

# Evaluation of a New IV Fluid and Blood Warming System to Prevent Air Embolism

**Charles E. Smith, MD, FRCPC**

*Associate Professor  
Department of Anesthesia  
MetroHealth Medical Center  
Case Western Reserve University  
Cleveland, Ohio, USA  
e-mail: csmith@metrohealth.org*

**Abdallah Kabbara, MD**

*Senior Resident  
Department of Anesthesia  
MetroHealth Medical Center  
Cleveland, Ohio, USA*

**Richard P. Kramer, BCPP**

*Perfusionist  
Department of Cardiothoracic Surgery  
MetroHealth Medical Center  
Cleveland, Ohio, USA*

**Inderjit Gill, MD**

*Staff Surgeon  
Department of Cardiothoracic Surgery  
MetroHealth Medical Center and Cleveland Clinic Foundation  
Cleveland, Ohio, USA*

During resuscitation of patients in hemorrhagic shock (e.g., trauma, surgical bleeding), the anesthesiologist must infuse normothermic fluid and blood products in order to maintain thermal homeostasis and tissue oxygen delivery. Occasionally, it may be necessary to pressurize the intravenous (IV) fluid or blood product bag in order to increase flow to the patient.

Several fluid warming systems use a pneumatic external compressor that automatically squeezes the IV fluid or blood bag.<sup>1,2</sup> While these systems have been used for many years to provide faster and easier fluid delivery, problems do arise such as accidental IV delivery of air to the patient,<sup>3-6</sup> and extravasation of fluid, causing a compartment syndrome.<sup>7,8</sup>

The FMS2000 fluid warming system (Belmont Instrument Corp., Billerica, MA) is a new IV fluid and blood warmer that uses an integrated peristaltic pump to eliminate the

requirement for compression and pressurization of the fluid bag (Fig. 1). The system automatically heats fluid to normothermia at all flows  $\geq 10$  ml/min. For flow  $\geq 60$  ml/min, the fluid is heated to 37.5°C. For flows between 10 and 50 ml/min, fluid is heated to 39°C. There is no heating at 2.5 and 5 ml/min. Heating is not adjustable. The maximum flow rate of the pump is 500 ml/min. The system also contains two air detectors, an automatic air purge, and a line pressure sensor.

The purpose of the study was to evaluate the ability of the FMS2000 to deliver warm fluid and blood during a variety of flows (rapid, moderate, and slow). The thermal stress of infusing fluids with the FMS2000 was calculated. The study also evaluated the performance of the fluid warmer during two simulated conditions that may be encountered in the operating room environment: 1) empty air-filled fluid bag and 2) extravasated IV site.

## Methods

The study was performed in the operating room of a Level 1 trauma center. Room temperature was set at 22°C. Lactated Ringer's solution (LR) or 0.9% normal saline, at room temperature, was used for crystalloid evaluations. Refrigerated packed red blood cells (RBCs), mixed with 100 ml of room-temperature 0.9% saline, were used for blood evaluations. All red cells were obtained from outdated standard blood bank supply, had been collected in Adsol, and were kept refrigerated until use.

