CAPIOX® FX Advance

Oxygenator with Integrated Arterial Filter and Hardshell Reservoir

Expanded patient range. Advanced outcomes.

Technology inspired for life.™

TERUMO CARDIOVASCULAR

Designed to meet patient needs

Terumo Cardiovascular has led the way in oxygenator innovation and quality for more than 30 years and was the first — and is the only — company to manufacture its own hollow fiber.

Our unique approach to a full line of oxygenators helps perfusionists to meet each patient's oxygenation and blood management needs more precisely.

Studies have shown that controlling hemodilution through lower prime volume circuits can result in fewer blood transfusions.[1,2,3] That's why we offer you a choice of three different sizes within our proven CAPIOX® line of oxygenators.

Choose the oxygenator that expands your options and advances patient outcomes. Choose the CAPIOX FX Advance Oxygenator.

TERUMO CARDIOVASCULAR

Advancing Outcomes

The right size oxygenator can make a difference towards better patient outcomes.

CAPIOX® FX15 Advance Oxygenator

The CAPIOX FX15 Advance Oxygenator significantly lowers prime volume for patients at risk for a higher rate of blood transfusions. With the CAPIOX FX15 Advance Oxygenator, smaller patients can have surgery with an oxygenator that best fits their unique metabolic needs. The increased blood flow rate available with the 3,000 mL hardshell reservoir expands the use of a smaller oxygenator to more patients.*

- Maximum blood flow: 5.0 L/min
- Oxygenator priming volume: 144 mL
- Reservoir storage capacity:
  - 3,000 mL: 70 mL minimum operating level
  - 4,000 mL: 150 mL minimum operating level

FX15 Advance with 3,000 mL reservoir

**Use of Vacuum Assisted Venous Drainage may be required to achieve flow rate of 5 L/min.*

Low prime volume oxygenators reduce hemodilution, blood transfusions and the risk of Acute Kidney Injury (AKI) resulting in lower total hospital costs.

It is well known, with a high level of evidence (Class 1 Level A), that excessive hemodilution during cardiopulmonary bypass leads to an increased incidence of red blood cell transfusions.

A 2015 study demonstrated that reducing hemodilution with a low prime volume oxygenator, by as little as 150 mL, is associated with fewer blood transfusions and reduced risk of post-operative Acute Kidney Injury (AKI).[4]

CAPIOX FX Advance Oxygenators allow you to minimize hemodilution and other risks associate with cardiopulmonary bypass providing optimal patient care and lower hospital expenditure.

"Excessive hemodilution during cardiopulmonary bypass (CBP) is associated with an increased rate of red blood cell (RBC) transfusion and acute kidney injury (AKI). Minimization of the oxygenator priming volume is a measure to contain hemodilution."[4]

Ranucci M. Effects of Priming Volume Reduction on Allogeneic Red Blood Cell Transfusions and Renal Outcome After Heart Surgery. *Perfusion*. 2015; Vol 30(2) 120-126.

"Increased use of the CAPIOX® FX15 oxygenator and R30 circuit components was associated with decreased prime volumes and contributed to less hemodilutional anemia as shown by the rise in the average Hgb nadir."[5]

The Mayo Clinic was able "to demonstrate a significant increase in the percent of patients with no transfusions from 49% to 56%."[5]

Bronson, et al. Prescriptive Patient Extracorporeal Circuit and Oxygenator Sizing Reduces Hemodilution and Allogeneic Blood Product Transfusion during Adult Cardiac Surgery. *J Extra Corpor Technol*. 2013; 45:167-172.

"The CAPIOX FX1540 was effective in reducing intraoperative packed red cell transfusions...

Aside from the possible clinical advantages of reduced transfusions, potential financial benefits may also exist...

Using smaller oxygenator/venous reservoir combinations may, therefore, also stand up to economic reasoning by reducing the total cost per hospitalization."[6]

Lahanas, A. A Retrospective Comparison of Blood Transfusion Requirements During Cardiopulmonary Bypass with Two Different Small Adult Oxygenators. *Perfusion*. 2013;28:(9).

Study found "lowest hematocrit significantly associated with worse renal function, more myocardial injury, longer ventilator support, longer hospital stay, and increased mortality."[7]

Killic, Arman. Blood Transfusions in Cardiac Surgery: Indications, Risks, and Conservation Strategies. *Ann Thorac Surg*. 2014;97:726-34.

