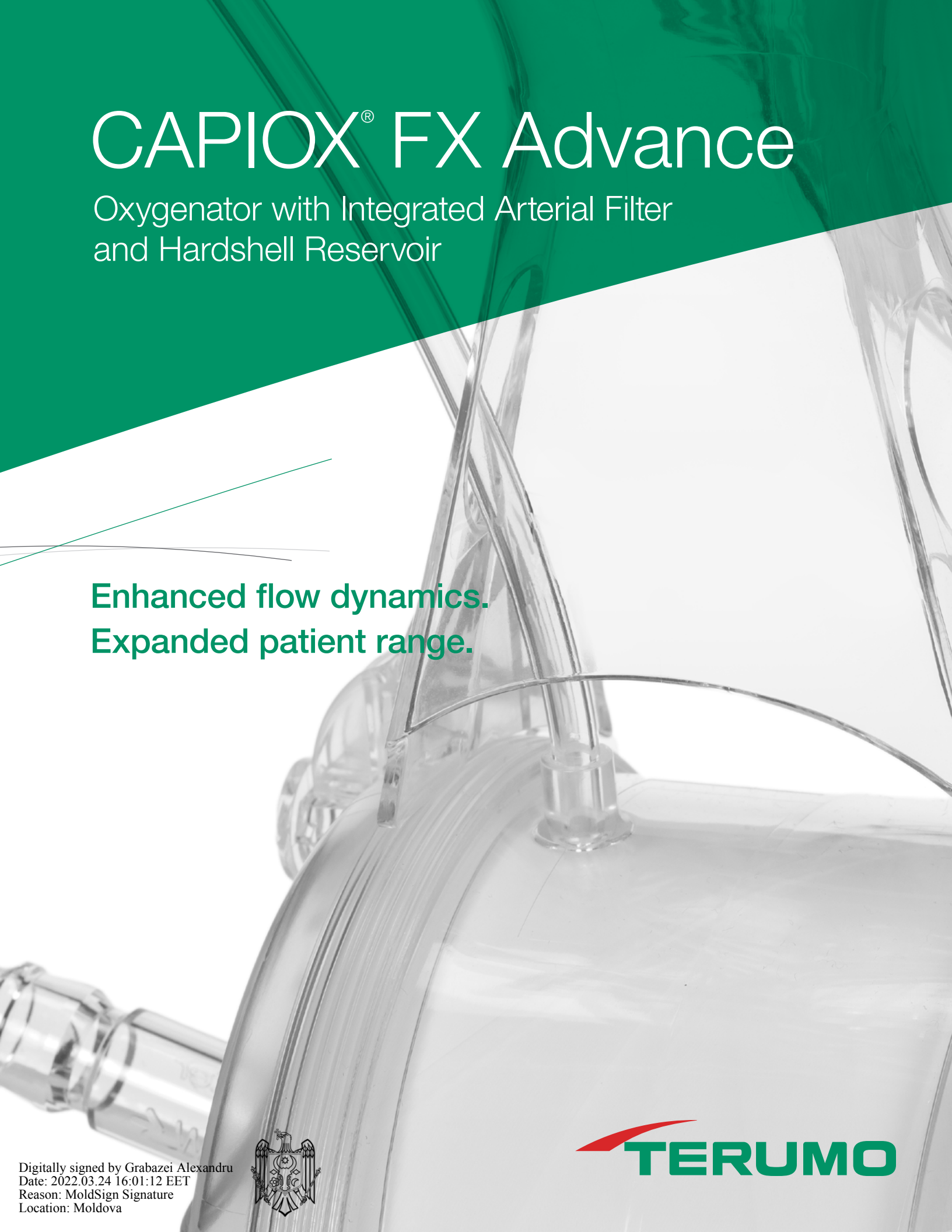
CAPIOX® FX Advance

Oxygenator with Integrated Arterial Filter and Hardshell Reservoir



Enhanced flow dynamics.
Expanded patient range.

TERUMO

TERUMO

Advance to the next level.

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

The new CAPIOX® FX Advance Oxygenator advances your oxygenator to the next level by enhancing flow dynamics,[1] resulting in lower minimum operating levels and increased maximum blood flow rates. Now, you can expand your options and choose a smaller, lower prime oxygenator for even more patients.

Working together with your surgery team, Terumo Cardiovascular Group helps save lives every day. That's why we never compromise quality. And it's why we constantly strive to deliver new technologies that advance patient outcomes and deliver exceptional clinical value.

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

Terumo Cardiovascular Group

terumo-cvgroup.com
terumo-europe.com

Introducing the CAPIOX® FX Advance Oxygenator with improved flow dynamics.

Patients come in all shapes and sizes — so do CAPIOX FX Oxygenators. Now, you can expand the use of CAPIOX FX Oxygenators through the enhanced flow dynamics offered on the CAPIOX Advance Hardshell Reservoir.

Advancements include an increased blood flow rate on the 3,000 mL reservoir — available on the CAPIOX FX15 Advance Oxygenator — and a lower minimum operating level on the 4,000 mL reservoir — available on the CAPIOX FX15 and FX25 Advance Oxygenators.

3,000 mL Hardshell Reservoir

Advantage:

Increased maximum blood flow to 5 L/min on the CAPIOX FX15 Advance Oxygenator*

Benefit:

Flexibility to use on a wider range of patients and the lowest prime adult oxygenator available today

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

4,000 mL Hardshell Reservoir

Advantage:

Reduced minimum operating level of 150 mL on the CAPIOX FX15 and FX25 Advance Oxygenators

Benefit:

Further helps minimize hemodilution with the lowest-prime full-size oxygenator[2]

CAPIOX FX15
Advance Oxygenator

TERUMO

Advancing Outcomes

Built around Terumo CV Group's integrated arterial filter with self-venting technology, the CAPIOX® FX Advance Oxygenator helps clinicians reduce prime volume and lower hemodilution.[2] The design of the CAPIOX FX Advance Oxygenator contributes to fewer blood transfusions[4] and reduced hospital costs.[2]

Curved venous inlet enhances flow dynamics

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

Enhanced flow dynamics.
Expanded patient range.

Low prime volume oxygenators reduce hemodilution, blood transfusions and the risk of Acute Kidney Injury

It is well known, with a high level of evidence (Class 1 level a), that excessive hemodilution during cardiopulmonary bypass (CPB) can lead to an increased incidence of red blood cell transfusions and other patient risks, including post-operative Acute Kidney Injury (AKI).

A recent study demonstrates 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 AKI.[3]

CAPIOX FX Advance Oxygenators allow you to minimize hemodilution, resulting in fewer blood transfusions and may decrease the risk of AKI.

Hardshell Reservoir

Enhanced flow dynamics

- Improved flow dynamics reduces blood turbulance and enhances gaseous microemboli removal
- Rotating, curved venous inlet enhances ease-of-use
- Increased maximum blood flow to 5 L/min on the CAPIOX FX15 Advance Oxygenator, with 3,000 mL reservoir, for use on a wider range of patients*
- Decreased minimum operating level of 150 mL on the CAPIOX FX15 and FX25 Advance Oxygenators, with the 4,000 mL reservoir, reduces hemodilution
- 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 increases convenience and assurance

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

CAPIOX FX Oxygenator

Proven performance and fully integrated arterial filter

- Features self-venting technology
- 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

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.

TERUMO

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. And now, 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 4,000 mL

FX15 Advance 3,000 mL

CAPIOX FX25 Advance Oxygenator

The design of the CAPIOX FX25 Advance Oxygenator provides a full-size oxygenator with a low prime volume, 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
4,000 mL

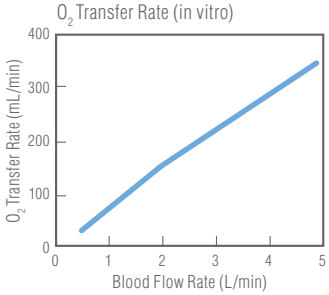
CAPIOX FX05 Oxygenator

The CAPIOX FX05 Oxygenator offers exceptionally low prime volume and high performance.[5] Your most delicate patients deserve the lowest prime volume possible.

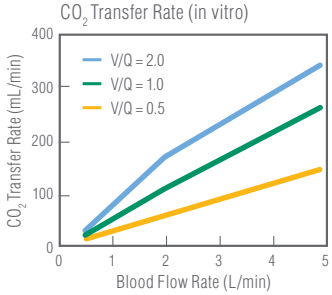
- Maximum blood flow: 1.5 L/min
- Oxygenator priming volume: 43 mL
- Reservoir storage capacity: 1,000 mL
- Minimum operating level: 15 mL

FX05
1,000 mL

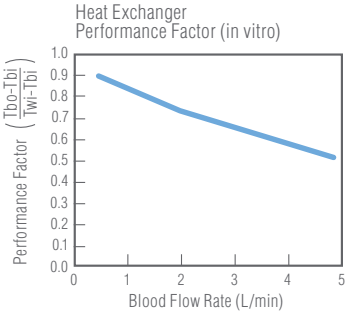
CAPIOX® FX15 Advance Oxygenator Performance Data[1]



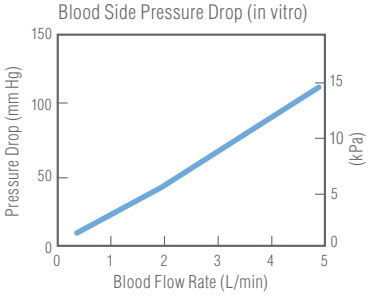
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg
B.E. = 0 ± 5 mEq/L
V/Q = 1.0



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
B.E. = 0 ± 5 mEq/L

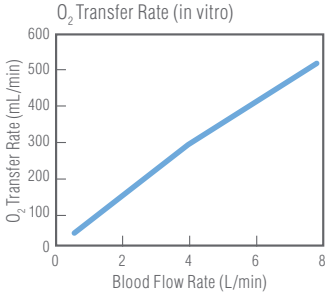


Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Water Flow Rate = 15 L/min
Tbi = 30 ± 1°C
Twi = 40 ± 1°C

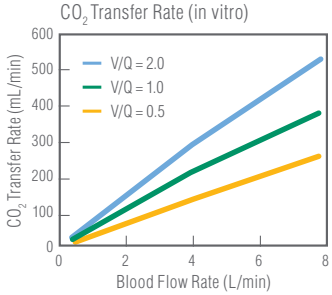


Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
B.E. = 0 ± 5 mEq/L
Temp = 37 ± 1°C

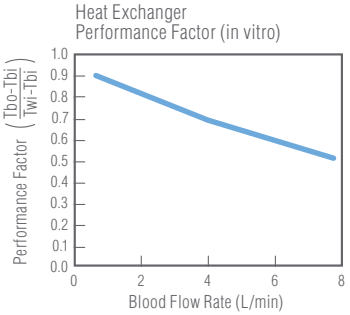
CAPIOX FX25 Advance Oxygenator Performance Data[1]



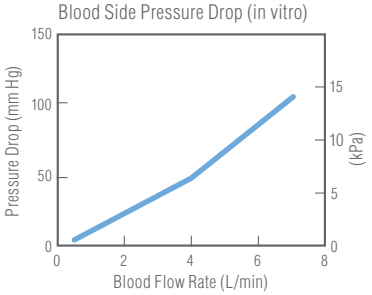
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg
B.E. = 0 ± 5 mEq/L
V/Q = 1.0



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
B.E. = 0 ± 5 mEq/L

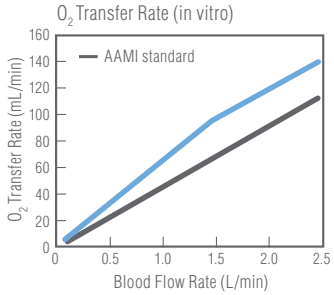


Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Water Flow Rate = 15 L/min
Tbi = 30 ± 1°C
Twi = 40 ± 1°C