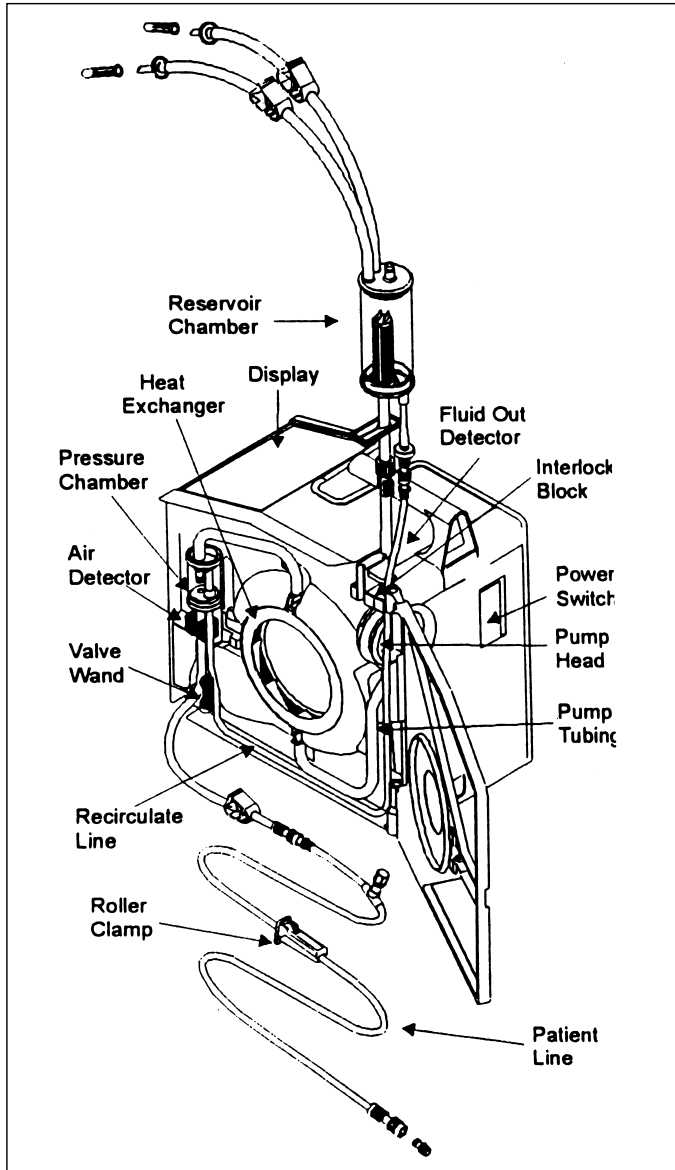
Standard FMS2000 disposable sets (Model 2516) were used for the experiments (Fig. 2). The disposable consisted of three bag spikes with clamps, a 120-ml reservoir chamber with a 170-micron filter, pump tubing, fluid out detector, magnetic



**Figure 1.** Belmont FMS 2000 warming system. The system consists of an integrated volumetric infusion pump coupled with a high-capacity magnetic induction heater. There are two ultrasonic air detectors—one at the fluid inlet and the other at the outflow to the patient coupled to an automatic shutoff.

Financial support: Belmont Instrument Corporation, Billerica, MA, provided loan of the fluid warmer and donated fluid warmer disposables. The study was funded internally by the MetroHealth Medical Center Anesthesia Department. The authors have no financial interest in the materials or equipment used in the study.

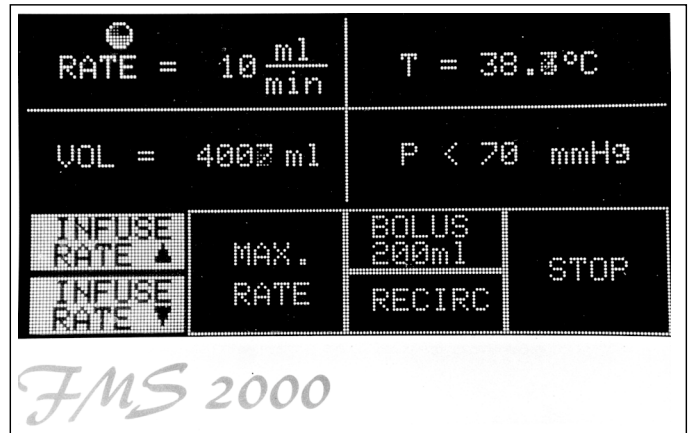
Presented in part at the 2001 American Society of Anesthesiologists Annual Meeting, New Orleans.



**Figure 2.** The disposable set consists of a 120-ml reservoir chamber, fluid out detector, pump tubing, pressure chamber, recirculating line, and patient line. Total priming volume is 220 ml.

induction heat exchanger, line pressure chamber, valve wand, recirculating line, and patient line. No extensions, filters, or stopcocks were added.

