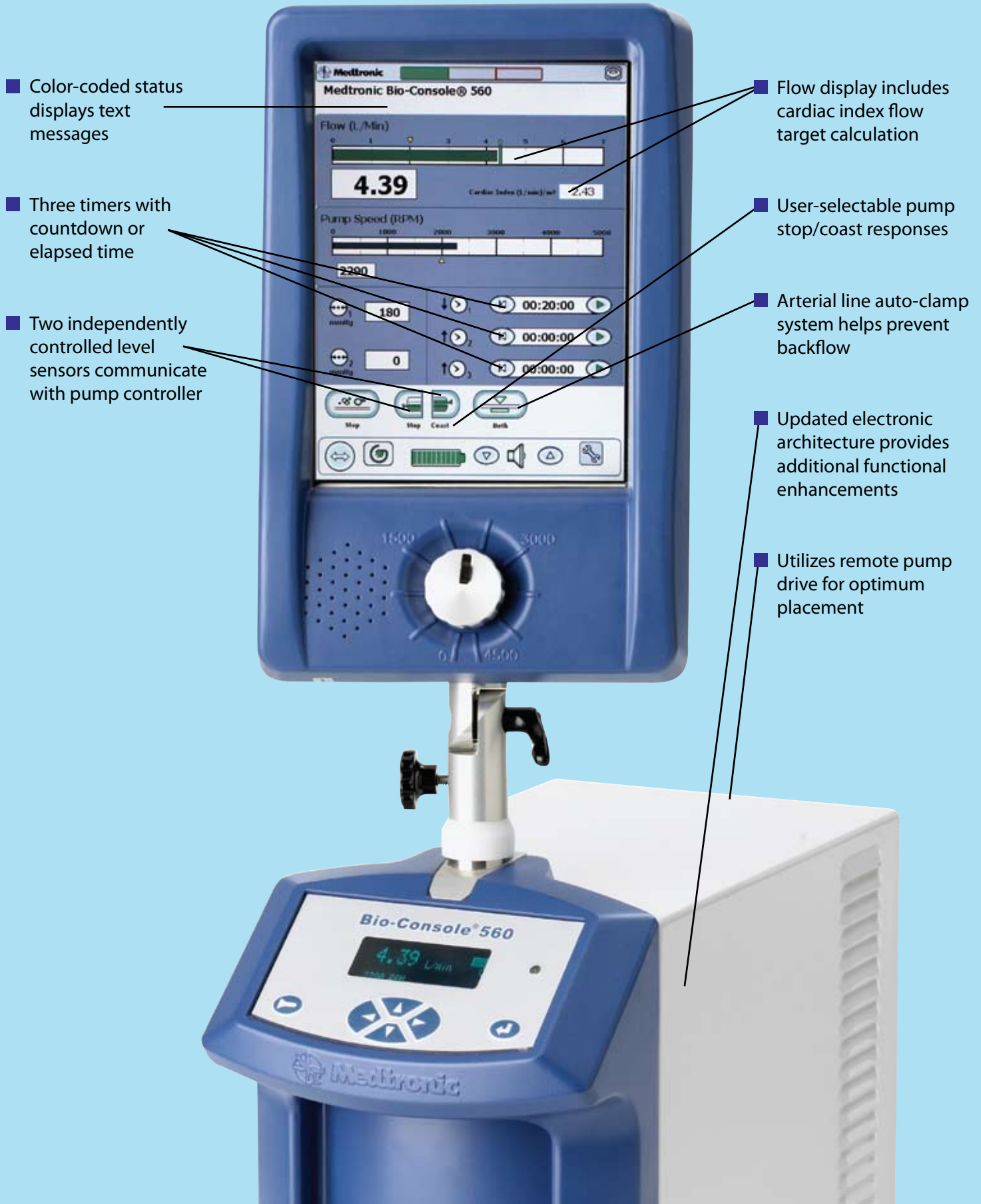


Bio-Console® 560

The Bio-Console® 560 combines reliability with user-friendly features and patient-adaptable functions



ORDERING INFORMATION	
560BCS1	Bio-Console® 560BCS1 Speed Controller
ACS500	System Autoclamp Kit
BD38	Bubble Detector Cable – Adult
BD14	Bubble Detector Cable – Pediatric
LS100	Level Sensor
LST	Level Sensor Tape
BPX-80	Bio-Pump® Plus Centrifugal Blood Pump
CBBPX-80	Bio-Pump® Plus Centrifugal Blood Pump with Carmeda® BioActive Surface
BPX-80T	Bio-Pump® Plus Centrifugal Blood Pump with Trillium® BioSurface
ADDITIONAL REQUIREMENTS	
TX50	Flow Transducer (not included)
540T	External Drive Motor (not included)
BP150	Hand Crank (not included)

