enFlow®

IV fluid and blood warmer

System manual

About this manual

This 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 System 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 Customer Service or Technical Support for assistance:

Customer Service	Technical Support
E-mail: gmb-medspec-custservice@carefusion.com Phone: 1.800.323.9088, option 1	Phone: 1.973.956.5431

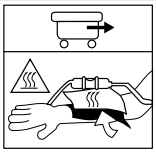
Manufactured for
Vital Signs, Inc. a GE Healthcare Company
20 Campus Road
Totowa, New Jersey 07512, USA

EC REP GE Medical Systems SCS
283 rue de la Miniere,
78530 Buc, France

Symbols used on the equipment

The following symbols may be viewed on 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	LATEX 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
STERILIZE	Do Not Re-Sterilize		Do Not Use if Package is Damaged
	Caution		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	Temperature Range		Effect or action in both directions towards a reference point (Close)
DEHP	Not made with Di(2-ethylhexyl) phthalate		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
IP31	Degree of protection provided by enclosure, no ingress of object > 2.5 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		Surface may be hot
	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.
XX	System Fault XX		Low Battery
	Lock or Password Required		Unlock
	Do Not Throw in Trash	CE	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).
c ETL us Intertek 4005716	Intertek 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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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 4 m of the patient when the device is in use to enable visualization 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 Bussmann® part #S500-5-R or equivalent.
- The Disposable Cartridge should not be used for more 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.
- Do not connect the enCheck® to an enFlow system while it is in any way connected to a patient.

Cautions

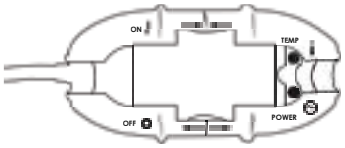
- Follow the AABB "Guidelines for the Use of Blood Warming Devices" (© 2006) which caution against warming when administering platelets, cryoprecipitate, or granulocyte suspensions.
- Some drugs or drug preparations may be sensitive to warming. As with any fluid or blood warming system, carefully review 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.
- Warmer Strap (980304VS30) may be used with the Warmer for transport purposes only, such as field use (for the military) and inter-hospital transport and ambulatory circumstances. Do not strap for non-transport scenarios.
- 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 (defined as >22% O_2).
- No modification of this equipment is allowed.
- Do not position the device in a way that makes it difficult to disconnect the device.
- 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 (Appendix F) should be performed at least once a year, or as required by your accrediting body.
- The enCheck is to be used only with the enFlow Warmer and Controller.
- Do not touch the enCheck contact plate surface during or immediately after use since it may be very hot.
- The warmer and controller may be a potential biohazard during or after use. Handle and dispose of in accordance with acceptable medical practice and applicable regulations at the end of their life.

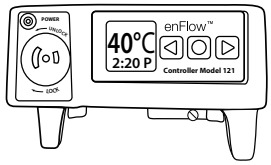
enFlow IV fluid/blood warming system description

The enFlow IV fluid/blood warming system consists of the enFlow Warmer (Model 100 series), the enFlow Controller (Model 121 series), the enFlow Disposable Cartridge with IV extension set (Model 202) or without IV extension set (Model 200). Within seconds, this warming system delivers normothermic infusate to the patient at flow rates of Keep Vein Open (KVO defined as 2 mL/min) to 200 mL/min when input fluid temperature is 20 °C.

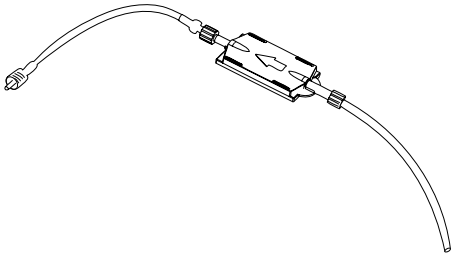
The Warmer is the reusable heating unit designed to work in conjunction with the Disposable Cartridge. Two multicolored light emitting diode (LED) indicators on the Warmer indicate its power status and the fluid/blood infusate temperature. The infusate within the Disposable Cartridge is warmed when in 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, not made with natural rubber latex or DEHP. 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.



Indications 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.

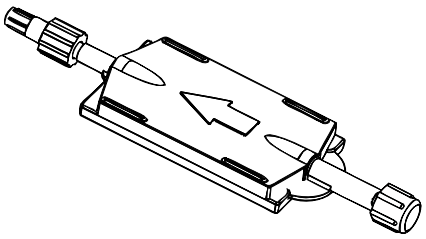
Clinical and training information

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.

Unpacking the enFlow IV fluid/blood warming system

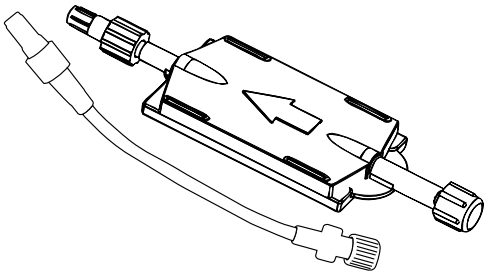
Upon receipt of the enFlow IV fluid/blood warming system components, visually inspect the shipping containers and internal contents for damage that may have occurred during shipment. If there is any visible or mechanical damage to the contents, or if the order is incomplete, please contact Customer Service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

- Model 100
  - Warmer
  - Warmer Cord Clip
  - IV Line Clip
  - USB Manual
  - Patient Leakage Report
  - Certificate of Conformance
- Model 121
  - Controller
  - Patient Leakage Report
  - Warmer Mount (Warmer Mount Instructions)
  - USB Manual
- Model 200
  - Disposable Cartridge
  - IFU



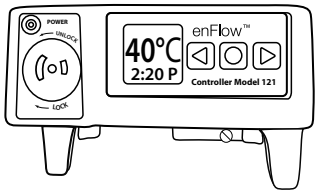
Model 202

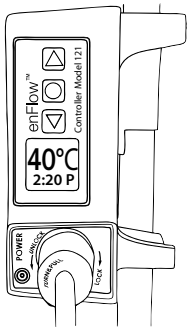
- Disposable Cartridge with IV extension set
- IFU

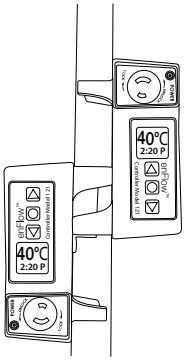


To begin operation of the enFlow IV fluid/blood warming system

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.





