



Medtronic

Affinity Pixie™

OXYGENATION SYSTEM
WITH BALANCE™ BIOSURFACE



Performance
and
Possibilities
for Your Small
Patients

Innovating for life.

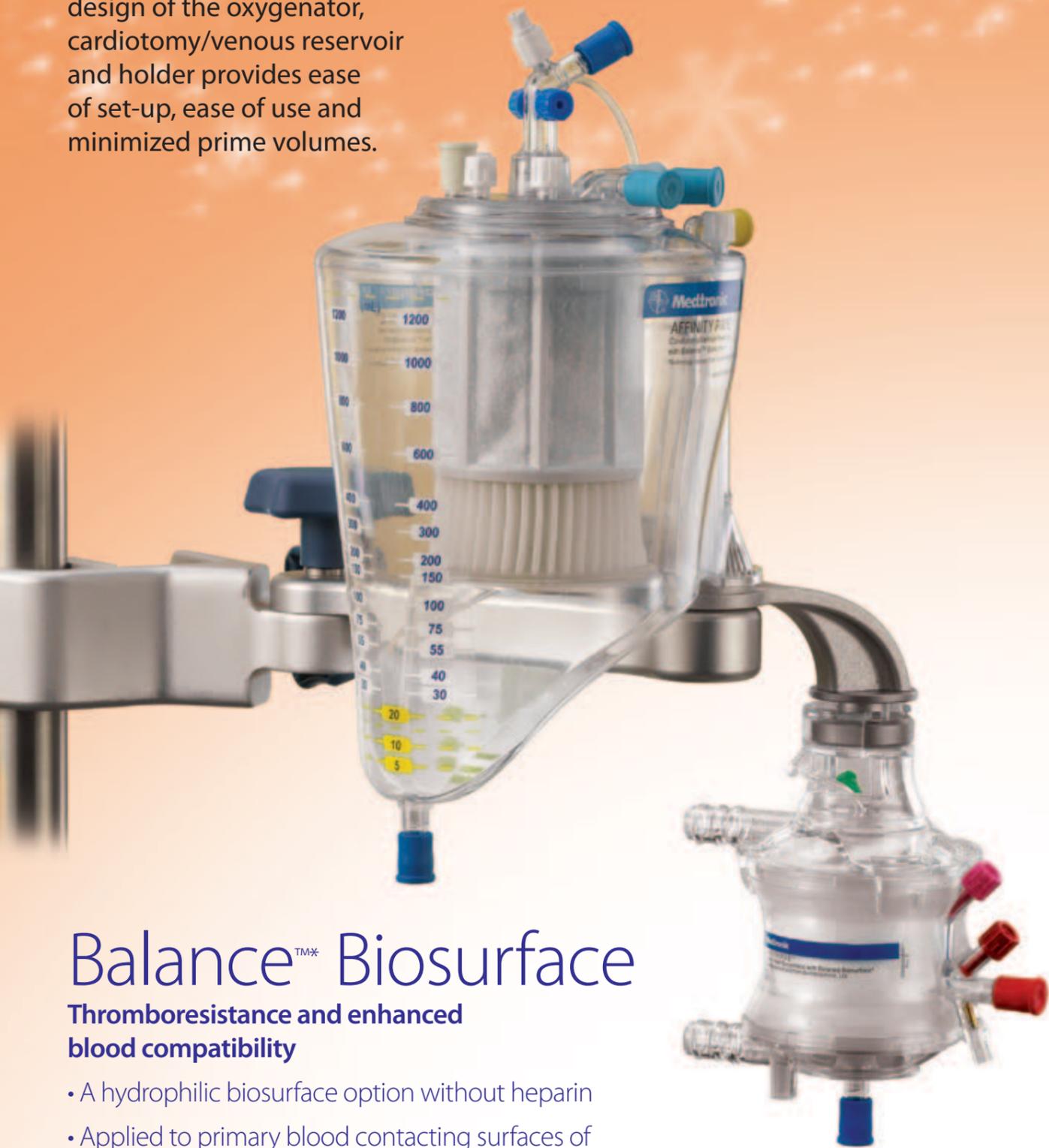
INTRODUCING THE

Affinity Pixie™

OXYGENATION SYSTEM

Our addition to the Affinity® family

The comprehensive system design of the oxygenator, cardiotomy/venous reservoir and holder provides ease of set-up, ease of use and minimized prime volumes.



