INITIAL SALES TRAINING

THE BELMONT® RAPID INFUSER RI-2

Internal Use Only

BELMONT® MEDICAL TECHNOLOGIES

INDICATIONS FOR USE

The Belmont Rapid Infuser 2 is used for infusion of crystalloid, colloid, and blood products, including packed red blood cells and fresh frozen plasma.

Common applications include:

- Liver transplantation surgery
- Vascular surgery
- Transplant surgery
- Complicated obstetrical cases
- Aneurysm repairs
- Trauma

THE BELMONT®
RAPID INFUSER RI-2

CLINICAL APPLICATION

CLINICAL APPLICATION

Trauma Victim Resuscitation and Treatment

- Traumatic injury remains the leading cause of potentially preventable death, and, in many cases, delayed or inadequate fluid resuscitation is associated with increased mortality.
- Often, massive transfusion of warmed fluids is a life saving measure in the management of severely injured trauma victims. Gun Shot Wounds (GSW), Stabbings, Motor Vehicle Accidents (MVA), Blunt Force Traumas, and Traumatic Falls are common scenarios where injuries result in massive hemorrhage.

Postpartum Hemorrhage (PPH) Management

- Postpartum hemorrhage *(the loss of more than 500 mL of blood following vaginal delivery or 1000 mL following a cesarean delivery)* is the leading cause of maternal death in the developing world as well as in high resource countries.
- 54-93% of maternal hemorrhage-related deaths could have been prevented with improved clinical response which includes quantitative blood loss measurement and early activation of a massive transfusion protocol[1].

1. Bingham D, Jones R. Maternal death from obstetric hemorrhage. Jnl of Obstetric, Gynecologic, and Neonatal Nursing. 2012;41:531–539.

CLINICAL APPLICATION

Triple A's – Abdominal Aortic Aneurysm

- One of the most dangerous medical emergencies, where the abdominal aorta stretches to larger than 3cm – which is 50% larger than average. When this occurs the aorta becomes susceptible to rupturing. Most of the time, there are no symptoms until the aorta ruptures.
- Only about 20% of patients with a ruptured Triple A will survive and 80% usually die before reaching the hospital.

Liver Transplant Surgery

- Liver transplantation is a complex procedure to replace a diseased liver with a healthy liver in patients with end-stage liver disease, irresectable primary liver tumors, and metabolic disorders.
- Due to the vascular nature of the organ, significant blood loss requires massive transfusions virtually universally in liver transplantation surgery.

Gastrointestinal Bleeds

- Extremely common and often associated with other medical issues such as high blood pressure, liver disease, chronic gastritis, and patients undergoing chemotherapy treatments. Elderly patients are more prone to GI bleeds.
- Generally these patients don't require rapid infusion, but some providers prefer to utilize The Belmont Rapid Infuser at lower flow rates due to warming efficiency and air removal.

FLUID MANAGEMENT

- Fluid resuscitation to restore intravascular volume is among the most important interventions in the management of severely bleeding patients.
- Successful resuscitation relies on warming of all cold intravenous fluids including colloid, crystalloid, or blood products to combat trauma's lethal triad of hypothermia, acidosis and coagulopathy.

"Trauma is the leading cause of death worldwide in those under the age of 40 years, and accounts for ~10% of all deaths worldwide."

"Hemorrhage is responsible for 30-40% of trauma mortality, and, among those who reach care, early mortality is caused by continued hemorrhage, coagulopathy, and incomplete resuscitation."

"Hypothermia occurs in 10% of all trauma patients and 30-50% in severely injured patients. In civilian trauma, exposure, hypovolemia (decreased blood volume), coagulopathy and the infusion of cold fluids are likely the most important factors contributing to temperature loss in an injured individual."

Sauaia A: Epidemiology of trauma deaths: a reassessment. J Trauma 1995, 38: 185-193. 10.1097/00005373-199502000-00006
Kauvar DS, Lefering R, Wade CE: Impact of hemorrhage on trauma outcome: an overview of epidemiology, clinical presentations, and therapeutic considerations. J Trauma 2006, 60: S3-11. 10.1097/01.ta.0000199961.02677.19
Søreide, K. (2014). Clinical and translational aspects of hypothermia in major trauma patients: From pathophysiology to prevention, prognosis and potential preservation. *Injury*, *45*(4), 647-654. doi:10.1016/j.injury.2012.12.027

FLUID MANAGEMENT DEFINITIONS

Intravascular volume

- Volume of blood in a patient's circulatory system

Hypothermia

- Core body temperature below 35°C

Acidosis

- Increased acidity in the blood and other body tissue

Coagulopathy

- Disorder of the blood that makes it difficult for blood to coagulate

Crystalloid and Colloid

- Crystalloids are aqueous solutions of mineral salts or other water-soluble molecules. Colloids contain larger insoluble molecules, such as gelatin. The most commonly used crystalloid fluid is normal saline, a solution of sodium chloride at 0.9% concentration, which is close to the concentration in the blood (isotonic).

KEY FACTORS FOR SUCCESSFUL FLUID MANAGEMENT

Removal of Air to Reduce the Risk of Air Emboli

- Venous air embolism (VAE) is a potentially lethal condition that can occur during transfusion of fluid at high flow rates. Fatal neurological conditions including ischemic stroke have been linked with air emboli crossing the blood-brain barrier (cerebral air embolism). Infusion devices designed without air handling systems can increase the risk of VAE by allowing large volumes of air into the cardiovascular system.

Sterility of Infusate

- Pathogens and antibiotic-resistant organisms from infusion reservoirs have become a growing concern. Prevention strategies suggest removal of all sources of water-borne pathogens, including fluid reservoirs.

Rapid Heating

- Life-saving massive transfusions require immediate access to equipment that is ready to warm and infuse blood within seconds. Most rapid infusers require several minutes before target temperature can be reached.

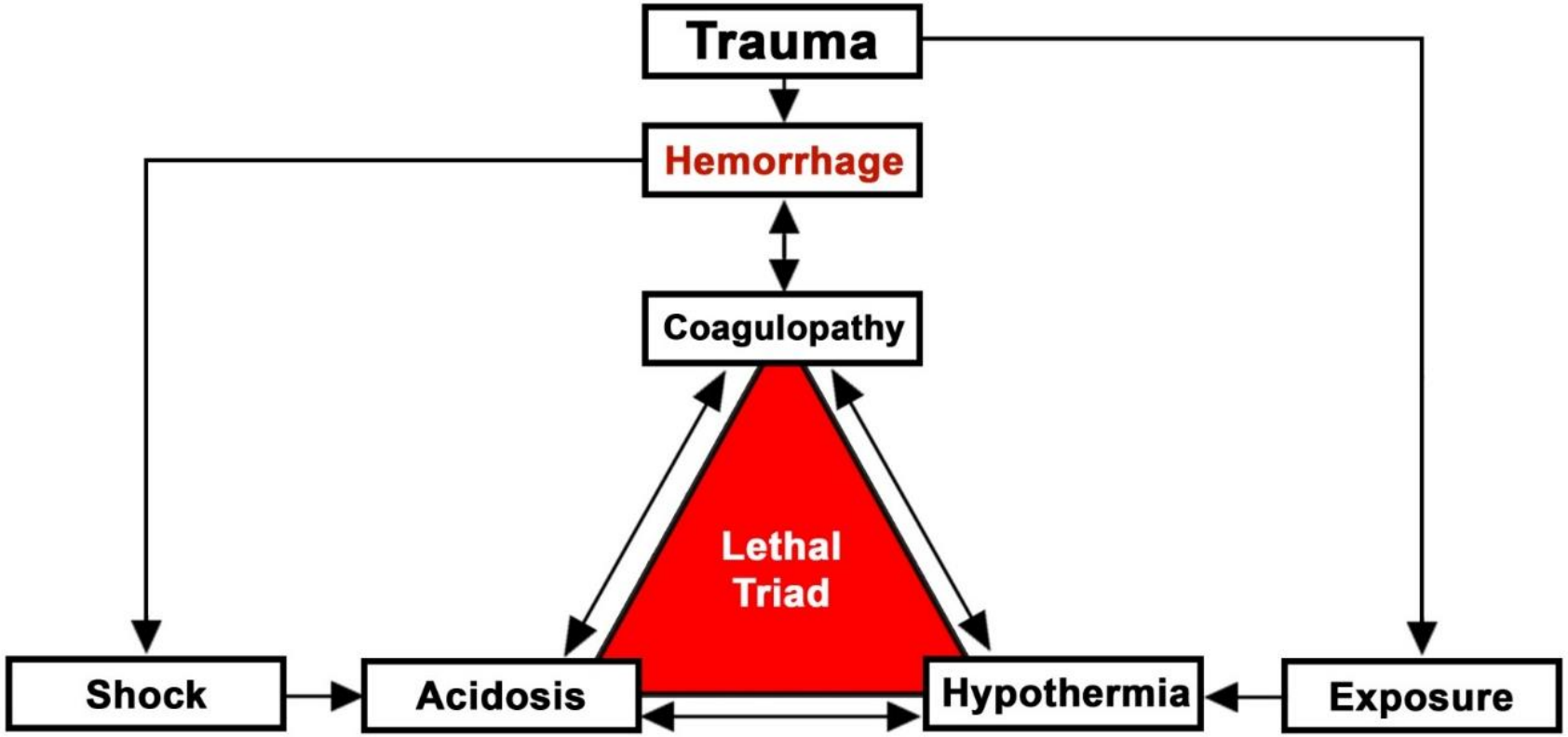
Maintenance of Temperature

- Precise control of fluid temperature is important to avoid over-heating or under-heating of blood and fluids which can lead to hemolysis (damage to red blood cells) or the acceleration of hypothermia.