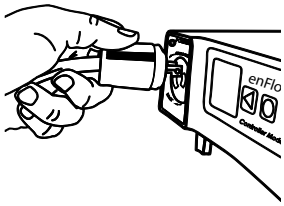


b. Plug the Controller into a hospital grade outlet.

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. (Please refer to the "enFlow Controller (Model 121 series) indicators and operations" section for directions to set the clock).

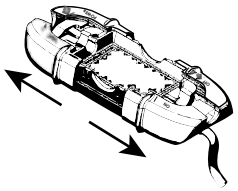
d. Connect the Warmer cable to the Controller. This action is accomplished in three steps:

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.



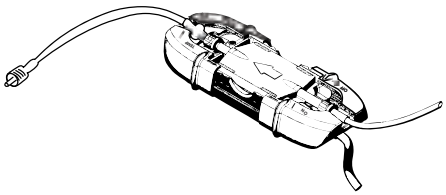
2. The plug and receptacle are keyed in both orientation and configuration. This feature ensures that the Warmer can only be plugged in properly. Additionally, it prevents other plug devices from fitting into this receptacle.
3. Turn right to lock. (See arrows on label.)

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 100, 115, or 240 VAC (100-240 VAC).

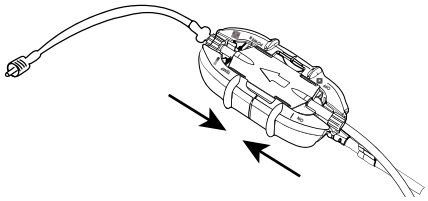


f. Open the covers on the Warmer by sliding them apart.

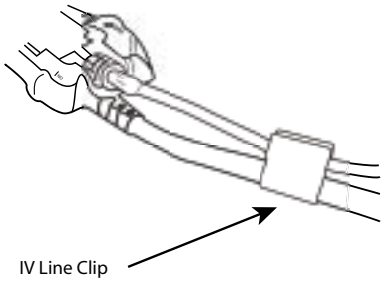
g. Connect the infusion set and/or extension set to the Disposable Cartridge; then prime with fluid using standard medically approved protocols. Next, connect the infusion set to the patient and place the Disposable Cartridge into the Warmer.



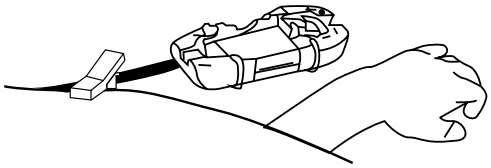
h. Completely close the covers on the Warmer by pressing down on the cartridge and sliding the covers inward toward each other until they meet. Upon closing the covers, a short audible beep occurs indicating that the Warmer self-test is being performed and confirms operation of temperature sensors and 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.



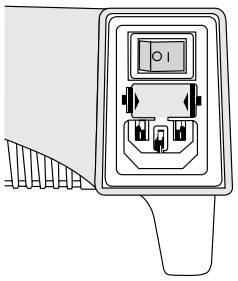
j. The Warmer is designed to be placed on the bed and/or attached to patient coverings in close proximity to the site of infusion using the cord clip P/N 980309VS-20. Cushion the patient from the Warmer to aid in the prevention of perioperative peripheral neuropathies or heat-related dermal injury.



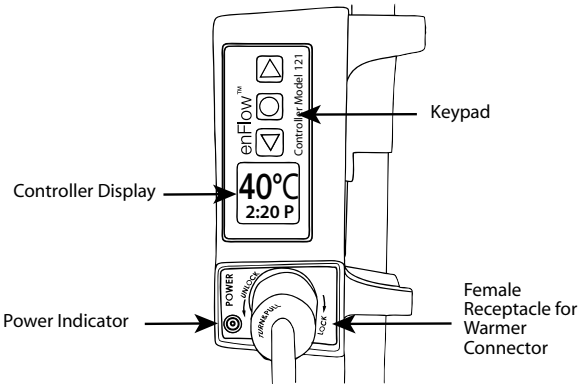
k. Do not wrap the Warmer in towels, sheets, blankets or drapes.

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 121 series) indicators and operation



Controller (Model 121 series)—setup instructions

1. Set the clock
   a. To modify the initial default mode of the Controller, press the center button 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 display default mode to symbols (International Mode)
   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. The password is 781.
   c. An underscore will display under the first digit field. Press the arrow key to set the appropriate digit.
   d. Next, press the center key again to toggle to the next place.
   e. 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.
   f. 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.
   g. Press the center key again to set. The system begins to operate.
   h. After the initial setup, whenever the Controller is powered on, the display screen defaults to the last mode entered.

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 tables:

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 temperature 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, Cartridge 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 temperature LED
Mute button activated	Over Temp Muted	Identical to Warmer temperature LED
Fault detected	System Fault XX If a system fault message is on the Controller display, refer to the system fault section Appendix B or 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).

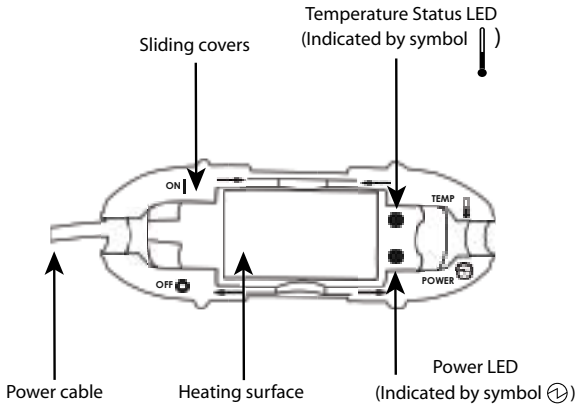


Table 4: Warmer indicator status							
Status	Warmer covers	Disposable cartridge	Power LED indicator	Temperature LED indicator	Audible indicator	Description	Action required
Ready	Open or closed	None	Flashing Green every 3 seconds	Unlit	None	Warmer unit has power, but is not heating	None
Device power up	Closed	In place	Red ½ second duration	Red ½ second duration	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 °C should only be entered periodically during changes in flow rate or infusate temperature.
In operation	Closed	In place	Flashing Red	N/A-Varies	Continuous audible bursts	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 bursts	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 by 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.)
  - Abrasive cleaners

- Do not sterilize the Warmer with:
  - Steam sterilization (autoclave)
  - 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:

- 40% bleach sodium hypochlorite and 60% water solution
- Isopropyl alcohol
- Clorox® Bleach Germicidal Wipe
- Cidex® OPA
- CIDEX® Glut
- CaviWipes®
- Super Sani-Cloth®
- Sani-Cloth® HB
- Sani-Cloth® AF

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. Be sure to wipe clean the orange heating surface regularly. If the heating surface starts to grey or if the controller displays a system fault 50, thoroughly clean with isopropyl alcohol and inspect for damage to the heating surface.
4. Rinse thoroughly with distilled water. Do not immerse the Warmer's electrical plug connector.

