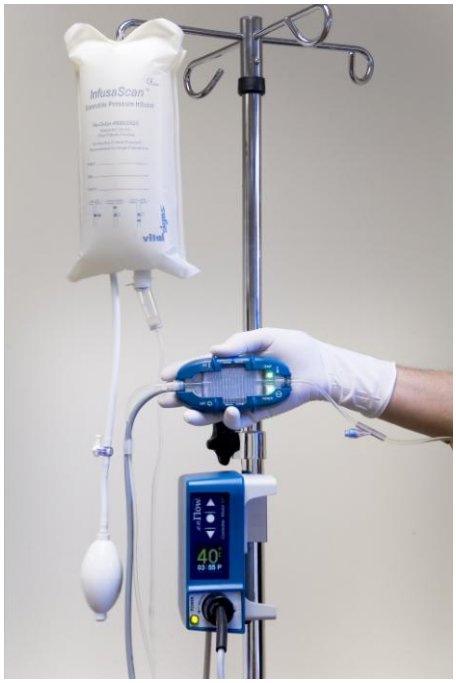
enFlow*

IV Fluid / Blood Warming System

Service Manual



imagination at work

Vital Signs
a GE Healthcare Company

About this Manual

This Service Manual has been developed to provide authorized agents of Vital Signs Inc., with the necessary information to service the enFlow IV Fluid/Blood Warming System. It is important that all such agents responsible for servicing this device read and understand all the information contained within this Service Manual. Please note an Operator's Manual is also available.

WARNING:

This Service Manual is available in English only.

- If a customer's service provider requires a language other than English, it is the customer's responsibility to provide translation services.
- Do not attempt to service the equipment unless this Service Manual has been consulted and is understood.
- Failure to heed this Warning may result in injury to the service provider, operator or patient from electric shock, mechanical or other hazards.

If you have questions or concerns regarding these manuals or product, please contact one of the following for assistance:

Customer Service
Phone: 800.932.0760m, option 1
Email: vitalsignscustomerservice@ge.com

Technical Support
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20 Campus Road
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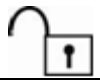
Enginivity, LLC., a subsidiary of Vital Signs, Inc.
Vital Signs, Inc., a General Electric company, doing business as GE Healthcare.

Symbols Used on the Equipment

Symbol	Symbol Description	Symbol	Symbol Description
The following symbols may be viewed on the any of the products or accessories that comprise the enFlow IV Fluid/Blood Warming System.			
LOT	Batch Code		On
REF	Catalog Number		Off
SN	Serial Number	Not made with natural rubber latex	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)
70°C -30°C	Storage Temperature Range		Effect or action in both directions towards a reference point. (Close)
DEHP	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 US	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).
	Not Heating		Heating, Normal Operation
	Alarm Muted (for an intermittent time period)		Press Any Key to Mute Alarm.
	System Fault XX	EC REP	Authorized Representative in the European Community
	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, IC 60601-1:2005 Ed 03, IEC 60601-1 -6:2010 Ed 3 and IEC 60601-1-8: 2006 Ed 2.		

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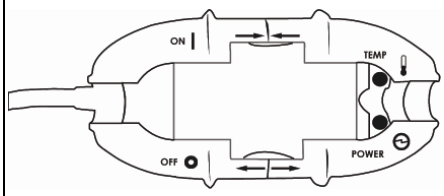
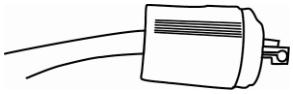
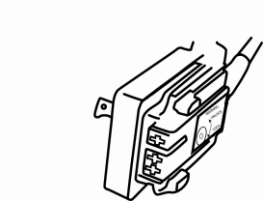
enFlow IV Fluid/Blood Warming System Description

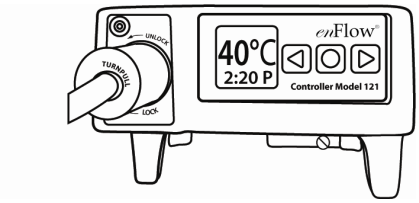
The enFlow IV Fluid/Blood Warming System consists of the enFlow Warmers (Model 100 series, the enFlow Controller/AC Power Pack (Model 120 series), the enFlow AC Power Pack (Model 120 series), the enFlow Disposable Cartridge with or without an IV Extension Set (Model 200 series). Within seconds, this 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.

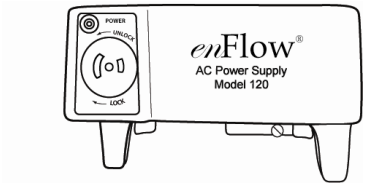
The only distinction between the two versions of the Warmer, both of which are Model 100 series, is the connector at the end of the power cord, which determines whether the unit will powered from alternating or direct current.

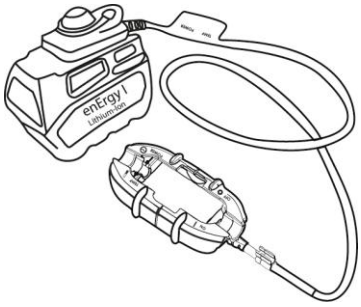
Model 100	**Hubbell Connector**	**Multi-Purpose Military Hubbell Connector (MMHC)**
		
	~ Alternating Current	~/⎓ Alternating Current **/** or Direct Current

The Controller/AC Power Pack serves as a power supply for the Warmer unit. The Controller/AC Power Pack is designed to mount on an IV pole or sit on a table top. The front panel includes a temperature display reading in degrees C, as well as a keypad, which controls the clock and the mute feature. Regardless of the orientation of the unit, the temperature readout is always displayed in a “right-side-up” view.

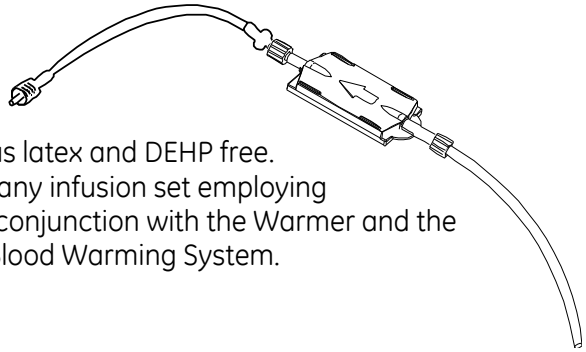


The AC Power Pack also serves as a power source for the Warmer unit. It is similar in design to the Controller/AC Power Pack only without the display feature.