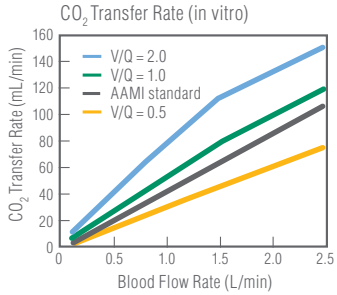


Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
B.E. = 0 ± 5 mEq/L
Temp = 37 ± 1°C

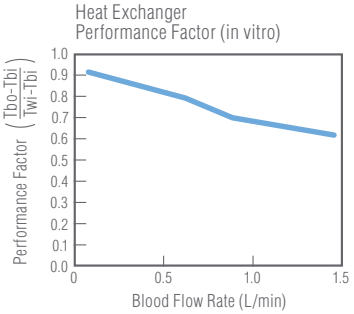
CAPIOX FX05 Oxygenator Performance Data[1]



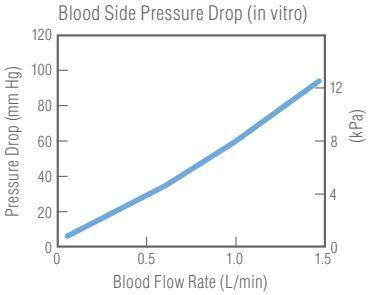
Conditions:
Blood = Bovine
Hb = 12 ± 1 g/dL
Temp = 37 ± 1°C
pH = 7.4
SvO_2 = 65 ± 5%
$PvCO_2$ = 45 ± 5 mm Hg
B.E. = 0 ± 5 mEq/L
V/Q = 1.0



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
B.E. = 0 ± 5 mEq/L



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



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

Holder Systems


XX*CXH18R/801804


XX*XH032


XX*CXH15


XX*CXH25F


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® FX15/FX25 Advance Hardshell Reservoir and CAPIOX® FX05 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**		**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)			N/A

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

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 Oxygenator		
CX*FX15W+	With integrated arterial filter, “west” orientation	4
CX*FX15E+	With integrated arterial filter, “east” orientation	4
CAPIOX® FX15 Advance Oxygenator		
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 Oxygenator		
CX*FX25W	With integrated arterial filter, “west” orientation	4
CX*FX25E	With integrated arterial filter, “east” orientation	4
CAPIOX FX25 Advance Oxygenator		
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		
CX*FX05RW^	With integrated arterial filter, 1,000 mL hardshell reservoir, “west” orientation	4
CX*FX05RE^	With integrated arterial filter, 1,000 mL hardshell reservoir, “east” orientation	4
Holders for CAPIOX FX Oxygenators		
XX*CXH15	FX15/25 oxygenators	1
XX*CXH18R	FX15/25 Advance oxygenators with hardshell reservoir	1
XX*CXH25F	FX15/25 Advance oxygenators when separated from 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		
CX*BP021	Blue thermistor wire	10
CX*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. Internal testing, data on file.
2. 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.
3. 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).
4. 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).
5. Deptula, J., et al. Clinical Evaluation of the Terumo CAPIOX FX05 Hollow Fiber Oxygenator with Integrated Arterial Line Filter. *JECT.* 2009; 41:220-225.

TERUMO

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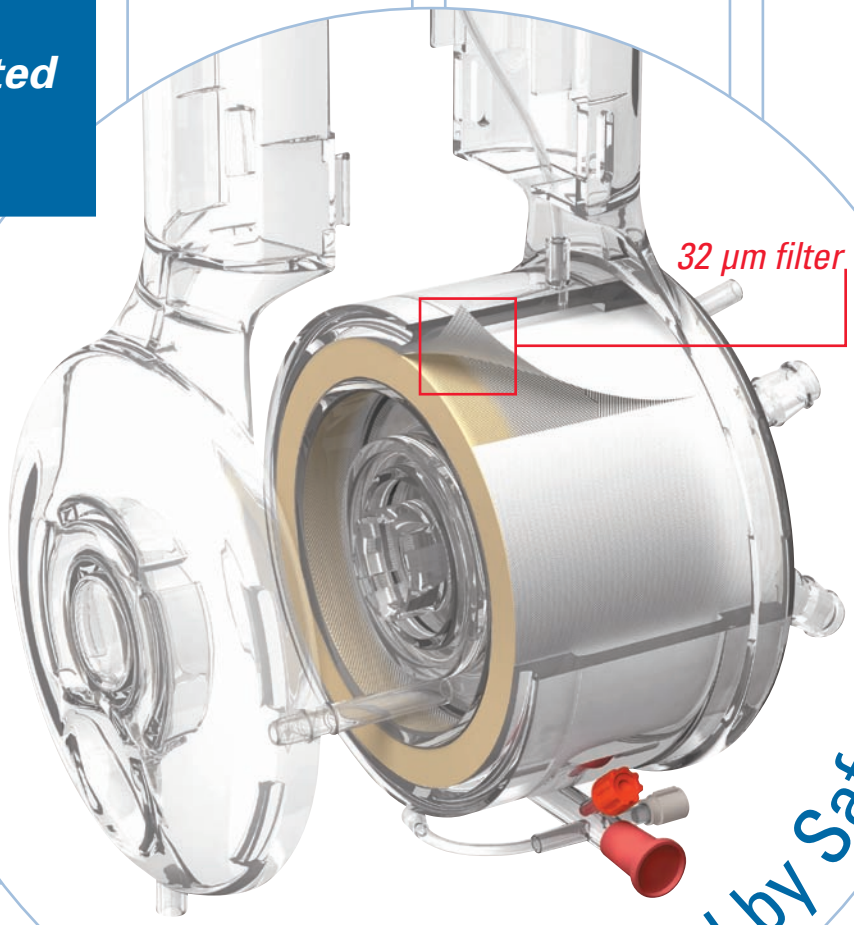
CAPIOX® FX Family of Oxygenators with Integrated Arterial Filter

Breakthrough technology for added patient safety

With integrated filter!



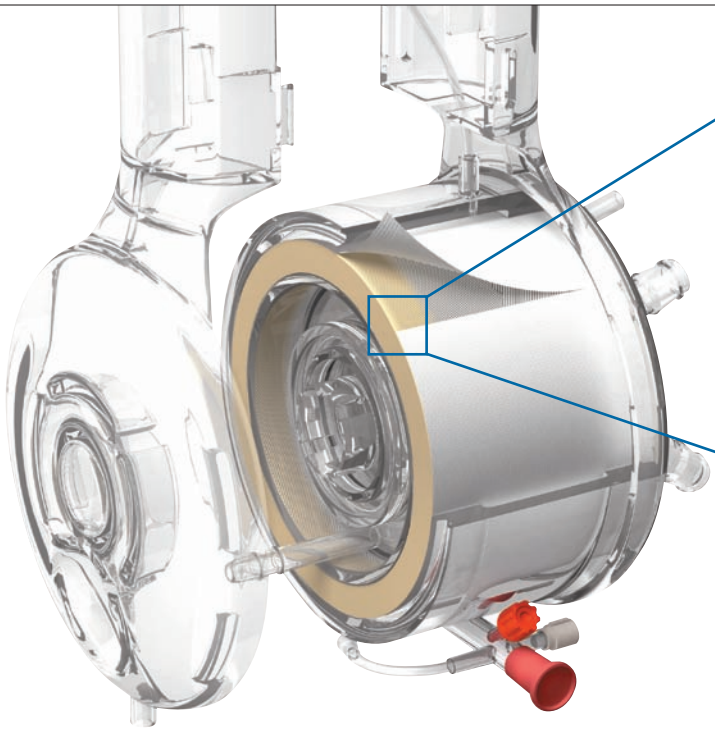
Surrounded by Safety

TERUMO®

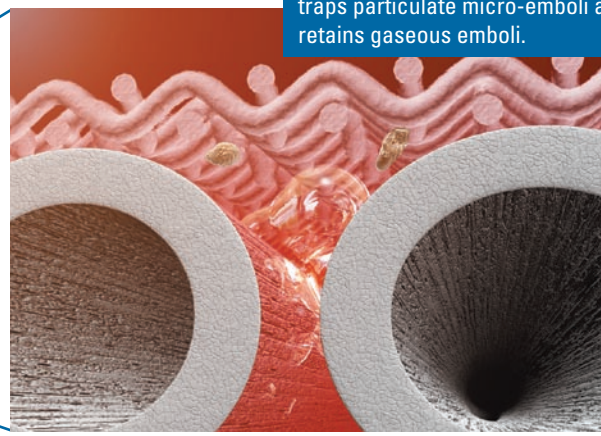
CAPIOX® FX Family of Oxygenators

Integrated arterial filter with self-venting technology

A 32 µm screen filter surrounds the fiber layer of the oxygenator. Particulate micro-emboli that may be present in the blood are trapped in the filter mesh while gaseous emboli remain inside the oxygenator and in contact with the hollow fibers. Driven by the pressure difference, gaseous emboli enter the inner lumen of the microporous hollow fiber and are eliminated via the gas outlet.

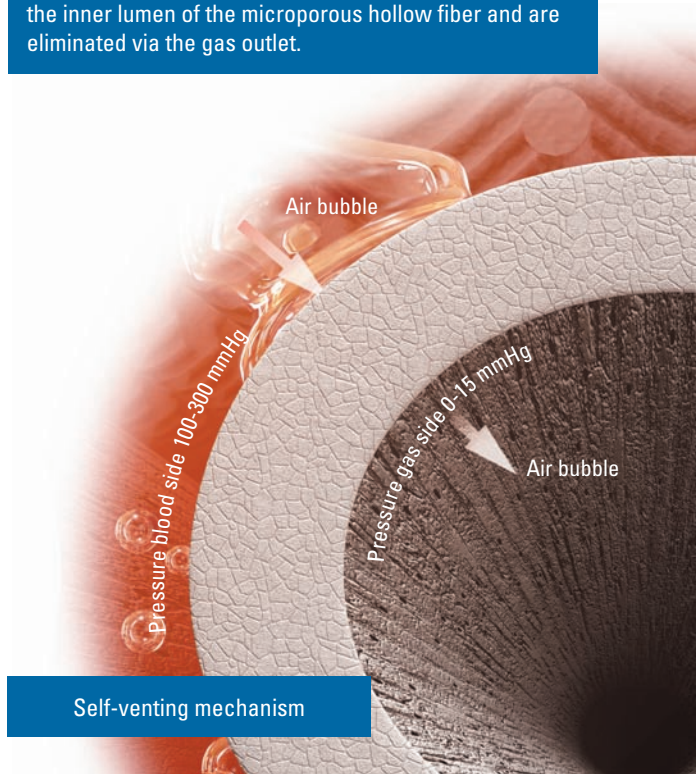


Screen filter surrounds the fiber layer, traps particulate micro-emboli and retains gaseous emboli.



Driven by the pressure difference between the blood side and gas side of the oxygenator, gaseous emboli enter the inner lumen of the microporous hollow fiber and are eliminated via the gas outlet.

