Medtronic

Affinity Pixie™

OXYGENATION SYSTEM

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.

Thromboresistance and enhanced blood compatibility
The primary blood contact surfaces of the oxygenator and cardiotomy/venous reservoir are coated with either:

Carmeda®* BioActive Surface
- Durable, non-leaching End Point Attached heparin

Balance™ Biosurface**
- A hydrophilic biosurface option without heparin

The Affinity Pixie™

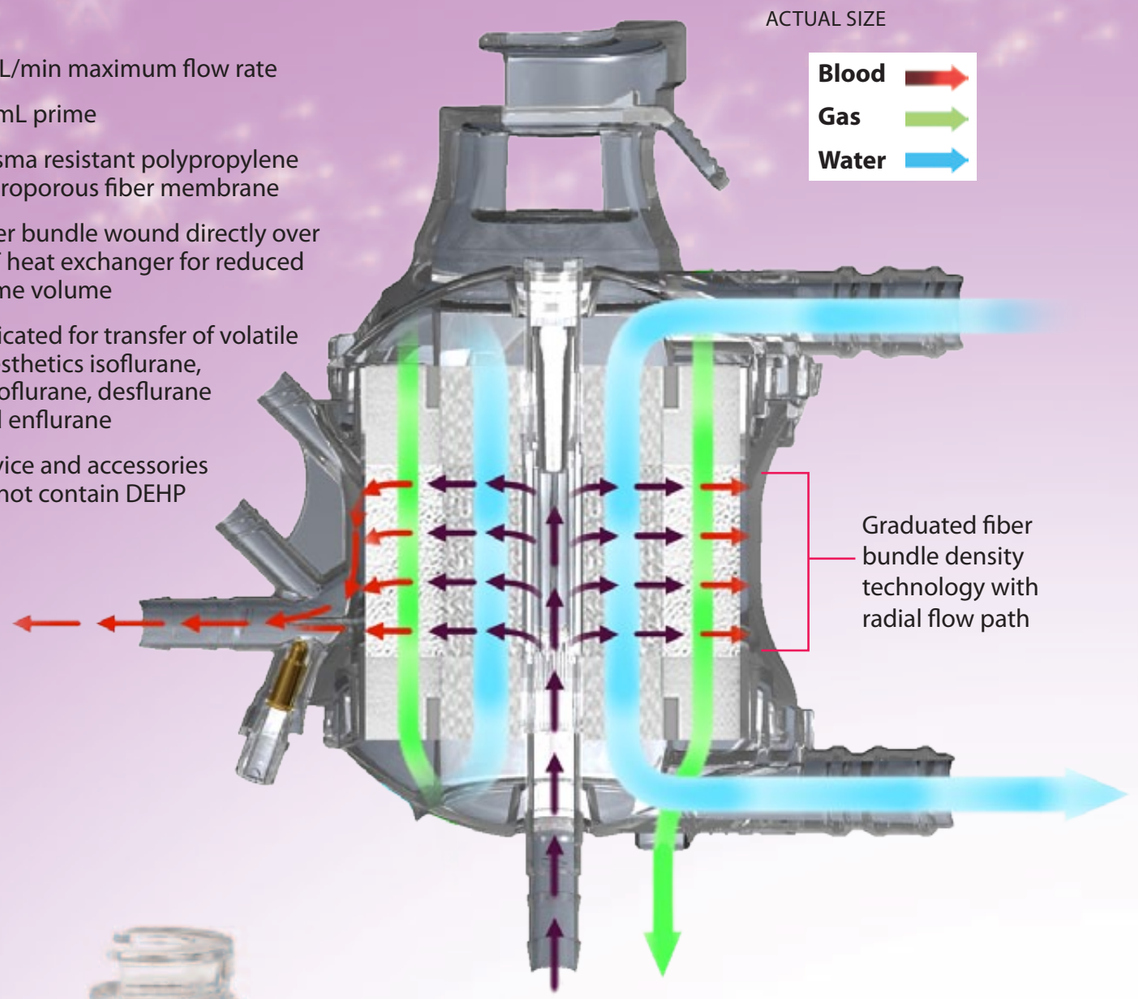
Oxygenation System delivers performance and versatility for neonates, infants and small children requiring cardiopulmonary bypass at flow rates up to 2.0 L/min.

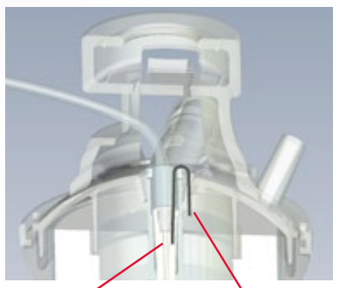
This addition to the Affinity family is part of Medtronic's commitment to providing more options for pediatric patients undergoing cardiopulmonary bypass.

