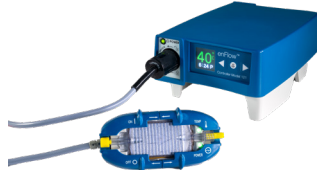


# enFlow™ IV fluid and blood warming system

## Technical Data Sheet



<b>Product Codes and Product Description</b>	980121EU	enFlow™ Controller Model 121				
	980105VS	enFlow™ IV Fluid/Blood Warmer Model 100				
	980202EU	enFlow™ Disposable IV Fluid/ Blood Warmer Cartridge with IV Extension Model 202				
	980200EU	enFlow™ Disposable IV Fluid / Blood Warmer Cartridge Model 200				
<b>General Product Description</b>	<p>The enFlow™ IV fluid/blood warming system consists of the enFlow™ Warmer (Model 100 series), the enFlow™ Controller (Model 121 series), the enFlow™ Disposable Cartridge with IV extension set (Model 202) or without IV extension set (Model 200). Within seconds, this warming system delivers normothermic infusate to the patient at flow rates of Keep Vein Open (KVO defined as 2 mL/min) to 200 mL/min when input fluid temperature is 20°C.</p>					
<b>Pack factor</b>	980121EU/ 980105VS	1 per Box				
	980202EU/ 980200EU	30 per pack				
<b>EAN/GTIN</b>	980121EU	EA	10190752125803	980105VS	EA	10190752125780
	980202EU	EA	10190752147102	980200EU	EA	10190752178281
<b>Intended Use</b>	<p>The enFlow IV fluid/blood warming system's intended use is for warming blood, blood products and intravenous solutions prior to administration. It is designed to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.</p>					
<b>Instructions for Use</b>	Please refer to the System Manual.					
<b>Characteristics</b>	<p>The cartridges are single-use and are indicated for use by trained medical personnel</p> <ul style="list-style-type: none"> <li>• Simple to operate. Prime, insert the cartridge</li> <li>• Turn on and fluids will be warmed to target temperature of 40°C occurs in seconds</li> <li>• Small, disposable cartridge, with the ability to easily transfer between systems, meaning less waste</li> <li>• Thin parylene cartridge coating to prevent the leaching of aluminum to IV liquids</li> <li>• Low priming volume of 4mL reduces the time needed to reach the temperature set point</li> <li>• Designed to move easily with the patient, enabling you to warm fluids in all care areas, using only one disposable cartridge</li> <li>• Helps lessen complications and speed up recovery time</li> <li>• Helps shorten patient stays and reduce hospital costs</li> <li>• Low maintenance. Vyair recommends a functional test every year</li> </ul>					
<b>Compatibility</b>	<p>Disposable Cartridge connects to the IV extension set or any infusion set employing standard luer connectors compatible to ISO 80369-7:2016</p>					
	<p>Power cord, 91000170 (continental EU), 91000172 (UK). The 10' power cord plug into the back of the controller to supply power to the system.</p>					
<b>Regulation</b>	<p>Classifications:</p> <p>EU – Cartridge class 2a, warmer and controller class 2b.</p> <p>Products are compliant with REACH and RoHs directives.</p>					
<b>Biocompatibility</b>	<p>enFlow Disposable cartridges have been tested and assessed against the below biocompatibility standards.</p> <ul style="list-style-type: none"> <li>• Chemistry E&amp;L – ISO 10993-18 Second edition 2020-01</li> <li>• Cytotoxicity Test – ISO 10993-5 Third edition 2009-06-01</li> <li>• Hemocompatibility Test – ISO 10993-4 Third edition 2017-04</li> <li>• Systemic Toxicity – MMP ISO 10993-11 Third edition 2017-09</li> <li>• Systemic Toxicity – Acute Systemic Toxicity and Subchronic Systemic Toxicity ISO 10993-11 Third edition 2017-09</li> <li>• Sensitization ISO 10993-10 Third Edition 2010-08-01</li> <li>• Irritation ISO 10993-10 Third Edition 2010-08-01</li> <li>• Infusion extension set compatible with ISO 8536-4 Particulate Testing ISO 8536-4 Sixth edition 2019-09</li> </ul>					

