enFlow*

IV Fluid / Blood Warming System

Operator's Manual

imagination at work

Vital Signs
a GE Healthcare Company

About this Manual

This Operator's Manual has been developed to provide the user with the information necessary to operate and maintain the enFlow® IV Fluid/Blood Warming System. It is important that all medical personnel that operate this device read and understand all the information contained within this Operating Manual. This material is not meant as a substitute for formal training in the use of intravenous delivery systems, which may be required by local, regional or state protocol. As with any medical device, please consult your local medical director or governing agency for further information and requirements. If you have questions or concerns regarding this manual or product, please contact one of the following for assistance:

Customer Service
E-mail: vitalsignscustomerservice@ge.com
Phone: 1.800.932.0760, option 1

Technical Support
Phone: +1 973.956.5431
FAX: +1.973.956.5440

Service Center Address:
Vital Signs
20 Campus Road
Totowa, New Jersey, 07512 USA

EC REP

GE Medical Systems SCS,
283 rue de la Miniere,
78530 BUC, FRANCE
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Fax: +33 130704440

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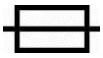
a GE Healthcare Company
20 Campus Road
Totowa, New Jersey, 07512, USA

Symbols Used on the Equipment

The following symbols may be viewed on the any of the products or accessories that comprise the enFlow IV Fluid/Blood Warming System.

Symbol	Symbol Description	Symbol	Symbol Description
LOT	Batch Code		On
REF	Catalog Number		Off
SN	Serial Number		Not made with natural rubber latex
NSN	National Stock No. (US Military)		Expiration Date
	Single Use Only; Do Not Re-Use		Direct Current
STERILE R	Sterilized Using Irradiation		Alternating Current
	Keep Dry		Type BF applied part, defibrillation-proof
	Do Not Re-Sterilize		Do Not Use if Package is Damaged.
	ATTENTION		Fuse
	Temperature; Thermometer	NON-PYROGENIC	Non-Pyrogenic
	Danger High Voltage	Note	This symbol indicates that additional information is being provided.
	Electric Energy		Effect or action in both directions away from reference point. (Open)
	Storage Temperature Range		Effect or action in both directions towards a reference point. (Close)
	Di(2-ethylhexyl) phthalate Free		In transport applications it is advised to cushion and insulate the Warmer from the patient's skin and apply the Warmer as loosely as acceptable checking regularly for signs of potential pressure related injury.
	Manufacturer	IP67	Degree of protection provided by enclosure, dust tight, temporary water immersion
IP21	Degree of protection provided by enclosure, no ingress of object > 12.5 mm diameter, protected against dripping water	IP68	Degree of protection provided by enclosure, dust tight, continuous water immersion
Rx ONLY	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.		TUV Rheinland of North America, Inc. is accredited by OSHA as a NRTL, as well as by the Standards Council of Canada. This mark indicates that the product has been tested to UL 60601-1:2003 R6.03, CAN/CSA-C22.2 No. 601.1-M90, IEC 60601-1-1:2000, and IEC 60601-1-4:2000.
	Consult Instructions for Use		Do not encase the Warmer with any external coverings like: towels, sheets, blankets or drapes. Covering the Warmer restricts the natural convection of heat.

	System Fault XX		Low Battery
	Lock or Password required		Unlock
	Do not throw in trash		The CE Mark is the manufacturer's or importer's mark of conformity declaring compliance with all applicable directives (Safety, EMC, Machinery, Medical and others).
	Interek is accredited by OSHA as a NRTL, as well as by the Standards Council of Canada. This mark indicates that the product has been tested to 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.		Mute the audible 'High Priority Alarm' for 1 minute.

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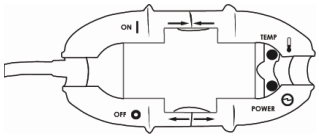
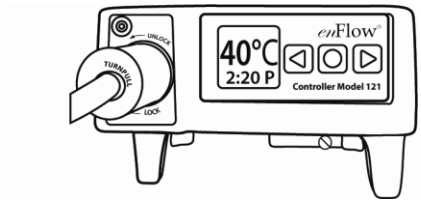
enFlow IV Fluid/Blood Warming System Description

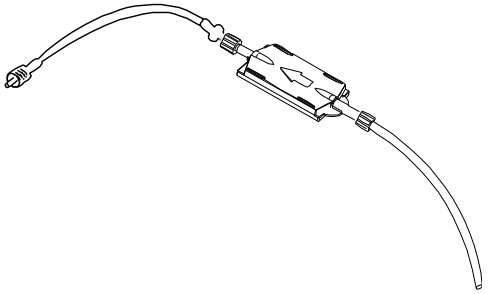
The enFlow IV Fluid/Blood Warming System consists of the enFlow Warmer (Model 100 series), the enFlow Controller (Model 120 series), the enFlow Disposable Cartridge with or without IV Extension Set (Model 200 series). Within seconds, this Warming System delivers normothermic infusate to the patient at flow rates of Keep Vein Open (KVO) to 200 mL/min when input fluid temperature is 20 °C.



The Warmer is the reusable heating unit designed to work in conjunction with the Disposable Cartridge. Two multicolored light emitting diode (LED) indicators on the Warmer indicate its power status and the fluid/blood infusate temperature. The infusate within the Disposable Cartridge is warmed when in contact with the heating surface of the Warmer. This surface is heated by means of electrical resistance. The Warmer contains redundant temperature sensors to help ensure fluid temperature accuracy and reliability**.** It also includes two independent over-heating protectors. Continuous internal diagnostics monitor essential components and system parameters when heating fluid/blood.