REFERENCES

1. Data on file at Medtronic Perfusion Systems.
2. Meta-analysis** data on file at Medtronic Perfusion Systems.
3. Pederson, Karlsen. An in-vitro study of the new Medtronic Bio-Medicus BPX-80 Centrifugal Pump with respect to the handling of free micro-gasbubbles. A technical report by: MTS. Medisinsk Teknisk Sikkerhetskontroll. Ans. Oslo, Norway, January 21, 1998.
4. Uretzky G, Landsberg G, Cohn D, et al. Analysis of microembolic particles originating in extracorporeal circuits. *Perfusion* 1987; 2; 9
5. Throckmorton A, Song X, Wood H, et al. Computational flow analysis of a continuous flow pediatric ventricular assist device. Paper presented at Summer Bioengineering Conference; June 26-29 2003; Key Biscayne, Florida.

* Carmeda® BioActive Surface is manufactured under license from Carmeda AB, Sweden. Carmeda is a registered trademark of Carmeda AB.

** Meta-analysis is a statistical methodology that integrates findings from smaller groups into one large sample for statistical analysis. It provides a method of more accurately predicting outcomes in a general population.

SPECIFICATIONS

AC POWER

One of the following types of power will be present:

- 100 VAC, 50-60 Hz, 3 amps
- 110-120 VAC, 50-60 Hz, 3 amps
- 220-240 VAC, 50-60 Hz, 1.5 amps

EXTERNAL PUMP DRIVE MOTOR

- Brushless DC (non-arcing)

INTERNAL BATTERIES

- Type: Two, series connected, 12 VDC lead-acid gel; rechargeable
- Discharge Time: Refer to Appendix C in product manual: Battery Longevity
- Recharge Time: 18 hours to 90% capacity; 24 hours to 100% capacity

DIMENSIONS: BASE UNIT

- Size: 31.88 cm (12.55 in) high by 22.83 cm (8.99 in) wide by 43.02 cm (16.9 in) long
- Weight: 17.19 kg (37.9 lb)

DIMENSIONS: USER INTERFACE

- Overall Size: 22.18 cm (8.7 in) wide by 34.5 cm (13.6 in) long
- Screen Size: 26.41 cm (10.4 in) diagonal
- Weight: 4.26 kg (9.4 lb)

SYSTEM LIMITS

- Flow: -9.99 to +9.99 L/min +/- (5% + 50 mL)
- RPM: 0 to 4500 RPM
- Pressure: -300 to +999 mm Hg +/- (5% + 5 mm Hg)

OPERATING LIMITS

Temperature: +18° to +33°C, +64° to +92°F
Humidity: 10% - 95%, noncondensing

STORAGE LIMITS

Temperature: -40° to +66°C, -40° to +150°F
Humidity: 10% - 95%, noncondensing

OUTPUT SIGNAL

- Digital: RS 232 Interface: flow, RPM, pressure, alarm status
- Baud Rate: 1200 to 19200

CARDIAC SURGERY SERVICE: Worldwide service network with service plans available for all of your Medtronic service and maintenance needs. Contact your local sales representative to learn more. In the US, call 1.800.433.4311.

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Bio-Medicus[®] Perfusion System

BIO-PUMP[®] PLUS CENTRIFUGAL BLOOD PUMP
AND BIO-CONSOLE[®] 560 SYSTEM
WITH SAFETY SYSTEMS

The Tradition Continues



The Medtronic Bio-Medicus® Perfusion System utilizes the Bio-Pump® Plus centrifugal blood pump and the Bio-Console® 560 pump speed controller with remote drive.

By combining the reliability and performance of Bio-Pump® Plus with the latest enhancements to Bio-Console® 560, the Bio-Medicus® Perfusion System offers user-friendly, patient-adaptable features and safety systems to help meet your evolving practice requirements.



Bio-Pump® Plus **Centrifugal Blood Pump**

There's Still Only One Bio-Pump® Plus.

