

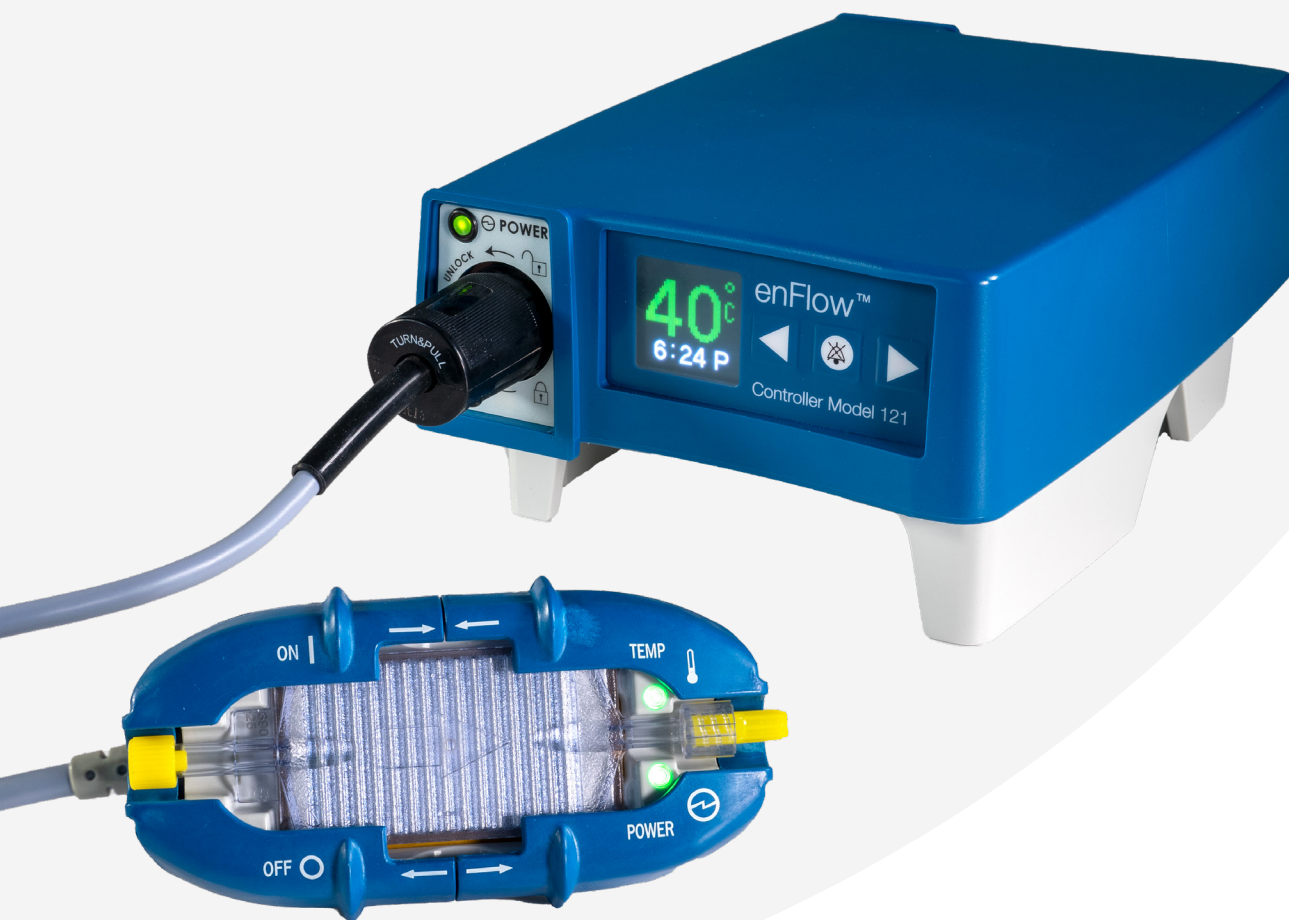


enFlow™

IV fluid and blood warming system

ENFLOW™

 **vyaire**™
MEDICAL



Advantages of the enFlow IV fluid and blood warming system

Maintaining normothermia is a necessity

Keeping surgical patients at a normal body temperature is a daily struggle for clinicians caring for patients with impaired thermoregulation. Among the millions of surgeries performed annually around the world, it is estimated that 50–90% of those patients suffer from hypothermia.³ Hypothermia is defined as a core temperature below 36°C.⁴ A small reduction in core temperature can have a significant negative impact on postoperative outcomes, affecting patient satisfaction and recovery.⁵ This, in combination with the extra financial burden, is the reason more and more hospitals are taking actions to address the accidental hypothermia in the clinical and pre-hospital environment.