**Fluid and Blood Warming.** The disposable was primed with crystalloid or blood, depending on the experimental condition. Air was not evacuated from any IV bag. Total priming volume was 220 ml. Temperature of fluid at the outlet of the heat exchanger ( $T_{outlet}$ , within the warming unit) was measured with an internal infrared sensor and displayed on the fluid warming device (Fig. 3). Distal temperature ( $T_{distal}$ ) was measured at the point at which the patient line of the disposable set would be attached to the IV using a Fluke 52 K/J Rapid Response Thermometer (John Fluke Mfg Co., Everett, WA). Calibration of the thermometer was traceable to National Institute of Standards and Technology (NIST;  $\pm 0.05\%$  of



**Figure 3.** The graphical interface of the FMS2000 displays the volume infused, flow, temperature of the fluid distal to the heat exchanger, and line pressure. A fixed volume fluid bolus can be delivered automatically.

reading or  $0.3^{\circ}\text{C}$ , Hayes Instrument Service Inc., Bellerica, MA). The temperature of the blood was measured with a thermocouple inserted into the bag (Monatherm temperature probe, Mallinckrodt Medical, St. Louis, MO) and displayed on a Monatherm monitor (Model 6510 unit, Mallinckrodt Medical). Room temperature was measured with the second channel of the Monatherm unit.

Temperature data were collected during fluid runs.<sup>9,10</sup> Each liter bag of crystalloid and each unit of RBCs could be used for a fluid run. Data collection began after verification of steady flow. Data were collected at 5-second intervals. If the bag ran out, the bag was replaced and the system reprimed. Data collection continued after reaching steady state. Infusion rates tested were 10, 20, 30, 40, 50, 100, 200, 250, 300, 400, and 500 ml/min. A total of 175 measurements were done for crystalloid and 142 for diluted RBCs.

The effect of infusing fluids using the FMS2000 on core temperature was calculated as follows<sup>9</sup>:

$$\text{Change in core temperature} = \frac{\text{thermal stress of infused fluids}}{(\text{weight} \times \text{sp heat})}$$

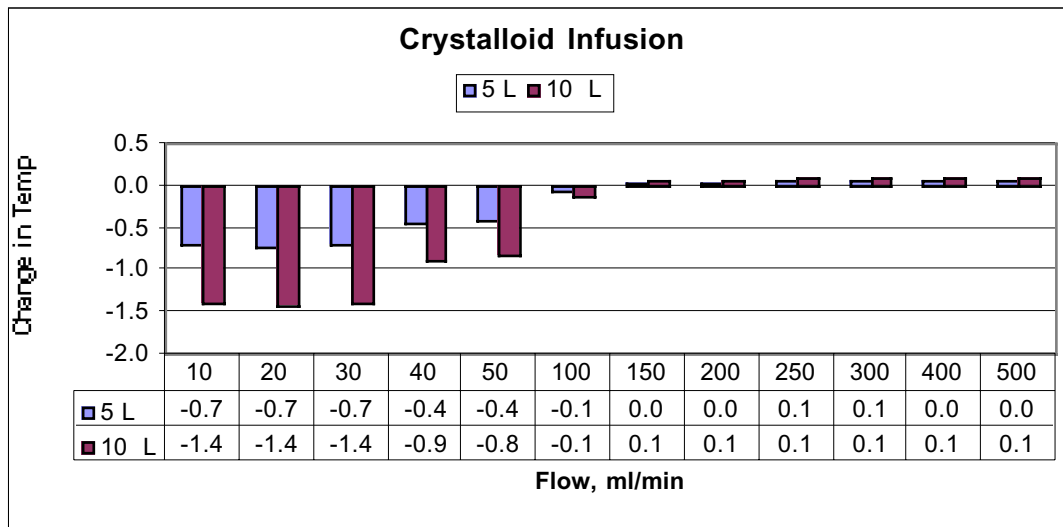
where

thermal stress = temperature difference between core and infused fluids  $\times$  specific heat of infused fluid  $\times$  volume of fluid infused,

