



PROACTIVE COUNTERPULSATION®
Automatic timing accuracy—even during arrhythmias



WELCOME TO A BREAKTHROUGH IN IABP THERAPY

Teleflex's Arrow International brand of innovative IABP therapy — called ProActive CounterPulsation — enables you to provide 98% inflation timing accuracy during IABP support — even when patients have severe arrhythmias^{1,2}.

WHAT IS PROACTIVE COUNTERPULSATION?

ProActive CounterPulsation is the unique ability of the AutoCAT2 WAVE® system with FiberOptix® catheter technology to proactively anticipate individual AV closures *before* they occur and provide accurate inflation timing as well as triggering, even during severe arrhythmias. Don't settle for traditional “predictive timing” — get proactive with ProActive CounterPulsation.

THE ANATOMY OF PROACTIVE COUNTERPULSATION

Arrow FiberOptix Catheter

Captures and transmits the high-fidelity AP signal at the speed of light, overcoming the delays seen with traditional fluid-filled AP signal systems

Proprietary WAVE® Algorithm

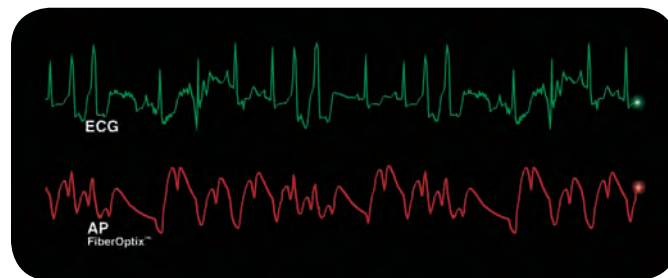
The brain of the pump calculates aortic flow based on the AP signal from the FiberOptix catheter for each beat rather than historic data from previous beats

Unique Aortic Flow Timing

Proactively determines AV closure with 98% inflation timing accuracy during IABP support — even when patients have severe arrhythmias^{1,2}

AutoPilot™ Mode of Operation

Delivers simple, touch-of-a-button monitoring of, and response to, physiologic conditions to ensure consistent triggering and timing



The AutoCAT2 WAVE consistently tracks this severe arrhythmia and accurately times IABP inflation/deflation — that's ProActive CounterPulsation

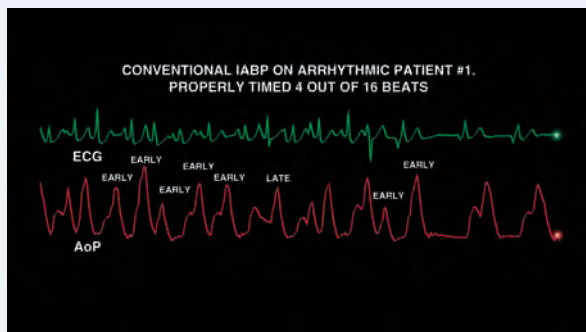
¹ Donelli A, Jansen JRC, Hoeksel B, et al. Performance of a real-time dicrotic notch detection and prediction algorithm in arrhythmic human aortic pressure signals. *J Clin Monit.* 2002;17:181-185.

² Schreuder JJ, Castiglioni A, Donelli A, et al. Automatic intraaortic balloon pump timing using an intrabeat dicrotic notch prediction algorithm. *Ann Thorac Surg.* 2005;79:1017-1022.

THE AUTOCAT2 WAVE

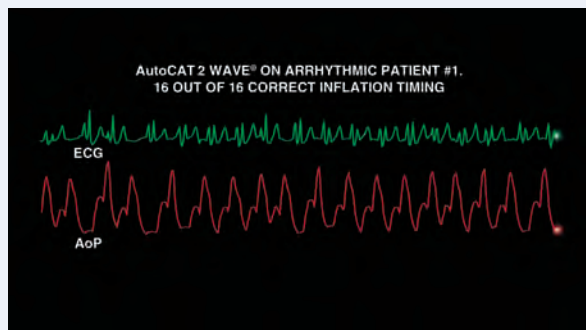
Automaticity, proactivity, and much more.

TIMING COMPARISON: PROACTIVE COUNTERPULSATION VS TRADITIONAL IABP SYSTEM



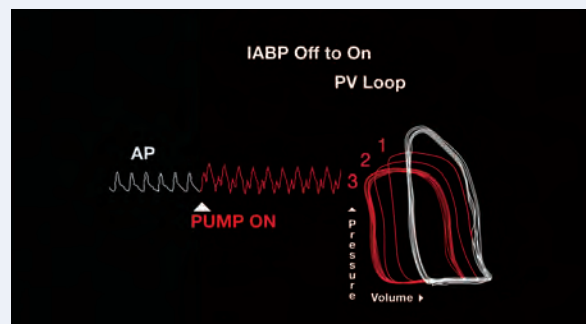
INACCURATE TIMING CAN REDUCE THE EFFICACY OF IABP

Because the timing of fluid-filled systems is based on historic data, arrhythmic episodes can lead to poor performance in patient support. In this example, the fluid-filled system properly timed only 4 out of 16 beats.