One of the contributing factors to accidental hypothermia is the intravenous (IV) delivery of cold fluids. One study concluded that each liter of IV fluid infused into adult patients at ambient temperature decreases the mean body temperature by approximately 0.25°C.² A further analysis in 2010 also concluded that infusion of warm fluid is effective in keeping patients nearly normothermic and prevents postanesthetic shivering.^{6,7}

The enFlow system delivers the right temperature in the right place, at the right time, and...

The right temperature

By consistently helping to maintain the right patient body temperature, enFlow can help provide both clinical and economic benefits for your hospital. Maintaining normothermia can help lessen complications and speed up recovery time—all while helping to shorten patient stays and reduce hospital costs.^{1,2}

The right place

The system's mobility and small transferable cartridge allow enFlow to help maintain normothermia in the right place—throughout all care areas. It can be used before, during and after procedures, in any orientation. And, because its cartridge is easily transported from room to room, enFlow maintains your workflow while saving steps and enabling continuous patient warming.

The right time

The enFlow system enables warmed infusate delivery at the right time across all clinical areas, right away— in less than 18 seconds. Its low priming volume of 4mL reduces the time needed to reach the temperature set point, thus allowing the warming process to start quickly. Additionally, its close proximity to the patient reduces heat loss across the IV line.

The right way

The redesigned enFlow cartridge now features a parylene coating, protecting the fluids it warms from the equipment itself. This has been extensively tested. In clinical use, IV fluid and blood warmers are used with a wide range of solutions such as saline or electrolyte solutions as well as blood and blood products. The results indicate biological safety with the use of a variety of intravenous solutions and in different therapeutic scenarios.

enFlow features and benefits

Intuitive design

Designed for use by soldiers in extreme conditions, enFlow is very simple to operate. Simply prime, insert the cartridge, switch on and the system is ready for use.

Fast warming

The known thermal efficiency of our warmer material and the design of the disposable cartridge allow the IV fluid to reach temperature in seconds, thus minimising prep and waiting time. Simply turn on and fluids will be warmed in seconds.

Minimized cooling

The lightweight warmer (11.6 oz/328.8 g) can be placed close to the patient—allowing less opportunity for fluid-cooling in the IV line.

Small, mobile, disposable and safe cartridge

The cartridge is only 4 cm x 11 cm and has a priming volume of 4 mL. It's designed to combine great thermocoupling with the ability to transfer the cartridge from warmer to warmer. enFlow's cartridge features a thin parylene coating to prevent the leaching of aluminum to the IV liquids it warms. This allows you to deliver fluid warming to your patient safely across care areas that have the enFlow device, without having to transport the actual warming system.

Less waste

A very small, disposable cartridge, coupled with the ability to easily transfer between systems, means less waste.

Application

enFlow is simple to use and requires very little application training. Its setup is quick, application is easy and warming time to reach a target temperature of 40°C occurs in seconds. By using enFlow you will be warming fluid close to the patient with little loss of temperature as it travels to the patient through the short extension of 3"/7.5 cm (approximately 1°C for every meter).⁴

Unlike the majority of IV fluid warmers, the enFlow disposable cartridge is designed to move easily with the patient, enabling you to warm fluids in all care areas should the need arise, using only one disposable cartridge.

Maintenance

enFlow is designed to be low maintenance. The enFlow IV fluid and blood warming system components have been designed to be durable, long lasting and water resistant. The system uses current Surface Mount Technology (SMT) and materials. Vyair recommends a functional test every year. Additionally, we have developed the enCheck tester device to enable your biomedical engineers to check the alarm functionality of the enFlow system quickly and effectively on an annual basis, or per the protocol of individual hospitals.



enFlow mobility

Designed for easy patient transport throughout the hospital



Pre-op

Preoperative warming reduces the impact of heat redistribution caused by anesthesia, leading to a more stable core temperature when your patient reaches the postanesthesia care unit (PACU).⁸



Outpatient procedures

Hypothermic patients, on average, take 40 minutes longer to recover.⁵

Hypothermia can occur in up to 90% of all surgeries.³ Now, with millions of day surgeries being performed every year (*nearly half of which take place in the outpatient setting*), it is imperative that patients recover safely and quickly to streamline the demand on surgical services.



