enFlow

IV Fluid / Blood Warming System

Preventive Maintenance Record

Serial No. _____

⚠ Please consult Operator's Manual for Equipment Symbol List

Vital Signs
a GE Healthcare Company

imagination at work

Employ local regulations to determine the frequency of required testing (i.e. Earthing Impedance, Leakage Current) for the enFlow Warmer (Model 100), Controller (Model 121), and AC Power Pack (Model 120).

	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

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 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 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/AC Power Pack.
   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 Procedure A

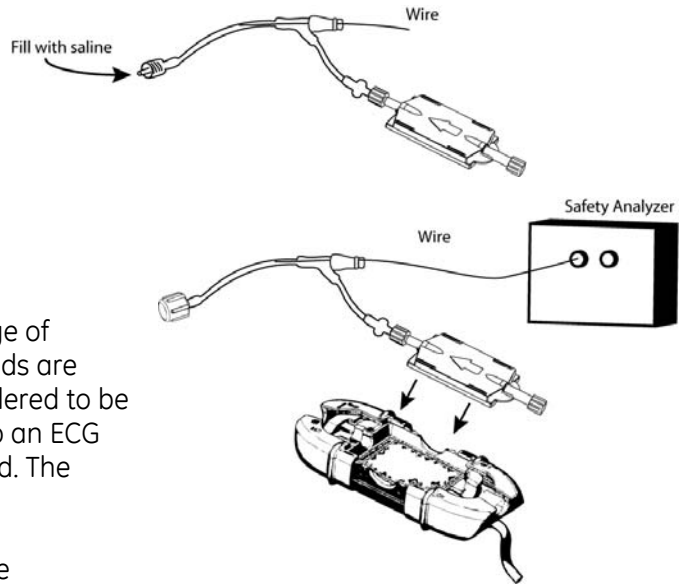
2. Plug the cord of the safety analyzer into the Controller/AC Power Pack.
3. Follow steps 5-8 in Procedure A
4. Record the resistance reading. An acceptable reading is a maximum of 100.0 mΩ at a current of 25 A.

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



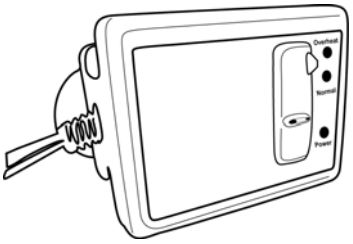
Equipment
enFlow Warmer and Disposable Cartridge
Safety analyzer with ECG leads
Saline
Wire
Extension set with a non-venting cap
Purpose
The purpose of this test is to check the leakage of current from the Warmer into saline. As IV fluids are generally conductive, a fluid warmer is considered to be electrically 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**



Equipment
enCheck (Includes "K" type probe.)
Thermal thermocouple meter with ± 5 °C accuracy
enFlow Controller/AC Power Pack
enFlow Warmer
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. Temperatures of > 42 °C are shown in Yellow on the Controller display and Warmer Temp LED indicating above normal conditions. These are visual alarms alerting 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 Method - Simulated Use Performance Testing

Equipment

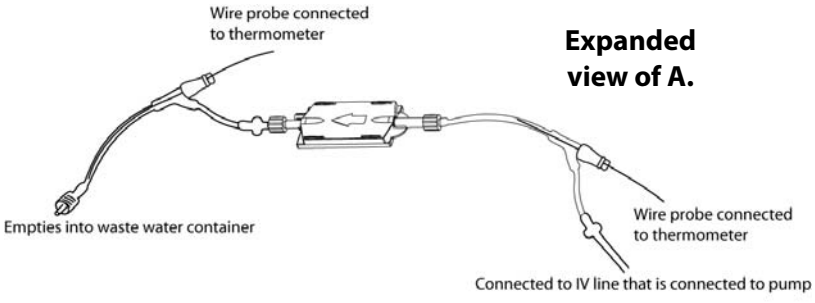
enFlow system
Power source
Infusion pump capable of maintaining up to 200 mL/min
IV line set
Water Bath
Source of distilled water or normal fluid - 0.5 L at 20 °C ± 2.0 °C
2 Extension sets - 22.9 cm (9 in.)
Thermometer - capable of measuring 10 °C to 60 °C accurate to ± 0.1 °C, plus 2 external "K" type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