The nonocclusive design of the Bio-Pump® Plus centrifugal blood pump promotes laminar flow and effective blood handling capabilities that include decreased blood trauma often associated with extracorporeal circulatory support (during cardiopulmonary bypass).²

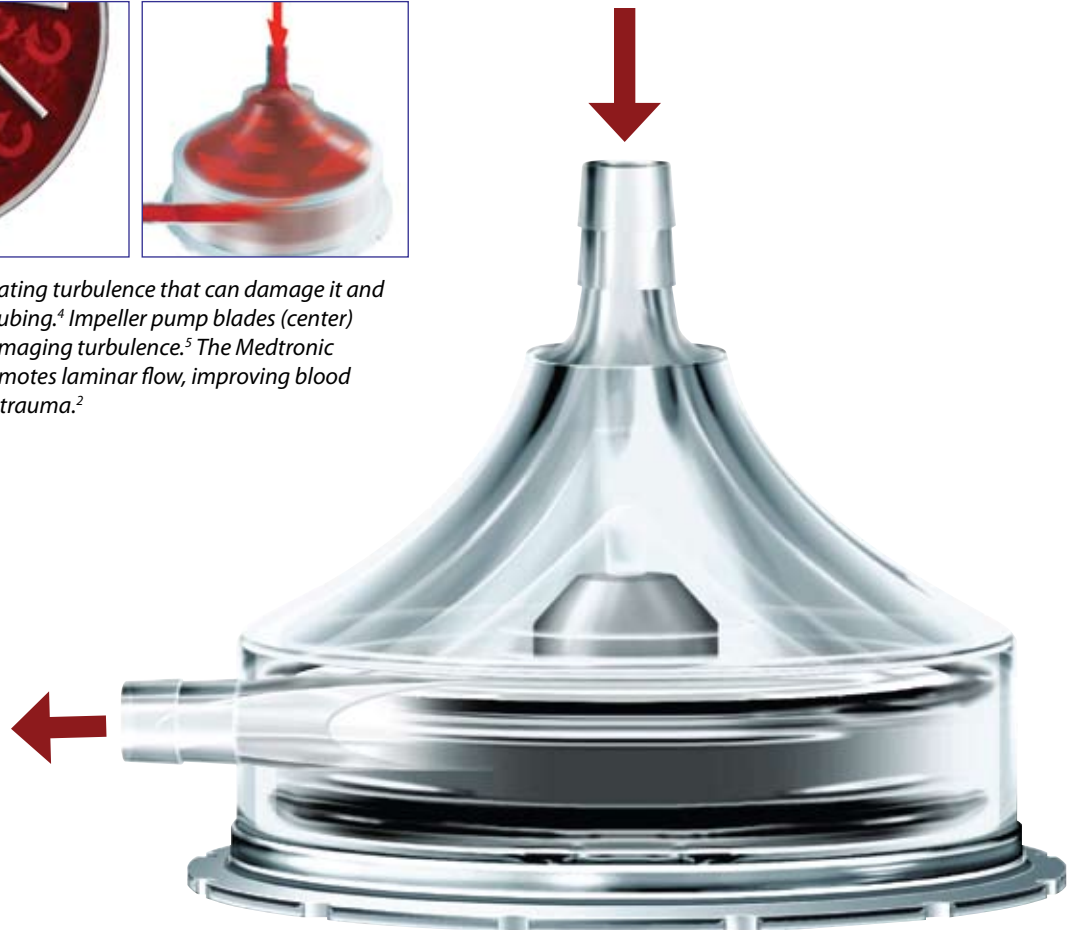
Bio Pump® Plus utilizes a patented vertical cutwater outlet design based on computational flow dynamics (CFD), and features durable polycarbonate construction along with enhanced double-lip, seal-bearing design.

Available with Carmeda®* BioActive Surface or Trillium® Biosurface, the Bio-Pump® Plus uses the constrained, forced-vortex pumping principle in which a series of the smooth-surfaced, rotating cones pull the blood into the vortex created by the rotation. As the blood flows toward the pump outlet, the air-handling vortex energy created by the cones transfers to the blood in the form of pressure and velocity.

*laminar flow improves
blood- and air-handling capabilities*



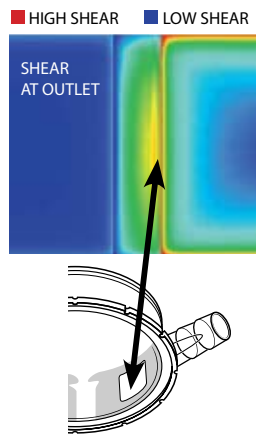
Roller pumps (left) push the blood along creating turbulence that can damage it and create debris by spalling particles from the tubing.⁴ Impeller pump blades (center) push through the blood causing areas of damaging turbulence.⁵ The Medtronic Bio-Pump® Plus centrifugal pump (right) promotes laminar flow, improving blood handling capabilities and decreasing blood trauma.²



