ARROW®

Optimized therapy even in the most challenging patient conditions

When already-compromised patients develop arrhythmias or tachycardia, the AC3 Optimus™ IABP is at its best. Its ability to deliver accurate and safe timing means patients who were not previously considered candidates can benefit from IABP therapy.

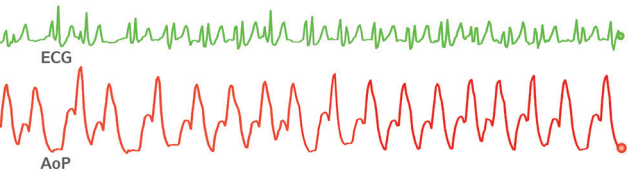# Proprietary algorithms drive accuracy and precision

The remarkable performance of the AC3 Optimus IABP is based upon AutoPilot® Mode, which uses a trio of proprietary algorithms. Individually, they help address key challenges; together, they help improve the clinical efficacy of IABP therapy and simplicity with which it's delivered.[5]

- WAVE® Inflation Timing
- Deflation Timing Management
- Best Signal Analysis

ProActive CounterPulsation® Technology
Exclusive ProActive CounterPulsation Technology determines individual AV closure points to provide intra-beat inflation timing accuracy during IABP support, even in patients with severe arrhythmias.[1-3]

Accurate inflation timing results in optimal IABP performance
With its proprietary WAVE Algorithm, the AC3 Optimus IABP sets the inflation point in real time, within the beat — even during severe arrhythmias. The WAVE Algorithm has been shown to deliver 98% timing accuracy[1] — in the illustration below, inflation was timed properly for 16 out of 16 beats.[3,6] The combination of WAVE Technology and FiberOptix® Sensor Technology eliminates delays associated with fluid-filled systems for fast reactions and accurate timing during early, unexpected beats.

Effective IABP therapy improves left ventricular performance
Once the IABP is turned on, the PV loop indicates lower pressure and increased stroke volume. The IABP acutely improves LV performance, primarily by afterload reduction and subsequent reduction in preload.[4,6] Simply turning the pump on increases stroke volume by as much as 18%–22% within just 4 beats which subsequently improves cardiac output.[4,6] This direct patient benefit is evident in the PV loop shown below.

WAVE Inflation Timing on arrhythmic patient

ECG
AoP

*Representative of study. Individual results may vary.

Initiating therapy

AP
Initiating Therapy
Pressure
Volume
1 2 3

Accurate deflation timing
Among the most real-time, comprehensive, and accurate timing methods available today. Automated Deflation Timing Management ensures accurate and safe deflation timing.
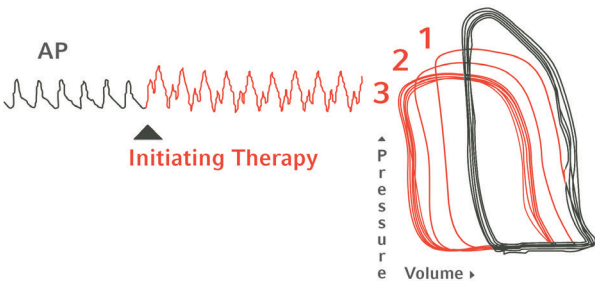
Up to 200 bpm
Provides precise and accurate support for patients with the most severe arrhythmias and heart rates as high as 200 bpm.[1]

References:

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(3-4):181-185. Study sponsored by Teleflex.

2. Hoeksel S, Jansen J, Blom J, et al. Detection of dicrotic notch in arterial pressure signals. *J Clin Monit.* 1997;13(5):309-316. Study sponsored by Teleflex.

3. Schreuder J, Castiglioni A, Donelli A, et al. Automatic intraaortic balloon pump timing using an intra beat dicrotic notch prediction algorithm. *Ann Thorac Surg.* 2005;79(3):1017-1022. Study sponsored by Teleflex.

4. Schreuder J, Maisano F, Donelli A, et al. Beat-to-beat effects of intra-aortic balloon pump timing on left ventricular performance in patients with low ejection fraction. *Ann Thorac Surg.* 2005;79(3):872-880. Study sponsored by Teleflex.

5. Torracca, L. Overcoming electro-surgical inference in IABP therapy with the combined use of AutoPilot and FiberOptix IAB sensor signal. 2007. *(case report, data on file).* Study sponsored by Teleflex.