Filter Pore Size 32 µm



Self-venting mechanism

Xcoating™, *Terumo's own biocompatible amphiphilic polymer surface coating, is a standard feature of all CAPIOX® FX oxygenators.*

Integrated arterial filter

- Filter inside oxygenator housing
- 32 µm pore size
- Self-venting technology

CAPIOX® FX05 Oxygenator

For neonates and infants

Oxygenator

Proven performance

- Fully integrated arterial filter with self-venting technology
- Low priming volume, high gas exchange and low pressure drop are optimally balanced for superb performance
- Hollow fibers manufactured exclusively by Terumo using a patented technology means total quality management from raw materials to finished product
- Woven fiber bundle ensures consistent and high-performance gas exchange
- Choice of blood outlet port configurations for easy access and increased circuit flexibility
- No DEHP used in PVC tubing

Hardshell Reservoir

Full featured

- Elongated shape provides stable blood flow path and enhanced visibility at all levels from all angles
- Rotating venous inlet improves set-up flexibility
- Connecting mount increases flexibility in circuit set-up and oxygenator rotation
- Funnel-shaped cardiotomy filter improves breakthrough and residual volumes
- No DEHP used in PVC tubing

- *Maximum blood flow: 1.5 L/min*
- *Oxygenator priming volume: 43 mL*
- *Arterial filter surface area: 130 cm²*
- *Reservoir storage capacity: 1000 mL*

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

Choose the blood outlet port configuration that best suits your circuit

CAPIOX® FX15 Oxygenator

For children, small adults and minimized circuits

Available in two reservoir sizes

- Maximum blood flow: 4.0 L/min
- Oxygenator priming volume: 144 mL
- Arterial filter surface area: 360 cm^2
- Reservoir storage capacity: 3000 mL

- Maximum blood flow: 5.0 L/min
- Oxygenator priming volume: 144 mL
- Arterial filter surface area: 360 cm^2
- Reservoir storage capacity: 4000 mL

CAPIOX® FX25 Oxygenator

For all adults

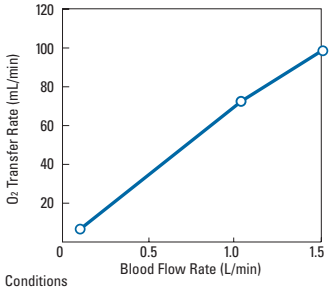
- Maximum blood flow: 7.0 L/min
- Oxygenator priming volume: 260 mL
- Arterial filter surface area: 600 cm^2
- Reservoir storage capacity: 4000 mL

TOTM – an alternative plasticizer

Terumo is ever striving to develop new medical technologies with minimal negative impact to patients and the environment. In line with this goal, Terumo provides an alternative plasticizer for the manufacturing of its products. TOTM (trioctyl trimellitate) offers outstanding physical properties (such as flexibility) to the material and low plasticizer elution.

CAPIOX FX05 Performance Data

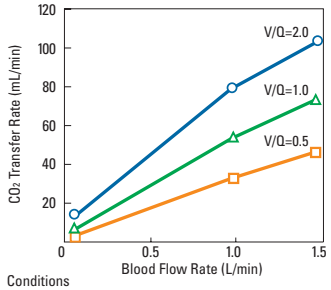
O_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4	V/Q	= 1.0

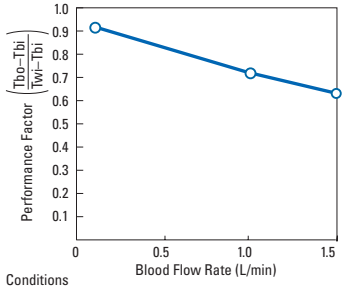
CO_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1 g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4		

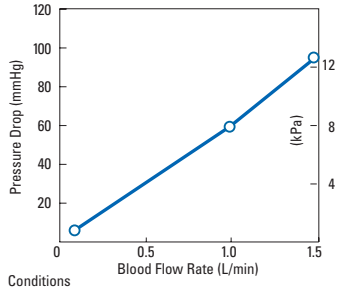
Heat Exchanger Performance Factor (in vitro)



Conditions

Blood	= Bovine		
Hb	= 12 ± 1 g/dL	Twi	= 40 ± 1°C
Tbi	= 30 ± 1°C	Water flow rate	= 15 L/min

Blood Side Pressure Drop (in vitro)

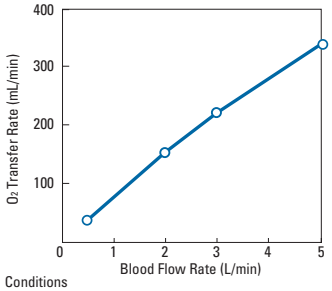


Conditions

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

CAPIOX FX15 Performance Data

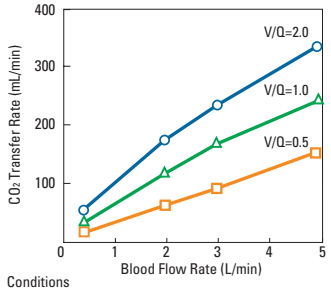
O_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4	V/Q	= 1.0

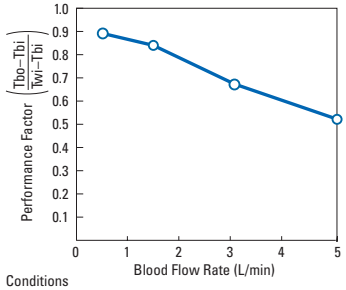
CO_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1 g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4		

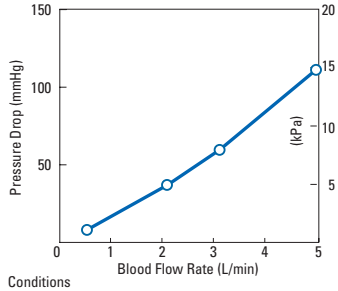
Heat Exchanger Performance Factor (in vitro)



Conditions

Blood	= Bovine	Twi	= 40 ± 1°C
Hb	= 12 ± 1 g/dL	Water flow rate	= 15 L/min
Tbi	= 30 ± 1°C		

Blood Side Pressure Drop (in vitro)

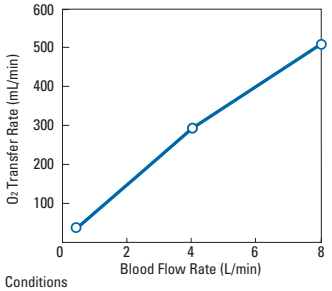


Conditions

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

CAPIOX FX25 Performance Data

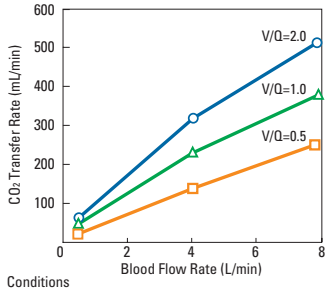
O_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4	V/Q	= 1.0

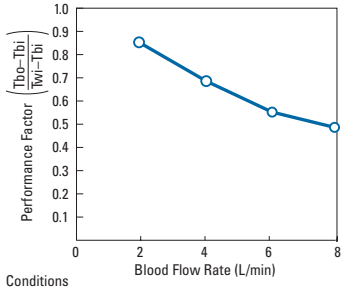
CO_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1 g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4		

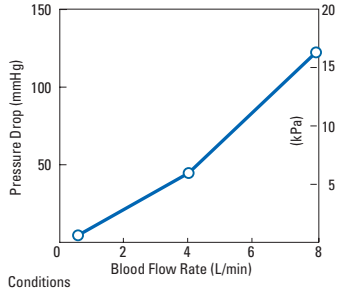
Heat Exchanger Performance Factor (in vitro)



Conditions

Blood	= Bovine	Twi	= 40 ± 1°C
Hb	= 12 ± 1 g/dL	Water flow rate	= 15 L/min
Tbi	= 30 ± 1°C		

Blood Side Pressure Drop (in vitro)



Conditions

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

Holder Systems

CAPIOX FX05 Oxygenator

Order # XX*CXH05R

Order # XX*CXH05

CAPIOX FX15 and CAPIOX FX25 Oxygenators

Order # 801804
XX*CXH18R (Europe only)

Order # 801139
XX*XH032 (Europe only)

Order # 812613 for FX25 (US only)
812614 for FX15 (US only)
XX*CXH15 (Europe only)

CAPIOX FX Family of Oxygenators

Specifications

Oxygenator

Material		
	Housing	Polycarbonate
	Fibers	Microporous polypropylene
	Heat exchanger	Stainless steel

Oxygenator	FX05	FX15	FX25
Fiber bundle surface area	Approx. 0.5 m^2	Approx. 1.5 m^2	Approx. 2.5 m^2
Heat exchanger surface area	Approx. 0.035 m^2	Approx. 0.14 m^2	Approx. 0.2 m^2
Blood flow range	0.1 – 1.5 L/min	0.5 – 5.0 L/min, 0.5 – 4.0 L/min (with R30)	0.5 – 7.0 L/min
Reference blood flow (AAMI std.)	2.5 L/min	7.0 L/min	n.a.
Priming volume (static)	43 mL	144 mL	260 mL
Blood inlet port (from pump)	1/4" (6.4 mm)	3/8" (9.5 mm)	
Blood outlet port	1/4" (6.4 mm)	3/8" (9.5 mm)	
Cardioplegia port	–	1/4" (6.4 mm)	
Luer port (for recirc. or blood cardioplegia)	One luer lock on blood outlet port	n.a.	
Gas inlet port	1/4" (6.4 mm)		
Gas outlet port	5/16" (7.9 mm)	1/4" (6.4 mm)	
Water ports	1/2" (12.7 mm) Hansen quick-connect fittings		
Maximum pressure Blood inlet	1000 mmHg (133 kPa)		
Maximum pressure Water inlet	2 kgf/cm^2 (196 kPa) (28.5 psi)		
Arterial filter			
Filter material	Polyester screen type		
Pore size	32 µm		
Surface area	130 cm^2	360 cm^2	600 cm^2

Hardshell Reservoir

Material		
	Housing	Polycarbonate
	Venous filter	Polyester screen type, Pore size 47 µm
	Cardiotomy filter	Polyester depth type
	Defoamer	Polyurethane foam

Hardshell reservoir	FX05	FX15 R30 (for FX15)	FX15 R40 (for FX15)	FX25
Blood flow range Venous flow Cardiotomy inlet Combined flow	0.1 – 1.5 L/min Max. 1.5 L/min Max. 1.5 L/min	0.5 – 4.0 L/min Max. 4.0 L/min Max. 4.0 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
Blood storage capacity	1000 mL	3000 mL	4000 mL	4000 mL
Min. operating volume	15 mL	70 mL	200 mL	200 mL
Venous blood inlet port	1/4" (6.4 mm) rotatable	3/8" (9.5 mm) rotatable	1/2" (12.7 mm) rotatable	1/2" (12.7 mm) rotatable
Blood outlet port (to pump)	1/4" (6.4 mm)	3/8" (9.5 mm)		
Suction ports	Five 3/16" – 1/4" (4.8 mm – 6.4 mm) rotatable	Six 1/4" (6.4 mm)		
Vertical port (to CR filter)	n.a.	3/8" (9.5 mm)		
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 mmHg (-20.0 kPa)			

Ordering Information

DESCRIPTION	CATALOG NO.	UNITS/CASE
CAPIOX FX05 Oxygenator		
Oxygenator with integrated arterial filter[1]	CX*FX05W	4
Oxygenator with integrated arterial filter[1]	CX*FX05E	4
Oxygenator with integrated arterial filter/hardshell reservoir[2]	CX*FX05RW	4
Oxygenator with integrated arterial filter/hardshell reservoir[2]	CX*FX05RE	4
CAPIOX FX15 Oxygenator		
Oxygenator with integrated arterial filter[3]	CX*FX15W	4
Oxygenator with integrated arterial filter[3]	CX*FX15E	4
Oxygenator with integrated arterial filter/hardshell reservoir[4]	CX*FX15RW30	2
Oxygenator with integrated arterial filter/hardshell reservoir[4]	CX*FX15RE30	2
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX15RW40	2
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX15RE40	2
CAPIOX FX25 Oxygenator		
Oxygenator with integrated arterial filter	CX*FX25W	4
Oxygenator with integrated arterial filter	CX*FX25E	4
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX25RW	2
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX25RE	2