Additionally, another portable source of power compatible with the enFlow Warming System is the Battery Pack (Model 300 series). (For further information on this item please reference the Energy I Operator's Manual.)



Each Disposable Cartridge and the Disposable Disposable Cartridge with extension set are radiation sterilized and non-pyrogenic as well as latex and DEHP free. The Disposable Cartridge connects to the enFlow IV Extension Set or any infusion set employing standard luer connectors. Once primed, the Disposable Cartridge in conjunction with the Warmer and the Controller/AC Power Pack 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. This device may also help make patients more comfortable during IV infusions.

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 # GDB 5A 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
    - place an insulating and cushioning fabric layer, such as soft cotton towels or gauze, at least .25" or 6 mm thick in between the underside of the Warmer and the patient. Do not use foam or gel pads. Cushioning the patient from the Warmer will help prevent perioperative peripheral neuropathies.
    - 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.
- 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/AC Power Pack should only be plugged into a hospital grade outlet.
- Do not block the fan in the Controller/AC Power Pack 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/AC Power Pack 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/AC Power Pack 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 clip provided 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.

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/AC Power Pack 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.

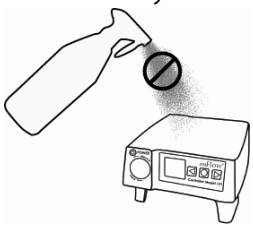
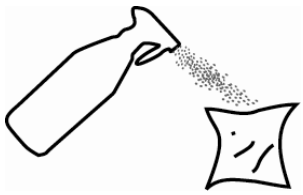
Disinfecting

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/AC Power Pack to the ON position, and allow the start up procedure to run until complete.

Cleaning the Controller/AC Power Pack or AC Power Pack

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/AC Power Pack 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/AC Power Pack should be stored in a clean, dust free environment. (See Appendix A)

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 Inc., 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 (+1 973.956.5431) or by e-mail at vitalsignscustomerservice@ge.com.

The Technical Support 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 Technical Support 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.

Replaceable parts Warmer:
IV line clip
Covers
Warmer cord clip

To order replacement parts, please reference the Recommended Supply List for specific product numbers.

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.

For information on safety checks, please see Appendix F: Preventive Maintenance Procedure.

Controller/AC Power Pack (Model 120 series) - Setup Instructions

1. **Set the clock**
    a. To modify the initial default mode of the Controller, press any of the front keys of the display window prior to pushing the power switch that is located in the back of the unit. The key must be held down continuously until the clock is displayed.
    b. Once the clock appears, toggle the center button to move through the fields. To change a field, press the right or left arrow keys.
2. **Set the Controller/AC Power Pack display default mode to symbols**
    a. Continue to toggle through to the set zone field. Press either the right or left arrow key to access the padlock symbol to enter the password screen.
    b. An underscore will display under the first digit field. Press the arrow key to set the appropriate digit.
    c. Next, press the center key again to toggle to the next place.
    d. Repeat steps three and four for the second and third digits. If an incorrect password is entered, the system reverts to the set zone screen.
    e. After the third digit is set, press the center key again. First a green padlock and then the zone USA will appear. Press the right arrow to change to INTL.
    f. Press the center key again to set. The system begins to operate.
    g. After the initial setup, whenever the Controller/AC Power Pack is powered on the display screen defaults to the last mode entered.
    h. The password is 781.

Controller/AC Power Pack (Model 120 series) and AC Power Pack (Model 120 series)

The enFlow Controller/AC Power Pack (Model 120 series) and AC Power Pack (Model 120 series) contains some parts that may be replaced. Check the fuses located in the power entry module if the Controller/AC Power Pack or AC Power Pack fails to function. The AC line power cord must be removed to do this.

Replaceable parts Controller/AC Power Pack and AC Power Pack:
Clock battery (See below for instructions on how to replace.)
Fuse - Bussmann #GDB 5A or equivalent (See below for instructions on how to replace.)
Cover (Bottom Only)
Screws
Pole clamp screw
Power cord
Warmer Mount

To order replacement parts, please reference the Recommended Supply List for specific product numbers.

For information on safety checks, please see Appendix F: Preventive Maintenance Procedure.

Instructions for replacing the Controller/AC Power Pack clock battery.

1. Turn Controller/AC Power Pack over.

Diagram 1

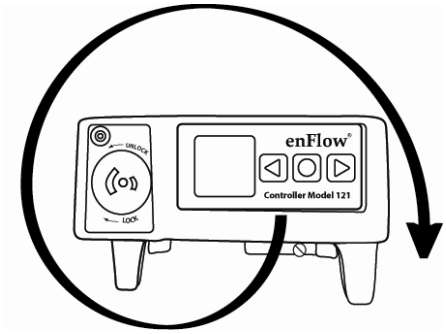
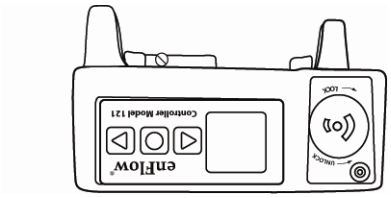