6. Data on file.

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

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Arrow®
AC3 Optimus™ Intra-Aortic Balloon Pump
Greater precision with increased simplicity; an evolution in IABP performance

Teleflex®

Unmatched simplicity, right from the start

The AC3 Optimus™ Intra-Aortic Balloon Pump is up and running with the push of a button. Set up is fast and easy, guided by visual prompts on the large high-definition touchscreen — including confirmation that therapy can be initiated. In AutoPilot® Mode, the AC3 Optimus IABP automatically adjusts timing and triggering parameters, freeing clinicians to focus on the patient rather than the pump. A simple touch of the waveform provides access to controls, including the option to adjust volume.

Control and access to alarm history allows all alarm controls to be set

Icon indicates zero status of current AP source and provides controls to zero the status

All IABP functions are controlled with six keys

Easy to connect horizontal FOS port

Illuminating switch indicates pump is alarming and the priority level

Assisted and unassisted hemodynamic values are displayed in separate colors

A touch of the waveform accesses signal related controls for lead selection and scaling

More than advanced, approachable

With a highly-advanced software platform and proprietary suite of algorithms, the AC3 Optimus Intra-Aortic Balloon Pump delivers outstanding hemodynamic support across a wide range of patient conditions. A user-friendly design, intuitive interface, and state-of-the-art AutoPilot Mode makes it incredibly simple to use. With this powerful combination, Teleflex has elevated counterpulsation therapy while making it more accessible than ever.

- **Alarm history and trends feedback**
  Allows quick review of past alarms and ability to assess repeated alarms
- **Touchscreen**
  Allows for fast and easy interaction. Action bar combines assessment and action in a single location
- **Waveform**
  New touchscreen access to waveform controls

- **Graphics**
  Simple green, yellow, and red graphics allow for clear communication of parameter status
- **Routine tasks**
  Startup checklist provides simple and quick confirmation that setup is complete. The therapy status report provides a fast, single page summary of patient and pump settings for simple and accurate charting

Key actions and assessments made easy and accessible:

Getting Started ⊗
1) Check Helium Supply ✔
   Helium Verified
2) Connect ECG and AP ✔
   Trigger Verified
3) Connect IAB ✔
   IAB Volume: 40cc

Start Pump

FOS (Optional)
1) FOS Sensor Connected ✔
2) FOS CAL Data Read (Loaded) ✔
3) Auto Zero in Progress ✔
4) Auto Zero is Complete, ✔
   Insert IAB

AP Waveform Present

Therapy Status

HR	81 bpm
SYS (A/U)	118 / -- mmHG
AUG	100 mmHG
DIA (A/U)	101 / -- mmHG
MAP (A/U)	103 / -- mmHG
Assist Ratio	1:1
BVOL	40.0 cc
Trigger Mode	Afib
Mode	Autopilot
Timing Method (I/D)	Wave / RWave
Timing Settings	30 msec - Rwave
Alarms	On

Done

Dynamic Startup Checklist

An interactive review of the three step startup and confirmation when the pump is ready to start.

Therapy Report

One-button summary of patient hemodynamics (response to IABP therapy) and therapy settings. Allows for one key stroke charting, with ability to print reports.

Third-generation AutoPilot® Mode — dynamic and adaptive for intra-beat adjustments

Patient conditions can be ever-changing — maintaining optimal therapy requires continuous monitoring and adjustment. The third-generation AutoPilot Mode of the AC3 Optimus IABP makes it easy to track, sense, and adapt to changing conditions without any clinician intervention. Our exclusive Best Signal Analysis identifies the best signal for triggering and timing and implements adjustments with speed and precision beyond that of a manual operator.

AutoPilot Mode is automatically activated when therapy is initiated, providing full support from the first beat. It begins with full-assist and full volume at startup, and immediately begins monitoring and managing signals.

As innovators in intra-aortic balloon pumping technology, we continue to advance the performance and reliability of automated therapy.

Advanced alarms for enhanced safety and confidence

Understanding and managing alarms is crucial to patient safety and clinician productivity. The AC3 Optimus IABP offers an advanced configuration to deliver on both counts.

