Comparison of Warming Capabilities Between Buddy Lite, enFlow, and Thermal Angel for US Army Medical Personnel in Austere Conditions

A Literature Review

Donald J. Vallier, DNP, CRNA[1]; Wesley J.L. Anderson, CRNA[2]; Jennifer V. Snelson, CRNA[3]; Young J. Yauger, PhD, CRNA[4]; Justin R. Felix, BS[5]; Kaitlyn I Alford, RN[6]; William A. Bermoy, EMT[7]*

ABSTRACT

US Army Forward Surgical Elements (FSEs) are highly mobile teams that provide damage control surgery (DCS) and damage control resuscitation (DCR) in austere locations that often lack standard hospital utilities (electricity, heat, food, and water). FSEs rely on portable battery-operated intravenous (IV) fluid warmers to remain light and mobile. However, their ability to warm blood in a massive resuscitation requires additional analysis. The purpose of this literature review is to examine the three most common battery-operated IV fluid warmers as determined by type and quantity listed on the Mission Table of Organization and Equipment (MTOE) of organic mobile medical units. These include the Buddy Lite, enFlow, and Thermal Angel, which are available to deployed US Army FSEs for blood resuscitation therapy. Based on limited available evidence, the enFlow produced higher outlet temperatures, effectively warmed greater volumes, reached the time to peak temperature faster, and produced greatest flow rates, with cool saline (5–10°C), compared to the Thermal Angel and Buddy Lite. However, recently the US Food and Drug Administration (FDA) issued a Class 1 recall on enFlow cartridges. Testing demonstrated aluminum elution from enFlow cartridges into IV solutions, thereby exposing patients to potentially unsafe aluminum levels. The authors recommend FSE units conduct a 100% enFlow cartridge inventory and seek an alternative IV fluid warming system prior to enFlow cartridge disposal. If an alternative does not exist, or the alternative warming system does not fit mission requirements, then medical personnel must carefully weigh the risks and benefits associated with the enFlow delivery system.

KEYWORDS: *Thermal Angel; enFlow; Buddy Lite; fluid warmer; intravenous fluids, IVF; cartridge*

Introduction

Currently US Army FSEs provide DCS and DCR for trauma patients in nonlinear battle spaces with limited resources and equipment. FSEs traditionally extend the golden hour to higher echelons of care, thus increasing survivability while decreasing operational risk in remote locations outside the traditional 60-minute medical evacuation (MEDEVAC) ring. Unfortunately, FSEs are restricted in space and weight during transport to their mobile surgical sites, which often lack standard utilities found in fixed medical facilities such as water, heat, and a reliable power source. In order to remain fully mission capable, FSEs transport medical equipment, supplies, blood products, power generation capabilities, fuel, food, and water. Therefore, ideal characteristics for FSE items are small, lightweight, durable, and battery-operated.

Currently, three battery-operated IV fluid warmers exist for mobile operational units that lack central power. The Buddy Lite (Belmont Instruments, https://belmontmedtech.com/disposable-accessory-categories/buddy-litetm), enFlow (MEDLINE, https://www.medline.com/media/catalog/Docs/MKT/ENFLOW-FLUID-WARMING-SYSTEM.PDF), and Thermal Angel (Estill Medical Technologies, https://www.medwrench.com/equipment/2101/estill-medical-technologies-thermal-angel-ta-200) which are used in aviation units, Special Operation Forces (SOF), and FSEs. These devices are ideal for austere conditions due to their small sizes, favorable weights, and battery-operated capabilities. Despite their ideal structural characteristics, their ability to warm blood products during massive resuscitation requires additional analysis.