Drying

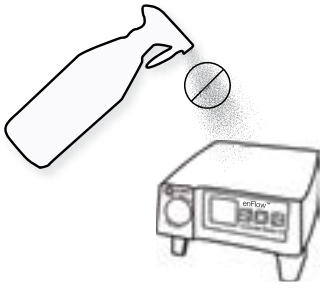
1. After cleaning, dry completely before placing back into use.
2. If disinfecting is required, dry completely before disinfecting so that the disinfecting solution will not be diluted.

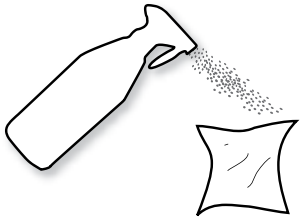
Disinfecting

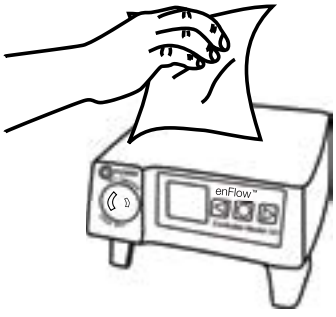
1. The enFlow Warmer may be disinfected using commercially available solutions with no greater than 2.4% glutaraldehyde and by following the solution manufacturer's recommendations. (Refer to list in Cleaning Section, above.)
2. Soak the Warmer in the disinfectant solution according to the manufacturer's 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)

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 system uses current Surface Mount Technology (SMT) and materials. If a System Fault error occurs, then remove the device from service and refer to the table in Appendix B for proper evaluation and handling. Do not return the device or place it back into service unless it has been cleaned per the instructions above and evaluated by a trained technician using the instructions in Appendix E and Appendix F. If the unit stops working properly, contact Customer Service to obtain an Return Goods Authorization (RGA) number prior to returning the unit to Vital Signs. If damage has occurred to the heating surface, immediately remove it from service.

RGA number

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 unit will be shipped to you within 48 hours. (If the product is no longer under warranty, the Customer Advocacy Representative will discuss replacement options.) You will be issued a RGA number. You will be instructed to return the product in sufficient packaging to prevent damage in transit, clearly marking the RGA number on the outside of the box. The return address will be provided to you.

Warmer (Model 100 series)

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

Controller (Model 121 series)

See "Servicing the enFlow IV fluid/blood warming system components" below for information on user serviceable parts inside the Controller. Check the fuses located in the outside power entry module if the Controller fails to function. The power cord must be removed to do this.

Replaceable parts for the Controller:

- Clock battery (See below for replacement instructions)
- Fuse – Bussmann #S500-5-R or equivalent (See below for replacement instructions)
- Cover
- Screws
- Pole clamp screw
- Power cord
- Warmer mount

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

Instructions for replacing the Controller clock battery

Clock Battery Specifications	
Cell #	CR2032
Classification	Lithium Coin
Chemical System	Lithium / Manganese Dioxide (Li/MnO_2)
Designation	ANSI / NEDA-5004LC, IEC-CR2032
Nominal Voltage	3.0 Volts
Typical Capacity	220 mAh

1. Turn Controller over.

Diagram 1

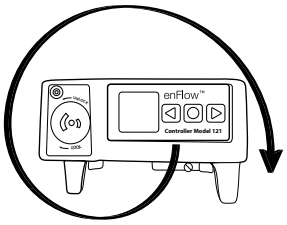
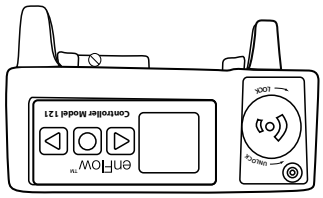


Diagram 2



2. To remove the bottom, unscrew pole clamp screw; unscrew six (6) screws shown below. Next, lift the cover.

Diagram 3

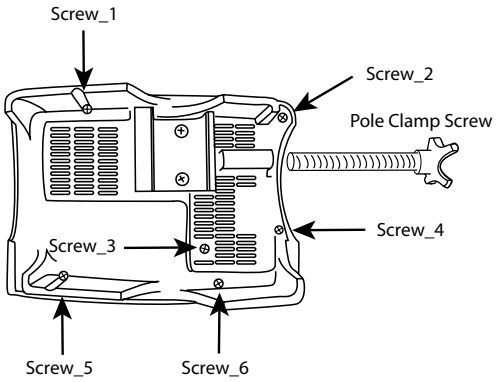
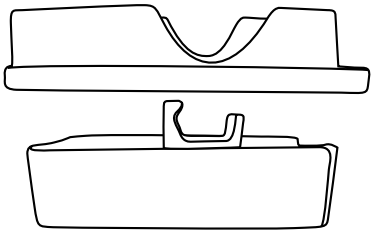


Diagram 4



3. Remove power supply assembly
   a. On the power supply assembly, unscrew two (2) screws shown below (see Diagram 5). Also remove the screws holding the zip ties to the post for the ferrite bead securement.
   b. Gently lift assembly by holding pole clamp, and prop up with a small block or box (see Diagram 6).