Maintenance of Flow Rate and Pressure

- Precise control and display of flow rate ensures fluid delivery at desired volumes, reducing the risk of transfusion-associated circulatory overload (TACO), the second leading cause of transfusion related fatality in the United States. Line pressure monitoring reduces the risk of vessel trauma caused from over-pressurization of the patient line and poor venous access.

TRAUMA'S LETHAL TRIAD



Source: Jansen, Jan & Thomas, GO & Loudon, Malcolm & Brooks, Adam. (2009). Damage control resuscitation for patients with major trauma. BMJ (Clinical research ed.). 338. b1778. 10.1136/bmj.b1778.

TRAUMA'S LETHAL TRIAD

- **Trauma –> Exposure:** A majority of trauma injuries occur outside, exposing victims to harsh environmental conditions including rain, low temperatures and strong winds. Victims are often left lying on the ground in wet clothing as they wait for responders, leading to substantial heat loss and the onset of hypothermia. Even as paramedics arrive at the scene patients are still at risk of exposure. Clothing is usually removed to treat injuries or assess tissue damage, exposing large body surface areas to cold air temperatures.
- **Trauma –> Hemorrhage:** Hemorrhage is responsible for 30 to 40% of all trauma related deaths, with half of hemorrhage victims succumbing to their injuries before ever reaching a hospital. In many cases, hemorrhage related death is completely preventable, and can be reversed by minimizing blood loss and restoring circulatory volume.
- **Hemorrhage –> Shock:** As the body continues to lose more blood it enters a state known as hypovolemic shock. After losing more than 20% of the body's fluid supply, the heart is unable to sufficiently pump blood to the entire body, causing a failure of adequate circulatory volume to tissue and organs. Continued fluid loss leads to a sudden dramatic decrease in blood pressure, lowering of body temperature, and the eventual shutdown of vital organs.
- **Exposure –> Hypothermia:** The risk of hypothermia is commonly underestimated in mild climates where ambient temperatures may be well above freezing. Most healthy people are able to regulate their body temperature in these environments, but babies, the elderly, and ill adults are often victims of hypothermia that is not easily recognized due to these differences.
- **Shock –> Acidosis:** Reduced tissue perfusion due to hypovolemia causes cells throughout the body to switch from aerobic to anaerobic metabolism. Lactate quickly begins to buildup in blood and tissues, while a lack of oxygen inhibits the body from converting lactate back to glucose. This cycle continues until oxygen delivery to tissues can be restored.
- **Hypothermia <–> Acidosis:** Shivering is an automatic response to rewarm the body but uses up available oxygen and glucose in muscles that further contribute to increased lactate production. Total body metabolism and oxygen demand is also reduced with increased degree of hypothermia. For every 1°C drop in body temperature, there is a 6% reduction in oxygen consumption. Oxygen delivery is further impaired by vasoconstriction of blood vessels that prevent heat loss by diverting blood to the center of the body.
- **Coagulopathy <–> Hypothermia:** Hypothermia is associated with increased mortality and blood loss in trauma patients. The risk of severe bleeding leading to greater injury is caused by hypothermia's impairment of coagulation factors and alteration of platelet function. Hypothermia directly inhibits the enzymatic reactions of the clotting cascade creating a coagulopathy . If the coagulopathy is not corrected by rewarming the patient, further fluid loss can continue to progress despite resuscitation efforts.
- **Acidosis <–> Coagulopathy:** Acidosis is a key indicator of coagulopathy in trauma patients. Similarly to the effects of hypothermia, acidosis impairs coagulation enzyme activity and depletes platelet counts. Acidosis also affects clotting by disturbing the synthesis and increasing the breakdown of fibrinogen. The disturbance in fibrinogen levels increases the time needed for blood to clot, extending the length of time and severity of a hemorrhage.

CONSEQUENCES OF HYPOTHERMIA

Surgical Site Infections

- One of the most important causes of morbidity associated with hypothermia
- Estimated that SSIs increase postoperative hospitalization by an average of 4 days and result in an increased attributable cost of $8,0006 to $25,000

Myocardial Ischemia

- Patients with cardiovascular disease who are hypothermic are three times more likely to have adverse myocardial outcomes

Prolongation of Drug Effects

- Can lead to delayed awakening and prolonged postoperative anesthesia care unit (PACU) stay
- Alters the effects of many classes of drugs, including muscle relaxants, volatile agents, and intravenous anesthetic agents.

Shivering

- Can increase oxygen consumption by 50-400%

Skin Integrity and Length of Hospital Stay

- Linked to pressure ulcer development and increased length of hospital stay for surgical patients

Patient Satisfaction

- Patients report greater satisfaction and less anxiety when warmed

Increased Bleeding

- Hypothermia plays an important role in coagulopathy and acidosis in hemorrhaging trauma patients and is a known factor associated with increased trauma mortality and morbidity

Sources:

- National Collaborating Centre for Nursing and Supportive Care (UK). The Management of Inadvertent Perioperative Hypothermia in Adults [Internet]. London: Royal College of Nursing (UK); 2008 Apr. (NICE Clinical Guidelines, No. 65.) 8, CONSEQUENCES OF HYPOTHERMIA REVIEW. Available from: https://www.ncbi.nlm.nih.gov/books/NBK53806/
- Zhou, J., & Poloyac, S. M. (2011). The effect of therapeutic hypothermia on drug metabolism and response: cellular mechanisms to organ function. *Expert opinion on drug metabolism & toxicology*, *7*(7), 803–816. doi:10.1517/17425255.2011.574127

PUBLICATIONS

HYPOTENSIVE EVENTS FOLLOWING RAPID INFUSION

ANESTHESIA & ANALGESIA (A&A) ONLINE ARTICLE

Timeline of Events

- 4/16/2018: Belmont became aware of an on-line article entitled "Profound Intraoperative Hypotension Associated with Transfusion via the Belmont Fluid Management System" published on www.anesthesia-analgesia.org by several doctors from Mount Sinai Hospital in New York and the University of California at San Francisco.
- 4/18/2018: Brian and Dr. Comunale drafted letter to the editor calling out the inaccuracies of the article
- 4/23/2018: We submitted the letter to the editor in response to the article
- August 2018: Letter was accepted and published online by A&A

Questions Raised by "Profound Intraoperative Hypotension Associated With Transfusion via the Belmont Fluid Management System"

To the Editor

The recent publication by Miller et al[1] concerning hypotension associated with use of the Belmont Fluid Management System raises several questions that we feel should be addressed.

First, what is the local practice with regard to the administration of platelets, cryoprecipitate, or granulocyte suspensions via the Belmont device? The American Association of Blood Banks Guidelines for the Use of Blood Warming Devices[2] caution against such administration: "Administration of Platelets, Cryoprecipitate, or Granulocyte suspensions… may render these products less effective," as does the Belmont Operator's Manual: "The system should not be used to warm platelets, cryo-precipitates, or granulocyte suspensions." It is not clear from the article by Miller et al[1] how they were administered in the sentinel cases. The summary table reveals that platelets were infused in 9 of the 15 cases (60%) and cryoprecipitates were used in 5 of the 15 cases (33%).

Second, although Miller et al[1] mention that "washing pRBCs might remove possible sources of hypotension...," what is the local practice protocol for washing and administering cell-saver blood? The table reveals that cell savers were used in 6 cases. It is possible that in these 6 cases, the administration of unwashed or incompletely washed cell-saver blood may have contributed to hypotension because of citrate toxicity, especially in their patient population of decreased liver function.[3]

Third, who analyzed most of the Belmont devices and disposables? Although Miller et al[1] state that "The device manufacturer evaluated all machines and disposables, and found them to be in working order," our records indicate that 3 rapid infusers were returned for evaluation but none of the disposables.

Fourth, we note that 1 patient experienced repeated hypotension when the same blood was removed from the Belmont and reinfused using a bag and rapid infuser catheter, indicating a vasoactive substance in the transfusate. However, in 3 cases (33%), there were no adverse reactions when infusion was reinitialized with the same Belmont, nor was there an adverse reaction when a second Belmont was added in 1 of those 3 cases. How do you account for these discrepancies?