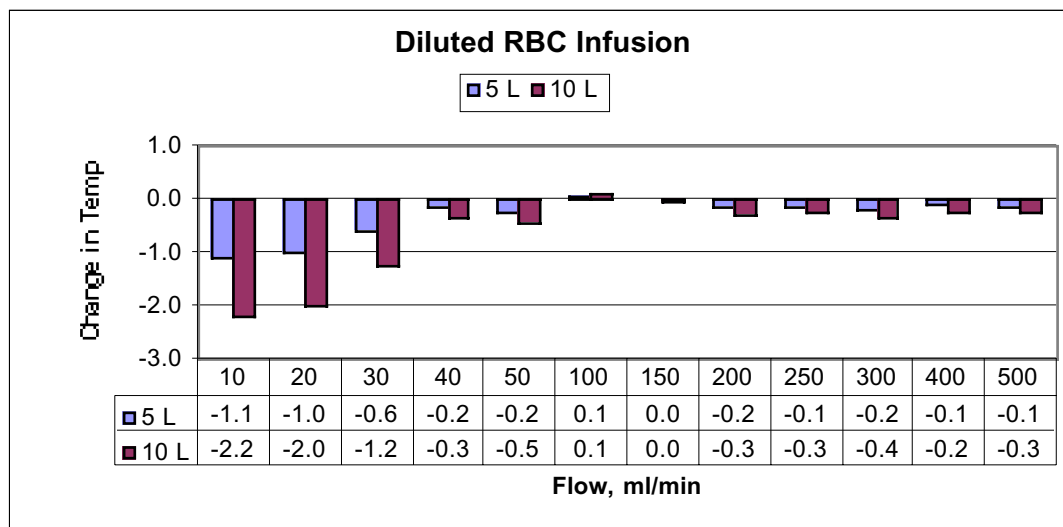
weight = weight of patient in kg, and  
 sp heat = specific heat of the patient ( $0.83 \text{ kcal/L}^{\circ}\text{C}$ ).<sup>11,12</sup>

For the calculations, it was assumed that a 70-kg anesthetized normothermic patient ( $37^{\circ}\text{C}$ ) with a metabolic rate of 40 to 60 kcal/h<sup>13</sup> was receiving fluids at the various flows. It was also assumed that heat loss of 50 to 70 kcal/h would reduce core temperature by  $1^{\circ}\text{C}$  in an anesthetized patient. The specific heat of crystalloid was estimated as  $1 \text{ kcal/L}^{\circ}\text{C}$ , while that of blood was  $0.89 \text{ kcal/L}^{\circ}\text{C}$ .<sup>14</sup>

**Fluid Out Detector (Air).** The disposable was primed with crystalloid. The crystalloid fluid bags connected to the spikes were clamped, and one spike was left open to air. The infusion rate was set at 100, 200, 300, and 400 ml/min. Time to automatic shutoff and alarm was determined five times for each infusion rate. The disposable was reprimed after each shutoff.



**Figure 4.** Theoretic change in core temperature when infusing 5 and 10 L of crystalloid fluids using the FMS2000. At slow flow (10–30 ml), core temperature may decrease 0.7 to 1.4°C. At moderate flow, the decrease is 0.4 to 0.9°C. Thermal homeostasis is maintained at rapid flow.



**Figure 5.** Theoretic change in core temperature when infusing 5 and 10 L of refrigerated red blood cells diluted with 100 ml 0.9% saline using the FMS2000. At slow flow (10–30 ml), core temperature may decrease 0.6 to 2.2°C. At moderate flow, the decrease is 0.2 to 0.5°C. Thermal homeostasis is maintained at rapid flow.

**Extravasated IV Fluid.** The disposable was primed with crystalloid. A 14G IV catheter was attached to the patient line and the infusion rate was set at 100, 200, 300, and 400 ml/min. The catheter was then occluded. Time to detect occlusion, shut off automatically, and signal an alarm was recorded five times for each flow. A new IV catheter was used for each flow.

**Results**

The device required about 5 minutes to load the disposable and prime the tubing. Data are reported as mean±SD.

**Fluid and Blood Warming.** Room temperature was 22.6±0.7°C (range, 21.0 to 23.6°C). Temperature of diluted RBCs was 10±2.1°C (range, 5 to 13°C). At slower flow (10, 20, and 30 ml/min), there was a 10 to 14°C decrease in T distal compared with T proximal for crystalloid and diluted RBCs (Table 1). At more rapid flow ((100 ml/min), T distal was >36°C for crystalloid and ≥35°C for diluted RBCs (Tables 1 and 2). The change in core temperature when infusing crystalloid and RBCs at the various flows is shown in Figures 4 and 5.

**Fluid Out Detector (Air Entrainment).** Time to empty the 120-ml reservoir chamber and immediate shutoff was dependent on flow (Table 2). Air entrainment began immediately, but air was detected only after the reservoir chamber was empty. During each experimental run, it was not possible to infuse air. The display warned that the IV bag was empty and repriming was necessary. It was always possible to automatically reprime the system without advancing air into the patient line by closing the clamp to the spike left open to air and opening the clamp to the spike connected to the bag of crystalloid.

