

# enFlow\* IV Fluid/Blood Warming System

## FAQs

What is enFlow? How does it work? What makes it different from other fluid warming systems? We know you've got questions. We have answers.

**1. How close to the patient may the warming unit be placed?**

The enFlow warmer can and should be placed as close as possible to the patient without being in contact unless insulated from the patient. This will minimize heat loss between the output of the warmer and the infusion site. As with almost all other devices containing magnets, we recommend that the warmer be placed at least 6 inches from a pacemaker.

**2. How does the warming unit function?**

The enFlow warmer warms with dry, electrical-resistance heating. The design couples a thin, flexible heater in the body of the warmer to a relatively high mass, finned aluminum plate in the single-use cartridge. The heater is kept in tight contact with the kapton by mechanical pressure from the sliding warmer covers -- rather than by the variable fluid pressure of the IV solution or blood being infused as with other warmers, allowing consistent heating.

**3. Does your design have any "Hot Spots"?**

No, our special gel-like material covering in the warmer molds itself to the surface of the heater for uniform thermal contact. Our product's efficiency and responsiveness is further enhanced because of the high heat conductivity ratio of our aluminum heat transfer plate, in contrast to some products that transfer heat less efficiently from a plate through plastic.

**4. How does the enFlow system protect against overheating?**

The warmer contains two, independent over-heating protectors. Redundant temperature sensors ensure fluid temperature, accuracy, and reliability. Continuous internal diagnostics monitor essential components and system parameters when heating fluid/blood. Additionally, an audio/visual alarm is activated when fluid reaches a temperature of 45°C. A more detailed technical explanation of the safety features and electronic safeguards can be provided for BioMed if needed.

**5. Does the enFlow warmer meet AABB requirements for blood warmers?**

The AABB (American Association of Blood Banks) and CAP (College of American Pathologists) require that blood warmers be FDA-cleared, properly maintained, and equipped with special features such as a visible thermometer and audible alarm so that use of the system does not result in damage to the blood component that is being warmed. The enFlow system complies with these guidelines.

**6. What evidence exists that the enFlow system will not damage blood?**

The warmer has been tested successfully for hemolysis with packed red blood cells by the U.S. Army's Walter Reed Institute for Blood Research. The hemolysis and related data generated by the Army were also reviewed by the FDA as part of the 510(k) clearance process for the enFlow product. Additionally, a recent evaluation of PRBC quality after using the enFlow system for warming blood and its components by the Institute of Hematology and Transfusion Medicine verified these earlier findings.



**7. When transfusing blood, how often should the cartridge be changed?**

The disposable cartridge should not be used for greater than 24 hours and must be used in compliance with local hospital policy.

**8. Can I use enFlow with a blood filter?**

There are no prohibitions against placing a filter in-line but keep in mind that almost anything placed in-line will increase systemic resistance. Increases in resistance can result in a decrease in flow rates delivered to the patient. The enFlow cartridge is tested to 100 PSI.

**9. We normally only warm patients that are receiving 1 liter or more of fluid or procedures of an hour or longer. What is recommended?**

Warming protocols are up to the discretion of each hospital, but according to Sessler and Kurz in "Mild Perioperative Hypothermia," patients lose up to 1.5° C during the first hour of anesthesia and the infusion of 1 liter at room temperature can consume up to 24% of a person's warming capacity. That same study also infers that it is better to maintain normothermia -- rather than try to rewarm a hypothermic patient.

**10. Is warming perioperatively worth the additional steps and change to workflow?**

According to the Association of Registered Nurses (AORN), a patient that receives preoperative continuous warming before the induction of anesthesia will be more likely to remain normothermic throughout the care journey. This is because actively-warmed patients do not need to do as much core-to-peripheral redistribution of body heat. Studies have shown that 1–2 hours of pre-warming prevent intraoperative hypothermia, even in unwarmed patients undergoing prolonged abdominal surgery, and laboratory studies suggest that as little as 30 minutes of pre-warming can provide clinical benefit. enFlow allows caregivers to start the warming process early with few additional steps or changes to current workflow. To see how enFlow works across this workflow, visit the See enFlow in Action tool.

**11. How long does it take for enFlow to meet its temperature set point?**

Testing has shown that it takes enFlow 14 seconds or less to achieve 37°C when fluid is infused at a rate of 75 ml/min and 18 seconds or less for fluid infused at a flow rate of 150 ml/min. Testing was performed using a 9" extension set and 20°C distilled water.<sup>4</sup>

**12. What are your recommendations regarding secondary/extension tubing length when considering heat loss potential?**

Based on the size and design of the enFlow warmer, it can be placed extremely close to the patient to reduce the potential for fluid cooling in the IV line. A study conducted by Bissonnette et al. was designed to determine the effect of various infusion rates, length of extension tubing and fluid composition on the temperature of the infusate warmed by a fluid warmer -- and subsequently flowing to the distal end of the administration system. Charts demonstrating the temperature of fluid at 20cm intervals within the IV tubing can be found in the study. This report may be accessed here: <http://www.springerlink.com/content/t16pp6m2w15t8532/fulltext.pdf>.

**13. How do you recommend minimizing kinking of the IV or extension tubing immediately proximate and distal to the warmer?**

The enFlow warmer cord has an IV line clip attached to it that allows the user to lace the IV line to the cord in order to prevent it from kinking. To minimize kinking of the IV line coming out of the warmer, it is recommended that the enFlow warmer be laid flat in bed with the patient and that the IV line be allowed to sit, uncovered, by the patient.