Diagram 5

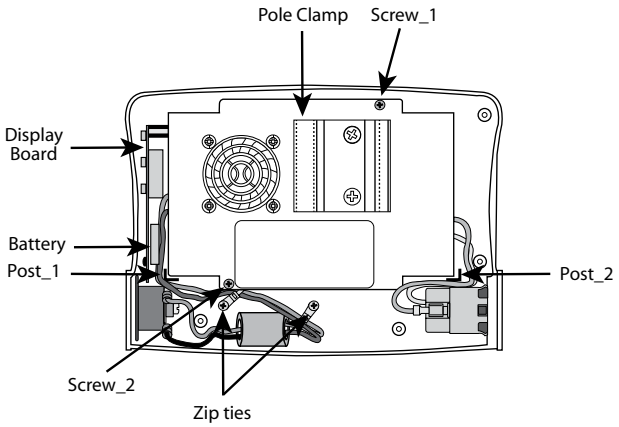
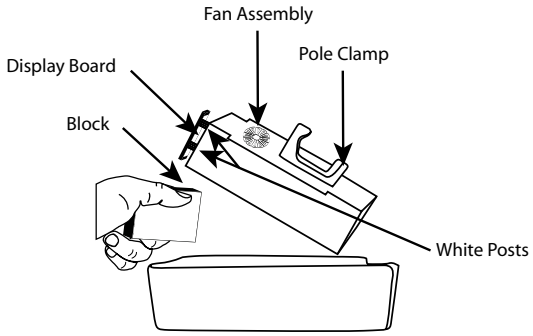
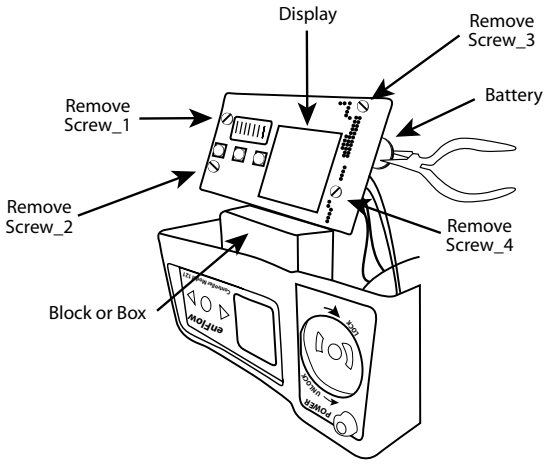


Diagram 6



4. Remove display panel
    a. On the display panel, remove the four (4) screws at the end of the panel next to the display screen (see Diagram 7).
    b. Pull the display panel away from the fan assembly.
    c. With pliers, gently pull out battery.
    d. Insert new battery in the same direction as the old battery. Push firmly into place.
    e. Reinsert and tighten all screws on the display board.

Diagram 7

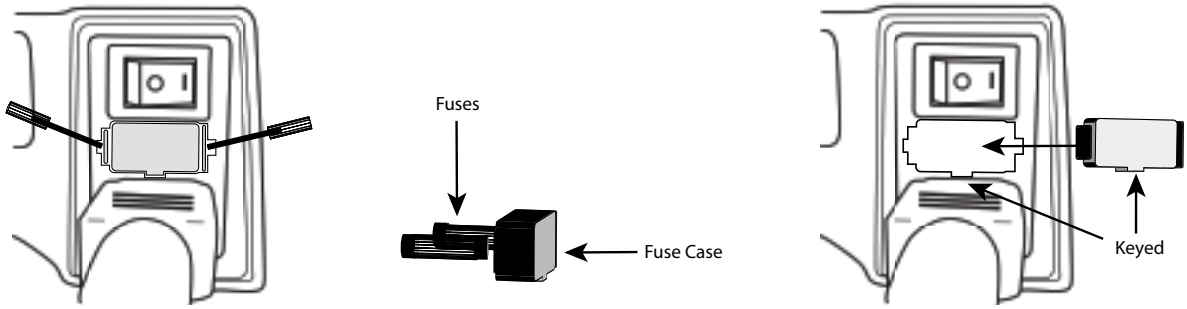


5. Reassembly
    a. Reseat fan assembly and display board (see Diagram 5).
    b. When reseating display board, make sure that all wires are between the two white posts (see Diagram 6).
    c. When reseating the fan assembly on the display board end, make sure that the wires are inside the corner post_1 (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.
    e. Reinsert and tighten the two (2) screws for the power assembly (see Diagram 5).
    f. Reinstall the two screws for the zip ties that were taken apart in step 3a.
    g. Attach bottom cover; reinsert and tighten the six (6) related cover screws (see Diagram 3).
    h. Reinsert pole clamp screw.
    i. Dispose of the old battery in accordance with any government regulations in effect in your area.

Instructions for changing the Controller fuse

Note ✍: Remove power cord before inserting screwdriver.

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 fuse out of the case.
3. Replace the fuse with (Bussmann #S500-5-R or equivalent). The socket in the Controller is keyed so that the fuse case 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 overheating 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 system 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. 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 E: 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 medical literature.
- There are published suggestions to reduce or eliminate the interference that 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 warming system, as with all electrical devices, can be associated with some electromagnetic interference (EMI); however, it has been uncommon and inconsistently experienced. Below are troubleshooting suggestions for situations where interference is observed:

Interference confirmation

Turn the unit off. Turn the power supply on the back of the Controller to the OFF position. Reassess the interference. 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 reduction steps

Check the monitoring pads

All monitoring pads should be fully adhered to the patient's properly prepared skin. 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 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 be present and applied according to the manufacturer's instructions. As previously suggested, confirm the ground pad is fully adhered to a properly prepared skin surface.

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[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.

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, which is being 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.

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

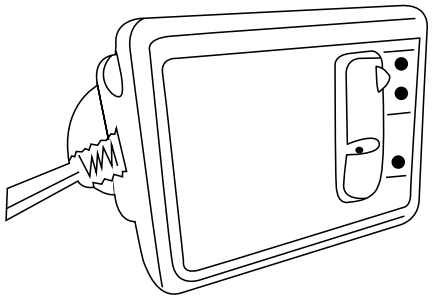
Confirm the monitoring cables and lead wires are in proper working order
The insulating layer on lead wires and cables degrades over time and with use. Confirm the insulation is intact and operates at its stated specifications.

Review the monitor's notch filter
Check to ensure that the monitoring system's 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 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 Vital Signs 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.

enCheck (Model 400) user guide



Intended use

Use this product only for the purpose for which it was designed; refer to product description below.

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 enFlow's installation site.

Procedure

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. (See Appendix E, section on "Simulated Use Performance Testing.")

enCheck system description

The enCheck is designed to verify the Warmer operation at enFlow's installation site. In the Normal Mode, it allows for confirmation of the temperature output of the Warmer. In the Overheat Mode, it heats the Warmer to an over-temperature scenario causing the alarm to sound.

There are three LEDs on the enCheck.

1. Lighted Orange LED indicates the power is on.
2. Lighted Green LED indicates the enCheck is in the Normal Mode.
3. Lighted Red LED indicates the enCheck is in the Overheat mode.

There is a slide switch for switching the overheating on/off.

There is a thermocouple adapter for connecting to a calibrated thermometer for verification.

