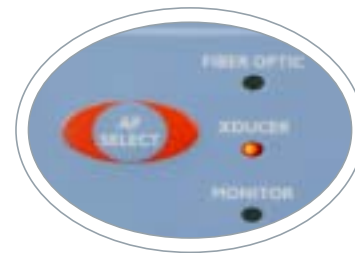
■ Standard transduced central lumen



- Select transducer cable



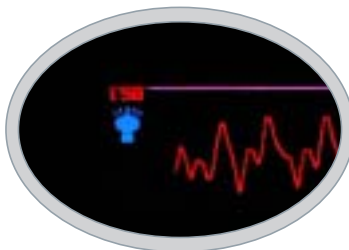
- Connect to pump



- Press AP select to highlight xducer



- Level as usual, open stopcock, press transducer zero



- Close stopcock; verify waveform on screen

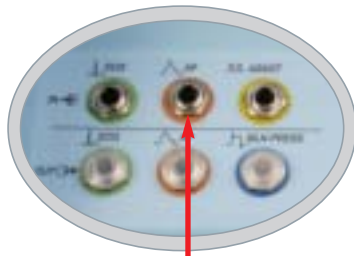
Arterial Pressure Patient Connections (cont.)

Alternate arterial pressure signal options:

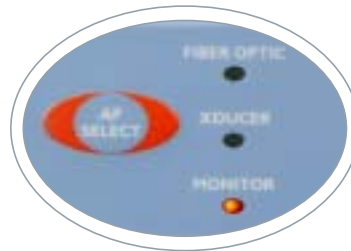
- To slave arterial pressure from remote monitor



- Standard 1/4" phono cable



- Connect to pump



- Press AP select to highlight monitor



- Zeroing procedure performed at primary monitor

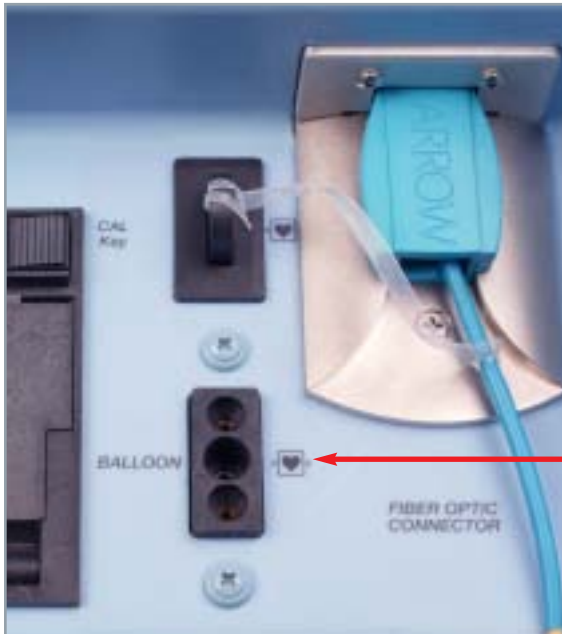
NOTE: In OFF and STANDBY modes, unassisted AP values appear in white on right side of screen.

In ON mode in 1:1 pumping, assisted AP values appear in white.

In ON mode in 1:2, 1:4 and 1:8 pumping, assisted AP values appear in white and unassisted AP values appear in yellow subscript.

Start up

Balloon Connection



- Push firmly, right side up or upside down; it does not matter



Start up



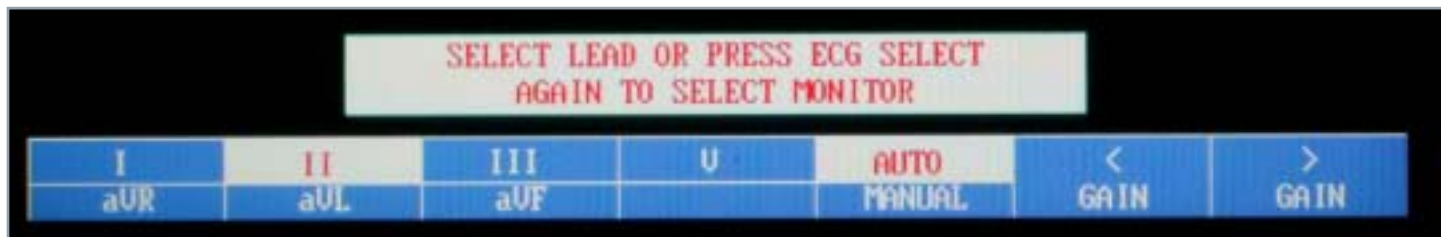
Verify:

- Flashing Heart Icon
- White Overlay on ECG
 - Both denote valid trigger
- Correct IAB Volume display
- Adequate Helium display
 - **RED BAR** indicates less than 125 PSI in tank
- Press Pump ON

Control and Function Keys

ECG Select

- **ECG SELECT** provides selection choices for desired LEAD, input source and gain mode
 - To change a skin lead, press ECG SELECT once. The current lead is highlighted in white. Press the soft key under the desired LEAD label to switch leads.
 - AUTOGAIN is the preset gain mode. To manually gain the ECG lead, press the soft key to change the white highlight to manual and adjust gain as desired.
 - To select an ECG that is brought in from another monitor source, press the ECG SELECT key twice.
- NOTE: Illuminated LED indicates source selected.

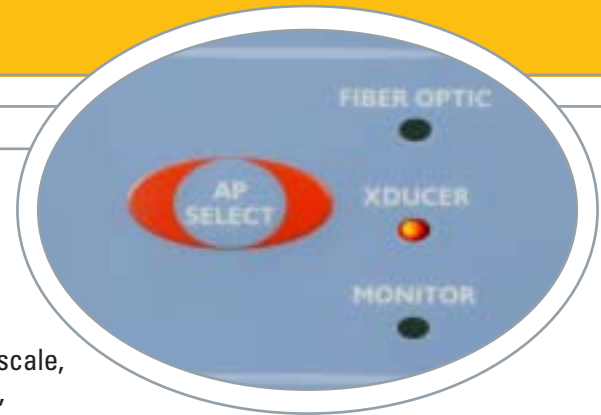


Control and Function Keys

AP Select

- **AP SELECT** provides selection for source, scale, alarm parameter and limit as well as zero and calibration functions.

- To change input source, press AP SELECT twice.
Note: Illuminated LED indicates source selected.
- AP scaling is automatic based on patient waveform. To change AP scale, press AP SELECT once. Then press the soft key under AP SCALING, and select desired scale.
- To enable an AP alarm, press AP SELECT once, then press the soft key under AP Alarm Off. This will turn the alarm ON. Press the soft key under AP ALARM MAP to toggle between a mean AP or augmentation alarm. Select the desired alarm limit by pressing the soft key to raise (>) or lower (<) the limit. A yellow box will appear on the display to the left of the arterial pressure waveform indicating the selected AP alarm source and the limit.



Control and Function Keys

Pump Status

■ ON

- Starts pumping.
- If pressed before STNDBY, pumping starts after one purge cycle and the pneumatic system fills with helium to 2.5mmHg.

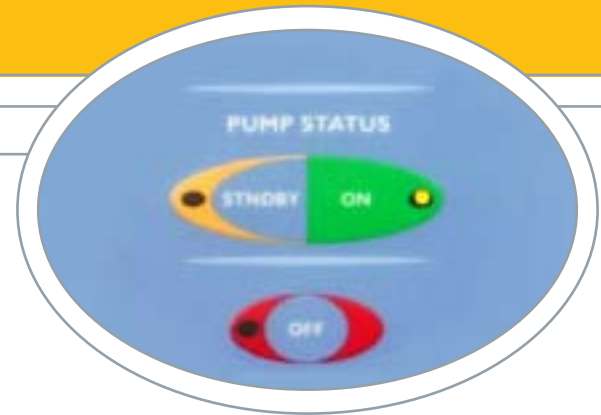
NOTE: The first time pump ON is pressed a special purge cycle is initiated. This is a purge beat followed by 9 beats, and is repeated automatically up to three times to optimize helium concentration.