Three main reasons warrant additional analysis of currently used fluid warmers. First, aviation and SOF units, along with

*Correspondence to Wesley.j.anderson.mil@mail.mil
[1]**CPT Donald J. Vallier** and [2]**COL Wesley J.L. Anderson** are certified registered nurse anesthetists affiliated with the Department of Anesthesiology, Brooke Army Medical Center, Fort Sam Houston, TX. [3]**LTC Jennifer Snelson** is a certified registered nurse anesthetist and is the Commander of the 758th Medical Detachment (Forward Surgical), Dahlke, Afghanistan. [4]**LTC Young J. Yauger** is an associate professor at the US Army Graduate Program in Anesthesia Nursing at Baylor University, Waco, TX. [5]**CPT Justin R. Felix** is a captain in the US Army Medical Corps. [6]**CPT Kaitlyn I. Alford** is a registered nurse in the US Army Nurse Corps. [7]**SSG William A. Bermoy** is an emergency medical technician in the US Army.

FSEs, carry limited quantities of cold (1–6°C) low-titer O whole blood (LTOWB). Second, the Joint Trauma System (JTS) Clinical Practice Guidelines (CPGs) recommends warming blood products to 37°C for transfusion.[1] This recommendation is secondary to battlefield casualties being the most susceptible to hypothermia due to prolonged evacuation times, significant injury patterns, altered intrinsic thermoregulation abilities, and environmental factors. Finally, cold blood administration would further influence a casualty to enter the triad of death, defined as hypothermia, coagulopathy, and acidosis. Profound hypothermia affects the triad of death by worsening coagulopathy, decreasing drug elimination, and increasing overall hemorrhage. Therefore, to mitigate the deleterious effects of cold blood administration, the far forward employment of battery-operated IV fluid warmers is often used for early blood administration in patients that require resuscitation.

In March 2019, the US FDA issued a Class 1 recall on enFlow cartridges manufactured from January 2016 to March 2019.[2] Testing demonstrated aluminum elution from enFlow cartridges into IV solutions, thereby exposing patients to potentially unsafe aluminum levels.[3,4] Despite this FDA recall, the enFlow delivery system and its components remain assigned to FSEs, SOF units, and aeromedical units.

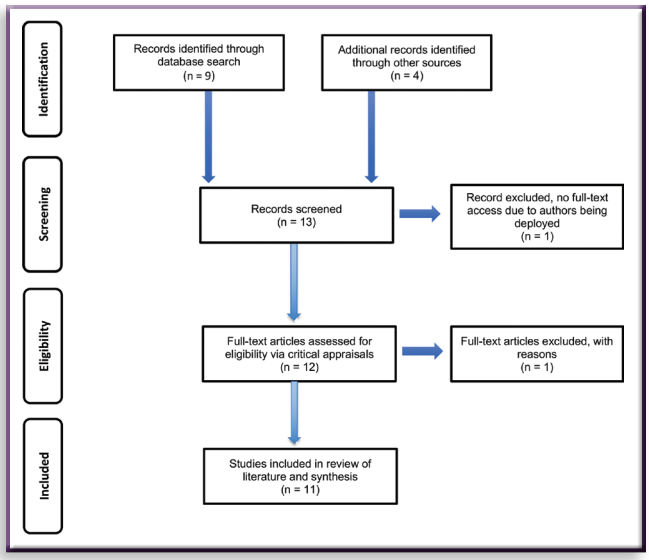
This literature review seeks to determine the ideal portable battery-operated IV fluid warmer (Buddy Lite, enFlow, Thermal Angel) for trauma patients undergoing massive blood transfusions in austere settings. Additionally, the authors provide a risk mitigation analysis for the enFlow delivery system.

Search Strategies

The authors systematically searched the following databases: EBSCO, Google Scholar, MEDLINE PubMed, AHRQ EPC Evidence Reports, Cochrane Databases, Dynamed Plus, Defense Technical Information Center (DTIC), Federal Research in Progress, Evidence-Based Medicine Reviews, Military and Government Collection, and the *New England Journal of Medicine*. The search included the following MeSH terms and key words: portable fluid warmers, Buddy Lite, enFlow, Thermal Angel, blood warmer, and military massive transfusion. The authors also searched gray literature, to include the JTS Quarterly, which features literature reviews pertaining to combat casualty care.