Alternative equipment

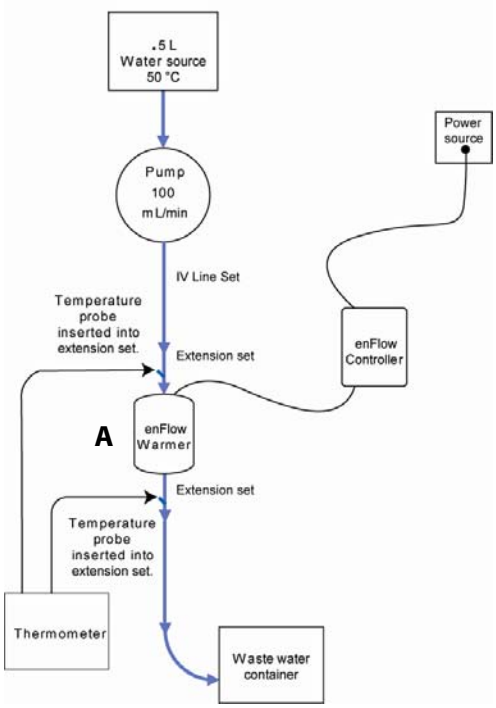
Graduated cylinder, 100 to 500 mL.

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.



Expanded view of A.



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 maintained 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 ± 20 mL/min.

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

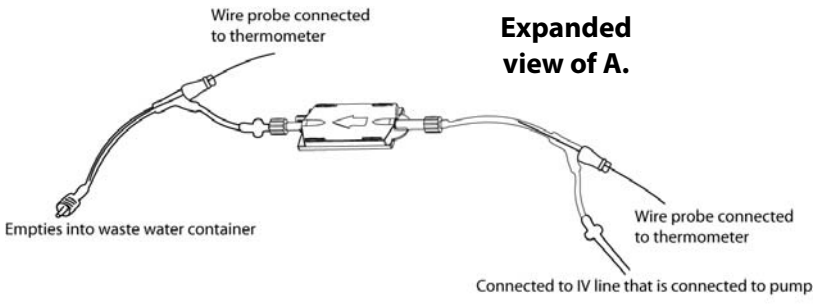
enFlow system
Power source
Infusion pump capable of maintaining up to 100 mL/min
IV line set
Water Bath
Source of distilled water or normal fluid - 0.5 L at 50 °C ± 2.0 °C
2 Extension sets - 22.9 cm (9 in.)
Thermometer - capable of measuring 10 °C to 60 °C accurate to ± 0.1 °C, plus 2 external probes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

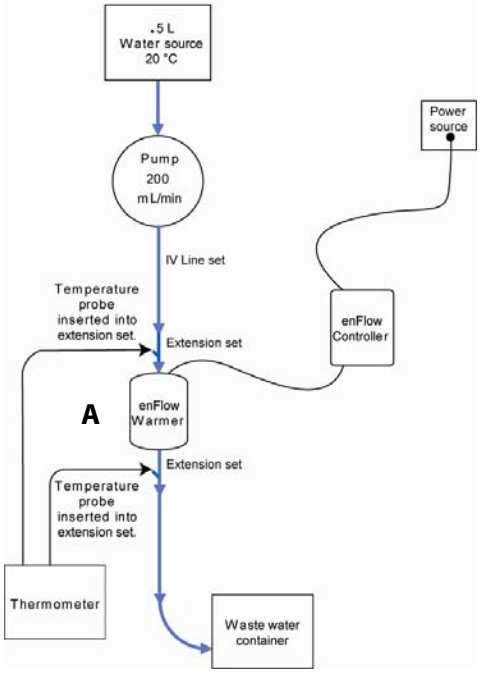
Purpose

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

Procedure

1. Use the performance testing setup described in steps 1-5 above.





2. Use a clamp to stop the flow in the IV line.
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 read 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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enFlow IV Fluid/Blood Warming System Operational Checklist

Warmer Serial No_____ Controller or AC Power Pack Serial No_____

Warming System Location/Identifier_____ Date:

Test	Pass/Fail or Recorded Value	Date & Initials	Pass/Fail or Recorded Value	Date & Initials	Pass/Fail or Recorded Value	Date & Initials	Pass/Fail or Recorded Value	Date & Initials
Inspections								
Temp readout display and LED's								
Electrical Safety								
enCheck Alarm								
enCheck Temperature Output								
Alarm								
Performance								
Comments								