■ STANDBY

- If pump is ON, immediately stops pumping but does not vent the pneumatic system.
- If the pump is OFF, completes a four beat purge cycle and pressurizes the pneumatic system to 2.5mmHg.
- After three minutes in the standby position, the system will issue an audible alert.

■ OFF

- Immediately stops pumping, deflates the balloon and vents the pneumatic system to atmosphere.



Control and Function Keys

Inflate

- Adjusts the inflation point in Operator mode. Inflation occurs earlier when the left arrow is depressed and later when the right arrow is depressed. Allows the operator to optimize timing by monitoring the hemodynamic changes produced on the AP waveform.



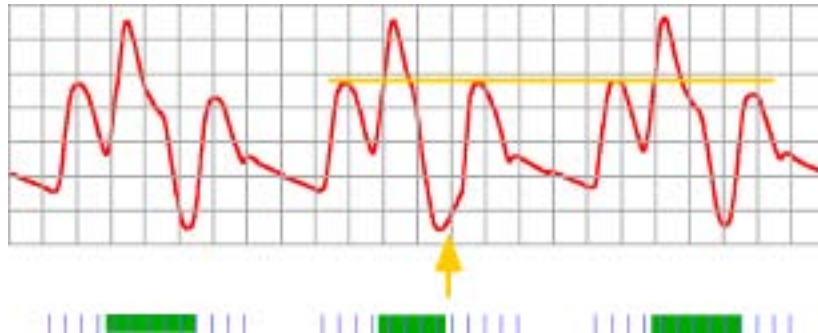
- 1) Move the inflation point to the right until you can clearly see the dicotric notch (DN) on the arterial pressure waveform (green arrow).
- 2) Slowly move the inflation point to the left until the dicotric notch (40ms in front of the DN) is no longer visible.
- 3) Check Augmentation. Generally AUG should be greater than SYS. If not, additional assessment of the patient or IABP may be required.



Control and Function Keys

Deflate

- Adjusts the deflation point in Operator mode. Deflation occurs earlier when the left arrow is depressed and later when the right arrow is depressed. Allows the operator to optimize timing by monitoring the hemodynamic changes produced on the AP waveform.



- 1) Move the deflation point to the left to see the effect on the AP waveform (yellow arrow). Note the rise in the ASYS and the "U" shape of the ADIA.
- 2) Move the deflation point to the right to lower the ASYS while simultaneously keeping the ADIA lower than or equal to the DIA.
- 3) Return the ASSIST RATIO to 1:1.

Control and Function Keys

Arrhythmia Timing

- The arrhythmia timing key activates or deactivates the arrhythmia timing and/or R wave deflation function of the pump when in AutoPilot mode. The AutoCAT 2 system will automatically recognize arrhythmias and implement real-time R wave deflation when the arrhythmia timing function is ON and conditions are acceptable for R wave deflation. This will be indicated by the LED light on.
- If automatic R wave deflation is NOT desired, press the ARRHYTHMIA TIMING ON/OFF key, then the soft key under ARR. TIMING until OFF is displayed. ARRHYTHMIA TIMING OFF will be displayed on the screen (when an arrhythmia is present) and an alternate algorithm will be utilized for deflation.
- To select R wave deflation ON at all times, press the ARRHYTHMIA TIMING ON/OFF key, then the soft key under R-WAVE DEFL until ON is displayed. In this case, R wave deflation (AFIB trigger) will be selected whether an arrhythmia is present or not.



Control and Function Keys

Trigger Modes (Operator Mode Only)

Select Operator mode and then Press the trigger key to change trigger modes. The selections will appear on the bottom of the display.

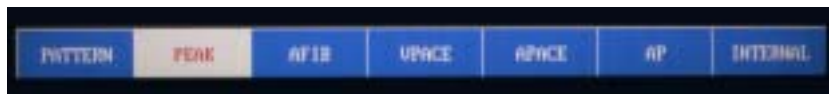
■ PATTERN

- Preset trigger; triggers on ECG. Recommended for regular rhythms with normal QRS complex and HR <130. Rejects pacer spikes.



■ PEAK

- Triggers on ECG. Recommended for regular rhythms with HR >130. Recommended for wide or abnormal QRS complexes. Recommended for irregular rhythms when R-wave deflation is not desired. Rejects pacer spikes.