ACCURATE TIMING RESULTS IN OPTIMAL IABP PERFORMANCE

The AutoCAT2 WAVE sets the inflation point in real time, within the beat — even during arrhythmias. In this example, the AutoCAT2 WAVE properly timed inflation for all 16 out of 16 beats.



EFFECTIVE IABP THERAPY CAN IMPROVE LEFT VENTRICULAR PERFORMANCE

Once the IABP is turned on, the PV loop indicates lower pressure and increased stroke volume. Simply turning the pump on increases cardiac output by as much as 18%–22% within just 3 beats **when accurately timed**. This direct patient benefit is evident in the PV loop shown here.

DELIVERING A NEW LEVEL OF IABP RELIABILITY AND EASE OF USE

AutoCAT2 WAVE relies on a unique combination of FiberOptix sensor technology, aortic flow timing, proprietary WAVE software and the AutoPilot mode of operation to achieve its high level of performance — even in patients with severe arrhythmias.

- Speed-of-light AP signal transmission overcomes delays of fluid-filled systems
- Reliably anticipates and determines AV closure — before it occurs
- 98% timing accuracy within 12 milliseconds (ms) — even during severe arrhythmias
- WAVE algorithm sets inflation point within the beat, even during arrhythmias
- Increases time for coronary perfusion and decreases afterload
- AutoPilot mode consistently maintains triggering and timing — Proprietary Best Signal Scoring software brings automaticity to a new level of reliability

WITH THE FIRST AND ONLY PROVEN FIBEROPTIX IAB CATHETER

Arrow FiberOptix, the world's first fiber-optic IAB catheter, has been proven in thousands of patients. It is also the only one that works with the unique components of the AutoCAT2 WAVE to deliver ProActive CounterPulsation.

- **Consistent AP signal:** Transmits better information faster
 - Unaffected by dampening, noise, and movement; will not degrade over time
 - No maintenance of fiber-optic signal
 - No electrical interference from cautery
 - No transducer-induced motion artifact
- **Back-up safety for AP signal:** Should it be required, the FiberOptix catheter can be used as a traditional fluid-filled catheter
- **Abrasion-resistant:** The Cardiothane™ II membrane offers a unique design of abrasion resistant material with hydrophilic coating
- **Universal design:** Sheathed or sheathless insertion options; optional hemostasis device for post-insertion bleeding control

The accurate, real-time advantages of FiberOptix catheters are available only when the catheter is used with the AutoCAT2 WAVE pump console. However, FiberOptix can be used as a conventional catheter with any IABP, ensuring continuity and ease in cases of patient transfer.



ORDERING INFORMATION

FIBEROPTIX 8 INTRA-AORTIC BALLOON CATHETERS

PRODUCT NUMBER	PRODUCT DESCRIPTION	CATHETER SIZE	BALLOON VOLUME	INSERTABLE LENGTH [‡]	CATHETER O.D.	SHEATH LENGTH	CENTRAL LUMEN I.D. (INCH)	MAXIMUM GUIDEWIRE (INCH)	BALLOON MEMBRANE MATERIAL	CATHETER MATERIAL	BALLOON MEMBRANE LENGTH	INFLATED DIAMETER
IAB-05840-LWS	IAB Catheter	8.0 Fr.	40cc	27.3" (69.3 cm)	8.0 Fr. /0.105"	6" (15 cm)	.027	.025	Cardiothane II	Polyurethane/ Nylon	10.2" (260 mm)	15 mm
IAB-05830-LWS	IAB Catheter	8.0 Fr.	30cc	25.3" (64.3 cm)	8.0 Fr. /0.105"	6" (15 cm)	.027	.025	Cardiothane II	Polyurethane/ Nylon	9.1" (230 mm)	13.9 mm

REPLACEMENT INSERTION KITS

PRODUCT NUMBER	PRODUCT DESCRIPTION
IAK-06845	Replacement Insertion Kit for use with FiberOptix 8, 30cc and 40cc (IAB-05830-LWS and IAB-05840-LWS) catheters Each kit contains the following: <ul style="list-style-type: none"> • One: 18 Ga. x 2 1/2" Arterial Needle • Two: .025 x 175 cm PTFE Coated 3 mm 'J' Extra Stiff Wire Guides • One: 8.0 Fr. Sheath Dilator Assembly • One: 8.0 Fr. Vessel Pre-Dilator • One: 8.0 Fr. Sheath with Sideport and Dilator • One: #11 Scalpel
IAK-02691	Driveline Tubing with Pre-Attached Arrow 30cc Pump Connector for use with Arrow pump consoles and FiberOptix 30cc IAB catheters
IAK-02692	Driveline Tubing with Pre-Attached Arrow 40cc Pump Connector for use with Arrow pump consoles and FiberOptix 40cc IAB catheters
IAK-02263	Driveline Tubing for use with Datascope® Balloon Pumps and FiberOptix 30cc and 40cc IAB catheters