OUTLET DESIGN REDUCES SHEAR AND HEMOLYSIS¹

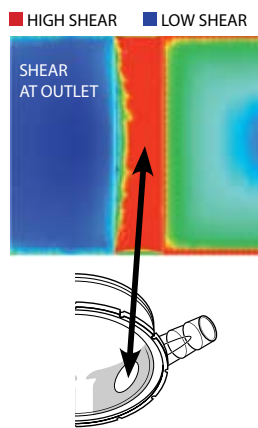
UNIQUE VERTICAL PROFILE

An outlet-opening design has been created and evaluated using calculations governing fluid flow. The result is a vertical cutwater outlet design that reduces hemolysis by 20% (comparing Bio-Pump® Plus BPX-80 to the original Bio-Pump BP-80 blood pump), defying conventional theory that circular outlets are more conducive to blood flow.¹ Computational flow dynamic (CFD) analysis shows the reduction in shear that is achieved by the straight, vertical profile of the Bio-Pump® Plus blood pump.

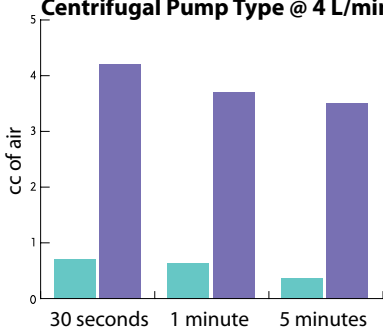


HISTORICAL CURVED PROFILE

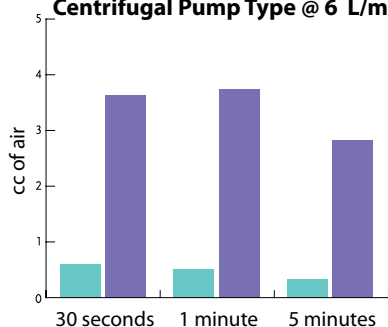
CFD analysis identified the curved outlet opening (used in the original Bio-Pump® blood pump and competitive pump designs) as an area of recirculation and shear stress that can contribute to cellular trauma.¹



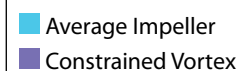
Average Air Retention by Centrifugal Pump Type @ 4 L/min



Average Air Retention by Centrifugal Pump Type @ 6 L/min



In-house testing indicates a 10 times greater air retention at 4 and 6 L/min.¹ Effective air retention means less air passes through the pump outlet and downstream toward the patient. (5 cc injected at 5 cc/sec. rate.)



BIO-PUMP® PLUS BPX-80 BLOOD PUMP Features and Benefits

GENTLE BLOOD HANDLING¹

(compared to the original Bio-Pump BP-80 blood pump)

- Decreased platelet activation and better platelet preservation
- Reduced complement activation
- Reduced use of blood products
- Patented vertical cutwater outlet design
 - Reduces shear in the cutwater region
 - Reduces hemolysis by 20% overall¹

REDUCED POSTOPERATIVE COMPLICATIONS²

(BP-80 compared to roller pumps)

- Decreased pulmonary complications
- Less microemboli generation
- Reduced neurological deficits
- Meta-analysis suggests improved clinical outcomes and lower overall patient costs

IMPORTANT SAFETY FEATURES

- Smooth vortex cone design provides superior micro air retention when compared to impeller centrifugal pump designs.³ In-house testing indicates a 10 times greater air retention at 6 L/min.¹ Effective air retention means less air passes through the pump outlet and downstream toward the patient.
- Flow ceases with draining of venous reservoir preventing passage of gross air due to pre-load sensitivity.
- Pressure sensitivity reduces the risk of tubing circuit disruption.
- Pressure sensitivity allows more gradual, physiological response to pressure changes.

RELIABILITY

- Robust double-lip, seal-bearing design adds sealing integrity, reduces air volume in bearing chamber, and resists moisture ingress.
- Polycarbonate outer housing and inlet/outlet ports provide increased strength and resistance to alcohol and other chemicals to minimize risk of breakage.