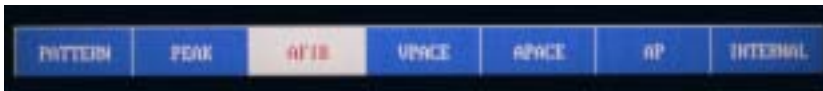


Control and Function Keys

Trigger Modes (Operator Mode Only)

■ AFIB

- Triggers on ECG. Recommended for irregular rhythms. Provides REAL TIME (R-wave) deflation. Rejects pacer spikes.



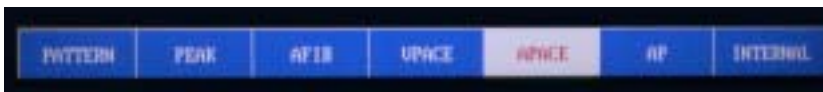
■ VPACE

- Uses V-pacer spikes to trigger. MUST BE 100% PACED. For V or AV sequential pacers. Recommended for V or AV paced rhythms with poor QRS complex.



■ APACE

- Uses A-pacer spikes to trigger. MUST BE 100% PACED. For Atrial pacers only. Recommended for A paced rhythms with poor QRS complex.



Control and Function Keys

Trigger Modes (Operator Mode Only)

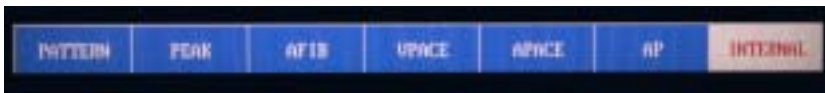
■ AP

- Uses AP waveform to trigger. Recommended when ECG is not available or too noisy. AP NOT RECOMMENDED FOR IRREGULAR RHYTHMS.



■ INTERNAL

- Uses IABP internal signal for triggering. Used only when patient has no ECG and no Cardiac Output. ASYNCHRONOUS TO PATIENT CARDIAC ACTIVITY. Press INT again to confirm.
- Not available in AutoPilot mode.



Control and Function Keys

Assist Ratio

■ ASSIST RATIO 1:1

- Initiates one inflation-deflation cycle for each cardiac cycle. Preset assist ratio at start-up. Maximizes counterpulsation support.



■ ASSIST RATIO 1:2

- Initiates one inflation-deflation cycle for every other cardiac cycle. Generally used to assess and optimize timing in Operator mode and to wean patient from IABP support.



■ ASSIST RATIO 1:4

- Initiates one inflation-deflation cycle for every fourth cardiac cycle. Used to wean patient from IABP support.



■ ASSIST RATIO 1:8

- Initiates one inflation-deflation cycle for every eighth cardiac cycle. Used to wean patient from IABP support.



Control and Function Keys

Balloon Volume

- Press **BALLOON VOLUME** key.
- Select **INCREASE / DECREASE** until desired volume is displayed. Press **FULL VOLUME** to return to volume based on balloon connector.
- Press **APPLY** key to initiate change. Press **CANCEL** key to cancel change.



DELIVERY VOLUME : 39.5 c.c. 98 %

CANCEL

<
DECREASE

>
INCREASE

FULL
VOLUME

APPLY

Control and Function Keys

Recorder

■ To change recorder settings:

- Press HOME
- Press RECORDER SETUP
- Select desired waveforms or set recorder automatic print interval
- Recorder will print waveforms highlighted in white. Press soft key under desired waveforms to select or de-select.