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<b>Storage</b>	Temp (C°): -30 – 70(C°) Relative Humidity Range Warmer: 10–90% Controller: 10–90% Disposable cartridge: 10–90% Altitude: Up to 4,572 m (15,000ft) Air pressure: 570 hPa, (17 inHg) to 1,060 hPa (31 inHg)	
<b>Controller (980121EU) Materials</b>	PC Lexan 920 Polycarbonate, glass fiber, silicone	
<b>Warmer (980105VS) Materials</b>	Warmer Mount Heater Housing, Top Litepipe Heater Housing, Bottom Plug, Lower Warmer Housing Thermophase-Kapton Cable Strain Relief Overmold Warmer Door Wrist Strap Ski Rubber Bushing Hubbell Plug	PC Lexan 920 PC Lexan 920 Optical grade acrylic PC Lexan 920 PC Lexan 920 Laird Thermogont T-Gard K52-2 PVC and Pellethane Polycarbonate, glass fiber, silicone LEXAN 121 Silicone Nylon
<b>Disposable Cartridge (980200EU) Materials</b>	Aluminum Extrusion Disposable Housing Luer Lock Female Luer Lock Male Luer Lock Adhesive	6063 Aluminum Paryfree coating LEXAN™ HPS1 resin LEXAN™ HPS1 resin LDPE NA207-66 HDPE LH606 Adhesive- Dymax 1180-M-T
<b>Disposable Cartridge IV Extension Set (980202EU) Materials</b>	Aluminum Extrusion Disposable Housing Luer Lock Female Luer Lock Male Luer Lock Adhesive Extension Assembly Extension Tube Male Luier cap Extension Female Luer cap extension Female Luer Extension Male Luer Extension	6063 Aluminum Paryfree coating LEXAN™ HPS1 resin LEXAN™ HPS1 resin LDPE NA207-66 HDPE LH606 Adhesive- Dymax 1180-M-T N/A PVC 7477G-015 HDPE LH606 LDPE NA207-66 Makrolon RX-1805 451118 Makrolon RX-1805 451118
<b>GMDN Code</b>	47616 – Warmer and Controller 47619 – Cartridge	
<b>Operating</b>	Temp (C°): -5 – 50(C°)	
<b>Disposal</b>	The Disposable Cartridge may be a potential biohazard during or after use. Handle and dispose of in accordance with acceptable medical practice and applicable regulations. See manual for cautions on warmer and controller disposal.	

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<b>Does it contain PVC, DEHP and/or Latex</b>	Disposable Cartridge with IV extension set are radiation sterilized and non-pyrogenic, not made with natural rubber latex or DEHP. Extension cable of 980202EU contains PVC
<b>Country of Origin</b>	China
<b>Legal Manufacturer</b>	Vyaire Medical
<b>Type of protection against electrical shock</b>	Class I or internally powered
<b>Degree of protection against electrical shock</b>	Type BF, defibrillation-proof
<b>Mode of operation</b>	Continuous
<b>Disposable cartridge priming volume</b>	4 mL
<b>Disposable cartridge sterility</b>	Gamma sterilized
<b>Fluid temperature output</b>	40°C ± 2°C
<b>Flow rate range</b>	KVO to 200 mL/min
<b>Input voltage</b>	Warmer: 28.5 VDC at a maximum of 350 watts. Controller: 100-240 VAC
<b>Temperature set point</b>	40°C
<b>Warming element</b>	Parylene coated aluminum
<b>Input current</b>	5 A
<b>Over-temperature set point</b>	ASTM F-2172-02
<b>Alarms</b>	IEC60601-1-8
<b>Water resistance</b>	Warmer: IEC 529 IP67 30 min immersion at a depth of 91.4 cm (36") Controller: IEC 529 IP31 dripping water Disposable cartridge: IEC 529 IP68 continuous immersion  Warmer: IEC 529 IP67 dust tight Controller: IEC 529 IP31 ≥ 2.5 mm diameter against ingress of solid foreign bodies Disposable cartridge: IEC 529 IP68 dust tight
<b>Electrical safety</b>	CAN/CSA C22.2 No. 60601-1:14 AAMI/IEC 60601-1:2005 + AMD 1:2012, AMD1:2012

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