The Controller serves as a power supply for the Warmer unit. The Controller is designed to mount on an IV pole or sit on a table top. The front panel includes a Controller reading in degrees Celsius, as well as a keypad, which controls the clock and the mute feature. The Controller display is always shown "right-side-up".



Each Disposable Cartridge and the Disposable Cartridge with IV extension set are radiation sterilized and non-pyrogenic as well as latex and DEHP free. The Disposable Cartridge connects to the IV Extension Set or any infusion set employing standard luer connectors. Once primed, the Disposable Cartridge in conjunction with the Warmer and the Controller combine to complete the enFlow IV Fluid/Blood Warming System.

Indication for Use

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.

Clinical and Training Information

Operators must be trained to set up and deliver blood/ IV solutions in a medically approved manner, including aseptic techniques and standard hospital procedures. Use of the enFlow IV Fluid/Blood Warming System, when properly administered, will help to prevent hypothermia and the complications arising therefrom.

WARNINGS

- **All IV fluid bags must be vented of air per IV fluid manufacturers' directions prior to connecting to the infusion set. Standard IV line protocols for priming the complete infusion set, the enFlow Disposable Cartridge, and the extension set must be followed before connecting to a patient. Care must be taken to ensure there is not sufficient air in the fluid bag and lines to cause an air embolism.**
- **The 'High Priority Alarm' is a flashing RED LED, a flashing RED Controller display, and an audible alarm, indicating that the infusate is over temperature. Stop the fluid flow, and slide the Warmer covers open to stop warming. If the above occurs, then replace the Warmer and contact Technical Support. The attending practitioner should remain within 4m of the patient when the device is in use to enable visualisation of the enFlow display and hear the audible high priority alarm.**
- **The Warmer contains magnets; do not operate within 15 cm (6 in.) of a pacemaker or other devices that may be sensitive to strong magnetic fields.**
- **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.**
- **Do not use in the presence of flammable anesthetics.**
- **Replace the fuses with only Bussmann® part # S500-5-R or equivalent. Bussmann® is registered in the United States or abroad by Cooper Industries, Inc. or its subsidiaries.**
- **The Disposable Cartridge should not be used for greater than 24 hours.**
- **Ensure that the Disposable Cartridge expiration date has not passed.**
- **If the IV line runs dry, disconnect the Disposable Cartridge from the Warmer. Re-prime the entire IV system using aseptic techniques. Ensure all the air is removed from both the line and the Disposable Cartridge. Replace the Disposable Cartridge in the Warmer.**
- **The enFlow Warmer is to be used only with approved enFlow power sources and the enFlow Disposable Cartridge.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply main that is grounded. Should the need arise the device may be disconnected by the appliance coupler.**

Cautions

- Follow the AABB "Guidelines for the Use of Blood Warming Devices" (© 2006) which caution against warming when administering platelets, cryoprecipitate, or granulocyte suspensions.
- Some drugs or drug preparations may be sensitive to warming. As with any fluid or blood warming system, carefully review the drug manufacturer's literature for information about thermal sensitivity.
- The disposable cartridge contains aluminum. Review the preparation or solution manufacturer's instructions for use about chemical sensitivity.
- Do not affix, place or bind the Warmer directly to a patient during general use.
- Do not wrap the Warmer in towels, sheets, blankets or drapes.
- If the enFlow system is used for pre hospital transport or transfer to another facility
    - Do not use the Warmer Strap 980304EU during general use in the hospital environment.
- The Warmer heating surface and Disposable Cartridge can get quite warm when heating cold IV fluids/blood at high flow rates. Wait a few seconds after stopping the IV fluid/blood flow before removing the Disposable Cartridge.
- The Controller should only be plugged into a hospital grade outlet.
- Do not block the fan in the Controller as this may cause overheating.

- Although the Warmer has been tested to insure it will survive a drop of 1 m (3.28 ft.), care should be taken that the device is not dropped to reduce the potential of damage.
- Do not clean with:
    - ketones (MEK, acetone, etc.) or
    - abrasive cleaners.
- Do not sterilize the Warmer with:
    - steam sterilization (autoclave) or
    - dry heat.
- Do not disinfect or sterilize the Controller.
- Do not spray or pour cleaning solutions directly on the Controller.
- Do not allow cleaning solutions to accumulate on the Controller.
- When using the Controller mounted to an IV pole, it must be tightly secured on the pole no higher than 122 cm (48 in.) from the ground. The pole should have a base diameter of no less than 61 cm (24 in.). A Controller mounted too high on the IV pole may cause instability. IV pole accessories or the attachment of fluid bags may also cause instability.
- Normal wear and tear during use of the Warmer may cause the device to be susceptible to fluid ingress. Carefully inspect the heating surface of the Warmer for tears or foreign matter before each use and take out of service if necessary.
- Always secure the infusion set with the provided IV Line Clip on the Warmer power cable to prevent kinking in the line.
- Do not use a stiff bristle brush or sharp probe to remove foreign material.
- Do not use compressed air to dry.
- Avoid puncturing the heating surface. If damaged, remove the Warmer from service and replace immediately.
- This equipment is not intended for use in an oxygen rich environment.
- No modification of this equipment is allowed.
- Do not position the device in a way which makes it difficult to disconnect the device.