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





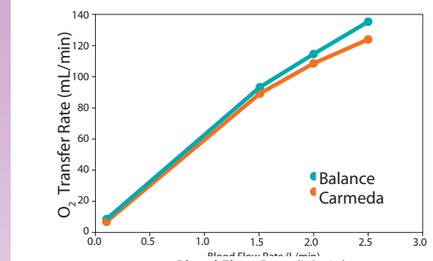
Electrical shunt

The oxygenator features an electrical shunt which equilibrates voltage between the blood and water pathways. This eliminates the potential for electrostatic discharge that may develop inside the blood pathway due to rotation of the roller pump heads.

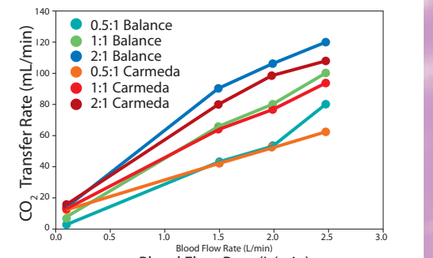
Oxygenator Performance Data

Data on file – ISO Standard Conditions

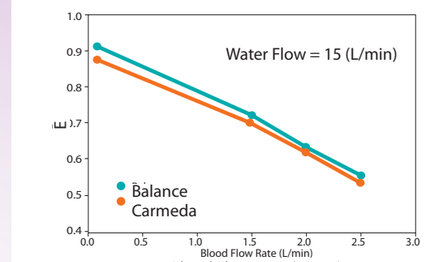
O_2 Transfer Rate



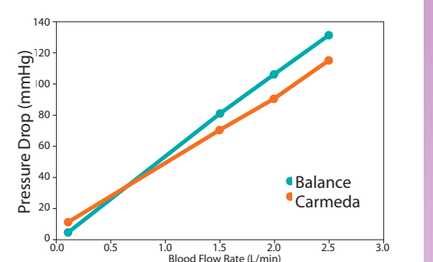
CO_2 Transfer Rate



Heat Exchange Effectiveness



Blood Side Pressure Drop



The oxygenator's proprietary

graduated fiber bundle density technology

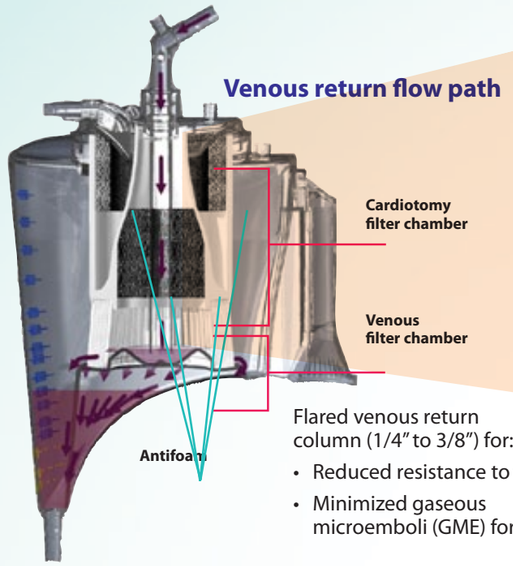
together with radial flow path design provide enhanced gas transfer, low blood-side pressure drop, decreased prime volume, uniform blood flow distribution and avoidance of areas of stasis.

Cardiotomy/Venous Reservoir

Ergonomic, easy to use design
Minimized blood contact with antifoam

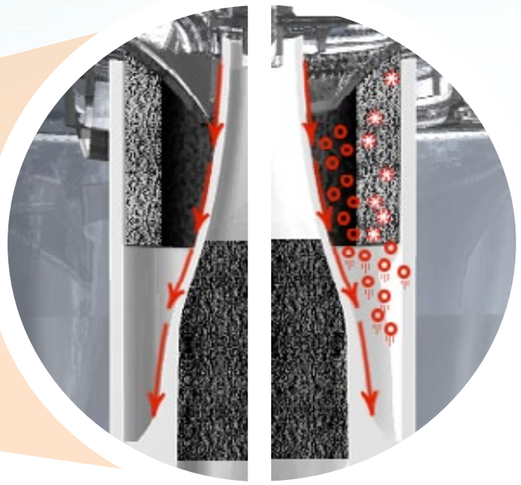
- 2.0 L/min maximum flow rate
- 1200 mL volume capacity
- 20 mL minimum operating volume without vortex formation
- Independent rotation of venous inlet and cardiotomy turret
- Port locations and spacing allow easy tubing attachment
- Vacuum assisted venous drainage-ready design
- Device and accessories 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

FEATURING THE

Affinity Orbit™ Holder System

Quick set-up. Custom device positioning and orientation

- 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
CBP211	Hollow Fiber Oxygenator with Carmeda® BioActive Surface	4
BBP211	Hollow Fiber Oxygenator with Balance™ Biosurface	4
CBP241	Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Carmeda® BioActive Surface	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

* Products are coated with Carmeda BioActive Surface, which is licensed from Carmeda AB for use only as part of an extracorporeal blood circulation system or circuit that includes an oxygenator or blood pump. Carmeda® is a registered trademark of Carmeda AB.

** 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

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 options	Carmeda® BioActive Surface or 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 options	Carmeda® BioActive Surface or 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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