Balance™ Biosurface

Thromboresistance and enhanced blood compatibility

- A hydrophilic biosurface option without heparin
- Applied to primary blood contacting surfaces of the oxygenator and cardiotomy/venous reservoir

The Affinity Pixie™

Oxygenation System delivers performance and versatility for neonates, infants and small children requiring cardiopulmonary bypass at flow rates up to 2.0 L/min.

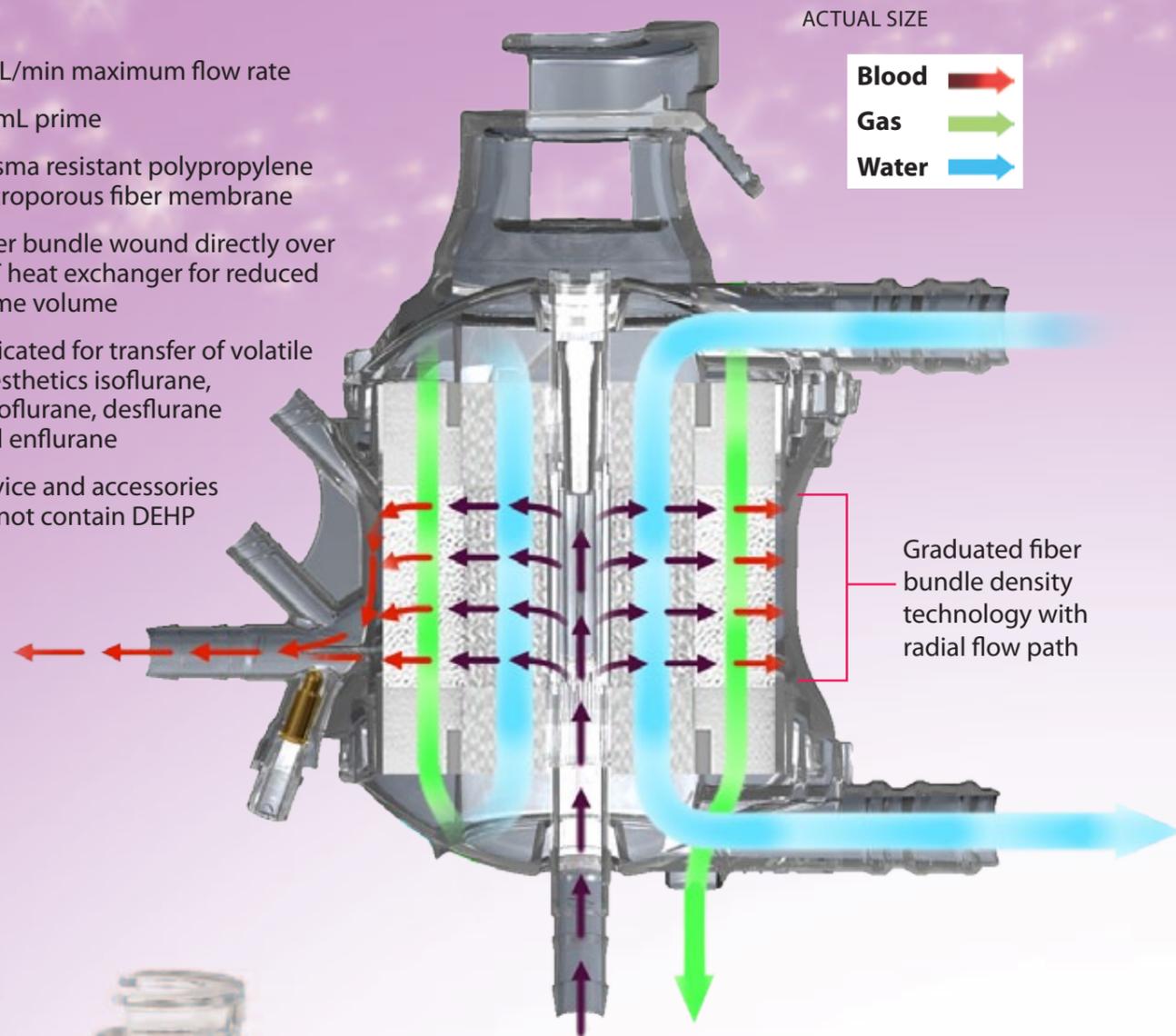
This addition to the Affinity family is part of Medtronic's commitment to providing more options for pediatric patients undergoing cardiopulmonary bypass.