**Extravasated IV Fluid.** In the presence of increased line pressure, the time to automatically shutoff and simultaneously signal an alarm was 1 to 3 seconds (Table 3).

**Discussion**

The study showed that there was considerable heat loss along the length of the tubing at slow and moderate flow, similar to that reported previously.<sup>9,15</sup> Temperature performance was, however, satisfactory at rapid flow. Thus, use of magnetic induction as a heat source is capable of warming

**Table 1. Temperature of Crystalloid and Diluted Packed Red Blood Cells After the Heat Exchanger (T Proximal) and at the Point Where Fluid Would Enter The Patient (T distal)**

Flow, ml/min	Crystalloid T proximal, °C	Crystalloid T distal, °C	Diluted Red Blood Cells T proximal, °C	Diluted Red Blood Cells T distal, °C
Slow				
10	37.3± 0.3	28.9± 0.4	33.3± 0.8	22.6± 0.2
20	39.2± 0.4	28.6± 0.2	37.2± 0.8	23.9± 0.8
30	39.5± 0.4	28.8± 1.2	38.4± 0.4	28.9± 1.7
Moderate				
40	39.6± 0.4	31.8± 1.2	38.3± 0.5	34.8± 1.2
50	38.8± 0.9	32.1± 1.0	38.9± 0.5	33.9± 0.9
Rapid				
100	37.6± 0.3	36.2± 0.6	37.9± 0.9	37.7± 0.5
150	37.6± 0.5	37.3± 0.9	37.4± 0.4	36.7± 0.2
200	38.3± 0.4	37.4± 0.1	37.5± 0.6	35.0± 0.8
250	38.6± 0.8	37.6± 0.4	37.3± 0.4	35.3± 0.4
300	38.5± 0.8	37.6± 0.2	37.2± 0.6	34.7± 0.6
400	38.6± 0.5	37.5± 0.5	37.3± 0.5	35.4± 0.8
500	39.0± 0.3	37.5± 0.3	37.4± 1.1	35.3± 3.0

Data are means± SD.

fluids even at very rapid flow, similar to that observed with countercurrent water bath and metal heat exchange devices (e.g., Level 1 System H1000, FW537).<sup>9,15</sup>

The study also showed that it was not possible to infuse air. This is because there are two ultrasonic air detectors—one proximal to the heat exchanger and the other distal to the heat exchanger just behind the pressure sensor. The proximal air detector activates the valve wand located at the outlet of the unit with as little as 0.8 ml of air in the input line, whereas the distal detector activates the wand if 0.1 ml of air is detected in the fluid line. Activation of the valve wand closes off the patient line. The recirculation line is then opened and air is swept back to the reservoir. The fluid warming device then instructs the user to reprime the system, which involves pressing a button and recirculating 100 ml of fluid through the heat exchanger. There is no need to break the system apart to remove the air.

The inadvertent infusion of air through intravascular catheters can result in devastating morbidity and death.<sup>16</sup> With the use of pressurized infusion systems, the risk of air embolism is increased because 1-liter bags of commonly used crystalloid solutions contain 40 to 100 ml of air,<sup>3,17</sup> whereas cell saver bags may contain considerably more. The frequency of fatal air embolism after pressurized readministration of cell saver blood was approximately 1:30,000 to 1:38,000.<sup>18</sup> The air eliminator of the commonly used Level 1 D300 fluid administration set (1.5 cm diameter, semi-permeable, air-venting membrane, Level 1 Technologies, Rockland, MA) does not reliably eliminate macroboluses of air and was easily overwhelmed during conditions in which air was not completely and rigorously eliminated from the 1-liter bag of fluid.<sup>17</sup> As

**Table 2. Time in Seconds to Automatically Shut Off During Rapid Infusion**

Flow, ml/min	Time to Empty 120-ml Reservoir after Air Entrainment	Time to Detect Occluded 14G IV Catheter
100	94.9± 0.9	3.4± 0.9
200	47.2± 0.8	2.4± 0.6
300	34.6± 1.5	1.4± 0.2
400	30.8± 0.8	0.9± 0.2