Fifth, are you still using the Belmont system at your respective institutions? We appreciate the clear statement by Miller et al[1] that the hypotension was "associated with" clinical situations involving use of the Belmont system and not caused by it. We are as interested as Miller et al[1] in determining the mechanism(s) causing the hypotension they observed and would like to be part of the solution.

The Belmont Rapid Infuser is in use at >2300 institutions worldwide and has performed as expected in almost 700,000 patients, including thousands of liver transplants, major vascular cases, and cardiac surgeries.

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Billerica, Massachusetts
bellacott@belmontinstrument.com

Belmont Instrument Corporation is the manufacturer of the Belmont Fluid Management System. M. E. Comunale is a Consultant Medical Director for Belmont Instrument Corporation.

REFERENCES

1. Miller J, Kim S, Adelmannn D, et al. Profound intraoperative hypotension associated with transfusion via the Belmont fluid management system. *Anesth Analg*. 2018 [Epub ahead of print].
2. AABB. *Guidelines for the Use of Blood Warming Devices*. Bethesda, MD: American Association of Blood Banks; 2002.
3. Sreelakshmi TR, Eldridge J. Acute hypotension associated with leucocyte depletion filters during cell salvaged blood transfusion. *Anaesthesia*. 2010;65:742–744.

DOI: 10.1213/ANE.0000000000003702

CLINICAL ARTICLES REFERENCE LIST

DESCRIPTION	LINK
Far Forward Anesthesia and Massive Blood Transfusion: Two Cases Revealing the Challenge of Damage Control Resuscitation in an Austere Environment	https://pdfs.semanticscholar.org/f9c5/14668829bf692ce94fd9a989c5b1949b53f5.pdf
A Laboratory Evaluation of the Level 1 Rapid Infuser (H1025) and the Belmont Instrument Fluid Management System (FMS 2000) for Rapid Transfusion	https://journals.lww.com/anesthesia-analgesia/Fulltext/2003/10000/A_Laboratory_Evaluation_of_the_Level_1_Rapid.26.aspx?trendmd-shared=%25SPONSORED%25
The Scope of Wounds Encountered in Casualties From the Global War on Terrorism: From the Battlefield to the Tertiary Treatment Facility	https://journals.lww.com/jaaos/Fulltext/2006/00001/The_Scope_of_Wounds_Encountered_in_Casualties_From.5.aspx
Evaluation of a New IV Fluid and Blood Warming System to Prevent Air Embolism	http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.546.7635&rep=rep1&type=pdf
Profound Intraoperative Hypotension Associated With Transfusion via the Belmont Fluid Management System	https://journals.lww.com/anesthesia-analgesia/Abstract/publishahead/Profound_Intraoperative_Hypotension_Associated.96837.aspx
Veteran Medics Help Reduce Iraq Fatalities	https://www.latimes.com/archives/la-xpm-2006-feb-12-fg-medical12-story.html
High-Energy Trauma and Damage Control in the Lower Limb	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2887001/
A Promising Technique for Treating Circulatory Arrest Associated Coagulopathy	https://journals.lww.com/anesthesia-analgesia/Fulltext/2003/03000/A_Promising_Technique_for_Treating_Circulatory.56.aspx

VALUE PROPOSITION

RAPID INFUSER VALUE PROPOSITION

CLINICAL PROBLEM(S) WE SOLVE:

- *Traumatic injury remains a leading cause of potentially preventable death*
- *Fluid resuscitation to restore intravascular volume is among the most important interventions in the management of severely bleeding patients*
- *Hypothermia is associated with increased mortality and blood loss in trauma patients*
- *54-93% of maternal hemorrhage-related deaths could have been prevented with improved clinical response*
- *100% aluminum free fluid delivery*

OUR VALUE PROPOSITION:

- ***Fast**, **reliable**, and **bubble-free** delivery of life-saving warmed fluids at the touch of a button.*
- *Overcome every challenge with agility, ease, and peace of mind knowing you're prepared for the worst, because you're using the best – The Belmont Rapid Infuser RI-2*

THE BELMONT®
RAPID INFUSER RI-2

COMPLEX THORACOABDOMINAL AORTIC ANEURYSM (TAAA) REPAIR

TAAA repairs are one of the most intensive operations undertaken by surgeons. The procedure pushes the limits of what the human body can tolerate and is considered so risky that a patient was recently refused the surgery at numerous hospitals in Germany.

Using The Belmont® equipped with the large volume reservoir, Dr. Sheinbaum was able to successfully perform the procedure which required the transfusion of 37 liters of fluid. He credits the procedure's success to The Belmont's accuracy of infusion rates, efficiency of warming fluid, and automatic de-airing and filtering of blood products.

"It would have been essentially impossible to keep up using the traditional Level 1 type system"

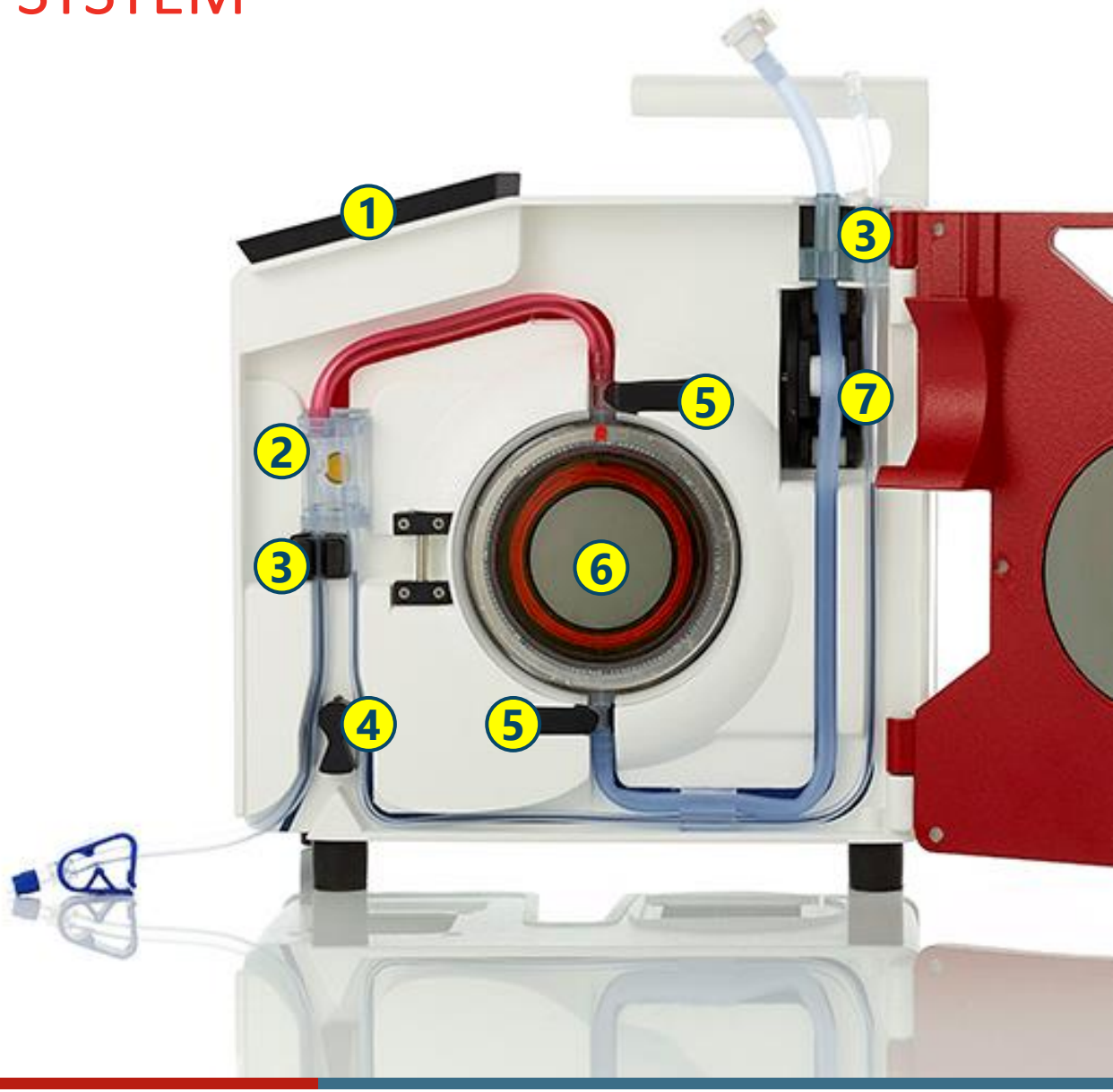
- Dr. Roy Sheinbaum

PRODUCT HANDS-ON TRAINING

DEVICE SETUP AND OPERATION

THE BELMONT® RAPID INFUSER RI-2 SYSTEM

1. Touch-screen display
2. Pressure sensor
3. Input/output air detector
4. Patient safety/recirculation valve wand
5. Input/output temperature probes
6. Electromagnetic heat exchanger
7. High-speed peristaltic pump



TOUCH-SCREEN DISPLAY

STEP-BY-STEP INSTRUCTIONS AND TOUCH-SCREEN CONTROLS

- The Belmont Rapid Infuser's large touch-screen displays all infusion variables in real time while also providing access to device operation controls.
- On-screen instructions provide an easy to follow guide for proper installation and priming of the disposable set.
- Instructions are also provided when alarms/alerts are triggered allowing users to quickly identify and correct unsafe operating conditions.