Diagram 2



2. To remove the bottom, unscrew Pole Clamp screw; unscrew 4 screws shown below. Next, lift the cover.

Diagram 3

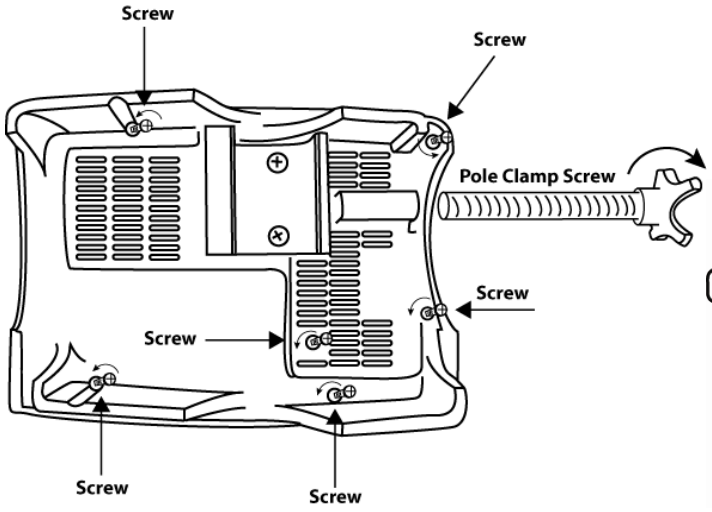
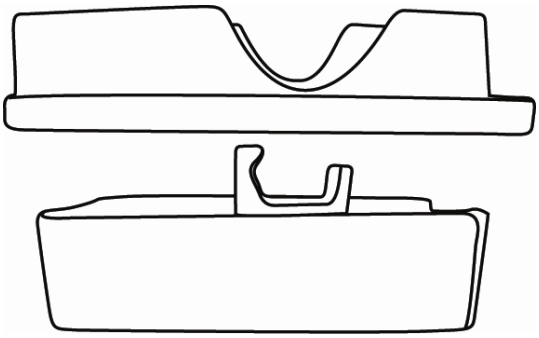


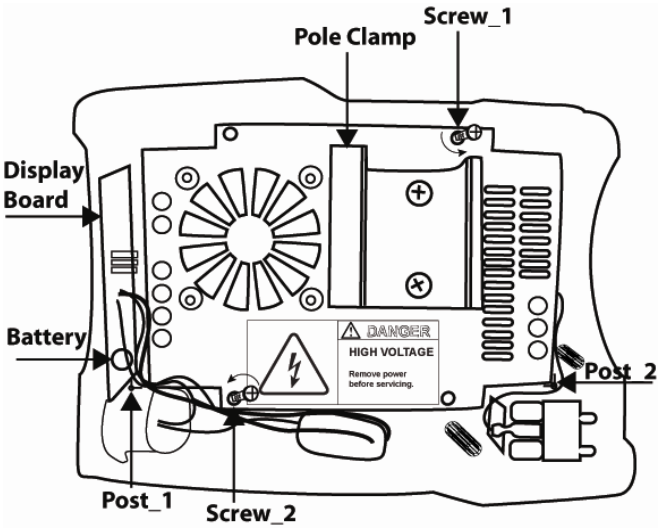
Diagram 4

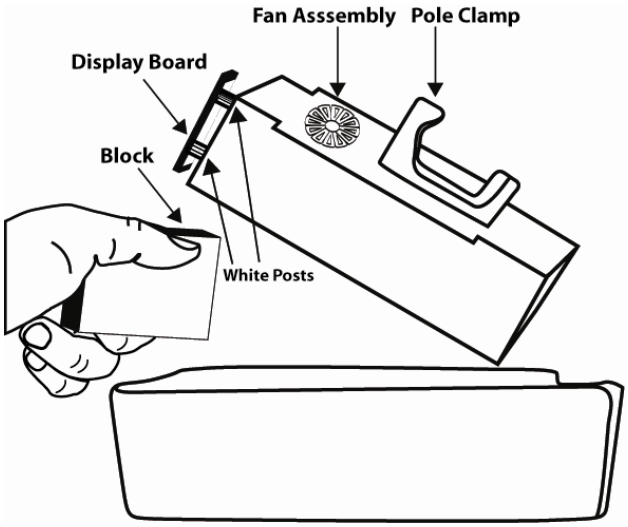


3. Power Assembly
   a. On the power supply assembly, unscrew 2 screws shown below (see **Diagram 5)**.
   b. Gently lift up assembly by holding pole clamp, and prop up with a small block or box (see **Diagram 6)**.

Diagram 5

Diagram 6

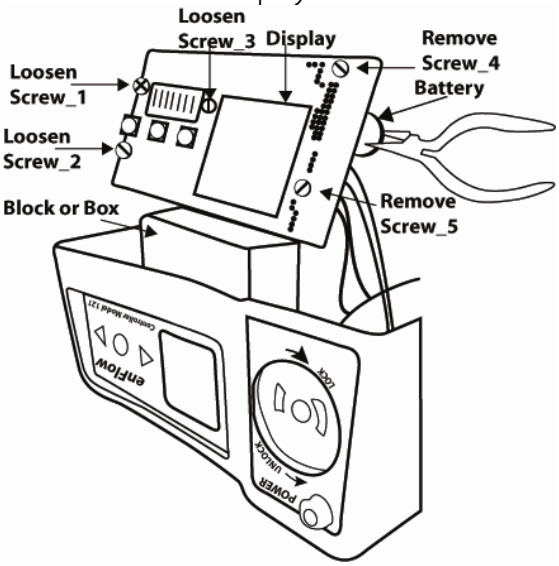




4. Display Panel

a. On the display panel remove the two screws (4 and 5) at the end of the panel next to the display screen (see **Diagram 7)**.
b. There are three other screws (1-3) that need to be loosened half-way on this panel.
c. Pull the display panel away from the fan assembly.
d. Take a pair of pliers and gently pull out battery.
e. Insert new battery. Push firmly into place.
f. Reinsert and tighten all screws on the display board