DESCRIPTION	CATALOG NO.	UNITS/CASE
Holders for CAPIOX FX Oxygenators		
Holder for FX05 oxygenator	XX*CXH05	1
Holder for FX05 oxygenator with hardshell reservoir	XX*CXH05R	1
Adapter for SX holder for FX05	XX*CXH05AD	1
Holder for FX15/25 oxygenator with hardshell reservoir (short arm)	801139	1
Holder for FX15/25 oxygenator with hardshell reservoir (long arm)	801804	1
Holder for FX25 oxygenator (US only)	812613	1
Holder for FX15 oxygenator (US only)	812614	1
Holder for FX15/25 oxygenator (Europe only)	XX*CXH15	1
Holder for FX15/25 oxygenator when separated from reservoir	XX*CXH25F	1
Holder for FX15/25 oxygenator with hardshell reservoir (Europe only)	XX*CXH18R	1
Holder for FX15/25 oxygenator with hardshell reservoir, short arm (Europe only)	XX*XH032	1

[1] Contains 2 adapters 3/16" – 1/4" and a recirculation line
[2] Contains 4 adapters 3/16" – 1/4", 1 adapter 1/4" – 3/8" and a recirculation line
[3] Contains 2 adapters 1/4" – 3/8"
[4] Contains 4 adapters 1/4" – 3/8"

TERUMO®

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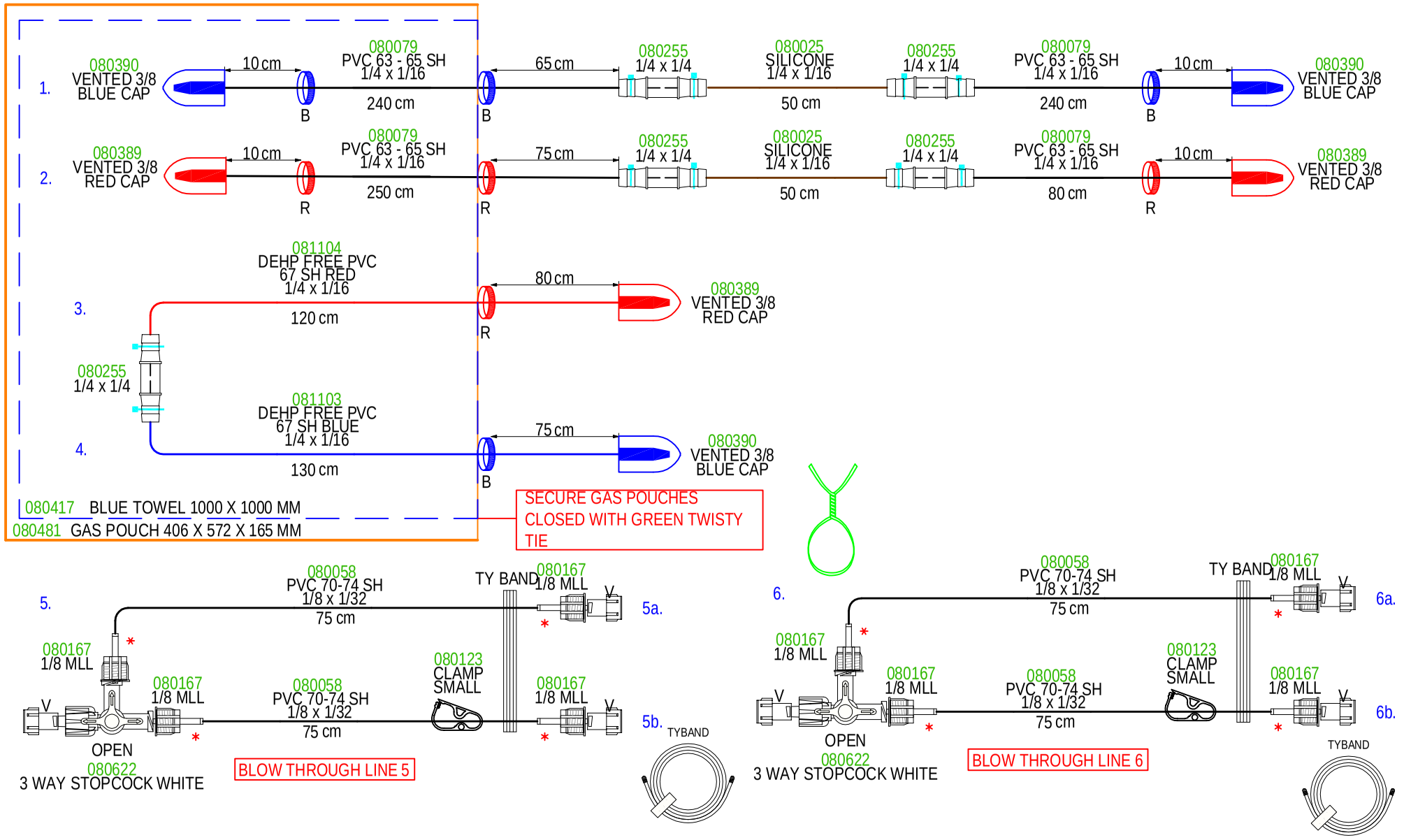
CV01FXFAMGB-0109FKFK-I5(01.09)E



CUSTOMER:	DESCRIPTION:
CHISINAU	PEDIATRIC PACK FOR <16 KG
MOLDOVA	FOR USE WITH FX05RW

PRODUCT CODE:	DRAWING TYPE:	Total Priming Volume:
CX-ML027	PRODUCTION	

DRAWN BY: STEPHEN FLYNN	ISSUED: 16/01/2018	ISSUE No: 4
INT. AMEND:	AMENDED: 30/05/2019-SF	SHEET No: 1/6

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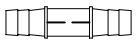
7.

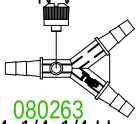
080255
1/4 x 1/4



080520 PEEL POUCH 100 X 150 MM

8.

N-V

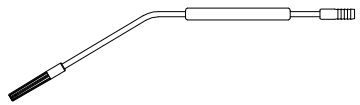


080263
1/4x1/4x1/4 LL

080523 PEEL POUCH 100 X 200 MM

9.

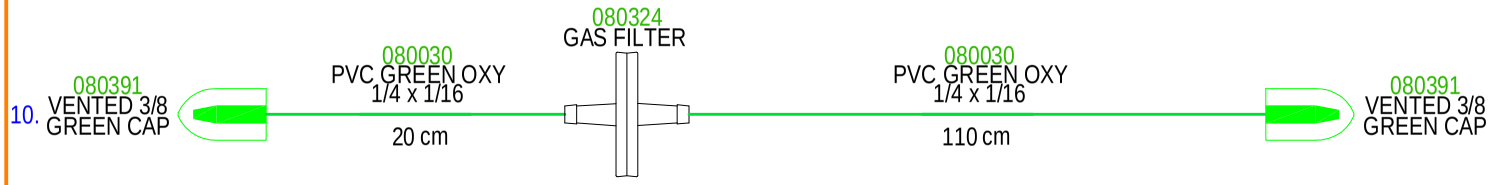
080825
PAEDIATRIC SUCKER



LENGTH CUT TO - 50 cm
080509 VIEWREEL 100 mm

LENGTH CUT TO - 50 cm
080509 VIEWREEL 100 mm

10.



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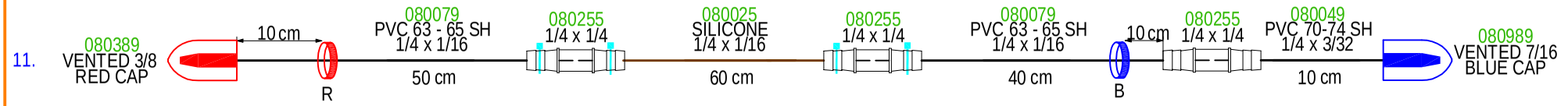

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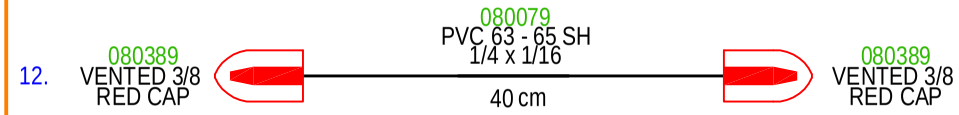

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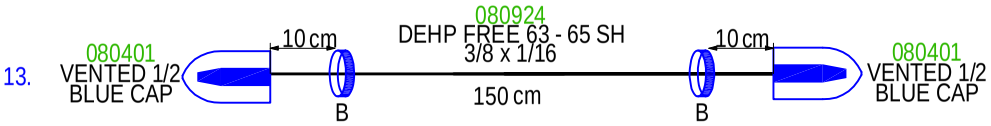

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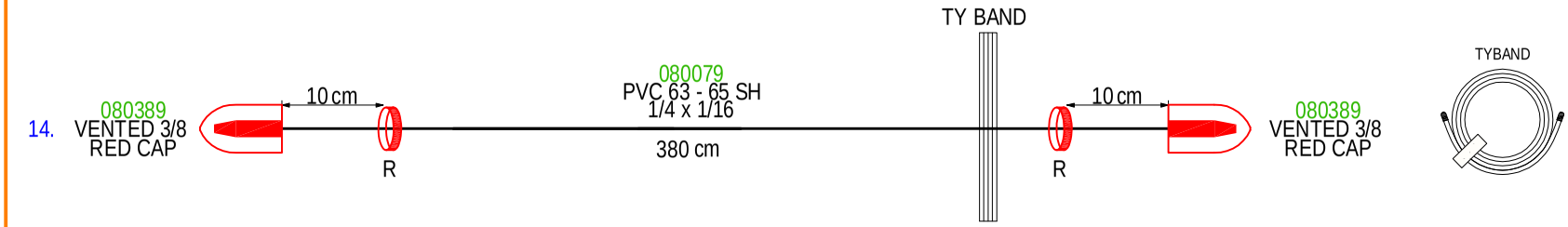

CUSTOMER:	DESCRIPTION:
CHISINAU	PEDIATRIC PACK FOR <16 KG
MOLDOVA	FOR USE WITH FX05RW

PRODUCT CODE:	DRAWING TYPE:	Total Priming Volume:
CX-ML027	PRODUCTION	

DRAWN BY: STEPHEN FLYNN	ISSUED: 16/01/2018	ISSUE No: 4
INT. AMEND:	AMENDED: 30/05/2019-SF	SHEET No: 2/6

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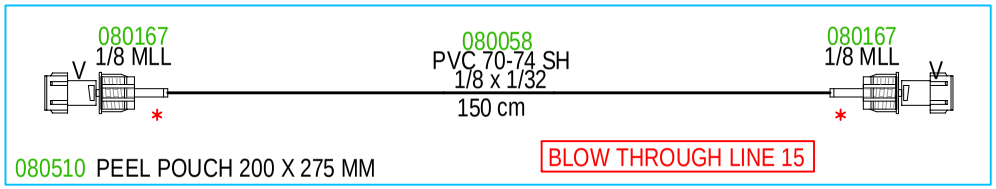
15.