Unpacking the enFlow IV Fluid/Blood Warming System

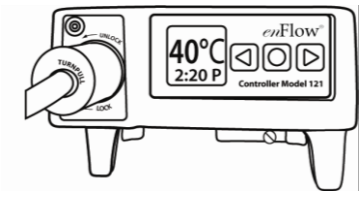
Upon receipt of the enFlow IV Fluid/Blood Warming System components, visually inspect the shipping containers and internal contents for damage that may have occurred during shipment. If there is any visible or mechanical damage to the contents, or if the order is incomplete, please contact Customer Service immediately. The parts list for each model is reflected below:

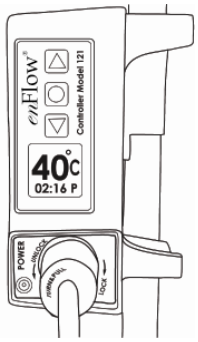
- Model 100
  - Warmer
  - Warmer Cord Clip‡
- Model 121
  - Controller
  - Warmer Mount (Warmer Mount Instructions)
- Model 200
  - Disposable Cartridge
  - IFU
- Model 202
  - Disposable Cartridge with IV Extension Set
  - IFU
- All systems shipped with power cord and operators manual.

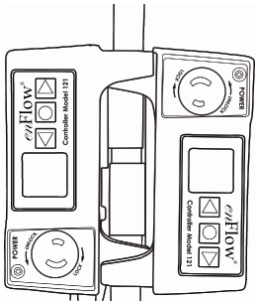
‡ Units shipped prior to 2012 may not contain the Warmer Cord Clip

To Begin Operation of the enFlow IV Fluid/Blood Warming System

a) Place the Controller on a firm, level surface or on an IV pole with an outside dimension of no greater than 3.0 cm (1.25 in.) Two Controllers may also be mounted next to each other on an IV pole as shown below. The Controller's display will have a "right-side-up" orientation regardless of its position.



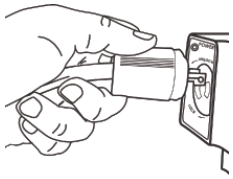




b) Plug the Controller into a hospital grade outlet.

c) Setting the clock to the local time is optional, but usually done on initial use. No changes in performance are affected by the clock's setting.

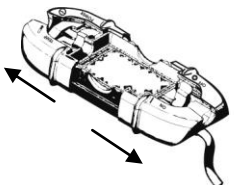
d) Connect the enFlow IV Fluid/Blood Warmer cable to the Controller. This action is accomplished in three steps:



1. Insert the male plug end of the Warmer into the female receptacle on the front face of the Controller. Push it in so that the plug cover is tight against the receptacle.
2. The plug and receptacle are "keyed" in both orientation and configuration. This feature ensures that the Warmer can only be plugged in properly. Additionally, it prevents other plug devices from fitting into this receptacle.

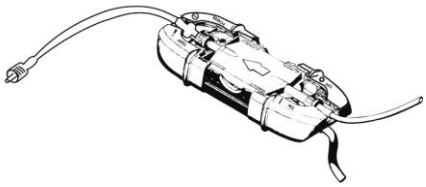
3. Turn right to lock. (See arrows on label.)

e) The rear mounted I/0 (ON/OFF) switch on the Controller turns the power on and off. Switch the Controller to ON. Upon startup, the Controller conducts a self-test. The power indicator illuminates green, the Controller display flashes "enFlow", a short audible "Beep" occurs, and the LED's light up for about one (1) second.
Note✍ The Controller automatically switches for operation at either 115 VAC or 230 VAC

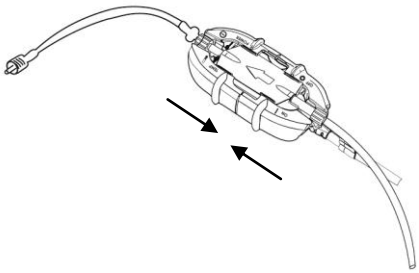


f) Open the covers on the Warmer by sliding them apart.

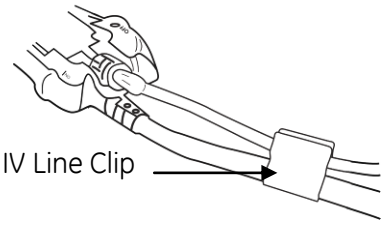
g) Connect the infusion set and or extension set to the Disposable Cartridge; then prime with fluid using standard medically approved protocols. Next, connect the infusion set to the patient and place the Disposable Cartridge into the Warmer.



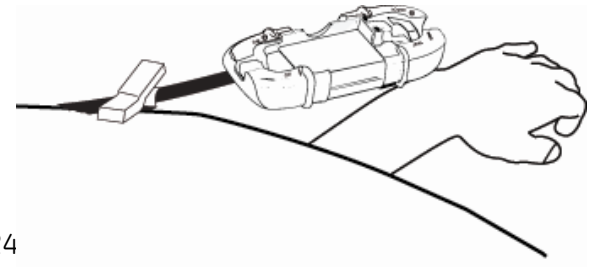
h) Completely close the covers on the Warmer by sliding them inward toward each other until the covers meet. Upon closing the covers, a short audible "Beep" occurs indicating that the Warmer self-test is being performed that confirms operation of temperature sensors and alarm indicators. After this process is complete, regulated power is delivered to the Warmer's heating surface, which then begins heating the infusate through the Disposable Cartridge. Adjust the fluid flow to the desired rate.



i) Place the IV line in the IV Line clip in order to prevent it from kinking.