PRESSURE SENSOR

ALERTS USER IF THE PATIENT LINE/ACCESS BECC BLOCKED OR RESTRICTED

- The pressure monitoring system automatically senses and adjusts flow rates as pressure starts to exceed 300 mmHg, while also alerting the user if the patient line becomes blocked.

- The pressure limit is set at the factory to the maximum limit of 300 mmHg. Limit can be changed. The possible setting ranges from 100 to 300 mmHg. Refer to Chapter 4 of the Operator's Manual, pressure limit section.

- Line pressure monitoring can prevent unsafe infusion conditions including over-pressurization of the patient line and poor venous access.

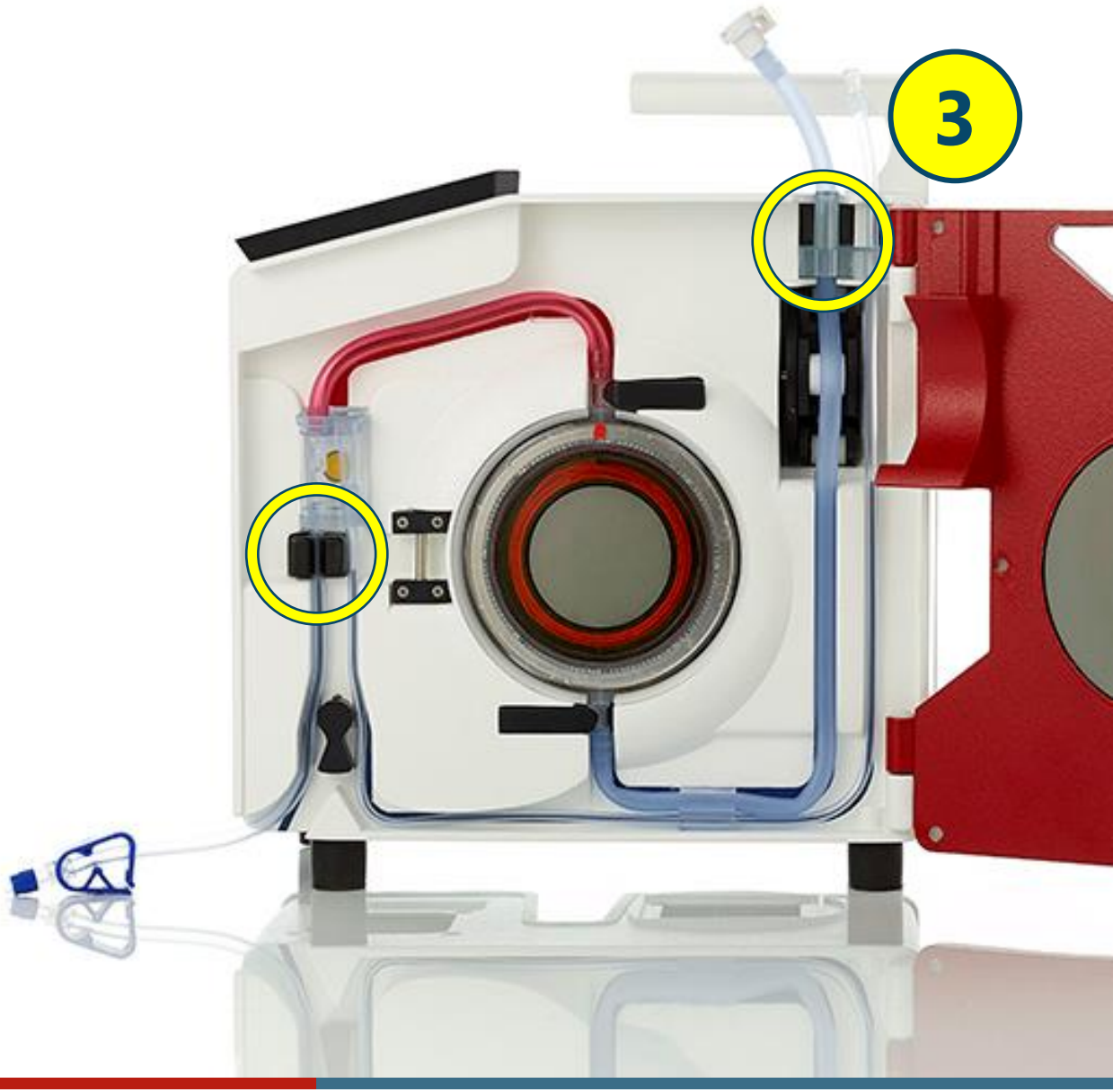
INPUT/OUTPUT AIR DETECTORS

AUTOMATIC AIR DETECTION AND REMOVAL

- Two ultrasonic air detectors continuously monitor infuse lines for air that may be contained in fluid bags or accidently introduced into the system.

- Upon detection, the patient safety valve wand occludes the patient line to protect the patient from air embolus, and then automatically vents the air out through the recirculation line.

- Automatic air detection and removal is a vital safety feature which can help reduce the incidence of air embolism during fluid resuscitation.



PATIENT SAFETY/RECIRCULATION VALVE WAND

BLOCKS PATIENT LINE TO PROTECT PATIENT FROM AIR EMBOLUS

- The patient safety/recirculation valve wand occludes the patient line when air is detected in the system, or when the RECIRC option is utilized.

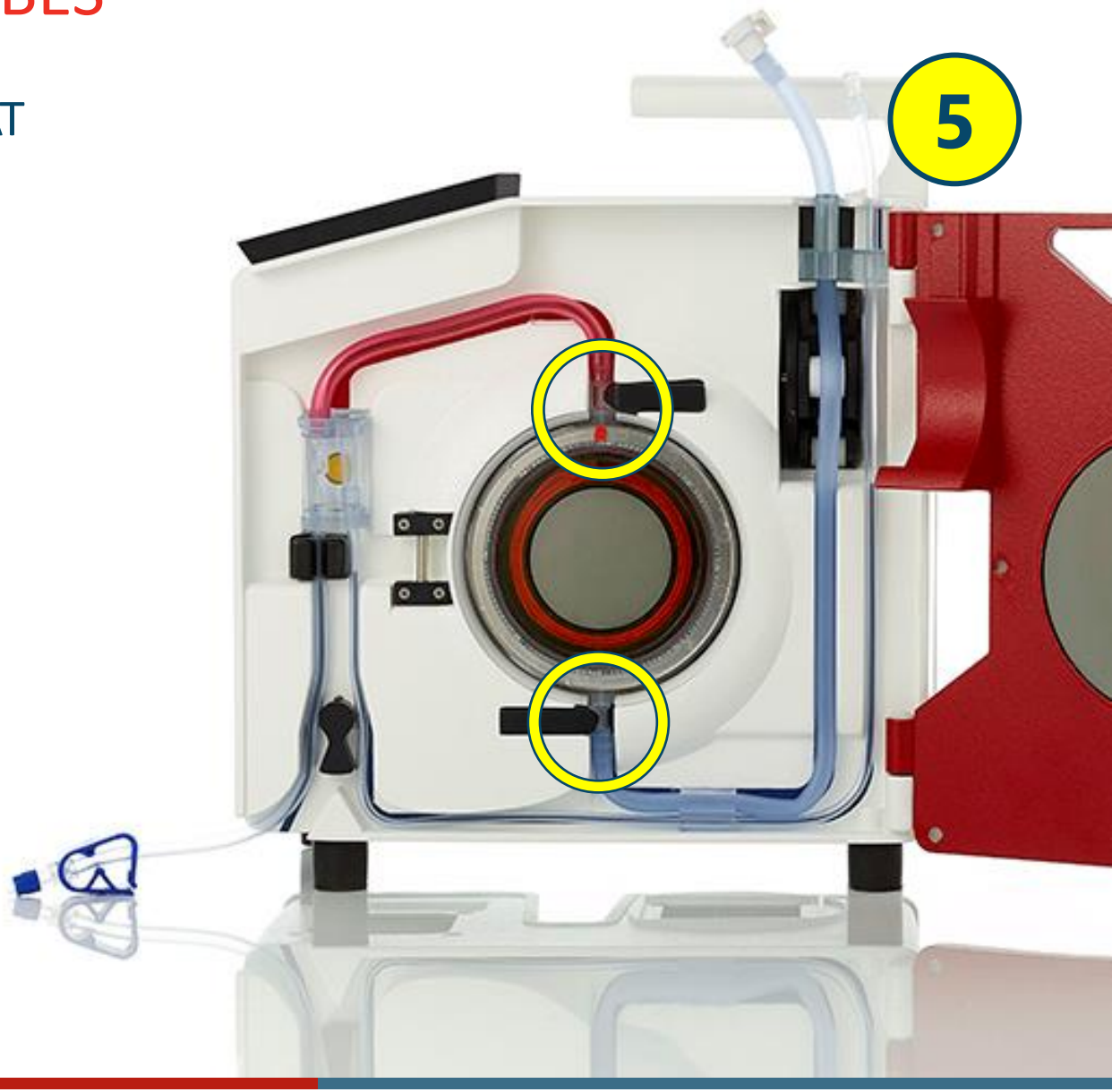
- This valve wand allows for recirculation of fluid through the reservoir while still connected to the patient. Air can also be automatically vented from the system without the need to disconnect to re-prime.