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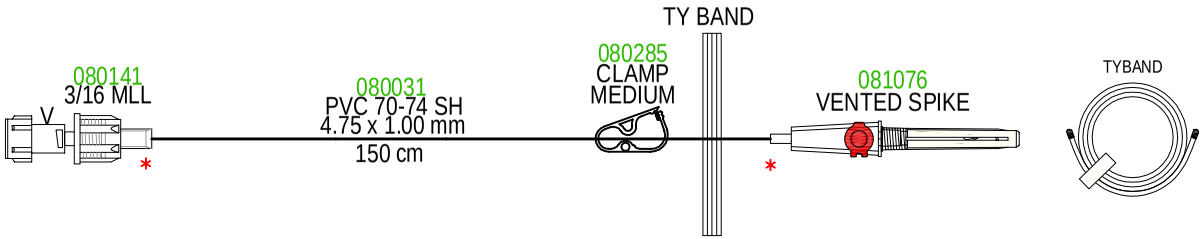

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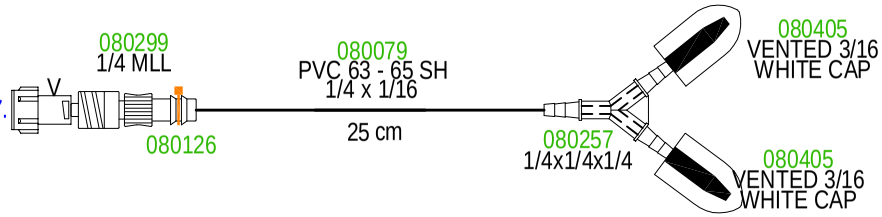

CUSTOMER:	DESCRIPTION:
CHISINAU	PEDIATRIC PACK FOR <16 KG
MOLDOVA	FOR USE WITH FX05RW
PRODUCT CODE: CX-ML027	**DRAWING TYPE:** PRODUCTION
	Total Priming Volume:

DRAWN BY: STEPHEN FLYNN	**ISSUED:** 16/01/2018	**ISSUE No:** 4
INT. AMEND:	**AMENDED:** 30/05/2019-SF	**SHEET No:** 3/6

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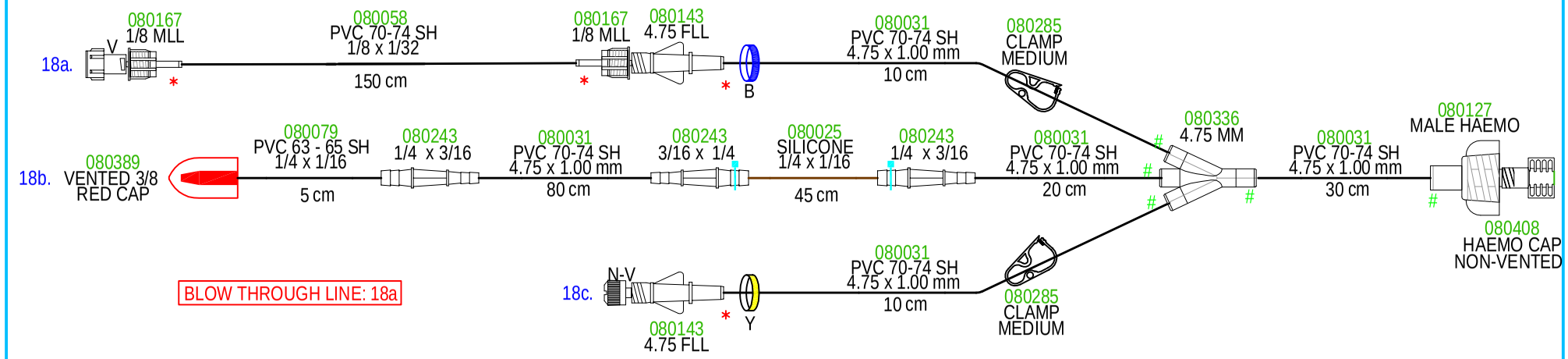
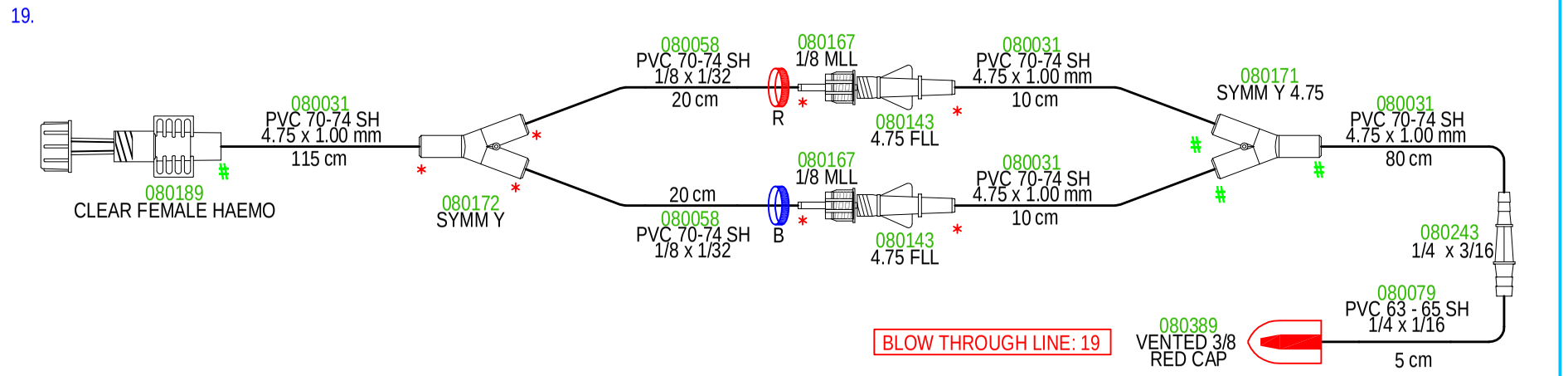




080511 PEEL POUCH 250 X 485MM LABEL

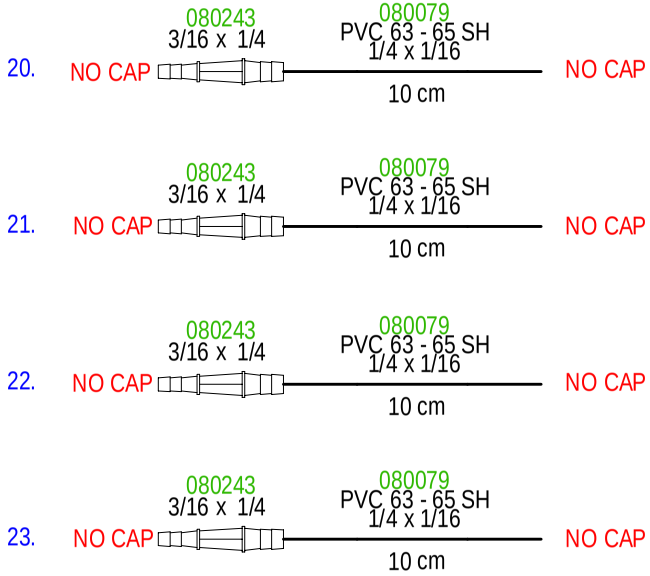
080512 PEEL POUCH 300 X 510MM LABEL

CUSTOMER:	DESCRIPTION:
CHISINAU	PEDIATRIC PACK FOR <16 KG
MOLDOVA	FOR USE WITH FX05RW

PRODUCT CODE:	DRAWING TYPE:	Total Priming Volume:
CX-ML027	PRODUCTION	

DRAWN BY: STEPHEN FLYNN	ISSUED: 16/01/2018	ISSUE No: 4
INT. AMEND:	AMENDED: 30/05/2019-SF	SHEET No: 4/6

TERUMO



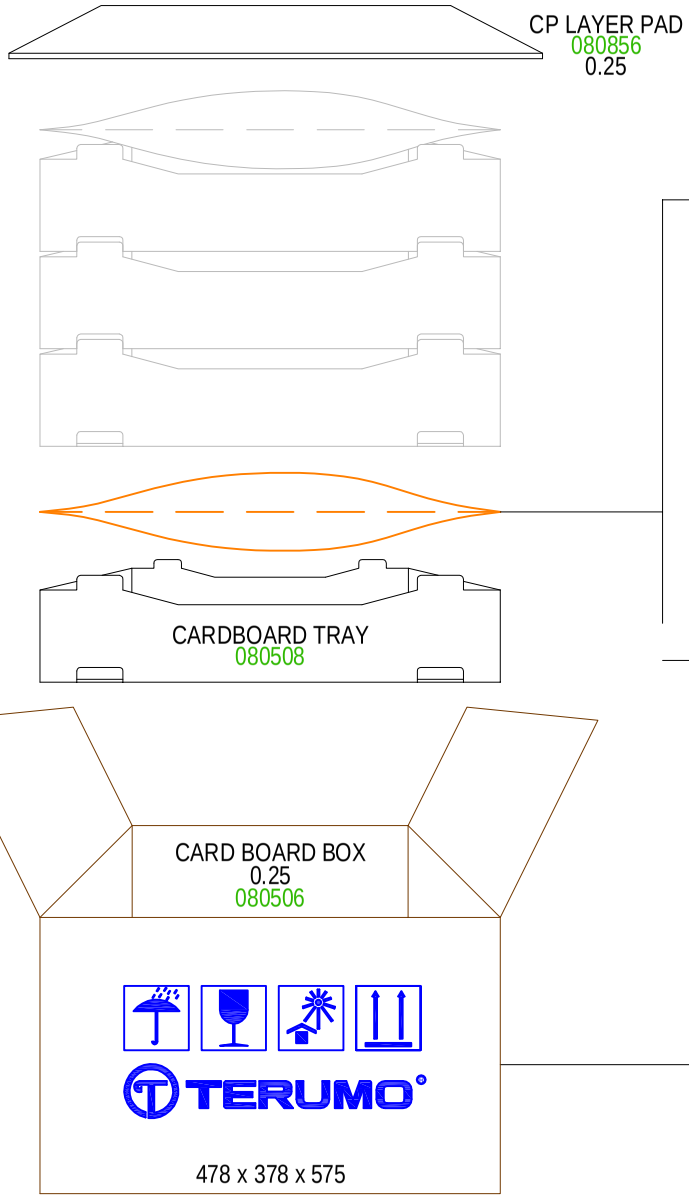
080510 PEEL POUCH 200 X 275 MM

080483 GAS POUCH 508 X 648 X 165 MM

CUSTOMER:		**DESCRIPTION:**		
CHISINAU		PEDIATRIC PACK FOR <16 KG		
MOLDOVA		FOR USE WITH FX05RW		
PRODUCT CODE: CX-ML027	**DRAWING TYPE:** PRODUCTION	**Total Priming Volume:**		

DRAWN BY: STEPHEN FLYNN	**ISSUED:** 16/01/2018	**ISSUE No:** 4
INT. AMEND:	**AMENDED:** 30/05/2019-SF	**SHEET No:** 5/6

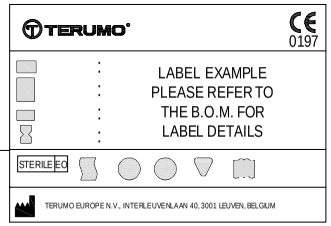
TERUMO



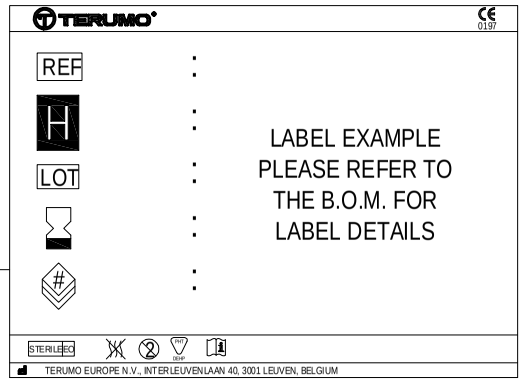
PACKING INFORMATION

EACH GAS POUCH IS TO BE PACKED IN A CARDBOARD TRAY,ONE ON TOP OF ANOTHER. 4 PACKS PER BOX

PACK LABEL EXAMPLE



BOX LABEL EXAMPLE



CUSTOMER:	**DESCRIPTION:**
CHISINAU	PEDIATRIC PACK FOR <16 KG
MOLDOVA	FOR USE WITH FX05RW
PRODUCT CODE: CX-ML027	**DRAWING TYPE:** PRODUCTION
Total Priming Volume:	

DRAWN BY: STEPHEN FLYNN	**ISSUED:** 16/01/2018	**ISSUE No:** 4
INT. AMEND:	**AMENDED:** 30/05/2019-SF	**SHEET No:** 6/6

TERUMO

Terumo® Advanced Perfusion System 1

Proven design, continuously enhanced
to increase safety and reduce risk.