Environmental Requirements	Performance
Operating Temperature Range: -5 ˚C to 40 ˚C	Input Voltage: 12-30 V--- 0.5A
Storage Temperature Range: -30 ˚C to 70 ˚C	Maximum of 14 W
Relative Humidity Range: 10% to 90%	

Cleaning the enCheck

1. Use only approved cleaning solutions. (Please reference "Cleaning the enFlow IV fluid/blood warming system components" for a list of approved cleaning solutions.)
2. Moisten a clean cloth with the cleaning solution; do not spray or pour cleaning solutions directly onto the enCheck.
3. Wipe the surface of the enCheck, taking care not to leave excess residual cleaner on the enCheck. If fluid ingress is detected, set the enCheck aside for an extended period of time to allow it to dry.

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 1.75 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: 121 mm L x 10.6 mm W (4.7 in L x 0.4 in W)
Weight	Warmer (w/o disposable): 330 g (11.6 oz) Controller: 1.9 kg (4.2 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 (2 mL/min) - 200 mL/min
Input Voltage	Warmer: 28.5 VDC at a maximum of 350 Watts Controller: 100-240 VAC
Temperature Set Point	40 °C
Over Temperature Set Point	ASTM F-2172-02
Alarms	IEC60601-1-8:2006
Max 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 IP31 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 IP31 ≥ 2.5 mm diameter Disposable Cartridge (and optional IV extension set): IEC 529 IP68 dust, (IV extension set): IEC 529 IP68 dust tight
Electrical Safety	CAN/CSA-C22.2 No. 60601-1:2008 Ed 03, AAMI ES60601-1:2005, IEC 60601-1:2005 Ed 03, IEC 60601-1 -6:2010 Ed 3 and IEC 60601-1-8: 2006 Ed 2.
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)
Radiated Magnetic Field Emissions	EMC IEC 60601-1-2:2014
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 warming system has been tested and found to comply with the limits for medical devices as set forth in IEC 60601-1-2: (2014) 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.

Guidance and Manufacturer's Declaration – Emissions		
The enFlow 100 with enFlow 121 is intended for use in the electromagnetic environment specified below. The customer or user of the enFlow 100 with enFlow 121 should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions Radiated CISPR 11	Group 1, Class A	The enFlow 100 with enFlow 121 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 121 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 121 is intended for use in the electromagnetic environment specified below. The customer or user of the enFlow 100 with enFlow 121 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 121 requires continued operation during power mains interruptions, it is recommended that the enFlow 100 with enFlow 121 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: During the 5 second event, the enFlow 100 and 121 power off, but return to normal operation as soon as power is restored.			

Guidance and Manufacturer's Declaration – Emissions			
The enFlow 100 with enFlow 121 is intended for use in the electromagnetic environment specified below. The customer or user of the enFlow 100 with enFlow 121 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 121 by no less than the distances calculated/ listed below where P is the max power in watts and D is the recommended separation distance in meters: 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 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 121 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the enFlow 100 with enFlow 121 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the enFlow 100 with enFlow 121 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

Appendix B: Warmer fault code table

Warmer Fault Code Displayed on Controller		
#	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 fault code is indicative of a non-recoverable heater over-temperature, fuse open, condition.
41	Covers failure	This fault occurs every time the covers are opened while heating.
50	Heater MOSFET failure or Circuit Breaker Trip	This fault code is indicative of a Heater Over-temperature protection fault.
52	Clock oscillator failure	This fault is activated if the external crystal oscillator fails.
53	Internal temperature ˚C failure	This failure is indicative of the Warmer being too hot inside 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 is unable to determine the fault.

Please follow these instructions if any of the fault conditions listed above are displayed on the controller:

1. Thoroughly clean the warmer using the instructions provided in this manual (refer to section titled "Cleaning the enFlow IV fluid/blood warming system components.")
2. Evaluate the exterior of the device. If there is any physical damage to the housings or power cord that would allow fluid ingress into the device, or if the heating element surface is physically damaged, deformed, or breached, then remove the device from service and return the device using the RGA instructions provided in this manual (refer to "Servicing the enFlow IV fluid/blood warming system components.")
3. If there is no obvious physical damage to the device, then evaluate the device using the instructions in Appendix E and Appendix F.
4. If the device passes the evaluation, then it may be returned to normal use.

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

Part number	Part	Part number	Instructions For Use
980105VS	Warmer	44000024	System Manual (USA)
980105INT	Warmer (International)	44000073	Instructions For Use German (DE)
980121EU	Controller	44000074	Instructions For Use Danish (DA)
980121VSD	Domestic only controller	44000075	Instructions For Use Spanish (ES)
980105VSD	Domestic only warmer	44000076	Instructions For Use Finnish (FI)
980121INT	Controller (International)	44000077	Instructions For Use French (FR)
980122VS	Controller (Japan)	44000078	Instructions For Use Italian (IT)
980200EU	Disposable Cartridge	44000079	Instructions For Use Dutch (NL)
980202EU	Disposable Cartridge with IV extension set	44000080	Instructions For Use Norwegian (NO)
980202INT	Disposable Cartridge with IV extension set (International)	44000081	Instructions For Use Swedish (SV)
980305VS	Warmer holder	44000083	Instructions For Use Chinese (ZH-S)
980309VS-20	Warmer cord clip	44000084	Instructions For Use Turkish (TR)
980400	enCheck alarm testing tool	44000085	Instructions For Use Portuguese (PT)
91000178	Power Cord USA	44000113	Instructions For Use Bulgarian (BG)
91000170	Power Cord Continental Europe	44000114	Instructions For Use Croatian (HR)
91000172	Power Cord Great Britain	44000115	Instructions For Use Czech (CS)
91000173	Power Cord Italy	44000116	Instructions For Use Greek (EL)
91000174	Power Cord Israel	44000117	Instructions For Use Polish (PL)
91000171	Power Cord Switzerland	44000118	Instructions For Use Russian (RU)
91000175	Power Cord India	44000119	Instructions For Use Serbian (SR)
91000176	Power Cord Denmark	44000123	Instructions For Use Latvian (LV)
91000177	Power Cord South Africa	44000124	Instructions For Use Lithuanian (LT)
91000179	Power Cord China	44000125	Instructions For Use Romanian (RO)
91000180	Power Cord Australia	44000126	Instructions For Use Slovakian (SK)
91000181	Power Cord New Zealand	44000127	Instructions For Use Slovenian (SL)
980304VS30	Insulated Strap	44000128	Instructions For Use Hungarian (HU)
		44000140	Instructions For Use Estonian (ET)
		44000141	Instructions For Use Korean (KO)
		44000142	Instructions For Use Japanese (JA)
		44000143	Instructions For Use Traditional Chinese (ZH-T)

To order the parts below, call the respective manufacturer.