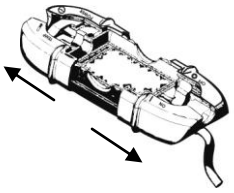
j) The Warmer is designed to be placed on the bed and/or attached to a patient coverings in close proximity to the site of infusion using the cord clip P/N 980309VS. Cushion the patient from the Warmer to aid in the prevention of perioperative peripheral neuropathies or heat related dermal injury



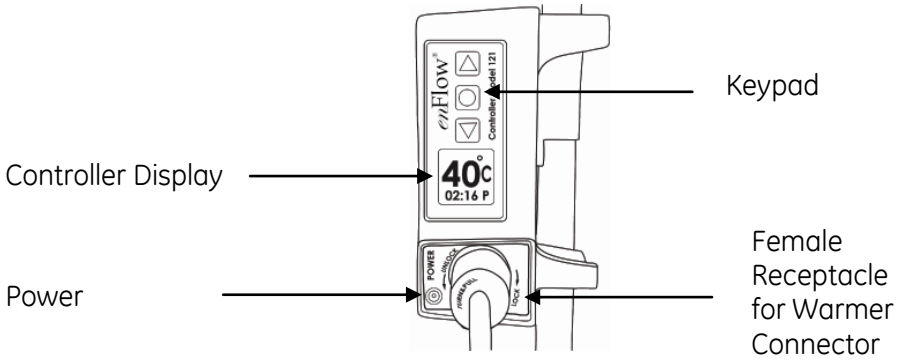
k) Do not wrap the Warmer in towels, sheets, blankets or drapes.

l) Opening the Warmer covers immediately stops the **heating** but **not** the **flow**.

m) To turn off the device, use the switch located at the rear of the controller.



enFlow Controller (Model 120 series) Indicators and Operation



Controller Display

The Controller display continuously reflects the specific infusate temperature that the Warmer monitors and maintains.

The various readouts that may be depicted on the Controller display are described in the following tabulation:

Table 1: Controller Display: Normal Operating Model

Activity	Display Reads	Display Color and Function
Warmer is connected and power is engaged.	Temperature and Clock 40 °C 9:00 A	Identical to Warmer Temp LED
Warmer is not connected, but Controller is powered on.	Not Heating	Yellow
Warmer is connected, but covers are open on Warmer.	Not Heating	Yellow
Warmer is connected, and covers are either open or closed on Warmer; however, disposable is not in Warmer.	Not Heating	Yellow

Table 2: Controller Display: Alarm Mode

Activity	Display Reads	Display Color and Function
Warmer Over Temperature	Display alternates between Over Temp and Press Key to Mute	Identical to Warmer Temp LED
Mute button activated.	Over Temp Muted	Identical to Warmer Temp LED
Fault detected	System Fault XX If a system fault message is on the Controller display, contact Technical Support.	Red High Priority Alarm

Table 3: Controller Display: Setup Mode

Activity	Display Reads	Display Color and Function
While powering up the Controller, hold the center button down until the clock screen is displayed. Then, use the buttons to set the clock.	09:00 A 	Blue

enFlow Warmer (Model 100 series) Indicators and Operation

The Warmer monitors and maintains the infusate temperature at 40 °C ± 2 °C . On the top of the Warmer, there are two status indicator lights (multicolored LEDs), which reflect the following:

Power - indicates the power and operational status of the Warmer.
Temperature - indicates that the infusate temperature is within an acceptable operating range (35 °C to 42 °C).