Thirteen articles met the screening criteria. Four subject matter experts in deployment medicine independently graded ten articles with the Joanna Briggs Institute Critical Appraisal Tool. After independent appraisal, a unanimous decision determined if an article was included or excluded. The experts excluded two articles from this literature review: one article due to the inability to obtain a full-text copy while deployed, and the other due to its exploration of the mathematical energy requirements to treat hypothermia, rather than clinical applications for portable IV fluid warmers. See Figure 1 for search flow diagram.

FIGURE 1 *Search flow diagram.*



Review of Literature

The physical characteristics and heating elements are unique for each device. The following weights are a sum of the unit, battery, and priming volumes for each delivery system: enFlow (3.04 lb), Thermal Angel (2.16 lb), and Buddy Lite (1.69 lb). The enFlow uses an uncoated disposable aluminum heated plate to warm IV fluids. In 2019, the *Anaesthesia Journal* published two articles that demonstrated uncoated disposable aluminum heated plates elute aluminum into IV fluids.[3,4] The FDA subsequently announced a Class 1 recall on enFlow cartridges manufactured from January 2016 to March 2019.[2] The Thermal Angel and Buddy Lite do not use uncoated aluminum heated plates. See Figures 2, 3, and 4 for device photographs

FIGURE 2 *enFlow with battery accessory.*

FIGURE 3 *Buddy Lite.*

The authors operationally defined criteria for an ideal massive blood transfusion based on flow rate, output temperature, and blood product amount. Ideal flow rates should approach 100mL/min, which approximates maximum crystalloid flow rates through a 1¼-in-length, 18-gauge peripheral intravenous (PIV) catheter (BRAUN, Introcan Safety, https://www.bbraun.com/en/products/b/introcan-safety.html). Deployed medical

FIGURE 4 *Thermal Angel with UB1 Battery Pack.*

personnel (combat medics, flight medics, and FSEs) most commonly carry BRAUN 18-gauge IV catheters. Per JTS guidelines for DCR management, IV fluid warmers should ideally warm blood products to 37°C without substantially reducing flow rates. Last, a massive blood transfusion constitutes ≥10 units of red blood cells (RBCs) and/or whole blood (WB) in 24 hours.[1]

Experimental designs included in this review tested the performance capabilities for the Buddy Lite, enFlow, and Thermal Angel. The outcomes of interest include average fluid outlet temperatures, volume of fluid effectively warmed, time to peak heating, maximum flow rates, and battery characteristics with each device. The authors further explore each device's performance capabilities with crystalloid/colloid, and WB/PRBCs.

Buddy Lite. Manufacturer recommendations state the heating element can warm IV fluids to physiologic temperatures for ambient cooled crystalloids up to 80mL/min, and for 10°C red cells up to 50mL/min.[5] No colloid (Hextend or albumin) experimental trials exist with the Buddy Lite at this time.