Part number	Part /manufacturer
458-M101L	Mega Electronics Locking Power US power cord
S500-5-R	Fuse – Bussmann®
CR2032	Battery – Panasonic®

Appendix E: Preventive maintenance procedure

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

	Frequency
Functional and Operational Testing Protocols	As required by accrediting body or once a year
Inspections	X
Temperature Readout Display and Status Indicator Lights	X
Electrical Safety	X
Simulated Use Performance Testing: enCheck Model 400 or Alternative Method	X
Alarm Test: enCheck Model 400 or Alternative Method	X

Inspections

1. Ensure 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 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 Vital Signs as soon as possible.

Temperature readout display and status indicator lights

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

Electrical safety

1. Ground wire resistance

Equipment

enFlow Controller
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 from the IV pole.
2. Reinsert the pole clamp screw; screw in tight 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 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 Procedure A.
2. Plug the cord of the safety analyzer into the Controller.
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

Purpose

This test is run to check the chassis leakage in microamps. For the purpose of this test, the Controller is the chassis.

Procedure

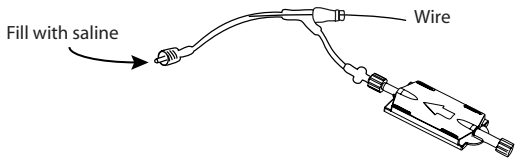
1. Plug the power cord of the Controller into the safety analyzer.
2. Turn the knob on the safety analyzer to the chassis leakage function.
3. Power the safety analyzer by plugging in and setting the MAINS power to ON.
4. Record the polarity and ground readings for the Controller for both power on and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

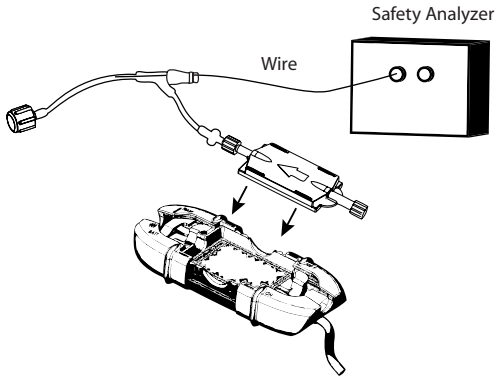
Equipment

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 Disposable Cartridge.
2. Put an extension set on the male end.
3. Insert a piece of wire into the extension set tubing.
4. Fill the Disposable 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 Disposable 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.

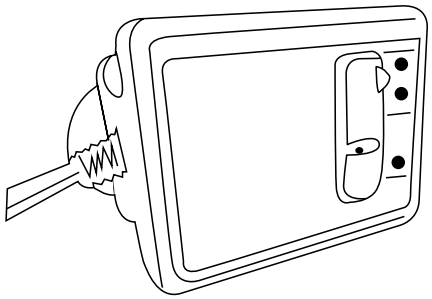
Current	Normal	Single Fault
Earth leakage	5 mA	10 mA
Touch/chassis leakage	100 µA	500 µA
Patient leakage	100 µA	500 µA
From Table I. Leakage current limits (from IEC 60601-1)		

Simulated use performance testing

A. enCheck Model 400

Equipment

enCheck (includes K type probe)
Thermal thermocouple meter with ± 5 °C accuracy
enFlow Controller (Model 121)
enFlow Warmer (Model 100)



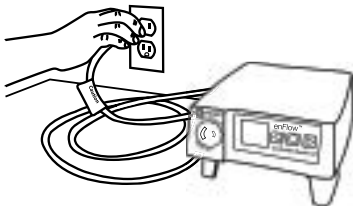
Purpose

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 enFlow's installation site.

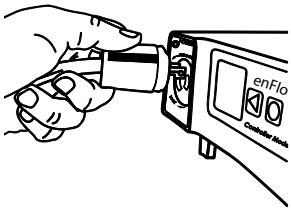
Procedure

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.

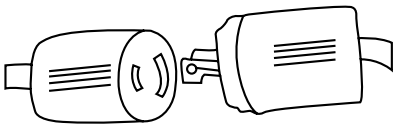
1. Plug the Controller into a hospital grade outlet.



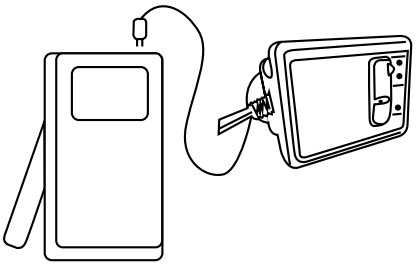
2. Connect the enCheck to the Controller by inserting the male plug end of the enCheck Hubbell connector into the female receptacle on the front face of the Controller. Push it in so that the plug cover is tight against the receptacle.



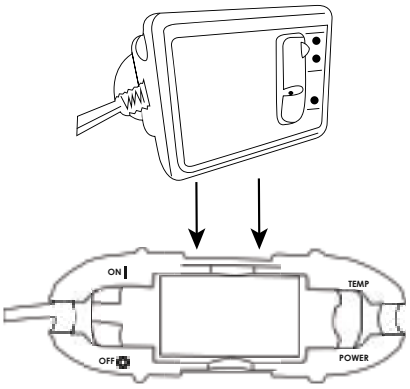
3. Next, connect the Warmer to the enCheck by inserting the male plug end of the Warmer into the enCheck female receptacle.



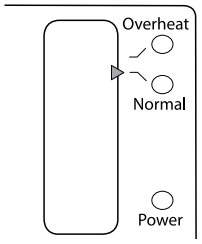
4. Insert the temperature probe connector on the enCheck into a thermometer. Set thermometer to "K" type setting.



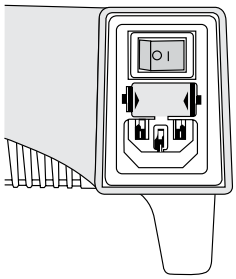
5. Insert the enCheck unit into the Warmer. The end of the unit is keyed similar to the Cartridge so it will only fit in the correct orientation. Close the covers.