AUTOCAT® 2 SERIES

PRODUCT NUMBER	PRODUCT DESCRIPTION
IAP-0500	AutoCAT 2 WAVE 1 (IABP) system includes: <ul style="list-style-type: none"> • FiberOptix sensor technology • WAVE algorithm—proprietary timing software[†] • Aortic flow timing method • AutoPilot mode of operation
IAP-0400	AutoCAT 2 1 (IABP) system includes: <ul style="list-style-type: none"> • AutoPilot mode of operation

AERO® SERIES (AIR TRANSPORT MODEL)

PRODUCT NUMBER	PRODUCT DESCRIPTION
IAP-0535	AERO Series: AutoCAT 2 WAVE
IAP-0435	AERO Series: AutoCAT 2

* These products are also available in multiple languages. Contact Arrow for availability.

† U.S. Patent Nos. 6,258,035, 6,569,103, 6,887,206, and 5,913,814; additional patents pending.

‡ Sheathless insertions without hemostasis device.

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 and components included in IAB and IAB insertion products. Product specifications, components and part numbers are subject to change without notice.

AutoCAT 2 WAVE®

WITH FIBEROPTIX® SENSOR TECHNOLOGY

PRODUCT SPECIFICATIONS

DESIGN

- FiberOptix® capability:
 - AP signal transmitted at speed of light
- Proprietary WAVE® algorithm
- Proprietary Aortic Flow Timing Method
- AutoPilot™ mode of operation
- Microprocessor-based system architecture
- Modular system consisting of display/control module and pneumatic drive unit
- Proprietary deflation timing management

ELECTRICAL

- AC requirements:
 - 90–264 VAC 47–63 Hz
- Typical power consumption: 245 watts
- Maximum power consumption: 420 watts
- Battery operating time:
 - 90 minutes minimum with full charge
 - 180 minutes with optional second battery
- Typical battery recharging time:
 - 80% in 4 hours from full discharge
 - Recharge to 80% indicated by yellow light

MECHANICAL DIMENSIONS

- Control module with monitor:
 - 10" high (25.4 cm) x 13.75" wide (35 cm) x 2" deep (5 cm)
- Pneumatic drive unit:
 - 31.5" high (80 cm) x 13.5" wide (34.3 cm) x 21" deep (53.3 cm)

MECHANICAL WEIGHT

- Control module:
 - 5 lbs (2.3 kg)
- Pneumatic unit for AutoCAT 2 WAVE®:
 - 95.5 lbs (42.4 kg)
- Total weight for AutoCAT 2 WAVE:
 - 100.5 lbs (44.7 kg)
- Total weight for AERO® Series:
 - 91.5 lbs (40.7 kg)

PNEUMATICS

- Drive system: Stepper motor-driven bellows
- Drive gas: USP-grade helium
- Helium tank:
 - Disposable canister (500 psi) or refillable (2000 psi) cylinder—US Approval; (2900 psi) cylinder—European Approval
- Pumping volume:
 - 0.5cc to 50cc, adjustable in 0.5cc increments
- Counterpulsation rate: 40 to 200 pulsations/minute
- Assist ratio options

CONDENSATION REMOVAL

- Thermoelectric system removes moisture continuously from pneumatic system without interrupting counterpulsation

SYSTEM MODES

- AutoPilot:
 - Automatically selects ECG/AP signal, sources, trigger mode, and timing method as well as timing settings
 - Automatically changes settings to optimize assist
 - Proprietary software sets timing to correspond to individual patient needs
- Operator:
 - Allows user control of most pump functions

TRIGGER MODES

- ECG (PATTERN, PEAK, AFIB):
 - Microprocessor-based R-waveform trigger detection algorithms
- Pacer (VPACE, APACE):
 - Low level (skin) ECG input
 - Pulse width 0.1 to 0.5 ms and pulse amplitude => +5 to +700 mV
 - Pulse width => 0.5 to 2 ms and pulse amplitude => +2 to +700 mV
 - High level (monitor) input
 - Pulse width 0.1 to 2 ms and pulse amplitude => 1 V
 - AV pacer detection is <250 msec between pacer pulses
- Arterial pressure (AP):
 - Microprocessor-based waveform trigger detection algorithm
- Internal:
 - Default to 80 bpm; adjustable 40 to 120 bpm
- Filtering:
 - Diathermy, 30 Hz low pass

GENERAL TRIGGER SELECTION CRITERIA (AUTOPILOT MODE)

ECG TRIGGER MODES:

- PATTERN: HR <130 bpm no arrhythmia
- PEAK: HR >130 bpm or arrhythmia detected and arrhythmia timing OFF*
- AFIB: Any HR with arrhythmia detected*
- VPACE: Single or dual pacer (<250 msec apart) and no QRS or AP waveform detected
- APACE: Single pacer with R-wave >100 msec later Transition only

AP TRIGGER MODE:

- No ECG signal or noisy ECG signal

*Based upon deflation timing management.