Oxygenator

Advanced Affinity® oxygenator technology in a compact, low-prime design

- 2.0 L/min maximum flow rate
- 48 mL prime
- Plasma resistant polypropylene microporous fiber membrane
- Fiber bundle wound directly over PET heat exchanger for reduced prime volume
- Indicated for transfer of volatile anesthetics isoflurane, sevoflurane, desflurane and enflurane
- Device and accessories do not contain DEHP



Blood contact: blood side of pre-membrane purge port

Water contact: water pathway above heat exchanger

Electrical shunt

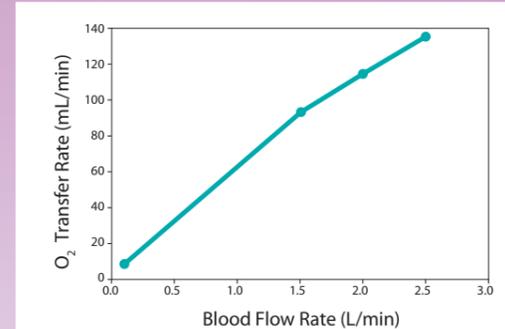
This safety feature dissipates electrostatic charge that may develop inside the oxygenator's blood pathway due to rotation of the roller pump heads.

Electrostatic charge is shunted from the blood path to the water path where it is discharged through the heater/cooler unit's electrical grounding system.

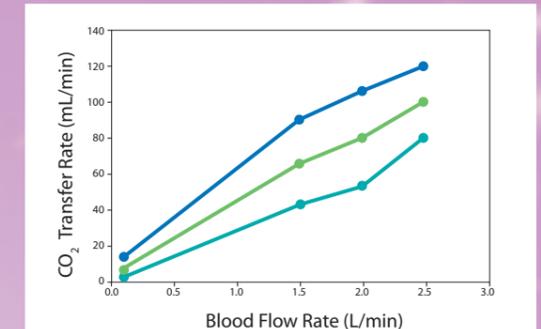
Oxygenator Performance Data

Data on file – ISO Standard Conditions

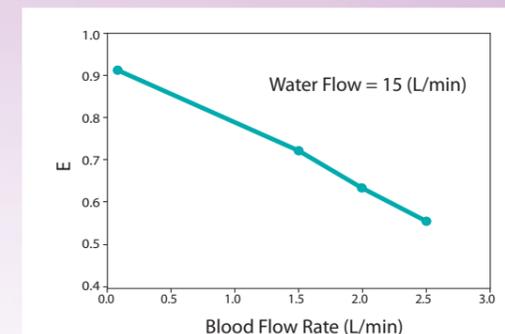
O₂ Transfer Rate



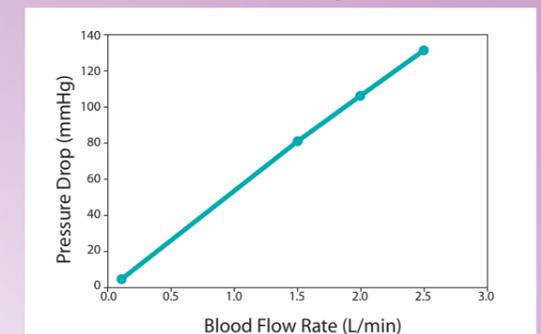
CO₂ Transfer Rate



Heat Exchange Effectiveness



Blood Side Pressure Drop



The oxygenator's proprietary graduated fiber bundle density technology together with radial flow path design provide enhanced gas transfer, low blood-side pressure drop, decreased prime volume, uniform blood flow distribution and avoidance of areas of stasis.