- *Saline*. At 5°C input saline temperatures, the Buddy Lite heated saline to a combined average output temperature of 31.8°C for all flow rate groups (25–100mL/min).[6] At 10°C input saline temperatures, the Buddy Lite failed to achieve >36°C output temperatures at flow rates above 50mL/min.[6–8] In terms of effective saline volume warmed, the Buddy Lite failed to effectively warm any measurable amount of volume with 10°C input saline temperatures at 100mL/min.[8]
- *Blood*. A single study measured outlet temperatures with expired whole blood cooled to 9.5°C at 50mL/min. The Buddy Lite warmed expired whole blood to 35.2°C.[9]
- *Time to Peak Heating, Maximum Flow Rates, and Battery Characteristics*. The Buddy Lite reaches time to peak heating in 263.5 and 270.8 seconds with 20°C and 5°C input saline at fixed flow rates (30, 50, and 100mL/min).[6] Maximum flow rates through a 14-gauge PIV pressurized system (274–374mmHg) yields 330mL/min and 390mL/min.[8] The Buddy Lite's battery capacity measures at 89 watt-hours (wh). In one study, experimenters infused 4–5L of cooled saline, and the device struggled to generate stable thermal outputs until 30 minutes lapsed.[8]
- ***enFlow.*** Manufacturer recommendations state the heating element can warm IV fluids from to keep open (TKO) to 200mL/min, but no recommendations for red cells.[11] No WB/PRBC or colloid experimental trials currently exist with the enFlow at this time.
- *Saline*. At 5°C input saline temperatures, the enFlow heated saline to a combined average output temperature of 39.5°C for all flow rate groups (25–100mL/min).[6] At 10°C input saline temperatures, the enFlow warmed saline to >38°C for flow rates up to 100mL/min.[6–8] In terms of effective saline volume warmed, for 20°C input saline temperatures at 100mL/min, the enFlow heated 2.8L to >36°C before its battery depleted.[8] For 10°C input saline temperatures at 100mL/min, the enFlow produced an average output temperature of 33.7°C for 1.8L.[8]
- *Time to Peak Heating, Maximum Flow Rates, and Battery Characteristics*. The enFlow reaches time to peak heating in 13.4 and 18.3 seconds with 20°C and 5°C input saline at fixed flow rates (30, 50, and 100mL/min).[6] Maximum flow rates through a 14-gauge PIV pressurized system yields 414mL/min and 488mL/min.[8] The enFlow is capable of either adapting AC power or using a portable battery system (66 wh).
- *Aluminum Elution*. The enFlow's unprotected heat plate elutes aluminum at different concentrations depending on the following variables: type of crystalloid, type of blood product, and flow rate. The FDA recommends the maximum level of aluminum in IV nutrition to not exceed 25µg/L.[3,4] Renal function status influences the rate of elimination, but this varies with patients depending on their age.[3] In infants, repeated large aluminum exposures may lead to neurological impairment and bone growth malformation.[3] See Table 1 for aluminum elution concentrations at 60-minute durations for varied crystalloids and blood products.[4]

TABLE 1 *Mean Aluminum Concentrations From Crystalloid and Blood Products Warmed via enFlow (40°C) at 2 and 16mL/min*[4]

	Aluminum (mg/L)			
	Plasma-Lyte 148	0.9% Saline	PRBCs	FFP
2mL/min flow at 60-min duration	6,027.9	80.1	72.8	61.8
16mL/min flow at 60-min duration	658.0	N/A	N/A	N/A

PRBC = packed red blood cell; FFP = fresh frozen plasma.

Thermal Angel. Manufacturer recommendations state the device can warm IV fluids and blood for flow rates up to 150mL/min.[12] The Thermal Angel is the only device to have trialed saline, colloid, and blood.

- *Saline*. For 20°C input saline temperatures at 100mL/min, the Thermal Angel produced an average output temperature of 36.4°C.[8] In terms of effective volume of saline warmed, the Thermal Angel could only heated 0.98L to nearly 36°C before its battery depleted.[8] For 10°C input saline temperatures at 100mL/min, the Thermal Angel warmed 0.8L to an average output temperature of 29.4°C.[8] The Thermal Angel failed to effectively warm cold lactated Ringer's (4–7°C) at 180mL/min, but warmed cold LR to 33–34°C at 140mL/min.[13]
- *Colloids and Blood*. The Thermal Angel achieved >33°C average temperature output for cold (4–7°C) PRBCs and 6% Hextend at low flow rates (~60mL/min), and >35°C for PRBCs and cold Hextend at higher flow rates