ER

Each liter of intravenous fluid infused into adult patients at an ambient temperature decreases the mean body temperature by approximately 0.25°C.²

Trauma patients often arrive in a hypothermic state and continue to lose body heat during examination by healthcare providers. Warming blood and IV fluids will help maintain normothermia, which can reduce the risks associated with a core temperature below 36°C.⁹



PACU

Normothermic patients are less prone to postoperative cardiac events and leave the PACU earlier than those suffering from hypothermia.^{11,12}



Labor and delivery

Studies looking at the impact of perioperative warming on women undergoing cesarean delivery with epidural anesthesia found that maternal and fetal hypothermia were prevented, maternal shivering was reduced and umbilical vein pH was improved.¹⁰



ICU

Hypothermia reduces resistance to surgical wound infections.^{2,13,14} Fluids or blood may continue to be delivered in the ICU where patients remain at risk from the effects of hypothermia.



Transport

The enFlow system is small, designed to be easy to transport along with the patient as they move from department to department throughout the hospital.

enFlow products



Controller, PN 980121EU

The controller unit serves as the power supply for the warmer unit. It is designed to mount on an IV pole or sit on a table top. The front panel includes a temperature display and keypad.



Warmer holder, PN 980305VS, box of 20

The warmer holder affixes to the side of the controller to allow clinicians a place to hang the warmer when it is not in use.



Warmer, PN 980105VS

The warmer is designed to work in conjunction with the disposable cartridge to warm IV fluids. The innovative design of the enFlow warmer allows it to be placed within inches of the IV site, reducing the potential for fluid cooling within the IV line.



Cord clip, PN 980309VS-20, box of 20

The cord clip allows caregivers to affix the cord of the warmer to the patient's bed sheet or clothing.



Disposable cartridge, PN 980200EU, box of 30

The disposable cartridge can be connected to any standard luer IV set. The cartridge may stay in-line and travel with the patient for up to 24 hours. It requires less than 4 mL of priming volume.



Insulated warmer strap, PN 980304VS30, box of 30

The warmer strap with an integrated insulated pad allows the user to attach the warmer to the patient's limb. The insulated warmer strap should be used only when transporting the patient.



Disposable cartridge with 3" extension set, PN 980202EU, box of 30

Patient-dedicated cartridges with a 3"/7.5 cm extension set are also available for customers who require extra length at the end of the cartridge to allow for the placement of IV accessories.



Replacement pole clamp, PN 980330VS-1

A replacement pole clamp is available to secure the enFlow controller to an IV pole.



Power cords, PN 91000170 (continental EU), PN 91000172 (UK)

The 10' power cord plugs into the back of the controller to supply power to the system.



System manual, PN 44000024

The system manual provides important information related to operation, service and preventative maintenance of the enFlow device. This is the English version.



IV clips, PN 980331VS-200, box of 200

IV line cord clips allow caregivers to affix the patient line to the warmer cord to prevent kinking in the line.

enFlow IV fluid/blood warmer system

Warmer	12.7 cm x 6.6 cm x 3.0 cm (5.0" x 2.6" x 1.75")
Controller	23.6 cm x 16.8 cm x 9.7 cm (9.3" x 6.6" x 3.8")
Disposable cartridge	11 cm x 4 cm x 1 cm (4.5" x 1.5" x 0.4")
Weight	Warmer: (w/o disposable cartridge): 330 g (11.6 oz.) Controller: 1.9 kg (4.2 lb) Disposable cartridge: 33 g (1.2 oz.)

Performance detail

Disposable cartridge priming volume	4 mL
Disposable cartridge sterility	Gamma sterilized
Fluid temperature output	40°C ± 2°C
Flow rate range	KVO to 200 mL/min
Input voltage	Warmer: 28.5 VDC at a maximum of 350 watts Controller: 100-240 VAC
Temperature set point	40°C
Warming element	Parylene coated aluminium
Input current	5 A

Environmental/Physical requirements

Operating temperature	-5°C to 50°C
Storage temperature	-30°C to 70°C
Operating and storage relative humidity	Warmer: 10-90% Controller: 10-90% Disposable cartridge: 10-90%
Operating and storage altitude	Up to 4,572 m (15,000')
Operating and storage air pressure	570 hPa, (17 inHg) to 1,060 hPa (31 inHg)

Compliance with standards

Biocompatibility disposable cartridge	ISO 10993
Infusion set compatible disposable cartridge	ISO 8536-4
Over-temperature set point	ASTM F-2172-02
Alarms	IEC60601-1-8
Water resistance	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
Penetration	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
Electrical safety	CAN/CSA-C22.2 No. 60601-1:2008 Ed 03, AAMI ES60601-1:2005, IEC 60601-1:2005 Ed 03, IEC 60601-1-6:2010 Ed 3 and IEC 60601-1-8: 2006 Ed 2

Safety classifications

Type of protection against electrical shock	Class I or internally powered
Degree of protection against electric shock	Type BF, defibrillation-proof
Mode of operation	Continuous

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