Cardiotomy/Venous Reservoir

FEATURING THE Affinity Orbit™ Holder System

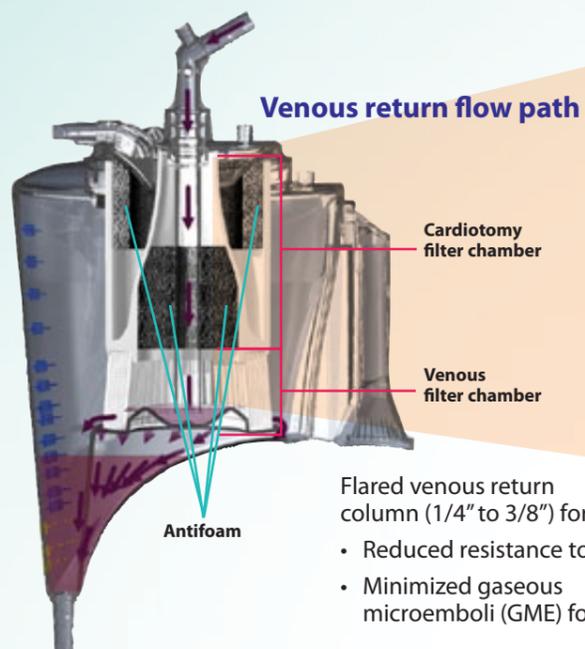
Quick set-up. Custom device positioning and orientation

Ergonomic, easy to use design
Minimized blood contact with antifoam



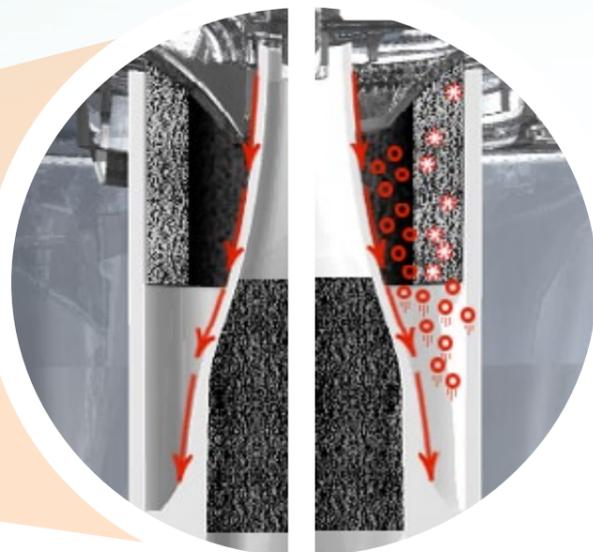
- 2.0 L/min maximum flow rate
- 1200 mL volume capacity
- 20 mL minimum operating volume without vortex formation
- Independent rotation of venous inlet and cardiotomy turret
- Port locations and spacing allow easy tubing attachment
- Vacuum assisted venous drainage-ready design
- Device and accessories do not contain DEHP

Minimized blood contact with antifoam



Flared venous return column (1/4" to 3/8") for:

- Reduced resistance to flow
- Minimized gaseous microemboli (GME) formation



Non-foaming blood does not contact antifoam at typical venous reservoir operating levels (<470 mL)

Foaming cardiotomy suction blood is defoamed and filtered before entering the venous reservoir

- Quick and easy device attachment
- Adapts to any pump set-up
- Versatile device positioning and port orientation
 - Holder arm, oxygenator arm and cardiotomy/venous reservoir pivot for custom device positioning
 - Oxygenator rotates 360° for desired port orientation
- Facilitates reductions in circuit tubing length and associated prime volume
- Designed for use with future Medtronic perfusion technologies



Custom device positioning and orientation



Affinity® Manifold Holder

- Holds a standard flat-plate stopcock manifold in either horizontal or vertical orientation
- C-clamp for easy and stable attachment to both IV poles and larger diameter pump masts

Even greater
positioning flexibility
to adapt to your preferred circuit setup.