Control and Function Keys

Alarm Control

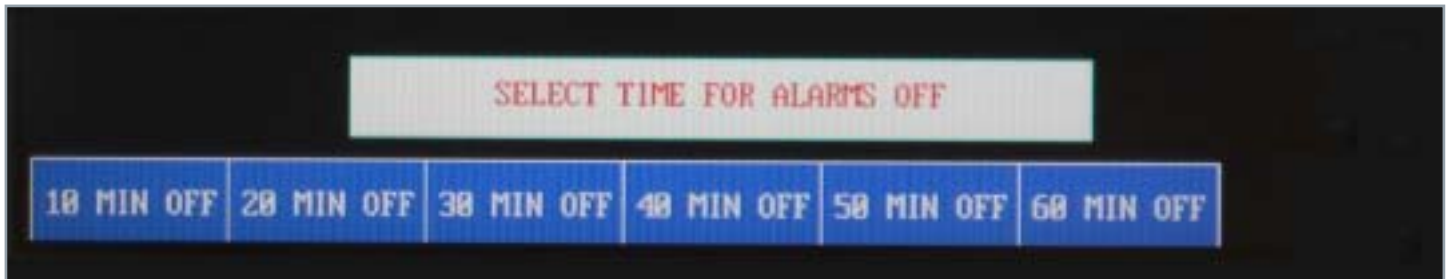
■ RESET

- Silences the audible alarm tone and clears the alarm message. If pumping was interrupted, the alarm message is not cleared until STNDBY or ON is pressed. If there is more than one alarm condition, one message is cleared at a time.

■ ON/OFF

- Turns pneumatic alarms audio, recording, drain and refill on or off. Alarm message will be displayed. To select alarm time off, press key under desired setting. Time remaining for alarms off is displayed above AP Scale. Press ON/OFF again to turn on alarms.

NOTE: DO NOT leave pump unattended with pneumatic alarms disabled.



Control and Function Keys

Home

■ AP SCALING

- Selects AP Scaling mode and scales for display and recorder.

■ RECORDER SETUP

- Selects waveforms to be recorded and time interval for automatic recordings.

■ WEANING SETUP

- Allows the user to make changes in volume and/or assist ratio and set the time interval for the weaning step. It allows the user to start the weaning step and cancel the weaning step.

■ SHOW STATUS

- This key will display a summary of all current operational settings as well as selected information which is tracked by the AutoCAT 2.



Control and Function Keys

Home- (continued)

AUDIO SETUP

- Allows the user to set the key volume, and turn it ON/OFF and independently set alarm volume.

HEMODYNAMICS

- Automatically calculates:

1. AUG-SYS
2. AUG-ADIA

Freezes the hemodynamic numbers for 30 seconds and displays the assisted pressures in white and the unassisted pressures in yellow.

CLOCK SETUP

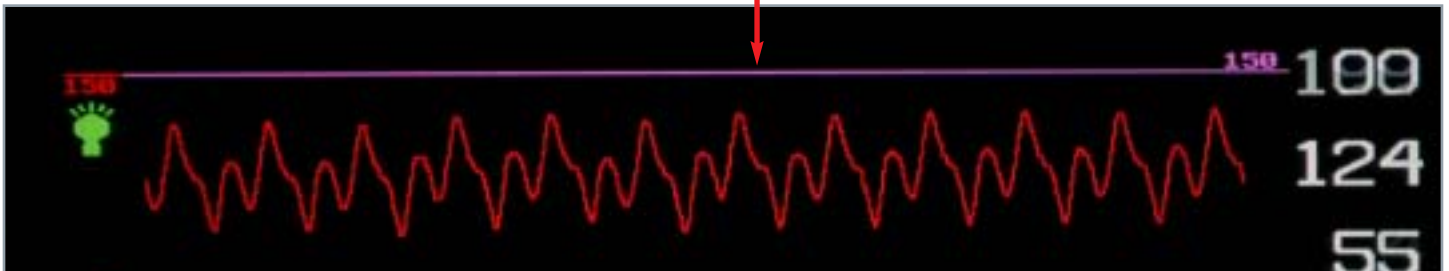
- Allows the user to set the time and date for the pump.



Control and Function Keys

Cursor

- Moves horizontal cursor to desired assessment point. Value is displayed above cursor on the right hand side.



Alarms/Alerts

NOTE: An alarm may cause the pump to stop pumping. The pump will display a message on the screen to assist in troubleshooting. Once the condition is corrected:

To resume pumping

- Press Alarm RESET
- Press Pump ON

If the alarm condition repeatedly appears, refer to the Operator's Manual for further information or call Arrow's IABP support line at 800/447-IABP.