CAPIOX® FX25 Advance Oxygenator

The design of the CAPIOX FX25 Advance Oxygenator provides a full-size oxygenator with a low prime volume for adults with higher demand, and the hardshell reservoir offers a reduced minimum operating level.

- Maximum blood flow: 7.0 L/min
- Oxygenator priming volume: 260 mL
- Reservoir storage capacity: 4,000 mL
- Minimum operating level: 150 mL

FX25 Advance with 4,000 mL reservoir

FX05 with 1,000 mL reservoir

CAPIOX® FX05 Oxygenator

The CAPIOX FX05 Oxygenator offers exceptionally low prime volume and high performance.[8] Your most delicate patients deserve the lowest prime volume possible.

- Maximum blood flow: 1.5 L/min
- Oxygenator priming volume: 43 mL
- Reservoir storage capacity: 1,000 mL
- Minimum operating level: 15 mL

Proven Performance. Enhanced Flow Dynamics.

Advance Hardshell Reservoir Features

- Improved flow dynamics reduces blood turbulance and enhances gaseous microemboli removal
- Rotating, curved venous inlet enhances ease-of-use
- Elongated shape provides stable, smooth blood flow path
- Volume indicators on three sides enhances visibility at all levels and angles
- Built-in positive pressure relief valve for increased convenience and safety

Oxygenator Features

- Proven self-venting technology and integrated arterial filter provide the safety of arterial filtration with less foreign surface area and no added prime volume – simplifying the circuit and assuring that the oxygenator is fully primed
- Low priming volume, high gas exchange and low pressure drop are optimally balanced for superb performance
- Terumo's exclusive hollow fiber technology enables total process control from raw materials to finished product
- Woven fiber bundle design provides consistent and high-performance gas exchange
- Less foreign surface area contact minimizes systemic inflammatory response
- Multiple blood outlet port configurations allow easy access and circuit flexibility

CAPIOX FX15
Advance Oxygenator

Curved venous inlet enhances flow dynamics

3/8”-1/4” adapters for the CAPIOX FX15 Oxygenator with 3,000 mL reservoir

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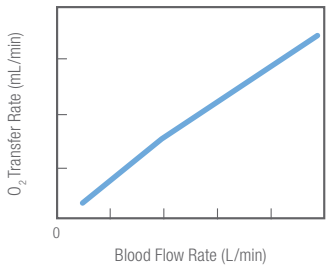
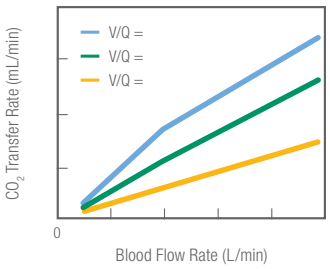
CAPIOX® FX15 Advance Oxygenator Performance Data[9]

O_2 Transfer Rate (in vitro)



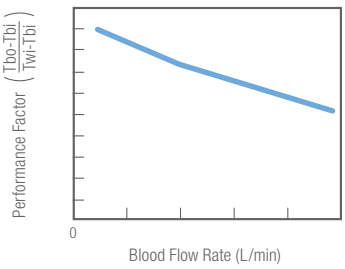
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg

CO_2 Transfer Rate (in vitro)



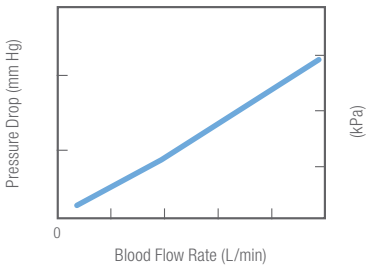
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg

Heat Exchanger Performance Factor (in vitro)



Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Water Flow Rate = 15 L/min
Tbi = 30 ± 1°C
Twi = 40 ± 1°C

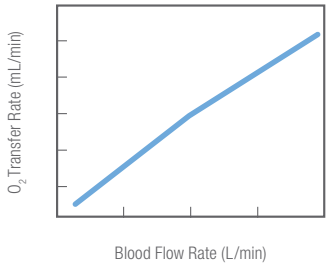
Blood Side Pressure Drop (in vitro)



Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
B.E. = 0 ± 5 mEq/L
Temp = 37 ± 1°C

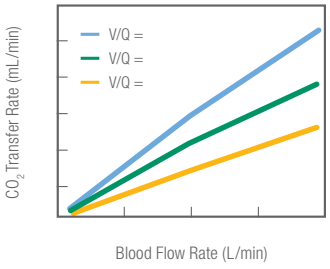
CAPIOX FX25 Advance Oxygenator Performance Data[9]

O_2 Transfer Rate (in vitro)



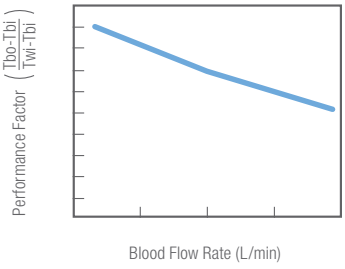
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg

CO_2 Transfer Rate (in vitro)



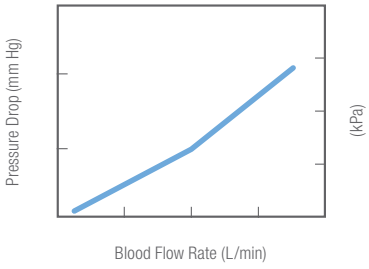
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg

Heat Exchanger Performance Factor (in vitro)



Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Water Flow Rate = 15 L/min
Tbi = 30 ± 1°C
Twi = 40 ± 1°C

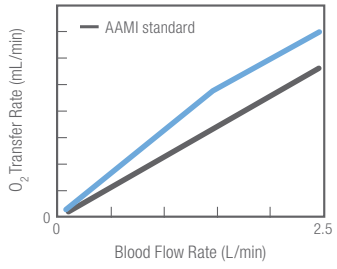
Blood Side Pressure Drop (in vitro)



Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
B.E. = 0 ± 5 mEq/L
Temp = 37 ± 1°C

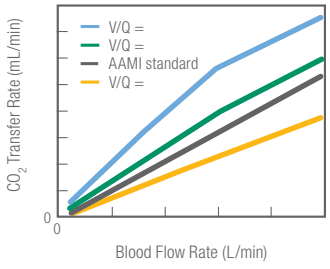
CAPIOX FX05 Oxygenator Performance Data[9]

O_2 Transfer Rate (in vitro)



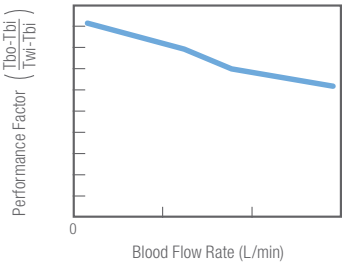
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg

CO_2 Transfer Rate (in vitro)



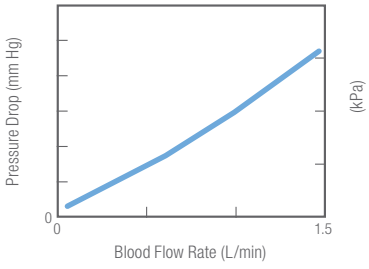
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg

Heat Exchanger Performance Factor (in vitro)



Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Water Flow Rate = 15 L/min
Tbi = 30 ± 1°C
Twi = 40 ± 1°C

Blood Side Pressure Drop (in vitro)



Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C

Holder Systems


XX*CXH18R/801804


XX*XH032/801139


XX*CXH15


XX*CXH18


XX*CXH05R

Specifications

Oxygenator and Heat Exchanger			
Material	Housing	Polycarbonate	
	Oxygenator fibers	Microporous polypropylene	
	Heat Exchanger	Stainless steel	
Oxygenator	**FX15**	**FX25**	**FX05**
Fiber bundle surface area	Approx. 1.5 m^2	Approx. 2.5 m^2	Approx. 0.5 m^2
Heat exchanger surface area	Approx. 0.14 m^2	Approx. 0.2 m^2	Approx. 0.035 m^2
Blood flow range	0.5 - 5.0 L/min	0.5 - 7.0 L/min	0.1 - 1.5 L/min
Priming volume (static)	144 mL	260 mL	43 mL
Blood inlet port (from pump)	3/8" (9.5 mm)		1/4" (6.4 mm)
Blood outlet port	3/8" (9.5 mm)		1/4" (6.4 mm)
Cardioplegia port	1/4" (6.4 mm)		N/A
Luer port (for recirc. or blood cardioplegia)	N/A		One luer lock on blood outlet port
Gas inlet port	1/4" (6.4 mm)		
Gas outlet port	1/4" (6.4 mm)		5/16" (7.9 mm)
Water ports	1/2" (12.7 mm) Hansen quick connect fitting		
Maximum pressure blood inlet	1.000 mm Hg (133 kPa) (1.36 kgf/cm^2)		
Maximum pressure water inlet	1,470 mm Hg (196 kPa) (2 kgf/cm^2)		
Arterial Filter			
Filter material	Polyester screen type		
Pore size	32 µm		
Surface area	360 cm^2	600 cm^2	130 cm^2

CAPIOX® Advance Hardshell Reservoir				
Material	Housing	Polycarbonate		
	Venous filter	Polyester screen type, pore size 47 µm		
	Cardiotomy filter	Polyester depth type		
	Defoamer	Polyurethane foam		
Hardshell Reservoir	**FX15**	**FX15**	**FX25**	**FX05**
	R30C	R40C		
Blood flow range – Venous flow – Cardiotomy inlet – Combined flow	 0.5 - 5.0 L/min Max. 4.0 L/min Max. 5.0 L/min	 0.5 - 5.0 L/min Max. 5.0 L/min Max. 5.0 L/min	 0.5 - 7.0 L/min Max. 5.0 L/min Max. 7.0 L/min	 0.1 - 1.5 L/min Max. 1.5 L/min Max. 1.5 L/min
Blood storage capacity	3,000 mL	4,000 mL	4,000 mL	1.000 mL
Minimum operating volume	70 mL	150 mL	150 mL	15 mL
Venous blood inlet port	3/8" (9.5 mm) Rotatable	1/2" (12.7 mm) Rotatable	1/2" (12.7 mm) Rotatable	1/4" (6.4 mm) Rotatable
Blood outlet port (to pump)	3/8" (9.5 mm)			1/4" (6.4 mm)
Suction ports	Six, 1/4" (6.4 mm)			Five, 3/16" - 1/4" (4.8 mm - 6.4 mm) Rotatable
Vertical port to CR filter	3/8" (9.5 mm)			N/A
Quick prime port	1/4" (6.4 mm)			
Vent port	1/4" (6.4 mm)			
Auxiliary port	1/4" - 3/8" (6.4 mm - 9.5 mm)			
Luer ports	Three filtered luer locks to cardiotomy filter. One non-filtered luer lock. Two luer locks on venous inlet.			
Maximum sustainable negative pressure in reservoir	-150 mm Hg (-20 kPa)			
Positive pressure relief valve	0 - 8 mm Hg (1.1 kPa)			

Xcoating™

Xcoating™ Surface Coating. Terumo's biocompatible amphiphilic polymer surface coating is a standard feature on all CAPIOX FX Advance Oxygenators.

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Ordering Information

West Outlet Port
Oxy inlet on right when outlet is facing away from user.

East Outlet Port
Oxy inlet on left when outlet is facing away from user.