Affinity Pixie™ Oxygenation System

ORDERING INFORMATION

| Oxygenation Systems | | |
|-------------------------|--|------------|
| Model Number | Description | Units/case |
| BBP211 | Hollow Fiber Oxygenator with Balance™ Biosurface | 4 |
| BBP241 | Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance™ Biosurface | 4 |
| Accessories and Holders | | |
| Model Number | Description | Units/case |
| ATP210 | Affinity® Temperature Probe | 1 |
| AUH2093 | Affinity Orbit™ Holder System | 1 |
| AMH2014 | Affinity® Manifold Holder | 1 |

*Technology licensed under agreement from BioInteractions, Limited, United Kingdom. Balance™ is a trademark of Medtronic, Inc.

For information on other Medtronic technologies for extracorporeal circulation, blood processing and diagnostics, visit: www.perfusion.medtronic.com

Related products: Contact your Medtronic Sales Representative for information on additional Medtronic technologies for pediatric cardiopulmonary bypass, including arterial filters, cannulae products and custom perfusion systems incorporating Medtronic pediatric CPB devices

The Affinity Pixie™ Oxygenation System is indicated for use in an extracorporeal circulation circuit during cardiopulmonary bypass procedures up to 6 hours in duration. A strict anticoagulation protocol should be followed and anticoagulation should be routinely monitored during all procedures. The benefits of extracorporeal support must be weighed against the risk of systematic anticoagulation and must be assessed by the prescribing physician.

For a listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product.

SPECIFICATIONS

| | |
|--|---|
| Oxygenator | |
| Membrane type | Microporous polypropylene hollow fiber |
| Membrane surface area | 0.67 m ² |
| Heat exchanger | Polyethylene Terephthalate (PET) |
| Static priming volume | 48 mL |
| Recommended blood flow range | 0.1 – 2.0 L/min |
| Maximum water pressure | 1550 mmHg (206 kPa) |
| Maximum blood pressure | 750 mmHg (100 kPa) |
| Venous blood inlet | 1/4 in (0.6 cm) |
| Arterial blood outlet | 1/4 in (0.6 cm) |
| Arterial sample port | Female luer |
| Recirculation port | Female luer |
| Pre-membrane purge port with one-way valve | 1/16 in (0.16 cm), male luer |
| Biosurface | Balance™ Biosurface |
| Accessories | |
| Tubing adapter | 3/16 in (0.5 cm) (2) |
| Recirculation line | 3/16 in (0.5 cm) (1) |
| Cardiotomy/Venous Reservoir | |
| Reservoir volume capacity | 1200 mL |
| Recommended blood flow range | 0.1 – 2.0 L/min |
| Maximum cardiotomy flow rate | 2.0 L/min |
| Minimum operating level | 20 mL |
| Cardiotomy filter | 30 µm nominal polyester depth filter |
| Venous inlet screen | 64 µm |
| Venous return inlet, rotatable | 1/4 in (0.6 cm) |
| Venous reservoir outlet | 1/4 in (0.6 cm) |
| Venous inlet luer locks | 2 luer locks |
| Cardiotomy inlet, step-up | 3/16 in (0.5 cm) to 1/4 in (0.6 cm) (3) |
| Cardiotomy inlet | 1/4 in (0.6 cm) (1) |
| Filtered luer locks to cardiotomy filter | 4 luer locks |
| Nonfiltered luer locks | 2 luer locks |
| Filtered quick prime port | 1/4 in (0.6 cm) |
| Nonbarbed vent port | 1/4 in (0.6 cm) |
| Maximum rated pressure | + 20 mmHg/ - 100 mmHg |
| Positive/negative pressure relief valve | < 5 mmHg positive/ 60 mmHg vacuum |
| Biosurface | Balance™ Biosurface |
| Accessories | |
| Tubing adapter | 3/16 in (0.5 cm) (2) |
| Tubing adapter | 3/8 in (1.0 cm) (2) |
| Flexible luer lock adapter | 2 adapters |
| Sampling manifold | 1 manifold assembly |

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