**14. How do you recommend positioning the warmer i.e. patient/extension set side pointed up or flat on the patient's bed?**

The warmer is designed to be placed on the bed or attached to a bed sheet in close proximity to the site of infusion. It is recommended that the warmer be laid flat to avoid kinking of the IV to occur.

**15. Do you recommend placing the enFlow controller on a table or mounting it to an IV pole?**

Either way is fine as the controller's display will have a "right-side-up" orientation regardless of its position. 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.

**16. What does enCheck do relative to preventative maintenance and requirements for quarterly or annual documentation for the utilization of blood warming systems? Are any other checks needed?**

According to the AABB, the transfusion service medical director has ultimate responsibility for ensuring the proper function of blood warmers throughout the hospital. This responsibility includes determining procedures, frequency of testing, and review and retention of records. enCheck is designed 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. enCheck is also designed to verify the warmer operation at the enFlow installation site. While enCheck facilitates testing of alarm activation, other important quality assurance tests such as electrical safety checks, effluent temperature/thermometer calibration, and cleaning and disinfecting are not covered by enCheck. The enFlow preventative maintenance manual outlines step-by-step directions for completing these additional testing procedures.

**17. Do you have a mount that allows for enFlow to be affixed to our anesthesia machines?**

We all know real estate in the OR is limited. We now have a mount available to attach the enFlow system to anesthesia delivery equipment. For more information, talk to your Vital Signs Product Sales Specialist.

**18. What cleaning solutions can I use to clean my enFlow system?**

The following list of approved cleaning solutions may be used to clean the warmer and controller: isopropyl alcohol, mild detergent solution, diluted chlorine bleach (30 mL/L water), ammonia based cleaners, glutaraldehyde-based cleaners, hydrogen peroxide and chlorhexidine.

**19. How did GE choose 40 degrees to be the target point for the warmer's delivery of blood or fluids?**

enFlow's target temperature point is 40°C for specific clinical reasons. Research has shown that blood and fluid warmed to this temperature may significantly increase the amount of heat returned to the hypothermic patient. When considering blood, according to the American Association of Blood Banks, blood warmers should be limited to a maximum temperature of 42°C. Additionally, a study by Kruskall et. al. looking at the effects of prolonged exposure of blood through a 40°C heat exchanger using flow rates equivalent to the transfusion of a unit of blood over four hours found that blood units showed no significant changes in plasma hemoglobin, mean corpuscular hemoglobin concentration, potassium, ATP, pH, and osmotic fragility.



**20. With so many warming options, why should I consider fluid warming?**

Each liter of intravenous fluid infused into adult patients at ambient temperature, or each unit of blood infused at 4°C, decreases the mean body temperature approximately 0.25 °C. Multiple studies have shown that fluid warming improves the likelihood of maintaining normothermia when used in conjunction with convection warming. Additionally, research shows that heat transfer from warmed fluid is efficient, immediate and independent of the peripheral to core temperature gradient, allowing warmed blood to flow back to the core within seconds.

**21. What sets enFlow apart from other fluid warming systems?**

There are many differentiating features to enFlow including its transportability, flexibility and ease of use. When it comes to differentiating specifications, enFlow has one of the lowest priming volumes (4mL), fastest warming speeds (<18 seconds), significant applicability (~98% of procedures), and much more. Talk to your local Vital Sales Product Sales Specialist for more benefits -- or to schedule a demonstration.

**22. Where can I use enFlow in my hospital? Just in the OR?**

enFlow is ideal for multiple care areas within your hospital that reach well beyond the operating room. We currently have customers using enFlow in L&D, emergency departments, intensive care units, blood centers and many more care areas. To learn more about the use of enFlow in these different areas of the hospital, please visit the Care Area section of the enFlow site.

**23. Is enFlow a product of GE Healthcare or of Vital Signs? I have seen it linked to both companies.**

On October 30, 2008, Vital Signs Inc. became a GE Healthcare company making enFlow a product of both entities. GE Healthcare has maintained a separate sales force dedicated to Vital Signs products -- to ensure our customers have access to clinical consumables experts.

**24. I want to read up on the benefits of maintaining normothermia. Where can I learn more?**

To learn more about the clinical and economic value of maintaining normothermia, please visit the Education section of the enFlow site. Here you will find links to various clinical studies, patient warming recommendations from industry associations, and more.

**25. Where can I see an enFlow IV Fluid/Blood Warming System in person?**

If you would like to see an in-person demonstration of the enFlow system, contact us and we will have the Vital Signs Product Sales Specialist in your area reach out to you to schedule an in-person demonstration.

Have more questions that were not answered here? Please contact your Vital Signs Product Sales Specialist for additional information.



## References

1. Knobel, Robin; Holditch-Davis, Diane. Thermoregulation and Heat Loss Prevention After Birth and During Neonatal Intensive-Care Unit Stabilization of Extremely Low-Birthweight Infants. *Advances in Neonatal Care*: October 2010 - Volume 10 - Issue - p S7-S14.
2. Maura Galligan MSN, RN, FNP. Proposed Guidelines for Skin-to-Skin Treatment of Neonatal Hypothermia. *MCN, The American Journal of Maternal/Child Nursing*. September/October 2006. Volume 31 Number 5, Pages 298 – 304.
3. Paut, Olivier MDa,b; Lacroix, FrédéricMDb. Recent developments in the perioperative fluid management for the pediatric patient. *Current Opinion in Anaesthesiology*: June 2006 - Volume 19 - Issue 3 - pp 268-277.
4. Vital Signs Devices. Fluid Warming Time Using 20°C Fluid to Achieve 37°C. 150 ml/min. Testing was performed using a 9" extension set and 20°C distilled water – Company data on file.



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