- Automatic re-priming during events where air has been detected minimizes interruptions and reduces the time needed to get the system back to operation status.

INPUT/OUTPUT TEMPERATURE PROBES

PRECISELY MONITORS TEMPERATURE OF FLUID AT INPUT AND OUTPUT

- Two infrared temp probes monitor fluid temperature
- Precise temperature monitoring allows fluid to be warmed from 4°C to 37.5°C in a single pass



ELECTROMAGNETIC INDUCTIVE HEATER

PROVIDES INSTANT HEAT WITHOUT WATER BATHS OR HOT PLATES

- The Belmont Rapid Infuser's electromagnetic inductive heating technology allows for warming of fluid within the sterile fluid path, which contains a large surface area (118 in^2 or 761 cm^2) and low thermal mass.

- The minute difference in temperature between the heat exchanger and the fluid reduces the risk of red cell thermal damage and hemolysis, which can result in a reduced transfusate oxygen carrying capacity and subsequent electrolyte disturbance.

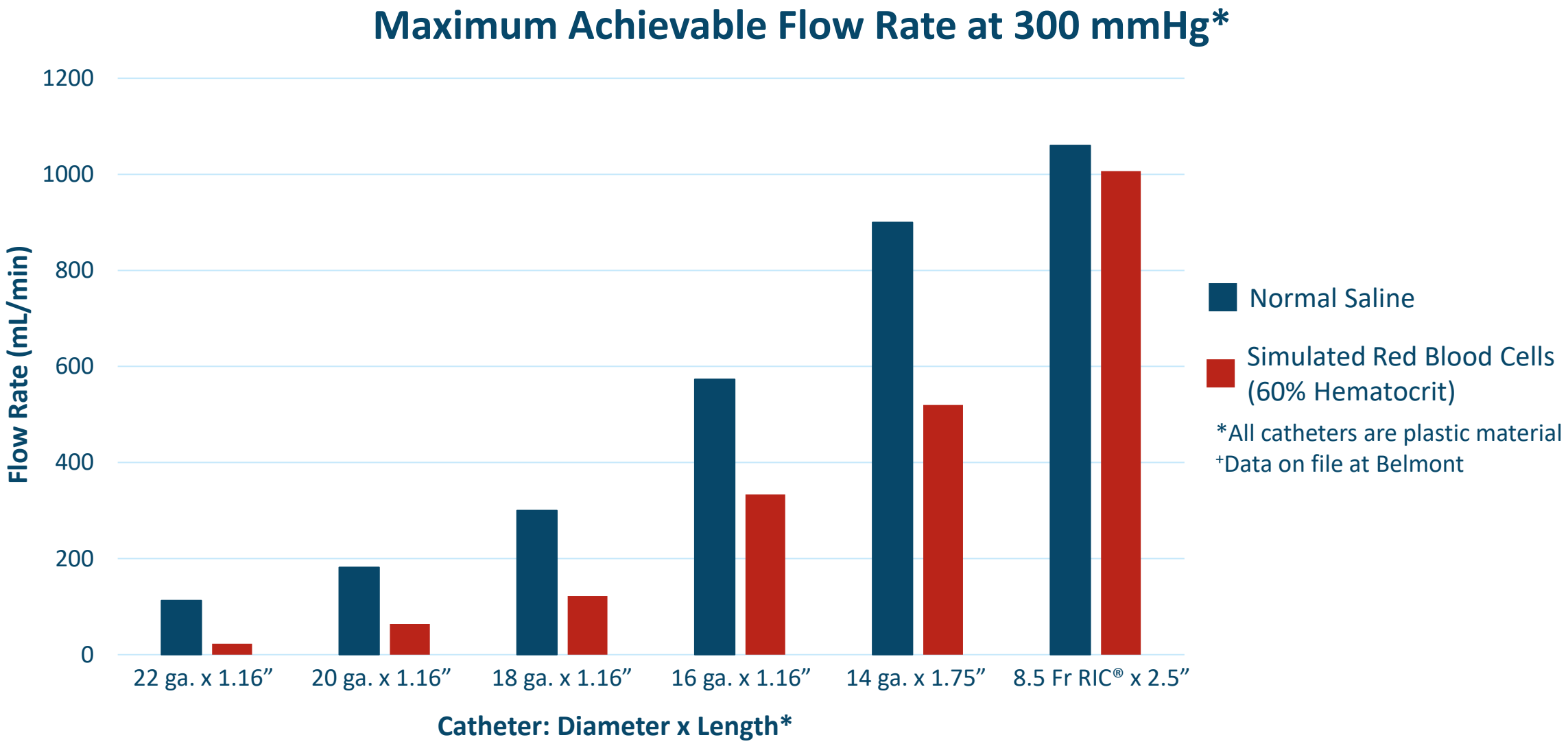
HIGH-SPEED PERISTALTIC PUMP

ALLOWS FOR PRECISE CONTROL OF INFUSION WITHOUT THE NEED OF PRESSURE INFUSERS

- The high-speed peristaltic pump is able to deliver precise control of infusion from 2.5 to 1,000 mL per minute.

- The peristaltic pump eliminates the need for conventional pressure infusers which require additional support to monitor and maintain fluid bags.

CATHETER SIZE LIMITS THE FLOW RATE



PRIMING FLUID & HYPERCHLOREMIA CONCERNS NORMAL SALINE VS. PLASMALYTE

Old Protocol:

Hyperchloremia – high levels of sodium chloride in the blood

- Can cause renal failure and kidney damage
- Increased the risk of metabolic acidosis

"Hyperchloremia is Independently Associated with Mortality in Critically Ill Children Who Ultimately Require Continuous Renal Replacement Therapy" – Barhight et al

- Prime with normal saline

New Protocol:

- Prime with normal saline **OR** plasmalyte

Barhight MF, Lusk J, Brinton J, Stidham T, Soranno DE, Faubel S, Goebel J, Mourani PM, Gist KM. Hyperchloremia is independently associated with mortality in critically ill children who ultimately require continuous renal replacement therapy. Pediatr Nephrol. 2018 Jun;33(6):1079-1085.

THE SYSTEMS *CAN* BE USED TO WARM:

- Crystalloid
- Colloid
- Blood products
  - Packed red blood cells (PRBCs)
  - Fresh frozen plasma (FFP)

THE SYSTEM SHOULD *NOT* BE USED TO WARM:

- Platelets
  - Platelets can bond to the inner surfaces of the disposable set, reducing the amount of platelets reaching the patient and consequently affect device operation.
- Cryoprecipitate
  - Cryo should not be run through a rapid infuser to prevent dilution.
- Granulocyte suspensions
  - Granulocytes are fragile cells and therefore should not be administered through a rapid infuser.
- Drugs or biologics

DO ***NOT*** MIX WITH BLOOD PRODUCTS:

- Lactated Ringer's solution (or solutions containing calcium)
  - Sodium citrate is added to blood products as an anticoagulant, which prevents blood from clotting. The introduction of calcium containing solutions to anticoagulated blood products will lead to clotting of blood, and ultimately affect device operations.
- Dextrose in water
- Hypotonic sodium chloride solutions

**Always refer to compatible fluids list! (#701-0218-2 Rev D)*

ALUMINUM TOXICITY CONCERNS

In September 2021, the FDA Published, "Potential Risk of Aluminum Leaching with Use of Certain Fluid Warmer Devices - Letter to Health Care Providers"