PUMP ACTIONS	GAS ALARMS (CLASS 1 ALARMS)	TRIGGER LOSS ALARMS (CLASS 2 ALARMS)	AUDIBLE ALERTS (CLASS 3 ALERTS)	MESSAGE ALERTS (CLASS 4 ALERTS)
	<ul style="list-style-type: none"> • Pump to OFF • IAB deflated • Helium vented to atmosphere • Audible alarm • Freeze display • Alarm/troubleshooting message displayed • Prints 10 second strips (3 prior to alarm/7 after alarm) 	<ul style="list-style-type: none"> • Pump to Stand-by • IAB deflated • Helium maintained in bellows • Audible alarm • Alarm/troubleshooting message displayed • Automatic reset of some alarms when condition is corrected 	<ul style="list-style-type: none"> • Pump remains ON • Audible alarm • Alarm/troubleshooting message displayed • Automatic reset of some alarms when condition is corrected 	<ul style="list-style-type: none"> • Pump remains ON • Alarm/troubleshooting message displayed • Automatic reset of some alarms when condition is corrected

Alarms/Alerts

ALARMS	GAS ALARMS (CLASS 1 ALARMS)	TRIGGER LOSS ALARMS (CLASS 2 ALARMS)	AUDIBLE ALERTS (CLASS 3 ALERTS)	MESSAGE ALERTS (CLASS 4 ALERTS)
	<ul style="list-style-type: none"> • System error alarms 1-8 • Unable to Refill • Possible Helium loss 2 and 3 • High Pressure • High Baseline • Large Helium Leak • Purge Failure 	<ul style="list-style-type: none"> • Stand-by alarm disabled • Pump in Stand-by for greater than 3 minutes • ECG trigger loss (Operator mode) • AP trigger loss (Operator mode) • ECG lead fault (Operator mode) • Trigger loss (AutoPilot mode) 	<ul style="list-style-type: none"> • Drain failure • Deflation beyond 100% (Operator mode) • Insufficient Time to Inflate • Insufficient time to Deflate • Battery Inoperative • System Running on Battery • Battery time less than 20, 10 and 5 minutes • Possible ECG detected • Weaning Step Complete • Arterial Pressure alarm • Low Helium Tank Pressure • AP FOS Signal Weak • AP FOS CAL key missing or corrupt • AP FOS Sensor out of range 	<ul style="list-style-type: none"> • Possible Late Deflation • Erratic Trigger: R-Wave Deflation • Erratic Triggering • ECG Lead Fault (Autopilot mode) • No ECG Signal Available • No AP Signal Available • Arrhythmia Timing not available • Bad Real time clock Battery • Bad Ram Battery

Alarms/Alerts

USER ACTIONS	GAS ALARMS (CLASS 1 ALARMS)	TRIGGER LOSS ALARMS (CLASS 2 ALARMS)	AUDIBLE ALERTS (CLASS 3 ALERTS)	MESSAGE ALERTS (CLASS 4 ALERTS)
	<ul style="list-style-type: none"> • Reset alarm • Review alarm message and troubleshooting information • Correct condition if known • Restart pump • Review alarm strip • If alarm persists refer to Chapter 8 of the Operator's manual for further information. 	<ul style="list-style-type: none"> • Correct condition if known. Many alarms will reset automatically when the condition is cleared -OR- • Reset alarm • Review alarm message and troubleshooting information • Correct condition if known • Restart pump • If alarm persists refer to Chapter 8 of the Operator's manual for further information. 	<ul style="list-style-type: none"> • Correct condition if known. Many alarms will reset automatically when the condition is cleared -OR- • Reset alarm • Review alarm message and troubleshooting information • Correct condition if known • If alarm persists refer to Chapter 8 of the Operator's manual for further information. 	<ul style="list-style-type: none"> • Correct condition if known. Many alarms will reset automatically when the condition is cleared -OR- • Reset alarm • Review alarm message and troubleshooting information • Correct condition if known • If alarm persists refer to Chapter 8 of the Operator's manual for further information.

Notes:

www.arrowintl.com

Caution: Federal law restricts 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. U.S. Patent Nos. 6,258,035; 6,569,103; and 6,887,206.

Applicable to software version 2.22 and greater.

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