Diagram 7

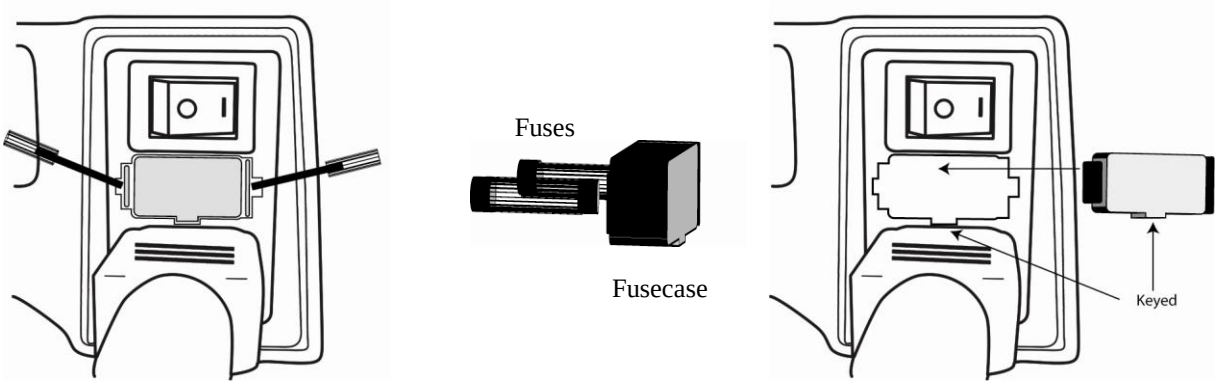


5. Reassembly

a) Reseat fan assembly and display board (see **Diagram 5)**.
b) When reseating display board, make sure that all wires are between the two white posts (see **Diagram 6)**.
c) When reseating the fan assembly on the display board end, make sure that the wires are **inside** the corner post_1 (see **Diagram 5)** and wrap around the edge of the fan assembly.
d) On the opposite end from the display board, make sure the wires go **around** the outside of the corner post_2 (see **Diagram 5)**.
e) Reinsert and tighten the 2 screws for the power assembly (see **Diagram 5)**.
f) Attach bottom cover; reinsert and tighten the six related cover screws (see **Diagram 3)**.
g) Reinsert pole clamp screw.
h) Dispose of the old battery in accordance with any government regulations in affect in your area.

Instructions for changing the Controller/AC Power Pack or AC Power Pack fuse.

1. Insert a screwdriver on either side of the fuse box and push gently to pop the fuse case out of its socket.



2. Pull the broken fuse out of the case.

3. Replace the fuse with (Bussmann #GDB 5A or equivalent). When reinserting the fuse case into the socket on the Controller, it is keyed so that it can only be inserted in the correct orientation. Push the case in gently, but firmly, until it snaps into place. At this point, it will be flush with the surrounding surface.

enFlow Fluid Warming System Temperature Control and Alarms

Temperature Control

The enFlow IV Fluid/Blood Warming System includes multiple safety features to prevent over-heating of infusion fluids. There are built in redundancies and back-up safety systems as means for protection in the event of a failure in the primary control mechanism. Several aspects of the system work together to accomplish desired and appropriate safety:

1. Closed-loop temperature control software
2. Audible and visual alarms
3. Software system monitor
4. Independent heater temperature monitoring circuit

Audible / Visual Alarms

The enFlow Warmer incorporates an audible/visual alarm system. This system monitors the fluid temperature for an over-temperature condition and system faults. The alarm function is tested each time a Cartridge is inserted. The audible alarm is briefly sounded, and the red light emitting diode indicator is also briefly illuminated. If a dangerous condition occurs, a continuous audible and visual alarm is activated. When used with the Model 121 Controller, the audible alarm will come from the Controller, and the display will identify the alarm condition. When the Warmer is used with Model 120 power supply, the temperature LED will flash and the audible alarm will come from the Warmer. Over-temperature conditions are calculated according to ASTM Standard F2172-02 (an FDA Recognized Standard for fluid warmers). This standard allows for spikes in the fluid temperature without activating an alarm. The alarm has a linear time-temperature relationship, therefore, the hotter the fluid the less time it will take for the alarm to be activated. At 45 ºC the alarm will sound after about 20 seconds while at 50 ºC it will be essentially instantaneous. The alarm will be activated by either the Warmer over-heating the fluid or if the fluid entering the Warmer is too hot. The audible aspect of the alarm can be muted for 1 minute by pressing any key on the Controller. The alarm can also be ended completely by sliding open the covers on the Warmer. (For further information, please reference test for Over-temperature Alarm located in Appendix F: Preventive Maintenance Procedure.

enFlow Troubleshooting

Electromagnetic Interference

- ECG, EEG or EMG (cardiac or neuro monitoring) artifact or other interference caused by the enFlow is an uncommon event.
- Cardiac or neuro monitoring interference is common and well documented in the medical literature.
- There are published suggestions to reduce or eliminate the interference which should be employed.

"Interference of the monitored or recorded electrocardiogram is common within operating room and intensive care unit environments."[1] The enFlow® IV Fluid / Blood Warmer System as with all electrical devices can be associated with some electromagnetic interference (EMI), however, it has been uncommon and inconsistently experienced, even within accounts reporting the issue.
On previous occasions when interference has been reported, we have frequently been successful in resolving the issue using common troubleshooting suggestions. Please review each and be prepared to implement them should an account voice a concern.

Interference Confirmation

Turn the unit off.
Turn the power supply on the back of the Controller/AC Power Pack to the OFF position. Reassess the inference. Knowing that cardiac or neuro monitoring is being affected determine if the interference adversely affects your ability to care for the patient. Consider attempting to reduce the level of interference by employing some simple and readily available solutions.

Interference Reductions

Check the monitoring pads
All monitoring pads should be full adhered to the patient's properly prepared skin. Please confirm that the pad's foam insulator is not curled up, peeled back or otherwise exposing the conductive gel layer. Confirm that the leadwires' connectors are properly and fully attached. Consider reapplying monitoring electrodes if there is any suspicion they have become dried out

Confirm the patient is properly grounded.
In many cases, and in all cases using mono-polar or bi-phase cautery a grounding pad should present and applied according to the manufacturers instructions. As previously suggested confirm the ground pad is fully adhered to a properly prepared skin surface.

Confirm the enFlow and the ECG monitor are plugged into different outlets
There are two reasons for this action. It is possible that the two systems are in an electrical phase related conflict and it is getting expressed on the monitor. Secondly, it is possible that the outlets are not properly grounded or grounded in different locations. While rare it can be the case and outwardly there would be no way to tell not even on most other equipment in use.

Confirm the warmer cord is not entwined or near the ECG lead cable.
Separating the two cords will allow each ones shielding to work to its full potential.

Confirm the monitoring cables and lead wires are in proper working order
The insulating layer on lead wires and cables degrades over time and with use. Please confirm that the insulation is intact and operates at its stated specifications.

Review the monitor's notch filter.
Check to ensure that the monitoring systems frequency filter is set appropriately.

Determine the monitor's sensitivity setting.
Many physiological monitors have the ability to interpret electrical signals in two distinct modes: a highly

[1] Patel, Santosh I. M.D., F.R.C.A. and . Souter, Michael J, M.B., Ch.B., F.R.C.A.; ***Equipment-related Electrocardiographic Artifacts, Causes, Characteristics, Consequences, and Correction***; Anesthesiology 2008; 108:138–48.

sensitive ‘Diagnostic” mode or a more filtered “Monitoring” mode. Determine the current mode of operation. If the current mode is set on “Diagnostic” consider adjusting it to “Monitoring”.