TIP-TO-TIP BIOSURFACE CAPABILITIES

- Available in Carmeda® BioActive Surface* and Trillium® BioSurface

Medtronic Bio-Console® 560 Ex

BIO-CONSOLE® 560 SYSTEM Features and Benefits

VERSATILE LCD DISPLAY WITH IMPROVED SCREEN FEATURES

- Three timers with countdown/elapsed time capability
- Easy-to-read, high-contrast background
- Remote design for optimum placement
- Adjustable viewing angles
- Dedicated storage position for durability
- Unique mast mounting bracket with adjustable capability

FLOW CONTROL KNOB WITH DETENT

- Ergonomic design for ease of control
- Positive, tactile control of even small increments
- Remotely located on LCD panel for more user flexibility
- Independent of software for greater security

BASE UNIT DISPLAY

- Offers redundancy and limp home capability for critical flow information
- Menu and value selection touch pad provides safety redundancy
- Battery status and charge indicators
- Always charging capability, even when in standby mode

ADAPTABLE REMOTE DRIVE CONFIGURATION

- Offers potential for reduced priming volume
- Flexible configuration
- Uses standard 540T remote drive

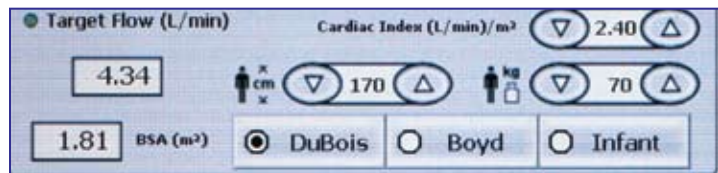
OPTIONAL SAFETY SYSTEM UPGRADES

- Dual position level sensors with user settings and independent control
- Ultrasonic bubble detector for 3/8 inch or 1/4 inch lines for flexible placement
- Arterial line autoclamp to prevent backflow with user-selectable "response" setting choices for level sensors and bubble detector
- Updated software with user-selectable pump coast/stop capabilities

ADDED FEATURES OF THE BIO-CONSOLE® 560 (Comparing the new Bio-Console® 560 BCS1 to the former BCS version)

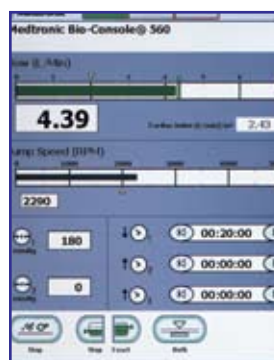
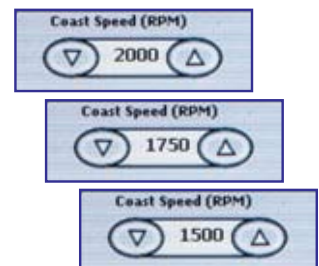
- Pump turns on prior to software boot completion for emergency-on
- User-selectable coast speed options
- Displays body surface area (BSA)
- Fewer steps to open autoclamp
- Redefined backflow parameters to minimize unnecessary alarms

User-friendly features and patient-adaptable functions of the Bio-Console® System offer significant advantages to the patient, the surgeon and the perfusionist.



SETTINGS SCREEN

- Body surface area (BSA) displayed
- Three user-selectable coast speeds



SAFETY SYSTEMS

- User-selectable responses
 - Message only
 - Alert and coast
 - Alarm and stop flow
 - Optional clamp capability
- Color-coded text messages
- Color-coded status icons



Tracorporeal Blood Pumping Console



BUBBLE DETECTOR

- Ultrasonic technology
- $\geq .50$ mL detection capability
- Placement Options
 - Easy, slip-on design
 - Not combined with flow sensor
 - Can be placed pre-pump
- 3/8 inch and 1/4 inch tubing versions
- Optional arterial auto-clamping



LEVEL SENSORS

- Upper level sensor can be disabled to eliminate alert message
- Reliable capacitive technology
- Single or dual sensor capable
 - Upper alert ■
 - Lower alarm ■
- Independently adjustable and response selectable
- LEDs confirm operational system



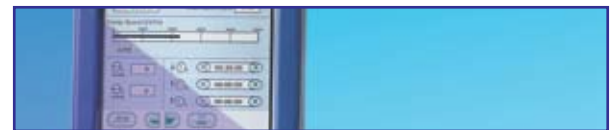
PUMP COAST/STOP OPTIONS

- Optional coast feature is patient adaptable (1500, 1750, 2000 RPM selections)
- Variable coast can be changed on the fly
- Coast to selected RPM and ramp back to original setting
- Split RPM displays actual and previous settings during coast mode



BACKFLOW ALARM

- Arms when pump initially exceeds 250 mL flow
- Alarm activated at -100 mL flow
- Can be selected to activate autoclamp



ARTERIAL CLAMP

- Selections include PUMP STOP, BACKFLOW, or BOTH
- Open by pneumatic pressure spring
- Closed at rest
- Expedient, two-step reopen process
- Optional feature