- There is the potential risk of aluminum toxicity when using certain fluid warmers whose heat exchanger is aluminum and in direct contact with the infusate.[1]
- High levels of aluminum may result in adverse clinical effects and symptoms such as:
  - Bone, muscle pain and muscle weakness. [1]
  - Blood and metabolic derangements (such as increased levels of calcium or interference with iron absorption leading to anemia). [1]
  - Neurological effects (such as altered consciousness, seizures, and coma). [1]
- High levels of aluminum have also been linked to Alzheimer's, metabolic conditions such as osteoporosis and some cancers.[2]
- The FDA Recommends
  - Avoid using these fluid warmers in high-risk patient populations including those with poor renal function, neonates, infants, pregnant mothers, and the elderly because exposure to small amounts of aluminum may lead to toxicity.[1]
  - If available, use alternative therapies to maintain patient temperature, **such as an alternative fluid warmer which uses a different design**, or a warming blanket. [1]

1. https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-aluminum-leaching-use-certain-fluid-warmer-devices-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
2. Igbokwe IO, Igwenagu E, Igbokwe NA. Aluminium toxicosis: a review of toxic actions and effects. Interdiscip Toxicol. 2019;12(2):45-70. doi:10.2478/intox-2019-0007 - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7071840/

RECALLS DUE TO ALUMINUM HEAT EXCHANGERS

- enFlow™
  - Low flow device with uncoated aluminum in the fluid path
  - Class I recall and full market withdrawal in 2019
- ThermaCor
  - Aluminum plate in the fluid path
  - Class I US FDA recall February 2021
    - Warning that aluminum exposure may occur with use of the device, warnings against using Lactated Ringer's, using the device at low flows, and to avoid using the device in high-risk patient populations including those with poor renal function, neonates, infants, pregnant mothers, and the elderly.
- Level 1 Fast Flow and NORMOFLO
  - Aluminum tubing in the fluid path
  - Class I US FDA recall August 2021
    - Warning that aluminum exposure may occur with use of the device, warnings against using Lactated Ringer's, using the device at low flows, and to avoid using the device in high-risk patient populations including those with poor renal function, neonates, infants, pregnant mothers, and the elderly.
  - Temporary CE Mark Suspension February 2022

Belmont disposables do NOT contain aluminum

- **Medical grade stainless steel**

ALUMINUM CONCERN TESTIMONIAL

Regarding enFlow™ Aluminum Concerns

"In 35 years of researching human exposure to aluminum I have not come across a more serious situation for human health than that posed by this device.

The concentrations of aluminum measured in what would be described as a benign solution (where corrosion is concerned) are alarming and would be considerably higher still when blood or blood products come in to contact with the aluminum.

Considering the widespread use of this device over many years it must be inevitable that the aluminum released has caused deaths and myriad complications in many survivors of transfusions containing such high concentrations of aluminum. You only need to think back to aluminum-induced dialysis encephalopathy where renal patients were dialysed against tap water containing, perhaps, 100-200 ppb aluminum. We are talking about aluminum concentrations at least an order of magnitude higher in the case of this device.

Immediate follow-up of all, from preterm infants to aged adults, patients receiving transfusions using this device is now absolutely paramount."

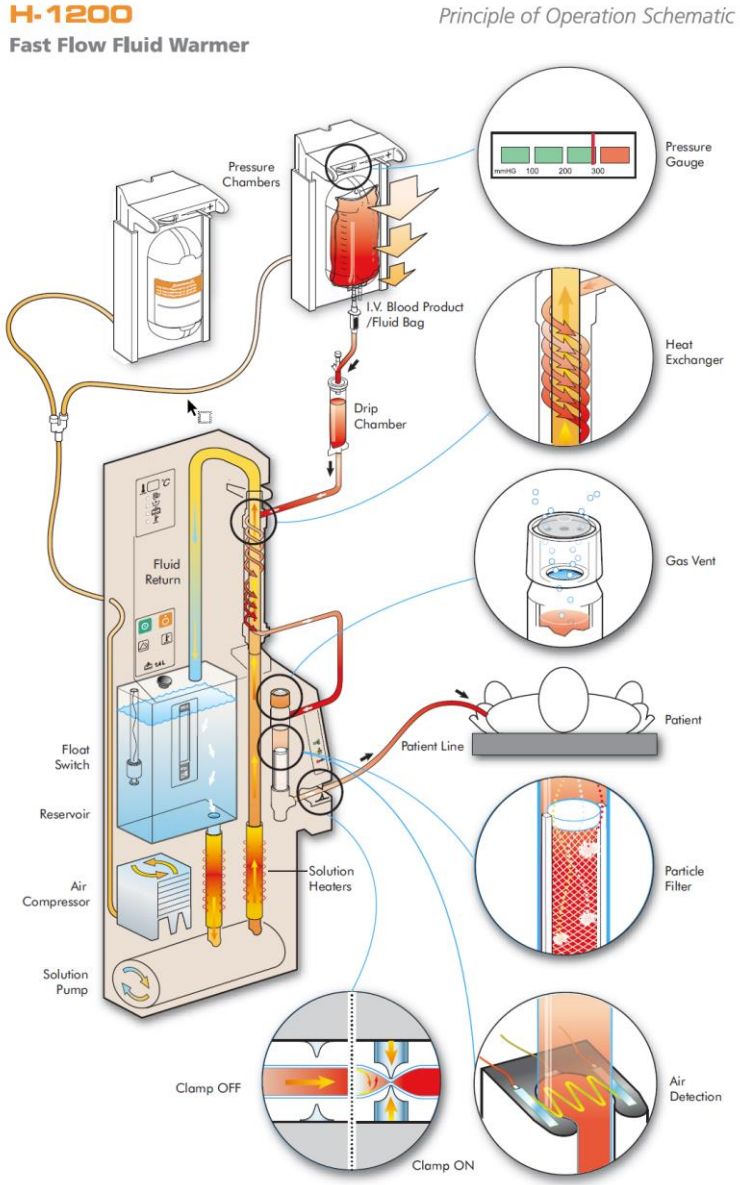
Christopher Exley
PhD in the ecotoxicology of aluminum
Professor of Bioinorganic Chemistry
Keele University

https://www.bmj.com/content/364/bmj.l1126/rr

COMPETITION REVIEW

LEVEL 1® PRODUCT OVERVIEW

- Product
  - H-1025 in EU and JP
  - H-1200 in all other markets
- Key characteristics:
  - Automated pressure chambers
  - **Aluminum heat exchanger**
  - Optional air detector (not available worldwide)
- Aggressive pricing
  - US disposable price ranging from $65-80 vs. Belmont at $145
  - Equipment ~$5K – 6.5K // $8K – 9K
- Geographic presence:
  - Present worldwide; Market leader



GLOBAL RECALL OR SAFETY NOTICE DUE TO ALUMINUM HEAT EXCHANGER

Class I Recall

- Initiated August 2021
- Includes:
  - Level 1 Fluid Warmer Models: H-1000, H-500, H-1028, H-1200,
  - Level 1 Normothermic I.V. Fluid Administration Set Models: D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL
  - NORMOFLO Irrigation Warming Set Models: IR-40, IR-500, IR-600, IR-700, IRI-600, IRI-600B, IR-700
- Who may be affected:
  - Pediatric patients, particularly neonates and infants
  - Pregnant women
  - Elderly
  - Patients with poor renal function or on dialysis
- Required Actions:
  - Hang a manufacturer provided warning label on all active machines
  - No device return required
- More information is available here: https://www.fda.gov/medical-devices/medical-device-recalls/smiths-medical-recalls-normoflo-irrigation-fluid-warmers-and-warming-sets-due-possibility-harmful

Temporary CE Mark Suspension

- Initiated February 2022 after an inquire due to a global safety notification
- Initiates a stop ship to countries that utilize the CE marking as part of the regulatory approval process for medical device sales

- **Belmont disposables do NOT contain aluminum**
  - **Medical grade stainless steel**

AIR ELIMINATION CAPABILITY

Level 1® Air Detector/Clamp not available in EU

- On January 31, 2019, the FDA issued a Safety Communication entitled: “Intravascular Air-in-Line and Air Embolism Risks Associated with Infusion Pumps, Fluid Warmers, and Rapid Infusers.”
- The purpose of the communication was to provide important safety information and recommendations for users who operate, train, and maintain fluid warmers, infusion pumps, and rapid infusion devices, with the goal to reduce the risk of air-related adverse events.

