

AC3 Optimus[™] Intra-Aortic Balloon Pump (IABP)

With FiberOptix™ Sensor Technology

Product Specifications

Display

- Type: Color, high-resolution Liquid Crystal Display (LCD) 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 multicolor waveforms
 - Electrocardiogram (ECG): Green trace with white highlight on assisted portion
 - Arterial Pressure (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 (in mmHg) of AP and balloon pressure waveforms

Design

- · Fiber optic capability
- Proprietary WAVE™ IntraBeat™ 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 240 VAC
- Maximum power consumption: 5.1 Amp at 110 VAC and 2.8 Amp at 240 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:
 - IAH-09045 Disposable canister (500 psi) or IAH-09048 refillable (2000 psi) cylinder
- · Pumping volume:
 - 0.5 cc to 50 cc, adjustable in 0.5 cc increments
- Counterpulsation rate: 40 to 200 pulsations/minute
- Assist ratio options: 1:1, 1:2, 1:4, 1:8

Alarms and Notifications

- Comer switch, 360° viewable:
 - Red, yellow, blue alerts
- · Pump off timer
- · Start up checklist list with FOS zero
- · Alarm log (last 100 alarms)
- IABP therapy report
- Pump off, alarm off
- Diagnostic alarm/help messages: Pre-programmed troubleshooting prompts/help

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
 - 50 uV minimum amplitude
- Arterial pressure (AP):
 - Microprocessor-based waveform trigger detection algorithm
 - 3 mmHg minimum pulse pressure with consistent upstroke
- Pacer (VPACE, APACE):
 - Detection
 - > 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
 - Atrio-Ventricular pacing: maximum A-V interval of 250mS

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™ IntraBeat™ Algorithm sets the timin within +/- 12 msec of aortic valve closure¹	
	Predictive	AP waveform analysis to set inflation	
	Weissler	ECG only, inflation timing based on systolic time intervals	

DEFLATION TIMI	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		

MANU	AL		

User sets 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		

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 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

Strip Chart

- Printing Options: 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 hemodynamics. Formatted prints: Alarm log, IABP therapy report, IABP pump status

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[™] Catheter (WAVE[™] AP), transducer (spectramed or equivalent), 50 mV/V/cmHg high-level monitor input (1 V = 100 mmHg)

Ordering Information

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ORDER NO.	DESCRIPTION		
IAP-0700	AC3 Optimus™ IABP system includes:		
IAA-00003	25 ft Phone to Phone Cable		
IAA-00175	Pump IV Pole		
IAA-00437	5 Lead ECG Cable		
IAA-01003	Accessory Pak, including:		
IAA-09004	Strip Chart Paper (Qty: 10)		
IAA-14660	North America 15 ft Power Cord		
IAH-09045	Disposable Helium (Qty: 4, shipped separately)		
IAH-09145	Helium Tank Adaptor		
IAM-9010	Operators Manual		
2500-9085-002	Helium Washers (Qty: 2)		

Reference:

1. Schreuder J, Castiglioni A, Donelli A, et al. Automatic intra-aortic balloon pump timing using an intra beat dicrotic notch prediction algorithm. Ann Thorac Surg. 2005;79(3):1017-1022. Study sponsored by Teleflex. Dr. Schreuder was formerly a paid consultant of the study sponsor. Co-authors J. Bovelander, R. Hanania, and P. Hanlon are current or former employees of the study sponsor.

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