Check the ECG pads impedance.
Contact your current supplier of monitoring pads or your local GE Healthcare representative to determine if a lower impedance version is available. High impedance monitoring pads are less sensitive to the very low signal strength from the heart beat and appear to be more prone to pronounced interference.

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 IPX7 30 minutes immersion at a depth of 91.4 cm (36 in.); **Controller:** IEC 529 IPX1 dripping water; **Disposable Cartridge and (optional IV Extension Set):** IEC 529 IPX8 **IV Extension Set):** IEC 529 IPX8 continuous immersion
Penetration	**Warmer:** IEC 529 IP6X dust tight **Controller:** IEC 529 IP2X ≥ 12.5 diameter **Disposable Cartridge and (optional IV Extension Set):** IEC 529 IP6X dust **IV Extension Set):** IEC 529 IP6X 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/AC Power Pack 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/AC Power Pack into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer for help.

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

Clock Battery Specifications
Cell #..... CR2032
Classification..... Lithium Coin
Chemical System..... Lithium / Manganese Dioxide (Li/MnO2)
Designation..... ANSI / NEDA-5004LC, IEC-CR2032
Nominal Voltage..... 3.0 Volts
Typical Capacity..... 220 mAh

enErgy Battery Specifications
Voltage..... 28VDC
Capacity..... 3 A hrs.
Chemistry..... Li-ion

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 61000-4-3	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) 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

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 lowvoltage 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	100% Dip for 0.5 Cycle 60% Dip for 5 Cycles	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

	30% Dip for 25 Cycles >95% Dip for 5 Seconds	30% Dip for 25 Cycles See Note 1	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 61000-4-3	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) 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 IP2X ≥ 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: Warmer Fault Code Table

Warmer Fault Code Table Displayed on Controller/AC Power Pack		
#	**Name**	**Description**
10	Fluid out temperature sensor reading failure	Sensor is reading a temperature outside the normal operating range or has been determined to be open or shorted.
11	Fluid in temperature sensor reading failure	Sensor is reading a temperature outside the normal operating range or has been determined to be open or shorted.
12	Heater out temperature sensor reading failure	Sensor is reading a temperature outside the normal operating range or has been determined to be open or shorted.
13	Heater in temperature sensor reading failure	Sensor is reading a temperature outside the normal operating range or has been determined to be open or shorted.
20	Average VCC failure	Warmer internal operating voltage is out of range.
21	Average TRef failure	Warmer internal reference voltage is out of range.
30	RAM Memory Test Failure	Data is written to and then read from RAM and verified at power up.
31	ROM Memory Test Failure	A check sum is done on the memory at power up.
32	Flash Memory Test Failure	A check sum is done on the memory at power up.
40	OT Fuse or Low Battery Failure	This is a dual function failure. First, if the Warmer is powered either by the battery or the Controller/AC Power Pack and the output voltage is too low, this fault code will be activated. It is accompanied by a YELLOW power light on the Warmer. Second, if this fault code occurs while the Warmer is running from the Controller/AC Power Pack and the RED power LED is flashing, it is indicative of an Over- temperature fuse open circuited.
41	Covers Failure	This fault occurs every time the covers are opened while heating.
50	Heater MOSFET failure	Heater Control MOSFETs are checked to ensure that they are performing as commanded by the software. If the MOSFET does not respond as the software has commanded, this fault is generated.
51	Test failure	*Test purposes only*
52	Clock Oscillator failure	This fault is active if the external crystal oscillator fails.
53	Internal Temperature ˚C failure	This failure is indicative of it being too hot inside the Warmer and is caused by operating in an environment that is too warm.
54	Error Clock failure	A system clock failure has occurred.
99	General System Fault	The Controller/AC Power Pack is unable to determine the fault.

Appendix C: Glossary

enFlow IV Fluid/Blood Warming System	The enFlow IV Fluid/Blood Warming System consists of three products: the Warmer (Model 100 series), the Controller/AC Power Pack (Model 120 series), and the Disposable Cartridge (Model 200 series), which together form a system designed to warm intravenous fluids and blood products helping reduce hypothermic effects.
Warmer (Model 100 series)	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 series)	The Controller/AC Power Pack 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 series)	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 series)	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 D: 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 E: Parts List

980105VS	Warmer
980121EU	Controller
980200EU	Disposable cartridge
980202EU	Disposable cartridge with IV extension set
380304EU	enFlow warmer strap
980305VS	Warmer holder
980309VS	Warmer cord clip
980307	enCheck Alarm testing Tool
44000060	Service manual (electronic version only, not available in print)
44000108	Preventive Maintenance Record English (EN) (electronic version only, not available in print)
44000120	enCheck Users Guide English(EN)
91000178	Power cord USA
91000103	enFlow warmer battery and adapter
91000120	enFlow Power Pack AC 115-230 VAC
91000302	enErgy battery charger 115-230 VAC
91000123	enErgy I battery power pack
91000153	Warmer blood/fluid all inclusive kit
91000156	enFlow blood/fluid hospital kit
91000154	enFlow blood/fluid transport kit
44000024	Operator's manual (USA)
44000073	Instructions For Use German (DE)
44000074	Instructions For Use Danish (DA)
44000075	Instructions For Use Spanish (ES)
44000076	Instructions For Use Finnish (FI)
44000077	Instructions For Use French (FR)
44000078	Instructions For Use Italian (IT)
44000079	Instructions For Use Dutch (NL)
44000080	Instructions For Use Norwegian (NO)
44000081	Instructions For Use Swedish (SE)
44000084	Instructions For Use Turkish (TR)
44000092	Instructions For Use English (UK)
44000083	Instructions For Use Chinese (CN)
44000085	Instructions For Use Portuguese (PR)
44000108	Preventive Maintenance Record English (EN)
44000113	Instructions For Use Bulgarian (BG)
44000114	Instructions For Use Croatian (HR)
44000115	Instructions For Use Czech (CZ)
44000116	Instructions For Use Greek (GR)
44000117	Instructions For Use Polish (PL)
44000118	Instructions For Use Russian (RU)
44000119	Instructions For Use Serbian (RS)
44000120	enCheck Users Guide English(EN)
44000123	Instructions For Use Latvian (LV)
44000124	Instructions For Use Lithuanian (LT)
44000125	Instructions For Use Romanian (RO)
44000126	Instructions For Use Slovakian (SK)
44000127	Instructions For Use Slovenian (SI)
44000128	Instructions For Use Hungarian (HU)
44000140	Instructions For Use Estonian (EE)
91000178	Power Cord USA
91000170	Power Cord Continental Europe
91000172	Power Cord Great Britain
91000173	Power Cord Italy
91000174	Power Cord Israel
91000171	Power Cord Switzerland
91000175	Power Cord India
91000176	Power Cord Denmark
91000177	Power Cord South Africa
91000179	Power Cord China
91000180	Power Cord Australia
91000181	Power Cord New Zealand

Appendix F: Preventive Maintenance Record

Employ local regulations to determine the frequency of required testing (i.e. Earthing Impedance, Leakage Current) for the enFlow Warmer (Model 100), Controller/AC Power Pack (Model 121), and AC Power Pack.