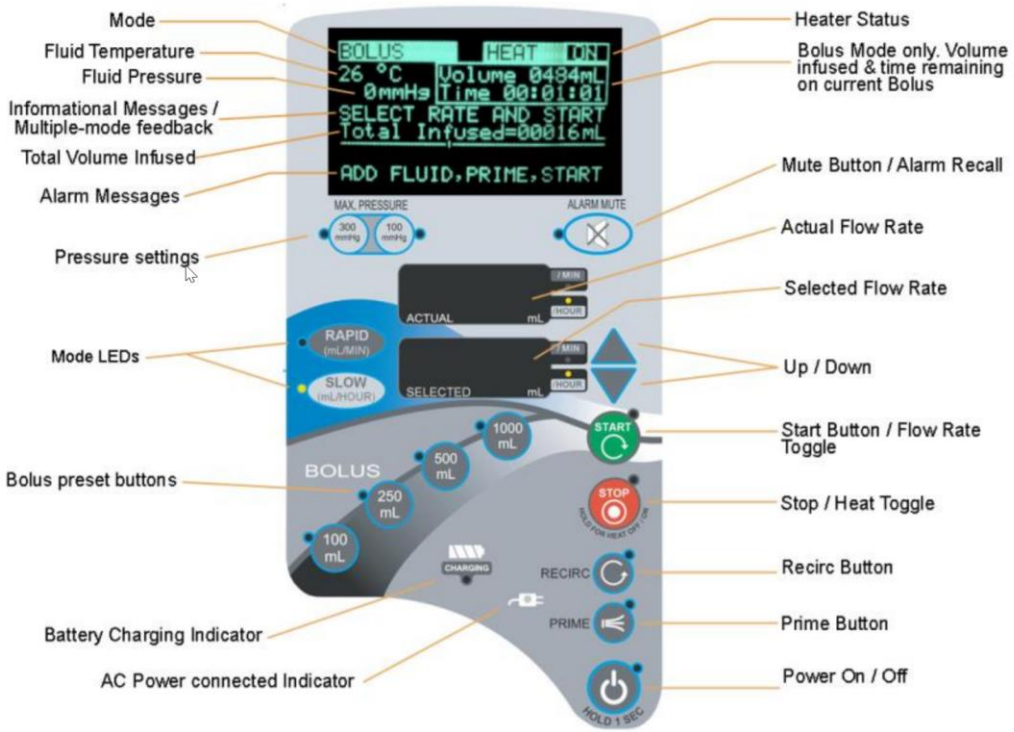
Manufacturer	Device	Event Date	Adverse Event
Smiths-Medical	H-1200	3/13/2019	Death
Smiths-Medical	H-1200	8/01/2018	Death
Smiths-Medical	H-1200	4/22/2016	Injury/Air leak
Smiths-Medical	H-1025	2/16/2016	Injury/Air leak
Smiths-Medical	H-1025	10/7/2015	Injury/Air leak
Smiths-Medical	H-1200	5/20/2014	Death
Smiths-Medical	H-1000	2/25/2014	Death
Smiths-Medical	H-1000	10/27/2011	Death
Smiths-Medical	H-1000	1/20/2011	Injury/Fluid leak
Smiths-Medical	H-1200	9/8/2010	Death/Air leak
Smiths-Medical	H-1200	3/25/2010	Injury/Air leak
Smiths-Medical	H-1200	2/26/2010	Air leak
Smiths-Medical	H-1200	8/8/2009	Injury/Air leak

USA: Air emboli events can lead to substantial legal claims. Air embolism claims have the highest median payment and a rate of 100% payment-per-claim (Median payment rate: $325,000 in 2007 with a range of $25,800–$4,120,200 per claim).

Sources: MAUDE database; Bhananker, S. M., Liau, D. W., Kooner, P. K., Posner, K. L., Caplan, R. A., & Domino, K. B. (2009). Liability Related to Peripheral Venous and Arterial Catheterization: A Closed Claims Analysis. Anesthesia & Analgesia, 109(1), 124-129. doi:10.1213/ane.0b013e31818f87c8

THERMACOR® PRODUCT OVERVIEW

- Product
  - ThermaCor® 1200
- Key characteristics:
  - Peristaltic pump (no pressure chambers)
  - Dry, plate warmer
  - Integrated “ShurGard Vortex” air trapping system
  - One-latch, fast loading cassette
  - Automatic priming
  - Pressure regulation and control (100 or 300 mmHg)
  - Large volume reservoir available
  - **Aluminum in cassettes**
- Latest and “greatest”
  - Positions self as newest, easiest, and best technology
  - Premium priced device and disposables
- Geographic presence:
  - US, expanding to EU and Australia



Videos
- *Long and detailed with closeups*
- *Shorter version*
- *In clinical environment by “rep”*

INADVERTENT ADMINISTRATION OF COLD FLUID

CARDIAC CONCERNS

- Unlike other fluid warmers, ThermaCor allows users to toggle heating off

- Flow rate is not limited during battery operation allowing for rapid infusion of near freezing fluid

- Rapid infusion of cold fluid can induce hypothermia, worsen bleeding, and potentially cause cardiac arrest in trauma patients

ALUMINUM CONCERNS

ThermaCor® & Aluminum Concerns

- ThermaCor Disposable Cassettes Recall

Belmont Disposable: No Aluminum

- Belmont disposables do not contain aluminum
  - Medical grade stainless steel

Regarding ThermaCor Recall

- On March 26, 2021, the FDA issued a Class 1 Device Recall for ThermaCor 1200 Cassette disposables notifying customers of results from a Toxicological Risk Assessment related to potential for aluminum ions to leach into warmed fluids.
- The recall concerns ThermaCor disposable part numbers DNC-1200, PTC-1200 and PNC-1200.
- Additional information regarding this notice can be found on the FDA's website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=86808

HOW TO SELL THE BELMONT® RAPID INFUSER RI-2

701-00395 Rev A

WHAT DIFFERENTIATES BELMONT FROM COMPETITORS?

Belmont Differentiators	Description	Benefits
AUTOMATIC AIR DETECTION & REMOVAL	Two ultrasonic air detectors and patient safety valve safeguard against air emboli	• Safe for the patient; • Time & cost efficient for the staff & hospital (1 person required to operate; legal risks) • Easy to use & operate
AUTOMATIC PRIMING	Fully prime in under 1 minute and easily re-prime without patient disconnection	• Same
HIGH SPEED PERISTALTIC PUMP	Precise control of fluid delivery with flow rates ranging from 2.5 to 1000 ml/min.	• Reliable
ELECTROMAGNETIC INDUCTIVE HEATING	Dry, inductive heating technology and two infrared temperature sensors provide consistent normothermic fluid within seconds	• Fast • Eliminate water contamination concerns
ADVANCED PRESSURE REGULATION	Automatic pressure monitoring and flow rate adjustment when pressure exceeds 300 mmHg	• Safe for the patient
INTUITIVE TOUCH-SCREEN DISPLAY	High contrast display provides easy to follow on-screen instructions, clear descriptions of alarms and alerts, and quick access to device operations	• Easy to use & operate • Safe • Fast • Reliable
EASY TO USE, ALUMINUM FREE DISPOSABLE	A single, color-coded, pre-assembled disposable allows for easy and fast installation by a single operator.	• Aluminum free • Quick to install

DIFFERENT HOSPITALS/DIFFERENT CONCERNS – TAILOR YOUR MESSAGE

COMMUNITY/PRIVATE HOSPITAL

- When you need it you have it
- Easy to Use (less than 1 minute!)
  - Simple! Confident to use even if infrequent (don't need to re-train)
  - On-screen instructions
- You load it dry
- Can be moved from Trauma to OR - Portable
- Reliable

UNIVERSITY/PUBLIC HOSPITAL

- Low & Fast infusions rates to meet patient requirements
- Easy to use
- Quick priming
- Transportable
- Never have to disconnect from patient
- How do you handle those big bleeder cases like Liver Transplant, etc.

TAILOR THE PRODUCT DEMONSTRATION TO AUDIENCE

Hospital Department	Features of Interest to Audience to Demonstrate
ED Staff	• Easy setup, pre-assembled, color-coded • Self-priming • Automatic air removal • Runs on battery for transport to OR, ICU • Faster heat, precise • Able to infuse several products at once
Anesthesia	• Automatic air removal • Easy set-up, self-priming • Precise infusion with bolus option & temp control • One person can operate • Small footprint and portable • Larger reservoir option
ICU	• Infection control • No water baths • Runs on battery for transport to OR and back to ICU
Biomed	• Belmont is committed to servicing units • Reduced Preventative Maintenance (no water bath) • Built in safeguards (performs self-test at start-up, alarms if not fully functional
Labor & Delivery	• On-screen step-by-step instructions
All Departments	• Belmont Rapid Infuser disposables do not contain aluminum

GENERAL PROBING QUESTIONS

- What do you use for fluid warming?
- How do you handle air removal today?
- How often are staff familiar with current technology you use today? (trauma units)
- How often do you need and how easy is it to re-prime? (impact costs, time, frustration)
- How concerned are you about aluminum leaching into the fluid path?