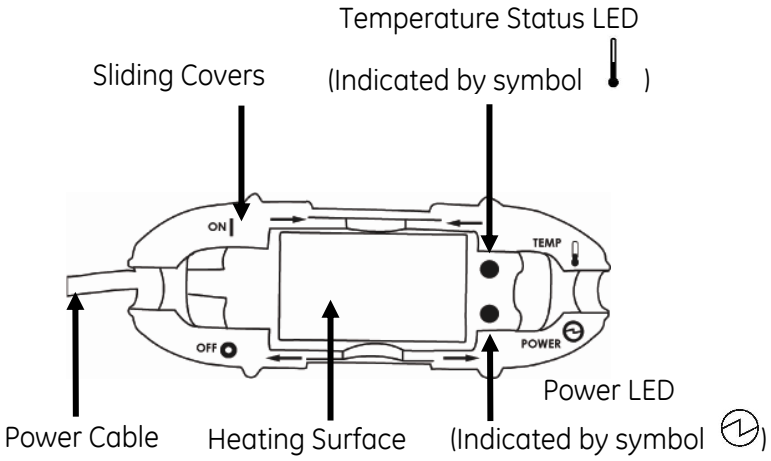


Table 4: Indicator Status

Status	Warmer Covers	Disposable Cartridge	Power LED Indicator	Temperature LED Indicator	Audible Indicator	Description	Action Required
Ready	Open or Closed	None	Flashing Green every 3 seconds	Unlit	None	Warmer unit has power, but is not heating	None
Power up of device	Closed	In place	Red ½ second	Red ½ second	½ second beep	Successful device power up and over temperature circuit test	Observe. If the LED does not flash red, replace the Warmer; and contact Technical Support.
In Operation	Closed	In place	Solid Green	Flashing Blue	None	Infusate temperature is < 33 °C.	None
In Operation	Closed	In place	Solid Green	Solid Blue	None	Infusate temperature is ≥ 33 °C and < 35 °C.	None
In Operation	Closed	In place	Solid Green	Solid or Flashing Blue >30 seconds	None	Warmer is unable to heat the infusate within operational range. Infusate temperature is < 20 °C and/or the flow rate is > 200 mL/min.	Reduce the flow rate if possible. If there is no change in operational temperature, consider replacing the Warmer and contact Technical Support.
In Operation	Closed	In place	Solid Green	Solid Green	None	Infusate temperature is ≥ 35 °C and ≤ 42 °C.	None
In Operation	Closed	In place	Solid Green	Solid Yellow	None	Infusate (and/or ambient temperature) is > 42 °C but less than an "Over Temp" condition.	Observe. This state whereby the infusate is > 42 ºC should only be entered periodically during changes in flow rate or infusate temperature.
In Operation	Closed	In place	Flashing Red		Continuous audible burst	Internal failure in the Warmer	Replace the Warmer if this occurs, and contact Technical Support.
Continuous Operation	Closed	In place	Solid Green	Flashing Red High Priority Alarm	Continuous audible burst	Infusate (and/or ambient temperature) is > 45 °C signifying an "Over Temp" condition.	Stop the fluid flow, and slide the Warmer covers open to stop warming. Replace the Warmer if this occurs, and contact Technical Support.

Refer to Appendix C for the chart on "Warming System Response versus Fluid Temperature".

Refer to Warnings for additional information.

Cleaning the enFlow IV Fluid/Blood Warming System Components

Caution

Do not clean with:

- ketones (MEK, acetone, etc.) or
- abrasive cleaners.

Do not sterilize the Warmer with:

- steam sterilization (autoclave) or
- dry heat.

Do not disinfect or sterilize the Controller.
Do not spray or pour cleaning solutions directly on the Controller.
Do not allow cleaning solutions to accumulate on the Controller.

The Warmer and Controller are chemically resistant to most common hospital grade instrument cleaning solutions and non-caustic detergents. The following list of approved cleaning solutions may be used to clean the Warmer and Controller:

- Isopropyl alcohol
- Mild detergent solution
- Diluted chlorine bleach (30 mL/L water)
- Ammonia based cleaners
- Glutaraldehyde-based cleaners
- Chlorhexidine

Cleaning the Warmer

Wipe down and or wash

1. After each use, clean the Warmer only as required. In many instances, it may only need to be wiped clean.
2. If the warmer needs to be cleaned more intensively, use a cleaning solution and a soft bristle brush to gently scrub the Warmer to remove any foreign material.
3. Rinse thoroughly with distilled water. Do not immerse the Warmer's electrical plug connector.

Drying

1. After cleaning, dry completely before placing back into use.
2. If disinfecting is required, dry completely before disinfecting so that the disinfecting solution will not be diluted.

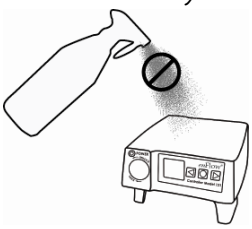
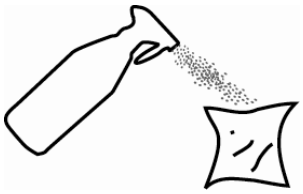
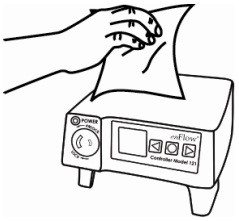
Disinfecting

1. The enFlow Warmer may be disinfected using commercially available solutions with no greater than 2.4 % glutaraldehyde and by following the solution manufacturers' recommendations.
2. Soak the Warmer in the disinfectant solution according to the manufacturer's application time guidelines. Do not immerse the Warmer's electrical plug connector in the solution.
3. Thoroughly rinse the Warmer of all solution using distilled water.
4. Completely dry the Warmer before placing into service.

5. Confirm operation. Connect the Warmer to a Controller. Insert a Disposable Cartridge into the Warmer and close the covers. Turn the Controller to the ON position, and allow the start up procedure to run until complete.

Cleaning the Controller

1. Use only approved cleaning solutions.
2. Moisten a clean cloth with the cleaning solution; do not spray or pour cleaning solutions directly on to the Controller.
3. Wipe the surface of the Controller, taking care not to leave excess residual cleaner on the Controller. If fluid ingress is detected, set the Controller aside for an extended period of time to allow it to dry.

Storing the enFlow IV Fluid/Blood Warming System Components

The Warmer and Controller should be stored in a clean, dust free environment. (See Appendix A)

enFlow IV Fluid/Blood Warming System Operational Checklist

Warmer Serial No_____ Controller Serial No_____
Warming System Location/Identifier_____
Date:

Procedure Instructions	Pass Fail	Input Temp	Output Temp
Inspection Ensure that all cords and connectors are in good condition and void of any cuts, cracks, or frays.			
Ensure that the units are clean and void of any cracks or other signs of damage.			
Performance Test Setup Set up the system for normal operation. Provide a 0.5 liter source of fluid at 20 °C ± 2 °C. Measure the temperature within 22.9 cm (9 in.) of both the input and output connections of the Disposable Cartridge by inserting a T connector in the direct fluid path which will accommodate a temperature probe. Connect the temperature probes to a meter capable of measuring between 10 °C and 60 °C with 0.1 °C accuracy. Prime the IV line setup according to standard IV protocols. Turn the enFlow system on and establish a fluid flow of 100 ± 20 mL/min. Wait for the temperature probes to stabilize.			
Record the input fluid temperature. Input fluid temperature 20 °C ± 2 °C.			
Record the output fluid temperature. Output fluid temperature 40 °C ± 2 °C.			
Over-Temperature Alarm Check Use performance testing setup. Change the source of fluid's temperature to 50 °C ± 2 °C. Turn the enFlow system on and establish a fluid flow of 100 ± 20 mL/min. Wait for the temperature at the probes to stabilize.			
Record the input and output fluid temperatures.			
The High Priority Over Temp Alarm occurs within less than 20 seconds of reaching input temperature. (See Appendix C)			
High Priority Alarm indicated by Audible beep and Over-Temp message in Red appearing on the Controller.			
Red Temperature LED flashes on the Warmer, Also indicating a High Priority Alarm			
Electrical Safety Follow safety analyzer manufacturer's instructions			
Test leakage current at the AC power cord using a safety analyzer.			
Test leakage current of the Warmer to the saline in the IV line using a safety analyzer.			
Inspected By Enter initials and confirm date.			
Comments, Observations or Corrective Actions			

Note✍ Please reference the Service Manual for the specific procedures in order to perform the tests listed above.

Servicing the enFlow IV Fluid/Blood Warming System Components

The enFlow IV Fluid/Blood Warming System components have been designed to be durable and long lasting. The systems use current Surface Mount Technology (SMT) and materials. If service is required, it must be performed by Vital Signs – a GE Healthcare Company or one of its authorized agents. Service by others voids the warranty and transfers the liability for malfunctions of the device to the servicer. If the unit stops working properly, contact Customer Service to obtain an RGA number prior to returning the unit to the enFlow Service Center. If damage has occurred to the heating surface, immediately remove it from service.

RGA Number

Prior to returning any Product, Original Purchaser must receive prior consent and must receive a Return Goods Authorization (RGA) number from Vital Signs, Inc. No Product may be returned without an RGA number. Our Customer Service Representatives can be reached by phone at 800-932-0760 or by e-mail at customerserviceVSD@ge.com.

The Service Representative will troubleshoot your Product issue with you on the phone. If it is necessary to return a Product under warranty, a replacement loaner will be shipped to you within 48 hours. (If the Product is no longer under warranty, the Service Representative will discuss repair/replacement options.) You will be issued a Return Goods Authorization (RGA) number. You will be instructed to return the Product in packaging sufficient to prevent damage in transit, clearly marking the RGA number on the outside of the box. The return address will be provided to you.

Note✍ Federal (U.S.A.) Law requires contaminated Medical Equipment to be cleaned and disinfected before shipment. If this is not done, your unit will be immediately returned as it is received.

Warmer (Model 100 series)

The Warmer is permanently sealed against fluid ingress and has no user serviceable parts inside.

Caution

Normal wear and tear during use of the Warmer may cause the device to be susceptible to fluid ingress. Carefully inspect the heating surface of the Warmer for tears or foreign matter before each use and take out of service if necessary.

Due to highly stable components, microprocessor control, and built-in self-tests, an annual performance check is sufficient.

The steps listed in the enFlow IV Fluid/Blood Warming System Operational checklist should be performed at least once a year, or as required by your accrediting body.

Controller (Model 120 series)

The Controller (Product No. 980121) contains no user serviceable parts inside. Check the fuses located in the power entry module if the Controller fails to function. The AC line power cord must be removed to do this.

The Controller should be subjected to routine safety checks as required by local regulations, (i.e. Earthing Impedance, Leakage Current).

Appendix A: Technical Specifications

Size	**Warmer:** 12.7 cm L x 6.6 cm W x 3.0 cm H, (5.0 in. L x 2.6 in. W x 1.2 in. H) **Controller:** 23.6 cm L x 16.8 cm W x 9.7 cm H, (9.3 in. L x 6.6 in. W x 3.8 in. H) **Disposable Cartridge:** 11.4 cm L x 3.8 cm W x 1.0 cm H, (4.5 in. L x 1.5 in. W x 0.4 in. H) **Extension Set:** 120 mm L x 10.6 mm W, (4.7 in. L x 0.4 in. W)
Weight	**Warmer:** (w/o Disposable)**:** 279 g, (9.8 oz.) **Controller:** 1.8 kg, (3.9 lb.) **Disposable Cartridge:** 33 g (1.2 oz.) **Extension Set:** 2 g (0.07 oz.)
Disposable Cartridge and (optional IV Extension Set):	
Priming Volume	**Disposable Cartridge:** 4 mL **(optional IV Extension Set):** 0.5 mL
Sterility	Gamma Sterilized
Biocompatibility	ISO 10993
Infusion Set Compatible	ISO 8536-4
Performance	
Fluid Temperature Output	40 °C ± 2 °C
Flow Rate Range	KVO to 200 mL/min
Input Voltage	**Warmer:** 28 VDC at a maximum of 300 Watts **Controller:** 110-120 or 220-240 VAC
Temperature Set Point	40 °C
Over Temperature Set Point	ASTM F-2172-02
Alarms	IEC60601-1-8:2006
Input Current	5 A
Input Frequency Range	**Warmer:** DC **Controller:** 47-63 Hz
Environmental/ Physical Requirements	
Temperature, Operating	-5 °C to 50 °C
Temperature, Storage	-30 °C to 70 °C
Water Resistance	**Warmer:** IEC 529 IP67 30 minutes immersion at a depth of 91.4 cm (36 in.); **Controller:** IEC 529 IP21 dripping water; **Disposable Cartridge and (optional IV Extension Set):** IEC 529 IP68 **IV Extension Set):** IEC 529 IP68 continuous immersion
Penetration	**Warmer:** IEC 529 IP67 dust tight **Controller:** IEC 529 IP21 ≥ 12.5 diameter (See Page 23) **Disposable Cartridge and (optional IV Extension Set):** IEC 529 IP68 dust **IV Extension Set):** IEC 529 IP68 dust tight
Electrical Safety	UL 60601-1:2005 R6.03, CAN/CSA-C22.2 No. 60601.1:2008, IEC 60601-1-6:2010, AAMI ES60601-1:2005, IEC 60601-1-4:2000 (Canada)
Relative Humidity, Operating and Storage	**Warmer:** 10 % to 90 % **Controller:** 10 % to 90 % **Disposable Cartridge and (optional IV Extension Set):** 10 % to 90 %