	Frequency	
Functional and Operational Testing Protocols	**As required by accrediting body or once a year**	**As required by accrediting body or once every 5 years**
Inspections	x	
Temperature Readout Display and Status Indicator Lights	x	
Electrical Safety	x	
Simulated Use Performance Testing: enCheck Model 400 or alternate method		x
Alarm Test: enCheck Model 400 or alternate method		x

1. Functional and Electrical Procedure

Inspection

1. Ensure that all cords and connectors are in good condition and void of any cuts, cracks, or frays. Discoloration from cleaning solutions and disinfectants is normal and to be expected
2. Ensure that the unit is clean and void of any cracks or other signs of damage. If signs of damage are visible, remove it from service; and contact the service center as soon as possible.

Temperature Readout Display and Status Indicator Lights

1. Plug the Controller/AC Power Pack into a functioning power supply. Set the MAINS power to ON. Confirm the Controller/AC Power Pack power indicator is illuminated and displaying a "green" color. Confirm the display panel (Controller/AC Power Pack only) shows in yellow the conditional message "not heating."
2. Connect the Warmer without a Disposable Cartridge inside to the Controller/AC Power Pack. Confirm the "beep" signaling connection. Confirm the display (Controller/AC Power Pack only) continues to show the conditional message "not heating." Confirm the Warmer power LED is flashing green.

Electrical Safety Tests

1. Ground wire resistance

Equipment

enFlow Controller/AC Power Pack
Safety analyzer with test lead -

Purpose

The purpose of this test is to check the resistance in ohms of the ground pin to the chassis. For purposes of this check the pole screw will be considered to be the ground pin, and the chassis is the Controller.

Procedure

A. USA (Tests the equipment inclusive of its power cord.)

1. Remove the Controller/AC Power Pack off the IV pole.
2. Reinsert the pole clamp screw; screw in finger tight snug against the case. (Do not over-tighten.)
3. Attach the banana end of the ground lead on the safety analyzer to the pole clamp screw.

4. Plug the power cord of the Controller/AC Power Pack into the safety analyzer.
5. Set the function knob on the safety analyzer to Ground wire resistance.
6. Set the ground switch to normal.
7. Set the polarity switch to the off position.
8. Power the safety analyzer by plugging in and setting the MAINS power to ON.
9. Record the resistance reading. An acceptable reading is a maximum of 500.0 mΩ.

B. TUV (Tests the equipment exclusive of its power cord.)

1. Follow steps 1-3 in 1.3.2
2. Plug the cord of the safety analyzer into the Controller/AC Power Pack.
3. Follow steps 5-8 in Procedure A
4. Record the resistance reading. An acceptable reading is a maximum of 100.0 mΩ at a current of 25 A.

2. Leakage current at the AC power cord

Equipment

Safety analyzer with test lead
enFlow Controller/AC Power Pack

Purpose

This test is run to check the chassis leakage in microamps. For the purpose of this test the Controller/AC Power Pack is the chassis.

Procedure

1. Plug the power cord of the Controller/AC Power Pack into the safety analyzer.
2. Turn the knob on the safety analyzer to the chassis leakage function.
3. Power the safety analyzer by plugging in and setting the MAINS power to ON.
4. Record the polarity and ground readings for the Controller/AC Power Pack for both power on and off scenarios for the following configurations:

Allowable values of continuous LEAKAGE CURRENTS, in µA.		
ENCLOSURE LEAKAGE CURRENT	**TYPE BF**	
Normal polarity — normal ground	Normal Condition	100
Reverse polarity — normal ground	Single Fault Condition	500
Reverse polarity — open ground	Double Fault Condition	500
Normal polarity — open ground	Single Fault Condition	500

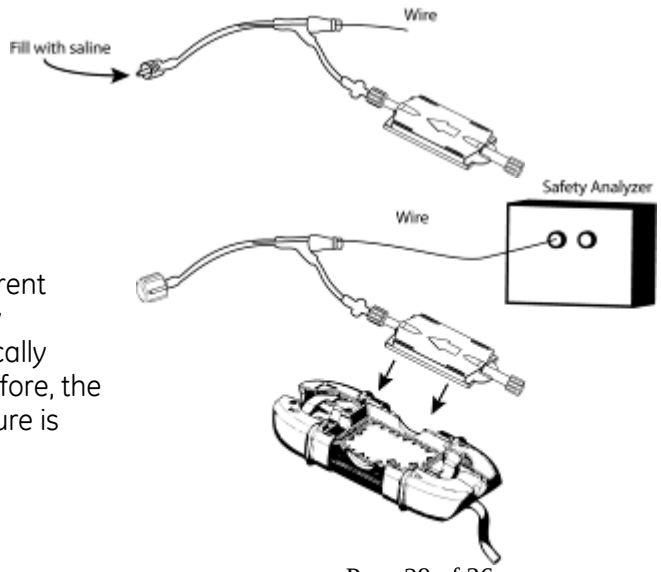
3. Leakage current of the Warmer to the saline in the IV line

Equipment

enFlow Warmer and Disposable Cartridge
Safety analyzer with ECG leads
Saline
Wire
Extension set with a non-venting cap

Purpose

The purpose of this test is to check the leakage of current from the Warmer into saline. As IV fluids are generally conductive, a fluid warmer is considered to be electrically connected to the patient similar to an ECG lead; therefore, the leakage needs to be tested. The setup for this procedure is described below.