TARGETED PROBING QUESTIONS

(BASED ON CURRENT DEVICE USED)

Differentiators/Limitations	Tailored Probing Questions to Uncover & Develop Need
Conversation Starters	• How long have you been using [competitive product]? • How often do you use a rapid infuser? (If low, why is that? Is staff not comfortable?) • What's your experience with the Belmont?
Easy to Use	• What do you do when you don't have 2 people? (Level 1) • How long does it take to set up [competitive device]? • What is your level of comfort setting up @ 4 AM? • How easy is it to keep your staff trained?
Automatic Air Removal	• What are your concerns with air bubbles? (Level 1) • What do you do when there is an air bubble? (Level 1) • How does this impact patient care? (Level 1)
Contains Aluminum	• What are your concerns with disposables that contain aluminum? (ThermaCor, Level 1)
Unknown Fluid Temp/Flow Rate	• How important is it to know temperatures of fluids going in? (Level 1) • What are your concerns with fluctuating flow rates? How do you ensure consistent flow rates? (Level 1)
Time to re-prime when air is detected	• When air is detected, how long does it take to re-prime? (Level 1) • What impact does that have on the patient?

Differentiators/Limitations	Tailored Probing Questions to Uncover & Develop Need
Sterility of Infusate	• What are your concerns with contamination? (Level 1) • How often do you have to deal with leakage? (ThermaCor)
Inconsistent Heating	• How do you provide precise fluid temp? (ThermaCor) • What are your concerns with a potential inconsistency? (ThermaCor) • How do cold temps affect outcomes? (ThermaCor) • How often do you deal with hotspots? How does that affect clinical outcomes? (ThermaCor) • Does that happen often and how often do you need to replace the pads? ($) (ThermaCor)
Large Volume Cassette	• If there is a problem with the 200 ml cassette, what happens to the blood?... do you have to throw it away? (ThermaCor) • How often do you use?.. (if often).. How do you control costs? (ThermaCor)
Clinical Support	• With staff turn-over, how do you train new people? (ThermaCor)
Other Good Probing Questions	• If you have to transport the patient… what do you do? • How often do you need to use more than one disposable? (costs) How long does it take for staff to re-prime and get it going again? (How does that impact patient care?) • What is your typical catheter size? What are your concerns with vessel trauma (?)

BELMONT RI-2 STRATEGY & COMPETITIVE POSITIONING

- Belmont DOES NOT compete on price!
- We compete on the following message:

BUBBLE-FREE.
RELIABLE. FAST.

- We have been gaining market shares worldwide
- Belmont has been providing blood equipment with air removal technology for over 30 years!
- As an example in the US, the Belmont RI-2 lists for ~$30K, a premium vs. value competitors ($9K)
- Aluminum free disposables

"THE BELMONT" BRINGS CONFIDENCE

Used in the most extreme situations for more than 20 years, The Belmont Rapid Infuser has earned the trust of clinicians worldwide. It's a simple, safe, and effective solution for high-speed delivery of warmed fluids. Experience peace of mind, knowing you're prepared for the worst but equipped with the best.

COMMON SALES OBJECTIONS

Typical Level 1 Objections	
Level 1 is easy to use and less complicated	*Reinforce how Level 1 (L1) is more complicated to operate* • It's my understanding that multiple technicians are needed to operate and monitor the L1, one to prep and change fluid bags and another to monitor air/device operation. The Belmont Rapid Infuser RI-2 can be operated by a single technician. • Is each one of your staff members able to set up the L1 quickly when needed? The Belmont Rapid Infuser RI-2 designed to allow all staff members to set up and load the device with ease and speed by offering on-screen instructions and a pre-assembled, color-coded disposable set. • It's recommended you burp bags before loading them into L1 pressure chambers, something that is not required with The Belmont Rapid Infuser RI-2. If air is detected during a case, I understand the patient must be disconnected from the L1 and a lengthy 12-step re-prime process is needed to vent the air. With Belmont there's no need to disconnect – you simply follow the on-screen instructions and you're back up and running in less than a minute.
Level 1 does the same thing at a fraction of the price	*Reinforce the differences in technologies and while L1 disposables might be less expensive per unit, more often multiple disposables will need to be used due to lower quality technology* • The technologies are different and therefore The Belmont Rapid Infuser RI-2 is a bit more expensive, but even at the disposable level your costs with L1 are more than they seem. • While the L1 disposables are less expensive, I understand you often use more than one during large cases due to the filter clogging up, slowing air venting and flow rate. The Belmont Rapid Infuser RI-2 can handle hundreds of liters of fluid with one disposable. • The L1 doesn't travel from departments, so therefore you'll need disposables in ED, OR, ICU to support patient transfers.
I'm happy with my current rapid infuser (Level 1)	*Reinforce L1 lacks a critical function (air removal) and speak to key differentiators – what is truly the most critical in a rapid infuser* • Physician have told me numerous times that the most critical factors when a patient needs a rapid blood infusion are (1) easy & quick setup (2) removal of air (3) efficient, precise, and reliable heating – The Belmont Rapid Infuser RI-2 is by far the most superior product to deliver just that.

COMMON SALES OBJECTIONS

Typical ThermaCor Objections	
ThermaCor can infuse up to 1200 ml/min	*Reinforce how ThermaCor would be unable to warm to normothermic fluid temperatures at max flow rate* • While that is true, the small surface area of the ThermaCor heat exchanger would not allow cold fluid to be warmed to normothermic temperatures at their highest advertised flow rate, resulting in non-normothermic fluid being rapidly infused. What are your concerns with giving cold blood? • Also, the small surface area of the heat exchanger which is isolated from the fluid by a silicone pad results in a need to drive the heat source to temperatures high enough to cross this isolation boundary. What are your concerns with hemolysis?
ThermaCor cost less/same but offers more	*Clarify true usage costs and that "more" does not always equate to increased clinical benefit* • While the equipment costs are comparable, the per usage cost of The Belmont Rapid Infuser RI-2 is considerably less expensive. ThermaCor cassettes are ~$250 compared to a ~$150 for the Belmont. Additionally, I understand that customers usually use the large volume reservoir to avoid the issue of getting the filter wet – that adds $200 to the cost per use. • Although ThermaCor promotes their features as offering a superior clinical benefit, they have actually increased the complexity and decreased the safety of rapid infusion in their strive to innovate the "next generation" of rapid infuser.
I'm happy with my current rapid infuser (ThermaCor)	*Reinforce the differences between the technologies and limitations of ThermaCor* • They are different systems. Oddly enough, the cassette format actually requires more work and can create more problems for you later. You need to be careful not to fill the reservoir to the top during priming. If the filter on top gets wet it will need to be replaced (increasing your costs). • ThermaCor may be the latest rapid infuser on the block, but their technology is nothing new and is a step back from the safety, efficiency, and simplicity of The Belmont Rapid Infuser RI-2.

COMMON SALES OBJECTIONS - OUS

Typical Fluido Objections	
Fluido is easy to use and less complicated	*Reinforce how Fluido is more complicated to operate* • It's my understanding that multiple technicians are needed to operate and monitor the L1, one to change fluid bags and another to monitor air/device operation. The Belmont can be operated by a single technician. • Is each one of your staff members able to set up the Fluido quickly when needed? The Belmont is designed to allow all staff members to set up and load the device with ease and speed by offering on-screen instructions and a pre-assembled, color-coded disposable set • If air is detected during a case, I understand you must manually remove air from the deaeration chamber with a syringe following a 5-step process. With The Belmont, you simply follow the on-screen instructions to automatically vent air and you're back up and running in less than a minute.
Fluido does the same thing at a fraction of the price	*Reinforce the differences in technologies and while Fluido disposables might be less expensive per unit, more often multiple disposables will need to be used and cold fluids cannot be warmed to normothermic temperatures* • The technologies are definitely different and therefore our RI is a bit more expensive, but even at the disposable level your costs with Fluido are more than they seem. • While the Fluido disposables are less expensive, I understand you cannot use the Standard Set for blood products without the addition of a blood filter. The Belmont disposable can be used with all blood products and handle hundred's of liters of fluid with one disposable. What is the volume limit on the Fluido Trauma set's blood filter? • The indirect cost of operating The Belmont is lower as it only requires a single technician to operate.
I'm happy with my current rapid infuser (Fluido)	*Reinforce Fluido lacks a critical function (normothermic fluid at high-flow/low fluid input temperature) and speak to key differentiators – what is truly the most critical in a rapid infuser* • Physician have told me numerous times that the most critical factors when a patient needs a rapid blood infusion are (1) easy & quick setup (2) removal of air (3) efficient, precise, and reliable heating – The RI-2 is by far the most superior product to deliver just that.

SALES TOOLS: *CAN BE FOUND ON THE BELMONT GOOGLE DRIVE*

- Compatible Fluids List
- Competitive Matrix
- Flow Rate/Catheter Charts
- Quick Cards
- Price List
- Brochures
- Blood Filter Information
- Clinical Studies
- 1:1 Pardot Templates
- Remote Demo Presentations
- RI-2 Error Codes
- Incident Report
- Clinical Training Report
- Training Presentations
- VAC Presentation
- Training Videos
- Level 1 Comparison One Pager

THANK YOU!

BELMONT® MEDICAL TECHNOLOGIES