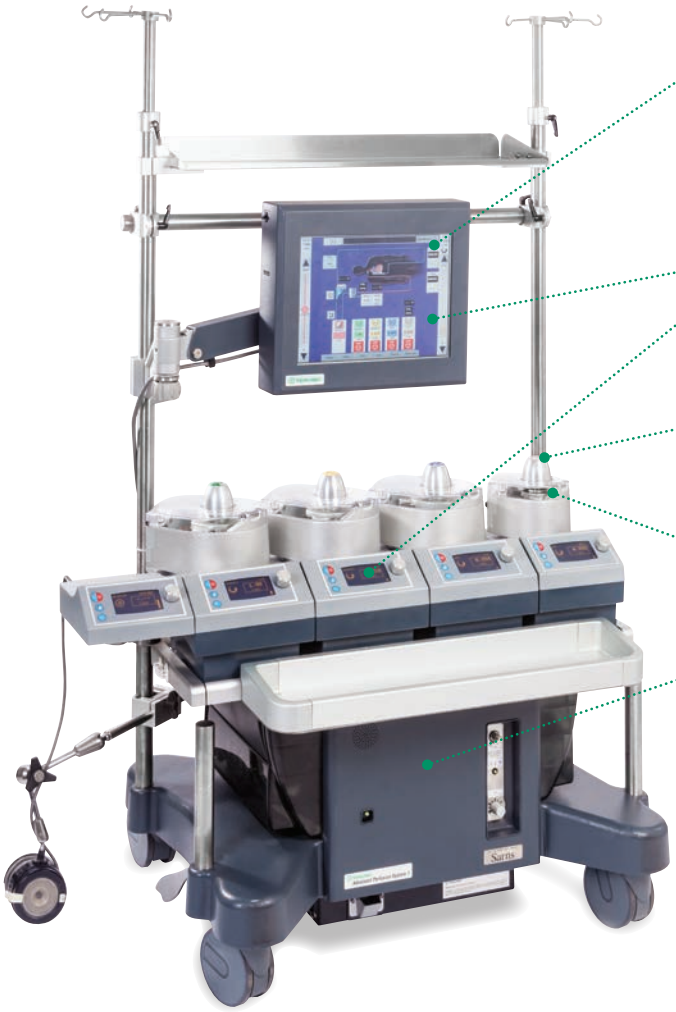
TERUMO


7.40
32
10.5
72
5.4
120
3.1
24.0
27
3
97

Continuing to set the standard in perfusion technology and patient care.

Since its introduction in 2002, perfusionists and surgical teams have relied on the Terumo® Advanced Perfusion System 1 to help them deliver the highest quality care and achieve the best possible patient outcomes. To maintain this standard of excellence, the technology and design of the Terumo System 1 have continuously evolved, resulting in an exceptional heart-lung machine for the perfusion team.

Superior Safety Features



- **Fast, intuitive access to information via Central Control Monitor (CCM) screen:** The CCM graphic interface provides central messaging using intuitive language plus colored icons. Clinicians can navigate through alerts and alarms in one or two screen touches.
- **Redundant controls:** Roller pumps and the Electronic Patient Gas System (EPGS) can be controlled locally or through the CCM, providing system redundancy and allowing options for speed adjustment.
- **"On the fly" occlusion adjustments:** The roller pump's occlusion mechanism with audible feedback can be adjusted while the pump is running. No need to stop the roller pump to adjust the occlusion setting.
- **Self-adjusting tube clamp mechanism:** Eliminates the need for changing tubing clamp inserts.
- **Extended battery life:** The system provides a minimum of 60 minutes of internal battery backup. Actual minutes remaining are clearly displayed on the battery icon on the CCM, providing essential information to users.

- **Uni-directional handcrank:** Only supports forward flow; it cannot be rotated in the wrong direction.

Performance claims based on product validation test results. Data on file.

Designed to help clinicians achieve the best possible outcomes.

Terumo Advanced Perfusion System 1

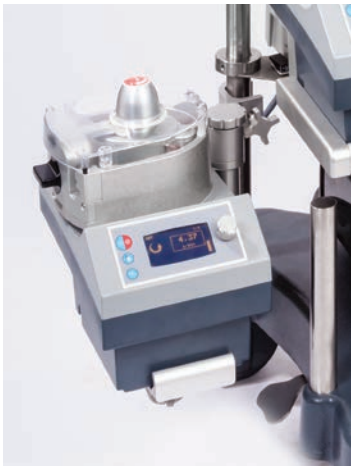
Centrifugal and Roller Pumps

- System supports up to eight pumps, including two centrifugal pumps.
- Base- or pole-mounted roller pumps with rotating raceways help reduce circuit length and hemodilution.
- Clinicans may choose 6" or 4" roller pumps to adapt to different protocols.
- Centrifugal and roller pumps can be controlled from the speed control knob or the Central Control Monitor.
- Fast power-on of roller and centrifugal pumps allows users to quickly respond in emergent situations.

Roller pumps are available in large and small raceways to adjust to different perfusion protocols.

- The roller pump's occlusion mechanism with audible feedback can be adjusted while the pump is running.
- The arterial pump displays alert and alarm messages that affect operation. Pump status and safety messages can be viewed on either the pumps' local display or the Central Control Monitor.
- Self-adjusting tube clamp mechanism eliminates the need to change tube inserts.
- Remote-mounted centrifugal pump motor helps to reduce tubing lengths.
- Non-invasive flow sensor eliminates the need for a disposable flow probe.
- Uni-directional hand crank ensures correct blood flow direction.
- Updated roller pump software improves pumping performance.
- Newly designed roller pump lids improve accessibility to the pump raceway. The metal pump lid hinge is strong and durable.
- Colorful new roller pump caps include instructional graphic to make operation more intuitive and help guide users as they change occlusion levels. Integrated magnet secures colored cap to occlusion knob.

Performance claims based on product validation test results. Data on file.



- Advanced functions can be performed:
  - Pulsatile flow operation on arterial pumps
  - User-selectable Coast™ response on centrifugal pumps
  - Pump flow setpoint and pressure setpoint (negative or positive) maintained by activating the Servo-Regulation feature
  - Master/Follower pump operation in which any two roller pumps can be used to deliver multi-ratio cardioplegia to minimize hemodilution and optimize myocardial protection

Flexible Design Evolves With User Needs

The Terumo System 1 is configurable and adapts to evolving practices or individual clinician needs.

The basic system configuration is intuitive, with quality and technology features that address today's perfusion practices. As perfusion techniques evolve, the system configures quickly and simply to adapt to new protocols and leading-edge practices.

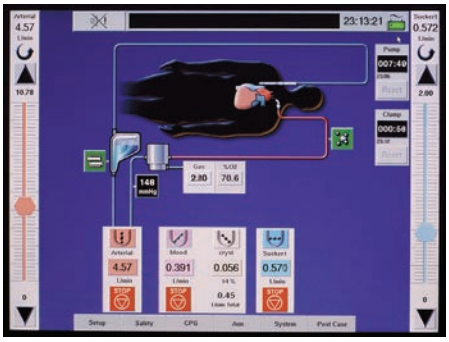
BASIC

ADVANCED

The advanced system configuration includes base- or pole-mount options for pumps. (Pole-mounting a pump closer to the patient and perfusion circuit components may minimize circuit size, thereby minimizing foreign surface exposure and hemodilution.) The pumps can be controlled locally or remotely using the CCM.

Central Control Monitor (CCM)

- Fast processing, high-resolution touch screen serves as both a safety monitor and as the central interface for operating the system components.
- Intuitive graphic interface helps users organize information and view current perfusion parameters on a single screen without having to look at multiple displays.
- Users can create up to 12 customized perfusion screens to accommodate different perfusion setups.
- Priority messaging area displays color-coded alarms, alerts, status, and error messages in order of priority.
- Critical patient and system information can be viewed and responded to with no more than two screen touches.



The Central Control Monitor features fast processing, a high-resolution screen, and intuitive user interface.

Safety and Monitoring Modules

- Users may integrate up to 18 safety and monitoring modules, selecting individual responses for each, with the option of adding or changing modules as needed.
- Modules plug into any of the slots in the system's base. They are easy to access and provide an uncluttered work environment.
- Modules are available for:
  - Ultrasonic level detector (alert/alarm)
  - Ultrasonic air bubble detectors (4)
  - Flow (4), pressure (8), and temperature (8) sensors
  - Electronic venous line occluder
  - CDI® Blood Parameter Monitoring Systems

The Terumo System 1 can integrate up to 18 modules. These compact modules are plugged into the base of the system.

Electronic Patient Gas System (EPGS)

- Unique technology allows the gas blender to be integrated into the base and controlled through the CCM or locally.
- An integrated oxygen analyzer measures oxygen content of the blended gas and displays it on the CCM.
- Settable low FiO_2 alarm displays on the CCM screen in the case of an out-of-range level.
- High and low gas source pressure alarms display on the CCM if the gas supply is outside the recommended pressures.
- A multi-colored LED on the base provides status indications.
- Software updates streamline and improve the EPGS calibration process.
- Increased messaging and changes to the CCM display better inform users of gas blender status.

Integrated electronic gas blender can be controlled through the Central Control Monitor or locally.

Internal Battery Backup and Power

- System provides a minimum of 60 minutes of internal battery backup.
- New circuitry and software algorithms enhance battery performance. New battery charge level display increases accuracy.
- Enhanced battery reporting and new A/C visual indicators on CCM splash screen during power up improve battery status communication to users.
- System periodically reminds users to perform a battery health test.
- Sealed power switch adds durability, and new protective plate on switch prevents inadvertent power downs.

Protective plate on power switch.

CCM splash screen.