6. Confirm the enCheck is set to the normal mode.

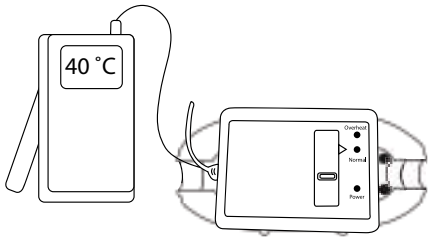


7. Move the MAINS power switch on the back of the Controller to the ON position. Wait for the thermometer to stabilize, ≈ 30 to 60 sec. assuming all equipment is close to 20 °C.



8. The temperature on the thermometer should be 40 °C ± 2 °C.

Note ✍: If the temperature in step 8 above is not 40 °C ± 2 °C, take the Warmer unit out of service. Call Customer Service for an RGA. Please reference the RGA section in "Servicing the enFlow IV fluid/blood warming system components" for further information regarding returns.



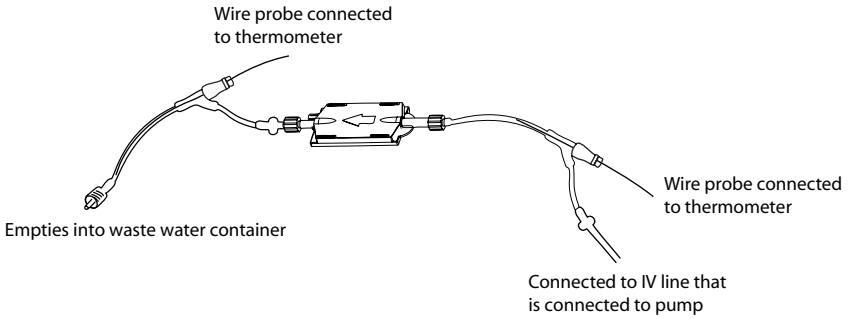
B. Alternative method

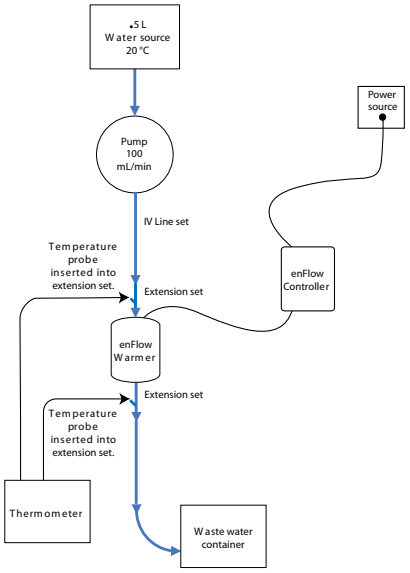
Equipment

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 type-K isolated probes
Timer
Waste water container
Graduated cylinder, 100 to 500 mL

Purpose

This test is performed to ascertain that the output fluid temperature of the enFlow 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 (Standard Flows). 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 (High Flows).





Procedure

Measure input and output temperature of fluid: standard flow

1. Set up the enFlow system for normal operation.
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. Confirm 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 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 mL a minute.

Measure input and output temperatures of fluid: 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.

Alarm test

A. enCheck Model 400

1. enCheck Model 400 (includes "K" type probe)
2. enFlow Controller/AC Power Pack (Model 121)
3. enFlow Warmer (Model 100)
4. Calibrated Thermometer with ± 0.5 °C accuracy (Fluke 54 or equivalent)

Test procedure

Alarm function test:

1. Plug the enFlow Controller into an AC outlet.
2. Confirm that the switch on the enCheck is set to the normal mode.
3. Connect the enCheck to the enFlow Controller, by inserting the male plug end of the enCheck Hubbell connector into the female receptacle on the front face of the enFlow Controller. Push in and twist the enCheck Hubbell connector so that the plug cover is locked snugly against the receptacle.
4. Connect the enFlow Warmer to the enCheck by inserting the male plug end of the Warmer into the female receptacle of the enCheck. Push the plugs together and twist to lock them snugly against each other.
5. Insert the enCheck temperature probe connector into the Calibrated Thermometer and set the Thermometer to "K" type setting.

6. Insert the enCheck unit into the Warmer so the bottom end of the unit is keyed similarly as the Warmer Cartridge, so that it only fits in the correct orientation (curved section on the left side), and close the Warmer covers.
7. Switch the Main power switch on the back of enFlow Controller to the ON or | position.
8. Verify that the Orange "power" LED indicator is illuminated on the enCheck.
9. After waiting, for approximately 30 to 60 seconds, confirm the temperature on the Calibrated Thermometer is reading in the range of 40 °C ± 2 °C, and that the Green "Normal" LED on the enCheck is illuminated.
10. Disconnect the enCheck temperature probe connector that is connected to the Calibrated Thermometer.
11. Place the Switch on the enCheck to the "Overheat" position and verify that the Red "Overheat" LED is illuminated on the enCheck.
12. At this time, observe the enFlow Controller display until the temperature rises to greater than 45 °C; the controller display should be Red and the audible alarm should sound, the Green "TEMP" LED on the enFlow Warmer should also have changed from a solid Green to a flashing Red.
13. Place the Switch on the enCheck to the "Normal" position and re-connect the enCheck temperature probe connector to the Calibrated Thermometer.
14. Verify the LED and display indicators are red. Monitor the temperature on the Calibrated Temperature meter and on the enFlow Controller display; the temperature will gradually drop, and as it falls below 45 °C, the Controller display and the Warmer LED should change state from Red to Yellow. Verify that the Warmer LED and the Controller display indicators change to yellow as the temperature transitions through the 44 °C and 43 °C temperature window; the Controller indicators and the LED will return to green as soon as the temperature drops to 42 °C and will remain green, until the temperature drops to below 35 °C.