(~110mL/min).[13] When combined with a Blizzard Blanket, the Thermal Angel demonstrated effectiveness when infusing 10°C Hextend and 4°C blood-shed at 150mL/min in a hemorrhagic swine model under simulated combat conditions. Despite a nadir core temperature dropping to 35.2°C during the experiment, the Thermal Angel and Blizzard Blanket actively rewarmed swine to >37°C.[14]

Time to Peak Heating, Maximum Flow Rates, and Battery Characteristics. No studies have directly measured time to peak heating. Maximum flow rates through a 14-gauge PIV pressurized system yields 296mL/min and 345mL/min.[8] Depending on the model, two different batteries exist with the Thermal Angel. The UB1 (30 wh) offers a weight roughly one-sixth of the standard battery and has a significantly smaller profile. Reported discrepancies in average fluid output temperatures with cold isotonic solutions revealed the UB1 and a standard battery pack perform differently.

Discussion

In battlefield operations, many factors predispose IV fluids to cold temperatures, such as night operations, seasonal changes, aeromedical transport, and extremes in altitude. Under these conditions, IV fluid warmers must perform reliably with ice-cold isotonic solutions at a range of flow rates. The enFlow demonstrates effective warming capabilities across all studies. The Thermal Angel is capable of warming ice-cold solutions, but not as well as the enFlow. In contrast, the Buddy Lite produced conflicting results, though most studies demonstrate effective heating outcomes when limited to flow rates ≤50mL/min.[7,13]

Ideally, IV fluid warmer battery life should support aeromedical and ground casualty evacuation transport times, which vary greatly depending on such things as weather status, enemy presence, and location. The Thermal Angel's UB1 (30 wh) depletes quickly with cold solutions and high flow rates; comparatively, the enFlow's battery (66 wh) outlasts the Thermal Angel under similar conditions. The authors cannot conclude whether the Thermal Angel's standard battery outlasts the newer UB1, because no experiments have compared the two. The Buddy Lite's battery (89 wh) life is sustainable, but its heating element is not reliable with cold fluids at high flow rates.

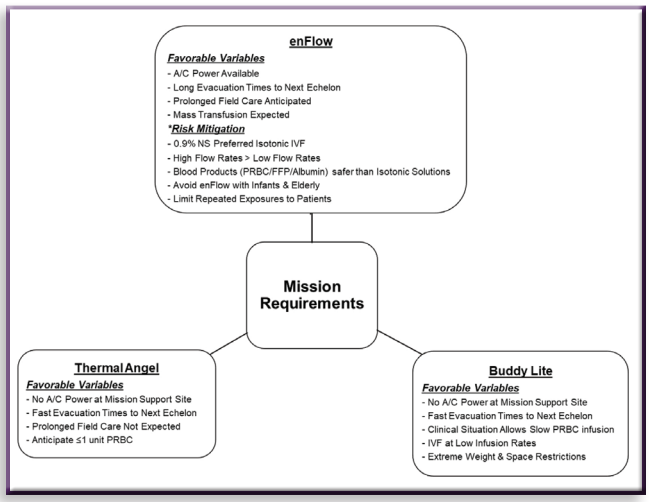
In terms of size and weight, the enFlow (3.04 lb) is larger and weighs more than the Thermal Angel (2.16 lb) and the Buddy Lite (1.69 lb). Despite these differences, the enFlow and its accessories fit into a standardized combat medic M9 bag. For medics that carry medical equipment, their decision to choose a specific IV fluid warmer should depend on space limitations, likelihood for prolonged field care, and access to durable items unique to each fluid warmer (cartridges, tubing, etc.). Conversely, due to their ability to offload and stage equipment, the enFlow may be most useful for aeromedical platforms and FSEs. Nevertheless, aeromedical and FSE personnel should consider space/weight limitations, transport times to the next echelon of care, and their ability to recharge batteries.