Altitude, Operating and Storage	up to 15,000 ft
Air Pressure, Operating and Storage	570 hPa, (17 inHg) to 1060 hPa (31 inHg)
Shock/Drop Abuse Tolerance	MIL-STD-810F
Vibration	MIL-STD-810F
Radiated Magnetic Field Emissions	MIL-STD 461D, RE101 (7 cm test limit 30 Hz-100Khz); EMC IEC 60601-1-2:2007
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

Note✍ Electromagnetic Compatibility (EMC)

The enFlow IV Fluid / Blood Warmer System has been tested and found to comply with the limits for medical devices as set forth in IEC 60601-1-2: (2001) and related standards. These limits are designed to provide reasonable protection against electromagnetic interference (EMI) in a typical medical installation. The enFlow System generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the enFlow System does cause interference to other devices, which can be determined by turning the Controller off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reposition the Warmer and any intertwined cables.
- Check ECG monitoring electrode contact and impedance.
- Confirm monitoring lead wires are functioning properly and shielding is intact.
- Connect the Controller into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer for help.

Guidance and Manufacturer's Declaration - Emissions

The enFlow 100 with enFlow 120 is intended for use in the electromagnetic environment specified below. The customer or user of the enFlow 100 with enFlow 120 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions Radiated CISPR 11	Group 1, Class B	The enFlow 100 with enFlow 120 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	Class A	The enFlow 100 with enFlow 120 is suitable for use in all establishments, other than domestic, and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The enFlow 100 with enFlow 120 is intended for use in the electromagnetic environment specified below. The customer or user of the enFlow 100 with enFlow 120 should ensure that it is used in such an environment.

Immunity Test	EN/ IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD EN/IEC 61000-4-2	Level 3 (±6kV) Contact Level 3 (±8kV) Air	Level 3 (±6kV) Contact Level 3 (±8kV) Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	100% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles See Note 1	Mains power quality should be that of a typical commercial or hospital environment. If the user of the enFlow 100 with enFlow 120 requires continued operation during power mains interruptions, it is recommended that the enFlow 100 with enFlow 120 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Note 1) During the 5 Second event, the enFlow 100 and 120 power off, but return to normal operation as soon as power is restored.

Guidance and Manufacturer's Declaration – Emissions

The enFlow 100 with enFlow 120 is intended for use in the electromagnetic environment specified below. The customer or user of the enFlow 100 with enFlow 120 should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF EN/IEC 61000-4-6 Radiated RF EN/IEC 61000-	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile communications equipment should be separated from the enFlow 100 with enFlow 120 by no less than the distances calculated/listed below: D=(3.5/3V/m)(Sqrt P)

4-3			D=(3.5/3V/m)(Sqrt P) 80 to 800 MHz D=(7/3V/m)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (3Vrms and 3V/m). Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the enFlow

The enFlow 100 with enFlow 120 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the enFlow 100 with enFlow 120 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the enFlow 100 with enFlow 120 as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	**Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)**	**Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)**	**Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)**
0.01	.1166	0.12	0.23
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

Controller: IEC 529 IP21 ≥ 12.5 diameter Testing

Rain- Operational

1. Place an enFlow Power Supply /Controller in the rain chamber.
2. Connect the enFlow IV Fluid Warmer and the extended power cable to the power supply.
3. Turn "on" the power supply.
4. Expose to 1" of rain per minute in its left IV pole orientation for 10 minutes.
5. Rotate the power supply 180 degrees to its right IV pole orientation.
6. Expose to 1" of rain per minute for 10 minutes.
7. Use the camera to record what happens while power supply is running in the rain chamber.
8. Turn "off" and remove from the rain chamber.
9. Unplug the power supply and wipe excess water away from the outside.
10. Perform validation test to confirm proper operation. Record serial numbers of test items. (TPTR_083)
11. Using a screwdriver, open the power supply. Note any moisture inside the power supply or use a camera to record its location inside the supply.