B. Alternative method

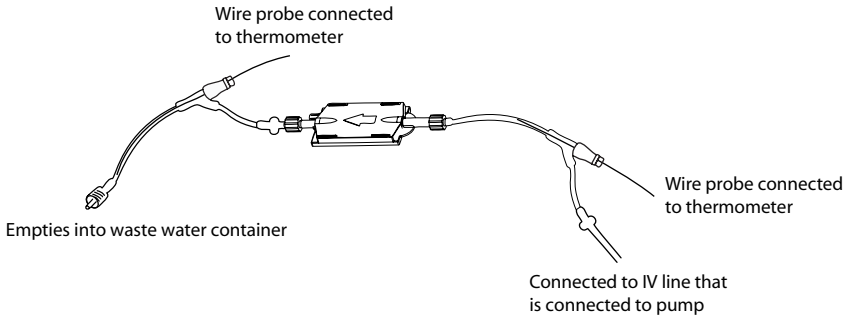
Equipment
enFlow system
Power source
Infusion pump capable of maintaining up to 100 mL/min
IV line set
Water bath
Source of distilled water or normal fluid – 0.5 L at 50 °C ± 2.0 °C
2 extension sets - 22.9 cm (9 in)
Thermometer - capable of measuring 10 °C to 60 °C accurate to ± 0.1 °C, plus 2 external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

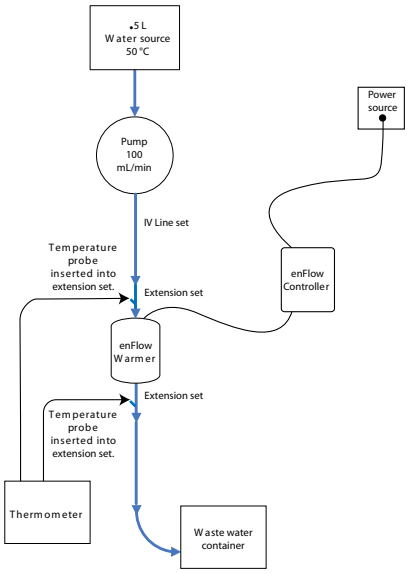
Purpose

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

Procedure

1. Use the Simulated Use Performance Testing- Alternative Method setup described in steps 1-5 above.
2. Use a clamp to stop the flow in the IV line.





3. Change the source fluid 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 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.

Preventative Maintenance Checklist

Warmer Serial No.	Controller Serial No.	Visual inspection (circle)	Temperature Readout Display(circle)	Status Indicator Lights (circle)	Electrical Safety- Ground Wire Resistance (circle)	Electrical Safety- Leakage Current (circle)	Electrical Safety- Leakage Current of the Warmer to the Saline in the IV Line (circle)	Simulated Use Test (circle)	Alarm Test (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	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	
		Pass Fail	Pass Fail	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	Pass Fail NA	

Appendix F: enFlow IV fluid/blood warming system operational checklist—alternative method

Warmer Serial No _____ Controller Serial No _____

Warming system location/identifier _____

Date _____

Procedure Instructions	Pass/Fail	Input Temp	Output Temp
Inspection Ensure all cords and connectors are in good condition and void of any cuts, cracks, or frays.			
Ensure 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 Preventative Maintenance Procedure (Appendix E) for the specific procedures in order to perform the tests listed above.

Appendix G: enFlow IV fluid/blood warming system operational checklist—enCheck Model 400 method

Warmer Serial No _____ Controller Serial No _____

Warming system location/identifier _____

Date _____

Procedure Instructions	Pass/Fail	Temperature
Inspection Ensure all cords and connectors are in good condition and void of any cuts, cracks, or frays.		
Ensure units are clean and void of any cracks or other signs of damage.		
Performance Test Setup Plug the Controller into a hospital grade outlet. Connect the enCheck to the Controller by inserting the male plug end of the enCheck Hubbell connector into the female receptacle on the front face of the Controller. Push it in so that the plug cover is tight against the receptacle. 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. The temperature on the thermometer should be 40 °C ± 2 °C.		
Record the temperature.		
Over-Temperature Alarm Check Plug the enFlow Controller into an AC outlet. Confirm that the switch on the enCheck is set to the normal mode. Connect the enCheck to the enFlow Controller, by inserting the male plug end of the enCheck Hubbell connector into the female receptacle on the front face of the enFlow Controller. Push in and twist the enCheck Hubbell connector so that the plug cover is locked snugly against the receptacle. Connect the enFlow Warmer to the enCheck by inserting the male plug end of the Warmer into the female receptacle of the enCheck. Push the plugs together and twist to lock them snugly against each other. Insert the enCheck temperature probe connector into the Calibrated Thermometer and set the Thermometer to "K" type setting. Insert the enCheck unit into the Warmer so the bottom end of the unit is keyed similarly as the Warmer Cartridge, so that it only fits in the correct orientation (curved section on the left side), and close the Warmer covers. Switch the Main power switch on the back of enFlow Controller to the ON or I position. Verify that the Orange "power" LED indicator is illuminated on the enCheck. After waiting, for approximately 30 to 60 seconds, confirm the temperature on the Calibrated Thermometer is reading in the range of 40 °C ± 2 °C, and that the Green "Normal" LED on the enCheck is illuminated. Disconnect the enCheck temperature probe connector that is connected to the Calibrated Thermometer. Place the Switch on the enCheck to the "Overheat" position and verify that the Red "Overheat" LED is illuminated on the enCheck. At this time, observe the enFlow Controller display until the temperature rises to greater than 45 °C; the controller display should be Red and the audible alarm should sound, the Green "TEMP" LED on the enFlow Warmer should also have changed from a solid Green to a flashing Red.		
Record the temperature.		
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 Preventative Maintenance Procedure (Appendix E) for the specific procedures in order to perform the tests listed above.

Appendix H: Glossary

enFlow IV fluid/blood warming system	The enFlow IV fluid/blood warming system consists of three products: the Warmer (No. 980105VS), the Controller (No. 980121EU), and the Disposable Cartridge (No. 980202EU/980200EU), which together form a system designed to warm intravenous fluids and blood products to reduce hypothermia.
Warmer (Model 100)	The Warmer is a small, lightweight, robust fluid warmer that heats blood, blood products, and intravenous fluids to 40 ºC from flow rates of KVO to 200 mL/min.
Controller (Model 121)	The Controller displays a temperature readout in degrees C, and features a keypad, to control the clock and the mute feature. Additionally, it converts AC line power to 28.5 Volts DC, and is used as a power source for the Warmer.
Disposable Cartridge (Model 200)	The sterile, single-patient-use Disposable Cartridge is used as an in-line component of an IV infusion set to heat fluids/blood being administered to the patient's body.
Disposable Cartridge with IV extension set (Model 202)	The Disposable Cartridge with IV extension set contains the same Disposable Cartridge described above. In addition, it includes a sterile, single-patient-use IV extension set.
Intravenous fluids	Fluids such as Normal Saline, Dextrose, Dextron, Packed RBC's
enCheck Model 400	enCheck alarm testing tool
KVO	Keep Vein Open refers to an intravenous infusion rate defined as approximately 2 mL/min (121 mL/hr).
LED	Light Emitting Diode
mL/min	Milliliters per minute
RBCs	Packed Red Blood Cells