The enFlow may be the ideal fluid warmer for massive resuscitation due to its ability to reach peak temperature faster, maximal flow rates, and sustained battery life. The enFlow has yet to trial blood, which makes it difficult for the authors to recommend the enFlow as the ideal fluid warmer with certainty. However, the authors extrapolate that saline and blood trials may yield similar warming outputs. A variety of blood products (LTOWB, PRBCs, and liquid plasma) are cooled to 1–6°C in combat theaters, the enFlow is able to warm ice-cold saline (5°C) to 37.1°C at 100mL/min.[6] The Thermal Angel's standard battery pack component is able to warm cold blood to >35°C at 110mL/min, but its battery life has not been tested.[13] The Thermal Angel's UB1 quick battery depletion limits its use in a massive blood resuscitation.

The enFlow demonstrates aluminum elution into IV fluids at varying concentrations dependent upon flow rates, type of crystalloid, and type of blood product. The FDA recommends the maximum level of aluminum in IV nutrition to not exceed 25 µg/L.[3,4] Independent of flow rate, blood products demonstrated a lesser amount of aluminum elution when compared to crystalloids.[4] Independent of flow rate, 0.9% saline demonstrated a considerably less aluminum elution compared to Plasma-Lyte.[4] A limitation to the research is that the primary flow rates analyzed (i.e., 2mL/min) may not be of practical clinical application during a resuscitation. Regardless of its clinical applicability, the enFlow manufacturer is in the process of redesigning their cartridges to eliminate the aluminum elution problem.

Figure 5 is a concept map to assist medical personnel in their decision-making process regarding battery-operated IV fluid warmers. Mission requirements are the central themes to the decision-making process; medical personnel must clearly identify mission variables in order to mitigate potential negative impacts on patient care. Common mission variables include the following: A/C power supply availability, evacuation times to the next echelon of care, likelihood for prolonged field care, and weight/space limitations. Consider employing risk mitigation measures with the enFlow to reduce aluminum elution exposure to the patient (shown in Figure 5).

FIGURE 5 *Concept Map for IV Fluid Warmer Selection*



NS = normal saline; IVF = intravenous fluids; PRBC = packed red blood cell; FFP = fresh frozen plasma.

Conclusion

FSEs are highly mobile teams that carry small, light, durable, and battery-operated medical equipment in order to provide DCS and DCR in remote locations that often lack standard hospital utilities (electricity, heat, water, etc.). Battery-operated

IV fluid warmers (Buddy Lite, enFlow, Thermal Angel) replace larger traditional hospital IV fluid warmers in theater, but their ability to warm blood in a massive resuscitation requires additional analysis. With cooled fluids (5–10°C), the enFlow consistently produced higher outlet temperatures, effectively warmed greater volumes, reached time to peak temperature fastest, and produced greatest flow rates, compared to the Thermal Angel and the Buddy Lite. The Thermal Angel outperformed the Buddy Lite in all outcome measures; however, the UB1 energy source limits performance. Combat conditions predispose Servicemembers to hypothermic conditions. Therefore, it is paramount that battery-operated IV fluid warmers can warm a range of fluids to maintain core temperatures (>35.5°C) during DCS and DCR operations. In DCR scenarios, IV fluid warmers must effectively warm large volumes of blood products at high flow rates to create the conditions conducive to a successful resuscitation. Based on the available evidence, the authors conclude that each IV fluid warmer provides utility in different clinical and operational circumstances. However, despite the enFlow's favorable performance metrics and versatility, the enFlow may expose patients to high levels of aluminum. In clinical situations where the benefits outweigh the risks, or when no alternative IV fluid warmer is available, the authors recommend employing strategies that may reduce aluminum elution to the patient.

Conflicts of Interest

The authors declare no financial conflict of interest with any of the battery-operated IV fluid warmers. However, some of the authors have personally used battery-operated IV fluid warmers for blood transfusions in patient care.

Disclaimer

The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the US Army Medical Department, the US Army Office of the Surgeon General, the Department of the Air Force, the Department of the Army, the Defense Health Agency, or the Department of Defense or the US Government.

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