Data are means± SD.

much as 200 ml of air can enter the circulation in as little as 4 seconds.<sup>18</sup> Air embolism from automatic pressurized infusers have resulted in legal settlements of \$385,000 to \$1,600,000 according to the ASA Closed Claims Study database.<sup>19</sup> Steps to prevent infusion of air include avoiding the use of constant pressure-augmented fluid administration systems, routine de-airing of all IV fluid bags, and use of devices that incorporate automatic detection of air coupled with a shutoff mechanism.<sup>3,20,21</sup> Of note, the amount of air in spiked 1-liter bags of crystalloid was shown to be higher than in non-spiked bags during clinical use in the operating room of a teaching hospital (61 vs. 56 ml), which suggests that de-airing is not as routine a procedure as previously thought.<sup>17</sup>

The line pressure of the FMS2000 is controlled to minimize the risk of extravasation of fluid with resultant compartment syndrome should the IV become extravascular. The pressure sensors monitors the line pressure for two things: 1) rapid changes in the pressure curve and 2) gradually increasing line pressure. For example, if the line pressure increases faster than 40 mmHg/ml or exceeds 300 mmHg, the high pressure alarm is activated and the unit stops infusing. The operator is instructed to look for a blocked line. In the present study, the line pressure sensor was very sensitive to complete occlusion and responded within 1 or 2 seconds at flows of 300 and 400 ml/min. Such rapid responses should minimize the risk of compartment syndrome resulting from pressurized infiltration of IV fluids. However, if the line pressure rises more slowly but approaches 300 mmHg, the unit will decrease flow automatically to maintain line pressure below 300 mmHg. Thus, there is still a risk of infusing extravascular fluid in the scenario of gradually increasing line pressures that remain below 300 mmHg. Threshold pressures considered consistent with a diagnosis of compartment syndrome have varied from 45 to 20 mmHg below diastolic blood pressure.<sup>22</sup> The maximum line pressure allowed with the FMS2000 unit can be decreased to 100 or 200 mmHg in the setup screen, which may still be considerably higher than threshold pressures for the development of compartment syndrome.


Choice of equipment for fluid and blood warming is based on ability to deliver warm fluids to the patient at both slow, moderate, and rapid flow; ease of setup; alarms; safety systems; and cost. For hypovolemic patients requiring massive and/or rapid transfusion, the FMS2000 device is a significant and practical improvement in the clinical problem of safe infusion of normothermic fluids at rapid flow.

Limitations of the FMS2000 include loss of heat from the tubing distal to the fluid warmer at slower flow, with resultant delivery of cold fluid; 5-minute setup time for loading and priming the disposable; and high acquisition costs (\$18,000 US for the device and \$75 US for the disposable). Finally, there is no evidence that the FMS2000 can prevent compartment syndrome if the maximum allowable line pressure is high compared with the tissue pressure.

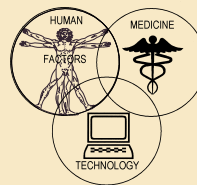
## Summary

Infusion of adequately warmed fluids is important to minimize thermal stress and maintain thermal homeostasis. The use of air bubble and line pressure sensors, coupled with a shutoff valve that automatically closes off all flow to the patient, are advantages of the FMS2000 fluid warmer during rapid flow.