INFLATION/DEFLATION TIMING METHODS

INFLATION TIMING METHODS:

- **Aortic Flow:** Proprietary WAVE algorithm sets the timing intra-beat on average 12 ms of aortic valve closure¹
- **Predictive:** AP waveform analysis to set inflation
- **Weissler:** ECG only, inflation timing based on systolic time intervals

DEFLATION TIMING METHODS:

- **R-wave:** Real-time deflation on R-wave
- **Predictive:** Deflation set to occur just prior to next systolic rise
- **Weissler:** ECG only, deflation timing based on diastolic intervals

MANUAL:

- User set inflation and deflation timing in Operator Mode

INFLATION/DEFLATION TIMING LIMITS (OPERATOR MODE)

- **ECG:** Inflation, 20%–80% of R-R interval
Deflation, 30%–120% of R-R interval
- **AP:** Inflation, 0–35% of peak systole-peak systole interval
Deflation, 35%–75% of peak systole-peak systole interval
- **AFIB Trigger:** Inflation 80 to 430 ms after R-wave trigger event
Mode Deflation on R-wave

DISPLAY

- **Type:** Color LCD flat screen
- **Channels:** Three-channel multicolor waveforms
 - **ECG:** Green trace with white highlight on assisted portion
 - **AP:** Red trace calibrated for direct reading of AP, white highlight on assisted portions when in Operator Mode
 - **Balloon pressure:** Blue trace calibrated in mm Hg and displayed continuously
- **Timing reference display:** Numerical timing settings in both operating modes as well as a bar graph displaying inflate/deflate events in Operator Mode
- **Cursor:** Measurement of AP and balloon pressure waveforms

ALPHANUMERIC DATA

- **Patient hemodynamics:** Heart rate, AP—systolic, augmented, diastolic, and mean arterial. When in 1:2 or lower assist ratio the assisted values are displayed in white and the unassisted values are displayed in yellow
- **Displayed parameters:** ECG source and gain state, alarm status with timer, ON Battery indication, operation mode selection, AP alarm parameter and limit, timing settings, helium tank level, arrhythmia detection, and timing status
- **Operations status:** Operational mode, trigger mode, helium tank gauge, alarm/battery charge status, balloon volume
- **Diagnostic alarm/help messages:** Preprogrammed troubleshooting prompts/help

STRIP CHART RECORDER

- **Recorder:** Dual-channel dot matrix: Dot density 400 dots/inch, 25 mm/s
- **Waveforms:** ECG, AP, or balloon pressure (one or two recorded)
- **Alphanumeric:** Operational mode, trigger mode, ECG lead/source, AP source, AP alarm status, timing settings, assist ratio, balloon volume, timing method, arrhythmia status, alarm condition, date, time, patient hemodynamics

DISPLAY FREEZE

- Freezes approximately 7 seconds of patient data on screen

PATIENT SIGNAL INPUTS

- **ECG:** 5 lead skin cable (I, II, III, aVR, aVL, aVF and V)
High level monitor input (0 to 5 V)
- **AP:** Fiber optic signal input from FiberOptix IAB Catheter (WAVE)
AP transducer (Spectramed or equivalent), 50 mV/V/cm Hg
High-level monitor input (1 V = 100 mm Hg)

ORDERING INFORMATION

ORDER NO.	DESCRIPTION
IAP-0500	AutoCAT 2 WAVE 1 (IABP) System includes: <ul style="list-style-type: none">FiberOptix Sensor TechnologyWAVE algorithm: Physiologically based, proprietary timing algorithmAortic flow timing methodAutoPilot mode of operation
IAP-0535	AERO Series–AutoCAT 2 WAVE

The products above are also available in multiple languages. Contact Arrow for availability.

Note: Additional system specifications are available from Arrow upon request. Specifications are subject to change without notice. Caution: U.S. Federal law limits this device to sale by or on order of a physician.

REFERENCE: ¹Schreuder JJ, Castiglioni A, Donelli A, et al. Automatic intraaortic balloon pump timing using an intrabeat dicrotic notch prediction algorithm. *Ann Thorac Surg.* 2005;79:1017-1022.

TELEFLEX MEDICAL
Research Triangle Park, NC 27709
Phone: 866.246.6990 Fax: 800.399.1028
Intl: 919.433.8088
TELEFLEX.COM

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