Catalog #	Description	Units/Case
CAPIOX® FX15 Advance Oxygenator		
1CX*FX15W+	With integrated arterial filter, “west” orientation	4
1CX*FX15E+	With integrated arterial filter, “east” orientation	4
3CX*FX15RW30C#	With integrated arterial filter, 3,000 mL hardshell reservoir, “west” orientation	4
3CX*FX15RE30C#	With integrated arterial filter, 3,000 mL hardshell reservoir, “east” orientation	4
3CX*FX15RW40C	With integrated arterial filter, 4,000 mL hardshell reservoir, “west” orientation	4
3CX*FX15RE40C	With integrated arterial filter, 4,000 mL hardshell reservoir, “east” orientation	4
CAPIOX FX25 Advance Oxygenator		
1CX*FX25W	With integrated arterial filter, “west” orientation	4
1CX*FX25E	With integrated arterial filter, “east” orientation	4
3CX*FX25RWC	With integrated arterial filter, 4,000 mL hardshell reservoir, “west” orientation	4
3CX*FX25REC	With integrated arterial filter, 4,000 mL hardshell reservoir, “east” orientation	4
CAPIOX FX05 Oxygenator		
1CX*FX05RW^	With integrated arterial filter, 1,000 mL hardshell reservoir, “west” orientation	4
1CX*FX05RE^	With integrated arterial filter, 1,000 mL hardshell reservoir, “east” orientation	4
Holders for CAPIOX FX Oxygenators		
801139	FX15/25 Advance oxygenators with hardshell reservoir, short arm	1
801804	FX15/25 Advance oxygenators with hardshell reservoir, long arm	1
1XX*CXH15	FX15/25 Advance oxygenators	1
1XX*CXH18	FX15/25 Advance oxygenators when separated from reservoir	1
XX*CXH18R	FX15/25 Advance oxygenators with hardshell reservoir	1
XX*XH032	FX15/25 Advance oxygenators with hardshell reservoir, short arm	1
XX*CXH05	FX05 oxygenator	1
XX*CXH05R	FX05 oxygenator with hardshell reservoir	1
XX*CXH05AD	Adapter for SX holder for FX05	1
Accessories for CAPIOX FX Oxygenators		
1CX*BP021	Blue thermistor wire	10
1CX*BP022	Red thermistor wire	10

+ *Contains two 1/4" - 3/8" adapters* **#** *Contains four 1/4" - 3/8" adapters* **^** *Contains four 3/16" - 1/4" adapters, one 1/4" - 3/8" adapters, and a recirculation line*

References:

1. Shann, et al. An evidence-based review of the practice of cardiopulmonary bypass in adults: A focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response. J *Thorac Cardiovasc Surg* 2006; 132:283-290.
2. Preston, et al. Clinical Gaseous Microemboli Assessment of an Oxygenator with Integral Arterial Filter in the Pediatric Population. *JECT* 2009; 41:226-230.
3. Gomez, et al. Evaluation of air handling in a new generation neonatal oxygenator with integral arterial filter. *Perfusion* 2009; 24 (2)107-112.
4. Ranucci, M., et al. Effects of priming volume reduction on allogeneic red blood cell transfusions and renal outcome after heart surgery. *Perfusion*. March 2015; 30(2).
5. Bronson, S., et al. Prescriptive Patient Extracorporeal Circuit and Oxygenator Sizing Reduces Hemodilution and Allogeneic Blood Product Transfusion during Adult Cardiac Surgery. *JECT*. 2013; 45:167-172.
6. Lahanas, A., et al. A retrospective comparison of blood transfusion requirements during cardiopulmonary bypass with two different small adult oxygenators. *Perfusion*. July 2013; 28(4).
7. Killic, Arman. Blood Transfusions in Cardiac Surgery: Indications, Risks, and Conservation Strategies. *Ann Thorac Surg*. 2014; 97:726-34.
8. Deptula, J., et al. Clinical Evaluation of the Terumo CAPIOX FX05 Hollow Fiber Oxygenator with Integrated Arterial Line Filter. *JECT*. 2009; 41:220-225.
9. Internal testing, data on file.

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TERUMO CARDIOVASCULAR
6200 Jackson Road, Ann Arbor, MI 48103-9300 USA
Tel: +1.734.663.4145 Fax: +1.734.663.7981
Email: cardiovascular@terumomedical.com

For a complete list of offices, please consult our website.
www.terumocv.com/offices

TERUMO CORPORATION
2-44-1 Hatagaya, Shibuya-Ku, Tokyo 151-0072 Japan
Tel: +81.3.3374.8111 Fax: +81.3.3374.8399

TERUMO EUROPE N.V.
Authorized EC Representative
Interleuvenlaan 40, 3001 Leuven, Belgium
Tel: +32.16.38.12.11 Fax: +32.16.40.02.49

TERUMO ASIA HOLDINGS PTE. LTD.
300 Beach Road, #33-03, The Concourse Singapore 199555
Tel: +65.6.295.1792 Fax: +65.6.294.2329

TERUMO LATIN AMERICA CORPORATION
8750 NW 36th Street, Suite 240, Miami, FL 33178 USA
Tel: +1.305.477.4822 Fax: +1.305.477.4872

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