Rain Operational (8)	Demo 03				TPTR_082			
Environment Temperature			Table		Left Side Pole Mount		Right Side Pole Mount	
Display sequence occurs	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No	☐ Yes	☐ No
Voltage Reading	☒ Yes 28.09V	☐ No	☒ Yes 28.09V	☐ No	☒ Yes 28.03V	☐ No	☐ Yes	☐ No
Audible alarm	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No	☐ Yes	☐ No
Mute button	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No	☐ Yes	☐ No
Orientation/Tilt	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No	☐ Yes	☐ No
Clock	9:04A		9:14A		9:31A			
Time	8:59AM		9:09AM		9:26AM		9:35AM	

Notes: The EDUT was placed in the Singleton Model 22 Rain Chamber.
• Opened up unit to it let dry out. The battery was also replaced. Unit is now functioning properly. See Retest below.

Rain (8) – retest 1/10/08	S/N 71130056				TPTR_082			
Environment Temperature	Start up		Table		Left side pole mount		Right side pole mount	
Display sequence occurs	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No
Voltage Reading	☒ Yes 28.06V	☐ No	☒ Yes 28.06V	☐ No	☒ Yes 28.06V	☐ No	☒ Yes 28.06V	☐ No
Audible alarm	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No	☒ Yes	☐ No
Mute button	☒ Yes	☐ No					☒ Yes	☐ No
Orientation/Tilt	☒ Yes	☐ No					☒ Yes	☐ No
Clock					10:47A		11:03A	
Time	10:20AM		10:33AM		10:45AM		11:01AM	

Notes: Mute button and Orientation tested at end of 3 rotations to minimize water getting inside the unit.
• Test ended at 10:56AM. Exterior of unit was dried off and then unit was tested.
• Voltage reading started out at 17.03V and started to climb. All features functioned at 20V. Voltage stabilized at 28.06V at 11:10AM.

Appendix B: Glossary

enFlow IV Fluid/Blood Warming System	The enFlow IV Fluid/Blood Warming System consists of three products: the Warmer (No. 980100), the Controller (No. 980121), and the Disposable Cartridge (No. 980200), which together form a system designed to warm intravenous fluids and blood products helping reduce hypothermic effects.
Warmer (Model 100)	The Warmer is a small, lightweight, rugged fluid warmer that heats blood, blood plasma, and intravenous fluids being delivered to the patient's body within seconds from 20 ºC to 40 ºC through a flow rate range of KVO to 200 mL/min.
Controller (Model 120)	The Controller displays a temperature readout in degrees C, as well as containing a keypad, which controls the clock and the mute feature. Additionally, it converts AC line power to 28 Volts DC, and is used as a power source for the Warmer.
Disposable Cartridge (Model 200)	The Disposable Cartridge uses a sterile, single use component to be used as an in-line component of an IV infusion set for the heating of the fluids/blood being infused into the patient's body.
Disposable Cartridge with IV Extension Set (Model 200)	The Disposable Cartridge with IV Extension Set product contains the same Disposable Cartridge described above. In addition, it includes a sterile, single use IV extension set.
Intravenous Fluids	Fluids such as Normal Saline, Dextrose, Dextron, Packed RBC's
KVO	"Keep Vein Open" refers to an intravenous infusion rate defined as approximately 2 mL/min (120 mL/hr).
LED	Light Emitting Diode
mL/min	Milliliters per minute
RBC's	Packed Red Blood Cells

Appendix C: Warming System Response by Temperature

Fluid Temp	Heater	Temperature LED on Warmer	Display on Controller	Audible Alarm
30 °C	Active	Blue Flashing	30°C Blue Flashing	No
31 °C	Active	Blue Flashing	31°C Blue Flashing	No
32 °C	Active	Blue Flashing	32°C Blue Flashing	No
33 °C	Active	Blue	33°C Blue	No
34 °C	Active	Blue	34°C Blue	No
35 °C	Active	Green	35°C Green	No
36 °C	Active	Green	36°C Green	No
37 °C	Active	Green	37°C Green	No
38 °C	Active	Green	38°C Green	No
39°C	Active	Green	39°C Green	No
40 °C	Active	Green	40°C Green	No
41 °C	Off	Green	41°C Green	No
42 °C	Off	Green	42°C Green	No
43 °C	Off	Yellow	43°C Yellow	No
44 °C	Off	Yellow	44°C Yellow	No
45 °C	Off	Red Flashing High Priority Alarm after 20 seconds	45°C after 20 seconds Red Flashing "Over Temp" message	After 20 seconds
46 °C	Off	Red Flashing High Priority Alarm after 16 seconds	46°C after 16 seconds Red Flashing "Over Temp" message	After 16 seconds
47 °C	Off	Red Flashing High Priority Alarm after 12 seconds	47°C after 12 seconds Red Flashing "Over Temp" message	After 12 seconds
48 °C	Off	Red Flashing High Priority Alarm after 8 seconds	48°C after 8 seconds Red Flashing "Over Temp" message	After 8 seconds
49 °C	Off	Red Flashing High Priority Alarm after 4 seconds	49°C after 4 seconds Red Flashing "Over Temp" message	After 4 seconds
50 °C	Off	Red Flashing High Priority Alarm (immediately)	Red Flashing "Over Temp" message (immediately)	Immediately

Appendix D: Parts List

980105VS	Warmer
980121EU	Controller
980200EU	Disposable cartridge
980202EU	Disposable cartridge with IV extension set
980305VS	Warmer Holder
980309VS	Warmer Cord Clip
980307	enCheck Alarm testing Tool
44000024	Operator's manual (USA)
44000060	Service manual (electronic version only, not available in print)
44000120	enCheck Users Guide English(EN)
91000178	Power Cord USA