## References

1. Iserson KV, Reeter A, Woods W, Criss E. Pressurization of i.v. bags: a new configuration and evaluation for use. *J Emerg Med* 1985; 3:89-92.
2. Iserson KV, Reeter AK. Rapid fluid replacement: a new methodology. *Ann Emerg Med* 1984; 13:97-100.
3. Ward CF, Ozaki GT. Pressure-augmented fluid administration: modified system and general results. *Crit Care Med* 1989; 17:70-2.
4. Adhikary GS, Massey SR. Massive air embolism: a case report. *J Clin Anesth* 1998; 10:70-2.
5. Benumof JL. Minimizing venous air embolism from reinfusion bags. *Anesthesiology* 1999; 91:1962.
6. Breen PH, Hong A. Beware of air in the blood pump. *Anesth Analg* 2000; 91:1038.
7. Willsey DB, Peterfreund RA. Compartment syndrome of the upper arm after pressurized infiltration of intravenous fluid. *J Clin Anesth* 1997; 9:428-30.
8. Tobias MD, Hanson CW, Heppenstall RB, Aukburg SJ. Compartment syndrome after pressurized infusion. *Br J Anaesth* 1991; 67:332-4.
9. Patel N, Smith CE, Pinchak AC. Comparison of fluid warmer performance during simulated clinical conditions. *Can J Anaesth* 1995; 42:636-42.
10. Patel N, Knapke DM, Smith CE, Napora TE, Pinchak AC, Hagen JF. Simulated clinical evaluation of conventional and newer fluid warming devices. *Anesth Analg* 1996; 82:517-24.
11. Gentilello LM, Cortes V, Moujaes S, Viamonte M, Malinin TL, Ho CH, Gomez GA. Continuous arteriovenous rewarming: experimental results and thermodynamic model simulation of treatment for hypothermia. *J Trauma* 1990; 30:1436-49.
12. Dubois EF. *Basal Metabolism in Health and Disease*. Philadelphia, Lee and Febiger, 1924, p 324.
13. Morrison RC. Hypothermia in the elderly. *Int Anesthesiol Clin* 1988; 26:124-33.
14. Mendlowitz M. The specific heat of human blood. *Science* 1948; 107:97.
15. Uhl L, Pacini D, Kruskall MS. A comparative study of blood warmer performance. *Anesthesiology* 1992; 77:1022-8.
16. Muth CM, Shank ES. Gas embolism. *N Engl J Med* 2000; 342:476-82.
17. Hartmannsgruber MW, Gravenstein N. Very limited air elimination capability of the level 1 fluid warmer. *J Clin Anesth* 1997; 9:233-5.
18. Linden JV, Kaplan HS, Murphy MT. Fatal air embolism due to perioperative blood recovery. *Anesth Analg* 1997; 84:422-6.
19. Comunale ME. IV fluid warmers create air embolus danger. *Anesthesia Patient Safety Foundation Newsletter* 2000; 15(3):41-42.
20. Woehlck HJ, Brennan SA. Equipment modification to prevent air embolism with LEVEL 1 H-500 fluid warmer. *Can J Anaesth* 1995; 42:1178-9.
21. Smith CE. Principles of fluid warming in trauma. In Smith CE, Rosenberg AD, Grande CM, ed. *Massive Transfusion and Control of Hemorrhage in the Trauma Patient. Seminars in Anesthesia, Perioperative Medicine and Pain* 2001; 20:51-59.
22. Botte MJ, Gelberman RH. Acute compartment syndrome of the forearm. *Hand Clinics* 1998; 14(3):391-403. 

## Medicine, Technology and Human Factors in Trauma Care: A Civilian/Military Perspective



### JOINTLY SPONSORED BY:

The University of Maryland School of Medicine  
Charles M.C Mathias National Study Center for  
Trauma & EMS

U.S. Army Medical Research and Materiel  
Command

University of Maryland School of Nursing

**November 15-16, 2001  
Baltimore, Maryland USA**

Open to all anesthesia, emergency medicine, nursing, surgery, trauma, and pre-hospital EMS personnel. The conference is free; however, pre-registration is required.

The scientific program includes national and international experts who will:

- 1) Identify the State of Integration of Medicine, Technology and Human Factors for emergency care of the injured.
- 2) Discuss innovations in resuscitation, recommendations for fluid resuscitation, management of bleeding and evaluation of pre hospital care and telemedicine for trauma.
- 3) Describe how emerging technologies can have application in emergency care of the injured.
- 4) Determine how coordination, safety, and training for trauma teams can be improved using human factors methodologies and simulations.

For program description, speaker listing and free registration, please visit <http://nsc.umaryland.edu> or send e-mail to [nsc-symposium@som.umaryland.edu](mailto:nsc-symposium@som.umaryland.edu).

The meeting is approved for 10.5 hours of Continuing Education Credits for physicians, 12.8 hours for nurses and 12 hours for emergency medical providers.

Contact: Ginny Goble, [ggoble@som.umaryland.edu](mailto:ggoble@som.umaryland.edu)  
or Colin Mackenzie, [cmack003@umaryland.edu](mailto:cmack003@umaryland.edu),  
or call the National Study Center at  
(410) 328-3007 for further information.