- 360° visibility of alarm severity
- Expanded alarm history review
- New corner switch to identify IABP alarming and alarm priority

- Alarms are active at all pump speeds offering faster response in AutoPilot Mode than user in Operator mode

Enhancing outcomes, optimizing value

Beyond its obvious clinical value, the AC3 Optimus IABP offers low cost of ownership. As budget pressures continue to grow, the cost-effective features like these become increasingly appealing:

- Pneumatic drive system with no scheduled replacement parts
- Low component replacement costs
- Minimal service required

Arrow
AC3 Optimus IABP
With FiberOptix Sensor Technology

Product Specifications

Design
• Fiber optic capability
• Proprietary WAVE Algorithm
• 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: 3.7 Amp at 110 VAC
  and 2.1 Amp 220 VAC
• Maximum power consumption: 5.1 Amp at 100 VAC
  and 2.8 Amp at 220 VAC
• 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:
  - 10.25″ high x 14.5″ wide x 2.0″ deep (26 cm x 36.8 cm x 5.0 cm)
• Pneumatic drive unit:
  - 33.3″ high x 13.0″ wide x 24.5″ deep (84.6 cm x 33 cm x 62.2 cm)

Mechanical Weight
• Control module:
  - 6 lbs (2.7 kg)
• Pneumatic unit AC3 Optimus IABP:
  - 98 lbs (44.5 kg)
• Total weight for AC3 Optimus IABP:
  - 104 lbs (47.2 kg)

Pneumatics
• Drive system: Stepper motor-driven bellows
• Drive gas: USP-grade helium
• Helium tank:
  - Disposable canister (500 psi) or refillable (2000 psi)
    cylinder—U.S. approval; (2900 psi) cylinder—European approval
• Pumping volume:
  - 0.5 cc to 50 cc, adjustable in 0.5 cc 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 Mode:
  - Automatically selects ECG/AP signal, sources, trigger
    mode, and timing method as well as timing settings
  - Automatically changes settings to optimise 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

*Based upon Deflation Timing Management

AP Trigger Mode:
• No ECG signal or noisy ECG signal

Inflation/Deflation Timing Methods

INFLATION TIMING METHODS	
Aortic Flow	Proprietary WAVE Algorithm sets the timing intra-beat within +/- 12 msec of aortic valve closure[1]
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)

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: Colour, high-resolution LCD (Liquid Crystal Display) touchscreen (1208 x 800) 13.3 inch diagonal
• Touchscreen: Glass-film-glass (GFG), resistive 5-wire (finger, gloved finger, stylus)
• Sweep speed: 25 msec (+/-1%)
• Channels: 3-channel multicolour 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 mmHg and displayed continuously
• Timing reference display: Numerical timing settings in both operating modes
• Cursor: Measurement of AP and balloon pressure waveforms

Alphanumeric Data
• Patient haemodynamics: 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 zero status with date and time of last zero for each AP source, AP alarm parameter and limit, timing settings, helium tank level, arrhythmia detection, and timing status
• Operations status: Operational mode, trigger mode, AP zero status with date and time of last zero for each AP source, AP alarm/battery charge status, balloon volume, battery charge icon and status, and zeros status icon
• Diagnostic alarm/help messages: Preprogrammed troubleshooting prompts/help
• Alarm history: Displays and prints the last 100 alarms with time/date
• IABP therapy report: Displays and prints patient haemodynamic data and IABP therapy related settings

Strip Chart Recorder
• Recorder: Dual-channel dot matrix: Dot density 400 dots/inch, 25 mm/s. Selectable recording length: 10, 15, 20, and 30 seconds. Automatic timed prints from 2, 15, 30, and 60 minutes and 2 or 4-hour intervals
• 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 haemodynamics. Formatted prints: Alarm log, IABP therapy report, IABP pump status

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 fiber optic IAB catheter (WAVE AP) transducer (spectramed or equivalent), 50 mV/V/cmHg high-level monitor input (1 V = 100 mmHg)

Ordering Information

ORDER NO.	DESCRIPTION
IAP-0700, IAP-0701	AC3 Optimus IABP 1 (IABP) system includes:
	FiberOptix Sensor Technology
	WAVE Algorithm: Physiologically based proprietary timing algorithm
	Aortic flow timing method
	AutoPilot Mode of operation

Note: Additional system specifications are available upon request.

Reference:
1. Schreuder J, Maisano F, Donelli A, et al. Beat-to-beat effects of intra-aortic balloon pump timing on left ventricular performance in patients with low ejection fraction. *Ann Thorac Surg.* 2005;79(3):872-880. Study sponsored by Teleflex.