Procedure

1. Leave the cap on the female end of the cartridge.
2. Put an extension set on the male end.
3. Insert a piece of wire into the extension set tubing.
4. Fill the cartridge and extension set tubing with saline. **Note:** it doesn't matter which way the wire is inserted into the tubing just be certain that the wire is in contact with the fluid.
5. Next, put a non-venting cap on the open end of the extension set.
6. Place the cartridge setup in the warmer.
7. Connect the ECG lead from the leakage tester to the wire inserted into the extension set tubing.
8. Perform the "ECG" lead leakage test.

Current	Normal	Single Fault
Earth leakage	5 mA	10 mA
Touch/chassis leakage	100 µA	500 µA
Patient leakage	100 µA	500 µA
From Table I. Leakage current limits (from IEC 60601-1).		

Functional Tests

1. enCheck Model 400

enCheck (includes "K" type probe.)
Thermal thermocouple meter with ± 5 °C accuracy
enFlow Controller/AC Power Pack (Model 121)
enFlow Warmer (Model 100)

Purpose

The enCheck Tester was developed to quickly and reliably trigger the over-temperature alarm condition on the enFlow Warmer. Within seconds, the enCheck unit will heat the Warmer to an over-temperature scenario causing the alarm to sound. Additionally, the enCheck is designed to verify the Warmer operation at the enFlow's installation site.

Procedure

A. Normal Mode – Simulated Use Performance Testing

When the enCheck is connected and running in the normal mode, the heat is generated from the warmer unit using the same technology as when a cartridge is installed. This mode allows for confirmation of the temperature output of the Warmer.

1. Plug the Controller/AC Power Pack into a hospital grade outlet.
2. Connect the enCheck to the Controller/AC Power Pack by inserting the male plug end of the enCheck Hubbell connector into the female receptacle on the front face of the Controller/AC Power Pack. Push it in so that the plug cover is tight against the receptacle.
3. Next, connect the Warmer to the enCheck by inserting the male plug end of the Warmer into the enCheck female receptacle.
4. Take the temperature probe connector on the enCheck and insert into a thermometer. Set thermometer to "K" type setting.
5. Insert the enCheck unit into the Warmer. The end of the unit is keyed similar to the Cartridge so it will only fit in the correct orientation. Close the covers.
6. Confirm the enCheck is set to the normal mode.
7. Move the MAINS power switch on the back of the Controller/AC Power Pack to the ON position. Wait for the thermometer to stabilize, ≈ 30 to 60 sec. assuming all equipment is close to 20 °C.
8. The temperature on the thermometer should be 40 °C ± 2 °C.

B. Overheat Mode – Alarm Test

When operated in the overheat mode, the heat is generated from the contact plate on the underside of the enCheck unit. The enCheck heats the Warmer to > 45 °C. This temperature range simulates an over-temperature situation demonstrating the functionality of the alarm (audible, LED's, and display (Controller only).

1. Setup is the same as in the above steps 1-7 with the exception of step 4. Skip step 4. (In the Overheat mode, it is only important to review the temperature of the Warmer, which is displayed on the Controller/AC Power Pack front panel. This circumstance obviates the need for the thermometer on this test.)
2. Always run in the **normal mode** first before switching to the overheat mode.
3. Next, switch to the overheat mode.
4. Displayed temperatures of > 42 °C are shown in Yellow, indicating above normal conditions as well the Temperature LED on the Warmer will move to Yellow. This is visual alarm indication to a potential over temperature condition.
5. After reaching temperatures of 45 °C, the Warmer LED will blink red, temperatures shown on the Controller display will be in Red, and the audible alarm will sound.
6. Move the MAINS power switch on the back of the Controller/AC Power Pack to the OFF position.
7. Open the Warmer covers and carefully remove the enCheck. Use caution as the surface of the contact plate on the underside of the enCheck may still be hot.

2. Alternate Methond – Simulated Use Performance Testing

Equipment

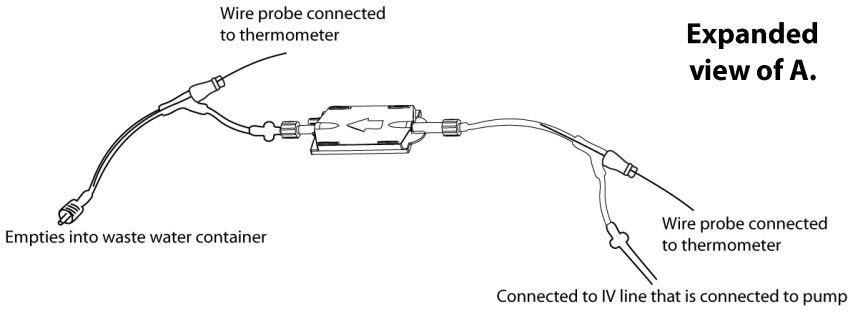
enFlow system
Power source
Infusion pump capable of maintaining up to 200 mL/min
IV line set
Water Bath
Source of distilled water or normal fluid - 0.5 L at 20 °C ± 2.0 °C
2 Extension sets - 22.9 cm (9 in.)
Thermometer - capable of measuring 10 °C to 60 °C accurate to ± 0.1 °C, plus 2 external "K" probes
Timer
Waste water container

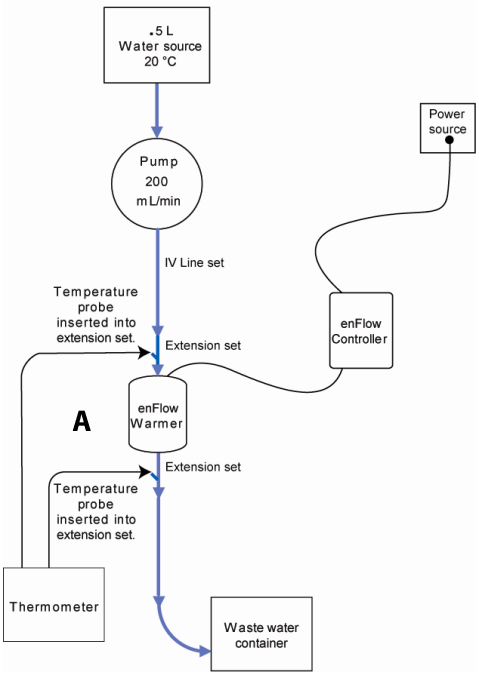
Alternative equipment

Graduated cylinder, 100 to 500 mL.