The Heart-lung Machine of Choice

For the hospital

For the clinician

For the patient

Proven technology

Increased safety features

Advanced functionality and flexibility

Unrivaled clinical and field support

Terumo's commitment to perfusion

Terumo Advanced Perfusion System 1

Specifications

Terumo System 1 Base	801763	801764
Voltage	100/115V, 50/60 Hz	220/240V, 50/60 Hz
Height	22.6" (57.4 cm)	22.6" (57.4 cm)
Width	35.2" (89.4 cm)	35.2" (89.4 cm)
Depth	26.5" (67.3 cm)	26.5" (67.3 cm)
Weight	262 lb (118.8 kg)	262 lb (118.8 kg)

Electronic O_2 Blender/Analyzer	801188
Operating range:	
Flow	0 – 10 L/min
FiO_2	0.21 – 1.00
Measured O_2	21% – 100%

Central Control Monitor	816300
Height	13.7" (34.8 cm)
Width	15.7" (39.9 cm)
Depth	3.4" (8.6 cm)
Weight	15 lb (6.8 kg)

Roller Pumps	816570 (Small)	816571 (Large)
Pumphead diameter	4" (10.2 cm)	6" (15.2 cm)
Voltage	24VDC	24VDC
Height	12.5" (31.8 cm)	12.5" (31.8 cm)
Width	7.1" (18.0 cm)	8.5" (21.6 cm)
Depth	11.8" (30.0 cm)	13.1" (33.3 cm)
Weight	21 lb (9.5 kg)	24 lb (10.9 kg)
Operating range	0 – 4 L/min	0 – 10 L/min

Centrifugal Control Unit	816572
Voltage	24VDC
Height	3.1" (8.0 cm)
Width	7.3" (18.4 cm)
Depth	8.5" (21.6 cm)
Weight	2.4 lb (1.1 kg)
Operating range	0 – 3,600 RPM

Flexible Halogen Lamps	801238	801558
Size	33" (83.8 cm)	15" (38.1 cm)
Voltage	24VDC	24VDC

Modules

Functional Modules	Flow Module 802018	Other Modules
Height	6.30" (160.0 mm)	3.54" (90.0 mm)
Width	3.63" (92.2 mm)	1.06" (27.0 mm)
Depth	1.33" (33.8 mm)	3.03" (77.0 mm)
Weight	0.95 lb (0.43 kg)	0.27 lb (0.12 kg)

Pressure Module 802112
Two pressure transducers per module
Operating range: (-250) mmHg – 900 mmHg
Maximum of eight transducers

Temperature Module 802114
Temperature module, YSI™ series 400 compatible (2 temperatures per module)
Operating range: 0 – 50° C
Maximum of eight sensors

Flow Module 802018
Non-invasive flow measurement, one per module
Operating range: (-9.9) L/min to 9.9 L/min
Maximum of four modules

Ultrasonic Level Detection Module 802111
One alarm sensor, one alert sensor per module
Reservoir: Functions with hardshell reservoirs that have a wall thickness of 0.07" – 0.15" (1.8 mm – 3.8 mm)
Maximum of one module

Ultrasonic Air Bubble Detector Module 802110
Operating range:
3/8" : 0.5 cc or larger up to 6 L/min
1/4" : 0.3 cc or larger up to 3 L/min
Maximum of four modules

Electronic Venous Occluder Module 803480
Operating range:
0 – 100% flow on 1/4" to 1/2" tubing
Maximum of one module

Interface Module for CDI® System 500 803479
One CDI System 500 monitor per module
Maximum of one module

Interface Module for RS-232 802113
Data output module
Maximum of one module

Ordering Information

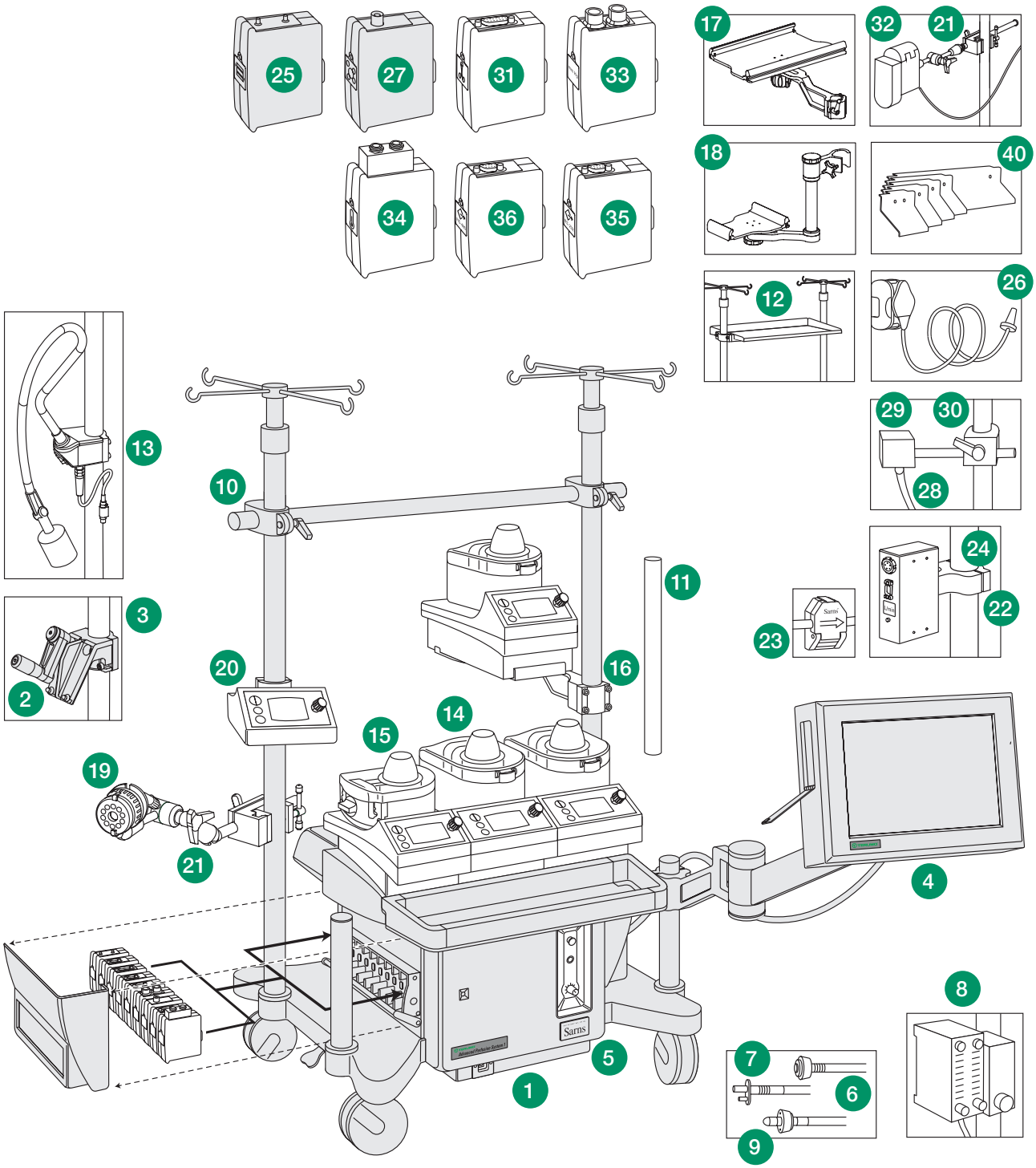
Catalog #	Description	Diagram #
Terumo System 1 Base*		
801763	100/115V base	1
801764	220/240V base	1
803739	Programmed PC card system configuration	4
801016	Hand crank (includes two hand cranks)	2
802089	Hand crank bracket	3
816300	Central Control Monitor	4
Base Options *(Each blender requires a hose kit and adaptor set.)*		
801188	Electronic O_2 blender/analyzer	5
3500CP-G21	Pole-mounted blender	8
	Hose kits	
814475	U.S. hose kit (three hoses: green, yellow, grey)	
814474	Non-U.S. hose kit (three hoses: white, white/black, grey)	
	U.S. Hose adaptor sets	
144207	NCG hose adaptor set	7
144215	D.I.S.S. hose adaptor set	6
144223	Ohio Diamond hose adaptor set	9
	Non-U.S. Hose adaptor sets	
815459	NCG hose adaptor set	7
815457	D.I.S.S. hose adaptor set	6
815461	Ohio Diamond hose adaptor set	9
Center Poles and Accessories		
145980	Crossbar fitting (required for each additional pole)	10
16553301	2' (0.6 m) pole	11
131115	3' (0.9 m) pole	11
16553401	4' (1.2 m) pole	11
816489	Shelf	12
816370	Metallic sliding back cover panel kit	40
Flexible Halogen Lamp		
801238	33" (83.8 cm) flexible halogen lamp	13
801558	15" (38.1 cm) flexible halogen lamp	13
Roller Pumps		
816571	Roller pump, 6" (15.2 cm) diameter	14
816570	Roller pump, 4" (10.2 cm) diameter	15
801093	Pole mount pump rest with bracket	16
816477	Dual pumps pole mount bracket	17
816483	Descending pole mount pump bracket	18

Catalog #	Description	Diagram #
Integrated Centrifugal System		
164267	Drive motor	19
816572	Control unit	20
164268	Manual drive	Included with 20
804372	Pole mount centrifugal display bracket	Included with 20
816620	Flexible mounting arm	21
Flow Sensing		
802018	Flow module	22
6382	Non-invasive flow sensor, 3/8" (9.5 mm) ID x 3/32" (2.4 mm) wall, reusable	23
801550	Mounting bracket (holds two modules)	24
Level Detection *(One each included with Terumo System 1)*		
802111	Level detect module	25
195215	Yellow transducer (alert)	26
195274	Red transducer (alarm)	26
195240	Level sensor pads (60 per box), gel included	
Air Bubble Detection *(One each included with Terumo System 1)* *One sensor required per air bubble detection system.*		
802110	Air bubble detect module	27
822763	Cable assembly	28
149876	Pole clip sensor holder	
	Ultrasonic air sensor (choose 1 of 3)	
5773	3/8" x 3/32" (9.5 mm x 2.4 mm)	29
5791	1/4" x 3/32" (6.4 mm x 2.4 mm)	29
5785	1/4" x 1/16" (6.4 mm x 1.6 mm)	29
5793	Air sensor bracket (optional)	30
Venous Occluder		
803480	Occluder module	31
806455	Occluder head	32
816620	Flexible mounting arm	21
Pressure Monitoring		
802112	Pressure module (two pressures per module)	33
Temperature Monitoring		
802114	Temperature module, YSI™ series 400 compatible (two temperatures per module)	34
Data Interface Modules		
802113	Serial interface module RS-232	35
803479	Interface module for CDI® System 500	36

** Shaded grey items in diagram are included with the Terumo System 1.*

Terumo System 1 Ordering Information Diagram

Shaded grey items in diagram are included with the Terumo System 1.



Keeping our promise so you can keep yours.

Our promise to continuously improve safety, continuously reduce risk, and relentlessly support your practice – makes your promise for exceptional patient care possible.

Terumo® Advanced Perfusion System 1

terumo-cvgroup.com/system1

TERUMO

Terumo Cardiovascular Group
6200 Jackson Road. Ann Arbor, MI 48103-9300 USA
Tel: +1.734.663.4145 Fax: +1.734.663.7981

Terumo Corporation
44-1, 2-chome, Hatagaya. Shibuya-Ku, Tokyo 151-0072 Japan
Tel: +81.3.3374.8111 Fax: +81.3.3374.8399

Terumo Asia Holdings Pte. Ltd.
300 Beach Road, #33-03 The Concourse 199555 Singapore
Tel: +65.6.295.1792 Fax: +65.6.294.2329

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

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8750 NW 36th Street, Suite 600. Miami, FL 33178 USA
Tel: +1.305.477.4822 Fax: +1.305.477.4872

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Al Masraf Tower, 22nd Floor, P.O. Box 20291, Dubai UAE
Tel: +971.4.2212220 Fax: +971.4.2213330

Terumo India Pvt. Ltd.
Unit No. 1601 & 1602 Tower B. 16th Floor, Unitech Cyber Park,
Sector-39. Gurgaon, Haryana 122001 India
Tel: +91.124.4718700 Fax: +91.124.4718718

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

Scope: Design and Development, Manufacture, Service and Sterilization (ETO, E-beam) of
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Haemoconcentration Filter
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Blood Reservoir
- Angiographic Catheter
- Stents
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Catheter Introducer
- Wire Twister
- Guiding Catheter
- Extension Tube
- Coronary Imaging Catheters
- Centrifugal Pump
- Radial Artery Hemostasis Band

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 12031333 010

Effective date: 2021-01-10

Expiry date: 2023-07-09

Issue date: 2020-12-23

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization:

Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

Design and Development, Manufacture, Service and Sterilization (ETO, E-beam) of
- Temperature Control Unit for Heart-Lung Bypass System Module
- Air/Fluid Level Detector for Heart-Lung Bypass System Module
- Centrifugal Pump Controller
- Syringe Infusion Pump
- Infusion Pump
- Clinical Electronic Thermometer
- Deep Body Temperature Monitor
- Clinical Electronic Blood-Pressure Meter
- Medical Equipment for Blood Collection
- Medical Equipment for APD Systems
- Sterile Tube Connecting Systems
- Coronary Optical Coherence Tomography Systems
- Blood Glucose Meters for Blood Glucose Monitoring Systems

Report No.: 12031333 010

Effective date: 2021-01-10

Expiry date: 2023-07-09

Issue date: 2020-12-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	Terumo Corporation Ashitaka Plant 150, Maimaigi-cho Fujinomiya-shi Shizuoka, 418-0015 Japan	Activities related to Design and Development, Manufacture and Sterilization (ETO, E-beam) of the same as the scope of the main certificate except for design and development of Blood Glucose Meters for Blood Glucose Monitoring Systems.

Report No.: 12031333 010

Effective date: 2021-01-10

Expiry date: 2023-07-09

Issue date: 2020-12-23

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

/02	Terumo Corporation - Tokyo office 3-20-2 Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Activities related to service of all the active medical devices in the scope of the main certificate except for Blood Glucose Meters for Blood Glucose Monitoring Systems. Specifically, Temperature Control Unit for Heart-Lung Bypass System Module, Air/Fluid Level Detector for Heart-Lung Bypass System Module, Centrifugal Pump Controller, Syringe Infusion Pump, Infusion Pump, Clinical Electronic Thermometer, Deep Body Temperature Monitor, Clinical Electronic Blood-Pressure Meter, Medical Equipment for Blood Collection, Medical Equipment for APD Systems, Sterile Tube Connecting Systems, Coronary Optical Coherence Tomography Systems.

Report No.: 12031333 010

Effective date: 2021-01-10

Expiry date: 2023-07-09

Issue date: 2020-12-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Masahiro Asami
TÜV Rheinland LGA Products GmbH
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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

/03	Terumo Corporation, Shonan Center 1500 Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Activities related to Design and Development and Service of all the active medical devices in the scope of the main certificate except for Blood Glucose Meters for Blood Glucose Monitoring Systems.Specifically, Temperature Control Unit for Heart-Lung Bypass System Module, Air/Fluid Level Detector for Heart-Lung Bypass System Module, Centrifugal Pump Controller, Syringe Infusion Pump, Infusion Pump, Clinical Electronic Thermometer, Deep Body Temperature Monitor, Clinical Electronic Blood-Pressure Meter, Medical Equipment for Blood Collection, Medical Equipment for APD Systems, Sterile Tube Connecting Systems, Coronary Optical Coherence Tomography Systems.

Report No.: 12031333 010

Effective date: 2021-01-10

Expiry date: 2023-07-09

Issue date: 2020-12-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

/04	Terumo Corporation - ME Center (Nagaizumi) 1002-1 Shimonagakubo Nagaizumi-cho, Sunto-gun, Shizuoka 411-0934 Japan	Activities related to Design and Development, Manufacture and Service of all the active medical devices in the scope of the main certificate except for Blood Glucose Meters for Blood Glucose Monitoring Systems.Specifically, Temperature Control Unit for Heart-Lung Bypass System Module, Air/Fluid Level Detector for Heart-Lung Bypass System Module, Centrifugal Pump Controller, Syringe Infusion Pump, Infusion Pump, Clinical Electronic Thermometer, Deep Body Temperature Monitor, Clinical Electronic Blood-Pressure Meter, Medical Equipment for Blood Collection, Medical Equipment for APD Systems, Sterile Tube Connecting Systems, Coronary Optical Coherence Tomography Systems.

Report No.: 12031333 010

Effective date: 2021-01-10

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TERUMO

No.DOC-DQ010- 0639

Rev.06

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

CAPIOX FX

Product : Extra-corporeal Membrane Oxygenator

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60121893 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, August 30, 2017
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

C	X	*	F	X	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Character number	Character & Meaning
1,2,4,5	Product name CAPIOX FX
3	Destination * : for export
6-7	Effective fiber surface area 25 : approx. 2.5m^2 05 : approx. 0.5m^2 15 : approx. 1.5m^2
8	Availability of hardshell venous reservoir R : Available Blank : Not available
9	Reserve W : Blood outlet port orientation is left when water ports faces this side. E : Blood outlet port orientation is right when water ports faces this side.
10-11	Types of hardshell venous reservoir *1 30 : With 3000mL Reservoir 40 : With 4000mL Reservoir *1 FX15 only

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60121893 0001

Report No.: 12031336 001

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products:
see attachement for products included

Replaces Approval, Registration No.: HD 60077473 0001

Expiry Date: 2022-08-29

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-08-30

Date: 2017-08-25

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60121893 0001
Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2017-08-25

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60121893 0001
Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2017-08-25

M.Aihara

M.Sc. M. Aihara

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Scope:
Design and Development, Manufacture, Distribution and Service of
- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki Aihara
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DAkkS
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D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Installation and serving of active medical devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TERUMO EUROPE N.V. Interleuvenlaan 40 3001 Leuven Belgium	Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories. Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices. Installation and serving of active medical devices
/02	c/o Terumo Europe UK 3 Unity Grove Knowsley Business Park South Merseyside, Knowsley L34 9GT United Kingdom	Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

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Tillystraße 2 · 90431 Nürnberg · Germany

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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/03	c/o Terumo Deutschland GmbH Ludwig-Erhard-Str. 6 65760 Eschborn Germany	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/04	c/o Terumo France S.A.S. Bâtiment Renaissance, 3 rond-point des Saules 78280 Guyancourt France	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/05	c/o Terumo Italia S.r.l. Via Paolo di Dono 73 00142 Roma Italy	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/06	c/o Terumo Europe España SL Avda. Juan Carlos I, N°13-7 Planta 28806 Alcalá de Henares (Madrid) Spain	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Wiedemuth

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/07	c/o Terumo Europe UK Ltd. Otium House 2 Freemantle Road Bagshot Surrey GU19 5LL United Kingdom	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/08	c/o Terumo Europe N.V. Benelux Sales Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/09	c/o Terumo Sweden AB Sven Källfets gata 16 SE-426 71 Västra Frölunda Sweden	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/10	c/o Terumo Deutschland GmbH Zweigniederlassung Switzerland Bodenäckerstrasse 3 8957 Spreitenbach Switzerland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

D. Wiedemuth

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D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/11	c/o Terumo Europe N.V. European Distribution Center Brikkenovenstraat 48 3600 Genk Belgium	Storage and distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/12	c/o Terumo Europe N.V. Terumo Interventional Systems EMEA (TIS-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/13	c/o Terumo Europe N.V. Terumo Cardiovascular Europe Middle East & Africa (TCV-EMEA) Ludwig-Erhard-Straße 6 65760 Eschborn Germany	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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Tillystraße 2 · 90431 Nürnberg · Germany

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Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/14	c/o Terumo Europe N.V. Terumo Medical Products EMEA (TMP-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/15	c/o Terumo Europe N.V. Diabetes Management EMEA (DM-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/16	c/o Terumo Europe N.V. Terumo Pharmaceutical Solutions Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices and active implantable medical devices
/17	c/o Terumo Deutschland GmbH Zweigniederlassung Austria Liebermannstrasse F10-301 2345 Brunn am Gebirge Austria	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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Dipl.-Ing. (FH) D. Wiedemuth
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Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/18	c/o Terumo Europe N.V. Emerging Market Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/19	c/o Terumo Poland Sp. Zoo Wisniowy Business Park budynek D ul. 1 Sierpnia 6 02-134 Warszawa Poland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60134707 0001

Report No.: 21240046 017

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60106290 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2020-04-21

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products included:

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

additional sites included:

Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Terumo Europe UK
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfzertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

Terumo Cardiovascular Group
125 Blue Ball Road, Elkton, Maryland 21921
Main: 410.398.8500
Toll-free: 800.283.7866
www.terumo-cvgroup.com

DECLARATION OF CONFORMITY

We, TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, located at 125 Blue Ball Rd., Elkton, Maryland USA 21921, and being the manufacturer of:

Terumo® Capiox Oxygenators/Reservoirs

Product Codes: CX*SX18R, CX*SX18X, CX*SX18RX, CX*SX18R03, CX*SX25R, CX*SX25X, CX*SX25RX, 3CX*RX25RE, 3CX*RX25RW, 3CX*RX15RW30, 3CX*RX15RE30, 3CX*RX15RW40, 3CX*RX15RE40, 3CX*FX15RW30C, 3CX*FX15RW40C, 3CX*FX15RE30C, 3CX*FX15RE40C, 3CX*FX25REC, 3CX*FX25RWC, 3CX*R4000C

Classification: Class IIa – Rule 3 of Annex IX

Declare that the above products are in conformity with the provisions of the EC Council directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in the EC Council Directive 93/42/EEC Article 11, 2 and 3(a) relating to the "Full quality assurance" set out in Annex II, under the supervision of BSI (Certificate Registration No. CE 584795), as Notified Body authorized by the Netherlands Competent Authority and carrying the Notified Body No. 2797.

Authorized European Representative:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven, Belgium

Adam Pickholtz
Regulatory Affairs Manager
Terumo Cardiovascular Systems Corp.
Elkton, Maryland 21921 USA

5/1/19
Date

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

TUBING SET with X-coating (optional)

Product: **Extra-Corporeal Blood Circuit for open heart surgery**
(See Appendix A for related product codes)

declare that the above product of Class IIa is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.2 and 11.3(a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3 (Registration No: HD 60106290 0001), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 21 December 2018
(place and date of issue)

M.J. Aerts
VP Regulatory & Quality
TERUMO EUROPE N.V.

Appendix A – Related product codes

The product code is composed of 10 digits maximum and explained as follows:

Customer requested device configurations

1	2	3	4	5	6	7	8	9	10
C	**X**	For Capiox® Cardiovascular Devices							
Manufacturer		**-**	Terumo Europe						
Coded countries of European sales branches/other sales blocks			**c**	**c**					
Sequential number					**n**	**n**	**n**	001, ...	
X-coating								**X**	Void if no X-coated component is included
Variant pack requested by customer								**A**	Sequential letter (A, B, ..., Z) – void if no variant pack

Standard device configurations

1	2	3	4	5	6	7	8	9	10
C	**X**	For Capiox® Cardiovascular Devices							
Manufacturer		**-**	Terumo Europe						
Standard Finished product			**F**						
Type of pack				**T**	**S**	Terumo Standard Pack			
Sequential number						**0**	**0**	**1**	
X-coating								**X**	X-coated components

Accessory packs for reduced prime circuits:

- Standard device configurations

1	2	3	4	5	6	7
C	X	For Capiox® Cardiovascular Devices				
Manufacturer		-	Terumo Europe			
Standard ROCsafe Accessory Pack		R	O	C		
Type of Accessory pack		A	with flexible venous resevoir			
		B	with hardshell venous reservoir and rigid adult sucker			
		C	with rigid adult sucker			
		G	Table Set			
		H	for pressure monitoring			

- Customer requested device configurations

1	2	3	4	5	6	7	8	9
C	X	For Capiox® Cardiovascular Devices						
Manufacturer		-	Terumo Europe					
Reduced prime optimised circuit		R	O	C				
Sequential letter					N	A, B, ...		
Sequential number						n	n	01, ...