Purpose

This test is performed to ascertain that the output fluid temperature of the enFlow Warming System, while using a 22.9 cm (9 in.) extension set, is 40 °C ± 2.0 °C when the input fluid is 20 °C through the flow rates of 25-100 mL/min. Additionally, it is run to determine that the rise in fluid temperature is >16.5 °C when the input fluid is 20 °C utilizing flow rates of 100-200 mL/min.





Procedure

Measure Input and Output Temperatures of Fluid

1. Set up the enFlow system for normal operation. (See Operator's Manual "To Begin Operation of the enFlow IV Fluid/Blood Warming System".)
2. Attach an IV line set to a 0.5 liter source of fluid at a temperature of ≈ 20 °C ± 2 °C. Then run the IV line through a pump capable of maintaining up to 200 mL/min. or determine flow rate using the graduated cylinder and timer.
3. Next, attach the IV line to the enFlow system.
4. The temperatures for this test should be measured within 22.9 cm (9 in.) of both the input and output connections of the Disposable Cartridge. This step is done by inserting T connectors in the direct fluid paths, which will accommodate a temperature probe. Connect the temperature probes to a thermometer capable of measuring between 10 °C and 60 °C with ± 0.1 °C accuracy.
5. Prime the IV line setup according to standard IV protocols.
6. Remember to confirm that the output end of the extension set empties into the waste water container.
7. Power on the enFlow system, and establish a fluid flow of 100 ± 20 mL/min. Then allow at least 20 seconds for the power-on self-test to complete, the temperature display to read a stable temperature, and for the temperature probes to stabilize.
8. Record the input fluid temperature. The acceptable temperature range is 20 °C ± 2.0 °C.
9. Record the output fluid temperature. The acceptable temperature range is 40 °C ± 2.0 °C.
10. It is recommended to repeat steps 1-9 for the flow rate of 60 ± 2.0 °C.

High Flows

11. Repeat steps 1-7 for the high flow rates of 125± 20 mL/min, 175 ± 20 mL/min, and 200 mL/min.. However, in place of steps 8 and 9, measure the *rise* in temperature of the output fluid over the input fluid value. The rise should be >16.5 °C.

3. Alternate Method – Alarm Test

Equipment

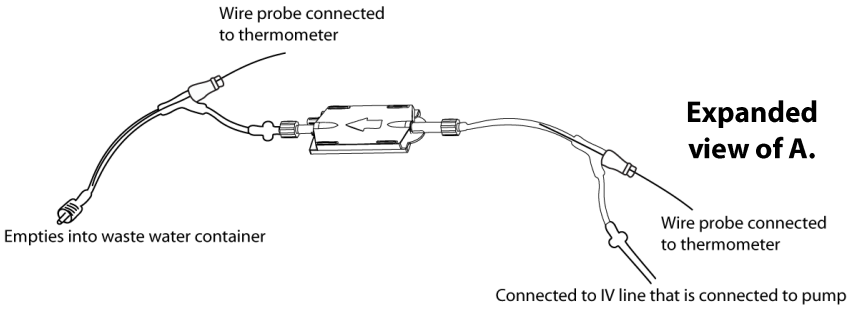
enFlow system
Power source
Infusion pump capable of maintain up to 100 mL/min
IV line set
Water bath
Source of distilled water or normal fluid – 0.5 L at 50 °C ± 2.0 °C
2 Extension sets - 22.9 cm (9 in.)
Thermometer - capable of measuring 10 °C to 60 °C accurate to ± 0.1 °C, plus 2 external probes
Waste water container

Purpose

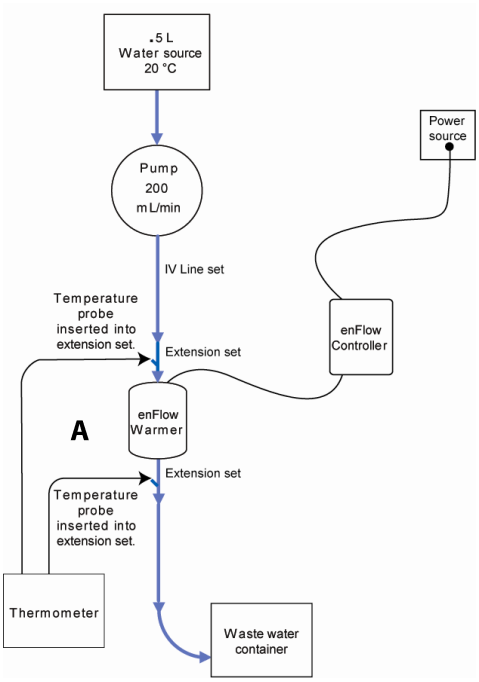
The purpose of this test is to determine that the over-temperature alarm on the Warmer is working properly.

Procedure

1. Use the performance testing setup described in steps 1-5 above.
2. Use a clamp to stop the flow in the IV line.



Expanded view of A.



3. Change the source fluid's temperature to 50 °C ± 2 °C. Take extra care while working with hot fluids.
4, Power on the enFlow system
5. Allow at least 20 seconds for the power-on self-test to complete and the temperature display to ready a stable temperature. Confirm all LEDS are illuminated green.
6. Release the clamp, and establish a fluid flow of 100 ± 20 mL/min.
7. With the thermometer, confirm the temperature of the fluid at both the input and output end of cartridge.
8. The Over-Temperature alarm sounds within approximately 20 seconds or less of the output fluid temperature reaching that of the input fluid level.

A. Confirm the Controller/AC Power Pack produces an audible beep and displays a red "Over-Temp" message on the display (Controller only).

B. Confirm the temperature LED on the Warmer flashes red indicating that the fluid has gone over-temperature.

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Warmer Serial No.	Controller Serial No.	Visual Inspection Free of Visible Damage (circle)	Display Operation (circle)	LED Operation (circle)	Electrical Safety Check Ground Wire Resistance (circle)	Estimated Leakage Current at the AC Power Cord (circle)	Estimate Leakage Current of the Warmer to the saline in the IV Line (circle)	enCheck Performance (circle)	enCheck Over Temp (circle)	enCheck Alternate Alarm Text (circle)	Initial and Date
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	